Global atlas of medical devices

2022

World Health Organization

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ISBN 978-92-4-006220-7 (electronic version)
ISBN 978-92-4-006221-4 (print version)

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Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

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Graphic design and layout: Genève Design.

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Acknowledgements

In order to respond to the World Health Assembly resolution 60.26 on health technologies, particularly medical devices, WHO secretariat, Adriana Velazquez Berumen, Team lead for medical devices and in vitro diagnostics, coordinated the work on the first Baseline country survey on medical devices (under the Global Initiative on Health Technologies) as well as the resulting Global Atlas of medical devices in 2010. Since then, to keep the data up-to-date, she coordinated various re-launches of the survey whose results were published as country profiles in book form and/or digital form on the WHO website in 2015 and 2017 and this present publication on 2022. The statistics are also found in the Global Health Observatory, where data has been updated after every edition. She worked in 2021, under the guidance from Dr Clive Ondari director of the Health Product Policy and Standards Department, and the leadership of Dr Mariangela Simao, Assistant Director General of the Access to Medicines and Health Products Division.

WHO acknowledges and is most grateful to the consultants, country focal points in the Ministries of Health and WHO staff at regional and country offices who dedicated their time and expertise to provide country data on medical devices. The survey was managed by Ricardo X. Martínez with the support of Heike Hufnagel and Valeria Montant. The analysis, evaluation, compilation, and verification of response data was coordinated and implemented by Ricardo X. Martínez with the assistance of Heike Hufnagel, Lucero López, Lucia Jiménez, Juan J. López, David López, Artiom Schepilov and Sebastián Losada.

The search for and retrieval of the answers to the survey in Member States was a collaborative effort of the appointed health technology focal points and/or the the medical device country focal points. The update of the country focal point contacts was possible thanks to the WHO regional advisers on health technologies, WHO health products focal points, and WHO representatives and liaison officers.

Three desk-reviews in the medical device areas “health technology assessment“(HTA), “nomenclature system”, and “regulatory agency” were accomplished in order to verify and complete the country data. They were coordinated by Ricardo X. Martínez and executed by Lucia Jiménez, Juan J. López, David López, Artiom Schepilov, and Lucero López.

Jani Müller, senior researcher and board director of Health Technology Assessment International (HTAi), contributed in the HTA-related survey 2021 answer verification as well as in the corresponding HTA desk-review. Thanks also to the Economic Evaluation and Analysis, unit of WHO headquarters, specially to Andrew Mirelman, Kratu Goel, and Tessa Edejer for their support in the HTA section.

Two country-consultations in September–November 2021 and April–May 2022, were done in order to verify the validity of the collected data. The outcome of these consultations was collected and updated by Olga Pineda, Daniela Rodriguez, and Lucia Jiménez.

Thanks to Riad F. Farah, Maurice Page, and Artiom Schepilov for their support in translating survey responses, emails and other communication in Arabic, French, and Russian language respectively.

Thanks to WHO technical officers in the regional officers, as follows: Edith Annan, Diana Taguembou and Aissatou Sarassa, Regional Office for Africa; Alexandre Lemgruber, Nilda Enriquez, Regional Office for the Americas/Pan American Health Organization; Tifenn Lucile Humbert, Regional Office for Europe; Mohamad Wehbi, Regional Office for the Eastern Mediterranean; Stephen Himley, Regional Office for South-East Asia; Jinho Shin, Regional Office for the Western Pacific.

Thanks to Daniela Rodriguez for her support in publishing this document by helping with the clearance, website creation, validation of indicator metadata and Jillian Reichenbach Ott for the data management.

Acronyms and abbreviations

CSoMD21	Country survey on medical devices 2020-2021
FY21	Fiscal Year 2021
EMDN	European Medical Device Nomenclature
GII	Global Innovation Index
GNI	gross national income
GHO	WHO Global Health Observatory
GMDN	Global Medical Device Nomenclature
HDI	Human Development Index
HTA	health technology assessment
IAEA	International Atomic Energy Agency
ICT	information, and communication technology
IDI	ICT Development Index
ITU	International Telecommunication Union
IHDI	inequality adjusted Human Development Index
IVDs	in vitro diagnostics
MOH	Ministry of Health
MOR	mortality
NCDs	noncommunicable diseases
OECD	Organisation for Economic Co-operation and Development
POP	population
SDGs	Sustainable Development Goals
UHC	Universal Health Coverage
UMDNS	Universal Medical Device Nomenclature System
UN	United Nations
UN POP	United Nations Population Division of the Department of Economic and Social Affairs
WB	World Bank
WHO	World Health Organization
WHS	World Health Statistics
WIPO	World Intellectual Property Organization
WPP	World Population Prospects

Preface

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis, and treatment of disease as well as patient monitoring. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007.

To determine the key areas that require support for the development or improvement of health technology programs in countries and regions, the first WHO Baseline country survey on medical devices was launched in February 2010 by the WHO Department of Essential Health Technologies and resulted in the first set of country profiles conveying the situation of medical devices globally. The country profiles were updated with a re-launch of the survey in November 2013 and since then, every 3 years, updates of the global medical device data have been published. In 2017 the Global Atlas of medical devices[1] book was published containing 177 country profiles, an introduction to the medical device topics covered by the survey, and the corresponding facts, figures, and maps. From November 2020 until March 2021, and then from September 2021 to May 2022, the latest complete re-launch of the survey was carried out and its results are presented in this publication containing all 194 country profiles. It should be noted that the COVID-19 situation alerted the challenges presented by lack of priority or basic medical devices.

This publication is intended for use as a reference by decision-makers in ministries of health, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels. For a deeper understanding of the importance and standing in the health care domain of each of the survey's topics please refer to the document Global Atlas of medical devices - WHO medical devices technical series 2017 that addresses these in separate chapters.

1 Global atlas of medical devices - WHO medical devices technical series", ISBN 978 -92 -4 -151231 -2 © World Health Organization 2017.

Methodology

The 2020 re-launch of the 2010 Baseline country survey on medical devices was conceptualized and realized by the medical devices team. The appointed health technology focal points of 177 Member States[2] and more than 500 country contacts, as well as WHO contacts and related contacts in the 17 countries without appointed focal points, were contacted by email in 4 different languages with a request to support and coordinate either the update of the information already available in the previous atlas data or - in case of countries that had not answered the previous surveys - their first participation in the survey. Additionally, the medical devices team with the help of consultants, performed a web-based desk review of all countries to verify, update or newly include valid links to national websites regarding regulation, health technology assessment, and nomenclature.

These efforts resulted in the final collection of all countries, either directly via nominated official health technology focal points i.e. 179 countries or indirectly via specific medical device country focal points. Results were analyzed, evaluated, compiled, and are now presented in this document in country profiles, together with additional information regarding the global and national medical device situations. The country profiles incorporate facts indicating the national status of medical devices in areas such as: medical device policies, regulations, incorporation, lists, inventories, nomenclature, health technology assessment, management, and biomedical engineering resources.

The focus of the 2021 edition of the Global Atlas is to point out how the status of medical device topics supports or hinders the accomplishment of the Sustainable Development Goals (SDGs) and supports the increased access to priority medical devices (including in vitro diagnostics) for emergencies, well being and universal health coverage (UCH).

During the Information sessions on nomenclature of medical devices, Member States requested to extend the open consultation to review the Global Atlas . Therefore, consultations took place in 2021 and 2022 by posting in the WHO medical devices newsletter and in the nomenclature page.

2 The countries' health technology focal points were nominated and their roles established in a two year effort upon the initiative of the WHO medical devices team in 2010.

Sources of the country profile's indicators

In the country profile there are four sections that contain indicators that may be taken from another source other than the Country Survey of Medical Devices 2020-2021 (CSoMD21) consultation. Among these sources we have the following: International Atomic Energy Agency: IAEA; Organisation for Economic Co-operation and Development OECD; and WHO Global Health Observatory: GHO. Here we specified each of the indicators, as well as their definition, details and sources.

Country indicators section

Total Population for all ages and both sexes (in millions) : corresponding population of year 2020 medium estimates. World population prospects: the 2019 revision. POP/DB/WPP/Rev.2019/POP/ F01-1. United Nations, Department of Economic and Social Affairs, Population Division (2019). World Population Prospects 2019, Online Edition, accessed June 2021. UNDP WPP 2019 (2020 POP).

World Bank Income group classification: (WB Income Classification) The World Bank assigns the world's economies to four income groups: low, lower-middle, upper-middle, and high-income countries. The classifications are updated each year on July 1 and are based on GNI per capita in current USD (using the Atlas method exchange rates) of the previous year (i.e. 2021 in this case). In this publication the classification used corresponds to the Fiscal Year of 2023: WB: FY23 (data year: 2021). . Accessed October 2022. (The link provided updates the year classification each 1st of July, If it is the case you must refer to the historical WB income classification to find the fiscal year of 2023: FY23).

Life expectancy at birth (years): The average number of years of life expected by a hypothetical cohort of individuals who would be subject during all their lives to the mortality rates of a given period. It is expressed as years. UN: WPP 2019, MORT (data year: 1990-2020). Accessed June 2022.

Under-five mortality rate (per 1000 live births) (SDG 3.2.1): Probability of dying by age 5 per 1000 live births. WHO Global Health Observatory (GHO) data. UN-IGME, SDG 3.2.1 (data year: 2020). Accessed October 2022.

Probability of dying 30-70 of NCDs (SDG 3.4.1): probability of dying between age 30 and exact age 70 years from any of cardiovascular disease, cancer, diabetes, or chronic respiratory disease. WHO Global Health Observatory (GHO) data. WHO: GHO, SDG 3.4.1 (data year: 2019). Accessed October 2022.

Human Development Index (HDI): This a summary measure of average achievement in key dimensions of human development: a long and healthy life (life expectancy at birth), being knowledgeable (education dimension measured by mean of years of schooling for adults aged years and more and expected years of schooling for children of school entering age), and have a decent standard of living (measured by gross national income per capita). Inequality adjusted HDI (IHDI): adjusts the HDI for inequality in the distribution of each of the three dimensions across the population. UNDP: HDR 2019/20, HDI and IHDI (data year: 2019).Accessed June 2022. HDI and IHDI technical notes

Information, communication technology (ICT) Development Index (IDI): is a composite index combining eleven indicators into one benchmark measure that serves to monitor and compare developments in ICT between countries and over time. It is composed by 3 ICT related components: readiness (infrastructure, access), use (intensity), and capability (skills). ITU: IDI 2017 (data year: 2017). Accessed June 2022. IDI methodology.

Service coverage Index (SDG 3.8.1): average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the general and the most disadvantaged population. WHO Global Health Observatory (GHO) data. WHO: GHO, SDG 3.8.1 (data year: 2019). Accessed June 2022.

Percentage of the population with out-of-pocket health spending exceeding 10% or 25% of the household expenditure/budget/income: (SDG 3.8.2). WHO Global Health Observatory (GHO) data. WHO: GHO, SDG 3.8.2, 10% (data year: latest 2010-18) and WHO: GHO, SDG 3.8.2, 25% (data year: latest 2010-18). Both accessed June 2022.

Global Innovation Index (GII): Is an annual ranking of countries by their capacity for, and success in, innovation. It is computed by taking a simple average of the scores in two sub-indices, the Innovation Input Index and Innovation Output Index, which are composed of five and two pillars respectively. Each of these pillars describes an attribute of innovation. Each pillar is divided into three sub-pillars, each of which is composed of individual indicators, a total of 80 indicators are in GII 2020 exploring a broad vision of innovation, including political environment, education, infrastructure and business sophistication. WIPO: GII (data year: 2020). Accessed June 2022. GII Conceptual Framework

High-technology exports (% of manufactured exports): Are products with high R&D intensity, such as in aerospace, computers, pharmaceuticals, scientific instruments, and electrical machinery. UN-WB: HtE (data year: latest 2017-19). Accessed June 2022.

National health technology assessment unit section

Designated unit/department for health technology assessment (HTA): states if the country country has a systematic formal process by which information is gathered to support healthcare decision-making at a national level (options: Yes or No). Latest country data during the period 2015 to 2021 from one of the following sources: WHO: HTA&HBP 2021 survey, WHO: HTA 2015 survey; and WHO CSoMD21. Both accessed June 2022.

Medical device nomenclature system section

Official nomenclature system for medical devices: states if the country has reported having an official nomenclature system for medical devices (options: Yes or No).

Type of nomenclature system for medical devices: states the reported type of official nomenclature system by the country. The following seven nomenclature categories were taken into account: 1: Based on GMDN (Global Medical Device Nomenclature); 2: Based on UMDNS (Universal Medical Device Nomenclature System); 3: Based on EMDN (European Medical Device Nomenclature System) 4: Nationally developed 5: Based on more than one system; 6: Other; 7: None.

"Based on" wording should be interpreted as includes original dataset or modified version.

Use of nomenclature system for medical devices states: the reported specific use of the official nomenclature system by the country. The following five categories of specific uses were taken into account: 1: For regulatory purposes; 2: For procurement purposes; 3: For regulatory and procurement purposes; 4: For various purposes; 5: Not specified.

The first version of data collection related to medical devices, the Country Survey of Medical Devices (CSoMD), was carried out during the 2010–2013 period. Thereafter, in the 2014–2017 and 2020–2021 periods, data relating to medical devices was collected in what has now been referred to as the **Country Survey (2020)**. The Global Atlas of Medical Devices 2022 data collection was reviewed and updated if necessary, at the request of the Member States, in an open consultation that lasted from September 2021 to May 2022, referred to as **Nomenclature and Global Atlas consultations (2021–2022)**.

Medical equipment section

Density of magnetic resonance imaging units (per million population): number of Magnetic Resonance (MRI) units from the public and private sectors, per million population (UN: WPP 2019, POP (data year: 2020)). Latest country data during the period 2013 to 2021 from one of the following sources: WHO CSoMD21, WHO: GHO, MD: MRI, and OECD, HE database (2017-19). Both accessed June 2022.

Density of computed tomography units (per million population): number of Computed tomography (CT) scan units from the public and private sectors, per million population (UN: WPP 2019, POP (data year: 2020)). Latest country data during the period 2013 to 2021 from one of the following sources: WHO CSoMD21, WHO: GHO, MD: CT, and OECD, HE database (2017-19). Both accessed June 2022.

Density of positron emission tomography units (per million population): number of Positron emission tomography (PET) units from the public and private sectors, per million population (UN: WPP 2019, POP (data year: 2020).Latest country data during the period 2013 to 2021 from one of the following sources: WHO CSoMD21, WHO: GHO, MD: PET, and OECD, HE database (2017-19). Both accessed June 2022.

Density of gamma camera or nuclear medicine units (per million population): number of Gamma camera or Nuclear medicine units from the public and private sectors, per million population (UN: WPP 2019, POP (data year: 2020)). Latest country data during the period 2013 to 2021 from one of the following sources: CSoMD21, WHO: GHO, MD: GC-NC, and OECD, HE database (2017-19). Both accessed June 2022.

Density of mammographs (per million females aged between 50 and 69 years old): Number of mammographs units from the public and private sectors, per million population (UN: WPP 2019, POP (data year: 2020). Latest country data during the period 2013 to 2021 from one of the following sources: WHO CSoMD21 and WHO: GHO, MD: MAM, and OECD, HE database (2017-19). Both accessed June 2022.

Density of radiotherapy units (per million population): number of radiotherapy units (RU) including the following: circular and linear accelerators (LINAC), Radionuclide teletherapy units, Brachytherapy units, proton ion therapy or particle accelerators, and X-Ray generators (as defined by IAEA); per million population (UN: WPP 2019, POP (data year: 2020)). Latest country data during the period 2013 to 2021 from the latest available of the following sources: WHO CSoMD21; WHO: GHO, RU and IAEA: DIRAC database (2017-21). Both accessed June 2022.

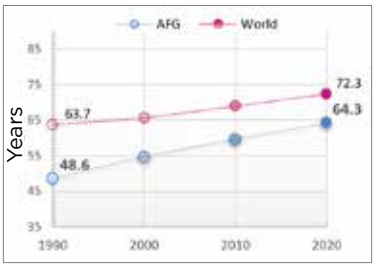
Medical devices workforce section

Number of biomedical/clinical engineers professionals in the country: Number of biomedical engineers (holding the corresponding university degree). Latest country data during the period 2017 to 2021 from the latest available of the following sources: CSoMD21; and WHO: GHO, HW. Accessed October 2022.

Country profiles

Afghanistan

Country indicators - WHO country information

Population 000s (rank):[a]	38,928 (37)	Under-five mortality (per 1000 live births):[d]	57.98	UHC - Service coverage index (1-100):[h]	37
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	35.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	14.6% (2.0%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.51 (—): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	2 (159)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: Yes, but it is only a recommendation

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit comments (...Annex 1): The National HTA unit is not yet established.

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

National regulatory comments (...Annex 1): —

Name of regulatory agency: General Directorate Pharmaceutical Affairs, Ministry of Public Health (MoPH).

Website(s): http://moph.gov.af/en

Contact: Mr. Abdul Hafiz Quraishi Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	3	0.1
Computerized Tomography Scanner:[α]	6	0.2
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	0	0
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Radiology, Ministry of Public Health. Unit website: —
Contact name: Mr. Mirza Said Hashimi Contact email: moph.ird@gmail.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Dr. Asheq Khan Sadaty
Email: moph.dds@gmail.com

Name: Mr. Mirza Said Hashimi
Email: moph.ird@gmail.com

WHO Country officer(s):
Name: Dr. Dapeng Luo
Email: luod@who.int

Name: Dr. Najibullah Safi
Email: safin@who.int

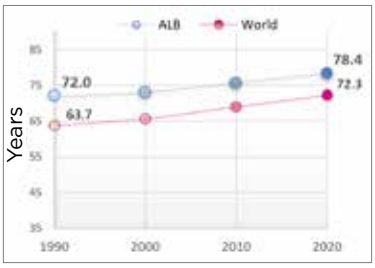
General comments (...Annex 1):

Concerning the HT national policy, it can be found the following document, within the provided website: ley-18211-dec-5-2007 SNIS.pdf.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Albania

Country indicators - WHO country information

Population 000s (rank):[a]	2,878 (137)	Under-five mortality (per 1000 live births):[d]	9.84	UHC - Service coverage index (1-100):[h]	62
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	11.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	16.7% (5.0%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.8 (0.71): high	Global innovation index (rank):[j]	27.1 (83)
		ICT Development Index (rank):[g]	5.1 (89)	High-technology exports (% of manufacture exports):[k]	0.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_albania.pdf
https://shendetesia.gov.al/

Language(s): English and Albanian

Ministry of health responsible for health technology policy implementation: Unit for the Management of Medical Devices.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: http://akbpm.gov.al/publikime/
http://akbpm.gov.al/wp-content/uploads/2020/12/Regjistri-i-Barnave-Dhjetor-2020.xlsx

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There is not yet an HTA national unit but it has been acknowledged at a political level by the MoH. There is a centralized system for managing health products pricing and reimbursement via the Ministry of Health, the National Agency for Drugs and Device, and the Drug Price Commission.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: National Agency for Drugs and Medical Devices (AKBPM).

Website(s): http://akbpm.gov.al/
https://shendetesia.gov.al/misioni-2/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Agjencia Kombetare e Barnave dhe Pajisjeve Mjekesore (National Agency for Drugs and Medical Devices).

Other agency's website: http://akbpm.gov.al/?lang=en

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For procurement purposes
Website: —

Nomenclature comments (...Annex 1):
This italian nomenclature system CIVAB comes with the Inventory system called CLINGO.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
It exists the National Policy for management of medical devices in Albania. The procurement of medical devices at national levels is done partially.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	5	1.58
Computerized Tomography Scanner:α	17	5.36
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	18	54.4
Radiotherapy:β	6	2.08

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Unit for the Management of Medical Devices. Unit website: —
Contact name: Ms. Ledina Picari Contact email: lpicari@moh.gov.al
Website with publically available technical specifications: —
Number of regional/state offices/units: 4

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Clingo.

Software comments (...Annex 1):
The inventory system is called CLINGO. The National Biomedical Centre manages the system. Each hospital (13 regional hospitals are involved) is in charge of adding their own data. It doesn't cover all the hospitals and other public health institutions.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 55

Contacts

National officer(s):
Name: —
Email: —

Name: Ms. Ledina Picari
Email: lpicari@moh.gov.al

WHO Country officer(s):
Name: Dr. Gerald Rockenschaub
Email: rockenschaubg@who.int

Name: —
Email: —

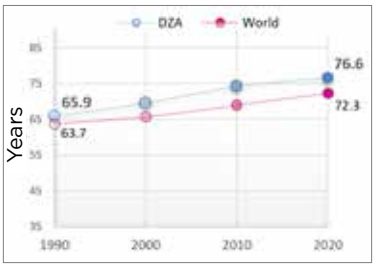
General comments (...Annex 1): Concerning the HT national policy, the following document was provided:

http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_albania.pdf

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Algeria

Country indicators - WHO country information

Population 000s (rank):[a]	43,851 (33)	Under-five mortality (per 1000 live births):[d]	22.68	UHC - Service coverage index (1-100):[h]	75
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	13.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.75 (0.6): high	Global innovation index (rank):[j]	19.5 (121)
		ICT Development Index (rank):[g]	4.7 (102)	High-technology exports (% of manufacture exports):[k]	1.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: http://www.sante.gov.dz/communiques/82-documentation/455-programmes-d-importation-des-produits-pharmaceutiques.html

Language(s): Français

Ministry of health responsible for health technology policy implementation: Direction Générale de la Pharmacie.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): Adopted EMA (European Medicines Agency) and ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH HTA is focused on pharmaceutics but not in medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministère de la santé, de la Population et de la Réforme Hospitalière.

Website(s): www.sante.gov.dz

Contact: Dr. Hamou Hafed Email: dgpharmacie@sante.dz

Name(s) of other regulatory agency eg. for radiation equipment etc.: Algerian Atomic Energy Commission (Comena).

Other agency's website: https://www.aps.dz/en/algeria/tag/Atomic%20Energy%20Commission

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	49	1.12

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: Sous direction de l'enregistrement des produits pharmaceutiques. Unit website: www.sante.gov.dz
Contact name: Dr. Soumia Yahiaoui Contact email: bensoumi20@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: —
Email: —

Name: Dr. Soumia Yahiaoui
Email: bensoumi20@yahoo.com

WHO Country officer(s):
Name: Dr. Bla François Nguessan
Email: nguessanf@who.int

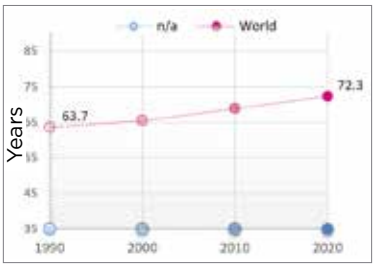
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Andorra

Country indicators - WHO country information

Population 000s (rank):[a]	77 (184)	Under-five mortality (per 1000 live births):[d]	2.53	UHC - Service coverage index (1-100):[h]	77
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	—	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.87 (—): very high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	7.7 (30)	High-technology exports (% of manufacture exports):[k]	28.50%

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There are identified HTA activities but not a national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: —
Email: —

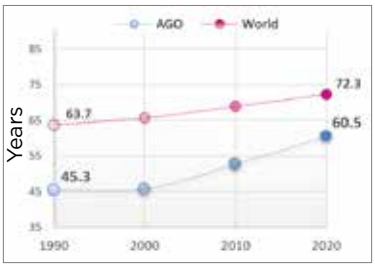
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Angola

Country indicators - WHO country information

Population 000s (rank):[a]	32,866 (44)	Under-five mortality (per 1000 live births):[d]	71.47	UHC - Service coverage index (1-100):[h]	39
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.58 (0.4): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	1.9 (160)	High-technology exports (% of manufacture exports):[k]	5.80%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Agência Reguladora de Medicamentos e Tecnologias de Saúde (ARMED)

Website(s): —

Contact: Dr. Boaventura Moura Email: boaventura.ao@gmail.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

June 4, 2021: With Presidential Decree 136/21 the extinction of the Direcção Nacional de Medicamentos e Equipamentos is announced and the Regulatory Agency for Medicines and Health Technologies (ARMED) is created, which will have its headquarters in Luanda, Angola and will be supervised by the Ministry of Health.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1	0.05
Computerized Tomography Scanner:[α]	9	0.42
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	5	6.33
Radiotherapy:[β]	4	0.12

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: Mr. Elisio de Carvalho Contact email: oisile2000@yahoo.com.br
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Mr. Elisio de Carvalho
Email: oisile2000@yahoo.com.br

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Djamila Khady Cabral
Email: cabrald@who.int

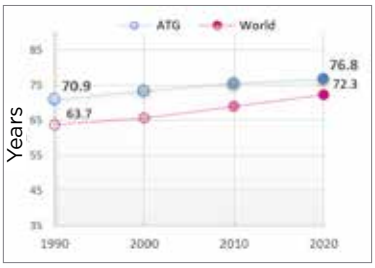
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Antigua and Barbuda

Country indicators - WHO country information

Population 000s (rank):[a]	98 (183)	Under-five mortality (per 1000 live births):[d]	6.39	UHC - Service coverage index (1-100):[h]	72
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	17.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (—): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	5.7 (76)	High-technology exports (% of manufacture exports):[k]	0.60%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

National regulatory comments (...Annex 1): —

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1	11.11
Computerized Tomography Scanner:[α]	2	22.23
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	2	272.15
Radiotherapy:[β]	1	10.2

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Mr. St. Clair A. Soleyn
Email: stclairsoleyn@gmail.com

Name: —
Email: —

WHO Country officer(s):
Name: Dra. Amalia Del Riego
Email: delriegoa@paho.org

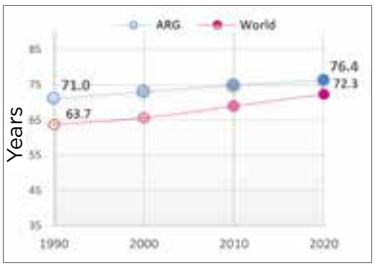
Name: Dr. Cecilia Acuna
Email: acunamar@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Argentina

Country indicators - WHO country information

Population 000s (rank):[a]	45,196 (32)	Under-five mortality (per 1000 live births):[d]	8.56	UHC - Service coverage index (1-100):[h]	73
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	15.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.85 (0.73): very high	Global innovation index (rank):[j]	28.3 (80)
		ICT Development Index (rank):[g]	6.8 (51)	High-technology exports (% of manufacture exports):[k]	5.20%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.argentina.gob.ar/ anmat

Language(s): Español

Ministry of health responsible for health technology policy implementation: Secretaría de Calidad en Salud - Ministerio de Salud

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Instituto Nacional de Productos Médicos - ANMAT

Website: https://www.argentina.gob.ar/anmat
https://helena.anmat.gob.ar/Boletin/
http://www.anmat.gov.ar/boletin_anmat/ principal.asp

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Existe una base de datos que contiene a las tecnologías sanitarias (denominados productos médicos) registradas y disponibles en el sitio -ver tercera liga web- (accesible con colocar nombre génerico de producto (por ej: apósito) o con su identificación (Nº de PM).

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.argentina.gob.ar/sssalud/hospitales

Website - laboratories: https://helena.anmat.gob.ar/Boletin/
http://www.anmat.gov.ar/ boletin_anmat/principal.asp

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

Cirugía, diagnóstico por imágenes, laboratorio, terapia intensiva.

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.argentina.gob.ar/salud/calidadatencionmedica

Specific lists comments (...Annex 1):

Actualmente existen lineamientos para la elaboración de guías. Disponible en la segunda página web proporcionada.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) - Instituto Nacional de Productos Médicos

Website(s): https://www.argentina.gob.ar/noticias/sobre-los-procesos-de-control-de-dispositivos-medicos
http://www.anmat.gov.ar/webanmat/normativas_productosmedicos_cuerpo.asp
http://www.iecs.org.ar
https://www.argentina.gob.ar/salud/conetec

Contact: Manuel Donato Email: farmdonatomanuel@gmail.com

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

In 2018, by Ministerial Resolution of Health No. 623, the National Commission for the Evaluation of Health Technologies (CONETEC) was created within the scope of the Ministry of Health, dependent on its General Coordination Unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) - Instituto Nacional de Productos Médicos

Website(s): https://www.argentina.gob.ar/anmat/regulados/productos-medicos

Contact: Lic. Andrea Bodnar Email: andrea.bodnar@anmat.gob.ar

Name(s) of other regulatory agency eg. for radiation equipment etc.: Autoridad Regulatoria Nuclear (ARN)

Other agency's website: https://www.argentina.gob.ar/arn

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS
Use: For regulatory purposes
Website: —

Nomenclature comments (...Annex 1):
The Administración Nacional de Medicamentos Alimentos y Tecnología Médica (ANMAT), reported the use of the Universal Medical Device Nomenclature System (UMDNS) for regulatory purposes of the medical devices in this country

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.anmat.gov.ar/webanmat/productos_medicos/recomendaciones_compraprod.medicos.asp
National level procurement: Yes Website: http://www.anmat.gov.ar/webanmat/productos_medicos/recomendaciones_compraprod.me dicos.asp

Medical device incorporation comments (...Annex 1):
For procurement of medical devices at national level we use the: "lista licitaciones".

Donations

Policy or guideline: Yes Website: https://www.argentina.gob.ar/anmat/regulados/productosmedicos/requisitos-para-el-ingreso-al-pais-de-productos-donados

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.argentina.gob.ar/anmat/regulados/productosmedicos/requisitos-para-el-ingreso-al-pais-de-productos-donados

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	179	3.96

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: Unidad Coordinadora de Evaluación y Ejecución de Tecnologías en Salud.
Unit website: https://www.argentina.gob.ar/anmat
Contact name: Dra. Analía del Carmen Amarilla Contact email: pngc@msal.gov.ar
Website with publically available technical specifications: https://www.argentina.gob.ar/anmat
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 1500

Contacts

National officer(s):
Name: Dra. Analia del Carmen Amarilla
Email: aamarilla@msal.gov.ar

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Eva Jané Llopis
Email: janellopis@paho.org

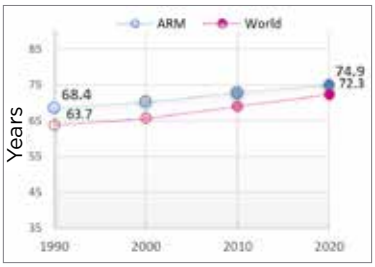
Name: Dra. Sonia Quezada
Email: quezadas@paho.org

General comments (...Annex 1): The MoH wants to push awareness/surveillance about health technology quality, technical specifications, etc.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Armenia

Country indicators - WHO country information

Population 000s (rank):[a]	2,963 (134)	Under-five mortality (per 1000 live births):[d]	10.94	UHC - Service coverage index (1-100):[h]	69
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	19.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	16.1% (4.9%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (0.7): high	Global innovation index (rank):[j]	32.6 (61)
		ICT Development Index (rank):[g]	5.8 (75)	High-technology exports (% of manufacture exports):[k]	9.80%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Health Project Implementation Unit and Scientific Centre of Drug and Medical Technology Expertise.

Website(s): https://healthpiu.am/ http://www.pharm.am/index.php/en/aboutus

Contact: Mr. Armen Madantsyan Email: healthpiu@gmail.com

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): Informing decisions of the cited institutions are not specifically HTA. Alternative email: info@healthpiu.arm.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of Health (MoH).

Website(s): https://www.moh.am/#3/27

Contact: Mr. Armen Karapeyan Email: akarapetyan@moh.am

Name(s) of other regulatory agency eg. for radiation equipment etc.: Armenian Nuclear Regulatory Authority (ANRA).

Other agency's website: http://www.anra.am/index.aspx http://www.pharm.am/index.php/en/

National regulatory comments (...Annex 1): "National Institute of Metrology"; National Institute of Standards"; "ArmAtomInspection"; and "Scientific Center of Drug and Medical Technology Expertise".

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The technical specifications are developed by the Health Project Implementation Unit (HPIU) biomedical engineer in cooperation with international consultants.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	7	2.35
Computerized Tomography Scanner:α	9	3.02
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	4	1.34
Mammograph:α,*	7	22.5
Radiotherapy:β	5	1.69

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Health Project Implementation Unit (HPIU). Unit website: http://www.pharm.am/
Contact name: Mr. Armen Madantsyan Contact email: Healthpiu@gmail.com
Website with publically available technical specifications: http://www.pharm.am/attachments/article/183/Appendix_2_%20Notice%20to%20Applicants_eng.pdf
http://www.pharm.am/index.php/en/orders/5472-order-of-minister-of-health-of-the-republic-of-armenia-n02-n-of-january-21-2020-on-approval-of-the-requirements-of-labeling-and-packaging-for-medicinal-products-pharmaceutical-substances-herbal-raw-materials-investigational-medicinal-products-as-well-as-f
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: http://www.pharm.am/
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):
Name: Mr. Armen Madantsyan
Email: healthpiu@gmail.com

Name: —
Email: Healthpiu@gmail.com

WHO Country officer(s):
Name: Dr. Jihane F. Tawilah
Email: tawilahj@who.int

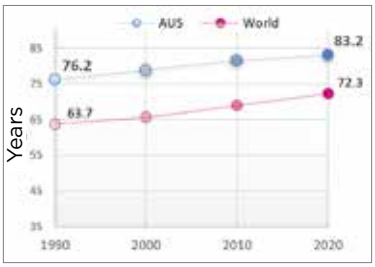
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Australia

Country indicators - WHO country information

Population 000s (rank):[a]	25,500 (55)	Under-five mortality (per 1000 live births):[d]	3.7	UHC - Service coverage index (1-100):[h]	87
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	8.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.7% (0.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.94 (0.87): very high	Global innovation index (rank):[j]	48.4 (23)
		ICT Development Index (rank):[g]	8.2 (14)	High-technology exports (% of manufacture exports):[k]	21.50%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: —

Unit: —

Website: www.tga.gov.au/australian-register-therapeutic-goods

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Australian Register of Therapeutic Goods (ARTG) – marketing approval and used to guide procurement in national and state/territory processes

Prostheses List of implanted medical devices for private patients -

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: GMDN

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Pharmaceutical Benefits Advisory Committee / Medical Services Advisory Committee / Prostheses List Advisory Committee / Therapeutic Goods Administration. Committees including the Advisory Committee on Medical Devices (ACMD)

Website(s): http://www.msac.gov.au/internet/msac/publishing.nsf/Content/Factsheet-02
https://www1.health.gov.au/internet/hta/publishing.nsf/Content/pbs-1
https://www1.health.gov.au/internet/hta/publishing.nsf/Content/mbs-1
https://www1.health.gov.au/internet/hta/publishing.nsf/Content/prostheses-1

Contact: — Email: hta@health.gov.au; devices@tga.gov.au

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):

The Therapeutic Goods Administration (TGA), the Medical Services Advisory Committee (MSAC), the Pharmaceutical Advisory Committee (PBAC), and the Prostheses List Advisory Committee (PLAC) perform Health Technology Assessment (HTA) processes to provide advice to the Australian Government Department of Health.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Australian Therapeutic Goods Administration (TGA).

Website(s): http://www.tga.gov.au/medical-devices-ivds

Contact: Tracey Duffy Email: devices@tga.gov.au

Name(s) of other regulatory agency eg. for radiation equipment etc.: Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

Other agency's website: https://www.arpansa.gov.au/

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN
Use: Therapeutic goods regulation (market authorisation) and procurement purposes by Government and non-Government entities and hospitals
Website: www.tga.gov.au

Nomenclature comments (...Annex 1):
The use of GMDN is a legal mandatory requirement for devices supplied in Australia, including IVDs.

Medical device incorporation

Procurement

Policy or guideline: National Medical Stockpile, National, State and Territory Governments Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: Government procurement websites at national and state/territory levels
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	375	14.71
Computerized Tomography Scanner:[α]	1782	69.88
Positron Emission Tomography Scanner:[α]	102	4
Gamma camera or nuclear medicine:[α]	483	18.94
Mammograph:[α,*]	589	201.23
Radiotherapy:[β]	237	9.29

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1):
The National Product Catalogue provides an inventory input to a number of hospital procurement and equipment managements systems. Also, various systems are used by public and private hospitals

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 320

Contacts

National officer(s):
Name: Mr. Chris Bedford
Email: chris.bedford@health.gov.au

Name: —
Email: —

WHO Country officer(s):
Name: —
Email: —

Name: —
Email: —

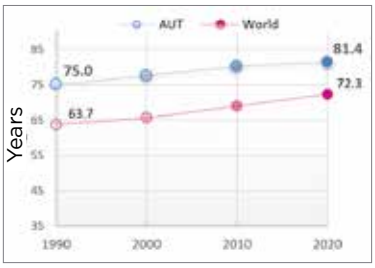
General comments (...Annex 1):

Australia's health system policy and delivery is at both a national and state/territory level. All medical devices must be included in the Australian Register of Therapeutic Goods.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Austria

Country indicators - WHO country information

Population 000s (rank):[a]	9,006 (96)	Under-five mortality (per 1000 live births):[d]	3.62	UHC - Service coverage index (1-100):[h]	82
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.92 (0.86): very high	Global innovation index (rank):[j]	50.1 (19)
		ICT Development Index (rank):[g]	8 (21)	High-technology exports (% of manufacture exports):[k]	11.50%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.sozialministerium.at/en.html

Language(s): German

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Hauptverband der österreichischen Sozialversicherungsträger.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.sozialministerium.at/public.html

Website - laboratories: https://www.sozialministerium.at/public.html

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.sozialministerium.at/public.html

Specific lists comments (...Annex 1): Österreichischer Strukturplan Gesundheit (up mentioned link) and various guidelines of the medical societies, internal guidelines of the hospitals, etc. Also, there is the Austrian Influenza Pandemic Plan.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: GOEG/BIQG

Website(s): http://www.goeg.at
https://aihta.at
http://www.sozialversicherung.at

Contact: Ms. Eva Kernstock Email: eva.kernstock@goeg.at

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): Only for the hospital benefit catalogue there is a national HTA process in place, but not for drugs. It is expected that it will be a process in place in the next 1-2 years.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Austrian Medicines and Medical Devices Agency (BASG).

Website(s): http://www.basg.gv.at/en/medical-devices/

Contact: Dr. Martin Renhardt Email: martin.renhardt@bmg.gv.at

Name(s) of other regulatory agency eg. for radiation equipment etc.: Austrian Federal Office for Safety in Health Care/Bundesamt für Sicherheit im Gesundheitswesen (BASG); International Atomic Energy Agency (IAEA).

Other agency's website: https://www.basg.gv.at
https://www-pub.iaea.org/MTCD/Publications/PDF/CSPS-7-P.pdf

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://goeg.at/Medizinprodukteregister

Nomenclature comments (...Annex 1):

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.hauptverband.at/

National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: No

Website: —

Medical device incorporation comments (...Annex 1):

The procurement is done with internal guidelines of the Hauptverband, insurance funds, hospitals, Bundesbeschaffungs GmbH, etc.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	208	23.1
Computerized Tomography Scanner:[α]	255	28.31
Positron Emission Tomography Scanner:[α]	24	2.66
Gamma camera or nuclear medicine:[α]	93	10.33
Mammograph:[α,*]	190	153.52
Radiotherapy:[β]	76	8.44

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Abteilung Medizinprodukte within MoH (BMSPGK). Unit website: http://www.bmg.gv.at

Contact name: Dr. Martin Renhardt Contact email: martin.renhardt@bmg.gv.at

Website with publically available technical specifications: https://www.sozialministerium.at/Themen/Gesundheit/Medizin-und-Gesundheitsberufe/Medizin/Medizinprodukte/Erlaesse-und-Richtlinien-im-Bereich-Medizinprodukte.html

Number of regional/state offices/units: 9

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: https://www.sozialministerium.at/

Use of management software: Yes Software name: Various: MTECS, Visual FM, SAP, etc.

Software comments (...Annex 1):

There are various software for the maintenance and inspection of medical devices in the hospital. Additionally, there is the implementation of a National Plan for high-cost technologies called: "Großgeräteplan".

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 800

Contacts

National officer(s):

Name: Dr. Martin Renhardt

Email: martin.renhardt@bmg.gv.at

Name: —

Email: —

WHO Country officer(s):

Name: —

Email: —

Name: —

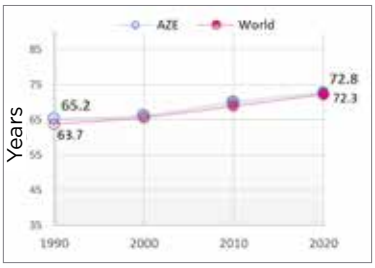
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Azerbaijan

Country indicators - WHO country information

Population 000s (rank):[a]	10,139 (89)	Under-five mortality (per 1000 live births):[d]	19.39	UHC - Service coverage index (1-100):[h]	65
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	27.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.76 (0.68): high	Global innovation index (rank):[j]	27.2 (82)
		ICT Development Index (rank):[g]	6.2 (65)	High-technology exports (% of manufacture exports):[k]	5.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Health Organization Department.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: Yes, but it is only a recommendation

Unit: Medical Technical Department of the Innovation and Supply Centre.

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): The HTA activities in pharmaceutics are not specifically for medical devices.

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: —

Website(s): https://www.isim.az/en/main

Contact: Mr. Kerimov Ramiz Talat Email: kerimov62@hotmail.com

Committee includes a biomedical or clinical engineer: —

National regulatory authority

National regulatory comments (...Annex 1): —

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: Analytical Expertise Center (MMA).

Website(s): http://www.pharma.az/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: State Agency for Normal and Radiological Activity Regulation (Ministry of Emergency Situations of the Republic of Azerbaijan).

Other agency's website: https://www.nuve.fhn.gov.az/organizations.php?aze-7

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: https://apps.who.int/iris/bitstream/handle/10665/44568/9789241501408_eng.pdf?sequence=1

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The Procurement guidelines are under development. For donations guidelines the WHO are the ones used. The corresponding technical specifications are under the responsibility of the Innovation and Supply Centre.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	14	1.38
Computerized Tomography Scanner:[α]	51	5.03
Positron Emission Tomography Scanner:[α]	2	0.2
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	25	22.5
Radiotherapy:[β]	12	1.18

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: Innovation and Supply Centre. Unit website: —
Contact name: Mr. Ramiz Kerimov Contact email: kerimov62@hotmail.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Mr. Kerimov Ramiz Talat
Email: kramiz62@hotmail.com

Name: Mr. Ramiz Kerimov
Email: kerimov62@hotmail.com

WHO Country officer(s):
Name: Dr. Fatos Hande Harmanci
Email: harmancih@who.int

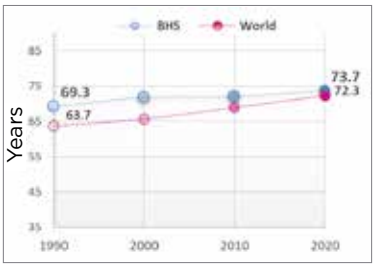
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Bahamas

Country indicators - WHO country information

Population 000s (rank):[a]	393 (170)	Under-five mortality (per 1000 live births):[d]	12.26	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	19.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.7% (0.2%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.81 (—): very high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	6.5 (57)	High-technology exports (% of manufacture exports):[k]	2.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): There are no lists recommending health technology for any of the above.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: Ministry of Health (MoH).

Website(s): https://www.bahamas.gov.bs

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: http://www.phabahamas.org/

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The Public Hospitals Authority, the corporate entity of the Ministry of Health, is responsible for managing the three Public Hospitals within the Bahamas. It uses the services of the ECRI Institute to assist in the procurement of medical devices.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	2.54
Computerized Tomography Scanner:α	5	12.72
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	4	95.1
Radiotherapy:β	2	5.09

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Supplies Management Agency. Unit website: —
Contact name: Mr. Audley Bain Contact email: abain1@pmh.phabahamas.org
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):
Name: Dr. Anthone Ward
Email: award@phabahamas.org

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Eldonna Boisson
Email: boissoel@paho.org

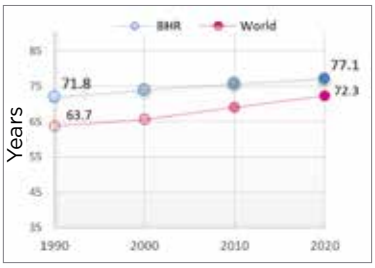
Name: Dr. Gabriel Vivas
Email: vivasfgab@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Bahrain

Country indicators - WHO country information

Population 000s (rank):[a]	1,702 (148)	Under-five mortality (per 1000 live births):[d]	6.76	UHC - Service coverage index (1-100):[h]	71
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.85 (—): very high	Global innovation index (rank):[j]	28.4 (79)
		ICT Development Index (rank):[g]	7.6 (31)	High-technology exports (% of manufacture exports):[k]	0.40%

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There are identified HTA activities but not a national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: National Health Regulatory Authority, Kingdom of Bahrain.
Website(s): https://www.nhra.bh/ https://www.moh.gov.bh/?lang=en
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministry of Health; Supreme Council for Environment.
Other agency's website: https://www.moh.gov.bh/?lang=en; ECD: https://www.sce.gov.bh/en/CommunicationGuide?cms=iQRpheuphYtJ6pyXUGiNqgEU69X91IJi

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: More than one system
Use: For regulatory and procurement purposes
Website: https://www.nhra.bh/Departments/MDR/
https://www.nhra.bh/

Nomenclature comments (...Annex 1):
It is needed the GMDN code for registration of medical devices, as well as the HS code.

Medical device incorporation

Procurement
Policy or guideline: — Website: —
National level procurement: — Website: —

Donations
Policy or guideline: — Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	2	1.18

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Tasnim Atatrah
Email: atatraht@who.int

Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
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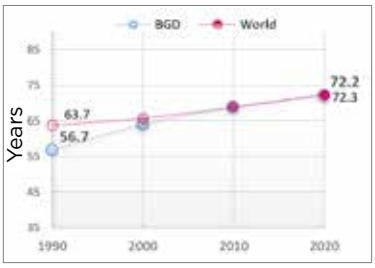
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Bangladesh

Country indicators - WHO country information

Population 000s (rank):[a]	164,689 (8)	Under-five mortality (per 1000 live births):[d]	29.1	UHC - Service coverage index (1-100):[h]	51
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	18.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	24.7% (9.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.63 (0.48): medium	Global innovation index (rank):[j]	20.4 (116)
		ICT Development Index (rank):[g]	2.5 (147)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Health Services Division.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: Yes

Unit: Directorate General of Drug Administration (DGDA).

Website: https://www.dgda.gov.bd/ index.php

Nomenclature systems used for devices and tests: National.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: Yes

Website - hospitals: —

Website - laboratories: http://dgda.gov.bd/index.php/2013-03-31-05-16-29/registered-medical-device-list/1102-list-of-registered-medical-device-for-import/file
https://www.dgda.gov.bd/ index.php/ information-center/ guidance-documents/ 1135-medical-device-registration-guideline- 2015

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

National regulatory comments (...Annex 1): Ms. S. M. Sabrina Yesmin is the Assistant Director of DGDA.

Name of regulatory agency: Directorate General of Drug Administration (DGDA).

Website(s): https://www.dgda.gov.bd/

Contact: Ms S. M. Sabrina Yesmin Email: sabrinayesmin22@gmail.com; sabrina@dgda.gov.bd

Name(s) of other regulatory agency eg. for radiation equipment etc.: Bangladesh Atomic Energy Regulatory Authority - Government of the People's Republic of Bangladesh; National Electro-Medical Equipment Maintenance Workshop and Training Center-Ministry of Health and Family Welfare.

Other agency's website: http://nememw.gov.bd/
http://www.baera.gov.bd/

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.cptu.gov.bd/default.aspx https://cptu.gov.bd/index.html
National level procurement: Yes Website: http://www.cptu.gov.bd/default.aspx https://cptu.gov.bd/procurement-policy-and-procedure-documents.html

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: https://cptu.gov.bd/index.html

Medical device incorporation comments (...Annex 1):
Technical specifications are not publically available.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	80	0.49
Computerized Tomography Scanner:α	50	0.3
Positron Emission Tomography Scanner:α	15	0.09
Gamma camera or nuclear medicine:α	14	0.09
Mammograph:α,*	12	1.12
Radiotherapy:β	43	0.26

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1):
Central Medical Stores Depot, Tejgaon, Dhaka-1208. Dhaka has all the data in this regards.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Mr. Salah Uddin
Email: salahuddin733@yahoo.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Bardan Jung Rana
Email: ranab@who.int

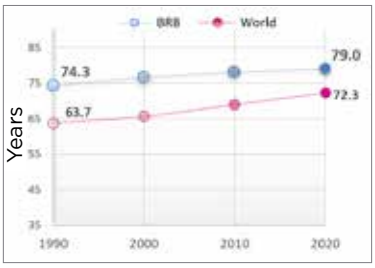
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Barbados

Country indicators - WHO country information

Population 000s (rank):[a]	287 (173)	Under-five mortality (per 1000 live births):[d]	12.25	UHC - Service coverage index (1-100):[h]	74
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	16.4% (3.8%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.81 (0.68): very high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	7.3 (34)	High-technology exports (% of manufacture exports):[k]	13.70%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): HTA activities have been identified, but there is not a national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
Procurement queries, comments, and information should be addresses to the Chief Supply Officer (email: joness@gob.bb).

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	2	7.03
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	1	3.51
Mammograph:[α,*]	1	28.96
Radiotherapy:[β]	2	6.97

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: Yes Software name: Equipment Management Software.

Software comments (...Annex 1):
There is not a national inventory but the Queen Elizabeth Hospital Engineering Services maintains an inventory of high-cost technologies and medical equipment; thus, there is an institutional inventory there. Also, all the polyclinics keep institutional inventory for medical equipment only. The institutional inventories at the hospital and the polyclinics are audited annually. Additionally, the Equipment management software is currently being installed at the Queen Elizabeth Hospital.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Mr. Dwayne Smith
Email: lordmonkman@yahoo.com

Name: Dr. Joy St. John
Email: cmo@health.gov.bb

WHO Country officer(s):
Name: Dra. Amalia Del Riego
Email: delriegoa@paho.org

Name: Dr. Cecilia Acuna
Email: acunamar@paho.org

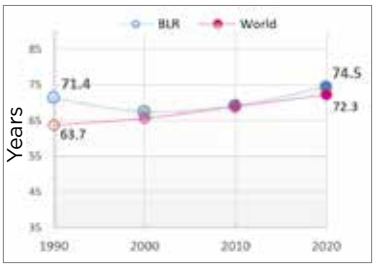
General comments (...Annex 1):

Concerning the Healthcare Infrastructure section: there are many single and grouped medical centres and general practice clinics/offices which perform primary care that includes emergency services. Some medical centres of the private sector perform secondary care services as well.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Belarus

Country indicators - WHO country information

Population 000s (rank):[a]	9,449 (95)	Under-five mortality (per 1000 live births):[d]	2.91	UHC - Service coverage index (1-100):[h]	74
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	23.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	9.2% (0.7%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.82 (0.77): very high	Global innovation index (rank):[j]	31.3 (64)
		ICT Development Index (rank):[g]	7.6 (32)	High-technology exports (% of manufacture exports):[k]	4.30%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://minzdrav.gov.by/en/dlya-spetsialistov/meditsinskie-izdeliya/
https://rceth.by/ru/Departments/Med/Documents?orderby=name&dir=desc

Language(s): Russian

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Department of Medical Technology of the Ministry of Health (MoH).

Website: http://www.pravo.by/

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
Documents: N° "2007 " and N° "458" in the specified website.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.rceth.by/
http://minzdrav.gov.by/upload/dadvfiles/%D0%BF%D1%80%D0%B8%D0%BB%D0%BE%D0%B6%D0%B5%D0%BD%D0%B8%D1%8F%20%D0%BA%201180.pdf

Website - laboratories: https://www.rceth.by/

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://minzdrav.gov.by/en/dlya-spetsialistov/standarty-obsledovaniya-i-lecheniya/
http://minzdrav.gov.by/en/dlya-spetsialistov/instruktsii-i-metodicheskie-rekomendatsii/index.php

Specific lists comments (... Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: The Republican Scientific and Practical Center for Medical Technologies, Informatization, Administration and Management of Health (BELC__) and Center for expertise and tests in healthcare (RCETH).

Website(s): https://www.rceth.by/ru/About/Activity
https://www.rceth.by/ru/Departments/Me
https://www.rceth.by/ru/Documents/Med/9
https://belcmt.by/en/Common

Contact: — Email: rceth@rceth.by

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
In BELCMT there are not informing decisions specifically for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of Health: Center of Expertise and Testing in Health Care; Department of Medical Equipment, Logistical Support, and Construction.

Website(s): http://www.rceth.by

Contact: A. Y. Stolyarov Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Department of Nuclear and Radiation Safety of the Ministry of Emergency Situations of the Republic of Belarus.

Other agency's website: https://gosatomnadzor.mchs.gov.by/en/o-gosatomnadzore/polozhenie-o-gosatomnadzore/

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: https://www.rceth.by/Documents/3mz3prN132420141216.pdf

Nomenclature comments (...Annex 1):
State register of medical equipment and medical supplies of Belarus.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://minzdrav.gov.by/en/ministerstvo/tsentralizovannye-zakupki.php
National level procurement: Yes Website: http://minzdrav.gov.by/en/dlya-spetsialistov/meditsinskie-izdeliya/zakupki-meditsinskikh-izdeliy.php
https://www.rceth.by/ru/Documents/Med
http://www.belmt.by/

Donations

Policy or guideline: Yes Website: http://minzdrav.gov.by/upload/dadvfiles/250.pdf

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Public procurement of medical devices and their specifications for each procurement procedure can be found in our website.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	24	2.57
Computerized Tomography Scanner:[α]	58	6.2
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	24	2.57
Mammograph:[α,*]	23	17.48
Radiotherapy:[β]	61	6.46

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department for the sale, installation and repair of medical equipment (Belmedtekhnika).
Unit website: http://minzdrav.gov.by/en/dlya-spetsialistov/meditsinskie-izdeliya/index.php
http://www.belmt.by/
Contact name: Mr. V. A. Hodzhaev Contact email: info@belmt.by
Website with publically available technical specifications: —
Number of regional/state offices/units: 7

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: http://minzdrav.gov.by/ru/sobytiya/cozdanie-kataloga-izdeliy-meditsinskogo-naznacheniya/
http://www.rceth.by
Use of management software: Yes Software name: —

Software comments (...Annex 1):
Go to website (first link) and find the document titled "mfindr".

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):

Name: Mr. V. A. Hodzhaev
Email: info@belmt.by

WHO Country officer(s):

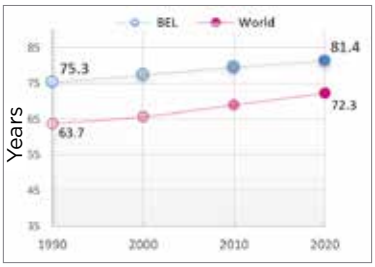
Name: Dr. Viatcheslav Grankov AI
Email: eurowhoblr@who.int

General comments (...Annex 1): –

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Belgium

Country indicators - WHO country information

Population 000s (rank):[a]	11,590 (80)	Under-five mortality (per 1000 live births):[d]	4.23	UHC - Service coverage index (1-100):[h]	85
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	11.5% (1.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.93 (0.86): very high	Global innovation index (rank):[j]	49.1 (22)
		ICT Development Index (rank):[g]	7.8 (25)	High-technology exports (% of manufacture exports):[k]	12.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.afmps.be/fr/humain/produits_de_sante/dispositifs_medicaux/generalites/legislation

Language(s): Français et Néerlandais

Ministry of health responsible for health technology policy implementation: Agence Fédérale des Médicaments et des Produits de Santé pour les dispositifs médicaux et les dispositifs médicaux implantables actifs et l'Institut Scientifique de Santé Publique -Section de Biologie clinique- pour les dispositifs médicaux de diagnostic in vitro.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Institut National d'Assurance Maladie Invalidité (INAMI).

Website: https://www.riziv.fgov.be/fr/Pages/default.aspx

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Ces listes existent indirectement par le remboursement de certains dispositifs médicaux et/ou le remboursement de certains tests cliniques effectués. Les dispositifs médicaux implantables et invasifs à long terme doivent se trouver

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: http://www.ejustice.just.fgov.be/cgi_loi/loi_a.pl?language=fr&caller=list&cn=2001111446&la=f&fromtab=loi&sql=dt=%27arrete%20royal%27&tri=dd+as+rank&rech=1&numero=1

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):

Ces listes existent indirectement par le remboursement de certains dispositifs médicaux et/ou le remboursement de certains tests cliniques effectués.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Health Care Knowledge Center (KCE).

Website(s): https://kce.fgov.be/en/health-technology-assessment
https://kce.fgov.be/en/towards-a-guided-and-phased-introduction-of-high-risk-medical-devices-in-belgium
https://www.wiv-isp.be/en
http://www.inami.fgov.be/

Contact: — Email: info@kce.fgov.be

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

The assestment includes pre-market clinical evaluation of innovative high-risk medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Agence Fédérale des Médicaments et des Produits de Santé (AFMPS).

Website(s): https://www.afmps.be/fr

Contact: Ms. Frédérique Meulders Email: frederique.meulders@afmps.be

Name(s) of other regulatory agency eg. for radiation equipment etc.: Competent Authority for in vitro diagnostic medical devices. Scientific Institute of Public Health - Dept. Clinical Biology Anne Van Nerom - and Agence Fédérale de Contrôle Nucléaire.

Other agency's website: https://afcn.fgov.be/fr

National regulatory comments (...Annex 1):

Agence Fédérale de Contrôle Nucléaire en ce qui concerne les dispositifs médicaux repris sous le point 3 de l'annexe XIII de l'Arrêté royal du 18/03/1999, qui veille au contrôle et à l'application du Règlement Général de la Protection de la population,

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://kce.fgov.be/en
https://www.famhp.be/en

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.afmps.be/fr
https://www.sciensano.be/en

National level procurement: No Website: https://www.afmps.be/fr
https://www.sciensano.be/en

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:131:0017:0030:fr:PDF

Medical device incorporation comments (...Annex 1):
Dans chaque Arrêté royal d'application se trouvent des exigences par rapport à la distribution et/ou la délivrance des dispositifs médicaux (docs: coord_tcm291-26685.pdf and tcm291-27069.pdf).|Décision de la Commission 2002/364/EC portant spécifications techniques communes des dispositifs médicaux de diagnostique in vitro.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	133	11.48
Computerized Tomography Scanner:α	272	23.47
Positron Emission Tomography Scanner:α	30	2.59
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	416	280.08
Radiotherapy:β	125	10.79

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 500

Contacts

National officer(s):

Name: Ms. Frédérique Meulders

Email: frederique.meulders@afmps.be

Name: Mr. Tom Clarijs

Email: —

WHO Country officer(s):

Name: —

Email: weu@who.int

Name: —

Email: —

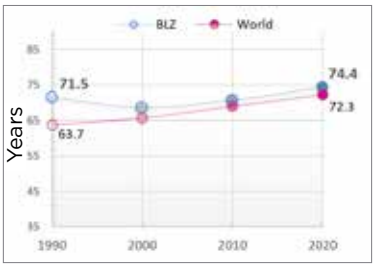
General comments (...Annex 1):

L'Agence fédérale de Contrôle nucléaire (AFCN) est en train de réviser les inventaires des dispositifs médicaux émettant des rayonnements ionisants présents en Belgique. Cet inventiare provient en partie de données fournies par les Organismes Agréés (AV Controlatom, TechniTest, ...). COCIR (European Coordination Committee of the Radiological, Electromedical and Medical IT Industries) peut également fournir des

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Belize

Country indicators - WHO country information

Population 000s (rank):[a]	398 (169)	Under-five mortality (per 1000 live births):[d]	11.66	UHC - Service coverage index (1-100):[h]	67
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.72 (0.55): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	3.7 (120)	High-technology exports (% of manufacture exports):[k]	0.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): English

Ministry of health responsible for health technology policy implementation: Regulatory Unit.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): Policy Analysis & Planning Unit, Ministry of Health.

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): There is no information about which lists are available.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): HTA activities have been identified, but there is not a specific national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
—

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The NEMC is trying to standardize equipment, and has suggested to set up a procurement committee. There is no follow up.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	3.01
Computerized Tomography Scanner:α	4	12.05
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	4	258
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 3

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
The NEMC is in the process of updating the Inventory, only for the public health facilities. The Karl Heusner Memorial Hospital (KHMH) has its own Inventory System.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Mr. Tony Nijssen
Email: mohnemc@gmail.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Jack Noreen
Email: jackn@paho.org

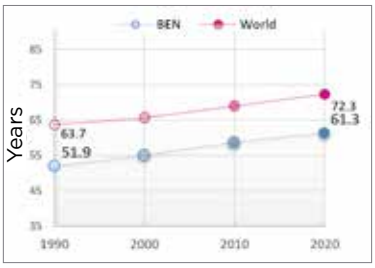
Name: Dr. Edwin Bolastig
Email: bolastie@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Benin

Country indicators - WHO country information

Population 000s (rank):[a]	12,123 (76)	Under-five mortality (per 1000 live births):[d]	85.94	UHC - Service coverage index (1-100):[h]	38
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	10.9% (5.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.55 (0.34): low	Global innovation index (rank):[j]	18.1 (126)
		ICT Development Index (rank):[g]	1.9 (161)	High-technology exports (% of manufacture exports):[k]	1.20%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Agence Béninoise de Régulation Pharmaceutique (ABRP)

Website: https://www.abrp.bj/

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.abrp.bj/dispositif.php

Website - laboratories: https://www.abrp.bj/reactifs.php
https://www.abrp.bj/documents/Liste_DME_30_mars_2020.pdf

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Direction de la programmation et de la prospective (DPP)

Website(s): https://sante.gouv.bj/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): Ilya la Direction de la programmation et de la prospective (DPP) et Direction des hôpitaux (fait HTA), mais n'est pas specifiquement pour des dispositifs médicaux.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Agence Béninoise de Régulation Pharmaceutique (ABRP)

Website(s): https://www.abrp.bj/

Contact: Mr. Isaac Houinsou Hans Email: ihhans@yahoo.fr

Name(s) of other regulatory agency eg. for radiation equipment etc.: International Atomic Energy Agency (IAEA).

Other agency's website: https://www.iaea.org/newscenter/news/iaea-advises-benin-on-strengthening-regulatory-infrastructure

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: http://www.sante.gouv.bj/

Nomenclature comments (...Annex 1):
La nomenclature CNEH: Centre National d'Expertise Hospitalière Nomenclature (from France) est utilisée de façon informelle dans certains de nos hôpitaux.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.abrp.bj/

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	3	0.29
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	7	16.09
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: —
Unit/Department: Agence des Infrastructure Sanitaire de l'Equipement et de la Maintenance (AISEM) Unit website: —
Contact name: Mr. Laurent Houndeton Contact email: houndetonlaurent@hotmail.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 2

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —

Use of management software: Yes Software name: Le fichier excel est utilisé dans certains cas. En outre, le logiciel G-MAINT, développé au Bénin, est en cours d'expérimentation dans certains hôpitaux.

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 16

Contacts

National officer(s):
Name: —
Email: —

Name: Mr. Laurent Houndeton
Email: houndetonlaurent@hotmail.com

WHO Country officer(s):
Name: Dr. Mamoudou Harouna Djingarey
Email: djingareyh@who.int

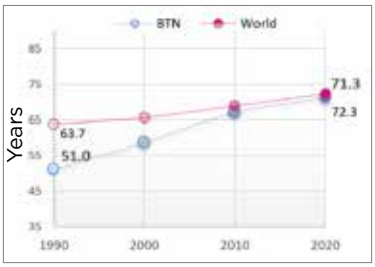
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Bhutan

Country indicators - WHO country information

Population 000s (rank):[a]	772 (160)	Under-five mortality (per 1000 live births):[d]	27.62	UHC - Service coverage index (1-100):[h]	62
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	18.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.8% (0.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.65 (0.48): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	3.7 (121)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No, only National Medicine Policy

Policy is part of the National Health Program/Plan: —

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Essentials Medicines and Technology Division.

Website: http://www.moh.gov.bt/

Nomenclature systems used for devices and tests: Adapted nomenclature to GMDN.

Approved devices lists comments (...Annex 1):

We have a list for each level of health centre used for annual identification for non drug items which includes equipments but we have not uploaded it in a website.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.moh.gov.bt/

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: http://www.moh.gov.bt/

Specific lists comments (...Annex 1):

At present we do not have national lists of recommended medical devices but we are developing a standard list of Equipment and non-drug items for each level of health facilities in Bhutan (national, regional, district hospital, Basic health unit I and

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Essentials Medicines & Technology Division.

Website(s): https://www.idsihealth.org/our-impact/bhutan/ http://www.moh.gov.bt/

Contact: Ugyen Tashi Email: utashi@health.gov.bt

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

HTA is focused on pharmaceutics and vaccines but not in medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: Drug Regulatory Authority (DRA).

Website(s): http://www.dra.gov.bt/

Contact: Wangdi Gyeltshen Email: wgyeltshen@dra.gov.bt

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

The Medical Devices regulation is currently being drafted

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: Not specified

Website: —

Nomenclature comments (...Annex 1):
Adapted nomenclature from GMDN

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.mof.gov.bt/

National level procurement: Yes Website: http://www.moh.gov.bt/

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
The procurement of MD is conducted by the Medical Supplies Procurement Division.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	1.33
Computerized Tomography Scanner:α	1	1.33
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	0	0
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Biomedical Engineer Division Unit website: —

Contact name: Tashi Penjor Contact email: tpenjor@health.gov.bt

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):
The Biomedical Engineering Division under the Department of Medical Services has maintained an Inventory of equipment above 25,000 rupees only.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):

Name: Dr. Karma Lhazeen

Email: klhazeen@health.gov.bt

Name: Ms. Soira Sonam Tamang

Email: —

WHO Country officer(s):

Name: Dr. Rui Paulo de Jesus

Email: jesusr@who.int

Name: —

Email: —

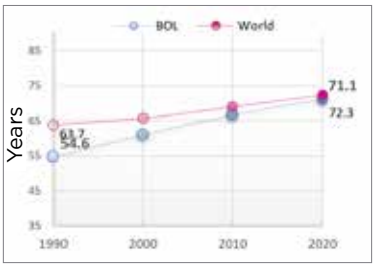
General comments (...Annex 1):

Concerning the Infrastructure section: there is 1 National Referral Hospital with 350 beds, 2 Regional referral hospitals with 150 beds each, 10 district hospitals with 60 to 40 beds. 12 district hospitals with 20 beds. Out of 192 health posts, 18 are Basic Health Unit grade I with 10 beds, and the remaining 174 health centres with 2 to 5 beds are Basic Health Unit grade II.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Bolivia (Plurinational State of)

Country indicators - WHO country information

Population 000s (rank):[a]	11,673 (79)	Under-five mortality (per 1000 live births):[d]	25.37	UHC - Service coverage index (1-100):[h]	67
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	17.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	6.0% (1.1%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.72 (0.55): high	Global innovation index (rank):[j]	22.4 (105)
		ICT Development Index (rank):[g]	4.3 (112)	High-technology exports (% of manufacture exports):[k]	5.10%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_bolivia.pdf

Language(s): Español

Ministry of health responsible for health technology policy implementation: Unidad de Medicamentos y Tecnología en Salud, Unidad de Servicios de Salud.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Agencia Estatal de Medicamentos y Tecnologías en salud

Website: https://www.agemed.gob.bo/archivo_uso_racional/linadime/R.A.LINADIME.pdf

Nomenclature systems used for devices and tests: Yes

Approved devices lists comments (...Annex 1):

There is a national medical devices list (LINADIME) and it is not based in any of the internationally recognized nomenclature.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.minsalud.gob.bo/

Website - laboratories: https://www.minsalud.gob.bo/images/Descarga/LINAME/proveedores/DBS-SELECCION-DE-PROVEEDORES-ULTIMO.pdf

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

Norma de caracterización de establecimientos de salud de primer nivel, La Paz, Bolivia, 2008.

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.minsalud.gob.bo/

Specific lists comments (...Annex 1):

Ver el Manual para la aplicacion de las prestaciones de seguros públicos de salud, La Paz, Bolivia.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Unidad de Medicamentos y Tecnología en Salud.

Website(s): https://www.agemed.gob.bo/
https://www.agemed.gob.bo/#tecnolovigilancia/contenido
http://redetsa.org/wp/?page_id=322

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Agencia Estatal de Medicamentos y Tecnologías en Salud

Website(s): https://www.agemed.gob.bo/

Contact: Dra. Jhoana Sidney Venegas Miranda Email: jvenegas@agemed.gob.bo

Name(s) of other regulatory agency eg. for radiation equipment etc.: Unidad de Seguros Públicos de Salud.

Other agency's website: https://aben.gob.bo/

National regulatory comments (...Annex 1):

Unidad de Seguros Públicos de Salud - Dante Ergueta tel. 591-22495053; Unidad de Servicios de Salud - Javier Luna Orozco tel. 591- 22495053.

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: Not specified

Website: https://www.agemed.gob.bo/

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: https://www.minsalud.gob.bo/

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: https://www.minsalud.gob.bo/

Medical device incorporation comments (...Annex 1):

Se cuenta con la propuesta de la norma "Pliego de especificaciones técnicas para la adquisición de dispositivos médicos" DBC. La adquisicion se realiza a través de los gobiernos municipales (Ley del Medicamento 1737, Reglamento a la ley del Medicamento 25235).

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	13	1.11

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No

Unit/Department: Unidad de Seguros Públicos. Unit website: —

Contact name: Mr. Dante Ergueta and Ms. Mari Tejerina Contact email: danteergueta@gmail.com

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: https://www.minsalud.gob.bo/

Use of management software: No Software name: —

Software comments (...Annex 1):

El inventario de equipos y la aplicación del plan para la adquisición de equipo médico solo se realizó para los departamentos de Oruro, Beni y Pando.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 45

Contacts

National officer(s):

Name: —

Email: —

Name: Mr. Dante Ergueta and Ms. Mari Tejerina

Email: danteergueta@gmail.com

WHO Country officer(s):

Name: Ms. Alma Fabiola Morales Salinas.

Email: moraleaf@paho.org

Name: Dr. Julio Pedroza

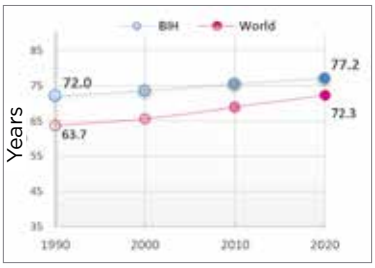
Email: pedrozajul@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Bosnia and Herzegovina

Country indicators - WHO country information

Population 000s (rank):[a]	3,281 (132)	Under-five mortality (per 1000 live births):[d]	5.73	UHC - Service coverage index (1-100):[h]	65
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	18.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	8.2% (1.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (0.67): high	Global innovation index (rank):[j]	29 (74)
		ICT Development Index (rank):[g]	5.4 (83)	High-technology exports (% of manufacture exports):[k]	5.30%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.met.gov.ba/bs-Latn-BA/
http://www.almbih.gov.ba/en/_doc/regulative/medicinal_products_and_medical_devices_act.pdf

Language(s): Bosnian, Croatian, Serbian (local), and English

Ministry of health responsible for health technology policy implementation: Health Sector.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: —

Website: http://www.almbih.gov.ba/

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.almbih.gov.ba/

Website - laboratories: http://www.almbih.gov.ba/_doc/m-sredstva/regms.pdf?123
https://ms.almbih.gov.ba/pages/view-registrovanamedicinskasredstva

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://www.almbih.gov.ba/

Approved devices lists comments (...Annex 1):

There are the lists of medical devices for procurement regarding the each general hospital as well as clinical centres (situation analysis of health care institutions). At the primary health care level, there is a list of medical equipments that is necessary for family medicine.

Health care facilities lists comments (...Annex 1):

The Rulebook on Normative Standards for Establishment of Health Institutions.

Specific lists comments (...Annex 1):

There are documents that regulate the necessary knowledge, skills, procedures and equipment (definition of medical technology) which are used by those group of diseases. Also, there are Guides for specific medical conditions, and there are adequate contingency plans for responding for public health threats

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://apps.who.int/iris/bitstream/handle/10665/336228/WHO-EURO-2020-1303-41053-55733-eng.pdf

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

The HTA is acknowledged in decentralized legislation, and present at a national level.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Agency for Medical Products and Medical Devices (ALMBiH); Institute for standardization of Bosnia and Herzegovina (ISBIH).

Website(s): http://www.almbih.gov.ba/

Contact: Mr. Ph. Tanja Savanovi_ Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Bosnia and Herzegovina State Regulatory Agency for Radiation Safety and Nuclear Safety.

Other agency's website: http://www.darns.gov.ba/en/EnglishDARNS/AboutAs

National regulatory comments (...Annex 1):

For the Republika Srpska: Regarding the procurement of various medical devices, the company that generally provides the medical device must ensure capable suppliers who can implement a proper assessment and who can carry out the

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: More than one system
Use: Not specified
Website: http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-lijekovima-i-medicinskim-sredstvima

Nomenclature comments (...Annex 1):
The nomenclature is based on GMDN and EDMA codes; the instructions request manufacturer and representative of manufactures to use GMDN or EDMA codes for making generic names. This country have free access to the GMDN base, and found a new version of EDMA codes on the internet.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.almbih.gov.ba/
National level procurement: Yes Website: http://www.almbih.gov.ba/

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Responsible authority in both entities. Ministry of Health of Republika Srpska is responsible for the procurement of high-cost technologies while the Health Care Institutions can provide procurement of other medical equipment.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	21	5.48
Computerized Tomography Scanner:α	63	16.45
Positron Emission Tomography Scanner:α	1	0.26
Gamma camera or nuclear medicine:α	6	1.57
Mammograph:α,*	88	182.72
Radiotherapy:β	13	3.96

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: Agency for Medical Products and Medical Devices. Unit website: http://www.almbih.gov.ba/
Contact name: Dr. Tanja Savanovi_ Contact email: t.savanovic@almbih.gov.ba
Website with publically available technical specifications: http://www.almbih.gov.ba/_doc/upustva-vodici/SPISAK_NEOPHODNE_DOKUMENTACIJE_ZA_UPIS_MED_SRED_U_REG_MS_BiH2018.pdf
http://www.almbih.gov.ba/_doc/upustva-vodici/Uputstvo_za_registraciju_proizvodjacaMS.pdf
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 50

Contacts

National officer(s):
Name: Ms. Sabina Sahman
Email: sabina.sahman@mcp.gov.ba

Name: Dr. Tanja Savanovi_
Email: t.savanovic@almbih.gov.ba

WHO Country officer(s):
Name: Dr. Erwin Aime Willy D. Cooreman
Email: cooremane@who.int

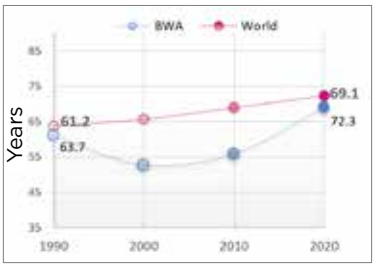
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Botswana

Country indicators - WHO country information

Population 000s (rank):[a]	2,352 (141)	Under-five mortality (per 1000 live births):[d]	44.84	UHC - Service coverage index (1-100):[h]	54
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	27.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.74 (—): high	Global innovation index (rank):[j]	25.4 (89)
		ICT Development Index (rank):[g]	4.6 (105)	High-technology exports (% of manufacture exports):[k]	0.40%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: https://www.who.int/medical_devices/survey_resources/health_technology_national_policy_botswana.pdf

Language(s): English

Ministry of health responsible for health technology policy implementation: Biomedical Engineering Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): Documents are in constant revision and update.

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: Clinical Services.

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): It is needed to strengthen the research to improve the HTA capacity.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Botswana Medicines Regulatory Authority (BoMRA).

Website(s): https://www.bomra.co.bw/index.php/news-updates

Contact: — Email: medicaldevices.services@bomra.co.bw

Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation Protection Inspectorate.

Other agency's website: https://gov.bw/public-safety/radiological-safety-inspections

National regulatory comments (...Annex 1): There is a drug regulatory unit. It has a draft for an Act that will regulate medicines and medical devices.

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: For procurement purposes

Website: https://www.bomra.co.bw/index.php/news-updates

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://ipms.ppadb.co.bw/login

National level procurement: Yes Website: https://ipms.ppadb.co.bw/login

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: No

Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	0.49
Computerized Tomography Scanner:α	2	0.99
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	2	19.1
Radiotherapy:β	3	1.28

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Biomedical Engineering Unit website: —

Contact name: Spencer Sibanda Contact email: ssibanda@gov.bw

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: Yes Software name: Customized Solution.

Software comments (...Annex 1): There is the Medical Equipment Asset Register which was completed in December 2009. The Custom Solution is being implemented; the contract was signed on May 19th 2010.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 52

Contacts

National officer(s):

Name: Dr. Ndwapi Ndwapi

Email: nndwapi@gov.bw

Name: Spencer Sibanda

Email: ssibanda@gov.bw

WHO Country officer(s):

Name: Dr. Josephine Namboze

Email: nambozej@who.int

Name: —

Email: —

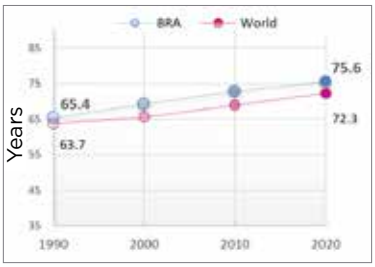
General comments (...Annex 1):

Concerning the Infrastructure section: there are 800 clinics, healthposts and mobile clinics.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Brazil

Country indicators - WHO country information

Population 000s (rank):[a]	212,559 (6)	Under-five mortality (per 1000 live births):[d]	14.7	UHC - Service coverage index (1-100):[h]	75
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	15.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.77 (0.57): high	Global innovation index (rank):[j]	31.9 (62)
		ICT Development Index (rank):[g]	6.1 (66)	High-technology exports (% of manufacture exports):[k]	13.30%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.gov.br/saude/pt-br

Language(s): Portugues

Ministry of health responsible for health technology policy implementation: Secretariat of Science, Technology and Strategic Inputs.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
Lists for diseases are Health Attention Secretariat (SAS) unit competence. Other lists are not available for the moment.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.gov.br/saude/pt-br

Specific lists comments (...Annex 1):
Competencia de la Health Attention Secretariat (SAS).

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Departamento de Gestão e Incorporação de Tecnologias em Saúde.

Website(s): http://conitec.gov.br/

Contact: Dr. Vania Canuto Santos Email: vania.canuto@saude.gov.br

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
Units within the Brazilian HTA Network (Rebrats) support CONETEC

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Brazilian Health Surveillance Agency (ANVISA)/ General Office of Medical Devices.

Website(s): http://antigo.anvisa.gov.br/

Contact: Mrs. Maria Fonseca Veloso Email: rel@anvisa@anvisa.gov.br

Name(s) of other regulatory agency eg. for radiation equipment etc.: Comissão Nacional de Energia Nuclear.

Other agency's website: https://www.gov.br/cnen/pt-br/comissao-nacional-de-energia-nuclear/#

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: For regulatory purposes

Website: www.anvisa.gov.br

Nomenclature comments (...Annex 1):

Anvisa started working to internalize the GMDN. So far, 100 of Anvisa's technical names are compatible with GMDN. Anvisa also works in the implementation of the Unique Device Identification (UDI) in Brazil. Anvisa is currently preparing a draft proposal in a working group with the participation of the private sector, which was sent to the Public Consultation (2021).

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://portalsaude.saude.gov.br/portalsaude/

National level procurement: Yes

Website: http://portal.saude.gov.br/portal/saude/gestor/area.cfm?id_area1504

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):

In the given website search for the corresponding documents in procurement field. There are Lists of OPM, Procedures and Protocols.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	541	2.55

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Department of Science and Technology (DECIT). Unit website: http://portal.saude.gov.br

Contact name: Dr. Leonor Santos Pacheco Contact email: leonor.santos@saude.gov.br

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: Yes Software name: Locally developed.

Software comments (...Annex 1):

Even though there is no standardized software for the medical equipment management in Brazil, some hospitals and other health facilities have developed and implemented their own. Besides that, the Post Market Surveillance of Medical Devices Unit of ANVISA, the Brazilian Regulatory Authority, intends to develop a software to address the main needs related to medical electrical equipment management (information related to the history of the medical equipment).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 600

Contacts

National officer(s):

Name: Dr. Leonor Maria Pacheco Santos

Email: leonor.santos@saude.gov.br

Name: —

Email: —

WHO Country officer(s):

Name: Dr. Socorro Gross Galiano

Email: grosssoc@paho.org

Name: —

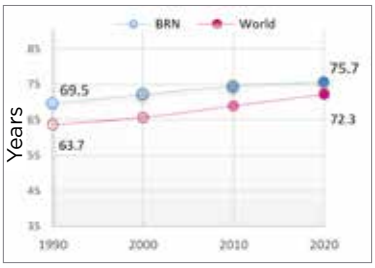
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Brunei Darussalam

Country indicators - WHO country information

Population 000s (rank):[a]	437 (168)	Under-five mortality (per 1000 live births):[d]	11.51	UHC - Service coverage index (1-100):[h]	77
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	18.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.84 (—): very high	Global innovation index (rank):[j]	29.8 (71)
		ICT Development Index (rank):[g]	6.8 (53)	High-technology exports (% of manufacture exports):[k]	8.50%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: bme@moh.gov.bn
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
It is a established system for setting healthcare priorities, which involves HTA.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1	2.39
Computerized Tomography Scanner:[α]	3	7.18
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	3	91.93
Radiotherapy:[β]	2	4.58

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Biomedical Engineering Unit (BME). Unit website: —
Contact name: — Contact email: bme@moh.gov.bn
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Mr. Abidin Bin Haji Othman
Email: abidin.othman@moh.gov.bn

Name: —
Email: —

WHO Country officer(s):
Name: —
Email: wpmyswr@who.int

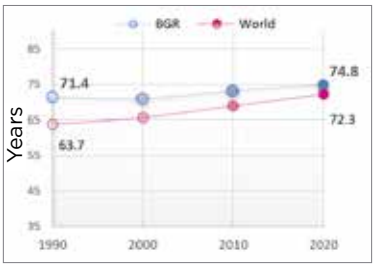
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Bulgaria

Country indicators - WHO country information

Population 000s (rank):[a]	6,948 (105)	Under-five mortality (per 1000 live births):[d]	6.15	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	12.8% (0.8%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.82 (0.72): very high	Global innovation index (rank):[j]	40 (37)
		ICT Development Index (rank):[g]	6.9 (50)	High-technology exports (% of manufacture exports):[k]	10.90%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: National Health Insurance Fund.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://www.ncpr.bg/en/health-technology-assessment.html
http://ncpha.government.bg
https://apps.who.int/iris/bitstream/handle/10665/336228/WHO-EURO-2020-1303-41053-55733-eng.pdf

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
It exists a limited number of trained HTA experts. Relevant health economic education is available at several universities in the region, and HTA experts or health economists work as consultants for the government (more info see third link).

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Bulgarian Drug Agency (BDA).

Website(s): https://www.bda.bg
http://mh.government.bg
https://mi.government.bg/bg

Contact: — Email: medical@bda.bg

Name(s) of other regulatory agency eg. for radiation equipment etc.: Nuclear Regulatory Agency.

Other agency's website: http://www.bnra.bg/

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://www.mh.government.bg/en/
https://www.bda.bg/en/information-for-companies/122-medical-devices-announcements-category

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.bda.bg/images/stories/documents/legal_acts/201910_MEDICAL%20DEVICES%20ACT.pdf
https://www.mh.government.bg/bg/

National level procurement: Yes Website: http://www.mh.government.bg/

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
Only for the devices which are supplied through a centralized procedure accomplished by the Ministry of Health.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	54	7.77

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 35

Contacts

National officer(s):
Name: Mr. Todor Darakchiev
Email: todor.darakchiev@bda.bg

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Skender Syla.
Email: sylas@who.int

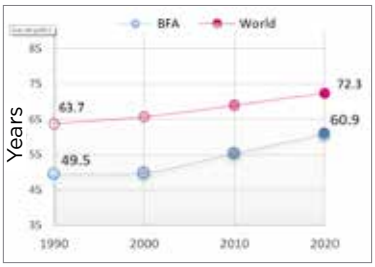
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Burkina Faso

Country indicators - WHO country information

Population 000s (rank):[a]	20,903 (58)	Under-five mortality (per 1000 live births):[d]	84.99	UHC - Service coverage index (1-100):[h]	43
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	23.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.1% (0.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.45 (0.32): low	Global innovation index (rank):[j]	20 (118)
		ICT Development Index (rank):[g]	1.9 (162)	High-technology exports (% of manufacture exports):[k]	25.80%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: Yes

Website - hospitals: https://www.sante.gov.bf/accueil

Website - laboratories: http://www.sante.gov.bf/SiteSante/documents/normes-infra.pdf

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

National regulatory comments (...Annex 1): The RPNS within the NRA is in the process of institutionalization.

Name of regulatory agency: —

Website(s): https://anrp.bf/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: National Regulatory Authority for Radiation Protection and Nuclear Safety

Other agency's website: https://www-pub.iaea.org/mtcd/meetings/PDFplus/2009/cn166/CN166_Presentations/Session%208/006%20Belemsaga.pdf

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Les achats se font selon plusieurs procédures en fonction de la source de financement (les projets font des appels d'offres de façon indépendante, les hôpitaux exécutent en interne une partie du budget achat, les achats groupés au niveau national sont en train d'être expérimentés par la CAMEG: Centrale d'Achat des Médicaments Génériques); des apels d'offres internationaux sont quelque fois lancés par les projets.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	2	0.1
Computerized Tomography Scanner:α	15	0.72
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	1	0.05
Mammograph:α,*	13	15.49
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of medical Products (DMP). Unit website: —
Contact name: Mr. Hamidou Sama Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 13

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: Yes Software name: PLAMAHS (Heart Consultancy).

Software comments (...Annex 1):
Inventaire technique au niveau national a été fait par la DGIEM en 2003 avec l'appui de la GTZ; un inventaire non technique a été fait par la DAF en 2007 suivant une procédure du Ministère de l'Economie et des Finances. La mise à jour de ces inventaires n'est pas effective. Il y a les deux types d'inventaire: national fonctionnel pour certain équipement médicale et non-fonctionnel pour d'autres.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Mr. O. Emmanuel Zida
Email: ezida2002@yahoo.fr

Name: Ms. Micheline Ouédraogo
Email: mkonkobo1@yahoo.fr

WHO Country officer(s):
Name: Dr. Alimata J. Diarra-Nama
Email: diarraal@who.int

Name: Dr. Daogo Sosthène Zombre
Email: zombres@who.int

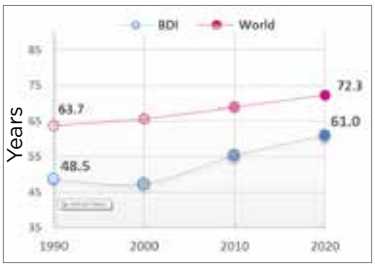
General comments (...Annex 1):

Concerning the HT national policy, a 2010 version was provided. Concerning the Section Infrastructure: There are 3 CHU and 1 Hôpital national.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Burundi

Country indicators - WHO country information

Population 000s (rank):[a]	11,891 (77)	Under-five mortality (per 1000 live births):[d]	54.35	UHC - Service coverage index (1-100):[h]	44
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	25.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.3% (0.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.43 (0.3): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	1.5 (172)	High-technology exports (% of manufacture exports):[k]	1.50%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Autorité Burundaise de Régulation des Médicaments et des Aliments

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Direction des Infrastructures Sanitaires et des Equipements (DISE).

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Nous avons des listes préétablies suivant le type de catégories conformes aux normes en vigueur au MoH.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

Nous avons également de la documentation sur la normalisation des équipements par structures de soins.

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):

Lists available for communicable and non communicable diseases, injuries, and public health emergency situations.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: —

Unit/department: Département des Infrastructures sanitaires et des équipements (DISE)

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Autorité Burundaise de Régulation des Médicaments et des Aliments

Website(s): —

Contact: Mr. Emmanuel Bamenyekanye Email: bamenyekanye@hotmail.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
Procédé aux achats/Système d'appel d'offres ouvert national/international. Il existe des entreprises nationales spécialisées dans la vente de ces produits.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	0	0
Computerized Tomography Scanner:α	2	0.2
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	1	2.69
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: —
Unit/Department: Direction des Infrastructures Sanitaires et des Equipements (DISE) Unit website: —
Contact name: Mr. Eugène Mujambere Contact email: mujambereeugene@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Mr. Déo Niyonkuru
Email: niyonkurunew@yahoo.fr

Name: Mr. Eugène Mujambere
Email: mujambereeugene@yahoo.fr

WHO Country officer(s):
Name: Dr. Xavier Crespin
Email: cxavier@who.int

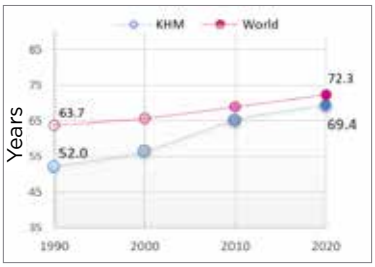
Name: Dr. Donatien Bigirimana
Email: bigirimanad@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Cambodia

Country indicators - WHO country information

Population 000s (rank):[a]	16,719 (70)	Under-five mortality (per 1000 live births):[d]	25.68	UHC - Service coverage index (1-100):[h]	61
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	15.3% (5.2%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.59 (0.48): medium	Global innovation index (rank):[j]	21.5 (110)
		ICT Development Index (rank):[g]	3.3 (128)	High-technology exports (% of manufacture exports):[k]	1.20%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): Khmer and English

Ministry of health responsible for health technology policy implementation: Hospital Services and Biomedical Engineering Bureau, Department of Hospital Services, Ministry of Health.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): a) Medical Equipment Standard list for CPA referral Hospitals; b) Medical Equipment Standard list for Minimum Package of activity (MPA) (Health Centre).

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: Department of Hospital Service.

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): It has been started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For procurement purposes
Website: —

Nomenclature comments (...Annex 1):
The Hospital Service Bureau has developed standard medical equipment nomenclature for public hospitals in Cambodia and it has been utilized for medical equipment management and maintenance.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Procurement: Health Sector Support Program (HSSP2) is the implementation project team under the direction of Health Sector Strategic Plan (HSP2) of the Ministry of Health. Medical Equipment standard list for CPA1,2,3 referral hospitals.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1	0.07
Computerized Tomography Scanner:[α]	18	1.19
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	3	0.18

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Planning and Health Information. Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: Yes Software name: MEDEMIS.

Software comments (...Annex 1):
The software was originally developed by the Ministry of Health (MoH). The Department of Hospital service is managing inventories for medical equipment of four National hospitals and 18 CPA3 level hospitals. The Controlled medical equipment requires management (monitoring), maintenance and repair.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Dr. Cheu Sivuthy
Email: cheusivuthy@gmail.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Ailan Li
Email: lia@who.int

Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Cameroon

Country indicators - WHO country information

Population 000s (rank):[a]	26,546 (52)	Under-five mortality (per 1000 live births):[d]	72.21	UHC - Service coverage index (1-100):[h]	44
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	23.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	10.8% (3.0%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.56 (0.38): medium	Global innovation index (rank):[j]	20 (119)
		ICT Development Index (rank):[g]	2.4 (149)	High-technology exports (% of manufacture exports):[k]	6.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): Français et Anglais

Ministry of health responsible for health technology policy implementation: Direction de l'Organisation des Soins et de la Technologie Sanitaire.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

National regulatory comments (...Annex 1): Il existe un organisme chargé de la réglementation concernant les équipements qui émettent les rayonnements ionisants. l'Agence Nationale de Radioprotection. Contact: Dr. SimoAugustin, e-mail: augsimo@yahoo.fr.

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: National Radiationprotection Agency (NRPA).

Other agency's website: https://gnssn.iaea.org/main/ANNuR/Activity%20Documents%20%20Public/Regional%20Workshop%20on%20Management%20a%20Safe%20Disposal%20of%20Radioactive%20Waste/CAMEROON.pdf

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
Procurement: Il existe des directives générales concernant tous les marchés publics. Les hôpitaux et autres formations disposent aussi de budgets propres pour l'achat de dispositifs médicaux.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	0.04
Computerized Tomography Scanner:α	14	0.63
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	1	0.04
Mammograph:α,*	15	17.4
Radiotherapy:β	1	0.04

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Studies and Project Division (DEP). Unit website: http://www.minsante.cm/
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 10

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Les bailleurs de fonds réalisent des inventaires dans leurs zones d'intervention, mais il n'existe pas d'inventaire national.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 19

Contacts

National officer(s):
Name: Mr. Vincent Ngaleu Toko
Email: vngaleutoko@yahoo.fr

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Phanuel Habimana
Email: habimanap@who.int

Name: Dr. Samuel Besong
Email: besongs@who.int

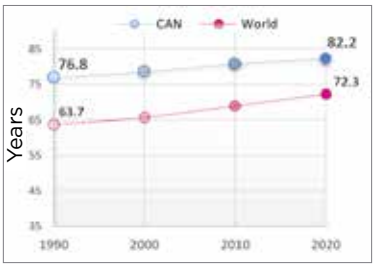
General comments (...Annex 1):

L'étude devrait inclure la formation dans le domaine. Le Cameroun dispose d'un cycle de formation de techniciens en maintenance hospitalière qui fonctionne depuis deux ans dans trois lycées techniques, le diplôme de sortie délivré au bout de trois ans est l'équivalent du bacccalauréat. Il existe également des cycles de formation dans le domaine en enseignement supérieur.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Canada

Country indicators - WHO country information

Population 000s (rank):[a]	37,742 (39)	Under-five mortality (per 1000 live births):[d]	4.99	UHC - Service coverage index (1-100):[h]	89
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	9.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.6% (0.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.93 (0.85): very high	Global innovation index (rank):[j]	52.3 (17)
		ICT Development Index (rank):[g]	7.8 (29)	High-technology exports (% of manufacture exports):[k]	16.50%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: www.cadth.ca

Language(s): English and Français

Ministry of health responsible for health technology policy implementation: Canadian Agency for Drugs and Technologies in Health (CADTH).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Canadian Agency for Drugs and Technologies in Health (CADTH).

Website(s): https://www.cadth.ca/

Contact: Dr. Lesley Dunfield Email: lesleyd@cadth.ca

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):

There are several HTA agencies, mainly regional.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Health Canada, Health Products and Food Branch, Medical Devices Directorate

Website(s): http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php

Contact: David Boudreau Email: mddpolicy-politiquesdim@hc-sc.gc.ca

Name(s) of other regulatory agency eg. for radiation equipment etc.: Consumer and Clinical Radiation Protection Bureau

Other agency's website: https://www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-regulates-1/radiation.html

National regulatory comments (...Annex 1):

In addition, for radiation emitting medical devices, there is Health Canada, Healthy Environments and Consumer Safety Branch, Consumer and Clinical Radiation Protection Bureau (http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: For regulatory purposes

Website: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-global-medical-device-nomenclature.html

Nomenclature comments (...Annex 1):
Canada uses both: Preferred Name Codes (based on US FDA Panel Codes) and GMDN. Not publicly available.

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	389	10.31
Computerized Tomography Scanner:α	557	14.76
Positron Emission Tomography Scanner:α	56	1.48
Gamma camera or nuclear medicine:α	588	15.58
Mammograph:α,*	669	134.45
Radiotherapy:β	351	9.3

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: CADTH maintains a Canadian Medical Imaging Inventory for medical imaging equipment.

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1):
Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level. While there are no national inventories, the Canadian Institute for Health Information produces regular reports on selected imaging technologies in Canada. The most recent report is available at: https://www.cihi.ca/en .

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 642

Contacts

National officer(s):

Name: Mr. David Boudreau

Email: mddpolicy-politiquesdim@hc-sc.gc.ca.

Name: Dr. Lesley Dunfield

Email: lesleyd@cadth.ca

WHO Country officer(s):

Name: Ms. Mary Lou Valdez

Email: valdezmar@paho.org

Name: —

Email: —

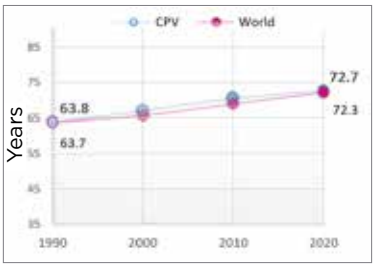
General comments (...Annex 1):

In several survey's sections (e.g. section health policy), we were not able to reflect the shared governance approach that Canada has evolved towards as several as the key organisations, namely, the Canadian Agency for Drugs and Technologies in Health are neither national nor provincial but entities whose governance and financing is shared among the Deputy Minister of Health of Canada's 14 jurisdictions (e.g. Federal, 10 provinces and 3

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Cabo Verde

Country indicators - WHO country information

Population 000s (rank):[a]	556 (165)	Under-five mortality (per 1000 live births):[d]	14.19	UHC - Service coverage index (1-100):[h]	69
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	17.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.67 (—): medium	Global innovation index (rank):[j]	23.9 (100)
		ICT Development Index (rank):[g]	4.9 (93)	High-technology exports (% of manufacture exports):[k]	0.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.minsaude.gov.cv

Language(s): Portuguese

Ministry of health responsible for health technology policy implementation: General Directorate of Planning, Budgeting and Management

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Standards: CARTA SANITÁRIA DE CABO VERDE (1999).

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.who.int/medical_devices/survey_resources/medical_devices_by_facility_cape_verde.pdf

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

Standards: CARTA SANITÁRIA DE CABO VERDE (1999).

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

No, it is done according to the needs and the procedures of our action plan for the next years.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

HTA is focused on pharmaceutics but not in medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Health Regulatory Independent Entity (ERIS)

Website(s): http://www.eris.cv

Contact: Ms. Edith Santos Email: edith.santos@gov.cv

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

There is a department in charge of medical devices, but there is no legislation nor registration of medical devices yet.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: http://www.minsaude.gov.cv

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	3	5.4
Computerized Tomography Scanner:α	8	14.39
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	5	124.25
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Health Infrastructure and Equipment Maintenance and Management Service Unit website: —
Contact name: Ms. Margarida Cardoso Contact email: margarida.cardoso@gocv.gov.cv
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): There is no national inventory of medical equipment. There's a plan to do it soon.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):

Name: —
Email: —

Name: Ms. Margarida Cardoso
Email: margarida.cardoso@gocv.gov.cv

WHO Country officer(s):

Name: Dr. Daniel A. Kertesz
Email: kerteszd@who.int

Name: —
Email: —

General comments (...Annex 1):

In conclusion, there is a need to organize the park of medical devices. We would like to make a national inventory for medical equipment, assess the needs, and organizing technical guidelines for procurement to elaborate a clear plan of medical devices management. We think it is time to develop legislation for medical devices.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Central African Republic

Country indicators - WHO country information

Population 000s (rank):[a]	4,830 (122)	Under-five mortality (per 1000 live births):[d]	103	UHC - Service coverage index (1-100):[h]	32
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	36.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.4 (0.23): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	1 (175)	High-technology exports (% of manufacture exports):[k]	29.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Unité de cession des médicaments et équipements médicaux.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

En concernant acquisition il ya une longue durée entre la commande et la réception.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):

Arrêté du ministre de la santé publique et de la population. Profil des participants: Médecin, chirurgiens, techniciens de santé, techniciens bio médicaux. Date de révision: Mars 2010.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Direction des Infrastructures Sanitaires.

Website(s): —

Contact: Mrs. Claudine Kaya Email: nzoulouc@yahoo.fr

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

No.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Achat groupé par les parténaires, passation de marché. Longue durée entre la commande et la réception.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	0	0
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	1	4.68
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Réalisée par la direction des infrastructures sanitaires. Il y a les deux types d'inventaire: national fonctionnel pour certain équipement médicale et non- fonctionnel pour d'autres.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: Mr. Leppa
Email: —

WHO Country officer(s):
Name: Dr. Ngoy Nsenga
Email: nsengan@who.int

Name: Dr. Florentine Sylvie Mberyo Yaah
Email: mberyos@who.int

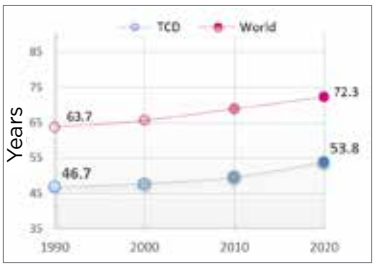
General comments (...Annex 1):

Concerning the HT national policy it is stated in the following document POLITINACIONALSAUDE_VERSÃOVALIDADA 2020.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Chad

Country indicators - WHO country information

Population 000s (rank):[a]	16,426 (71)	Under-five mortality (per 1000 live births):[d]	110.05	UHC - Service coverage index (1-100):[h]	28
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.4 (0.25): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	1.3 (174)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Direction Générale Technique Pharmacie, Médicament et Laboratoire (DGTPML)

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Direction Générale Technique Pharmacie, Médicament et Laboratoire (DGTPML)

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
It is needed to revise the list

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: Direction des infrastructures, équipements et maintenance (DIESM)

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Direction Générale Technique Pharmacie, Médicament et Laboratoire (DGTPML)

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: The Chadian Agency of Radiation Protection and Nuclear Security (ATRSN).

Other agency's website: https://www.iaea.org/sites/default/files/17/11/cn-254-alifei-presentation.pdf

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
There is a need to update the guideline.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1	0.06
Computerized Tomography Scanner:[α]	3	0.18
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	2	3.57
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Centrale Pharmaceutique d'Achats (CPA)- Division Approvisionnement and Division Assurance Qualité, Direction des infrastructures, équipements et maintenance Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: Periodic
Website: —
Use of management software: Yes Software name: G-Stock/MSPSN (2014-2015)

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 12

Contacts

National officer(s):
Name: Mr. Ngardibaye Madjimbaye
Email: madjimbayen@yahoo.fr

Name: Mr. Djémian Mongbe
Email: —

WHO Country officer(s):
Name: Dr. Jean-Bosco Ndihokubwayo
Email: ndihokubwayoj@who.int

Name: —
Email: —

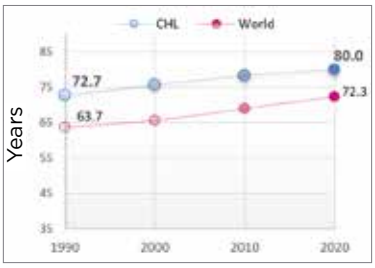
General comments (...Annex 1):

The lack of a national policy in matters of health technology does not allow access to information on medical devices that could support the action plan with regards to training of users, specialists and maintenance technicians.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Chile

Country indicators - WHO country information

Population 000s (rank):[a]	19,116 (62)	Under-five mortality (per 1000 live births):[d]	6.75	UHC - Service coverage index (1-100):[h]	80
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	14.6% (2.1%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.85 (0.71): very high	Global innovation index (rank):[j]	33.9 (54)
		ICT Development Index (rank):[g]	6.6 (56)	High-technology exports (% of manufacture exports):[k]	7.50%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Departamento Agencia Nacional de Dispositivos Médicos, Innovación y Desarrollo, ANDID - ISP

Website: https://www.ispch.cl/andid/ https://www.ispch.cl/andid/listado-de-dispositivos-medicos-establecimientos-y-empresas/

Nomenclature systems used for devices and tests: Yes

Approved devices lists comments (...Annex 1):

Existen 8 listas de los dispositivos médicos que están bajo control obligatorio en el país: Guantes de examinación, Guantes quirúrgicos, Preservativos masculinos y femeninos de látex y sintéticos, Agujas hipodérmicas, Jeringas hipodérmicas

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

No se dispone de las listas de tecnologías sanitarias de este apartado.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Institute of Public Health and MoH.

Website(s): https://www.ispch.cl/ http://redetsa.org/wp/?page_id=322; https://etesa-sbe.minsal.cl/

Contact: Dino Seplveda Email: dino.sepulveda@minsal.cl

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Departamento Agencia Nacional de Dispositivos Médicos, Innovación y Desarrollo, ANDID - ISP

Website(s): https://www.ispch.cl/andid/

Contact: Ms. Janepsy Díaz Email: jdiaz@ispch.cl

Name(s) of other regulatory agency eg. for radiation equipment etc.: Comisión Chilena de Energía Nuclear.

Other agency's website: https://www.cchen.cl/

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified

Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.ispch.cl/sites/default/files/normativa_andid/Decreto%20Exento%2093.pdf

National level procurement: Yes Website: http://www.minsal.cl

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1): http://www.minsal.cl

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	226	11.82
Computerized Tomography Scanner:α	446	23.33
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	58	32.18
Radiotherapy:β	56	2.93

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 650

Contacts

National officer(s):

Name: Mr. Luis Vera Benavides

Email: lvera@minsal.cl

Name: Mr. Luis Ampuero Velásquez

Email: lampuero@minsal.cl

WHO Country officer(s):

Name: Dr. Luis Fernando Leanes

Email: leanesf@paho.org

Name: —

Email: —

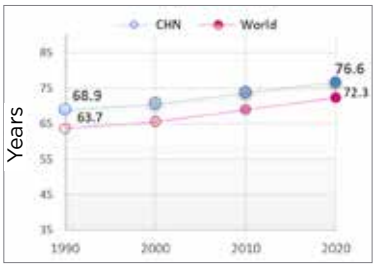
General comments (...Annex 1):

Concerning the Infrastructure section: Los 21 centros de salud están incorporados en los 100 hospitales distritales/rurales. Los Centros de Referencia de Salud (CRS) = 7 considera a los Hospitales de Chile denominados de Mediana Complejidad y que se ubican en la región metropolitana y demás regiones del país. Tambien existen también los hospitales de Chile denominados de Alta Complejidad. Se ubican en la región metropolitana y demás regiones del país. Estos hospitales tienen la calidad de "Establecimientos Auto-gestionados en red", incluyendo los base de regiones y los Institutos de especialidades, que se concentran en la Región Metropolitana. En lo que concierne a

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

China

Country indicators - WHO country information

Population 000s (rank):[a]	1,439,324 (1)	Under-five mortality (per 1000 live births):[d]	7.34	UHC - Service coverage index (1-100):[h]	82
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	15.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	19.7% (5.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.76 (0.64): high	Global innovation index (rank):[j]	53.3 (14)
		ICT Development Index (rank):[g]	5.6 (80)	High-technology exports (% of manufacture exports):[k]	30.80%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://en.nhc.gov.cn/
https://www.nmpa.gov.cn/

Language(s): —

Ministry of health responsible for health technology policy implementation: Department of Planning and Finance, State Food and Drug Administration.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: Yes

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: —

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Department of planning and finance MoH; China National Health Development Research Center (CNHDRC); Fudan University (Key Lab of Health Technology Assessment: KLHTA).

Website(s): http://www.futurehealthsystems.org/cnhdrc
https://chta.fudan.edu.cn/WHOCC-CHN86_HTA%20policy%20brief_2018_Issue%201.pdf

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

National regulatory comments (...Annex 1): —

Name of regulatory agency: Ministry of Health, State Food and Drug Administration.

Website(s): http://en.nhc.gov.cn/
https://www.nmpa.gov.cn/

Contact: Ms. Yasha Huang Email: huangys@cfda.gov.cn

Name(s) of other regulatory agency eg. for radiation equipment etc.: China Atomic Energy Authority; National Health Commission of the People's Republic of China.

Other agency's website: http://www.caea.gov.cn/
http://en.nhc.gov.cn/

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: Not specified

Website: https://www.nmpa.gov.cn/
http://english.nmpa.gov.cn/2019-12/14/c_432228.htm

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —

National level procurement: Yes Website: http://en.nhc.gov.cn/
https://www.nmpa.gov.cn/

Donations

Policy or guideline: Yes Website: http://en.nhc.gov.cn/
https://www.nmpa.gov.cn/

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: —

Website: http://en.nhc.gov.cn/
https://www.nmpa.gov.cn/

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	1818	1.26

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Department of Technology and Education. Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 661030

Contacts

National officer(s):

Name: —

Email: —

Name: —

Email: —

WHO Country officer(s):

Name: Dr. Gauden Galea

Email: galeag@who.int

Name: Ms. Jianrong Qiao

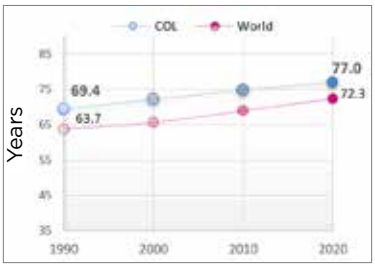
Email: qiaoj@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Colombia

Country indicators - WHO country information

Population 000s (rank):[a]	50,883 (29)	Under-five mortality (per 1000 live births):[d]	13.19	UHC - Service coverage index (1-100):[h]	78
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	9.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	8.2% (2.2%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.77 (0.6): high	Global innovation index (rank):[j]	30.8 (68)
		ICT Development Index (rank):[g]	5.4 (84)	High-technology exports (% of manufacture exports):[k]	9.10%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.who.int/medical_devices/survey_resources/health_technology_national_policy_colombia.pdf

Language(s): Español

Ministry of health responsible for health technology policy implementation: Dirección de Medicamentos y Tecnologías en Salud.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Dirección de Medicamentos y Tecnologías en Salud.

Website: https://www.minsalud.gov.co/salud/MT/Paginas/dispositivos-medicos-equipos-biomedicos.aspx

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

No existe un listado oficial. El acuerdo No.008 de La Comisión de Regulación en Salud (CRES) establece que los dispositivos médicos usados en los procedimientos listados son reembolsados dentro del Plan de Beneficios en Salud.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: https://web.sispro.gov.co/WebPublico/Consultas/ConsultarDetalleReferenciaBasica.aspx?Code=DispositivosMedicos

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[5] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: IETS centralizes HTA

Website(s): https://www.iets.org.co/

Contact: Adriana Robayo Email: adriana.robayo@iets.org.co

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

The INVIMA (Instituto Nacional de Vigilancia en Medicamentos y alimentos) and the IETS (Instituto de Evaluación Tecnológica en Salud) perform HTA.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA).

Website(s): https://www.invima.gov.co/en/dispositivos-medicos-y-equipos-biomedicos

Contact: Ms. Lucía Ayala Rodríguez Email: layalar@invima.gov.co

Name(s) of other regulatory agency eg. for radiation equipment etc.: Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA); Ministerio de Minas y Energía.

Other agency's website: https://www.invima.gov.co/en/dispositivos-medicos-y-equipos-biomedicos https://www.minenergia.gov.co

National regulatory comments (...Annex 1):

El INVIMA tiene dos dependencias relacionadas, la Subdirección de Registros Sanitarios que tiene un grupo funcional específico de dispositivos médicos y se encarga de la evaluación y autorización pre-mercado de los dispositivos médicos;

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For regulatory and procurement purposes
Website: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/resolucion-2535-de-2013.pdf
https://www.invima.gov.co/

Nomenclature comments (...Annex 1):
Nationally developed. It is in the phase of implementation.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: https://www.invima.gov.co/en/

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.minsalud.gov.co/Normatividad_Nuevo/Forms/DispForm.aspx?ID=5524

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	12	0.24
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	121	2.38

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: Dirección de Medicamentos y Tecnologías en Salud.
Unit website: https://www.minsalud.gov.co/Paginas/default.aspx
Contact name: Ms. Marleny Montenegro Guerrero Contact email: mmontenegro@minsalud.gov.co
Website with publically available technical specifications: https://www.invima.gov.co/web/guest/dispositivos-medicos-y-equipos-biomedicos#80220210341104 55-etabs-ecollapse-1-2
https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/Resoluci%C3%B3n_4002_de_2007.pdf
https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/proyecto-resolucion-ortesis-protesis.pdf
https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/observaciones-respuestas-proyecto-resolucion-dispositivos-ayuda-auditiva.pdf
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Actualmente no hay inventario nacional, se ha intentado elaborar mediante el catastro de equipamiento físico. En la normatividad vigente, el Decreto 4725 de 2005, establece que los equipos biomédicos de tecnología controlada deben contar con registro sanitario o con permiso de comercialización en Colombia.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 2000

Contacts

National officer(s):
Name: Ms. Marleny Montenegro Guerrero
Email: mmontenegro@minsalud.gov.co

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Gina Tambini
Email: tambinig@paho.org

Name: Dra. Monica Padilla
Email: padillamo@paho.org

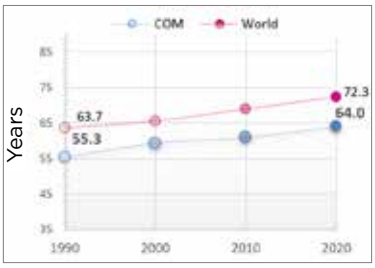
General comments (...Annex 1):

Actualmente se tiene reglamentado y en fase de implementación el Programa Nacional de Tecnovigilancia Post-mercado liderado por el Instituto Nacional de Vigilancia de Medicamentos y Alimentos

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Comoros

Country indicators - WHO country information

Population 000s (rank):[a]	870 (158)	Under-five mortality (per 1000 live births):[d]	61.34	UHC - Service coverage index (1-100):[h]	44
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	20.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	8.8% (1.6%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.55 (0.3): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	1.8 (164)	High-technology exports (% of manufacture exports):[k]	3.00%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Direction des Etablissements de soins Publics et Privés.
Website(s): —
Contact: Dr. Ahamada Said Fazul Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): Inspection Général de la Santé.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
La Evaluación de Tecnologías se reglamentó en el año 2011 mediante la Ley 1438, la cual será competencia del Instituto Nacional de Evaluación de Tecnologías que está en proceso de creación.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	1	1.15
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	1	24.28
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Dr. Ahamada Said Fazul
Email: sfazul@yahoo.fr

Name: Dr. Ahamada Said Fazul, Ministère de la santé
Email: —

WHO Country officer(s):
Name: Dr. Abdoulaye Diarra
Email: diarraa@who.int

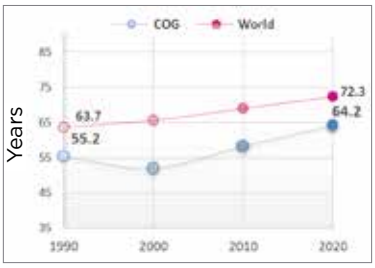
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Congo

Country indicators - WHO country information

Population 000s (rank):[a]	5,518 (115)	Under-five mortality (per 1000 live births):[d]	44.63	UHC - Service coverage index (1-100):[h]	40
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	4.6% (0.7%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.57 (0.43): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	6.70%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Direction des laboratoires.
Website(s): —
Contact: Mr. Arthur Ngole Email: arthurngolet@gmail.com
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: More than one system
Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
La Nomenclature officiel n'existe pas. Mais sinon, on utilise ce qui peut etre à la portée de la main et selon les circonstances.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
L'achat des dispositifs médicaux est décentralisé. il peut se faire au niveau national comme à l'étranger.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction des laboratoires. Unit website: —
Contact name: Mr. Arthur Ngolet Contact email: arthurngolet@gmail.com
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Mr. Arthur Ngolet
Email: arthurngolet@gmail.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Lucien Alexis Manga
Email: mangal@who.int

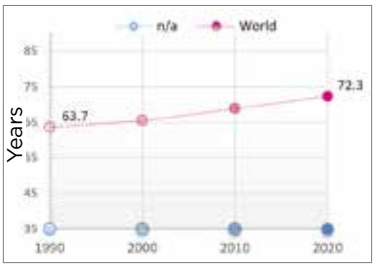
Name: Dr. Ray Mankele
Email: mankeler@cg.afro.who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Cook Islands

Country indicators - WHO country information

Population 000s (rank):[a]	18 (191)	Under-five mortality (per 1000 live births):[d]	7.39	UHC - Service coverage index (1-100):[h]	54
World Bank income group:[b]	—	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	—	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	— (—):	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There are identified HTA activities but not a national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

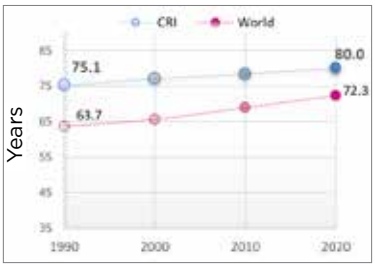
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Costa Rica

Country indicators - WHO country information

Population 000s (rank):[a]	5,094 (119)	Under-five mortality (per 1000 live births):[d]	7.91	UHC - Service coverage index (1-100):[h]	78
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	9.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	9.8% (1.7%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.81 (0.66): very high	Global innovation index (rank):[j]	33.5 (56)
		ICT Development Index (rank):[g]	6.4 (60)	High-technology exports (% of manufacture exports):[k]	17.60%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.ccss.sa.cr

Website - laboratories: https://www.ministeriodesalud.go.cr/index.php/informacion/productos-registrados https://www.ministeriodesalud.go.cr/index.php/informacion/productos-registrados/2754-emb/file

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://www.ccss.sa.cr

Specific lists comments (...Annex 1): Existen protocolos y procedimientos para las enfermedades y situaciones de emergencias en mención, pero no existen listas de dispositivos médicos como tales.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Dirección de Desarrollo Científico y Tecnológico en Salud (DDCTS) MoH and Caja Costarricense de Seguro Social (CCSS).

Website(s): https://www.ccss.sa.cr/ http://www.ministeriodesalud.go.cr

Contact: Gabriela Murillo Jenkins Email: gmurilloj@ccss.sa.cr

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): Two entities perform HTA: Caja Costarricense de Seguro Social (CCSS) and DDCTS. The extension of the HTA entities is at subnational level, not at national level.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministerio de Salud.

Website(s): http://www.ministeriodesalud.go.cr/index.php/

Contact: Ms. Giselle Rodriguez Email: grodriguez@ministeriodesalud.go.cr

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: https://www.sicop.go.cr/index.jsp

National regulatory comments (...Annex 1): El Ministerio de Salud tiene a su cargo el registro y control del equipo y material biomédico mediante el Reglamento Nº 34482-S para el uso, registro, clasificación, importación y control de equipo y material biomédico. El Sistema Integrado de Compras Públicas sigue la regulacion vigente para hacer sus respectivas compras de productos de salud.

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For regulatory and procurement purposes
Website: https://www.ministeriodesalud.go.cr/index.php/acceso-a-sistemas-de-informacion

Nomenclature comments (...Annex 1):
The GMDN has been adapted to the national needs.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: https://www.ccss.sa.cr/

Donations

Policy or guideline: Yes Website: https://www.ministeriodesalud.go.cr/index.php/registro-de-productos-de-interes-sanitario?id=637

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.ministeriodesalud.go.cr/index.php/registro-de-productos-de-interes-sanitario?id=637

Medical device incorporation comments (...Annex 1):
La Caja Costarricense de Seguro Social brinda cobertura universal a la población y es el mayor proveedor de servicios de salud del país, tanto en hospitales, clínicas y áreas de salud, por lo que se considera que hace la adquisición a nivel nacional. También hay adquisiciones en el sector privado de dispositivos médicos en menor escala; de esta última no se tiene acceso al inventario.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	4	0.82
Computerized Tomography Scanner:[α]	25	5.13
Positron Emission Tomography Scanner:[α]	1	0.21
Gamma camera or nuclear medicine:[α]	6	1.23
Mammograph:[α,*]	60	150.26
Radiotherapy:[β]	7	1.37

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Unidad de Gestión de Tecnologías en Salud/Dirección de Desarrollo Científico y Tecnológico en Salud.
Unit website: —
Contact name: Ms. Ana Eduviges Sancho Jiménez Contact email: esancho@ministeriodesalud.go.cr
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: http://www.ccss.sa.cr
Use of management software: Yes Software name: Visual Basic 6.0, Base de datos SQL Server 2005 and Access.

Software comments (...Annex 1):
El Ministerio de Salud cuenta con la base de datos de los productos de equipo y material biomédico registrados para el país. Para cualquier adquisición dentro del país es necesario contar con su registro, pero no es del tipo inventario pues no se contabiliza; el registro tiene cinco años de vigencia. En el caso de la CCSS (ver https://www.ccss.sa.cr/) se tiene un inventario por establecimiento (en los tres niveles de atención) tanto a nivel hospitalario como en clínicas y áreas de salud. Del sector privado se ha reportado que cuentan con inventarios de equipos por institución, sin embargo no se tiene

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 85

Contacts

National officer(s):
Name: —
Email: —

Name: Ms. Ana Eduviges Sancho Jiménez
Email: esancho@ministeriodesalud.go.cr

WHO Country officer(s):
Name: Dr. María Dolores Perez-Rosales
Email: perezmd@paho.org

Name: Dr. Gustavo Mery
Email: merygus@paho.org

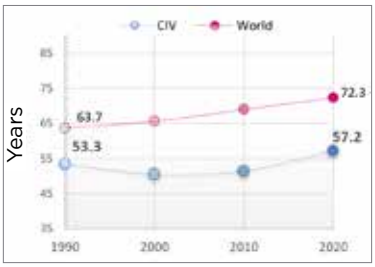
General comments (...Annex 1):

Es difícil que las instituciones den cierta información que consideran es confidencial, por el ejemplo: el acceso a sus inventarios de equipo. En el caso de la Caja Costarricense de Seguro Social, que es el mayor prestador de servicios de salud del país, se pudo obtener dicha información con las autoridades correspondientes, pero resulta complicado.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Côte d'Ivoire

Country indicators - WHO country information

Population 000s (rank):[a]	26,378 (53)	Under-five mortality (per 1000 live births):[d]	77.91	UHC - Service coverage index (1-100):[h]	45
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	12.4% (3.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.54 (0.35): low	Global innovation index (rank):[j]	21.2 (112)
		ICT Development Index (rank):[g]	3.1 (131)	High-technology exports (% of manufacture exports):[k]	11.20%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): Français

Ministry of health responsible for health technology policy implementation: Direction des Infrastructures, de l'Equipement et de la Maintenace.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Direction des Infrastructures, de l'Equipement et de la Maintenace (DIEM).

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Les listes d'acquisition provient du Plan National de développement Sanitaire PNDS.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

Document de travail de la Direction des Infraestructures, de l'Equipement et de la Maintenance (DIEM): ListeTypeEquip CHR_HG_CSU_CSR .

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1):

Les procédures et directives sont dans le mannuel de directives à l'attention du personnel des des établissemnts de soins. il n'existe pas de liste spécifique à un domaine ou un programme de santé.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Direction des Infrastructures, de l'Équipement, du Matériel et de la Maintenance.

Website(s): —

Contact: Dr. Duncan Rachel Email: rachdunc2002@yahoo.fr

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Il s'agit du Guide de la Direction des Marchés Publics.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	3	0.15
Computerized Tomography Scanner:[α]	14	0.69
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	0	0
Radiotherapy:[β]	2	0.08

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction des infrastructures de l'équipement et de la maintenance. Unit website: —
Contact name: Mr. Tra Bi Irié Contact email: trabidenis@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: 6

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
La base nationale de données n'est pas fonctionnelle.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 50

Contacts

National officer(s):
Name: Dr. Tra Bi Yrié
Email: denis.trabi@yahoo.fr

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Jean-Marie Vianny Yameogo
Email: yameogoj@who.int

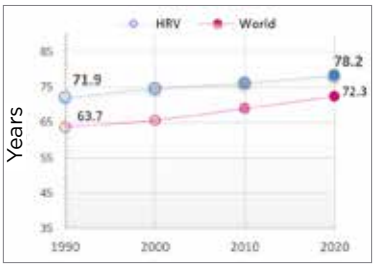
Name: Dr. Théodore Yao Kouadio
Email: yaot@ci.afro.who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Croatia

Country indicators - WHO country information

Population 000s (rank):[a]	4,105 (127)	Under-five mortality (per 1000 live births):[d]	4.55	UHC - Service coverage index (1-100):[h]	73
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.8% (0.3%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.85 (0.78): very high	Global innovation index (rank):[j]	37.3 (41)
		ICT Development Index (rank):[g]	7.2 (36)	High-technology exports (% of manufacture exports):[k]	8.30%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.aaz.hr/
http://narodne-novine.nn.hr/clanci/sluzbeni/2006_06_72_1719.html

Language(s): Croatian

Ministry of health responsible for health technology policy implementation: Agency for Quality and Accreditation in Health.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://narodne-novine.nn.hr/clanci/sluzbeni/2004_07_90_1694.html : http://narodne-novine.nn.hr/clanci/sluzbeni/2008_04_38_1318.html

Website - laboratories: https://www.halmed.hr/en/Medicinski-proizvodi/Baza-medicinskih-proizvoda/Pretraga-po-proizvodima/#rezultati

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1):
In 2007 the Ministry of Health and Social Welfare issued Ordinance on the organization and work procedures of the Ministry of Health and Social Welfare's Crisis Headquarters (http://narodne-novine.nn.hr/clanci/sluzbeni/2007_05_46_1563.html) which

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: Agency for Quality and Accreditation in Health.

Website(s): http://aaz.hr/sites/default/files/hrvatske_smjernice_za_procjenu_zdravstvenih_tehnologija.pdf
http://www.miz.hr/; www.hzzo.hr
http://www.hzjz.hr/english/

Contact: Mr. Renato Mittermayer Email: renato.mittermayer@aaz.hr

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
HTA is focused on pharmaceutics, not specifically in medical devices. HTA has three partners: the MoH, Health Insurance Fond (HIF) and Croatian Institute of Public Health (CIPH). However systematic use of HTA to support healthcare decision-making is in still in process, but expected over the next years.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Agency for Medical Products and Medical Devices, Subunit for Medical Devices.

Website(s): —

Contact: Mr. Krunoslav Kranjcec Email: krunoslav.kranjcec@almp.hr

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: https://narodne-novine.nn.hr/

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://www.halmed.hr/Medicinski-proizvodi/Upute-za-podnositelje-zahtjeva-41/Proizvodnja-medicinskih-proizvoda/

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.zdravlje.hr/

National level procurement: Yes Website: http://www.zdravlje.hr/

Donations

Policy or guideline: Yes

Website: http://narodne-novine.nn.hr/clanci/sluzbeni/2009_12_151_3696.html

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
Ministry of Health and Social Welfare currently conducts joined procurement of several groups of medical devices for more than 20 hospitals in the Republic of Croatia. The procurement procedure is managed by the expert divisions within the Ministry in collaboration with all hospitals included in the Procurement Plan and top medical experts for every group of the equipment. Due to continuous advancement in medical devices technology, a special commission is formed before every procurement procedure. The commission defines the required technical specifications of the device based on the most recent available data.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	31	7.23
Computerized Tomography Scanner:α	64	14.92
Positron Emission Tomography Scanner:α	2	0.47
Gamma camera or nuclear medicine:α	26	6.06
Mammograph:α,*	124	206.54
Radiotherapy:β	24	5.85

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No

Unit/Department: Directorate for Financial Affairs. Unit website: https://zdravstvo.gov.hr/

Contact name: Ms. Antoaneta Bilic Contact email: antoaneta.bilic@mzss.hr

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):
The Ministry of Health and Social Welfare has a national informal and internal inventory for medical devices in all public health institutions. This inventory is used mainly for analytical purposes and planning strategies within the Ministry. In 2008 Croatian National Institute of Public Health, as part of a pilot project under EUROSTAT guidelines, made an inventory of 10 most expensive medical devices (MRI, Computed Tomography, Linear Accelerator, etc.).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 250

Contacts

National officer(s):

Name: —

Email: —

Name: Ms. Antoaneta Bilic

Email: antoaneta.bilic@mzss.hr

WHO Country officer(s):

Name: Dr. Iva Pejnovic Franelic

Email: pejnovici@who.int

Name: —

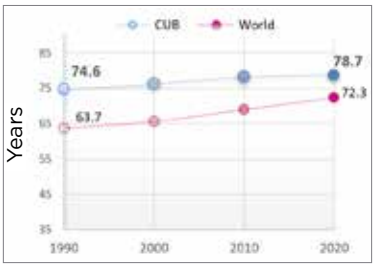
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Cuba

Country indicators - WHO country information

Population 000s (rank):[a]	11,327 (82)	Under-five mortality (per 1000 live births):[d]	5.11	UHC - Service coverage index (1-100):[h]	80
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (—): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	2.9 (137)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.gacetaoficial.gob.cu/pdf/GO_O_064_2008.rar

Language(s): Español

Ministry of health responsible for health technology policy implementation: Ministry of Health of Cuban Republic

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Medical Devices Department of CECMED (Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos)

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://dirinstituciones.sld.cu

Website - laboratories: http://dirinstituciones.sld.cu

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
Existe un listado de modelo de equipamiento médico destinado para cada nivel de atención. No está refrendado en ninguna web (no disponible).

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):
Cada especialidad médica tiene establecidas normas y programas a través de las recomendaciones de los grupos nacionales y apoyo del Consejo de Sociedades Científicas. En cuanto a las listas para diferentes enfermedades

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: CECMED/ Medical Devices Department/ Section of Conformity Assessment Medical Devices

Website(s): https://www.cecmed.cu/content/indicaciones-para-el-registro

Contact: Dr. Mario César Muñiz Ferrer Email: mario@cecmed.cu

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):
It also exists the Department of Innovation and Evaluation of Health Technologies attached to the National Directorate of Science and Technology of the Ministry of Public Health (MINSAP). Evaluations are made mainly for pharmaceutics not for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (CECMED)

Website(s): https://www.cecmed.cu

Contact: MSc. Olga Lidia Jacobo Casanueva Email: olga@cecmed.cu

National regulatory comments (...Annex 1):
En el caso de los medios de diagnóstico in vitro, estos son regulados y atendidos en el Centro de Control estatal de Medicamentos, Equipos y Dispositivos Medicos (CCEEM).

Name(s) of other regulatory agency eg. for radiation equipment etc.: Agencia de Energía Nuclear y Tecnologías de avanzada (AENTA); Oficina Nacional de Regulación y Seguridad Ambiental (ORASEN), Centro de Protección e Higiene de las Radiaciones (CPHR)

Other agency's website: http://aenta.cu
http://www.cphr.edu.cu

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: More than one system
Use: For procurement purposes
Website: https://www.cecmed.cu/
http://www.electromedicina.sld.cu

Nomenclature comments (...Annex 1):
It is use the SUCNEM, a nationally developed nomenclature, based on the Universal Medical Device Nomenclature System (UMDNS) and the Global Medical Device Nomenclature (GMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes
Website: http://legislacion.sld.cu/index.php?P=DownloadFile&Id=552
National level procurement: Yes Website: http://www.sld.cu/

Donations

Policy or guideline: Yes Website: http://www.cecmed.cu/sites/default/files/adjuntos/Reglamentacion/res_cecmed-185-2013_opt.pdf

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
Basado en la política de salud, los equipos médicos deben contar con el Registro Sanitario para su utilización en el Sistema Nacional de Salud (see: www.bvscuba.sld.cu) y en la Gaceta Oficial de la República de Cuba (www.gacetaoficial.cu). Para el proceso de importación se realiza una evaluación entre las autoridades competentes donde se efectúa previamente un análisis entre asistencia médica y electromedicina. La fichas técnicas para facilitar el proceso de adquisición no están publicadas.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	25	2.21
Computerized Tomography Scanner:α	60	5.3
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	16	1.41
Mammograph:α,*	30	18.49
Radiotherapy:β	33	2.91

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Centro de Ingeniería Clínica y Electromedicina Unit website: http://www.electromedicina.sld.cu
Contact name: Ing. Zholem Jorge Isaac Contact email: director@electromedicina.sld.cu
Website with publically available technical specifications: —
Number of regional/state offices/units: 15

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: https://instituciones.sld.cu/sigicem
Use of management software: Yes Software name: SIGICEM (Sistema de Gestión para la Ingeniería Clínica y Electromedicina)

Software comments (...Annex 1):
El Programa de Informatización de la Salud se encuentra en fase de desarrollo. There are 3 types of inventory for medical equipment: National for high cost technologies (such as MRI, CT or PET scanners), National for medical equipment and National functional for medical equipment.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 550

Contacts

National officer(s):
Name: —
Email: —

Name: Dr. Mario César Muñiz Ferrer
Email: mario@cecmed.cu

WHO Country officer(s):
Name: Dr. José Gerardo Moya
Email: moyajose@paho.org

Name: Dra. Lizette Perez
Email: perezliz@paho.org

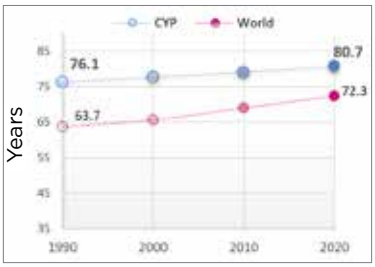
General comments (...Annex 1):

En términos de aclaración general indicamos que en Cuba, como es conocido, el Sistema de Salud tiene características de ser único, centralizado, público, gratuito y universal, refrendado en la Constitución de la República. La demanda de equipos médicos se realiza sobre la base de requirimientos acorde al

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Cyprus

Country indicators - WHO country information

Population 000s (rank):[a]	1,207 (154)	Under-five mortality (per 1000 live births):[d]	2.77	UHC - Service coverage index (1-100):[h]	79
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	8.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	16.1% (1.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.89 (0.81): very high	Global innovation index (rank):[j]	45.7 (29)
		ICT Development Index (rank):[g]	7.8 (28)	High-technology exports (% of manufacture exports):[k]	19.90%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): https://www.moh.gov.cy/moh/phs/phs.nsf/home_en/home_en?openform
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): Pharmaceutical Services within the Ministry of Health performs HTA evaluation of pharmaceutics.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Cyprus Medical Devices Competent Authority.
Website(s): —
Contact: Ms. Androulla Stylianou Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://www.moh.gov.cy/moh/mphs/mphs.nsf/page21_en/page21_en?OpenDocument

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —

National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
Procurement guidelines apply to the Public Sector only.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	16	14.02
Computerized Tomography Scanner:[α]	29	25.41
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	10	8.76
Mammograph:[α,*]	40	329.64
Radiotherapy:[β]	10	8.29

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 15

Contacts

National officer(s):

Name: Ms. Andoulla Stylianou

Email: cymda@mphs.moh.gov.cy

Name: —

Email: —

WHO Country officer(s):

Name: —

Email: —

Name: —

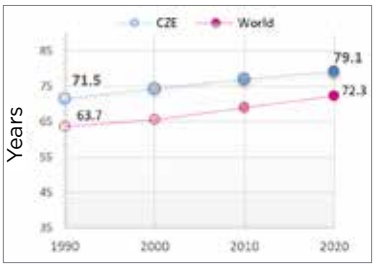
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Czechia

Country indicators - WHO country information

Population 000s (rank):[a]	10,709 (85)	Under-five mortality (per 1000 live births):[d]	2.92	UHC - Service coverage index (1-100):[h]	78
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	14.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.2% (0.1%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.9 (0.86): very high	Global innovation index (rank):[j]	48.3 (24)
		ICT Development Index (rank):[g]	7.2 (43)	High-technology exports (% of manufacture exports):[k]	20.80%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: VZP CR (General Health Insurance Company).

Website: http://www.vzp.cz/

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: https://www.mzcr.cz/

Website - laboratories: https://www.mzcr.cz/doporucujici-a-interpretacni-dokumenty-meddev/
https://eregpublicsecure.ksrzis.cz/Registr/RZPRO/ZdravotnickyProstredek

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: https://www.mzcr.cz/doporucujici-a-interpretacni-dokumenty-meddev/

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): http://www.mzcr.cz/en/
https://www.mzcr.cz/ministerstvo-zorganizovalo-dalsi-seminar-venovany-hta/
https://www.niszp.cz/en

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There are HTA activities in pharmaceutics, not specifically for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of Health.

Website(s): https://www.mzcr.cz/information-on-legal-provisions-regulating-the-field-of-medical-devices/

Contact: Ms. Karolina Pestova Email: karolina.pestova@mzcr.cz

Name(s) of other regulatory agency eg. for radiation equipment etc.: State Institute for Drug Control.

Other agency's website: https://www.sujb.cz/en/

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: —

Nomenclature comments (...Annex 1):

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):

—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	110	10.27
Computerized Tomography Scanner:[α]	171	15.97
Positron Emission Tomography Scanner:[α]	17	1.59
Gamma camera or nuclear medicine:[α]	127	11.86
Mammograph:[α,*]	119	87.29
Radiotherapy:[β]	114	10.65

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: Yes Software name: —

Software comments (...Annex 1):

—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):

Name: Ms. Karolina Pestova

Email: karolina.pestova@mzcr.cz

Name: Mr. Jan Zofka

Email: zofka@uzis.cz

WHO Country officer(s):

Name: Dr. Srdan Matic

Email: matics@who.int

Name: —

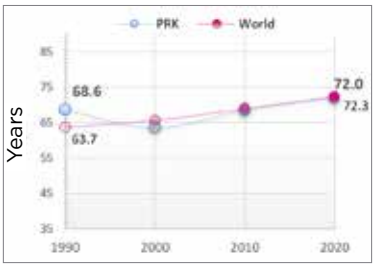
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Democratic People's Republic of Korea

Country indicators - WHO country information

Population 000s (rank):[a]	25,779 (54)	Under-five mortality (per 1000 live births):[d]	16.5	UHC - Service coverage index (1-100):[h]	68
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	23.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	— (—):	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: Yes

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: —

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: National Evidence-based healthcare Collaborating Agency (NECA).

Website(s): https://vortal.htai.org/index.php?q=node/379

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

National regulatory comments (...Annex 1): —

Name of regulatory agency: Department of Medical Device Management and Production.

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Medical Equipment. Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr Mohamed Jamsheed
Email: jamsheedm@who.int

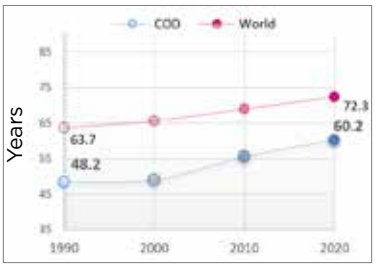
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Democratic Republic of the Congo

Country indicators - WHO country information

Population 000s (rank):[a]	89,561 (16)	Under-five mortality (per 1000 live births):[d]	81.18	UHC - Service coverage index (1-100):[h]	39
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	4.8% (0.6%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.48 (0.34): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	1.6 (171)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Il existe des listes de materiel dressé au niveau periphérique approuvé (district sanitaire). Pour le niceu intermediaires et niveau tertiaire cette liste est en élaboration.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: La Direction des laboratoires de Santé / Ministère de la Santé.

Website(s): https://www.minisanterdc.cd/

Contact: Mr. Daniel Ngeleka Mutolo Email: dangelemutolo@yahoo.fr

Name(s) of other regulatory agency eg. for radiation equipment etc.: Direction des laboratoirs de Sante; Direction des Equipements et Materiels medicaux, and Comite National de Protection Contre les rayonments ionisants (CNPRI).

Other agency's website: https://www.iaea.org/newscenter/news/democratic-republic-of-the-congo-signs-a-country-programme-framework-cpf-for-2018-2022

National regulatory comments (...Annex 1):

La Direction des laboratoirs de Sante veuille surtout au respect des normes de autres equipements des laboratoires et des services d'imagerie medicales. Tandis la Direction des Equipements et Materiels Medicaux s'occupes des autres materiel

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
La nomenclature officielle n'existe pas. Tout ce qui est à portée de main et selon les circonstances est utilisé.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
En R.D.Congo, les achats se font à tous les niveaux. L'Etat n'a pas pu reglementer ce secteur les achats se font à tous les niveaux et surtout les bailleurs de fonds pour leurs programmes spécifiques qu'ils appuient. Le directives à ce niveau sont fonction d'un appel offre, c'est en ce moment que celui qui lance l'offre dresse un certains critères des dispositifs qu'il veut

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	0	0
Computerized Tomography Scanner:α	5	0.07
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	1	0.01
Mammograph:α,*	2	0.74
Radiotherapy:β	1	0.01

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction des Equipements et Materiels Médicaux. Unit website: —
Contact name: Mr. Ngilo Eagbali Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 1

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
On est dans le processus de creér de pool de maintenance avec des ingenieurs sanitaires et de rehabiliter les ateliers qui existent . Il y a un programme de formation des ingenieurs et des utilisateurs.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 100

Contacts

National officer(s):
Name: Mr. Malaba Munyyanji Cleophas If
Email: malabac@yahoo.fr

Name: Mr. Ngilo Eagbali
Email: Ngilozagbali@yahoo.fr

WHO Country officer(s):
Name: Dr. Yokouidé Allarangar
Email: afwcocd@who.int

Name: Dr. Anastasie Mulumba M.
Email: mulumbaa@who.int

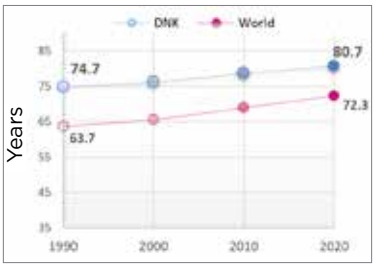
General comments (...Annex 1):

En tant pays post-conflit, dans le processus de l'organisation de son système national de santé, le gouvernement dispose deja d'une strategie de renforcement du système de santé qui est une strategie sectorielle. Ensuite, le pays vient de se doter d'un plan stragegique de développement sanitaire pour 5 ans avec un cadre des dépenses à moyen terme ou toutes ces technologies sont planifiées.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Denmark

Country indicators - WHO country information

Population 000s (rank):[a]	5,792 (113)	Under-five mortality (per 1000 live births):[d]	3.61	UHC - Service coverage index (1-100):[h]	85
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.9% (0.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.94 (0.88): very high	Global innovation index (rank):[j]	57.5 (6)
		ICT Development Index (rank):[g]	8.7 (4)	High-technology exports (% of manufacture exports):[k]	12.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): Danish

Ministry of health responsible for health technology policy implementation: Lægemiddelstyrelsen (Danish Medicines Agency).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): In the case of lists for different diseases and situations, there are some more general plans, but no specific medical devices recommended.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: HTA unit within the Danish Health Authority.

Website(s): https://www.sst.dk/en https://laegemiddelstyrelsen.dk/en/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Lægemiddelstyrelsen / Danish Medicines Agency.

Website(s): https://laegemiddelstyrelsen.dk/

Contact: Ms. Ellen Jespersen Email: eje@dkma.dk

Name(s) of other regulatory agency eg. for radiation equipment etc.: The Danish Health and Medicines Authority.

Other agency's website: https://www.sst.dk/da/Opgaver/Straalebeskyttelse

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://laegemiddelstyrelsen.dk/

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	77	13.7
Computerized Tomography Scanner:[α]	236	40.75
Positron Emission Tomography Scanner:[α]	48	8.29
Gamma camera or nuclear medicine:[α]	85	14.68
Mammograph:[α,*]	88	119.43
Radiotherapy:[β]	71	12.26

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: www.sis.dk

Use of management software: Yes Software name: Several systems: MEDUSA, MERIDA, QAMAP, REMEDY and more.

Software comments (...Annex 1):
The National Institute of Radiation Protection is in charge. The inventory covers all x-ray equipment, equipment for nuclear medicine and radiation therapy.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 450

Contacts

National officer(s):

Name: Ms. Nina Moss

Email: nmo@sum.dk

Name: Mr. Mads Frellsen

Email: maf@sst.dk

WHO Country officer(s):

Name: Dr. Hans Kluge

Email: eurordletters@who.int

Name: —

Email: —

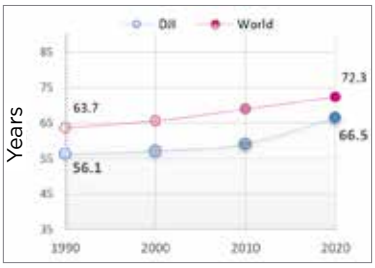
General comments (...Annex 1):

The National Board of Health is issuing some Health Technolgy Assessments, including but not limited to medical devices. Only a minority of technologies are handled, so this is regarded as being outside the scope of the Policy section.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Djibouti

Country indicators - WHO country information

Population 000s (rank):[a]	988 (156)	Under-five mortality (per 1000 live births):[d]	55.88	UHC - Service coverage index (1-100):[h]	48
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.52 (—): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	2 (158)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): https://sante.gouv.dj/
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): The development of the HTA unit is in progress, as well as the human resources to fill the workforce gap within the MoH.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Reinhilde Therese Van De Weerdt
Email: vanr@who.int

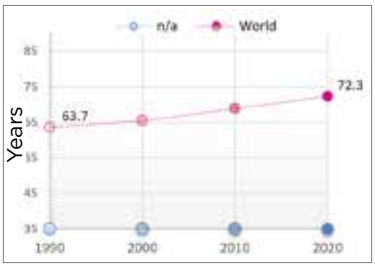
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Dominica

Country indicators - WHO country information

Population 000s (rank):[a]	72 (185)	Under-five mortality (per 1000 live births):[d]	35.45	UHC - Service coverage index (1-100):[h]	67
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	—	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.74 (—): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	5.7 (77)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —
HTA unit/department includes the assessment of medical devices: No
Unit/department: Biomedical Department, PMH.
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
HTA activities have been identified, but there is not a specific national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	1	13.89
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	2	206.69
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Central Medical Stores. Unit website: —
Contact name: Mrs. Theresa Shillingford Contact email: cms@cwdom.dm
Website with publically available technical specifications: —
Number of regional/state offices/units: 3

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: Yes Software name: —

Software comments (...Annex 1): The Software is currently awaiting for the setting-up.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Dr. Ruby Josephine Blanc
Email: blancruby@hotmail.com

Name: Mrs. Theresa Shillingford
Email: cms@cwdom.dm

WHO Country officer(s):
Name: Dra. Amalia Del Riego
Email: delriegoa@paho.org

Name: Dr. Cecilia Acuna
Email: acunamar@paho.org

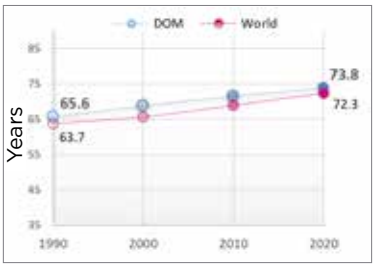
General comments (...Annex 1):

A manual exists in draft form to govern issues related to medical devices. It is still supposed to have a final review to begin the process of it's adoption and implementation.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Dominican Republic

Country indicators - WHO country information

Population 000s (rank):[a]	10,848 (84)	Under-five mortality (per 1000 live births):[d]	33.76	UHC - Service coverage index (1-100):[h]	66
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	19.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.76 (0.6): high	Global innovation index (rank):[j]	25.1 (90)
		ICT Development Index (rank):[g]	4.5 (106)	High-technology exports (% of manufacture exports):[k]	7.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Superintendencia de Salud y Riesgos Laborales (SISALRIL) y Electromedicina MoH.

Website(s): https://www.sisalril.gob.do/ https://redetsa.bvsalud.org/perfilesdepaises/perfil-de-paises/

Contact: Madeline Melissa Martínez García Email: m.martinez@sisalril.gob.do

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Viceministerio de Garantia de la Calidad.

Website(s): https://digemaps.msp.gob.do/menu/ https://www.msp.gob.do/web/

Contact: Ms. Cristina Hernández Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministerio de Salud Pública.

Other agency's website: https://www.msp.gob.do/web/

National regulatory comments (...Annex 1): La Ley General de Salud 42-01 y el Reglamento de Medicamentos Decreto 246-06 son el marco legal que fundamenta el accionar del Viceministerio de Garantía de la Calidad.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
No existe una nomenclatura oficial. Sin embargo, existe una propuesta que data del año 2006 que respondió a un proyecto de mantenimiento preventivo de equipos médicos.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: https://msp.gob.do/web/

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
En cuanto a la adquisición solo existen recomendaciones dadas en fichas técnicas y de acuerdo a la complejidad del establecimiento.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	27	2.49

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Electromedicina. Unit website: —
Contact name: Mr. Juan del Rosario Contact email: juan23955@hotmail.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 100

Contacts

National officer(s):
Name: —
Email: —

Name: Mr. Juan del Rosario
Email: juan23955@hotmail.com

WHO Country officer(s):
Name: Dr. Olivier Ronveaux
Email: ronveauoli@paho.org

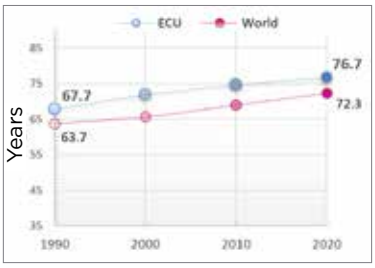
Name: Dr. Roger Montes
Email: montesr@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Ecuador

Country indicators - WHO country information

Population 000s (rank):[a]	17,643 (66)	Under-five mortality (per 1000 live births):[d]	12.95	UHC - Service coverage index (1-100):[h]	80
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	11.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	10.3% (2.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.76 (0.62): high	Global innovation index (rank):[j]	24.1 (99)
		ICT Development Index (rank):[g]	4.8 (97)	High-technology exports (% of manufacture exports):[k]	5.50%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://aplicaciones.msp.gob.ec/salud/archivosdigitales/documentosDirecciones/dnn/archivos/AM-00000113-2016%20OCT%2011.pdf

Language(s): Español

Ministry of health responsible for health technology policy implementation: Ministerio de Salud Pública-Autoridad Sanitaria Nacional

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: https://www.salud.gob.ec/ecuador-cuenta-con-lista-y-aplicativo-para-la-adquisicion-de-dispositivos-medicos-de-calidad-seguros-y-eficaces/

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.salud.gob.ec/

Website - laboratories: https://www.salud.gob.ec/ https://www.controlsanitario.gob.ec/base-de-datos/

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
Estatuto del MSP; Licenciamiento por Area en el I y II nivel.

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://www.investigacionsalud.gob.ec/

Specific lists comments (...Annex 1):
Reglamento para el registro y control sanitario de dispositivos médicos; reactivos bioquímicos y de diagnóstico y productos dentales. Reg. Oficial 573 del 20 de abril de 2009.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Coordinación General de Desarrollo Estratégico en Salud (Dirección Nacional de Inteligencia de la Salud).

Website(s): https://www.salud.gob.ec/direccion-de-inteligencia-de-la-salud/

Contact: Ms. Ruth Lucio Email: ruth.lucio@msp.gob.ec

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There are HTA activities for health products, not specified for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Coordinación Nacional de Desarrollo Estratégico, Dirección de Inteligencia and Instituto Nacional de Higiene y Medicina Tropical.

Website(s): https://www.salud.gob.ec/ https://www.controlsanitario.gob.ec/

Contact: Ms. Ruth Lucio Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Agencia Nacional de Regulación, Control y Vigilancia Sanitaria.

Other agency's website: https://www.controlsanitario.gob.ec/

National regulatory comments (...Annex 1):
Eco. Ruth Lucio, Coordinadora Nacional de Desarrollo Estratégico en Salud Dirección Nacional de Vigilancia y Control Sanitario en lo relativo a Publicidad y vigilancia. Dr. Liliana Sacoto es la Directora Nacional. Asi como la Dra. Amelia Prieto del Instituto Nacional de Higiene y Medicina Tropical.

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: More than one system
Use: For regulatory and procurement purposes
Website: https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/01/Resoluci%C3%B3n_ARCSA-026-YMIH-Dispositivos-M%C3%A9dicos.pdf

Nomenclature comments (...Annex 1):
For MD traceability purposes will be taken as a reference the Universal Medical Devices Nomenclature System (UMDNS) developed by Emergency Care Research Institute (ECRI). In case that UMDNS does not have a specific code for a MD, it will be taken as an alternative nomenclature, the Global Medical Devices Nomenclature developed by GMDN Agency.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: https://www.salud.gob.ec/direccion-nacional-de-medicamentos-y-dispositivos-medicos/

Donations

Policy or guideline: Yes Website: https://www.salud.gob.ec/direccion-nacional-de-medicamentos-y-dispositivos-medicos/

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
Las políticas de adquisición están en proceso de implementación por la Dirección de Inteligencia y Economía de la salud.
Programa Mi hospital: Adquisición de equipos para 8 hospitales declarados en emergencia sanitaria.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	2	0.13
Computerized Tomography Scanner:α	25	1.59
Positron Emission Tomography Scanner:α	2	0.13
Gamma camera or nuclear medicine:α	2	0.13
Mammograph:α,*	n/a	n/a
Radiotherapy:β	28	1.59

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Red de Hospitales. Unit website: https://www.salud.gob.ec/
Contact name: Dr. Luis Paredes Contact email: luis.paredes@msp.gob.ec
Website with publically available technical specifications: https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2014/04/dispositivos-medicos-y-dentales.pdf
https://www.controlsanitario.gob.ec/wp-content/plugins/download-monitor/download.php?id=7148&force=1
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Se está actualizando el inventario de los Hospitales declarados en emergencia.
Hay "National inventory only for high cost technologies (such as MRI, CT or PET scanners)" tambien.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 126

Contacts

National officer(s):
Name: Ms. Betzabé Tello
Email: betzabe.tello@msp.gob.ec

Name: Dr. Luis Paredes
Email: luis.paredes@msp.gob.ec

WHO Country officer(s):
Name: Dr. Oscar Martin Barreneche
Email: barreneosc@paho.org

Name: Dr. Javier Uribe
Email: uribejav@paho.org

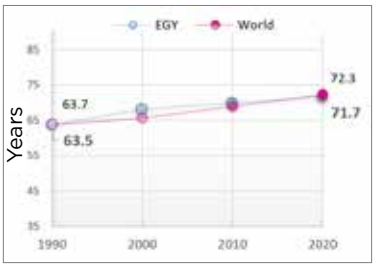
General comments (...Annex 1):

La regulación y el control de la publicidad de dispositivos médicos se realiza mediante el "Reglamento para la publicidad y promoción de medicamentos en General, Productos Naturales procesados de uso medicinal, medicamentos homeopáticos y dispositivos médicos". Reg. Oficial 416, acuerdo ministerial 179 del 30 de marzo de 2011.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Egypt

Country indicators - WHO country information

Population 000s (rank):[a]	102,334 (14)	Under-five mortality (per 1000 live births):[d]	19.46	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	28.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	26.2% (3.9%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.71 (0.5): high	Global innovation index (rank):[j]	24.2 (96)
		ICT Development Index (rank):[g]	4.6 (103)	High-technology exports (% of manufacture exports):[k]	2.30%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): Arabic and English

Ministry of health responsible for health technology policy implementation: Geographical Unit of Health Information (GIS), Aantrz National Health Information: administration of medical devices.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): Were counted by the sector ministry and therapeutic medicine, the National Information Center Ministry

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://gah.gov.eg/indexenglish.php

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): A pharmacoeconomics unit was officially established in 2011 under the Central Administration of Pharmaceutical Affairs within the Ministry of Health, but HTA is not obligatory for pricing or reimbursement. However, the recent universal health insurance law from 2018 mandates the representation of health economists in the

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Egyptian Nuclear and Radiological Regulatory Authority (ENRRA).

Other agency's website: https://gnssn.iaea.org/main/ANNuR/Activity%20Documents%20%20Public/6th%20ANNuR%20Plenary%20Meeting/Egypt1.pdf

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: https://www.edaegypt.gov.eg/

Nomenclature comments (...Annex 1):
Used in the database of geographical information system health.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Management of medical equipment and hospital management. Curative medicine sector and management of medical devices.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	143	1.4

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Quality Management. Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: —

Software comments (...Annex 1):
Database of geographical information system health.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 1000

Contacts

National officer(s):
Name: Dr. Sohier Saad Botrous Attalla
Email: ssb_attalla@yahoo.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Naeema Al Gasseer
Email: algasseern@who.int

Name: —
Email: —

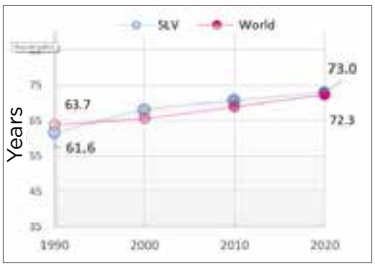
General comments (...Annex 1):

Concerning the Infrastructure section: the proposed names are not totally compatible with ours. Thus, the number of units is under the Ministry of Health only and is not confined to Tfsalia to the private sector in 2010.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

El Salvador

Country indicators - WHO country information

Population 000s (rank):[a]	6,486 (110)	Under-five mortality (per 1000 live births):[d]	12.88	UHC - Service coverage index (1-100):[h]	76
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.7% (0.3%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.67 (0.53): medium	Global innovation index (rank):[j]	24.8 (92)
		ICT Development Index (rank):[g]	3.8 (119)	High-technology exports (% of manufacture exports):[k]	5.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://asp.salud.gob.sv/regulacion/pdf/norma/Norma_diseno_y_equipamiento_casas_salud.pdf

Website - laboratories: https://www.medicamentos.gob.sv/index.php/es/servicios-m/en-linea/expediente-electronico-de-insumos-medicos

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): Norma técnica para el diseño y equipamiento de Casas de Salud.

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://asp.salud.gob.sv/ http://www.salud.gob.sv/

Specific lists comments (...Annex 1): Tomadas de la pagina web del MINSAL (ver link proporcionado). Norma técnica para radiología diagnóstica e intervencionista; Norma técnica para uso de fuentes radiactivas en braquiterapia; Norma técnica para la operación de equipos de teleterapia; Norma técnica uso de fuentes radiactivas no selladas

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[5] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Dirección Nacional de Medicamentos and Instituto Salvadoreño de Seguro Social

Website(s): https://www.isss.gob.sv/

Contact: Haryes Funes Email: haryes.funes@medicamentos.gob.sv

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Dirección Nacional de Medicamentos

Website(s): https://www.medicamentos.gob.sv/index.php/es/servicios-m/descargables/unidad-de-registro-de-dispositivos-medicos

Contact: Lic. Francisco Bosco Cortez Morales

Email: insumos.medicos@medicamentos.gob.sv

National regulatory comments (...Annex 1): El departamento está a cargo del Dr. Rivera, Director de Regulación y Legislación en Salud del Ministerio de Salud.

Name(s) of other regulatory agency eg. for radiation equipment etc.: Dirección de Protección Radiológica (DPR).

Other agency's website: https://www.salud.gob.sv/direccion-de-proteccion-radiologica/

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
El catálogo desarrollado es de equipo médico en general y sólo es para fines de compra. No existe distinción o clasificación de equipos de tecnología médica por su aplicación o incidencia en la salud del paciente.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	7	1.1
Computerized Tomography Scanner:[α]	30	4.73
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	6	0.95
Mammograph:[α,*]	30	69.99
Radiotherapy:[β]	11	1.7

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Unidad Nacional de Radiaciones Ionizantes. Unit website: —
Contact name: Ms. Carolina de Rivera Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 5

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: https://www.salud.gob.sv/direccion-de-proteccion-radiologica/
https://www.medicamentos.gob.sv/index.php/es/servicios-m/descargables/urim-m
Use of management software: No Software name: —

Software comments (...Annex 1):
Para el control de equipos con fuente de radiaciones ionizantes, la Dirección de Regulación a través de la Unidad Reguladora de Radiaciones Ionizantes (UNRA) tiene el inventario de los equipos como TC, Rayos X, Angiografía, Gamma Cámara, etc. Autorizados a nivel nacional en la actualidad, se remitirá el listado actualizado a la fecha a la OMS.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 231

Contacts

National officer(s):
Name: Lic. Sulay Stefanni Mejía Campos
Email: cooperacion@medicamentos.gob.sv

Name: Ms. Carolina de Rivera
Email: —

WHO Country officer(s):
Name: Dr. Giovanni Escalante Guzman
Email: gescalante@paho.org

Name: Dr. Laura Ramirez
Email: lramirez@paho.org

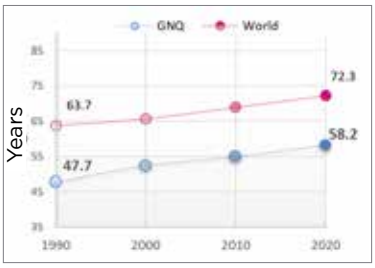
General comments (...Annex 1):

Las respuestas proporcionadas corresponden exclusivamente a la información disponible en la Unidad de Proyectos del Ministerio de Salud Pública y Asistencia Social. Agradecemos permitirnos participar de tan importante encuesta que nos permite establecer un enlace que estamos seguros contribuirá a mejorar nuestra gestión en la planificación, evaluación, adquisición y mantenimiento de los dispositivos médicos de nuestro sistema nacional de salud; así como a contribuir en el desarrollo de una política nacional de tecnología sanitaria en El

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Equatorial Guinea

Country indicators - WHO country information

Population 000s (rank):[a]	1,403 (149)	Under-five mortality (per 1000 live births):[d]	78.49	UHC - Service coverage index (1-100):[h]	43
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.59 (—): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	1.9 (163)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There are identified HTA activities but not a national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. George Fom Ameh
Email: amehg@who.int

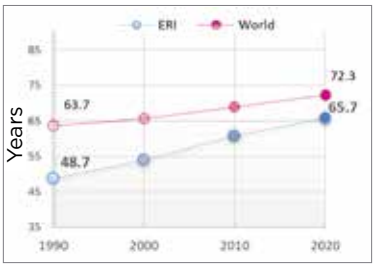
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Eritrea

Country indicators - WHO country information

Population 000s (rank):[a]	3,546 (130)	Under-five mortality (per 1000 live births):[d]	39.27	UHC - Service coverage index (1-100):[h]	50
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	26.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.46 (—): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	1 (176)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): English

Ministry of health responsible for health technology policy implementation: Department of Regulatory Services, Medicine and Medical Devices Control Division.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): Ministry of Health, Department of Regulatory Services, Medicine and Medical Devices Control Division.

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of Health, Department of Regulatory Services.

Website(s): —

Contact: Mr. Eyassu Bahta Email: bahtassy@gmail.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: https://shabait.com/

Nomenclature comments (...Annex 1):
Official nomenclature system for medical devices is currently on the process of development.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	0.16
Computerized Tomography Scanner:α	2	0.32
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	4	16.56
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Health services. Unit website: —
Contact name: Dr. Brhane Debru Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 6

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
National medical devices inventory on the six zones has started in 2008 and, currently, it is in the process of finalization (only one zone is partially remaining).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):
Name: Mr. Gherezghier Habtu
Email: wedirebi22@gmail.com

Name: Dr. Brhane Debru
Email: —

WHO Country officer(s):
Name: Dr. Martins Ovberedjo
Email: ovberedjom@who.int

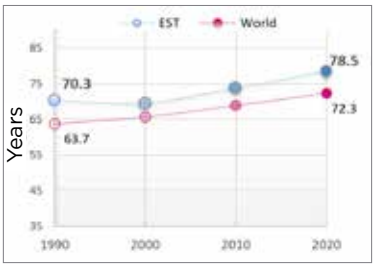
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Estonia

Country indicators - WHO country information

Population 000s (rank):[a]	1,327 (151)	Under-five mortality (per 1000 live births):[d]	2.11	UHC - Service coverage index (1-100):[h]	78
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	14.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.89 (0.83): very high	Global innovation index (rank):[j]	48.3 (25)
		ICT Development Index (rank):[g]	8.1 (17)	High-technology exports (% of manufacture exports):[k]	9.30%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: —

Website: https://www.riigiteataja.ee/index.html
https://www.riigiteataja.ee/ert/act.jsp?id=13284086
https://www.riigiteataja.ee/ert/act.jsp?id=13231527

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

The list about reimbursed medical devices used in outpatient conditions is available on web-site (second link) Medical devices used in inpatient conditions are financed though the prices of healthcare services (these prices include also costs of workforce, area, etc). List of healthcare sevices is available on web-site (third link).

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.riigiteataja.ee/ert/act.jsp?id=13252715

Website - laboratories: https://www.riigiteataja.ee/aktilisa/1300/4201/4006/SOM_m26_lisa.pdf#

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.riigiteataja.ee/ert/act.jsp?id=13252715

Specific lists comments (...Annex 1):

Recommended medical devices for specific procedures are described in diagnostic (and treatment) guidelines. They are composed and/or approved by specialists organizations.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: University of Tartu: Publich Health Department.

Website(s): https://tervis.ut.ee/en/health-technology-assessment/health-technology-assessment-estonia

Contact: — Email: dph@ut.ee

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

The HTA for medical products, mainly pharmaceutics, and treatments. There is mention of medical equipment too.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Health Board, Medical Devices Department.

Website(s): https://www.terviseamet.ee/et
http://www.terviseamet.ee/en/medical-devices.html

Contact: Mr. Andrei Knuut Email: mso@terviseamet.ee

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: https://www.riigiteataja.ee/index.html

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://www.terviseamet.ee/en/medical-devices-2/regulatory-controls-medical-devices

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.riigiteataja.ee/ert/act.jsp?id=13191371

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
The procurement of medical devices is regulated by the Public procurement law, as well as all other commodities (see specified website: riigiteataja).

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	18	13.56
Computerized Tomography Scanner:[α]	25	18.84
Positron Emission Tomography Scanner:[α]	3	2.26
Gamma camera or nuclear medicine:[α]	3	2.26
Mammograph:[α,*]	14	76.94
Radiotherapy:[β]	9	6.78

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Department of Public Health, University of Tartu. Unit website: http://www.arth.ut.ee/

Contact name: — Contact email: —

Website with publically available technical specifications: http://www.arth.ut.ee/

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 60

Contacts

National officer(s):
Name: Ms. Tairi Välinurm
Email: tairi.valinurm@sm.ee

Name: —
Email: —

WHO Country officer(s):
Name: Ms. Kristina Köhler
Email: kohlerk@who.int

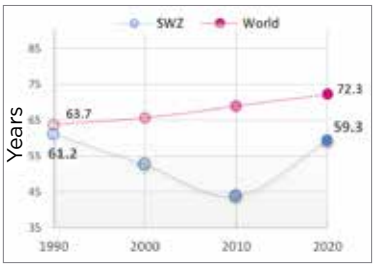
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Eswatini

Country indicators - WHO country information

Population 000s (rank):[a]	1,160 (155)	Under-five mortality (per 1000 live births):[d]	46.64	UHC - Service coverage index (1-100):[h]	58
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	35.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.61 (0.43): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	0.30%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1):
The list is still being developed by the Emergency Preparedness Group.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes
HTA unit/department includes the assessment of medical devices: —
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There is no HTA national unit per se. However, and adaptive HTA has been used to inform in areas such as benefits package in health interventions prioritisations packages.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: Pharmaceuticals & Medicines, Ministry of Health.
Website(s): http://www.gov.sz/index.php/3rd-national-health-and-research-conference
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The National guidelines on procurement are yet to be developed. The unit together with the bio-medical department forms a committee that recommends purchasing the needed equipment or rather requested equipment.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	0	0
Computerized Tomography Scanner:α	3	2.4
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	2	33.62
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Biomedical unit. Unit website: —
Contact name: Mr. Leornad Zwane Contact email: magmu@realnet.co.sz
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Though this inventory is still under development, we have only covered hospitals and health centres and will proceed to clinics (health posts for Swaziland).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Dr. Samuel Vusi Magagula
Email: magagulasam@gov.sz

Name: Mr. Leornad Zwane
Email: magmu@realnet.co.sz

WHO Country officer(s):
Name: Dr. Cornelia Atsyor
Email: atsyorc@who.int

Name: —
Email: —

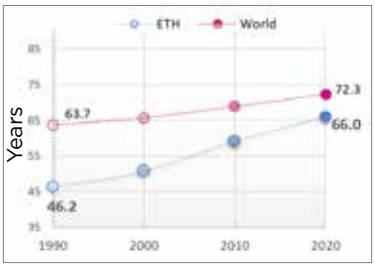
General comments (...Annex 1):

Concerning the Infrastructure section: In Swaziland Health Centres may have more than 20 beds. The referral levels are being defined by the ongoing essential health care package that is being developed.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Ethiopia

Country indicators - WHO country information

Population 000s (rank):[a]	114,964 (12)	Under-five mortality (per 1000 live births):[d]	48.71	UHC - Service coverage index (1-100):[h]	38
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	17.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	4.9% (1.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.49 (0.35): low	Global innovation index (rank):[j]	18.1 (127)
		ICT Development Index (rank):[g]	1.7 (170)	High-technology exports (% of manufacture exports):[k]	61.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Federal Ministry of Health (FMOH).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Pharmaceutical and Medical Device Directorate, FMOH.

Website: www.moh.gov.et

Nomenclature systems used for devices and tests: Several of the ones mention above.

Approved devices lists comments (...Annex 1):

We have capital and routine medical device list with technical specification categorized with health facility level.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: www.moh.gov.et

Website - laboratories: —

Nomenclature systems used for devices and tests: Use of several nomenclatures.

Health care facilities lists comments (...Annex 1):

The list of healthcare facilities is currently in progress.

National list for specific clinical interventions/emergencies:

Lists available: No

Website: www.fmhaca.gov.et

http://www.fmhaca.gov.et/publication/guideline-for-registration-of-medical-devices-2014/

Specific lists comments (...Annex 1):

A revision has started for each. It is use the WHO guidelines and other documents.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: Pharmaceutical and medical equipment directorate

Website(s): —

Contact: Mr. Regasa Bayisa Email: regasa.bayisa@moh.gov.et

Committee includes a biomedical or clinical engineer: No

HTA unit comments (...Annex 1):

An HTA unit is not yet established. Within the FMoH the Pharmaceutical and Medical Device Directorate and HEFA team are primary driving forces to generate and promote HTA based evidence. The HEFA team is tasked with spearheading the application of evidence-based health care decision making by organizing

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ethiopian Food and Drug Administration (EFDA).

Website(s): https://www.eris.efda.gov.et/; www.fmhaca.gov.et

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation & Protection Authority; Ethiopian standard Agency (ESA)

Other agency's website: http://www.moh.gov.et/ https://ethiostandards.org/

National regulatory comments (...Annex 1):

Radiation & Protection Authority.

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For various purposes
Website: www.fmhaca.gov.et
https://epsa.gov.et/featured-services/procurement-list/

Nomenclature comments (...Annex 1):
Nationally developed and adapted from both UMDN and GMDN. This nomenclature is done by EPSA, ESDA and FMoH in collaboration with skateholders. The nomenclature is mainly use for procurement and regulatory purposes. Established the Public Infrastructure Directorate are now started inventory to identify the type, source and status of the devices.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: http://www.moh.gov.et/ejcc/en

Donations

Policy or guideline: Yes Website: www.fmhaca.gov.et

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://epsa.gov.et/
https://epsa.gov.et/standard-docs/#1574929031127-db548281-5eb6

Medical device incorporation comments (...Annex 1):
The Plan, Monitoring and Evaluation Directorate (PMED), within Federal Ministry ofHealth (FMOH) is in charge of the procurement.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	18	0.16
Computerized Tomography Scanner:[α]	48	0.42
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	1	0.01
Mammograph:[α,*]	1	0.2
Radiotherapy:[β]	10	0.09

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Public Health Infrastructure Directorate; Pharmaceutical and Medical Device Directorate. Unit website: https://www.fmoh.gov.et
http://www.fmhaca.gov.et/publication/
Contact name: Mr. Regasa Bayisa Contact email: regasa.bayisa@moh.gov.et
Website with publically available technical specifications: https://epsa.gov.et/standard-docs/#1574929031127-db548281-5eb6
http://www.fmhaca.gov.et/publication/
Number of regional/state offices/units: 12

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: MEMIS (Medical Equipment Management Information System).

Software comments (...Annex 1):
AAU, Tikur Anbesa specialized Hospital update medical Inventory and Equipment history file in 2013.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 1000

Contacts

National officer(s):
Name: Mr. Regasa Bayisa
Email: regasa.bayisa@moh.gov.et

Name: Mr. Mekonnen Engida
Email: mekonen_engda@yahoo.com

WHO Country officer(s):
Name: Dr. Boureima Hama Sambo
Email: sambob@who.int

Name: Mr. Mulugeta Mideksa
Email: mulugetamideksa@yahoo.com

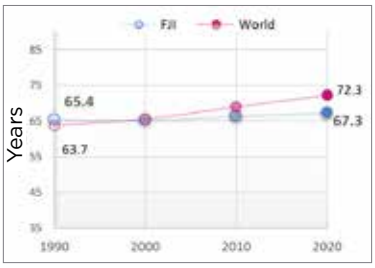
General comments (...Annex 1): Concerning

National policy on health technology: National Medical device strategy under development (draft) and National Medical device directive (final draft) will approved within 3 or 4 months. Concerning the HT national policy, it is stated in the

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Fiji

Country indicators - WHO country information

Population 000s (rank):[a]	896 (157)	Under-five mortality (per 1000 live births):[d]	27.43	UHC - Service coverage index (1-100):[h]	61
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	37.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.74 (—): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	4.5 (107)	High-technology exports (% of manufacture exports):[k]	3.90%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.health.gov.fj

Language(s): English

Ministry of health responsible for health technology policy implementation: Clinical Services MoH HQ.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Biomedical Engeering Units.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
The biomedical catalogue for procurement can be obtained by the Fiji Health Sector Improvement Program (FHSIP).

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.health.gov.fj/

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
CSN & CSP lists can be obtained from ministry of health, HQ.

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://www.health.gov.fj

Specific lists comments (...Annex 1):
CSN & CSP. Can be obtained from Ministry of Health, HQ.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Biomedical Engineering, CWMH.

Website(s): —

Contact: Mr. Virendra Deo Singh Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministry of Health & Medical Services.

Other agency's website: http://www.health.gov.fj/

National regulatory comments (...Annex 1):
Also, supported by the divisional biomedical engineering units.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: http://www.health.gov.fj/

Nomenclature comments (...Annex 1): –

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.health.gov.fj/
National level procurement: Yes Website: http://www.health.gov.fj/

Donations

Policy or guideline: Yes Website: –

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: http://www.health.gov.fj

Medical device incorporation comments (...Annex 1):
Mainly standardization of all medical equipment as per the national biomedical catalogue. Also, supported by the Ministry of Health central procurement centre at Fiji Pharmaceutical Services.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1	1.13
Computerized Tomography Scanner:[α]	3	3.4
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	2	28.83
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Biomedical Engineering. Unit website: –
Contact name: Mr. Mohammed Ifraz Contact email: mohammed.ifraz@health.gov.fj
Website with publically available technical specifications: –
Number of regional/state offices/units: –

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: –
Use of management software: Yes Software name: EMS, EPICOR.

Software comments (...Annex 1):
BME Equipment Inventory. The inventory has more than 8,600 items.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):

Name: Mr. Virendra Deo Singh
Email: virendra.singh@health.gov.fj

Name: Mr. Mohammed Ifraz
Email: mohammed.ifraz@health.gov.fj

WHO Country officer(s):

Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

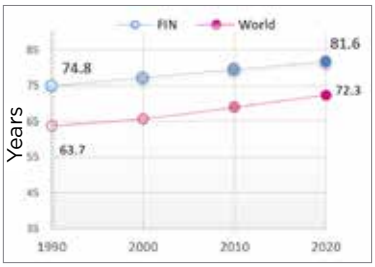
Name: Dr. Wendy Snowdon
Email: snowdonw@who.int

General comments (...Annex 1): –

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Finland

Country indicators - WHO country information

Population 000s (rank):[a]	5,541 (114)	Under-five mortality (per 1000 live births):[d]	2.31	UHC - Service coverage index (1-100):[h]	83
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	9.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	6.4% (1.0%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.94 (0.89): very high	Global innovation index (rank):[j]	57 (7)
		ICT Development Index (rank):[g]	7.9 (22)	High-technology exports (% of manufacture exports):[k]	9.20%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

HTA unit comments (...Annex 1): —

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: FinCCHTA.

Website(s): https://www.ppshp.fi/Tutkimus-ja-opetus/FinCCHTA/Sivut/default.aspx
https://palveluvalikoima.fi/en/recommendations
https://thl.fi/en/web/thlfi-en/about-us

Contact: — Email: —

Committee includes a biomedical or clinical engineer: Yes

National regulatory authority

National regulatory comments (...Annex 1): —

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Finnish Medicines Agency (FIMEA).

Website(s): http://www.fimea.fi
http://www.valvira.fi

Contact: Mr. Heikki Mattlar Email: heikki.mattlar@fimea.fi

Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation and Nuclear Safety Authority (STUK); Ministry of Social Affairs and Health (Radiation Protection).

Other agency's website: https://www.stuk.fi/web/en
https://stm.fi/en/environmental-health/radiation-protection;

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://www.fimea.fi/web/en/medical-devices

Nomenclature comments (...Annex 1):

Finland CA will implement the European Medical Device Nomenclature (EMDN) used by manufacturers/ARs when registering their medical devices in the EUDAMED database. The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland. Also, some other commercial nomenclature systems are used in healthcare organizations and

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):

—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	159	28.7
Computerized Tomography Scanner:α	91	16.42
Positron Emission Tomography Scanner:α	15	2.71
Gamma camera or nuclear medicine:α	42	7.58
Mammograph:α,*	156	214.37
Radiotherapy:β	57	10.29

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):

—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 850

Contacts

National officer(s):

Name: Ms. Mari Laurén-Häussler

Email: mari.lauren-haussler@stm.fi

Name: Mrs. Ritva Bly

Email: —

WHO Country officer(s):

Name: —

Email: —

Name: —

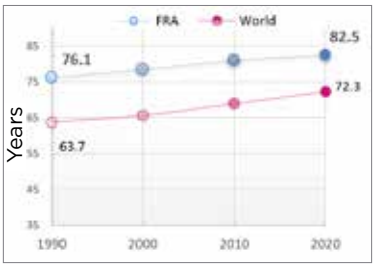
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

France

Country indicators - WHO country information

Population 000s (rank):[a]	65,274 (22)	Under-five mortality (per 1000 live births):[d]	4.37	UHC - Service coverage index (1-100):[h]	84
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.4% (0.2%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.9 (0.82): very high	Global innovation index (rank):[j]	53.7 (12)
		ICT Development Index (rank):[g]	8.2 (15)	High-technology exports (% of manufacture exports):[k]	27.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://solidarites-sante.gouv.fr/soins-et-maladies/autres-produits-de-sante/dispositifs-medicaux/

Language(s): Français

Ministry of health responsible for health technology policy implementation: Direction Générale de la Santé et Direction Générale de l'Offre de Soins.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Ministère chargé de la santé et de la sécurité sociale.

Website: http://www.who.int/medical_devices/survey_resources/medical_devices_for_procurement_reimbursement_france.pdf
https://www.ameli.fr

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
La liste des dispositifs médicaux et prestations pris en charge par l'assurance maladie est accessible à l'adresse donnée en ameli (chercher fournisseurs-de-biens-medicaux/exercer-au-quotidien/liste-des-produits-et-prestations-lpp/liste-des-produits-et-prestations-lpp/).

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.ameli.fr/

Website - laboratories: https://www.ansm.sante.fr/Activites/Surveillance-du-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMDIV/Dispositifs-medicaux-de-diagnostic-in-vitro-Controles-de-lot-ponctuels-en-laboratoire/(offset)/2

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Haute Autorité de Santé.

Website(s): https://www.has-sante.fr/jcms/c_2883073/fr/evaluation-des-technologies-de-sante-a-la-has-place-de-la-qualite-de-vie
https://www.has-sante.fr/jcms/c_821871/fr/securite-du-patient-guides-et-outils
https://www.has-sante.fr/jcms/c_428381/fr/accreditation-des-medecins-et-equipes-medicales

Contact: Mr. Jean-Patrick Sales Email: jp.sales@has-sante.fr

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There are three commissions: La commission de la transparence (CT); la commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (CNEDIMTS), and la commission évaluation économique et de santé publique (CEESP).

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministère du Travail, de l'Emploi et de la Santé.

Website(s): http://www.sante.gouv.fr/

Contact: Ms. Emmanuelle Barsky– Adjointe au chef de bureau Email: emmanuelle.barsky@sante.gouv.fr

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministère du Travail, de l'Emploi et de la Santé.

Other agency's website: https://ansm.sante.fr/; https://ec.europa.eu/jrc/en/emar/about/euratom

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For various purposes

Website: http://www.legifrance.gouv.fr; https://www.gmdnagency.org/

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: https://www.ameli.fr/professionnel-de-la-lpp/exercice-professionnel/facturation/liste-des-produits-et-prestations-lpp/liste-produits-prestations-lpp

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1034	15.84
Computerized Tomography Scanner:[α]	1222	18.72
Positron Emission Tomography Scanner:[α]	167	2.56
Gamma camera or nuclear medicine:[α]	462	7.08
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	599	9.18

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS). Unit website: —

Contact name: Mr. Jean-Claude Ghislain Contact email: Jean-Claude.GHISLAIN@ansm.sante.fr

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 600

Contacts

National officer(s):

Name: Ms. Geraldine Bonnin

Email: Geraldine.BONNIN@sante.gouv.fr

Name: Mr. Jean-Claude Ghislain

Email: Jean-Claude.GHISLAIN@ansm.sante.fr

WHO Country officer(s):

Name: —

Email: —

Name: —

Email: —

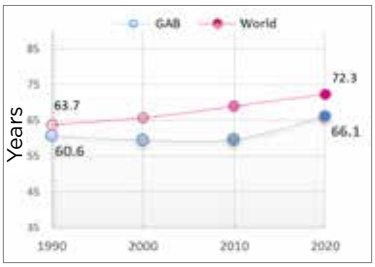
General comments (...Annex 1):

Dans cette enquete, nous avons mentionnées la HAS et l'ANSM qui sont deux agences qui sont chargées: HAS: Agence d'évaluation des dispositifs médicaux ANSM : Agence nationale de sécurité du médicament qui est chargée de la sécurité sanitaire des dispositifs médicaux.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Gabon

Country indicators - WHO country information

Population 000s (rank):[a]	2,226 (142)	Under-five mortality (per 1000 live births):[d]	41.73	UHC - Service coverage index (1-100):[h]	49
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.7 (0.54): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	4.1 (114)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
HTA activities have been identified, but there is not a specific national unit per se. Currently, the HTA unit is in progress towards the Universal Health Care (UHC) country goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: https://www.sante.gov.ma/Pages/ADM_Centrale/DMP.aspx

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	2	1.2
Computerized Tomography Scanner:[α]	6	3.59
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	6	73.12
Radiotherapy:[β]	2	0.9

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction Générale de la Planification, des Infrastructures et des Équipements. Unit website: —
Contact name: Mr. Martin Essono Contact email: martessono@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Mr. Martin Essono
Email: martessono@yahoo.fr

Name: Mr. Martin Essono
Email: martessono@yahoo.fr

WHO Country officer(s):
Name: Dr. Magaran Monzon Bagayoko
Email: bagayokom@who.int

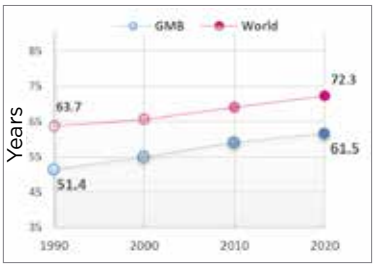
Name: Dr. Aboubacar Inoua
Email: inouaa@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Gambia

Country indicators - WHO country information

Population 000s (rank):[a]	2,417 (140)	Under-five mortality (per 1000 live births):[d]	49.37	UHC - Service coverage index (1-100):[h]	48
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	0.2% (0.0%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.5 (0.34): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	2.6 (144)	High-technology exports (% of manufacture exports):[k]	1.70%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Médecines Control Agency

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): HTA activities have been identified, but there is not a specific National unit. Currently, the HTA unit is in progress towards the Universal Health Care (UHC) country goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Médecines Control Agency

Website(s): www.mca.gm

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: International Atomic Energy Agency (IAEA).

Other agency's website: https://www.iaea.org/newscenter/news/iaea-advises-the-gambia-on-strengthening-regulatory-infrastructure

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: Not specified

Website: http://www.mrc.gm/

Nomenclature comments (...Annex 1):
The Medical Research Council (UK) unit "the Gambia" (refer to specified link) uses the UMDNS system via the ECRI Health Devices Sourcebook (ECRI website). Note that this is not used by the Ministry of Health.

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1	0.54
Computerized Tomography Scanner:[α]	3	1.24
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	4	43.89
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Royal Victoria Teaching Hospital. Unit website: —

Contact name: Mr. Michael Gomez Contact email: michael.gomez63@yahoo.com

Website with publically available technical specifications: —

Number of regional/state offices/units: 2

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: Yes Software name: AIMS Program.

Software comments (...Annex 1):
Recently inventories have been compiled for the National Laboratory Services. However, those for Hospital/Clinical equipment are not available yet. The Medical Research Council (UK) the Gambia has a full inventory of its biomedical equipment. It is comprised of 1,500 devices including minor clinical equipment, high-cost diagnostic and research laboratory equipment. We use a proprietary equipment management program from Phoenix Data Systems Inc. called AIMS (www.goaims.com).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):

Name: Mr. Andrew Demba

Email: anthems81@yahoo.com

Name: Mr. Michael Gomez

Email: michael.gomez63@yahoo.com

WHO Country officer(s):

Name: Dr. Desta Alamerew Tiruneh

Email: tirunehd@who.int

Name: —

Email: —

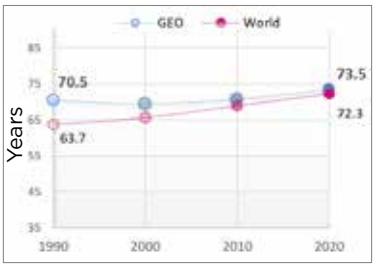
General comments (...Annex 1):

Concerning the Infrastructure section: the private sector section correspond to the responses for the Medical Research Council (UK) the Gambia; Concerning HT nactional policy we provide the following doc.: Medical Equipment and Devices Policy 2010 March.doc. Concerning Section Infrastructure: We have 3 CHU and 1 Hôpital national.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Georgia

Country indicators - WHO country information

Population 000s (rank):[a]	3,989 (129)	Under-five mortality (per 1000 live births):[d]	9.26	UHC - Service coverage index (1-100):[h]	65
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	29.2% (9.0%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.81 (0.72): very high	Global innovation index (rank):[j]	31.8 (63)
		ICT Development Index (rank):[g]	5.8 (74)	High-technology exports (% of manufacture exports):[k]	2.60%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): Governmental decree #153, 2007.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): State Regulation Agency for Medical Activities is in charge of HTA but not for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: State Regulation Agency for Medical Activities, Ministry of Labour, Health and Social Affairs.

Website(s): http://rama.moh.gov.ge

Contact: Mr. Ivane Pockhverashvili Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Georgian National Agency For Standards, Technical Regulations and Metrology.

Other agency's website: —

National regulatory comments (...Annex 1): Georgian National Agency For Standards, Technical Regulations and Metrology is responsible for standartization and metrology as well as calibration and accreditation of facilities, providing inspection of medical devices.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: https://matsne.gov.ge/ru

Nomenclature comments (...Annex 1):
According to Georgian legislation, Georgia recognizes international or national (according on a list of certain countries) certficates of medical devices there.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: http://www.moh.gov.ge

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	0	0
Computerized Tomography Scanner:α	38	8.75
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	3	0.69
Mammograph:α,*	23	40.74
Radiotherapy:β	21	5.26

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: https://www.moh.gov.ge/
Use of management software: No Software name: —

Software comments (...Annex 1):
Nuclear and Radiation Safety Service, Ministry of Environment and Natural Resources.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 250

Contacts

National officer(s):
Name: Ms. Eka Paatashvili
Email: epaatashvili@moh.gov.ge

Name: Mr. Nikoloz Pruidze
Email: kokap@moh.gov.ge

WHO Country officer(s):
Name: Dr. Silviu Domente
Email: domentes@who.int

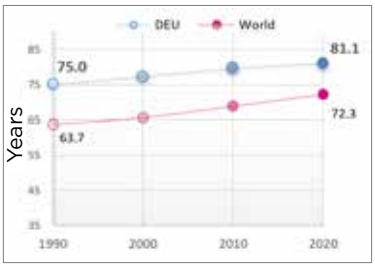
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Germany

Country indicators - WHO country information

Population 000s (rank):[a]	83,784 (19)	Under-five mortality (per 1000 live births):[d]	3.65	UHC - Service coverage index (1-100):[h]	86
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	12.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.7% (0.1%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.95 (0.87): very high	Global innovation index (rank):[j]	56.5 (9)
		ICT Development Index (rank):[g]	8.4 (12)	High-technology exports (% of manufacture exports):[k]	16.50%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: —

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) and DAHTA (previous DIMDI).

Website(s): https://www.bfarm.de/DE/Home/home_node.html
https://www.dimdi.de/dynamic/de/startseite
https://www.iqwig.de/en/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: Yes

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

National regulatory comments (...Annex 1): There are more than 30 regional Competent Authorities.

Name of regulatory agency: Federal Ministry of Health (BMG) - Unit Medical Devices.

Website(s): http://www.bmg.bund.de

Contact: Dr. Matthias Neumann Email: matthias.neumann@bmg.bund.de

Name(s) of other regulatory agency eg. for radiation equipment etc.: Federal Institute for Drugs and Medical Devices (BfArM); Central Authorithy of the Laender for Health Protection with Regard to Medicinal Products and Medical devices (ZLG).

Other agency's website: https://www.bfarm.de/EN/Home/home_node.html
https://www.bmu.de/en/; https://www.bfs.de/EN/bfs/laws-regulations/laws-regulations_node.html

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: http://www.dimdi.de

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: — Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: —

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	2869	34.24
Computerized Tomography Scanner:[α]	2904	34.66
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	895	10.68

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 2050

Contacts

National officer(s):

Name: —

Email: —

Name: —

Email: —

WHO Country officer(s):

Name: —

Email: —

Name: —

Email: —

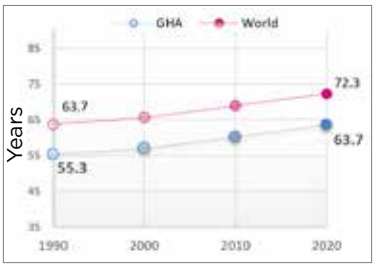
General comments (...Annex 1):

Germany does not complete the whole survey because of their federal system, which will imply to make the whole survey in their 16 states. Regarding the Regulations section: they follow the EU system, other matters are state´s competency.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Ghana

Country indicators - WHO country information

Population 000s (rank):[a]	31,073 (47)	Under-five mortality (per 1000 live births):[d]	44.71	UHC - Service coverage index (1-100):[h]	45
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.1% (0.1%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.61 (0.44): medium	Global innovation index (rank):[j]	22.3 (108)
		ICT Development Index (rank):[g]	4.1 (116)	High-technology exports (% of manufacture exports):[k]	1.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): English

Ministry of health responsible for health technology policy implementation: Clinical Engineering Department and the Biomedical Engineering Unit.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Clinical Engineering Department.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

The standard list serves as a guide. The actual procurement is based on the need of health facility, availability of utilities, and availability of professional user staff.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

There are identified HTA activities but there is not a national unit per se. HTA structures (Steering Committee, Technical Working Group and Secretariat) in the MOH have been set up and a national HTA strategy developed and yet to be launched. In progress towards the Universal Health Care country goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Food and Drug Board.

Website(s): https://www.fdaghana.gov.gh/

Contact: Ernest Afesey Email: eafesey@yahoo.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation Protection Institute.

Other agency's website: https://rpi.gaecgh.org/; https://gnra.org.gh/

National regulatory comments (...Annex 1):

The Radiation Protection Institute is responsible for the regulation of equipment with radiation sources such as X-Ray machines.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified

Website: https://fdaghana.gov.gh/images/stories/pdfs/downloads/GUIDELINES%20FOR%20THE%20REGISTRATION%20OF%20MEDICAL%20DEVICES-REVIEWED.pdf

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://pcghana.org/

National level procurement: Yes

Website: https://www.moh.gov.gh/procurement-supply/

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):

The Ghana National Procurement law as well as the Ministry of Health (MoH). Depending on the value of the procurement package, the health facilities are allowed to procure sometimes, the unit of the MoH also procures some of the capital equipment especially from other projects. All procurement of medical devices is carried out with the technical support of the Clinical Engineering Department of the Ghana Health Service or the Biomedical Engineering Unit of the MoH.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	7	0.23
Computerized Tomography Scanner:α	11	0.35
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	2	0.08
Mammograph:α,*	n/a	n/a
Radiotherapy:β	8	0.26

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: —

Unit/Department: Biomedical Engineering Department. Unit website: https://www.moh.gov.gh/

Contact name: Dr. Nichodemus Kafui Gebe Contact email: —

Website with publically available technical specifications: https://www.fdaghana.gov.gh/img/organisation/GUIDELINE%20FOR%20LICENSING%20OF%20PREMISES%20FOR%20MANUFACTURING%20MEDICAL%20DEVICES.pdf

Number of regional/state offices/units: 10

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):

Most inventories are held at a regional and an institutional level. We are yet to acquire the software for the management of the inventory at the national level.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 450

Contacts

National officer(s):

Name: Dr. Nicholas Adjabu

Email: adjabu95@yahoo.com

Name: Dr. Nichodemus Kafui Gebe

Email: —

WHO Country officer(s):

Name: Dr. Francis Chisaka Kasolo

Email: kasolof@who.int

Name: Ms. Edith Andrews Annan

Email: andrewsE@who.int

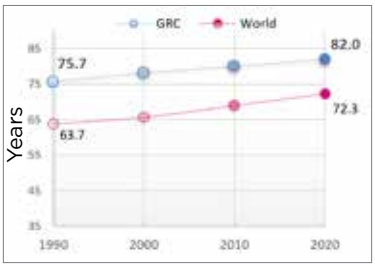
General comments (...Annex 1):

There is no written nor published national health technology policy yet but there are policies available that have been established by the systems and structures unit for health technology in Ghana. Ghana Health Service has drafted its operational policy for healthcare equipment and needs to be finalized.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Greece

Country indicators - WHO country information

Population 000s (rank):[a]	10,423 (86)	Under-five mortality (per 1000 live births):[d]	4.07	UHC - Service coverage index (1-100):[h]	78
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	12.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	16.9% (1.6%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.89 (0.79): very high	Global innovation index (rank):[j]	36.8 (43)
		ICT Development Index (rank):[g]	7.2 (38)	High-technology exports (% of manufacture exports):[k]	12.50%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: National Evaluation Center of Quality and Technology in Health (EKAPTY).

Website(s): https://www.ekapty.gr/
http://www.phs.uoa.gr/
http://www.eopyy.gov.gr
https://www.ifet.gr/en/

Contact: — Email: info@ekapty.gr

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1): Various HTA institutions are performing a variety of domains including medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: National Organization for Medicines.

Website(s): www.eof.gr

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Greek Atomic Energy Commission

Other agency's website: www.eeae.gr

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://www.gmdnagency.org/

Nomenclature comments (...Annex 1):

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —

National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: www.eof.gr

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: https://www.moh.gov.gr/

Medical device incorporation comments (...Annex 1):

The EU Directive for public procurement and national specific legislation for health procurement (law 3580/2007). A part of procurement of medical devices is carried out at a national level, by the Health Procurement Committee.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	315	30.22
Computerized Tomography Scanner:α	436	41.83
Positron Emission Tomography Scanner:α	13	1.25
Gamma camera or nuclear medicine:α	144	13.82
Mammograph:α,*	708	492.19
Radiotherapy:β	69	6.62

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Health Procurement Committee. Unit website: https://www.moh.gov.gr/articles/epitroph-promhtheiwn-ygeias

Contact name: — Contact email: —

Website with publically available technical specifications: https://www.moh.gov.gr/articles/epitroph-promhtheiwn-ygeias/diaboyleyseis-texnikwn-prodiagrafwn

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: —

Use of management software: Yes Software name: Various such as Praxis.

Software comments (...Annex 1):

"Praxis", was developed by the Institute of Biomedical Technology (INBIT), and it is a specific one. Also, it is used the Asset Management Software.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 300

Contacts

National officer(s):

Name: Mr. Tarsi Giannouli

Email: tgiannouli@ekapty.gr

Name: —

Email: —

WHO Country officer(s):

Name: Dr. Jaana Marianna Trias

Email: TriasJ@who.int

Name: —

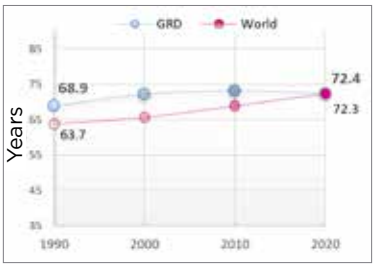
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Grenada

Country indicators - WHO country information

Population 000s (rank):[a]	113 (179)	Under-five mortality (per 1000 live births):[d]	16.35	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	23.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (—): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	5.8 (73)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): English

Ministry of health responsible for health technology policy implementation: Administration and Biomedical Engineering Department.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

The list can be requested from the management of the Hospital services. However there is no web to guideline because was never used as a policy of the MoH.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

No lists available.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For procurement purposes
Website: —

Nomenclature comments (...Annex 1):
A system was develop but it was not supported by management. There is no URL because this software was locally developed.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
There are procurement guideliness but they are not implemented or followed. The procurement of medical devices are carried out at a national level by the Central Medical Stores Unit (CMS). No specific devices have been selected but the needed assessment was done.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	9.44
Computerized Tomography Scanner:α	2	18.89
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	1	134.61
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 1

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Medical device Management System Software.

Software comments (...Annex 1):
The inventory for all medical equipment in the island can be found in the Biomedical Engineering Department, General Hospital. The system was locally developed, installed and called The Medical Device Management System Software.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Mr. Stephen Prince
Email: princealista@hotmail.com

Name: —
Email: —

WHO Country officer(s):
Name: Dra. Amalia Del Riego
Email: delriegoa@paho.org

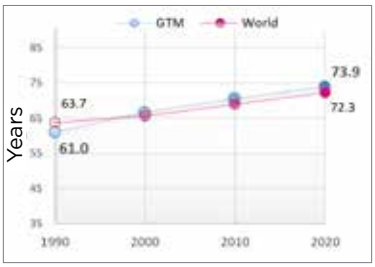
Name: Cecilia Acuña
Email: acunamar@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Guatemala

Country indicators - WHO country information

Population 000s (rank):[a]	17,916 (65)	Under-five mortality (per 1000 live births):[d]	23.65	UHC - Service coverage index (1-100):[h]	57
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.4% (0.0%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.66 (0.48): medium	Global innovation index (rank):[j]	22.4 (106)
		ICT Development Index (rank):[g]	3.4 (125)	High-technology exports (% of manufacture exports):[k]	4.90%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: https://medicamentos.mspas.gob.gt/phocadownload/Listado_de_Formas/F-AS-o-02%20V%2005-2020%20Listado%20codificado%20grupo%20terapeutico.pdf

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.mspas.gob.gt/

Specific lists comments (...Annex 1): Ver: Norma Técnica Vigente para inscripción sanitaria de dispositivos médicos. Específicamente la Normativa 37.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: Instituto Guatemalteco de Seguro Social is part of RedETSA

Website(s): https://sicoin.minfin.gob.gt https://siges.minfin.gob.gt

Contact: Florencia Garcia Email: flor.garcia@igssgt.org

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): HTA activities have been identified, but there is not a specific national unit. Currently, the HTA unit is in progress towards the Universal Health Care (UHC) country goal. There are the following units: Planificación Estratégica (SIGSA), Observatorio en Salud Reproductiva (OPSOMS/OSAR) y Sistema Informático

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Departamento de Regulación y Control de Productos Farmacéuticos y Afines.

Website(s): https://medicamentos.mspas.gob.gt/

Contact: Ms. Elizabeth Recinos de Posadas Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministerio de Energía y Minas.

Other agency's website: https://mem.gob.gt/?s=equipo+m%C3%A9dico&submit=Go

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: https://www.mspas.gob.gt/
https://medicamentos.mspas.gob.gt/

Nomenclature comments (...Annex 1):
La Clasificación In Vivo y según Clase se encuentra contemplada en el Anexo de la Norma Técnica No. 37.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: https://www.guatecompras.gob.gt/

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The procurement is done, at general level, by the Sistema de Adquisiciones del Estado de Guatemala.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	14	0.78

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
No se utiliza ninguno.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Ms. Elizabeth Recinos de Posadas
Email: drcpfa.jefatura@gmail.com

Name: Ms. Silvana Figueroa
Email: silufima@hotmail.com

WHO Country officer(s):
Name: Dr. Gerardo Alfaro
Email: alfaroge@paho.org

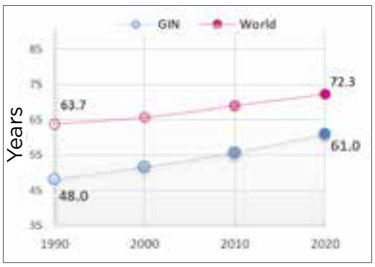
Name: Dra. Caroline Chang
Email: changcar@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Guinea

Country indicators - WHO country information

Population 000s (rank):[a]	13,133 (74)	Under-five mortality (per 1000 live births):[d]	95.56	UHC - Service coverage index (1-100):[h]	37
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	7.0% (1.3%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.48 (0.31): low	Global innovation index (rank):[j]	17.3 (130)
		ICT Development Index (rank):[g]	1.8 (166)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1): Les Normes ont été définies pour les formations sanitaires de base (postes, centres de santé), les Centres de santé améliorés, les Hôpitaux préfectoraux / districts sanitaires et les Hôpitaux Régionaux. Ces normes ne sont pas disponibles pour toutes les unités

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Division Equipement et Maintenance de la DNEHS.

Website(s): https://sante.gov.gn/

Contact: Mr. Amadou Timbi Bah Email: amadoutimbibah@yahoo.fr

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
For procurement or donnations: nous procédons par appel d'offres national ou international.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	0	0
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	0	0
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Section Equipement (SE). Unit website: —
Contact name: Mr. Mamadouba Camara Engagé Contact email: mamadoubaengage@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: 4

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1):
L'inventaire disponible n'est pas exhaustif en ce qui concerne tous les dispositifs medicaux actuellement utilisés

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Mr. Amadou Timbi Bah
Email: amadoutimbibah@yahoo.fr

Name: Mr. Mamadouba Camara Engagé
Email: mamadoubaengage@yahoo.fr

WHO Country officer(s):
Name: Dr. Georges Alfred Ki-Zerbo
Email: kizerbog@who.int

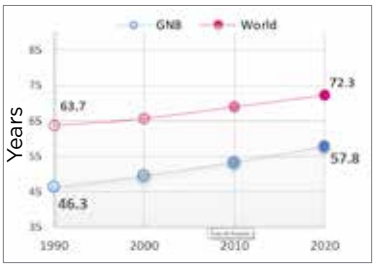
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Guinea-Bissau

Country indicators - WHO country information

Population 000s (rank):[a]	1,968 (146)	Under-five mortality (per 1000 live births):[d]	76.84	UHC - Service coverage index (1-100):[h]	37
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.48 (0.3): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	1.5 (173)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

National regulatory comments (...Annex 1): —

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	0	0
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	0	0
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 1

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): Inventário Nacional de Equipamentos Médicos: Trabalho curso e dados parciais para o sul do País.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):

Name: Mr. Fodé Carambá Sanhá
Email: focasa60@gmail.com

Name: Mr. Hamilton Ferreira
Email: hamiltonpnds@yahoo.es

WHO Country officer(s):

Name: Dr. Georges Alfred Ki-Zerbo
Email: kizerbog@who.int

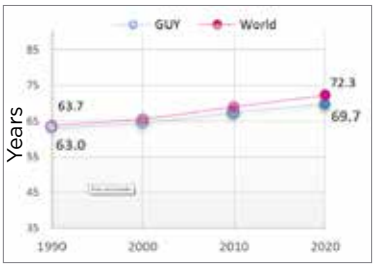
Name: Mr. Inácio Alvarenga
Email: alvarengai@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Guyana

Country indicators - WHO country information

Population 000s (rank):[a]	787 (159)	Under-five mortality (per 1000 live births):[d]	28.4	UHC - Service coverage index (1-100):[h]	74
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	29.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.68 (0.56): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	3.4 (124)	High-technology exports (% of manufacture exports):[k]	0.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

National regulatory comments (...Annex 1): —

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: https://gafdd.gy/inspectorate/#

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1	1.25
Computerized Tomography Scanner:[α]	3	3.75
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	3	69.98
Radiotherapy:[β]	2	2.54

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Regional Radiology. Unit website: —
Contact name: Ms. Donna Bowman Contact email: dasbowman@yahoo.co.uk
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): There are inventories for X-ray equipment. One public corporation uses an assets software to carry out the same function.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):

Name: Ms. Donna Bowman
Email: dasbowman@yahoo.co.uk

Name: Ms. Donna Bowman
Email: dasbowman@yahoo.co.uk

WHO Country officer(s):

Name: Dr. Luis Felipe Codina
Email: codinalu2@paho.org

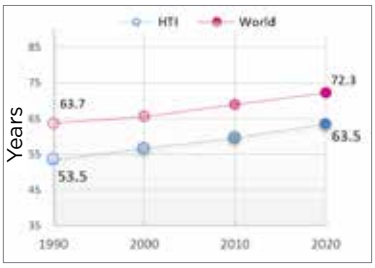
Name: Dr. Daniel Albretch
Email: albrechdan@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Haïti

Country indicators - WHO country information

Population 000s (rank):[a]	11,403 (81)	Under-five mortality (per 1000 live births):[d]	60.48	UHC - Service coverage index (1-100):[h]	47
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	31.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	11.5% (4.0%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.51 (0.3): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	1.7 (168)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
—

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	3	0.29
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	11	19.47
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: Yes Software name: GMAO.

Software comments (...Annex 1):
Il n'existe pas encore une liste d'inventaire technique national pour les equipements medicaux.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 50

Contacts

National officer(s):
Name: Mr. Roland Palme
Email: palmeroland@hotmail.com

Name: Dr. Duperval Mona
Email: Mspp_doss@yahoo.fr

WHO Country officer(s):
Name: Dr. Maureen Birmingham
Email: birminghamm@paho.org

Name: Dr. Pedro Lopez
Email: lopezped@paho.org

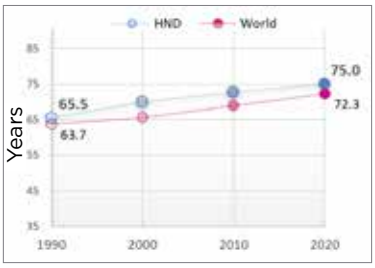
General comments (...Annex 1):

Concerning the Infrastructure section: les centres de santé sont dotés de 10 lits.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Honduras

Country indicators - WHO country information

Population 000s (rank):[a]	9,905 (91)	Under-five mortality (per 1000 live births):[d]	16.22	UHC - Service coverage index (1-100):[h]	63
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	18.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.63 (0.47): medium	Global innovation index (rank):[j]	23 (103)
		ICT Development Index (rank):[g]	3.3 (129)	High-technology exports (% of manufacture exports):[k]	2.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.salud.gob.hn/

Language(s): Español

Ministry of health responsible for health technology policy implementation: Agencia Regulatoria Sanitaria de Honduras.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit comments (...Annex 1): HTA activities have been identified, but there is not a specific national unit.

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

National regulatory comments (...Annex 1): —

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Agencia Regulatoria Sanitaria de Honduras (ARSA).

Website(s): https://www.arsa.gob.hn/index.php?page=dm&num=2

Contact: Dr. Francis Contreras Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Secretaría de Recursos Naturales y Ambiente (MiAmbiente+)

Other agency's website: http://www.miambiente.gob.hn/
https://www.ccichonduras.org/website/Descargas/LEYES/LEGISLACION_AMBIENTAL/REGLAMENTO_DE_PROTECCION_RADIOLOGICA.pdf

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For various purposes
Website: http://www.salud.gob.hn/site/

Nomenclature comments (...Annex 1):
El Reglamento para el Control Sanitario de Productos, Servicios y Establecimientos de Interés Sanitario, establece una nomenclatura con fines de Registro.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.honducompras.gob.hn
National level procurement: Yes Website: https://www.honducompras.gob.hn/

Donations

Policy or guideline: Yes Website: https://www.arsa.gob.hn/

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Ley de Contratación del Estado y Reglamento de Ley de Contratación del Estado (more information under https://www.arsa.gob.hn/). Cada uno de los Programas de Salud dependientes de la Dirección antes mencionada o entes cooperantes realizan compras de dispositivos médicos para proveer a nivel nacional, como pueden ser pruebas de laboratorio y anticonceptivos. El Programa de Equipamiento se elabora por demanda y por complejidad.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	9	0.91
Computerized Tomography Scanner:α	17	1.72
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	1	0.1
Mammograph:α,*	20	34.41
Radiotherapy:β	9	0.91

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Programa de Equipamiento. Dirección General de Sistemas y Servicios de Salud. Unit website: —
Contact name: Ms. Rosa María Rivas Contact email: roma_ribu@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 20

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: SIAFI.

Software comments (...Annex 1):
El inventario es por Objeto de Gasto. Existe el SIAFI que es un sistema informático para fines de presupuesto, el cual actualmente se encuentra en proceso de ampliación ya que permitirá la gestión del equipamiento en todas sus fases.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Dr. Francis Contreras
Email: franciscontreras@arsa.gob.hn

Name: Ms. Ritza Lizardo
Email: —

WHO Country officer(s):
Name: MSc. Piedad Huerta Arneros
Email: huertapi@paho.org

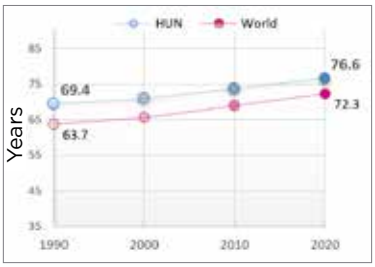
Name: Dra. Ana Gabriela Ramirez
Email: ramirezana@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Hungary

Country indicators - WHO country information

Population 000s (rank):[a]	9,660 (93)	Under-five mortality (per 1000 live births):[d]	4.05	UHC - Service coverage index (1-100):[h]	73
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	7.4% (0.3%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.85 (0.79): very high	Global innovation index (rank):[j]	41.5 (35)
		ICT Development Index (rank):[g]	6.9 (48)	High-technology exports (% of manufacture exports):[k]	17.50%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://ogyei.gov.hu/laws_and_regulations

Language(s): Hungarian

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: National Health Insurance Fund / Central Services Directorate General of the Prime Minister's Office, respectively.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2020&num=559

Website - laboratories: https://www.tuv.com/hungary/en/in-vitro-diagnostic-medical-device-regulation-(ivdr).html

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2020&num=559

Specific lists comments (...Annex 1): The uploaded Ministerial Decree lays down the minimum requirements for the provision of healthcare services. The criteria are equally specified for healthcare facilities (1.2.1) and specific procedures. The document has been uploaded only once. The decree is only available in Hungarian. The assigned URLs contain protocols for pandemic situation according to the National Influenza Pandemic Preparedness

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: National Institute for Strategic Health Research - Office of Health Technology Assessment.

Website(s): https://ogyei.gov.hu/health_technology_assessment/ https://ogyei.gov.hu/what_we_do_ http://semmelweis.hu/emk/en/

Contact: Dr. Marta Pekli Email: pekli.marta@eski.hu

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There are HTA activities for health products, rarely for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Office of Health Authorisation and Administrative Procedures - Authority for Medical Devices.

Website(s): —

Contact: Mr. György Ferenc Balazs Email: balazs.gyorgy@eekh.hu

Name(s) of other regulatory agency eg. for radiation equipment etc.: Department for Medical Devices, National Institute of Pharmacy.

Other agency's website: http://ogyei.gov.hu/presidency2011/about_department_for_medical_deviceseekh

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: —

Nomenclature comments (...Annex 1):

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99300009.NM

National level procurement: Yes Website: http://www.oep.hu

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):

For procurement guidelines see the "Decree of the Minister of Welfare" (No. 9/1993 NM) on the specific aspects of the financing of healthcare insurance services. In respect of certain medical devices procured at a national level over a certain amount, procurement is carried out by the Central Services Directorate General of the Prime Minister's Office. In the remaining cases, hospitals procure medical devices subject to itemized accounting individually and the National Health Insurance fund reimburses a certain level of the costs (see the list in the corresponding website, but with exception of pacemakers, heart valves, cochlear implants).

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	48	4.97
Computerized Tomography Scanner:[α]	92	9.52
Positron Emission Tomography Scanner:[α]	9	0.93
Gamma camera or nuclear medicine:[α]	114	11.8
Mammograph:[α,*]	150	111.13
Radiotherapy:[β]	59	6.11

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: https://ogyei.gov.hu/main_page/

Use of management software: Yes Software name: CT-EcoSTAT.

Software comments (...Annex 1):

Under high-cost (amounts exceeding EUR 400). Unfortunately, the real state is not a public registry. The access is ensured only for data providers, manufacturers and conformity assessment bodies. Most of the public institutions use the software CT-EcoSTAT.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 400

Contacts

National officer(s):

Name: —

Email: —

Name: —

Email: —

WHO Country officer(s):

Name: Dr. Ledia Lazeri

Email: lazeril@who.int

Name: —

Email: pusztaiz@who.int

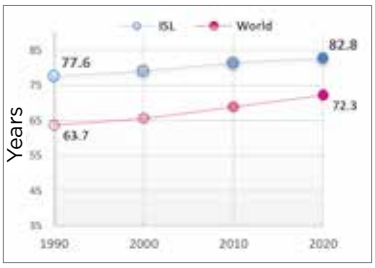
General comments (...Annex 1):

Concerning the HT policies: "Safety and Partnership Program" -the health program adopted by the Hungarian government on July 9th, 2008 - the acceptance of medical devices and health technologies into the social insurance scheme was defined in the context of improvement of insurance tasks until 2010. Concerning the HT units section: it has been listed units that are subordinated bodies but not within the Ministry of

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Iceland

Country indicators - WHO country information

Population 000s (rank):[a]	341 (171)	Under-five mortality (per 1000 live births):[d]	1.93	UHC - Service coverage index (1-100):[h]	87
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	8.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.95 (0.89): very high	Global innovation index (rank):[j]	49.2 (21)
		ICT Development Index (rank):[g]	9 (1)	High-technology exports (% of manufacture exports):[k]	38.10%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
Only CE marked medical devices are approved.

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Directorate of Health.
Website(s): http://www.landlaeknir.is/
Contact: Ms. Anna Björg Aradóttir Email: annabara@landlaeknir.is
Name(s) of other regulatory agency eg. for radiation equipment etc.: The Directorate of Health is the Competent Authority for Medical Devices.
Other agency's website: https://www.ima.is/medical_devices

National regulatory comments (...Annex 1):
According to Directives 93/42, 90/385 and 98/79.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: https://www.ima.is/medical_devices/about_medical_devices/

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	7	20.53
Computerized Tomography Scanner:[α]	17	49.85
Positron Emission Tomography Scanner:[α]	1	2.93
Gamma camera or nuclear medicine:[α]	3	8.8
Mammograph:[α,*]	6	149.7
Radiotherapy:[β]	3	8.8

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: Yes Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 56

Contacts

National officer(s):
Name: Mrs. Áslaug Einarsdóttir
Email: aslaug.einarsdottir@hbr.stjr.is

Name: —
Email: —

WHO Country officer(s):
Name: —
Email: —

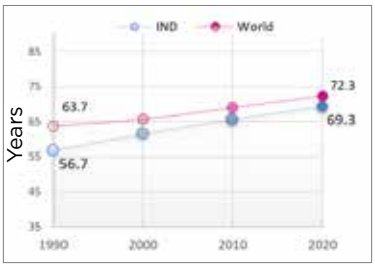
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

India

Country indicators - WHO country information

Population 000s (rank):[a]	1,380,004 (2)	Under-five mortality (per 1000 live births):[d]	32.63	UHC - Service coverage index (1-100):[h]	61
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	17.3% (3.9%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.65 (0.48): medium	Global innovation index (rank):[j]	35.6 (48)
		ICT Development Index (rank):[g]	3 (134)	High-technology exports (% of manufacture exports):[k]	10.30%

National policy on health technology

Health technology (medical device) national policy: —

Policy is part of the National Health Program/Plan: —

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: —

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Department of Health Research (MoH).

Website(s): https://htain.icmr.org.in/ https://nhsrcindia.org/hc-technology

Contact: — Email: htain-dhr@nic.in

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): HTAIN performs the evaluation and appropriateness and the cost-effectiveness of the available and new health technologies. It includes interventions, drugs, and medical equipment. It has 12 research regional hubs and several technical partners around the country.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Central Drugs Standard Control Organization.

Website(s): https://cdsco.gov.in/opencms/opencms/en/Home/

Contact: Dr. V. G. Somani Email: dci@nb.nic.in

Name(s) of other regulatory agency eg. for radiation equipment etc.: Atomic Energy Regulatory Board (AERB)

Other agency's website: https://www.aerb.gov.in/english/

National regulatory comments (...Annex 1): Notified medical devices are regulated under the Drugs and Cosmetics Act and Rules under the 14 rule of medical devices as notified under the corresponding Act.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified

Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —

National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	979	0.71

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 30000

Contacts

National officer(s):

Name: —

Email: —

Name: —

Email: —

WHO Country officer(s):

Name: Dr. Roderico Ofrin

Email: ofrinr@who.int

Name: —

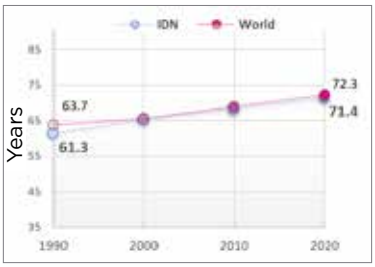
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Indonesia

Country indicators - WHO country information

Population 000s (rank):[a]	273,524 (4)	Under-five mortality (per 1000 live births):[d]	23	UHC - Service coverage index (1-100):[h]	59
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.7% (0.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.72 (0.59): high	Global innovation index (rank):[j]	26.5 (85)
		ICT Development Index (rank):[g]	4.3 (111)	High-technology exports (% of manufacture exports):[k]	7.60%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): Indonesian

Ministry of health responsible for health technology policy implementation: a) Directorate of Production and Distribution of Medical Devices (DG of Pharma. and Med.Dev., MoH); b) Directorate of Basic Medical Services (DG of Medical Services, MoH).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1): We do not have lists for different diseases/situations, but we use WHO recommendations.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Directorate of Basic Medical Services (DG of Medical Services, MoH).

Website(s): https://www.bpjsketenagakerjaan.go.id

Contact: Dr. Anwarul Amin Email: hta_indonesia@yahoo.com

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): It has been started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities. Social Security Management Agency for the Health Sector (BPJS) is focus on HTA for health products. Komite Penilaian Teknologi Kesehatan (Komite PTK) performs economic HTA (not for medical equipment). HTA for medical equipment is rarely performed.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of health.

Website(s): https://www.kemkes.go.id/index.php?lg=LN02

Contact: Ir Rosadi Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: National Nuclear Energy Agency of Indonesia.

Other agency's website: http://www.batan.go.id/index.php/en/

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes
Type: More than one system Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
It is used a Harmonization System code (HS) at the moment. After harmonization GMDN will be used.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: https://www.kemkes.go.id/index.php?lg=LN02

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
We follow the Presidential Decree No. 80 for general procurement. Both, yes and no. Yes, for vertical public hospitals, procurement conducted at national level. No, since re-centralization, procurement of medical devices at province/district's hospital conducted at local level (province and district level); see yanmed on the website.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	81	0.3

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1):
Inventories are still ongoing.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 55

Contacts

National officer(s):
Name: Dr. T. Bahdar Johan Hamid
Email: bahdar2007@yahoo.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Navaratnasamy Paranietharan
Email: paranietharann@who.int

Name: —
Email: —

General comments (...Annex 1): —

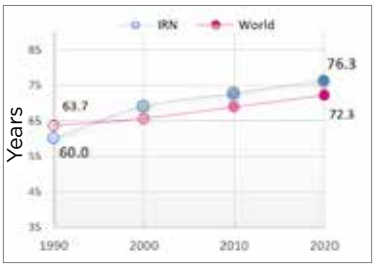
a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Iran (Islamic Republic of)

Country indicators - WHO country information

Population 000s (rank):[a]	83,993 (18)
World Bank income group:[b]	Lower-Middle

Life expectancy at birth (years):[c]



Under-five mortality (per 1000 live births):[d]	12.94	UHC - Service coverage index (1-100):[h]	77
Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	14.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	15.8% (3.8%)
Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (0.69): high	Global innovation index (rank):[j]	30.9 (67)
ICT Development Index (rank):[g]	5.6 (81)	High-technology exports (% of manufacture exports):[k]	0.80%

National policy on health technology

Health technology (medical device) national policy: —

Policy is part of the National Health Program/Plan: —

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: —

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: —

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: HTA Office under supervision of Health Technology Assessment, Standardization and Tariffs Office (MOHME's HTA Office).

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1): The HTA office under the umbrella of the Ministry of Health and Education (MOHME) was established in 2008, it produces HTA over health products and medical equipment.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Food and Drug Administration of Iran.

Website(s): http://www.fda.gov.ir/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Atomic Energy Organization of Iran (AEOI).

Other agency's website: www.aeoi.org.ir

http://dotic.ir/

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	137	1.63

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Syed Jaffar Hussain
Email: hussains@who.int

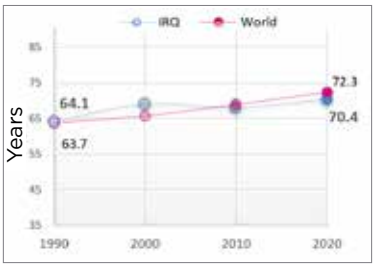
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Iraq

Country indicators - WHO country information

Population 000s (rank):[a]	40,223 (36)	Under-five mortality (per 1000 live births):[d]	25.24	UHC - Service coverage index (1-100):[h]	55
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	23.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.3% (0.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.67 (0.54): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Department of Medical Equipment within the Directorate of Technical Affairs (MoH).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Technical Affairs (Department of Medical Equipment Management and Needs Assessment).

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

The lists of medical equipments have been announced on annual basis.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_116238.asp

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: Dr. Iman M. Hussein Email: consultivedep@yahoo.com

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

It has been adopted the EMA (European Medicines Agency) and the ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH, HTA is focused on pharmaceutics not in medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: The State Company for Provision of Medicines and Medical Appliances (KIMADIA).

Website(s): https://kimadia.iq/en

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: This Company (KIMADIA).

Other agency's website: https://rpc.gov.iq/

National regulatory comments (...Annex 1):

The company KIMADIA is responsible for the bulk purchase of medicines, drugs, medical supplies and equipment for whole Iraq on behalf of the MoH. The regulations are pertaining to the procurement aspects.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified

Website: https://kimadia.iq/en

Nomenclature comments (...Annex 1):
The MoH is working on adapting a national nomenclature system and linking it to the UMDNS.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —

National level procurement: Yes Website: https://kimadia.iq/en

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: No

Website: —

Medical device incorporation comments (...Annex 1):
The company provides storage, distribution and marketing of medicines and supplies for all Iraq where it is the sole importer of the public sector as well as developing the basic rules for setting the prices for each class of drugs, chemicals and medical supplies to ensure the right price to the citizens and pharmacies and the relevant authorities. Works as well as the allocation of quantities of medicine (drugs and emergency life-saving drugs) as well as the necessary supplies to be used in exceptional emergency circumstances. In addition, to cover part of the needs of the health institutions of medicine and supplies is through national production.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	55	1.63
Computerized Tomography Scanner:α	75	2.22
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	5	0.15
Mammograph:α,*	49	35.43
Radiotherapy:β	19	0.47

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: State Company for Provision of Medicines and Medical Appliances (KIMADIA). Unit website: —

Contact name: Eng. Kadhim D. Sharz Contact email: kimadia_engineering@yahoo.com

Website with publically available technical specifications: —

Number of regional/state offices/units: 19

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: Yes Software name: MS Excel.

Software comments (...Annex 1):
The Ministry of Health at a central level keeps updated records on monthly basis for the functional status of the high-cost technologies. 2- World Health Organization is supporting the procurement of 3 CMMS (from GE - Asset Plus) for three Central Maintenance Repair shops in Baghdad, Erbil and AL-Muthanna Provinces. 3- The Inventories for 6 provinces out of 18 are completed and 6 provinces will be supported to carry out a functional inventory for their medical equipment during the current biennium 2010/11.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):

Name: —

Email: —

Name: Eng. Kadhim D. Sharz

Email: kimadia_engineering@yahoo.com

WHO Country officer(s):

Name: Dr. Ahmed Zouiten

Email: zouitena@who.int

Name: Dr. Ezechiel Bisalinkumi

Email: bisalinkumie@irq.emro.who.int

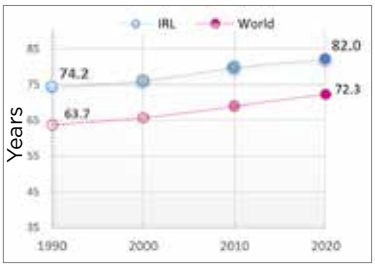
General comments (...Annex 1):

Data were obtained from the annual report from 2010, issued by the Department of Planning and Human Resource Development at the MoH Iraq.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Ireland

Country indicators - WHO country information

Population 000s (rank):[a]	4,938 (121)	Under-five mortality (per 1000 live births):[d]	3.02	UHC - Service coverage index (1-100):[h]	83
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	9.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	6.4% (0.7%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.96 (0.89): very high	Global innovation index (rank):[j]	53 (15)
		ICT Development Index (rank):[g]	8 (20)	High-technology exports (% of manufacture exports):[k]	26.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: https://www.hse.ie/eng/services/publications/corporate/medicaldevicesequipment.pdf

Language(s): —

Ministry of health responsible for health technology policy implementation: This is a policy of the Health Service Executive (HSE).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: n/a.

Unit: —

Website: www.pcrs.ie

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: n/a

Website - hospitals: n/a

Website - laboratories: n/a

Nomenclature systems used for devices and tests: EMDN.

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Approved devices lists comments (...Annex 1):

There are also several National Framework Agreement contracts for the supply of medical devices and equipment. List of reimbursable devices from Primary Care Reimbursement Service (PCRS). List of reimbursable devices from PCRS is available at pcrs website under -> online services -> list of reimbursable items.

Health care facilities lists comments (...Annex 1):

—

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: The National Patient Safety Office, Department of Health.

Website(s): https://www.hiqa.ie/areas-we-work/health-technology-assessment
http://www.ncpe.ie

Contact: Dr. Laura Dooley Email: laura_dooley@health.gov.ie

Committee includes a biomedical or clinical engineer: No

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Health Products Regulatory Authority (HPRA).

Website(s): https://www.hpra.ie/
http://www.imb.ie

Contact: — Email: devices@hpra.ie

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ireland's Health Services (HSE.ie) (Radiation Protection); Enviromental Protection Agency (Radiation).

Other agency's website: https://www.hse.ie/eng/about/who/acute-hospitals-division/radiation-protection/
http://www.epa.ie/radiation/regulation/rpa/

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: http://www.hpra.ie/homepage/medical-devices/medical-devices-information

Nomenclature comments (...Annex 1):

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.hse.ie/eng/about/who/healthbusinessservices/procurement/ http://www.hse.ie/eng/

National level procurement: Yes Website: Health Service Executive (HSE) https://www.hse.ie/eng/about/who/healthbusinessservices/procurement/ https://www.hse.ie/eng/

Donations

Policy or guideline: Yes Website: http://www.hse.ie

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: No

Website: —

Medical device incorporation comments (...Annex 1):

Portfolio & Category Management approach involves the development of medical devices/equipment procurement strategies at a national level and the facilitation of regional and local decision making consistent with these strategies and accompanying procedures. Go to the website and search for: services/Publications/corporate/procurementpolicy.pdf. Health Service Executive (HSE).

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	78	15.8
Computerized Tomography Scanner:[α]	105	21.26
Positron Emission Tomography Scanner:[α]	9	1.82
Gamma camera or nuclear medicine:[α]	23	4.66
Mammograph:[α,*]	82	149.96
Radiotherapy:[β]	55	11.14

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Health Service Executive (HSE): Corporate Estates. Unit website: —

Contact name: Mr. Ger Flynn Contact email: ger.flynn@hse.ie

Website with publically available technical specifications: n/a

Number of regional/state offices/units: 7

Inventories and medical equipment management software

Type of inventories available: —

Website: —

Use of management software: Yes Software name: No common software but a variery of systems including: HEX, SAP, MS Access,...

Software comments (...Annex 1):

There are no national inventories available to date. Inventories of medical equipment (including functional inventories) are maintained at a local level. Often there are separate asset management and medical equipment management inventories. There is an initiative to compile this data into regional/national inventories in the near future. There is no common software but a variety of systems are employed including HEX, SAP, MS Access.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 330

Contacts

National officer(s):

Name: Dr. Karen McNamara

Email: Legislation_Units@health.gov.ie

Name: Mr. Ger Flynn - National Clinical Head of Medical Devices, HSE

Email: —

WHO Country officer(s):

Name: —

Email: —

Name: —

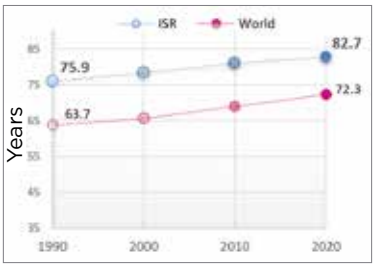
Email: —

General comments (...Annex 1): Concerning the Infrastructure section: the breakdown of infrastructures does not match to our public sector. We have 7 Hospital Groups.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Israel

Country indicators - WHO country information

Population 000s (rank):[a]	8,656 (99)	Under-five mortality (per 1000 live births):[d]	3.58	UHC - Service coverage index (1-100):[h]	84
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	8.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	6.7% (1.0%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.92 (0.81): very high	Global innovation index (rank):[j]	53.5 (13)
		ICT Development Index (rank):[g]	7.9 (23)	High-technology exports (% of manufacture exports):[k]	23.10%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): Hebrew

Ministry of health responsible for health technology policy implementation: Medical Device Deparment within the Medical Techology Administration.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Medical Technology Administration.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
List for procurement/reimbursement It is part of the National Insurance Law.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):
It is in the Israeli legislation.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Medical Devices Department and Medical Technology Division.

Website(s): https://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/MTPD/Pages/default.aspx
http://www.gertnerinst.org.il/e/health_policy_e/technology

Contact: Dr. Nadav Sheffer Email: nadav.sheffer@moh.health.gov.il

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
The HTA within the MoH, as well as research centers such as the Israeli Center for Technology Assessment in Health Care (ICTAHC).

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Medical Device Department.

Website(s): https://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/MLD/Pages/default.aspx

Contact: Mr. Nadav Sheffer Email: Nadav.sheffer@moh.health.gov.il

Name(s) of other regulatory agency eg. for radiation equipment etc.: Soreq Nuclear Research Center (SNRC).

Other agency's website: http://soreq.gov.il/mmg/eng/Pages/Radiation-Safety.aspx

National regulatory comments (...Annex 1):
Contact person: Avi Kravel within the Medical Devices department.

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: Not specified

Website: https://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/MLD/Pages/default.aspx

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1): Technical specifications are available only in hardcopy.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	46	5.31
Computerized Tomography Scanner:[α]	88	10.17
Positron Emission Tomography Scanner:[α]	14	1.62
Gamma camera or nuclear medicine:[α]	83	9.59
Mammograph:[α,*]	80	112.27
Radiotherapy:[β]	44	5.08

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Medical Technology Administration. Unit website: —

Contact name: Mr. Liron Zohar Contact email: liron.zohar@moh.health.gov.il

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: —

Use of management software: Yes Software name: Locally developed.

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 2000

Contacts

National officer(s):

Name: Dr. Nadav Sheffer

Email: Nadav.sheffer@moh.health.gov.il

Name: Mr. Liron Zohar

Email: liron.zohar@moh.health.gov.il

WHO Country officer(s):

Name: —

Email: —

Name: —

Email: —

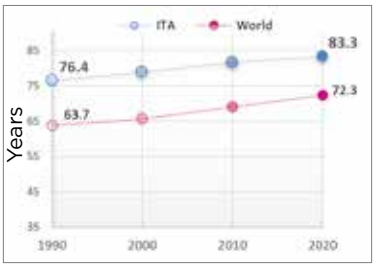
General comments (...Annex 1):

All the divisions and departments mentioned in this survey are part of the Medical Technology Administration of the Ministry of Health in Israel. The Administration is in charge of the regulation, licencing and policy making regarding all medical technologies in Israel (including medical devices).

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Italy

Country indicators - WHO country information

Population 000s (rank):[a]	60,462 (23)	Under-five mortality (per 1000 live births):[d]	2.91	UHC - Service coverage index (1-100):[h]	83
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	9.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	9.3% (1.1%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.89 (0.78): very high	Global innovation index (rank):[j]	45.7 (28)
		ICT Development Index (rank):[g]	7 (47)	High-technology exports (% of manufacture exports):[k]	8.10%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.salute.gov.it/portale/home.html

Language(s): Italian and English

Ministry of health responsible for health technology policy implementation: Directorate General of Medicines and Medical Devices, Department of Innovation, Ministry of Health.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Diretorate General of Health Programme.

Website: http://www.who.int/medical_devices/survey_resources/medical_devices_for_procurement_reimbursement_italy_3.pdf; https://www.salute.gov.it/portale/home.html

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
Documents are available at the websites. Documents are often updated, and many of them under revision.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: http://www.dati.salute.gov.it/dati/dettaglioDataset.jsp?menu=dati&idPag=1

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Directorate General for Medical Devices.

Website(s): http://www.agenas.it
https://www.aifa.gov.it/en/web/guest/home
http://www.sanita.padova.it
http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=dispositivi-medici&menu=tecnologie; https://www.policlinicogemelli.it/en/

Contact: Dr. Giuseppe Ruocco Email: g.ruocco@sanita.it

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
Agenzia Nazionale per i Servizi Sanitari Regionali (AGENAS) performs HTA for medical devices, and Italian medicines agency (AIFA) mainly in pharmaceutics and related. HTA is also performed in research institutes such as PoliclinicoGemelli (last link).

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Directorate General for Medical Devices, Pharmaceutical Services and Safety in Healthcare, Department of Planning and Organization of the National Health Service, Ministry of Health.

Website(s): http://www.salute.gov.it/portale/home.html

Contact: Ms. Marcella Marletta Email: m.marletta@sanita.it

National regulatory comments (...Annex 1):
Addresse and contact of the Medical Devices Directorate: Via Molise 2, 00187 Roma, Italy. Tel. +390647051.

Name(s) of other regulatory agency eg. for radiation equipment etc.: Italian National Agency for New Technologies, Energy and Sustainable Economic Development (IMRI); National Inspectorate for Nuclear Safety and Radiation Protection (ISIN). Other agency's website: https://www.inmri.enea.it/
https://www.isinucleare.it/en/about-us

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For various purposes

Website: http://www.salute.gov.it/imgs/C_17_pagineAree_328_listaFile_itemName_15_file.pdf
http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html

Nomenclature comments (...Annex 1):
CND Classificazione Nazionale dei Dispositivi Medici (correlated with GMDN). CND was nationally developped, and it is the base for EMDN. As mentioned on several occasions in the past, a map of correspondence between the GMDN nomenclature and the Italian CND classification has been created since 2007 to allow manufacturers to register in the Italian database of medical devices. This map is subject to

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.salute.gov.it/portale/home.html

National level procurement: No Website: http://www.salute.gov.it/

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: http://www.who.int/medical_devices/survey_resources/medical_device_technical_specifications_italy_1.pdf
http://www.who.int/medical_devices/survey_resources/medical_device_technical_specifications_italy_2.pdf

Medical device incorporation comments (...Annex 1):
Go to the website and look for: dispositivi/dispomed.jsp documents.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1736	28.71
Computerized Tomography Scanner:[α]	2122	35.1
Positron Emission Tomography Scanner:[α]	210	3.47
Gamma camera or nuclear medicine:[α]	465	7.69
Mammograph:[α,*]	2044	232.96
Radiotherapy:[β]	500	8.27

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Directorate General for Medical Devices. Unit website: http://www.salute.gov.it/portale/home.html

Contact name: Mr. Giuseppe Ruocco Contact email: g.ruocco@sanita.it

Website with publically available technical specifications: http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=89&area=dispositivi-medici&menu=caratteristichegenerali
http://www.salute.gov.it/imgs/C_17_pubblicazioni_1238_allegato.pdf

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: Yes Software name: More than one.

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 8477

Contacts

National officer(s):

Name: Dr. Giuseppe Ruocco

Email: g.ruocco@sanita.it

Name: —

Email: —

WHO Country officer(s):

Name: —

Email: —

Name: —

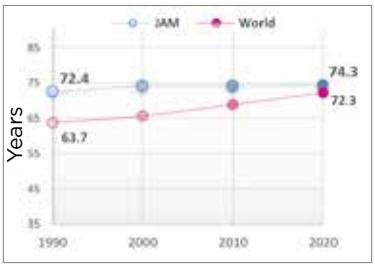
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Jamaica

Country indicators - WHO country information

Population 000s (rank):[a]	2,961 (135)	Under-five mortality (per 1000 live births):[d]	13.28	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.73 (0.61): high	Global innovation index (rank):[j]	29.1 (72)
		ICT Development Index (rank):[g]	4.8 (98)	High-technology exports (% of manufacture exports):[k]	3.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): Not available at present.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://www.moh.gov.jm/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): At the moment, the country does not have an official process for collecting evidence and preparing HTA reports as an input for making health coverage decisions, but they are interested in working towards it.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Hazardous Substances Regulatory Authority (HSRA), Caribbean Community, International Atomic Energy Agency.

Other agency's website: https://www.miic.gov.jm/content/hazardous-substances-regulatory-authority-hsra

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: https://www.moh.gov.jm/divisions-agencies/divisions/standards-and-regulation-division/guidelines-forms-lists/

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
The procurement is done at regional and hospital levels.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	4	1.44
Computerized Tomography Scanner:[α]	4	1.44
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	11	51.27
Radiotherapy:[β]	7	2.36

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Mr. Garfield Prescod
Email: gmprescod@yahoo.com

Name: Mr. Marlon Jones
Email: marloncurtis@hotmail.com

WHO Country officer(s):
Name: Mr. Ian Stein
Email: steinian@paho.org

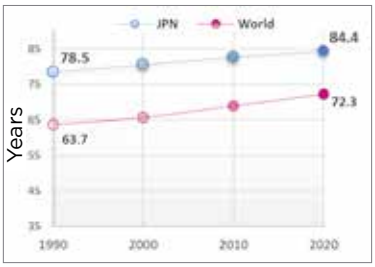
Name: Dr. Casimiro Canha
Email: canhaccas@paho.org

General comments (...Annex 1): Concerning the HT national policy is stated in the document Ritza 04.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Japan

Country indicators - WHO country information

Population 000s (rank):[a]	126,476 (11)	Under-five mortality (per 1000 live births):[d]	2.49	UHC - Service coverage index (1-100):[h]	85
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	8.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	4.4% (0.6%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.92 (0.84): very high	Global innovation index (rank):[j]	52.7 (16)
		ICT Development Index (rank):[g]	8.4 (10)	High-technology exports (% of manufacture exports):[k]	17.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): Japanese

Ministry of health responsible for health technology policy implementation: Economic Affairs Division, Health Policy Bureau.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Medical Economics Division, Health Insurance Bureau.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

New medical devices which begin to be reimbursed have been published by the Central Social Insurance Medical Council.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Medical Device Evaluation Division, PSEHB, MHLW

Website(s): https://www.mhlw.go.jp/english/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

There are a medical technology evaluation team, an expert committee for insurance care materials, an expert committee on drug prices (within the MoH: first link). Also, the National Institute of Public Health performs economic health evaluation (second link).

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Compliance and Narcotics Division, PSEHB, MHLW

Website(s): https://www.mhlw.go.jp/index.html

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Nuclear Regulation Authority (NRA JAPAN); Ministry of Economy, Trade and Industry (METI).

Other agency's website: https://www.nsr.go.jp/english/; www.meti.go.jp › english

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: For regulatory purposes

Website: https://www.std.pmda.go.jp/stdDB/index_en.html

Nomenclature comments (...Annex 1):
Japanese Medical Device Nomenclature was developed from the GMDN 2003 version.

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	6996	55.31
Computerized Tomography Scanner:[α]	14126	111.69
Positron Emission Tomography Scanner:[α]	586	4.63
Gamma camera or nuclear medicine:[α]	1455	11.5
Mammograph:[α,*]	4348	267.44
Radiotherapy:[β]	1278	10.1

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 41000

Contacts

National officer(s):

Name: —

Email: —

Name: —

Email: —

WHO Country officer(s):

Name: —

Email: —

Name: —

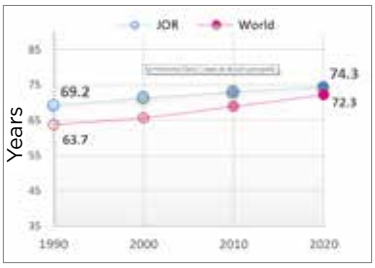
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Jordan

Country indicators - WHO country information

Population 000s (rank):[a]	10,203 (87)	Under-five mortality (per 1000 live births):[d]	15.02	UHC - Service coverage index (1-100):[h]	60
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	15.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.73 (0.62): high	Global innovation index (rank):[j]	27.8 (81)
		ICT Development Index (rank):[g]	6 (70)	High-technology exports (% of manufacture exports):[k]	1.40%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.moh.gov.jo

Language(s): Arabic and English

Ministry of health responsible for health technology policy implementation: Directorat of Biomedical Engineering.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Directorate of Biomedical Engineering / Department of Studies & Projects.

Website: http://dbe.gov.jo/

Nomenclature systems used for devices and tests: UMDNS.

Approved devices lists comments (...Annex 1):
The list is not published. It is within the updated document of the study department.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: UMDNS.

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):
We have a list but for a specific departments, it is not published. It is only updated and kept in the Study & Project Department. In the near future it will be published the Essential list at our website.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Directorate of Biomedical Engineering and the Study & Projects Department.

Website(s): http://dbe.gov.jo/
http://hhc.gov.jo/
https://www.khcc.jo/en
http://www.moh.gov.jo/Pages/viewpage.aspx?pageID=168

Contact: Eng. Mais Bny Sakher Email: mais.banysakher@yahoo.com

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):
Structured HTA capacity_building is being developed and implemented in the Department of the Pharmacy Center for Drug Policy and Technology Assessment (CDPTA), King Hussein Cancer Center (third link). Jordan started a hospital-level HTA at King Hussein Cancer Center (KHCC). The CDPTA at KHCC is responsible for conducting HTAs, their assessments are appraised by the Pharmacy and Therapeutic (P&T) Committee and HTA results are currently utilized to support formulary listing decisions.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Jordan Food & Drug Adminstration.

Website(s): http://www.jfda.jo/

Contact: Dr. Mai Masadeh Email: mai.masadeh@jfda.jo

Name(s) of other regulatory agency eg. for radiation equipment etc.: Jordan Atomic Energy Commission

Other agency's website: https://www.emrc.gov.jo/

National regulatory comments (...Annex 1):
It also exists the Energy & Minerals Regulatory Commission.

Medical device nomenclature system

Official nomenclature system for medical devices: Yes
Type: More than one system Use: For various purposes
Website: http://www.jfda.jo/Default.aspx

Nomenclature comments (...Annex 1):
This country will support the WHO standard nomenclature for medical devices. Until now, its nomenclature is based on UMDNS for management in the CMMS system, and the government procurement department uses UNSPSC nomenclature for procurement purposes.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://dbe.gov.jo
http://gsd.gov.jo
National level procurement: Yes Website: http://gsd.gov.jo

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: http://dbe.gov.jo

Medical device incorporation comments (...Annex 1):
The procurement is done at a national level by Ministry of Health. Some manufacturers have guidelines and technical specificatios such as: ECRI, AAMI, HTM (See: http://dbe.gov.jo). Although the list is not published neither available online, it's within the updated document of the study department.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	40	3.92
Computerized Tomography Scanner:[α]	80	7.84
Positron Emission Tomography Scanner:[α]	4	0.39
Gamma camera or nuclear medicine:[α]	12	1.18
Mammograph:[α,*]	85	129.07
Radiotherapy:[β]	14	1.37

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Directorat of Biomedical Engineering. Unit website: http://dbe.gov.jo
Contact name: Dr. Eng. Firas Abu Dalou Contact email: dfiras70@yahoo.com
Website with publically available technical specifications: http://dbe.gov.jo/Pages/viewpage?pageID=61
Number of regional/state offices/units: 30

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: Yes Software name: CMMS.

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 3000

Contacts

National officer(s):
Name: Dr. Firas Abu Dalou
Email: dfiras70@yahoo.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Jamela Saleh Mohamed Al-Raiby
Email: alraibyj@who.int

Name: Dr. Adi Nuseirat
Email: nuseirata@who.int

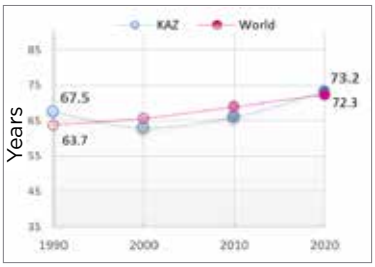
General comments (...Annex 1):

Concerning medical equipment management section: we have around 700 type medical equipment tech., spec., updated only in tenders are published; and we have 30 medical equipment, workshops MOH Hospitals.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Kazakhstan

Country indicators - WHO country information

Population 000s (rank):[a]	18,777 (63)	Under-five mortality (per 1000 live births):[d]	10.02	UHC - Service coverage index (1-100):[h]	76
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.6% (0.1%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.83 (0.77): very high	Global innovation index (rank):[j]	28.6 (77)
		ICT Development Index (rank):[g]	6.8 (52)	High-technology exports (% of manufacture exports):[k]	29.80%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.gov.kz/memleket/entities/dsm?lang=en
http://adilet.zan.kz/eng/docs/K2000000360
https://www.ndda.kz/upload/736_%D0%9F%D1%80%D0%B8%D0%BA%D0%B0%D0%B7.docx

Language(s): Russian

Ministry of health responsible for health technology policy implementation: Department of Medical and Pharmaceutical Activity Monitoring (MoH).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: National Expertise Center of pharmaceuticals, medical devices and equipment (REM) within Republican state enterprise (RES).

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
For list of approved medical devices for procurement we have the Medical State Register of Lekarstennyh.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: http://adilet.zan.kz/eng

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.gov.kz/memleket/entities/dsm/activities/2217?lang=ru

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Republican Center for Health Development of the MoH: HTA deparment.

Website(s): https://www.gov.kz/memleket/entities/dsm?lang=en
http://rcrz.kz/index.php/ru/menedzhment-zdravookhraneniya/22-informatsiya/1233-otsenka-meditsinskikh-tekhnologij2

Contact: Ms. Tulegalieva A. G. Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
Additional HTA contact: Zaid Zholdassov: zholdassov_z@rcrz.kz. The HTA is focused on pharmaceutics, sometimes performed for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Department of Medical and Pharmaceutical Activity Monitoring.

Website(s): https://www.gov.kz/memleket/entities/economy?lang=en
https://www.ndda.kz/category/mainpage

Contact: Mr. Baiserkin B.S. Email: b.baiserkin@mz.gov.kz

Name(s) of other regulatory agency eg. for radiation equipment etc.: Commitee of atomic and energy supervision and control of the Ministry of Energy of the Republic of Kazakhstan.

Other agency's website: https://www.gov.kz/memleket/entities/kaenk?lang=en

National regulatory comments (...Annex 1):
National center of examination of drugs (RGP), medical devices and medical equipment nazancheniya (MH RK).

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: https://www.ndda.kz/category/nomenklatura_men_izd

Nomenclature comments (...Annex 1):
Medical State Register of lekarstennyh.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.ndda.kz/category/gos_zakup
National level procurement: Yes Website: https://www.gov.kz/memleket/entities/dsm?lang=en
https://fms.ecc.kz/ru/searchanno

Donations

Policy or guideline: No Website: https://egov.kz/cms/en

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.gov.kz/memleket/entities/dsm?lang=en

Medical device incorporation comments (...Annex 1):
The procurement is done at a national level with the register of procurement of medical equipment. We have the National Register of medical devices.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	18	1.09
Computerized Tomography Scanner:α	24	1.46
Positron Emission Tomography Scanner:α	1	0.06
Gamma camera or nuclear medicine:α	1	0.06
Mammograph:α,*	34	22.1
Radiotherapy:β	83	4.42

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: AO Kazmedteh. Unit website: https://www.gov.kz/memleket/entities/kmfk?lang=en
http://kmtlc.kz/en/postavshchikam/trebovaniya-k-medicinskoy-tehnike1/
Contact name: Mr. Horoshash A. N. Contact email: —
Website with publically available technical specifications: http://kmtlc.kz/ru/postavshchikam/trebovaniya-k-medicinskoy-tehnike1/
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: https://www.ndda.kz/category/gos_reestr_excel
https://www.ndda.kz/category/Gosudarstvennyi_reesttr
https://portal.dari.kz/
Use of management software: Yes Software name: AIS-TEP Program.

Software comments (...Annex 1):
Medical State Register of lekarstennyh.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):
Name: —
Email: —

Name: Mr. Horoshash A. N.
Email: —

WHO Country officer(s):
Name: Dr. Caroline Francoise Clarinval
Email: clarinvalc@who.int

Name: —
Email: —

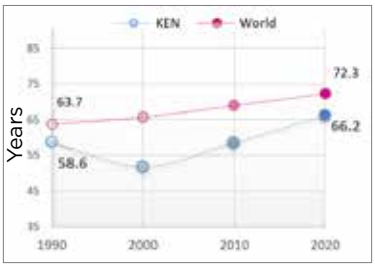
General comments (...Annex 1)

Concerning the Infrastructure section: the division for 20 beds on health centres is not applicable for the Kazakhstan centres network.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Kenya

Country indicators - WHO country information

Population 000s (rank):[a]	53,771 (27)	Under-five mortality (per 1000 live births):[d]	41.87	UHC - Service coverage index (1-100):[h]	56
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	5.4% (1.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.6 (0.44): medium	Global innovation index (rank):[j]	26.1 (86)
		ICT Development Index (rank):[g]	2.9 (138)	High-technology exports (% of manufacture exports):[k]	4.60%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Biomedical Engineering Department.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Lists are developed locally and available in hard copy only. Lists for procedures only cover surgical procedures.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):

It only covers surgical procedures which are locally developed. No available.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

The development of HTA framework for health products is in progress.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: —

Website(s): Kenya Pharmacy and Poisons Board

Contact: Dr. Fred Siyoi Email: fmsiyoi@gmail.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: The Radiation Protection Board (RPB)

Other agency's website: https://www.iaea.org/newscenter/pressreleases/iaea-mission-kenya-committed-to-radiation-safety-needs-to-ensure-regulatory-bodys-independence

National regulatory comments (...Annex 1):

Kenya has demonstrated its commitment to improve the national legal and regulatory framework for radiation safety. Currenty, The Radiation Protection Board (RPB) regulates such activities in Kenya, including those with sealed and unsealed radioactive sources as well as X-ray and other radiation-emitting devices.

-

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: For regulatory purposes
Website: —

Nomenclature comments (...Annex 1):
The GMDN is used for regulatory purposes

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: http://www.kemsa.co.ke/

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
The procurement at a national level is specifically done at the Ministry of Health. Guidelines for donations: IEC 60601, ISO 13485, Directive 93/42/EEC.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	7	0.16
Computerized Tomography Scanner:[α]	11	0.25
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	2	0.05
Mammograph:[α,*]	12	6.82
Radiotherapy:[β]	17	0.32

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Biomedical Engineering Division. Unit website: —
Contact name: Mr. Martin Owino Contact email: Martin.owino@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 8

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Locally developed.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 50

Contacts

National officer(s):
Name: Mr. Martin Owino
Email: martin.owino@yahoo.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Rudi Eggers
Email: eggersr@who.int

Name: Dr. Regina Mbindyo
Email: mbindyor@who.int

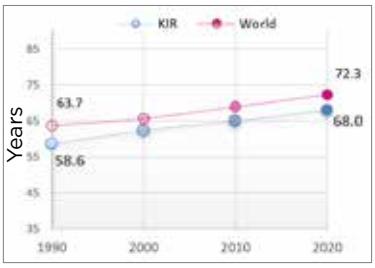
General comments (...Annex 1):

The corresponding technical specifications, as well as donation guidelines are available upon request in soft copy (not pdf versions).

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Kiribati

Country indicators - WHO country information

Population 000s (rank):[a]	119 (177)	Under-five mortality (per 1000 live births):[d]	49.59	UHC - Service coverage index (1-100):[h]	51
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	50.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.63 (0.52): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	2.2 (154)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Tungaru Central Hospital, Medical and Pharmacy Stores.

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Approved devices lists comments (...Annex 1):

We do not have a standard list in place but we do overseas and local procurement for specific medical devices needed for MoH; e.g., in 2009 overseas procurement for medical devices was made through medical healthcare prioritization according to doctors and head nurses. The selection and orders of medical devices were made to medical suppliers (such as South Austral

Health care facilities lists comments (...Annex 1):

—

Specific lists comments (...Annex 1):

We do not have a standard list in place but we do overseas and local procurement for specific medical devices needed for MoH; e.g., in 2009 overseas procurement for medical devices was made through medical healthcare prioritization according to doctors and head nurses. The selection

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The donations are second-hand medical devices from churches (LDS & CCatholics); such as defibrillator, computer, patient monitor-propaq, dressing trolleys.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	0	0
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	0	0
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
We have the inventory record and monitoring system with medical stores/ clinical wards/community health centres. In the case there is no inventory for specific medical equipment we refer to overseas medical supplier for assistance and good advices. In some cases there is inventory only for high cost technologies (such as MRI, CT or PET scanners).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Ms. Akineti Bauro
Email: bauroakineti@yahoo.com

Name: Dr. Teatao Tiira
Email: —

WHO Country officer(s):
Name: Dr. Wendy Dawn Snowdon
Email: snowdonw@who.int

Name: —
Email: —

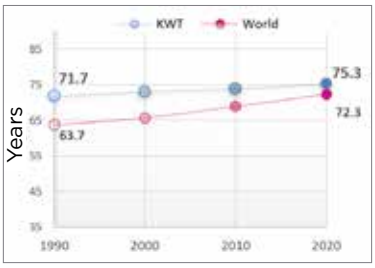
General comments (...Annex 1):

Medical devices components such as tools, knowledge, skills, repair and maintenance are very crucial and essential therefore Kiribati is very fortunate to be part of this surveillance thus is the only way to maintain our QA/QI (quality assurance and quality improvement) to achieve MoH objectives (utilization of quality medical/nursing care to all Kiribati individual patient/client to provide patient's safety, quality health care services and patient' satisfaction). We would appreciate being advised in ongoing training especially for nurses.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Kuwait

Country indicators - WHO country information

Population 000s (rank):[a]	4,271 (126)	Under-five mortality (per 1000 live births):[d]	8.86	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	11.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.81 (—): very high	Global innovation index (rank):[j]	28.4 (78)
		ICT Development Index (rank):[g]	6 (71)	High-technology exports (% of manufacture exports):[k]	0.90%

National policy on health technology

Health technology (medical device) national policy: —

Policy is part of the National Health Program/Plan: —

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: —

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): It has been started the institutionalizing of HTA within the MoH, with activities such as the building capacity.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: https://www.iaea.org/newscenter/news/iaea-assists-efforts-to-strengthen-kuwaits-legal-framework

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	6	1.4

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):

Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):

Name: Dr. Assad Hafeez
Email: hafeeza@who.int

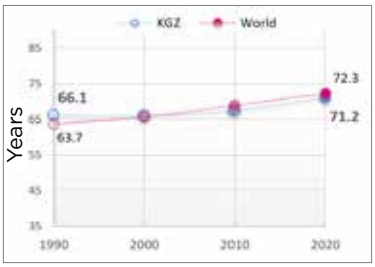
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Kyrgyzstan

Country indicators - WHO country information

Population 000s (rank):[a]	6,524 (109)	Under-five mortality (per 1000 live births):[d]	17.53	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	20.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.5% (0.7%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.7 (0.63): medium	Global innovation index (rank):[j]	24.5 (94)
		ICT Development Index (rank):[g]	4.4 (109)	High-technology exports (% of manufacture exports):[k]	6.80%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.pharm.kg/ru/legislation/
http://www.pharm.kg/ru/live_important/
http://www.pharm.kg/upload/LAW%20on%20Health%20Protection%20in%20KG.doc

Language(s): Russian

Ministry of health responsible for health technology policy implementation: Department of Medicines and Medical Devices under Ministry of Health of the Kyrgyz Republic.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Ministry of Health.

Website: www.med.kg; http://www.pharm.kg/

Nomenclature systems used for devices and tests: GMDN.

Approved devices lists comments (...Annex 1):
Standards: The law on the Health Care institutions. We have lists for communicable diseases, and public health emergency situations, as well as clinical protocols. The register of registered medical equipment is made at the website

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.pharm.kg/ru/medicalequipment/
http://www.who.int/medical_devices/survey_resources/medical_devices_by_facility_kyrgyzstan.pdf; http://www.pharm.kg/upload/%D0%9F%D1%80%D0%B8%D0%BB%D0%BE%D0%B6%D0%B5%D0%BD%D0%B8%D0%B5%201_1.pdf

Website - laboratories: http://212.112.103.101/reestr

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
Equipment timesheets are available, but without the use of nomenclature.

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://www.pharm.kg/ru/live_important/

Specific lists comments (...Annex 1):
Clinical protocols.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Department of Medicines and Medical Devices under Ministry of Health of the Kyrgyz Republic.

Website(s): http://www.pharm.kg/ru/live_important/

Contact: Ms. Ainura Abalieva Email: abalieva-a@yandex.ru

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Department of Medicines and Medical Devices under Ministry of Health of the Kyrgyz Republic.

Website(s): http://www.pharm.kg/
http://www.med.kg/ru/

Contact: Ms. Ainura Abalieva Email: abalieva-a@yandex.ru

Name(s) of other regulatory agency eg. for radiation equipment etc.: National Institute of Standardization and Metrology.

Other agency's website: http://www.nism.gov.kg/

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: For various purposes

Website: http://cbd.minjust.gov.kg/act/view/ru-ru/11978 http://cbd.minjust.gov.kg/act/view/ru-ru/111673; http://www.pharm.kg/ru/about

Nomenclature comments (...Annex 1):
The nomenclature is used for various purposes: regulation, procurement, in-vitro diagnostics lists and inventory.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://zakupka.med.kg/ru/ http://cbd.minjust.gov.kg/act/view/ru-ru/94539/10?cl=ru-ru;

National level procurement: Yes Website: http://zakupka.med.kg/ru/ http://www.med.kg/ru/

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: No

Website: No

Medical device incorporation comments (...Annex 1):
Kyrgyz Republic National Health Care Reform Program "Manas taalimi". Procurements are carry out through the National (budget) or donor projects.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	5	0.77
Computerized Tomography Scanner:[α]	13	1.99
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	4	0.61
Mammograph:[α,*]	6	11.72
Radiotherapy:[β]	3	0.46

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: No Professionally trained biomedical/clinical engineers: No

Unit/Department: Ministry of Health. Unit website: http://www.med.kg http://www.med.kg/index.php/en/

Contact name: Ms. Dinara Sagynbaeva Contact email: —

Website with publically available technical specifications: http://lisenzya.med.kg/images/myFile/2018/otraslevye_standarty_gemodializa.doc

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: http://www.pharm.kg

Use of management software: Yes Software name: Nationally developed database for material and technical facilities/medical facilities of public health institutions.

Software comments (...Annex 1):
The National Register for Medical Equipment and the National Functional Register for Medical Equipment. The National Functional Register for the Medical Equipment is a database for medical facilities of the public health institutions; meanwhile, the National Register of the Medical Equipment is a national list of pharmaceuticals and medical equipment authorized and registered for utilization in the Kyrgyz Republic. A database is employed for material and technical facilities and medical

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):

Name: Ms. Ainura Abalieva

Email: abalieva-a@yandex.ru

Name: Ms. Larisa Kachybekova

Email: —

WHO Country officer(s):

Name: Dr. Nazira Poolatovna Artykova.

Email: artykovan@who.int

Name: Ms. Saltanat Moldoisaeva

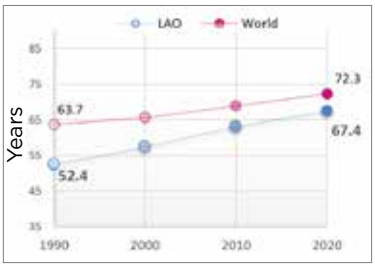
Email: moldoisaevas@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Lao People's Democratic Republic

Country indicators - WHO country information

Population 000s (rank):[a]	7,276 (103)	Under-five mortality (per 1000 live births):[d]	44.08	UHC - Service coverage index (1-100):[h]	50
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	26.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.61 (0.46): medium	Global innovation index (rank):[j]	20.6 (113)
		ICT Development Index (rank):[g]	2.9 (139)	High-technology exports (% of manufacture exports):[k]	20.60%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): Lao and English

Ministry of health responsible for health technology policy implementation: Medical Products Supply Center.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

It has been started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities. There are identified HTA activities but not national unit. The creation of a national health insurance authority towards the UHC goal is in progress.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Food and Drug Department

Website(s): https://moh.gov.la/

Contact: Dr. Somthavy Changvisommit Email: csomthavy_fdd@yahoo.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: Health Care Deparment.

Other agency's website: https://www.iaea.org/newscenter/news/lao-peoples-democratic-republic-signs-its-second-country-programme-framework-cpf-for-2020-2025

National regulatory comments (...Annex 1):

There is the political will to strenghten the Nuclear and radiation safety and security, as well as the corresponding legal framework (as seen in the 2020-2025 plan).

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: Not specified

Website: http://www.fdd.gov.la/index_en.php

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —

National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
The procurement at a national level is only for sophisticate and high-value equipment.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	0	0
Computerized Tomography Scanner:α	5	0.74
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	0	0
Radiotherapy:β	2	0.27

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Health Care Department. Unit website: —

Contact name: Dr. Chanhphomma Vongsamphanh Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: Yes Software name: PLAMAHS.

Software comments (...Annex 1):
In the whole country, the inventories are ongoing .

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):

Name: Mr. Thanom Insal

Email: mpsc@laotel.com

Name: Dr. Chanhphomma Vongsamphanh

Email: —

WHO Country officer(s):

Name: Dr. Ying-Ru Jacqueline Lo

Email: loy@who.int

Name: Ms. Sengphet Phongphachanh

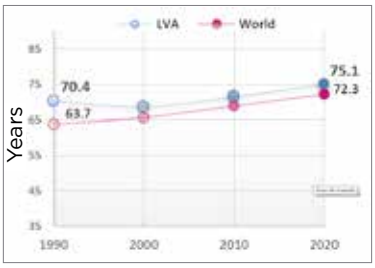
Email: phongphachanhs@wpro.who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Latvia

Country indicators - WHO country information

Population 000s (rank):[a]	1,886 (147)	Under-five mortality (per 1000 live births):[d]	4	UHC - Service coverage index (1-100):[h]	72
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.87 (0.78): very high	Global innovation index (rank):[j]	41.1 (36)
		ICT Development Index (rank):[g]	7.3 (35)	High-technology exports (% of manufacture exports):[k]	17.20%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: https://likumi.lv/

Language(s): Latvian

Ministry of health responsible for health technology policy implementation: Regulation of Cabinet of Ministers No. 581 (adopted 02082005).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.pharm.kg/ru/live_important/

Website - laboratories: https://eur-lex.europa.eu/legal-content/LV/TXT/HTML/?uri=CELEX:32017R0746&from=LV

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://www.likumi.lv/doc.php?id=187621

Specific lists comments (...Annex 1): Regulation of Cabinet of Ministers No. 60.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: State Agency of Medicines.

Website(s): https://www.zva.gov.lv/en/director/health-technology-assessment-department http://www.vmnvd.gov.lv/

Contact: Ms. Daiga Behmane Email: daiga.lagzdina@zva.gov.lv

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: State Agency of Medicines.

Website(s): http://www.zva.gov.lv

Contact: Ms. Daiga Lagzdina Email: daiga.lagzdina@zva.gov.lv

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: https://www.vvd.gov.lv/lv/pakalpojumi/darbibas-ar-jonizejosa-starojuma-avotiem

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: http://www.zva.gov.lv
https://www.gmdnagency.org/

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: Yes Website: https://www.zva.gov.lv/

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
The procurement of national devices at a national level started from the year 2010.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	26	13.79
Computerized Tomography Scanner:[α]	74	39.24
Positron Emission Tomography Scanner:[α]	2	1.06
Gamma camera or nuclear medicine:[α]	7	3.71
Mammograph:[α,*]	51	177.83
Radiotherapy:[β]	12	6.36

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Centre of Health Economics Unit website: https://www.vmnvd.gov.lv/en

Contact name: Ms. Iveta Gavare Contact email: iveta.gavare@vec.gov.lv

Website with publically available technical specifications: https://likumi.lv/ta/id/295401-medicinisko-iericu-registracijas-atbilstibas-novertesanas-izplatisanas-ekspluatacijas-un-tehniskas-uzraudzibas-kartiba

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 220

Contacts

National officer(s):

Name: —

Email: —

Name: Ms. Iveta Gavare

Email: iveta.gavare@vec.gov.lv

WHO Country officer(s):

Name: Dr. Uldis Mitenbergs

Email: umitenbergs@who.int

Name: —

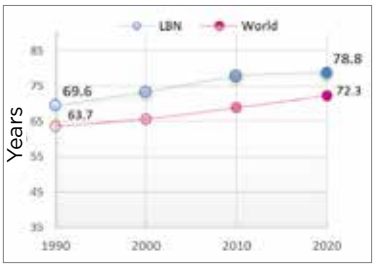
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Lebanon

Country indicators - WHO country information

Population 000s (rank):[a]	6,825 (107)	Under-five mortality (per 1000 live births):[d]	6.98	UHC - Service coverage index (1-100):[h]	72
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	19.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.74 (—): high	Global innovation index (rank):[j]	26 (87)
		ICT Development Index (rank):[g]	6.3 (64)	High-technology exports (% of manufacture exports):[k]	2.40%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: Projects and Health Programs.

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): The HTA is at initial stages to inform health policy and products. National strategy will incorporate several actors: MoH, National Social Security Funds, General Security, etc.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of Public Health.

Website(s): http://www.moph.gov.lb/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: National Council for Atomic Energy.

Other agency's website: http://www.laec-cnrs.gov.lb/Authorization.asp?Cat=Programs&SubCat=Radiation%20Protection,%20Safety%20And%20Security%20Of%20Radioactive%20Sources&SubCat2=Regulation,%20Authorization%20And%20Inspection%20Of%20Ionizing%20Radiations%20field&MyPage=Authorization.asp&SubCat3=Inspection&MyPage=Authorization.asp

National regulatory comments (...Annex 1): It controls the importation of all radiological devices (x-ray devices, tracers for nuclear medicine, etc.).

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: https://www.moph.gov.lb/userfiles/files/HealthCareSystem/Medical%20Technology/Laws%20and%20Regulations/karar%201506-2014.pdf

Nomenclature comments (...Annex 1):
The Ministry of Health is planning to acquire the Global Medical Devices Nomenclature system to adopt it and use it for regulatory and procurement purposes.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
The procurement of medical equipment for public hospitals is done by the Council for Development and Reconstruction in coordination with the Ministry of Public Health. A procurement procedure and bidding documents are used and adapted according to the specific project and considering the government rules for procurement. No guidelines exist in the private sector that is dominating the health sector (80% of beds are private).

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	40	8.3
Computerized Tomography Scanner:α	121	25.09
Positron Emission Tomography Scanner:α	6	1.24
Gamma camera or nuclear medicine:α	1	0.21
Mammograph:α,*	131	370.23
Radiotherapy:β	24	3.52

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Projects & Health Programs. Unit website: —
Contact name: Ms. Sizar Akoum Contact email: sizarak@hotmail.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners).
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1):
The Ministry of Health has acquired a GIS licence to establish a database which will include the available high-cost technologies.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 750

Contacts

National officer(s):
Name: Ms. Sizar Akoum
Email: sizarak@hotmail.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Iman Shankiti
Email: shankitii@who.int

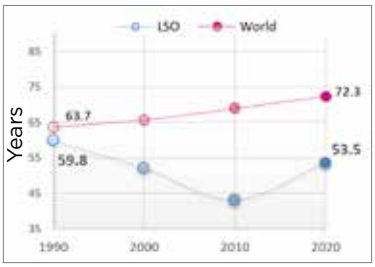
Name: Dr. Alissar Rady
Email: radya@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Lesotho

Country indicators - WHO country information

Population 000s (rank):[a]	2,142 (143)	Under-five mortality (per 1000 live births):[d]	89.52	UHC - Service coverage index (1-100):[h]	48
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	42.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	4.5% (1.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.53 (0.38): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	3 (133)	High-technology exports (% of manufacture exports):[k]	0.20%

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes
HTA unit/department includes the assessment of medical devices: —
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Richard Banda
Email: bandar@who.int

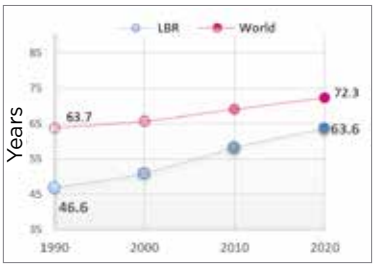
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Liberia

Country indicators - WHO country information

Population 000s (rank):[a]	5,058 (120)	Under-five mortality (per 1000 live births):[d]	78.28	UHC - Service coverage index (1-100):[h]	42
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	17.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.48 (0.33): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Approved devices lists comments (...Annex 1):

Lists of standards and lists are: "Basic Package of Health Services" which contains a list of the equipment at the "annexe". However, the list is subject to revision. The WHO guidelines are being used for donations. The process has been initiated for the adaptation of the guidelines.

Health care facilities lists comments (...Annex 1):

—

Specific lists comments (...Annex 1):

The list of equipment can be found in the index of the following document Basic Package of Health Services. However, the list is subject to revision.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: Liberia Medicines & Health Products Regulatory Authority (LMHRA).

Website(s): https://www.lmhra.org/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

Currently, there is a National Drug Regulatory Authority that is in the process of institutonalization.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
No comments as the nomenclature does not exist.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The procurements are based on the WHO guidelines and they are mainly organized through partners.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
The functional inventory of medical equipment is ongoing. The focus is to take inventory of all equipment in the Public Health facilties.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Mr. Thomas K. Nagbe
Email: tnknue31112@gmail.com

Name: Dr. Louise Kpoto
Email: —

WHO Country officer(s):
Name: Dr. Lugala Peter Lasuba Clement
Email: clementp@who.int

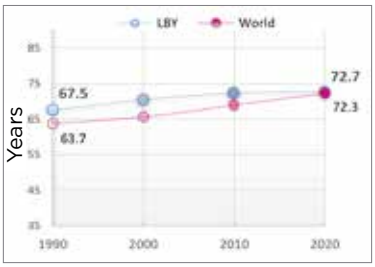
Name: Mr. Eric Johnson
Email: johnsoner@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Libya

Country indicators - WHO country information

Population 000s (rank):[a]	6,871 (106)	Under-five mortality (per 1000 live births):[d]	11.13	UHC - Service coverage index (1-100):[h]	60
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	18.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.72 (—): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	4.1 (115)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://health-ministry.ly/
http://seha.ly/en/

Language(s): Arabic

Ministry of health responsible for health technology policy implementation: Pharmacy and Medical Devices Department.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
There are national standards lists but they are not written. There are lists for Sundries Hospital consumable- Diagnostics Laboratory 37/3.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):
There are national standards lists but are not written. It exists also lists for interventions, and emergencies. See the following file: General_terms_and_conditions_for_medicines_and_medical_consumables_and_equipment.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Pharmacy Management, Equipment, Supplies and Medical Supplies Ministry of Health.

Website(s): http://www.health.gov.ly/

Contact: Dr. Mahdi Al Ekary. Email: pharmacy912@yahoo.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: Medical Supply Organization (MSO).

Other agency's website: https://gnssn.iaea.org/main/ANNuR/Activity%20Documents%20%20Public/Regional%20Workshop%20and%20Seminar%20on%20Capacity%20Building,%20Education%20and%20Training%20Review%20Service%20(ETRES)/National%20presentation-%20Libya.pdf

National regulatory comments (...Annex 1):
The Medical Supply Organization (MSO) is responsible for the procurement of medical appliances for the public sector.

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: For various purposes

Website: http://www.mhtc.ly
https://seha.ly/en

Nomenclature comments (...Annex 1):
For the medical equipment list, it is used a nomenclature based on the UMDNS. The nomenclature is used for inventory systems of healthcare facilities and lists.

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
In regards to the technical specifications of medical devices, we depend mainly on the technical committees which consist of experts in medicine, pharmacy and biomedical engineer. These committees set up decrees issued by the Secretariat of Health.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	32	5.16
Computerized Tomography Scanner:α	60	9.68
Positron Emission Tomography Scanner:α	1	0.16
Gamma camera or nuclear medicine:α	2	0.32
Mammograph:α,*	n/a	n/a
Radiotherapy:β	8	1.16

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —

Unit/Department: Pharmacy and Medical Equipment Administration. Unit website: http://health-ministry.ly/ http://seha.ly/en/

Contact name: Dr. Nasereddin Emhemed Alriyani Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 23

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):
The last version is from 2006.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 40

Contacts

National officer(s):

Name: Mr. Ezzedin S. Z. Durar

Email: edurar2004@yahoo.com

Name: Dr. Nasereddin Emhemed Alriyani

Email: —

WHO Country officer(s):

Name: Dr. Elizabeth Hoff

Email: hoffe@who.int

Name: Ms. Najwa El-Emam

Email: elemamn@who.int

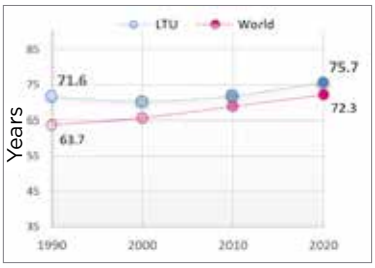
General comments (...Annex 1):

This is the first time for us to participate in this survey. Our standards and policies are under development and/or being updated. Many issues in this survey are available but still not documented.
"General_terms_and_conditions_for_medicines_and_medical_consumables_and_equipment"

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Lithuania

Country indicators - WHO country information

Population 000s (rank):[a]	2,722 (138)	Under-five mortality (per 1000 live births):[d]	3.28	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	19.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	9.8% (1.6%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.88 (0.79): very high	Global innovation index (rank):[j]	39.2 (40)
		ICT Development Index (rank):[g]	7.2 (41)	High-technology exports (% of manufacture exports):[k]	12.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/35834810004f11e4b0ef967b19d90c08/asr

Language(s): Lithunian

Ministry of health responsible for health technology policy implementation: Ministry of Health.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Public Procurement Office operating under the Ministry of Economy.

Website: http://www.who.int/medical_devices/survey_resources/medical_devices_for_procurement_reimbursement_lithuania.pdf

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Licensing regulations for health care facilities. General and specific requirements for institutional health care services. There is a list of medical devices that are mandatory for specialized and surgical health care services. Public Procurement

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.293780

Website - laboratories: https://vaspvt.gov.lt/en/node/276 https://vaspvt.gov.lt/files/Medicinos_prietaisai/sarasas_20-11-17.pdf

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=258027

Specific lists comments (...Annex 1):

These are lists of indications and reimbursement regulations for expensive health technology examination techniques (e.g. CT, MRI) and diagnostic procedures (e.g. diagnostic interventional procedures). Only available in lithuanian language. General and specific requirements for institutional health care services. There is a list of medical devices that are mandatory

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Health Technology Division of State Health Care Accreditation Agency under the Ministry of Health.

Website(s): http://www.vaspvt.gov.lt/en/node/270 http://www.hi.lt/

Contact: Ms. Neringa Puidokiene Email: neringa.puidokiene@vaspvt.gov.lt

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania.

Website(s): www.vaspvt.gov.lt

Contact: Ms. Jolanata Karavackaite Email: jolanta.karavackaite@vaspvt.gov.lt

Name(s) of other regulatory agency eg. for radiation equipment etc.: State Nuclear Power Safety Inspectorate (VATESI); Radiation Protection Centre (Ministry of Health).

Other agency's website: http://www.vatesi.lt/index.php?id=2 http://www.rsc.lt/index.php/pageid/418

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: http://www.vaspvt.gov.lt/en

Nomenclature comments (...Annex 1):

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=448409&p_query=&p_tr2=2
http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=443967&p_query=&p_tr2=2

National level procurement: Yes Website: http://www3.lrs.lt

Donations

Policy or guideline: Yes Website: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=228695&p_query=&p_tr2=

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: https://www.lrs.lt/

Medical device incorporation comments (...Annex 1):

Guidelines for procurement of expensive health technologies (i.e. MRI, CT etc.). Guidelines are in the Lithuanian language only. There are basic requirements for technical specification of medical devices that are procured in a public centralized way.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	40	14.7
Computerized Tomography Scanner:α	73	26.82
Positron Emission Tomography Scanner:α	2	0.73
Gamma camera or nuclear medicine:α	7	2.57
Mammograph:α,*	35	81.34
Radiotherapy:β	24	8.82

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Medical Devices Surveillance Division of State Health Care Accreditation Agency under the Ministry of Health. Unit website: https://vaspvt.gov.lt/node/106
http://www.vaspvt.gov.lt/en/node/275

Contact name: Ms. Jolanta Karavackaite Contact email: jolanta.karavackaite@vaspvt.gov.lt

Website with publically available technical specifications: http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=336532
https://vaspvt.gov.lt/en/node/276; https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.336532

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):

The State Health Care Accreditation Agency, under the Ministry of Health, is responsible for the management of national data regarding expensive health technologies (i.e. MRI, CT, etc.).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 250

Contacts

National officer(s):

Name: Ms. Nora Ribokien_

Email: vaspvt@vaspvt.gov.lt

Name: —

Email: —

WHO Country officer(s):

Name: Ms. Ingrida Zurlytė

Email: zurlytei@who.int

Name: Mr. Robertas Petkevicius

Email: per@euro.who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Luxembourg

Country indicators - WHO country information

Population 000s (rank):[a]	626 (163)	Under-five mortality (per 1000 live births):[d]	2.78	UHC - Service coverage index (1-100):[h]	86
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	9.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.4% (0.2%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.92 (0.83): very high	Global innovation index (rank):[j]	50.8 (18)
		ICT Development Index (rank):[g]	8.5 (9)	High-technology exports (% of manufacture exports):[k]	6.60%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: https://sante.public.lu/fr/politique-sante/ministere-sante/index.html
http://legilux.public.lu/eli/etat/leg/memorial/2009/54

Language(s): —

Ministry of health responsible for health technology policy implementation: Direction de la Santé.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: http://legilux.public.lu/eli/etat/leg/loi/2001/06/20/n2/jo

Website - laboratories: https://cns.public.lu/en/professionnels-sante/medicaments/dispositifs-medicaux.html

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): Contenues notamment dans le plan pandémie grippale qui n'est pas sur l'internet public.

Lists available: Yes

Website: http://legilux.public.lu/eli/etat/leg/loi/1986/02/27/n1/jo
http://legilux.public.lu/eli/etat/leg/rmin/2006/02/14/n5/jo (blood transfution)
https://sante.public.lu/fr/legislation/index.php?q=directive+93%2F42%2FCEE&~=do&from=search (implantables)

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Cellule d'expertise Médicale (CEM).

Website(s): https://cem.gouvernement.lu/fr.html
https://igss.gouvernement.lu/fr/service.html

Contact: Dr. Isabelle Rolland Email: isabelle.rolland@igss.etat.lu

Committee includes a biomedical or clinical engineer: Yes

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

National regulatory comments (...Annex 1): —

Name of regulatory agency: Ministère de la Santé.

Website(s): https://sante.public.lu/fr/politique-sante/ministere-sante/direction-sante/index.html; https://sante.public.lu/fr/politique-sante/ministere-sante/direction-sante/div-medecine-curative/index.html; http://legilux.public.lu/eli/etat/leg/rgd/1981/12/08/n3/jo

Contact: Dr. Anna Chioti Email: meddevices@ms.etat.lu

Name(s) of other regulatory agency eg. for radiation equipment etc.: Division de la Médecine Curative et de la Qualité en santé; Ministère-Direction de la Santé.

Other agency's website: https://sante.public.lu/fr/politique-sante/ministere-sante/direction-sante/div-medecine-curative/index.html

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://cns.public.lu/fr/professionnels-sante/medicaments/dispositifs-medicaux.html

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	9	14.38
Computerized Tomography Scanner:[α]	14	22.36
Positron Emission Tomography Scanner:[α]	1	1.6
Gamma camera or nuclear medicine:[α]	7	11.18
Mammograph:[α,*]	7	94.39
Radiotherapy:[β]	6	9.58

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Direction de la Santé. Unit website: —

Contact name: None Contact email: None

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: https://cns.public.lu/fr/professionnels-sante/medicaments/dispositifs-medicaux.html
https://sante.public.lu/

Use of management software: Yes Software name: Le Software est choisi par chaque hôpital individuellement.

Software comments (...Annex 1):
Software choisi par chaque hôpital individuellement.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):

Name: Dr. Françoise Berthet

Email: francoise.berthet@ms.etat.lu

Name: Mr. Carlo Back

Email: carlo.back@ms.etat.lu

WHO Country officer(s):

Name: —

Email: —

Name: —

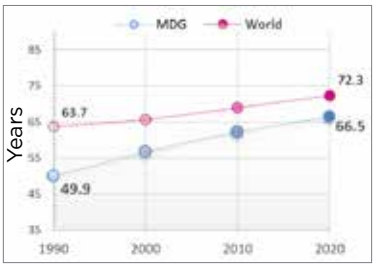
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Madagascar

Country indicators - WHO country information

Population 000s (rank):[a]	27,691 (51)	Under-five mortality (per 1000 live births):[d]	50.24	UHC - Service coverage index (1-100):[h]	35
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	26.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.6% (0.2%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.53 (0.39): low	Global innovation index (rank):[j]	20.4 (115)
		ICT Development Index (rank):[g]	1.7 (169)	High-technology exports (% of manufacture exports):[k]	0.50%

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: —
Language(s): Français
Ministry of health responsible for health technology policy implementation: Service des Equipements et de la Maintenance.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: http://www.agmed.mg/

Nomenclature comments (...Annex 1):
Nomenclature nationale pour la comptabilité matière du patrimoine de l'Etat (codification pour l'inventaire technique).

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
Specifications techniques pour: Matériels et équipements pour les Centres de Santé de base; matériels et équipements de laboratoire pour les Centres Hospitaliiers de Districts de niveau 2; matériels et équipements biomédicaux et hospitaliers pour les Centres Hospitaliers de Districts de niveau 2.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	3	0.13
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	6	6.23
Radiotherapy:[β]	2	0.07

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Service d'Appui aux Hôpitaux de Référence Nationaux et Régionaux (SAHRNR). Unit website: —
Contact name: — Contact email: siem@sante.gov.mg
Website with publically available technical specifications: —
Number of regional/state offices/units: 5

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Inventaire effectué en 2007 avec le projet CRESAN 2 (55 Centre Hospitalier de District de niveau 1 (CHD1), 29 Centres hospitalier de Districts de niveau 2 (CHD2), 18 Centres Hospitalier de Référence Régionale (CHRR), 10 Centre Hospitalier Universitaire (CHU) et Etablissements Sanitaires. Mise à jour en cours.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: Chef de Service
Email: siem@sante.gov.mg

WHO Country officer(s):
Name: Dr. Marcellin Nimpa Mengouo
Email: nimpamengouom@who.int

Name: —
Email: —

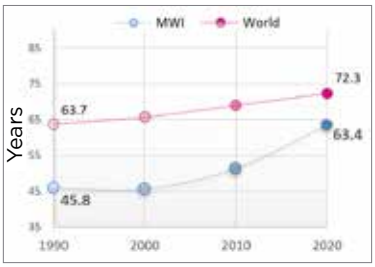
General comments (...Annex 1):

Formation en maintenance biomedicale a Madagascar: Depuis 1980, la multiplication des établissements hospitaliers et l'avenement des nouvelles technologies au service de santé ont induit une arrivée massive et diversifiée d'appareillages biomédicaux et ont fait apparaître le problème crucial de leur maintenance. La dernière action de recyclage (formation continue) des techniciens date de 2001.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Malawi

Country indicators - WHO country information

Population 000s (rank):[a]	19,130 (61)	Under-five mortality (per 1000 live births):[d]	38.58	UHC - Service coverage index (1-100):[h]	48
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	4.2% (0.9%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.48 (0.35): low	Global innovation index (rank):[j]	21.4 (111)
		ICT Development Index (rank):[g]	1.7 (167)	High-technology exports (% of manufacture exports):[k]	7.30%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://m.facebook.com/malawimoh/

Language(s): —

Ministry of health responsible for health technology policy implementation: Physical Assets Management Division.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Physical Assets Management.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

The standard list provided is for health centres, community hospitals and district hospitals. The standard list for central hospitals is being developed and will be published very soon (file names: "jica" and "customer", respectively).

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): https://m.facebook.com/malawimoh/

Contact: Mr. Godfrey Kadewere Email: gkadds@gmail.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: Atomic Energy Regulatory Authority

Other agency's website: https://www.iaea.org/sites/default/files/19/10/malawi_overview_2019.pdf

National regulatory comments (...Annex 1):

Radiation protection and nuclear safety is done via AERA and it is in process of institutionalization.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
There are the following pdf files: the "Public Procurement Act (2003)", the "Desk Instructions", and the "Procurement Regulations".

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	0.06
Computerized Tomography Scanner:α	5	0.31
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	0	0
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Physical Assets Management. Unit website: —
Contact name: Dr. Lovemore Mkukuma. Contact email: mkukuma@yahoo.co.uk
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Planning and Management of Assets in Health Sector (PLAMAHS).

Software comments (...Annex 1):
The inventory is in a database known as "Planning and Management of Assests in Health Sector (PLAMAHS)" and is not yet online.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Nonhlanhla Dlamini
Email: dlaminin@who.int

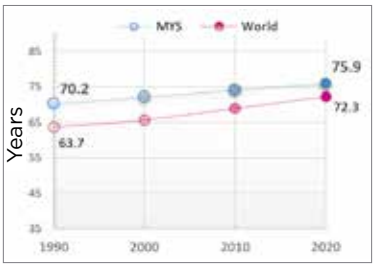
Name: Mr. Wilfred Dodoli
Email: dodoliw@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Malaysia

Country indicators - WHO country information

Population 000s (rank):[a]	32,366 (45)	Under-five mortality (per 1000 live births):[d]	8.62	UHC - Service coverage index (1-100):[h]	76
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	18.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.0% (0.2%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.81 (—): very high	Global innovation index (rank):[j]	42.4 (33)
		ICT Development Index (rank):[g]	6.4 (63)	High-technology exports (% of manufacture exports):[k]	51.80%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
The corresponding lists are only prepared based on the needs.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):
There is no standardized list. It is based on needs.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Health Technology Assessment Unit, Medical Development Division.

Website(s): https://www.moh.gov.my/ https://www.moh.gov.my/moh/resources/HTA_MANUAL_MAHTAS.pdf?mid=636

Contact: Dr. Izzuna Mudla Ghazali Email: izzuna@gmail.com

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
Malaysian Health Technology Assessment Section (MaHTAS) of the MoH performs HTA for health products including medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: Medical Device Authority, Ministry of Health Malaysia.

Website(s): https://portal.mda.gov.my/

Contact: Mr. Zamane Bin Abdul Rahman Email: zamane@mdb.gov.my

Name(s) of other regulatory agency eg. for radiation equipment etc.: Atomic Energy Licensing Board, Ministry of Science, Technology and Innovation.

Other agency's website: https://www.aelb.gov.my/malay/dokumen/perundangan/RADIATION%20PROTECTION%20LICENSING%20REGULATIONS%201986.pdf

National regulatory comments (...Annex 1):
The Medical Device Act 2012 (Act 737) has come into force on June 30th 2013, while the effective date for its subsidiary legislations, the Medical Device Regulations (MDR) 2012 was on July 1th 2013. Act 737 provides two and one years, respectively, of a transition period for the industry to submit applications for medical device registration and establishment licensing before the law is fully enforced. It exists a separate unit for the regulation of radiological equipment (i.e. within the Ministry of Energy): Radiation Health and Safety Section, Engineering Services Division, Ministry of Health Malaysia:

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: Not specified

Website: https://portal.mda.gov.my/documents/guideline-documents/30-guidelines-on-medical-device-registration-under-act-737-mda-gl-md-01-june-2014-2nd-edition/file.html

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1): Depending on the types of Medical Devices. Some are procured at a national level, some at the state level and some at the hospital level.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	86	2.89
Computerized Tomography Scanner:α	191	6.43
Positron Emission Tomography Scanner:α	11	0.37
Gamma camera or nuclear medicine:α	21	0.71
Mammograph:α,*	194	86.7
Radiotherapy:β	73	2.26

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Training Management Division. Unit website: https://mda.gov.my/

Contact name: — Contact email: —

Website with publically available technical specifications: https://mmdr.mda.gov.my/

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: https://mdar.mda.gov.my/frontend/web/index.php?r=carian

Use of management software: Yes Software name: Central Management Information System.

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 800

Contacts

National officer(s):

Name: —

Email: —

Name: Dr. Asmah Samat

Email: asmah_samat@moh.gov.my

WHO Country officer(s):

Name: —

Email: wpmyswr@who.int

Name: —

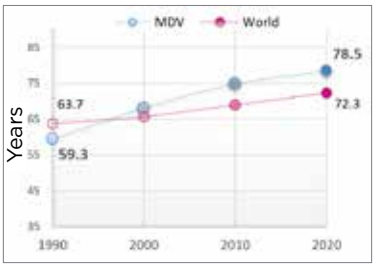
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Maldives

Country indicators - WHO country information

Population 000s (rank):[a]	541 (166)	Under-five mortality (per 1000 live births):[d]	6.46	UHC - Service coverage index (1-100):[h]	69
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	11.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	10.3% (4.1%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.74 (0.58): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	5.3 (85)	High-technology exports (% of manufacture exports):[k]	0.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

National regulatory comments (...Annex 1): —

Name of regulatory agency: Medicine and Therapeutic Goods / Maldives Food and Drug Authority.

Website(s): https://health.gov.mv/en

Contact: Ms. Shareefa Adam Manik Email: shareefa@health.gov.mv

Name(s) of other regulatory agency eg. for radiation equipment etc.: Medical Device Authority, Ministry of Health Malaysia.

Other agency's website: —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: http://health.gov.mv/

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: http://health.gov.mv

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
The procurement is done at a national level as well as for government health facilities.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	2.9
Computerized Tomography Scanner:α	2	5.8
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	1	57.09
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: —
Email: —

Name: Ms. Aishath Mohamed
Email: anthu9696@hotmail.com

WHO Country officer(s):
Name: Dr. Nazneen Anwar
Email: anwarna@who.int

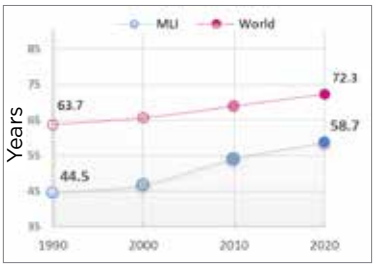
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Mali

Country indicators - WHO country information

Population 000s (rank):[a]	20,251 (59)	Under-five mortality (per 1000 live births):[d]	90.99	UHC - Service coverage index (1-100):[h]	42
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	6.5% (1.1%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.43 (0.29): low	Global innovation index (rank):[j]	19.2 (123)
		ICT Development Index (rank):[g]	2.2 (155)	High-technology exports (% of manufacture exports):[k]	1.20%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Division établissements sanitaires et réglementation - Direction nationale de la Santé

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Il n'existe pas de normes nationales pour des procedures spécifiques, en général elles sont traitées au cas par cas. Non, comme décrit précedemment, il n'existe pas de liste spécifique de dispositifs médicaux pour les cas cités. La liste

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

Il n'existe pas de normes nationales pour des procedures spécifiques , en général elles sont traitées au cas par cas. Pour diverses maladies et situations Il n'existe pas de liste spécifique de dispositifs médicaux pour les cas cités.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: —

Unit/department: Cellule de Planification et de Statistique

Website(s): http://www.sante.gov.ml/ http://www.reforme-justice.gouv.ml/#/mjm/accueil

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

The HTA is at initial stages to inform health policy and products but not for medical equipment.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Division établissements sanitaires et réglementation - Direction nationale de la Santé.

Website(s): http://cnom.sante.gov.ml/

Contact: Dr. Yattara Moussa Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
Il existe dans le document de la comptabilité matière une rubrique nomenclature sommaire ou les différents produits sont classés par catégories, mais c'est un domaine très important qui mérite une action.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
Guidelines for procurement: existe un document de projet de politique nationale en matière d'équipements et d'infrastructures sanitaires qui traite ces cas , mais il reste à être validé. Jusqu'à l'adoption de la loi hospitalière. La DFM était le seul organe d'achat de dispositifs médicaux. Vue que cette loi accorde un statut particulier à certaines structures sanitaires notamment l'autonomie de gestion, mais aussi dans le cadre de la décentralisation il y a le transfert de compétences entre le Ministère de la Santé et les collectivités territoriales, de sorte que ces structures peuvent acheter indépendamment

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	3	0.2
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	1	0.07
Mammograph:[α,*]	3	5.42
Radiotherapy:[β]	1	0.05

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: DNS/ DFM/ SEPAUMAT et Departement des Affaires financières (DAF). Unit website: —
Contact name: Mr. Alamir Touré Contact email: alamirtoure@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: 4

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Chaque année le Ministère de la santé à travers la DFM organise des inventaires mixtes dans lesquels participent comptables matières et techniciens biomédicaux, dans toutes les structures sanitaires du pays [centres de santé communautaire (cscom) , centre de santé de référence (csréf) et hôpitaux régionaux (HR).Ensuite les differentes fiches sont compilées et informatisés au niveau de la division comptabilité matières.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: Mr. Alamir Touré
Email: alamirtoure@yahoo.fr

WHO Country officer(s):
Name: Dr. Jean-Pierre Baptiste
Email: baptistej@who.int

Name: Mr. Alioune Ibnou Abytalib Diouf
Email: adiouf@who.int

General comments (...Annex 1):

Concerning the Infrastructure section: nous n'avons pas encore une politique nationale pour les équipements mais nous y travaillons, nous avons tenu deux ateliers: l'un pour l'élaboration des élements de la politique et l'autre pour la rédaction du document de politique. Le document attend sa validation lors d'un atelier national pour être soumis à l'Assemblée Nationale. Concerning the Section Infrastructure: la Division établissements sanitaires et réglementation (DESR) à la Direction Nationale de la Santé s'occupe également des établissements privés de santé mais ne dispose pas de données à jour (2010) sur leur nombre exact.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Malta

Country indicators - WHO country information

Population 000s (rank):[a]	442 (167)	Under-five mortality (per 1000 live births):[d]	6.46	UHC - Service coverage index (1-100):[h]	81
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	15.9% (2.8%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.9 (0.82): very high	Global innovation index (rank):[j]	46.4 (27)
		ICT Development Index (rank):[g]	7.9 (24)	High-technology exports (% of manufacture exports):[k]	29.80%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: https://deputyprimeminister.gov.mt/en/cpsu/Documents/News/Medical%20Devices%20Information%20Session/Medical%20Devices%20Presentation%20CPSU%20seminar%20-%20May%202019.pdf

Website - laboratories: http://www.medicinesauthority.gov.mt/home?l=1

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): Office of the Chief Medical Officer is in charge to perform HTA, mainly in pharmaceutics.

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://deputyprimeminister.gov.mt/en/pharmaceutical/Pages/assessment-unit.aspx

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

National regulatory comments (...Annex 1): —

Name of regulatory agency: Malta Standards Authority.

Website(s): https://deputyprimeminister.gov.mt/en/cpsu/Pages/Reports/Stock-Reports.aspx

Contact: Mr. David Pulis Email: david.pulis@msa.org.mt

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministry of Health (Medical Physics).

Other agency's website: https://deputyprimeminister.gov.mt/en/ahcs/Pages/medicalphysics.aspx

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: http://www.medicinesauthority.gov.mt/medicaldevices https://mccaa.org.mt/

Nomenclature comments (...Annex 1):

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: Yes Website: https://deputyprimeminister.gov.mt/en/Pages/health.aspx

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):

Procurement at national level: there is a strong collaboration between the two. For capital expenditure for new technologies it is usually the department, for others it is usually coordinated by the hospital itself.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	4	9.32
Computerized Tomography Scanner:α	4	9.32
Positron Emission Tomography Scanner:α	1	2.33
Gamma camera or nuclear medicine:α	3	6.99
Mammograph:α,*	6	99.69
Radiotherapy:β	4	9.05

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: Yes Software name: Clingo.

Software comments (...Annex 1):

The name of the Software is Clingo from the company Carestream Health Italia SRL.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):

Name: Dr. Renzo Pace Asciak

Email: renzo.pace-asciak@gov.mt

Name: —

Email: —

WHO Country officer(s):

Name: —

Email: —

Name: —

Email: —

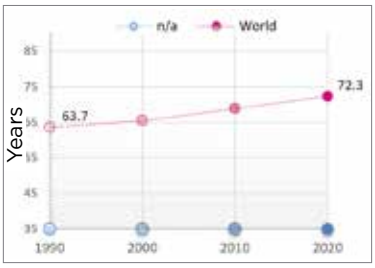
General comments (...Annex 1):

The Ministry of Health has started to provide emphasis on new health technology and its assessment. Over the last 2 years, it has been developed a short form and guidelines for the completion of all the requests for the implementation of new health technologies and services. Together, the Director Generals for Strategy & Sustainability, and Healthcare Services have met three times a year to evaluate the proposals received. It is envisaged that a health technology evaluation unit will be developed in the short term.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Marshall Islands

Country indicators - WHO country information

Population 000s (rank):[a]	59 (186)	Under-five mortality (per 1000 live births):[d]	30.67	UHC - Service coverage index (1-100):[h]	62
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	—	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.7 (—): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

National regulatory comments (...Annex 1): —

Name of regulatory agency: Ministry of Health Board.

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	1	19
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	1	142.73
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): Inventory is not available.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: Ms. Mary Hicking
Email: mhicking@gmail.com

WHO Country officer(s):
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

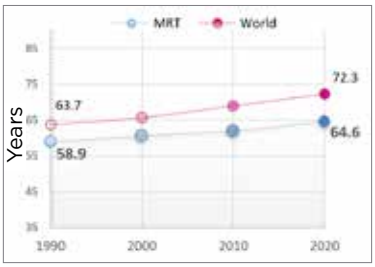
Name: Dr. Palvin Boris
Email: pavlinb@wpro.who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Mauritania

Country indicators - WHO country information

Population 000s (rank):[a]	4,650 (124)	Under-five mortality (per 1000 live births):[d]	70.71	UHC - Service coverage index (1-100):[h]	40
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	11.7% (3.0%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.55 (0.37): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	2.3 (151)	High-technology exports (% of manufacture exports):[k]	0.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.sante.gov.mr/?page_id=516

Language(s): Français

Ministry of health responsible for health technology policy implementation: Des Infrastructures, du Materiel et de la Maintenance (DIMM).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): Il existent des paquets d'activités par niveau des soins de la pyramide sanitaire.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://www.sante.gov.mr/?page_id=36 http://apps.who.int/iris/bitstream/handle/10665/259897/9789290312970-fre.pdf?sequence=1

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: —

Name of regulatory agency: Direction de la Medecine Hospitaliere (DMH).

Website(s): https://www.sante.gov.mr/?page_id=34

Contact: Dr. Moustapha Ould Abdallahi Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: National authority for radiation protection, safety and nuclear security (ARSN)

Other agency's website: https://www.iaea.org/sites/default/files/national_report_of_mauritania_for_the_6th_review_meeting_-_english.pdf

National regulatory comments (...Annex 1): Direction de la Medecine Hospitaliere qui a l'attribution de élabore et suit la reglementation et les normes hospitaliere, et prépare l'autorisation d'ouvertue a titre privé des cliniques et des cabinets de soins infirmier. Inspection General de la Santé (IGS) a l'attribution de verifier la gestion des activités de l'ensembles des services du departement et des organes sous tutelles, et leurs conformité aux lois et reglement en vigeur cf voir organigramme du ministere de la sante qui se trouve dans le site web du ministere.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.sante.gov.mr/?wpfb_dl=205
National level procurement: Yes Website: https://www.sante.gov.mr/?wpfb_dl=205

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Il existe un plan de passation des Marchés (search for the document admin07 in the specified website). Il existe le Centrale d'Achat des Médicaments, Equipements et Consommables Médicaux (CAMEC) en ce qui concerne la procuration des equipments medicaux: http://www.camec.mr/

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	3	0.77
Computerized Tomography Scanner:[α]	6	1.54
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	4	22.41
Radiotherapy:[β]	3	0.65

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction des Infrastructures, du Materiel et de la Maintenance. Unit website: https://www.sante.gov.mr/?page_id=34
Contact name: Mr. Roughaya Habott Contact email: hroughaya@yahoo.fr
Website with publically available technical specifications: https://www.sante.gov.mr/?p=2094
Number of regional/state offices/units: 5

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Un inventaire technique national etait diponible dans une base de donnée informatisée (GMAO) qui est malheusement deectueuse depuis 2004, et qui n'a jamais été actualisé au niveau national.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Mr. Roughaya Habott
Email: hroughaya@yahoo.fr

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Charlotte Faty Ndiaye
Email: ndiayechar@who.int

Name: Mme. Aminata Sakho Kelly
Email: kellyas@who.int

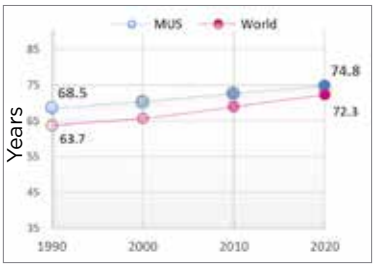
General comments (...Annex 1):

Le suivi de la maintenance des équipements est une mission confiée à la Direction des Infrastructures, du Matériel et de la Maintenance (DIMM) et mis en œuvre par le service de la Maintenance. Le service de la maintenance comprend deux divisions :- Division de la maintenance des infrastructures;- Division de la maintenance des équipements et des matériels. Le service de la maintenance dispose d'un plateau technique composé, au niveau central de 7. techniciens biomédicaux, de 2 ingénieurs biomédicaux et d'un ingénieur électrotechnicien, au niveau périphérique de : 5 unités régionale, qui assurent une maintenance de proximité. La qualité du service est insuffisante dans la quasi-totalité des structures de maintenance lié à la perception même de la composante maintenance, qui n'est généralement pas prise en compte lors de l'élaboration

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Mauritius

Country indicators - WHO country information

Population 000s (rank):[a]	1,272 (153)	Under-five mortality (per 1000 live births):[d]	16.52	UHC - Service coverage index (1-100):[h]	65
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	23.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	8.9% (1.8%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.8 (0.69): very high	Global innovation index (rank):[j]	34.4 (52)
		ICT Development Index (rank):[g]	5.9 (72)	High-technology exports (% of manufacture exports):[k]	2.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Equipment Committee under chairmanship of Director of the Health Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Approved devices lists comments (...Annex 1):

Some lists are available for certain specific conditions e.g pandemic, fogging, sprayers, etc. (an specific Plan is in preparation), there are no specific lists for non-comunicable nor communicable diseases. It must be pointed out that the Ministry

Health care facilities lists comments (...Annex 1):

—

Specific lists comments (...Annex 1):

Some lists are available for certain specific conditions e.g Pandemic, fogging, sprayers, etc. There is no specific list for Communicable Diseases but a PLAN is in preparation.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): http://www.camec.mr/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation Safety and Nuclear Security Authority (under the aegis of the Ministry of Energy and Public Utilities).

Other agency's website: https://rsnsa.govmu.org/Pages/default.aspx

National regulatory comments (...Annex 1):

Radiation Protection Authority for Radiation.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
We import all our devices.

Medical device incorporation

Procurement

Policy or guideline: No Website: http://www.camec.mr/index.php/appels-d-offre
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
Central Procurement Board has a policy. However, there is an equipment committee which looks after procurement of equipment spare parts. For public sectorn procurement is done at a level of the Ministry of Health and the central procurement board. Private equipment is done by direct purchase. In the public sector, we recommend certification based on the FDA, CE and TUV approved systems.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	6	4.82
Computerized Tomography Scanner:α	8	6.43
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	3	2.41
Mammograph:α,*	7	49.68
Radiotherapy:β	4	3.14

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: SSR National Hospital. Unit website: —
Contact name: Dr. Bissoondoyal Contact email: kbissoondoyal@mail.gov.mu
Website with publically available technical specifications: —
Number of regional/state offices/units: 5

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Locally developed.

Software comments (...Annex 1):
Each hospital has a separate inventory. Concerning Software there is one developed locally which is currently on trial. E-health is in preparation.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):
Name: —
Email: —

Name: Dr. Bissoondoyal
Email: kbissoondoyal@mail.gov.mu

WHO Country officer(s):
Name: Dr. Laurent Musango
Email: musangol@who.int

Name: —
Email: —

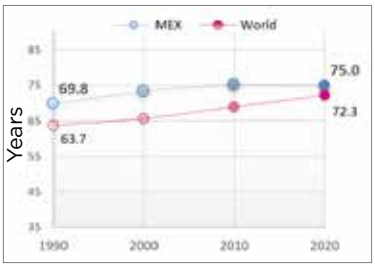
General comments (...Annex 1):

Concerning the HT national police it is stated in following document: politique santé.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Mexico

Country indicators - WHO country information

Population 000s (rank):[a]	128,933 (10)	Under-five mortality (per 1000 live births):[d]	13.67	UHC - Service coverage index (1-100):[h]	74
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	15.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.6% (0.2%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (0.61): high	Global innovation index (rank):[j]	33.6 (55)
		ICT Development Index (rank):[g]	5.2 (87)	High-technology exports (% of manufacture exports):[k]	20.40%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.gob.mx/cms/uploads/attachment/file/570535/PROGRAMA_Sectorial_de_Salud_2020-2024.pdf; https://www.gob.mx/salud%7Ccenetec/articulos/compendio-de-normas-oficiales-mexicanas-relacionadas-con-infraestructura-y-equipamiento-medico?idiom=es

Language(s): Español

Ministry of health responsible for health technology policy implementation: Centro Nacional de Excelencia Tecnológica en Salud.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Consejo de Salubridad General.

Website: http://www.csg.gob.mx/index.html
http://www.csg.gob.mx/Compendio/CNIS/cnis.html
http://www.csg.gob.mx/contenidos/priorizacion/cuadro-basico.html

Nomenclature systems used for devices and tests: National.

Approved devices lists comments (...Annex 1):
See "cuadro básico". The list is under new policies.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.gob.mx/salud/acciones-y-programas/biblioteca-virtual-dgplades; www.gob.mx/cms/uploads/attachment/file/35887/NOM-016-SSA3-2012.pdf

Website - laboratories: http://www.csg.gob.mx/descargas/pdf/priorizacion/cuadro-basico/aux_diag/catalogo/2017/EDICION_2017_CByC-AUX_DE_DIAGNOST.pdf

Nomenclature systems used for devices and tests: Nationally developed.

Health care facilities lists comments (...Annex 1):
The lists are updated constantly.

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.gob.mx/salud; https://www.gob.mx/salud/acciones-y-programas/areas-de-la-subsecretaria-de-prevencion-de-la-salud; http://sinaiscap.salud.gob.mx:8080/DGIS/; https://www.gob.mx/insabi/documentos/66-intervenciones?idiom=e

Specific lists comments (...Annex 1):
–

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Centro Nacional de Excelencia Tecnológica en Salud.

Website(s): https://www.gob.mx/salud/cenetec; http://www.cenetec.salud.gob.mx/descargas/detes/ETES_GuiaEvalClinicaDM_16_SPC_10_08_17.pdf; www.gob.mx/cms/uploads/attachment/file/293843/Guia_para_la_Evaluacion_Economica_de_Dispositivos_Medicos.pdf

Contact: Dr. Esteban Hernández San Román Email: esteban.hernandez@salud.gob.mx

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):
–

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS).

Website(s): https://www.gob.mx/cofepris

Contact: Alejandro Ernesto Svarch Pérez Email: asvarch@cofepris.gob.mx

Name(s) of other regulatory agency eg. for radiation equipment etc.: Comisión Nacional de Seguridad Nuclear y Salvaguardas.

Other agency's website: https://www.gob.mx/cnsns; https://www.gob.mx/cofepris; https://www.gob.mx/ineel;

National regulatory comments (...Annex 1):
–

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For various purposes
Website: –

Nomenclature comments (...Annex 1):
The nomenclature system is established and organized in charts for health technologies that can be used in public/social health services. As for the government administration for 2018-2024, the charts will be organized as a compendium and it is in the process of depuration.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: www.gob.mx/medico-e-instrumental-quirurgico-enestablecimientos; www.gob.mx/salud/cenetec/acciones-y-programas/certificado-de-necesidad-de-equipo-medico-278658; www.gob.mx/cms/uploads/attachment/file/601858/IB_Actualizacion_CDNEM_12dic2020.pdf; http://dof.gob.mx/5475093/2017; www.csg.gob.mx/GuiaBioeticaTriaje_30_Abril_2020_7pm.pdf
National level procurement: Yes Website: https://www.gob.mx/salud/cenetec/acciones-y-programas/direccion-de-ingenieria-biomedica; https://www.gob.mx/salud/cenetec/acciones-y-programas/certificado-de-necesidad-de-equipo-medico-278658; www.gob.mx/IB_Actualizacion_CDNEM_12dic2020.pdf; http://dof.gob.mx/5475093&fecha=02/03/2017

Medical device incorporation comments (...Annex 1):
There are some recommendations for this topic, but they are not policies. The specifications are only recomendations.

Donations

Policy or guideline: Yes Website: https://www.dof.gob.mx/nota_detalle.php?codigo=5571017&fecha=02/09/2019

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: www.gob.mx/salud/cenetec/acciones-y-programas/cedulas-de-especificaciones-tecnicas-para-equipo-medico

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	316	2.45
Computerized Tomography Scanner:[α]	793	6.15
Positron Emission Tomography Scanner:[α]	31	0.24
Gamma camera or nuclear medicine:[α]	115	0.89
Mammograph:[α,*]	1449	129.17
Radiotherapy:[β]	240	1.86

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Dirección de Ingeniería Biomédica. Unit website: https://www.gob.mx/salud/cenetec/acciones-y-programas/direccion-de-ingenieria-biomedica; http://www.csg.gob.mx/contenidos/priorizacion/cuadro-basico/iyem/actualizaciones.html# http://www.dgplades.salud.gob.mx/
Contact name: Dr. Oscar René Marrufo Melendez Contact email: oscar.marrufo@salud.gob.mx
Website with publically available technical specifications: www.gob.mx/salud/acciones-y-programas/cenetec-salud-cedulas-de-especificaciones-tecnicas-de-equipo-medico; www.csg.gob.mx/contenidos/priorizacion/cuadro-basico/iyem/catalogos.html
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: Other
Website: http://sinaiscap.salud.gob.mx:8080/DGIS
Use of management software: Yes Software name: There are not only one, in general these are made in each one of the units for their particular needs.

Software comments (...Annex 1):
Subsistema de Información de Equipamiento, Recursos Humanos e Infraestructura para la Atención a la Salud (Subsystem of Equipment, Human Resources and Infraestructure in Health). There are not only one, in general these are made in each one of the units for their particular needs.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 3000

Contacts

National officer(s):
Name: Mtra. Dafne Ruiz Vargas
Email: dafne.ruiz@salud.gob.mx

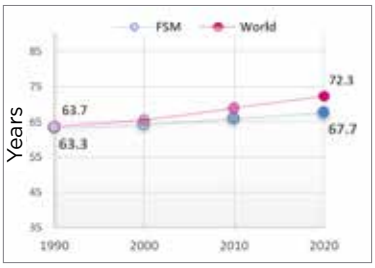
WHO Country officer(s):
Name: Dr. Miguel Malo Serrano
Email: malom@paho.org

General comments (...Annex 1): –

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Micronesia (Federated States of)

Country indicators - WHO country information

Population 000s (rank):[a]	115 (178)	Under-five mortality (per 1000 live births):[d]	24.65	UHC - Service coverage index (1-100):[h]	48
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	46.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.62 (—): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1):
There are no lists available.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
The unit of Budget and Planning with the department of finance and administration (DOFA) performs economic analysis, however, there is no HTA for medical products.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Medical devices may be purchased by the National Department of Health & Social Affairs, or the State Health Services. At a national level purchases are made by the coordinator of the program receving the grant or funds for the purchase in consultation with the department to receive the device (e.g. manager of state hospital radiography department, or chief of ancillary services). Guidelines are only for competitive quotes or bidding processes.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	1	8.7
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	0	0
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: No Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
The National Department of Health and Social Affairs, as well as state health services, keep assets registries for fixed assets over $1,000. Medical Devices will be included on these registers. Individual units (e.g. state laboratory) should have a functional inventory of devices/equipment.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Ms. Lisa Barrow Kohler
Email: lbarrow@fsmhealth.fm

Name: Mr. Andy Wilson
Email: awilson@fsmhealth.fm

WHO Country officer(s):
Name: Dr. Momoe Takeuchi
Email: takeuchim@who.int

Name: —
Email: —

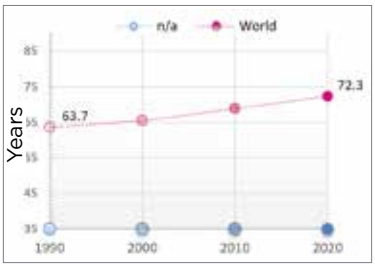
General comments (...Annex 1):

There is limited expertise in the country. There are no qualified radiographers nor pathologists. Only 3 over 30 laboratory technicians have a bachelors degree in medical laboratory science.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Monaco

Country indicators - WHO country information

Population 000s (rank):[a]	39 (188)	Under-five mortality (per 1000 live births):[d]	3.02	UHC - Service coverage index (1-100):[h]	85
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	—	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	— (—):	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	8.1 (19)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): There are "Plans d'urgence".

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-Sanitaire

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): La Direction de l'Action Sanitaire pourrait commander évaluations des technologies de Santé.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Direction de l'Action Sanitaire et Sociale.

Website(s): https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-Sanitaire

Contact: Ms. Anne Negre Email: dass@gouv.mc

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For regulatory purposes
Website: https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-et-de-l-Aide-Sociales

Nomenclature comments (...Annex 1):
Directive 93/42/CEE.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Procurement guidelines: marquage CE requis.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	5	132.17
Computerized Tomography Scanner:[α]	5	132.17
Positron Emission Tomography Scanner:[α]	1	26.43
Gamma camera or nuclear medicine:[α]	1	26.43
Mammograph:[α,*]	2	599.3
Radiotherapy:[β]	2	51.28

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Département des Affaires Sociales et de la Santé. Unit website: —
Contact name: Ms. Anne Eastwood. Contact email: aeastwood@gouv.mc
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Pas d'inventaire.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Ms. Anne Negre
Email: dass@gouv.mc

Name: Ms. Anne Eastwood.
Email: aeastwood@gouv.mc

WHO Country officer(s):
Name: —
Email: —

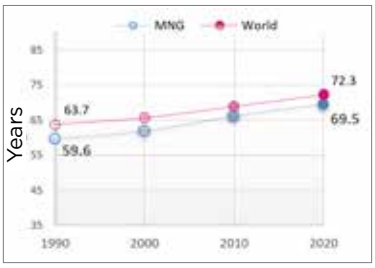
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Mongolia

Country indicators - WHO country information

Population 000s (rank):[a]	3,278 (133)	Under-five mortality (per 1000 live births):[d]	15.37	UHC - Service coverage index (1-100):[h]	63
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	35.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.4% (0.5%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.74 (0.63): high	Global innovation index (rank):[j]	33.4 (58)
		ICT Development Index (rank):[g]	5 (91)	High-technology exports (% of manufacture exports):[k]	18.90%

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): Mongolian
Ministry of health responsible for health technology policy implementation: Department of Strategic Policy and Planning.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: — Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	4	1.41
Computerized Tomography Scanner:[α]	23	8.1
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	2	0.7
Mammograph:[α,*]	6	33.26
Radiotherapy:[β]	6	1.83

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 240

Contacts

National officer(s):
Name: Ms. Bulgansuren
Email: bulgan_21@yahoo.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Sergey Diorditsa
Email: diorditsas@who.int

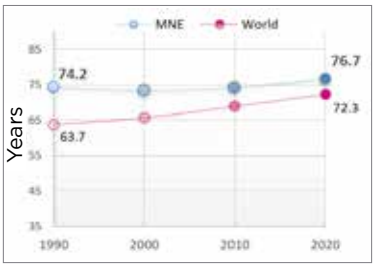
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Montenegro

Country indicators - WHO country information

Population 000s (rank):[a]	628 (162)	Under-five mortality (per 1000 live births):[d]	2.39	UHC - Service coverage index (1-100):[h]	67
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	10.3% (0.8%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.83 (0.75): very high	Global innovation index (rank):[j]	35.4 (49)
		ICT Development Index (rank):[g]	6.4 (61)	High-technology exports (% of manufacture exports):[k]	3.20%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.mzdravlja.gov.me/rubrike/strategija-razvoja-zdravstva-crne-gore/97487/MASTER-PLAN-RAZVOJA-ZDRAVSTVA-CRNE-GORE-ZA-PERIOD-2010-2013.html

Language(s): Montenegrin

Ministry of health responsible for health technology policy implementation: Unit for Management in Health Care.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Health Insurance Fond.

Website: http://www.mup.gov.me/biblioteka/strategije

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://mzdravlja.gov.me/ministarstvo

Website - laboratories: https://www.cinmed.me/Portal/faces/PretragaS?_adf.ctrl-state=feepi92qs_4&_afrLoop=7290369444662547

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: http://www.mup.gov.me/biblioteka/strategije

Approved devices lists comments (...Annex 1):

There is a list of medical devices (based on the opinion of a team of doctors) that are provided or reimbursed to the patient by the Health Insurance Fond. The list is created as a result of different indications mostly for treatment,

Health care facilities lists comments (...Annex 1):

—

Specific lists comments (...Annex 1):

There are no national standards for medical devices, but Competent Authority, in accordance with the law on medical devices recognize appropriate international standards (EC, ISO). There is the Law on Protection of Population against

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=7024818723742526&paramPut=Legislation++%3E++Instructions&paramRender=2&paramS=96&_adf.ctrl-state=3rt6t7bsn_177

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

There is no HTA framework yet, but positive political will.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Agency for Medicines and Medical Devices of Montenegro, Department for medical devices.

Website(s): https://www.cinmed.me/Portal/faces/dinamickeStrane?_adf.ctrl-state=1720yojvsi_112; http://calims.me/Portal/faces/glavna.jspx?_afrWindowMode=0&_afrLoop=180937849278149018_adf.ctrl-state=17pyrlqel8_92

Contact: Ms. Erna Sehovic Email: erna.sehovic@calims.me

Name(s) of other regulatory agency eg. for radiation equipment etc.: Environmental Protection Agency of Montenegro.

Other agency's website: —

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For regulatory purposes
Website: https://www.calims.me/Portal/Definitions+and+Classification&paramRender=2&paramS=70&_adf.ctrl-state=wn7tyvskh_894

Nomenclature comments (...Annex 1):
"Register (notification) of medical devices" that contains information on medical devices which are available for use in Montenegro has just recently been set up. As it is at the start of its operations, it will use GMDN as a referent nomenclature system and based on this, it will be developed a system that will be in Montenegrin language so that all users can use it properly and they will

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.calims.me/Portal/&putanja=Law+on+amendments +to+the+Law+on+medical+devices_2009.pdf https://www.calims.me/Portal//Fees_medical+devices_CALIMS_2009.pdf https://www.calims.me/Portal/faces/Zakon+o+medicinskim+sredstvima.pdf
National level procurement: Yes Website: https://www.calims.me/Portal/medical+device+in+the+register+of+medical+devices.pdf&; https://www.calims.me/Portal/medical+devices+-+May+2018.pdf; https://www.calims.me/Portal/faces/manufacturers+into+the+register.pdf&_adf.ctrl-state=wn7tyvskh_496

Medical device incorporation comments (...Annex 1):
The procurements of medical devices for public health institutions are in conformity with Law on public procurements. We recognize international standards in accordance with a law on medical devices.

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.calims.me/Portal/faces/Guidelines&paramRender=null&paramS=99&_adf.ctrl-state=wn7tyvskh_360

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	2	3.22
Computerized Tomography Scanner:[α]	10	16.09
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	1	1.61
Mammograph:[α,*]	15	196.48
Radiotherapy:[β]	4	6.37

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: Healh Insurance Fond. Unit website: https://fzocg.me/page.php?type=novost&id=320
Contact name: — Contact email: —
Website with publically available technical specifications: https://fzocg.me/Administracija/Documents/1589285931Politika%20sistema%20upravljanja%20kvalitetom%20i%20sigurnosti%20informacija.pdf
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologyes (such as MRI, CT, or PET scanners)
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
There are no specific national inventories but every year the Government of Montenegro provides a specific amount of money that can be used in special cases (public health emergency etc.).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 15

Contacts

National officer(s):
Name: Ms. Erna Sehovic
Email: erna.sehovic@calims.me

Name: Ms. Majda Sahman
Email: majda.sahman@calims.me

WHO Country officer(s):
Name: Ms. Mina Brajovic
Email: brajovicm@who.int

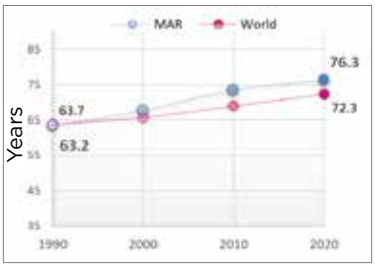
General comments (...Annex 1):

Concerning the Infrastructure section: We would like to inform you that we have specialized hospitals for only one speciality as psychiatric, orthopaedic and lungs diseases. We have 3 institutions like this.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Morocco

Country indicators - WHO country information

Population 000s (rank):[a]	36,911 (40)	Under-five mortality (per 1000 live births):[d]	18.69	UHC - Service coverage index (1-100):[h]	73
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.69 (—): medium	Global innovation index (rank):[j]	29 (75)
		ICT Development Index (rank):[g]	4.8 (100)	High-technology exports (% of manufacture exports):[k]	4.90%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): Français

Ministry of health responsible for health technology policy implementation: Department of Equipe Medicale (DEM) within MoH.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Des listes standardisées de dispositifs médicaux pour différents établissements de soins sont établies au niveau de la DEM.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1):

Concernant les points “b” et “c” des listes sont établies au niveau de la DEM. La DELM prend en charge les points “a” et “b” aussi (see comments of other lists).

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

Adopted EMA (European Medicines Agency) and ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH, HTA is focused on pharmaceutics but not in medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: Ministère de la Santé.

Website(s): https://www.sante.gov.ma/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation Safety and Nuclear Security Authority (Ministry of Energy and Public Utilities)and Moroccan Agency for Nuclear and Radiological Safety and Security (AMSSNuR).

Other agency's website: https://amssnur.org.ma/; http://dmp.sante.gov.ma/

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: Not specified

Website: —

Nomenclature comments (...Annex 1):
Nomenclature basée sur l'ECRI et le CNEH.

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: No

Website: —

Medical device incorporation comments (...Annex 1):
Un projet de mise en place d'une stratégie Nationale en matière de gestion des T.S est en cours. Les spécifications techniques sont établies selon les besoins des utilisateurs (grands projets de CHUs) et standardisées pour chaque type d'établissement de soins.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	12	0.36
Computerized Tomography Scanner:[α]	40	1.21
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	44	18.46
Radiotherapy:[β]	52	1.41

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 16

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: Yes Software name: Up Manager Praxis.

Software comments (...Annex 1):
La majorité des inventaires des régions sont sur support papier et non encore informatisé. L'alimentation de la base de données du progiciel de gestion des dispositifs médicaux est en cours.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):

Name: Ms. Nadia Gaagouch

Email: nadia.gaagouch@gmail.com

Name: —

Email: —

WHO Country officer(s):

Name: Ms. Maryam Bigdeli

Email: BigdeliM@who.int

Name: —

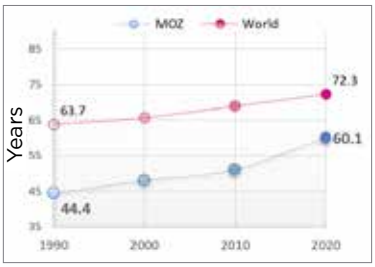
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Mozambique

Country indicators - WHO country information

Population 000s (rank):[a]	31,255 (46)	Under-five mortality (per 1000 live births):[d]	70.55	UHC - Service coverage index (1-100):[h]	47
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	30.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.6% (0.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.46 (0.32): low	Global innovation index (rank):[j]	18.7 (124)
		ICT Development Index (rank):[g]	2.3 (150)	High-technology exports (% of manufacture exports):[k]	5.60%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): Portuguese

Ministry of health responsible for health technology policy implementation: Direcção Nacional Assistência Médica.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: No

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
The Department of Health Information (DIS), Ministry of Health (MISAU), performs HTA for technologies related to prevention and control of diseases, but no specifically for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: Direction des Equipements et de la Maintenance, Ministère de la Santé.

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: National Atomic Energy Agency of Mozambique and the International Atomic Energy Agency (IAEA).

Other agency's website: https://www.iaea.org/newscenter/news/iaea-advises-mozambique-on-strengthening-regulatory-infrastructure

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	1	0.03

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: Centro de Abastecimiento. Unit website: —
Contact name: Dr. Ernesto Mazivilla Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: Yes Software name: Simorganizer.

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Mr. Amisse Momade
Email: amisse.momade@gmail.com

Name: Dr. Ernesto Mazivilla
Email: alessandro.campione@gmail.com

WHO Country officer(s):
Name: Dr. Severin Ritter Von Xylander
Email: xylanders@who.int

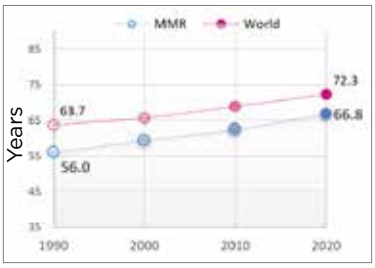
Name: Dr. Ana Fernandes
Email: fernandesa@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Myanmar

Country indicators - WHO country information

Population 000s (rank):[a]	54,410 (26)	Under-five mortality (per 1000 live births):[d]	43.65	UHC - Service coverage index (1-100):[h]	61
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	14.4% (2.8%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.58 (—): medium	Global innovation index (rank):[j]	17.7 (129)
		ICT Development Index (rank):[g]	3 (135)	High-technology exports (% of manufacture exports):[k]	2.80%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: www.mohs.gov.mm

Language(s): Myanmar and English

Ministry of health responsible for health technology policy implementation: Department of Food and Drug Administration, Department of Medical Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: Yes

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Department of Food and Drug Administration, Department of Medical services.

Website(s): www.mohs.gov.mm

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): It has started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Department of Food and Drug Administration.

Website(s): https://www.mohs.gov.mm/
http://www.fdamyanmar.gov.mm/
https://www.fda.gov.mm/?s=medical+devices

Contact: Dr. NweOo Email: drnweoo1980@gmail.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: Food and Drug Administration, Myanmar (Medical devices); Association of Southeast Asian Nations (ASEAN).

Other agency's website: https://www.fda.gov.mm/?s=medical+devices

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: www.mohs.gov.mm
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
The Procurement and Distribution Division, Department of Medical Services is in charge of procurement at a national level.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	13	0.24
Computerized Tomography Scanner:α	44	0.81
Positron Emission Tomography Scanner:α	2	0.04
Gamma camera or nuclear medicine:α	7	0.13
Mammograph:α,*	11	2.16
Radiotherapy:β	29	0.53

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Medical Services. Unit website: www.mohs.gov.mm
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
In some cases, there is an inventory only for high cost technologies (such as MRI, CT or PET scanners).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Dr. NweOo
Email: drnweoo1980@gmail.com

Name: Dr. Soe Aung
Email: drsoeaung@gmail.com

WHO Country officer(s):
Name: Dr. Stephan Paul Jost
Email: josts@who.int

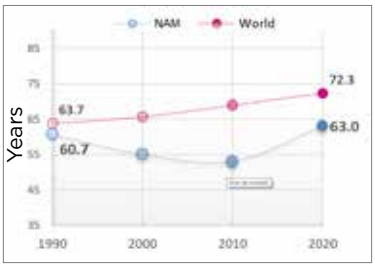
Name: Dr Thushara Eraj Indranath Fernando
Email: fernandot@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Namibia

Country indicators - WHO country information

Population 000s (rank):[a]	2,541 (139)	Under-five mortality (per 1000 live births):[d]	40.16	UHC - Service coverage index (1-100):[h]	62
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.65 (0.42): medium	Global innovation index (rank):[j]	22.5 (104)
		ICT Development Index (rank):[g]	3.9 (118)	High-technology exports (% of manufacture exports):[k]	0.20%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://mhss.gov.na/home
https://mhss.gov.na/procurement

Language(s): English

Ministry of health responsible for health technology policy implementation: Directorate of Tertiary Health Care & Clinical Support Services (THC & CSS).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://mhss.gov.na/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
MoH uses HTA for both regulatory and coverage purposes. Not performed for medical devices. However, an HTA has yet to be elevated to the national agenda. There is a written HTA. guideline, and formal identification of technologies for HTA.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Namibia Medicines Regulatory Council.

Website(s): https://nmrc.gov.na/

Contact: Mr. Axel Tibinyane Email: atibinyane@mhss.gov.na

Name(s) of other regulatory agency eg. for radiation equipment etc.: Directorate of Atomic Energy & Radiation Protection Authority.

Other agency's website: https://mhss.gov.na/home

National regulatory comments (...Annex 1):
According to the Atomic Energy and Radiation Protection Act No. 5 of 2005.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://mhss.gov.na/procurement-act
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: https://mhss.gov.na/

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
There are guidelines for Implementation of the National Health care Technology Policy & Medical Equipment Management. Since finances have been decentralised, each of the 13 political regions is responsible for budgeting and procuring medical equipment for the health facilities in that region. Advise on budgeting and tender specifications can be obtained from MEM at a National Level.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	2	0.87
Computerized Tomography Scanner:α	11	4.78
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	2	0.87
Mammograph:α,*	5	42.3
Radiotherapy:β	3	1.18

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Atomic Energy & Radiation Protection. Unit website: —
Contact name: Mr. A. Tibinyane Contact email: atibinyane@mhss.gov.na
Website with publically available technical specifications: —
Number of regional/state offices/units: 4

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Medical Equipment Management System Software (MEMS).

Software comments (...Annex 1):
Medical Equipment Management System Software (MEMS).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Ms. Belinda Woelbling
Email: bwolbling@mhss.gov.na

Name: Mr. A. Tibinyane
Email: atibinyane@mhss.gov.na

WHO Country officer(s):
Name: Dr. Charles Sagoe-Moses
Email: sagoemosesc@who.int

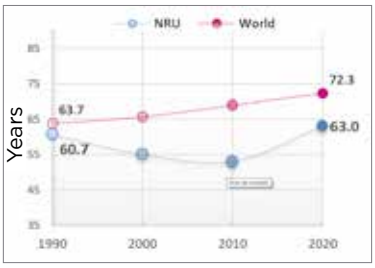
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Nauru

Country indicators - WHO country information

Population 000s (rank):[a]	11 (193)	Under-five mortality (per 1000 live births):[d]	28.49	UHC - Service coverage index (1-100):[h]	54
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	—	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	— (—):	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1):
SPC assist us with our supplies for the Pandemic preparedness but we do not have a list as most of these are consumables.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
—

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The procurement for the medical devices is based on the Hospital's Senior Management Team decision and the availability of the fund.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
We keep an asset register at the Administration Office and the Pharmaceutical Store which include all the medical equipment in the hospital.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Dr. Alani Tangitau
Email: alani.tangitau@nauru.gov.nr

Name: Mr. Jiosese Mailulu
Email: jiosese.mailulu@nauru.gov.nr

WHO Country officer(s):
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

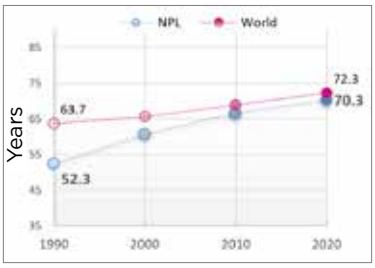
Name: Dr. Subhash Yadav
Email: syadav@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Nepal

Country indicators - WHO country information

Population 000s (rank):[a]	29,137 (49)	Under-five mortality (per 1000 live births):[d]	28.16	UHC - Service coverage index (1-100):[h]	53
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	10.7% (2.4%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.6 (0.45): medium	Global innovation index (rank):[j]	24.4 (95)
		ICT Development Index (rank):[g]	2.9 (140)	High-technology exports (% of manufacture exports):[k]	1.20%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://mohp.gov.np/uploads/Resources/1657873750667Health-Care-Technology-Policy.pdf
https://www.dda.gov.np/content/health-technology-product-an-medical-device-directive-2074

Language(s): English

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: http://182.93.95.152/tsb/

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There are identified HTA activities but not national unit per se. However, there is research in the health unit within the MoH. The HTA under the government umbrella is in progress and a requirement to reach the Universal Health Care country goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: Department of Health Services and Logistics Management Division.

Website(s): https://www.dda.gov.np/content/role-of-dda

Contact: Dr. Mingmar G. Sherpa Email: doctor_mingma@hotmail.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministry of Health and Population (MoHP).

Other agency's website: https://mohp.gov.np/en

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No
Type: More than one system Use: For various purposes
Website: —

Nomenclature comments (...Annex 1):
—

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
We follow the Public Procurement Act and the regulation of Nepal for procurement of medical devices also. Also, it is partially carried out at national level procurement of medical devices.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	11	0.38

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: Logistic Management Section – Department of Health Services Unit website: https://dohs.gov.np/logistic-management-section/
Contact name: Dr. Mingmar G. Sherpa Contact email: doctor_mingma@hotmail.com
Website with publically available technical specifications: http://182.93.95.152/tsb/
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: Yes Software name: Web-based LMIS web based equipment/instrument, Inventory Management System.

Software comments (...Annex 1):
Working on to develop national inventories.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: Dr. Mingmar G. Sherpa
Email: doctor_mingma@hotmail.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Rajesh Pandav
Email: pandavr@who.int

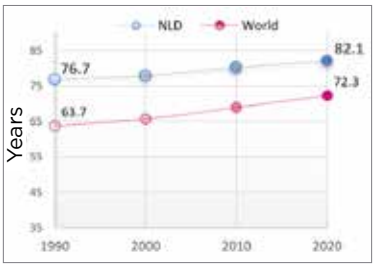
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Netherlands

Country indicators - WHO country information

Population 000s (rank):[a]	17,135 (68)	Under-five mortality (per 1000 live births):[d]	4.16	UHC - Service coverage index (1-100):[h]	86
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.94 (0.88): very high	Global innovation index (rank):[j]	58.8 (5)
		ICT Development Index (rank):[g]	8.5 (7)	High-technology exports (% of manufacture exports):[k]	23.10%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.rijksoverheid.nl/documenten/kamerstukken/2019/04/26/kamerbrief-over-visie-op-medische-technologie
https://www.government.nl/topics/health-insurance/documents/leaflets/2016/02/09/healthcare-in-the-netherlands
https://www.rivm.nl/en/medical-devices
https://www.eerstekamer.nl/wetsvoorstel/35043_wet_medische_hulpmiddelen

Language(s): Dutch

Ministry of health responsible for health technology policy implementation: Department Pharmaceutical Affairs and Medical Technology.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: Department of Pharmaceutical Affairs and Medical Technology.

Website: https://english.igj.nl/medical-technology/market-authorisation/registration-and-deregistration

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
The health insurance scheme takes care of the reimbursement of extramural medical devices in the Netherlands. The reimbursement of medical devices is function orientated.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: https://www.eerstekamer.nl/eu/documenteu/2017/745_verordening_van_het_europees/f=/vkxleq2mblth.pdf

Website - laboratories: https://www.eerstekamer.nl/eu/documenteu/2017/746_verordening_betreffende/f=/vkxlera1orfl.pdf

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):
In the Netherlands, the professional has to decide, recommend or indicate a medical device. The cupola of the professionals can publish a guideline for specific procedures. There is no national policy on diseases or situations.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Zorginstituut.

Website(s): http://www.zorginstituutnederland.nl/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):
—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of Health, Welfare and Sport, Department of Pharmaceutical Affairs and Medical Technology.

Website(s): https://www.rijksoverheid.nl/onderwerpen/medische-hulpmiddelen

Contact: Mr. Jan van Ginneken Email: j.v.ginneken@minvws.nl

Name(s) of other regulatory agency eg. for radiation equipment etc.: Dutch Healthcare Inspectorate; Authority for Nuclear Safety and Radiation Protection (ANVS).

Other agency's website: https://english.igj.nl/; www.anvs.nl

National regulatory comments (...Annex 1):
For vigilance and post market surveillance (more info in the medische-hulpmiddelen corresponding link).

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: —

Nomenclature comments (...Annex 1):

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:131:0017:0030:nl:PDF

Medical device incorporation comments (...Annex 1):

There is the Commission decision of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	203	11.85
Computerized Tomography Scanner:α	205	11.96
Positron Emission Tomography Scanner:α	40	2.33
Gamma camera or nuclear medicine:α	179	10.45
Mammograph:α,*	n/a	n/a
Radiotherapy:β	172	10.04

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: No Professionally trained biomedical/clinical engineers: No

Unit/Department: Health Care Insurance Board (CVZ). Unit website: http://www.gipdatabank.nl/ http://www.cvz.nl/

Contact name: Mr. J. A. C. van Ginneken Contact email: j.v.ginneken@minvws.nl

Website with publically available technical specifications: https://www.eerstekamer.nl/id/vhyxhx1knmz8/document_extern/w31469eg/f=/w31469eg.pdf https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX%3A32017R0746&from=EN

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1):

The Netherlands has no national inventory for medical devices.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 500

Contacts

National officer(s):

Name: Mr. Jan van Ginneken

Email: j.v.ginneken@minvws.nl

Name: Mr. J. A. C. van Ginneken

Email: j.v.ginneken@minvws.nl

WHO Country officer(s):

Name: —

Email: —

Name: —

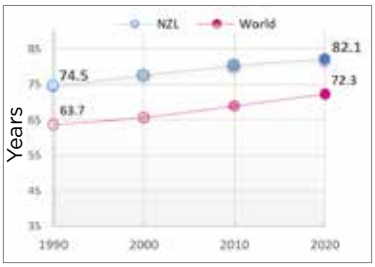
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

New Zealand

Country indicators - WHO country information

Population 000s (rank):[a]	4,822 (123)	Under-five mortality (per 1000 live births):[d]	4.72	UHC - Service coverage index (1-100):[h]	86
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.93 (0.86): very high	Global innovation index (rank):[j]	47 (26)
		ICT Development Index (rank):[g]	8.3 (13)	High-technology exports (% of manufacture exports):[k]	9.90%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Approved devices lists comments (...Annex 1):

Under New Zealand law there is no approval system for medical devices and hence no pre-market scrutiny of their safety and performance. There is a legal requirement for the sponsor (importer/exporter/supplier) of a medical device (with some exceptions) to notify the device to a database maintained by

Health care facilities lists comments (...Annex 1):

—

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

National Health Committee performs HTA in several areas, but not for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: The Medicines and Medical Devices Safety Authority (Medsafe), a business unit of the Ministry of Health.

Website(s): https://www.medsafe.govt.nz/regulatory/DevicesNew/3-2Explanation.asp

Contact: Ms. Susan Martindale Email: susan_martindale@moh.govt.nz

Name(s) of other regulatory agency eg. for radiation equipment etc.: Medicines and Medical Device Safety Authority (MedSafe).

Other agency's website: http://www.medsafe.govt.nz/

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN
Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
National requirements apply only to procurement of electro-medical devices through a set of AS/NZ standards such as AS/NZ3551:2004 which are mandated under a national law. Government publishes standards that are applicable to some devices.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	76	15.76
Computerized Tomography Scanner:[α]	76	15.76
Positron Emission Tomography Scanner:[α]	5	1.04
Gamma camera or nuclear medicine:[α]	18	3.73
Mammograph:[α,*]	97	162.36
Radiotherapy:[β]	36	7.47

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: Yes Software name: Hardcat, Tektrak and Beims.

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 26

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Corinne Reisinger Capuano
Email: CapuanoC@who.int

Name: —
Email: —

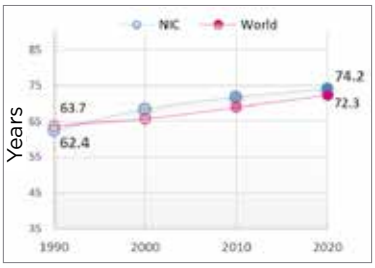
General comments (...Annex 1):

The definition of medical device used in NZ law (the Medicines Act 1981) is not currently aligned with the GHTF approach. Consequently, some products that are regarded as devices in other countries are currently regulated as medicines in NZ. Examples include pregnancy tests, condoms with spermicide, IUCDs with copper and nasal irrigation solutions.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Nicaragua

Country indicators - WHO country information

Population 000s (rank):[a]	6,625 (108)	Under-five mortality (per 1000 live births):[d]	16.04	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	15.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	14.8% (3.0%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.66 (0.51): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	3.3 (130)	High-technology exports (% of manufacture exports):[k]	1.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/repository

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.minsa.gob.ni/

Website - laboratories: http://www.minsa.gob.ni/index.php/repository/func-download/399/chk,be041b94ed602d617d517851511ca3b7/no_html,1/ http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Divisi%C3%B3n-General-de-Insumos-M%C3%A9dicos/Lista-B%C3%A1sica-de-Insumos/Lista-B%C3%A1sica-de-Insumos-de-Laboratorios/

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://www.minsa.gob.ni/index.php/repository/func-download/359/chk,850a55c3bca951031a3dc35ab94264a6/no_html,1/

Specific lists comments (...Annex 1): The Ministry of Health does not have lists recommending health technology for different diseases or situations.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There are identified HTA activities but not a national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Dirección General de Regulación Sanitaria.

Website(s): http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/repository

Contact: Lic. Luz María Torrez Email: dgrs@minsa.gob.ni

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: For regulatory purposes

Website: —

Nomenclature comments (...Annex 1):
For various reasons, there is not an official nomenclature system used for medical devices.

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: Yes Website: http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Divisi%C3%B3n-de-Adquisiciones/Normativas-y-Funciones/repository

Donations

Policy or guideline: Yes Website: http://www.minsa.gob.ni

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
The procurement department works as a team with the Health Services Department, the Sanitary Regulations Department and the Acquisition Unit of the Ministry of Health.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	0.16
Computerized Tomography Scanner:α	3	0.49
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	1	0.16
Mammograph:α,*	n/a	n/a
Radiotherapy:β	6	0.91

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Dirección General de Regulación Sanitaria. Unit website: http://www.minsa.gob.ni

Contact name: Lic. Luz María Torrez Contact email: dgrs@minsa.gob.ni

Website with publically available technical specifications: http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Normativa-064%E2%80%9CNorma-para-el-registro-de-dispositivos-m%C3%A9dicos%E2%80%9D/

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):
This inventory was carried out for the maintenance unit (CEMED). The last update was in 2009.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):

Name: Ms. Tatiana Valdez García

Email: didt01@minsa.gob.ni

Name: Lic. Luz María Torrez

Email: dgrs@minsa.gob.ni

WHO Country officer(s):

Name: Ing. Ana Solis-Ortega Treasure

Email: treasurea@paho.org

Name: Dr. Alexandre Florencio

Email: florencioa@paho.org

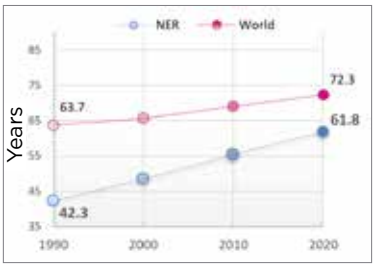
General comments (...Annex 1):

Our Ministry of Health is doing big efforts to normalize and regulate the procurement of medical devices, but we do require training for our personnel to perform a better job. We also have limitations in providing maintenance to the acquired equipment.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Niger

Country indicators - WHO country information

Population 000s (rank):[a]	24,207 (56)	Under-five mortality (per 1000 live births):[d]	77.52	UHC - Service coverage index (1-100):[h]	37
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	6.6% (1.9%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.39 (0.28): low	Global innovation index (rank):[j]	17.8 (128)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	3.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: Yes

Website - hospitals: https://hfr.health.gov.ng/resources https://hfr.health.gov.ng

Website - laboratories: https://www.health.gov.ng/index.php?option=com_content&view=article&id=130&Itemid=496

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

National regulatory comments (...Annex 1): —

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

Medical device nomenclature system

Official nomenclature system for medical devices: No
Type: More than one system Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
Il ya plusieurs types de codification testés. Les premières se sont inspirées du code CNEH (code national pour l'équipement hospitalier) français. Il n'ya pas de codification unique retenue au niveau national.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
Toutes les acquisitions réalisées dans le cadre des projets et programmes passent par la DIES. Mais certaines (ONG et associations caritaives) ne passent pas.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	0	0
Computerized Tomography Scanner:α	3	0.17
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	7	10.94
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction des Infrastructures et Equipements Sanitaires. Unit website: —
Contact name: Mr. Moumouni Alhassane Contact email: kouubii@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: 8

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Il ya eu plusieurs tentatives d'installation de logiciel de GMAO (Gestion de la Maintenance Assistée par Ordinateur) dont Gestmat (par la Société Deloitte et Touch Consulting) et OPTIM (par le Bureau BEEM Engineering France). Aucun logiciel n'est totalement fonctionnel en ce moment.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):
Name: Ms. Maman Kiassa Adamou
Email: kiassas@yahoo.fr

Name: Mr. Moumouni Alhassane
Email: kouubii@yahoo.fr

WHO Country officer(s):
Name: Dr. Blanche-Philomene Melanga Anya
Email: anyab@who.int

Name: —
Email: —

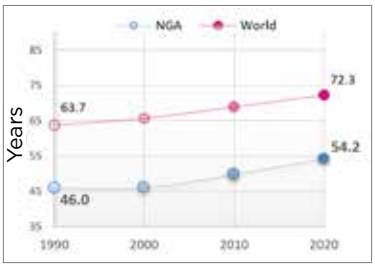
General comments (...Annex 1):

Le Niger dispose d'une stratégie nationale de maintenance adoptée depuis avril 2008.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Nigeria

Country indicators - WHO country information

Population 000s (rank):[a]	206,140 (7)	Under-five mortality (per 1000 live births):[d]	113.77	UHC - Service coverage index (1-100):[h]	44
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	15.1% (4.1%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.54 (0.35): low	Global innovation index (rank):[j]	20.1 (117)
		ICT Development Index (rank):[g]	2.6 (143)	High-technology exports (% of manufacture exports):[k]	1.50%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Food and Drug Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Nigeria Institute for Pharmaceutical Research and Development (NIPRD).

Website(s): https://www.niprd.gov.ng/
https://www.nhis.gov.ng/
https://www.nafdac.gov.ng/
https://health.gov.ng/doc/NSHDP%20II%20Final.pdf

Contact: — Email: information.niprd@niprd.gov.ng

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
Three organisms perform HTA at a national level: The Agency for Food and Drugs Administration and Control (NAFDAC), Nigeria Institute for Pharmaceutical Research and Development (NIPRD) and the National Health Insurance Scheme. (NHIS). The action plan 2018-2021 of the MoH states the progress to a National Quality Review & Health Technology Assessment Systems to determine which health interventions are cost effective including medical devices (see fourth link). HTA is a pliar for UHC's goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: National Agency for Food and Drug Administration and Control.

Website(s): http://www.nafdac.gov.ng/

Contact: Dr. Chinyere Ilonze Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: National Agency for Food and Drug Administration and Control (NAFDAC).

Other agency's website: http://www.nafdac.gov.ng/products/medicalsmenu

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	9	0.04

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Medical Devices Management and Standardization Unit. Unit website: —
Contact name: Mr. Esan Bukola Emmanuel Contact email: bukolaesan2000@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 280

Contacts

National officer(s):
Name: Mr. Esan Bukola Emmanuel
Email: bukolaesan2000@yahoo.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Walter Kazadi Mulombo
Email: kazadimulombow@who.int

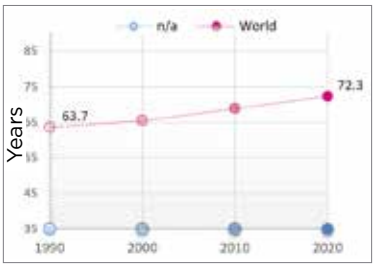
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Niue

Country indicators - WHO country information

Population 000s (rank):[a]	2 (194)	Under-five mortality (per 1000 live births):[d]	24.8	UHC - Service coverage index (1-100):[h]	55
World Bank income group:[b]	—	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	—	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	— (—):	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —
HTA unit/department includes the assessment of medical devices: —
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

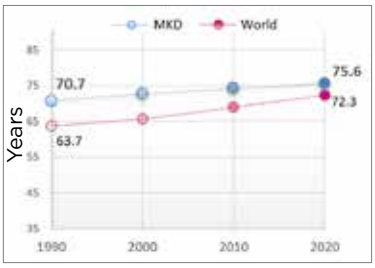
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

North Macedonia

Country indicators - WHO country information

Population 000s (rank):[a]	2,083 (144)	Under-five mortality (per 1000 live births):[d]	5.93	UHC - Service coverage index (1-100):[h]	68
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.77 (0.68): high	Global innovation index (rank):[j]	33.4 (57)
		ICT Development Index (rank):[g]	6 (69)	High-technology exports (% of manufacture exports):[k]	4.20%

National policy on health technology

Health technology (medical device) national policy: —

Policy is part of the National Health Program/Plan: —

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: www.fzo.org.mk

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

The reimbursement is performed by the National Health Insurance Fund, the list of medical devices that are reimbursed are posted on the "fzo website". In public health facilities the procurement is currently going through a public

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

There is not an HTA national unit yet per se but it has been acknowledged at a political level by the MoH. There are HTA activities for the selection of specific medicines. It exists a Centralized System for external price referencing and decentralized procurement prices of non-prescription medicines and devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Bureau of Drugs, Ministry of health is responsible for implementing the regulations for medical devices.

Website(s): www.zdravstvo.gov.mk

Contact: Ms. Katerina Aleksoska Email: katerina.aleksoska@zdravstvo.gov.mk

Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation Safety Directorate.

Other agency's website: https://www.iaea.org/sites/default/files/fyrm_nr-7th-rm.pdf

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
The GMDN code is being recognized.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	7	3.32
Computerized Tomography Scanner:[α]	13	6.17
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	2	0.95
Mammograph:[α,*]	20	79.81
Radiotherapy:[β]	5	2.4

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: —
Email: —

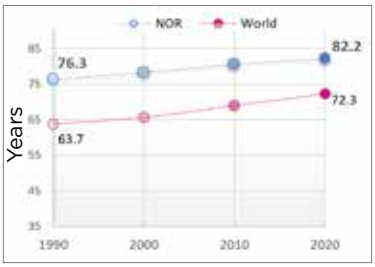
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Norway

Country indicators - WHO country information

Population 000s (rank):[a]	5,421 (117)	Under-five mortality (per 1000 live births):[d]	2.2	UHC - Service coverage index (1-100):[h]	86
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	8.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.96 (0.9): very high	Global innovation index (rank):[j]	49.3 (20)
		ICT Development Index (rank):[g]	8.5 (8)	High-technology exports (% of manufacture exports):[k]	22.60%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.regjeringen.no/no/dokumenter/meld-st-10-20122013/id709025/

Language(s): —

Ministry of health responsible for health technology policy implementation: The Department of Specialiced Health Care Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

A few devices - those being reimbursed via the blue prescription system i- are listed. Lists are made by The Norwegian Labour and Welfare Administration, refer to the procurement of medical devices at national level section.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.helsedirektoratet.no/tema/beredskap-og-krisehandtering

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Norwegian Knowledge Centre for the Health Services within Norwegian Institute of Public Health (NIH).

Website(s): https://www.fhi.no/en/qk/HTA/ https://helsedirektoratet.no/english

Contact: — Email: Folkehelseinstituttet@fhi.no

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

The system has two levels; a national level where decisions based on HTAs are made by the four regional health authorities in concert, and a local/"hospital-level" where decisions are made based on the mini-HTAs performed locally in each hospital. Pharmaceutics have to pass always by the national level. The Norwegian Knowledge Centre for the Health Services (member of the NIPH since 2016) do HTAs on selected

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Norwegian Directorate of Health, Department of Medical Devices and Medicinal Products.

Website(s): http://www.helsedir.no https://lovdata.no/dokument/SF/forskrift/2005-12-15-1690/*#&#x2a

Contact: Ms. Marit Endresen Email: meddev-no@helsedir.no

Name(s) of other regulatory agency eg. for radiation equipment etc.: Directorate of Health: Department of M;edical Devices and Medicinal Products.

Other agency's website: https://lovdata.no/dokument/SF/forskrift/2005-12-15-1690/*#&#x2a

National regulatory comments (...Annex 1):

The Directorate of Health, Department of medical devices and medicinal products is the Competent Authority for medical devices in Norway, it has the tasks of the competent authority as they are given in the European directives for medical devices. These tasks, however, are not identical with those listed under the corresponding ones of this survey.

-

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: For regulatory purposes

Website: —

Nomenclature comments (...Annex 1):
The use of GMDN is not imposed by law.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —

National level procurement: Yes Website: https://www.helfo.no/produkt-og-prislister/produkt-og-prislister?malgruppe=leverandor

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: No

Website: —

Medical device incorporation comments (...Annex 1):
Only procurement of devices being reimbursed via the blue prescription system is carried out at a national level, by The Norwegian Labour and Welfare Administration.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	55	10.15

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —

Unit/Department: Norwegian Knowledge center for the Health Care Services, Department for Evidence-based Health Care. Unit website: —

Contact name: Ms. Gro Jamtvedt and Ms. Inger Norderhaug Contact email: grj@nock.no

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —

Website: —

Use of management software: Yes Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):

Name: —

Email: —

Name: Ms. Gro Jamtvedt and Ms. Inger Norderhaug

Email: grj@nock.no

WHO Country officer(s):

Name: —

Email: —

Name: —

Email: —

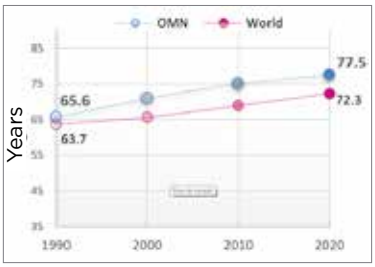
General comments (...Annex 1):

Concerning the HT national policy, it was provided the following document: plan van aanpak patientveiligheid medische technologie.pdf. Concerning the infrastructure section: As of 01.01.2009: 11 885 beds in specialised healthcare. 117 of these are in the private sector.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Oman

Country indicators - WHO country information

Population 000s (rank):[a]	5,107 (118)	Under-five mortality (per 1000 live births):[d]	11.01	UHC - Service coverage index (1-100):[h]	69
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.81 (0.71): very high	Global innovation index (rank):[j]	26.5 (84)
		ICT Development Index (rank):[g]	6.4 (62)	High-technology exports (% of manufacture exports):[k]	1.30%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Directorate of Medical Technologies.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1): Medical devices for specific procedures, whenever required, are prepared or modified based on the requirement from end users. Available at Directorate of Medical Technologies.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://www.moh.gov.om/en/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): Drug control, bulk procurement and distribution of drugs are managed by MoH. There are identified HTA activities but there is no national unit per se.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Directorate General of Medical Supply, Ministry of Health.

Website(s): https://www.moh.gov.om/web/directorate-general-of-medical-supplies

Contact: Engr. Rashid bin Hamdan Al Hajri, DMT. Email: ralhajri@omantel.net.om

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
—

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
The procurement guidelines are available at the Directorate of Medical Technologies.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	16	4.4
Computerized Tomography Scanner:α	25	6.88
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	4	1.1
Mammograph:α,*	15	149.75
Radiotherapy:β	3	0.59

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Directorate of Medical Technologies. Unit website: —
Contact name: Engr. Rashid bin Hamdan Al Hajri Contact email: ralhajri@omantel.net.om
Website with publically available technical specifications: —
Number of regional/state offices/units: 11

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Al Shifa.

Software comments (...Annex 1):
Available at the Directorate of Medical Technologies.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):
Name: Mr. Rashid Bin Hamdan Al Hajri
Email: ralhajri@omantel.net.om

Name: —
Email: —

WHO Country officer(s):
Name: Mr. Jean Yaacoub Jabbour
Email: jabbourj@who.int

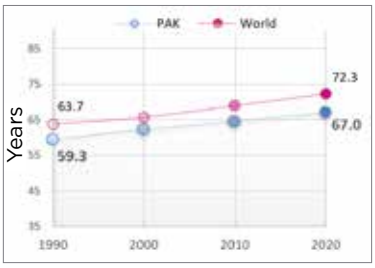
Name: Mrs. Reem Bou-Kamel
Email: boukamelr@oma.emro.who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Pakistan

Country indicators - WHO country information

Population 000s (rank):[a]	220,892 (5)	Under-five mortality (per 1000 live births):[d]	65.18	UHC - Service coverage index (1-100):[h]	45
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	29.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	4.5% (0.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.56 (0.38): medium	Global innovation index (rank):[j]	22.3 (107)
		ICT Development Index (rank):[g]	2.4 (148)	High-technology exports (% of manufacture exports):[k]	2.30%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.dra.gov.pk

Language(s): English

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: www.ppra.org.pk
https://www.dra.gov.pk

Specific lists comments (...Annex 1): The provinces develop their lists of equipment based on their health facilities, the available funds, and according to the Priced Vocabulary of Medical Stores (PVMS) (Available). World Health Organization Pakistan share such lists with the Ministry of Health at time of emergency.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Medical Devices and Medicated Cosmetics Division within the Drug Regulatory Authority.

Website(s): https://www.dra.gov.pk/about-us/organization/divisions/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Pakistan Nuclear Regulatory Authority (PNRA does a partially regulation for some medical devices) other wise, there is no authority.

Other agency's website: http://www.pnra.org/

National regulatory comments (...Annex 1): The WHO country team helped the Ministry of Health in drafting rules for regulations of medical devices, but they are not applicable after the 18th amendment.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: https://www.dra.gov.pk

Nomenclature comments (...Annex 1):
—

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.dra.gov.pk/Home/MDMC#gsc.tab=0
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: https://www.dra.gov.pk

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: http://www.sindhhealth.gov.pk/pprasindh.gov.pk

Medical device incorporation comments (...Annex 1):
The procurement service rules 2003 (KPK) issued by the finance department. The procurement is carried out at a provincial level and identified by SPRA etc. There is a National inventory for medical equipment.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	40	0.22
Computerized Tomography Scanner:α	61	0.33
Positron Emission Tomography Scanner:α	5	0.03
Gamma camera or nuclear medicine:α	7	0.04
Mammograph:α,*	15	1.61
Radiotherapy:β	77	0.35

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 6

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
A national inventory was previously maintained but now is at a province/region level, it is in pipeline.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 1200

Contacts

National officer(s):
Name: Mr. Ayaz Ali khan
Email: ayazalikhan1@gmail.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Palitha Gunarathna Mahipala
Email: mahipalap@who.int

Name: —
Email: —

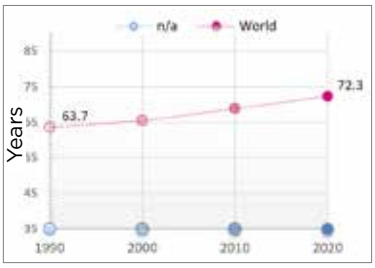
General comments (...Annex 1):

After the 18th amendment and devolution of the MoH, no person nor authority can provide information, the WHO as convening body of health systems in Pakistan collected the information separately from all regions/provinces then the information was compiled by the WHO focal person of health technologies.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Palau

Country indicators - WHO country information

Population 000s (rank):[a]	18 (190)	Under-five mortality (per 1000 live births):[d]	16.85	UHC - Service coverage index (1-100):[h]	59
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	—	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.83 (—): very high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	51.70%

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —
HTA unit/department includes the assessment of medical devices: —
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

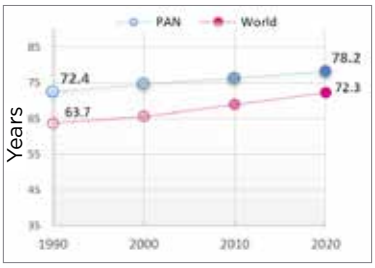
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Panama

Country indicators - WHO country information

Population 000s (rank):[a]	4,315 (125)	Under-five mortality (per 1000 live births):[d]	14.34	UHC - Service coverage index (1-100):[h]	77
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.82 (0.64): very high	Global innovation index (rank):[j]	29 (73)
		ICT Development Index (rank):[g]	4.9 (94)	High-technology exports (% of manufacture exports):[k]	13.70%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.minsa.gob.pa/normatividad/leyes

Language(s): Español

Ministry of health responsible for health technology policy implementation: Comisión Nacional de Registro Nacional de Oferentes - Departamento de investigación - Desarrollo Tecnológico en Salud y Comité Técnico Nacional Interinstitucional - Dirección Nacional de Farmacias y Drogras - Laboratorio Central de Referencia.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Comité Técnico Nacional Interinstitucional.

Website: http://appwebs.minsa.gob.pa/woferentes/ConsultaCatalogos.aspx

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
Available at the specified website.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://minsa.b-cdn.net/sites/default/files/transparencia/politicas_de_salud_del_minsa.pdf

Website - laboratories: http://www.minsa.gob.pa/contenido/direccion-nacional-de-farmacia-y-drogas

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): http://www.css.gob.pa/web/24-abril-2017ts.html https://www.gacetaoficial.gob.pa/pdfTemp/25915/7314.pdf http://www.gorgas.gob.pa/departamento-de-tecnologia-sanitaria/

Contact: Rusbel Batista Email: rusbelbatistaortega@gmail.com

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
HTA activities are performed in the MoH, Caja de Seguro Social (CSS), and institutions such as the Instituto Conmemorativo Gorgas de Estudios de la Salud (1928) (GORGAS). HTA is performed in several areas: pharmaceutics, interventions, cost-effectiveness, etc. In the ministry of health, they perform

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Dirección Nacional de Dispositivos Médicos del Ministerio de Salud de Panamá

Website(s): http://www.minsa.gob.pa/direccion/direccion-nacional-de-dispositivos-medicos

Contact: Rusbel Batista Ortega Email: rvbatista@minsa.gob.pa

Name(s) of other regulatory agency eg. for radiation equipment etc.: International Atomic Energy Agency (IAEA).

Other agency's website: https://www.iaea.org/es/el-oiea/lista-de-estados-miembros

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: http://www.minsa.gob.pa/ http://minsa.b-cdn.net/sites/default/files/normatividad/decreto_468_de_2007_para_publicar_en_gaceta_2.pdf

Nomenclature comments (...Annex 1):
El sistema UMDNS ha sido adoptado en la legislación. Su implementación está aún en proceso.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://minsa.b-cdn.net/sites/default/files/normatividad/ley_92_de_2019_0.pdf http://minsa.b-cdn.net/sites/default/files/normatividad/decreto_ejecutivo_490_de_2020.pdf
National level procurement: Yes Website: http://minsa.b-cdn.net/sites/default/files/normatividad/decreto_ejecutivo_490_de_2020.pdf http://appwebs.minsa.gob.pa/procedimientos/Procedimientos.aspx;

Medical device incorporation comments (...Annex 1):
La Caja de Seguro Social hace sus procesos de adquisición de forma independiente del Ministerio de Salud pero sujeto al sistema de Fichas Técnicas Nacionales en cuyas confecciones también participa.

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	11	2.85
Computerized Tomography Scanner:α	37	9.58
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	8	2.07
Mammograph:α,*	79	278.54
Radiotherapy:β	10	2.32

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Comisión Nacional de Oferentes. Unit website: http://minsa.b-cdn.net/sites/default/files/direcciones/informe_dndm_14_agosto_2020.pdf
Contact name: Dr. Alejandro Martinez Contact email: amartinez@minsa.gob.pa
Website with publically available technical specifications: http://appwebs.minsa.gob.pa/woferentes/ConsultaCatalogos.aspx
Number of regional/state offices/units: 7

Inventories and medical equipment management software

Type of inventories available: None
Website: http://appwebs.minsa.gob.pa/woferentes/ConsultaCatalogos.aspx
Use of management software: Yes Software name: ECRI.

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 325

Contacts

National officer(s):
Name: Lic. Sousa
Email: lsousa@minsa.gob.pa

Name: Dr. Alejandro Martinez
Email: amartinez@minsa.gob.pa

WHO Country officer(s):
Name: Dra. Ana Rivière Cinnamond
Email: rivierea@paho.org

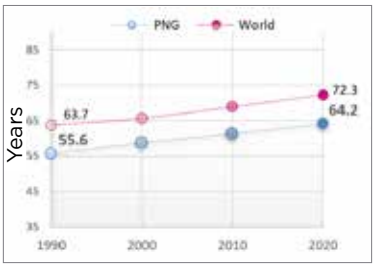
Name: Dra. Didia Sagastume
Email: sagastumed@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Papua New Guinea

Country indicators - WHO country information

Population 000s (rank):[a]	8,947 (97)	Under-five mortality (per 1000 live births):[d]	43.93	UHC - Service coverage index (1-100):[h]	33
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	36.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.56 (0.39): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): The 2011 initiative undertaken to establish a national e-health strategic framework and committee, as first steps. There are identified HTA activities but not national unit. The Universal Health Care country goal is in progress.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —

Name of regulatory agency: —

Website(s): —

Contact: Ms. Jonila Kepas. Email: jjonilak248@gmail.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	3	0.41
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	3	8.51
Radiotherapy:[β]	1	0.14

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National Inventory for medical equipment
Website: —
Use of management software: Yes Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Ms. Anna Alexandra S. Maalsen
Email: maalsena@who.int

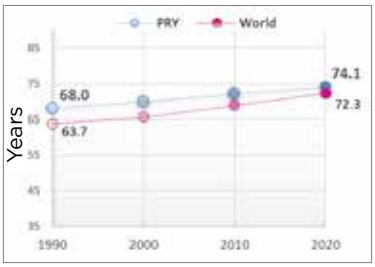
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Paraguay

Country indicators - WHO country information

Population 000s (rank):[a]	7,133 (104)	Under-five mortality (per 1000 live births):[d]	18.9	UHC - Service coverage index (1-100):[h]	61
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	7.1% (1.9%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.73 (0.56): high	Global innovation index (rank):[j]	24.1 (97)
		ICT Development Index (rank):[g]	4.2 (113)	High-technology exports (% of manufacture exports):[k]	7.20%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit comments (...Annex 1): HTA activities identified, but not proven at national or subnational level.

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: Mr. Adolfo Maldonado Email: ninomaldonado@hotmail.com

Committee includes a biomedical or clinical engineer: —

National regulatory authority

National regulatory comments (...Annex 1): —

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: Dirección Nacional de Vigilancia Sanitaria (DINAVISA)

Website(s): https://www.mspbs.gov.py/dnvs

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Autoridad Reguladora Radiológica y Nuclear.

Other agency's website: http://www.arrn.gov.py/

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
Se está elaborando un plan para proceder con la instalación de un sistema de nomenclatura.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Procurement guidelines: se inició la elaboración de directrices.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	2	0.29
Computerized Tomography Scanner:[α]	7	1.03
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	3	7.33
Radiotherapy:[β]	11	1.54

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Dirección de Desarrollo de Servicios de Salud. Unit website: —
Contact name: Ms. Ana Bordon Contact email: acbo@hotmail.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 10

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 60

Contacts

National officer(s):
Name: Dr. Julio Borba
Email: julioborba29@hotmail.com

Name: Mirta Morán
Email: nanita.moran@gmail.com

WHO Country officer(s):
Name: Dr. Marcelo Korc
Email: korcmarc@paho.org

Name: Dra. Alejandra Carrillo
Email: carrilloa@paho.org

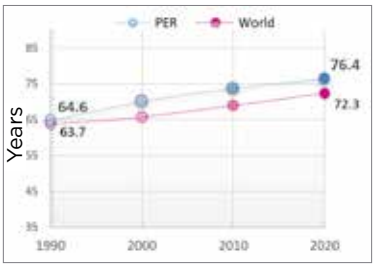
General comments (...Annex 1):

Concerning the HT national policy, it was provided the following document:
DECRETO EJECUTIVO 468.pdf

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Peru

Country indicators - WHO country information

Population 000s (rank):[a]	32,972 (43)	Under-five mortality (per 1000 live births):[d]	12.82	UHC - Service coverage index (1-100):[h]	78
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	9.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	9.2% (1.3%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (0.63): high	Global innovation index (rank):[j]	28.8 (76)
		ICT Development Index (rank):[g]	4.9 (96)	High-technology exports (% of manufacture exports):[k]	4.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: http://www.digemid.minsa.gob.pe/Main.asp?Seccion=474

Language(s): Español

Ministry of health responsible for health technology policy implementation: National Authority for Pharmaceutical Products, Medical Devices ans Sanitary Products (DIGEMID) from the Ministry of Health.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Dirección General de Medicamentos, Insumos y Drogas (DIGEMID)

Website: https://cdn.www.gob.pe/uploads/document/file/343934/Resoluci%C3%B3n_Ministerial_N__670-2019-MINSA.PDF

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.minsa.gob.pa/direccion/direccion-de-infraestructura-de-salud
http://ftp2.minsa.gob.pe/normaslegales/2011/RM369-2011-MINSA.PDF

Website - laboratories: http://www.digemid.minsa.gob.pe/main.asp?Seccion=933

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):
There are National Standards or list of recommended medical devices for specific procedures but it is managed by protocolos of care at the Hospital, Health Center or Specialty Hospital. For a), b) and c) there are protocolos of care at level of

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: National Network for Health Technology Assessment (RENETSA)

Website(s): https://web.ins.gob.pe/
http://www.essalud.gob.pe/ietsi/

Contact: INS Nora Reyes Puma Email: nreyes@ins.gob.pe

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
Three institutions perform HTA: Ministry of Health-DIGEMID; National Institute of Health (INS) and the Institute of Health Technology Assessment and Research (IETSI-ESSALUD).
Besides this 3 institutions, there is one more: INEN-Instituto Nacional de Enfermedades Neoplásicas, that perform

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Dirección General de Medicamentos, Insumos y Drogas (DIGEMED).

Website(s): http://www.digemid.minsa.gob.pe/Main.asp?Seccion=453

Contact: Ms. Silvia Perez Valdez Email: sperez@digemid.minsa.gob.pe

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Publicaciones/DocumentosConsulta/P08_234-2017-05-04.PDF
http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Normatividad/2020/DS_036-2020-SA.pdf

Nomenclature comments (...Annex 1):
Ley Nº29459-D.S and the D.S. Nº 016-2011-SA.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Ley29459.pdf
National level procurement: Yes Website: https://www.gob.pe/minsa

Donations

Policy or guideline: Yes Website: http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Ley29459.pdf

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	73	2.21

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: Unit of Medical Devices. Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
There are any kind of inventories for medical devices available in the country.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 360

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Carlos Garzon Becerra
Email: garzonc@paho.org

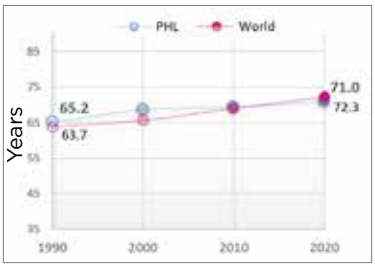
Name: Dr. Miguel Davila
Email: davilam@paho.org

General comments (...Annex 1): –

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Philippines

Country indicators - WHO country information

Population 000s (rank):[a]	109,581 (13)	Under-five mortality (per 1000 live births):[d]	26.37	UHC - Service coverage index (1-100):[h]	55
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	6.3% (1.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.72 (0.59): high	Global innovation index (rank):[j]	35.2 (50)
		ICT Development Index (rank):[g]	4.7 (101)	High-technology exports (% of manufacture exports):[k]	62.20%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Bureau of Health Devices and Technology(BHDT)- Department of Health (to be renamed as Center for Device Regulation, Radiation Health and Research-Food and Drug Authority).

Website: https://www.fda.gov.ph/

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
The lists are limited to diagnostics, no interventional equipment noted (ie, ECMO, DaVinci, etc.)

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: www.doh.gov.ph\licensing\bhfs
https://hfsrb.doh.gov.ph/

Website - laboratories: https://www.fda.gov.ph/

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: www.doh.gov.ph/asc_inspectiontool_partIII.general.pdf
https://gppb.gov.ph/assets/pdfs/NPM%203-2020_Negotiated%20Procurement%20(Emergency%20Cases).pdf

Specific lists comments (...Annex 1):
This is part of the requirements for the licensing of health facilities. The given URL is for general surgery. The indicated website can be browsed for other recommended medical devices for other procedures.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: HTA Department of Health.

Website(s): https://hta.doh.gov.ph/

Contact: Dr. Anna Melissa S. Guerrero Email: asguerrero@doh.gov.ph; hta@doh.gov.ph

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):
HTAC has one biomedical engineer and one medical physicist.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Bureau of Health Devices and Technology- Department of Health (to be renamed as Center for Device Regulation, Radiation Health and Research-Food and Drug Authority).

Website(s): https://www.fda.gov.ph/

Contact: Dir. Maria Cecilia P. Matienzo Email: cdrrhr@fda.gov.ph; cdrrhr.lrd@fda.gov.ph

Name(s) of other regulatory agency eg. for radiation equipment etc.: Food and Drug Administration; Philippine Nuclear Research Institute.

Other agency's website: https://www.fda.gov.ph/
https://www.pnri.dost.gov.ph/

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
The Philippines will be using the Nomenclature that will be decided by the member states of the ASEAN who are working on the harmonization of medical device regulation in the region, where medical device nomenclature is one of the concerns.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.gppb.gov.ph/gppb-admin/monitoring/app/APP20-DOH_CO.pdf
National level procurement: No Website: https://doh.gov.ph/node/1468

Donations

Policy or guideline: Yes Website: https://doh.gov.ph/node/1468

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://home.doh.gov.ph/auth

Medical device incorporation comments (...Annex 1):
The procurement for a medical device is part of the National Procurements system of the Philippine Government (see website). Procurement of medical devices can be done at a national level, at a regional level and local government units.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	30	0.3
Computerized Tomography Scanner:α	107	1.09
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	79	13.12
Radiotherapy:β	67	0.61

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: http://www.doh.gov.ph/asc_inspectiontool_partIII.general.pdf
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 50

Contacts

National officer(s):
Name: —
Email: —

Name: Ms. Gladys Cabrera
Email: —

WHO Country officer(s):
Name: Dr. Rabindra Romuald Abeyasinghe
Email: abeyasingher@who.int

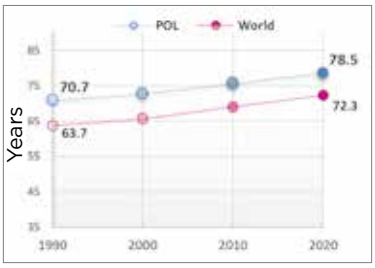
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Poland

Country indicators - WHO country information

Population 000s (rank):[a]	37,847 (38)	Under-five mortality (per 1000 live births):[d]	4.36	UHC - Service coverage index (1-100):[h]	74
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	17.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	14.1% (1.3%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.88 (0.81): very high	Global innovation index (rank):[j]	40 (38)
		ICT Development Index (rank):[g]	6.9 (49)	High-technology exports (% of manufacture exports):[k]	10.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Approved devices lists comments (...Annex 1):

The polish competent authority for medical devices is the Office for Registration of Medicinal products, Medical devices and Biocidal products, which keeps the register of medical devices in a database; it is only used for market surveillance and vigilance

Health care facilities lists comments (...Annex 1):

There are no lists, but basic (minimal) requirements regarding the necessary medical devices that are a part of the health benefit package regulations and are created concerning the type of facility (including specialisation) and with clear-

Specific lists comments (...Annex 1):

There are no lists, but basic (minimal) requirements regarding the necessary medical devices that are a part of the health benefit package regulations and are created concerning the type of facility (including specialisation) and with clear-

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: The Agency for Health Technology Assessment and Tariff System (AOTMiT).

Website(s): https://www.aotm.gov.pl/ https://www2.aotm.gov.pl/hta/

Contact: — Email: sekretariat@aotm.gov.pl

Committee includes a biomedical or clinical engineer: No

HTA unit comments (...Annex 1):

AOTMiT evaluates pharmaceutical and non-pharmaceutical technologies including medical devices assessment. The Agency for Health Technology Assessment and Tariff System evaluates pharmaceutical and non-pharmaceutical technologies including medical devices assessment.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

Website(s): http://urpl.gov.pl/en

Contact: — Email: wm@urpl.gov.pl

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

The Ministry of Health is the national regulatory authority in the area of the health system and The Office for registration of Medicinal Products, Medical Devices and Biocidal Products is the polish competent authority responsible for cooperation with European Commission in the medical device regulatory area. Another regulatory agency is the Market Surveillance, Vigilance system, Clinical trial registration and Inspection, Cooperation with the European Commission and other

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://ec.europa.eu/health/sites/health/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	350	9.25
Computerized Tomography Scanner:[α]	0	0
Positron Emission Tomography Scanner:[α]	33	0.87
Gamma camera or nuclear medicine:[α]	140	3.7
Mammograph:[α,*]	379	73.97
Radiotherapy:[β]	175	4.62

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 163

Contacts

National officer(s):

Name: Ms. Anna Rychert

Email: a.rychert@aotm.gov.pl

Name: Mr. Wojciech Marciszko

Email: —

WHO Country officer(s):

Name: Dr. Paloma Cuchi

Email: cuchip@who.int

Name: —

Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Portugal

Country indicators - WHO country information

Population 000s (rank):[a]	10,197 (88)	Under-five mortality (per 1000 live births):[d]	3.3	UHC - Service coverage index (1-100):[h]	84
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	11.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	18.4% (3.3%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.86 (0.76): very high	Global innovation index (rank):[j]	43.5 (31)
		ICT Development Index (rank):[g]	7.1 (44)	High-technology exports (% of manufacture exports):[k]	6.90%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.infarmed.pt/web/infarmed-en/medical-devices; https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos; https://www.infarmed.pt/web/infarmed/legislacao/legislacao-farmaceutica-compilada/titulo-v-produtos-de-saude/capitulo-ii-dispositivos-medicos

Language(s): Anglais et Portugais

Ministry of health responsible for health technology policy implementation: Administração Central do Sistema de Saúde (ACSS, IP).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: —

Website - laboratories: www.infarmed.pt/documents/15786/1076625/decreto_lei_20306-97.pdf
https://www.infarmed.pt/documents/15786/1076625/125_DL_189_2000_VP.pdf

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: —

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): Functions of Infarmed: Research, assessment, registration, monitoring and supervision of health products. Clinical research evaluation, assessment and registration of CE marked medical devices, notification of health care products and market supervision activities.

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: National Authority of Medicines and Health Products (INFARMED).

Website(s): http://www.infarmed.pt/; https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos/avaliacao-de-tecnologias-de-saude/comparticipacao-de-dispositivos-medicos

Contact: Helena Monteiro Email: dats@infarmed.pt; avalia.dispositivos@infarmed.pt

Committee includes a biomedical or clinical engineer: —

National regulatory authority

National regulatory comments (...Annex 1): —

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: National Authority of Medicines and Health Products (INFARMED, I.P.).

Website(s): https://www.infarmed.pt/web/infarmed
https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos

Contact: Dr. António Faria Vaz Email: daps@infarmed.pt

Name(s) of other regulatory agency eg. for radiation equipment etc.: National Authority of Medicines and Health Products (INFARMED, I.P.).

Other agency's website: —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://www.infarmed.pt/web/infarmed/pesquisa-dispositivos

Nomenclature comments (...Annex 1):
The Directorate-General of Health/ Ministry of Health of this country pointed out that the official nomenclature system for medical devices and IVDs for registry purposes is based on the European Medical Device Nomenclature (EMDN).

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: Yes Website: http://www.acss.min-saude.pt/category/providers/healthcare-contracting/
http://www.acss.min-saude.pt/category/providers/facilities-and-equipments/
https://www.infarmed.pt/documents/15786/1076625/portaria_1253-9720.pdf

Medical device incorporation comments (...Annex 1):
Go to the website and search for the "contratoseaquisicoes" documents.

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: —

Publically available: —

Website: —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	105	9.9
Computerized Tomography Scanner:α	291	27.43
Positron Emission Tomography Scanner:α	7	0.66
Gamma camera or nuclear medicine:α	54	5.09
Mammograph:α,*	375	272.05
Radiotherapy:β	73	7.16

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No

Unit/Department: — Unit website: https://extranet.infarmed.pt/SIDM-fo/

Contact name: — Contact email: —

Website with publically available technical specifications: https://extranet.infarmed.pt/SIDM-fo/

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: https://www.infarmed.pt/web/infarmed/pesquisa-dispositivos
https://www.infarmed.pt/web/infarmed/pesquisa-dispositivos#

Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 2060

Contacts

National officer(s):

Name: Ms. Luisa Taveira

Email: ltaveira@acss.min-saude.pt

Name: —

Email: —

WHO Country officer(s):

Name: —

Email: —

Name: —

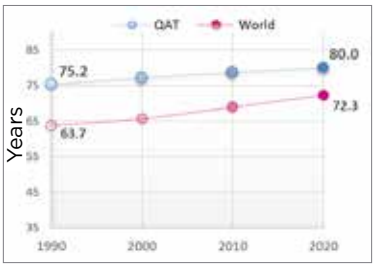
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Qatar

Country indicators - WHO country information

Population 000s (rank):[a]	2,881 (136)	Under-five mortality (per 1000 live births):[d]	5.76	UHC - Service coverage index (1-100):[h]	74
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.85 (—): very high	Global innovation index (rank):[j]	30.8 (70)
		ICT Development Index (rank):[g]	7.2 (39)	High-technology exports (% of manufacture exports):[k]	0.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: https://www.hamad.qa/EN/Pages/default.aspx

Language(s): English

Ministry of health responsible for health technology policy implementation: Bio-Medical Engineering Department.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Bio-Medical Engineering Department.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

There are functional inventory of medical devices for procurement and/ or reimbursement in HMC hospitals. HMC disciplines occupies functional inventory of medical devices for prompt delivery of patient care services. Emergency

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):

HMC disciplines occupies functional inventory of medical devices for prompt delivery of patient care services. It exists the emergency prepardness policy reference (including lists) too.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://www.moph.gov.qa/english/Pages/default.aspx

Contact: — Email: —

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):

There are identified HTA activities. HTA consultancy is required for building high-level infrastructure and there is the formation of an HTA workforce but there is not a national unit. Drugs pricing falls on External Reference Pricing stated in the national objectives towards Universal Health Care (UHC) implementation goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Medical Licensing Department.

Website(s): https://www.moph.gov.qa/english/derpartments/policyaffairs/facilitieslicensingandaccreditationdepartment/Pages/default.aspx
https://www.moci.gov.qa/en/

Contact: Dr. Jamal Rashid S. Khanji Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

If ever a private agency, hospital or clinic needs a specific product they should approach the Medical Licensing which in turn seeks technical evaluation (such as specification, safety, compliance, etc.) from the Bio-Medical Engineering to import the product to the country. Bio-Eng does verify FDA, CE and/ or equivalent compliance on medical device/ equipment for safety, especially for Hamad Medical Corporation (HMC) hospitals.

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: Not specified

Website: https://www.ecri.org/solutions/umdns/

Nomenclature comments (...Annex 1):
This is used for planning of medical equipment for new / upcoming projects.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —

National level procurement: Yes Website: https://www.hamad.qa/EN/Pages/default.aspx

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: No

Website: —

Medical device incorporation comments (...Annex 1):
The specification compliance on safety and clinical requisites is regularly updated. The Hamad Medical Corporation (HMC) Materials Management and Tender committee take over the procurement activities of Medical and Non-Medical Equipment/ items for HMC hospitals, and the ministry upon request, as deem necessary. Specification of equipment formulated in cooperation with end-user prepared by Bio-eng.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	20	9.22
Computerized Tomography Scanner:[α]	18	8.3
Positron Emission Tomography Scanner:[α]	1	0.46
Gamma camera or nuclear medicine:[α]	4	1.84
Mammograph:[α,*]	9	225.1
Radiotherapy:[β]	4	1.39

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Biomedical Engineering Department. Unit website: https://www.hamad.qa/EN/Pages/default.aspx

Contact name: Mr. Rashid al Mansoori Contact email: ralmansoori@hmc.org.qa

Website with publically available technical specifications: https://www.hamad.qa/en/hospitals-and-services/hhqi/pages/default.aspx

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment

Website: —

Use of management software: Yes Software name: AssetPlus (by GE).

Software comments (...Annex 1):
Maintained GE AssetPlus for the functional inventory of Medical equipment for the Hamad Medical Corporation (HMC), hospitals and Public Health Care Centers.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):

Name: —

Email: —

Name: —

Email: —

WHO Country officer(s):

Name: Dr. Rayana Ahmad Bou Haka

Email: emqatdesk@who.int

Name: —

Email: —

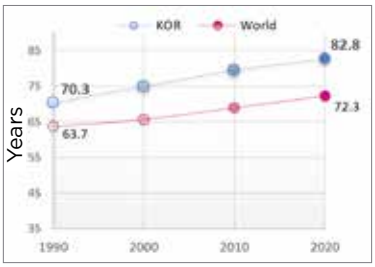
General comments (...Annex 1):

List of accredited HMC hospitals: Hamad General Hospital, Women's Hospital, Rumailah Hospital, Al Amal Hospital, and Al Khor Hospital. Emergency Medical Services (EMS), Pediatric Emergency, Trauma Centers, Orthopedic Center, Dental and School Health, Home Healthcare, Primary Health Centers, Skilled Nursing Facility. Upcoming projects: Qatar Heart Center, New Children's Hospital, Al-Wakra Hospital. Please visit the Hamad Medical Corporation website (www.hamad.qa) and the Qatar Supreme Council of Health website (https://www.moph.gov.qa/)

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Republic of Korea

Country indicators - WHO country information

Population 000s (rank):[a]	51,269 (28)	Under-five mortality (per 1000 live births):[d]	3.03	UHC - Service coverage index (1-100):[h]	87
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	7.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	21.8% (3.9%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.92 (0.82): very high	Global innovation index (rank):[j]	56.1 (10)
		ICT Development Index (rank):[g]	8.9 (2)	High-technology exports (% of manufacture exports):[k]	32.40%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://law.go.kr/

Language(s): Korean

Ministry of health responsible for health technology policy implementation: Division of Pharmaceutical Policy.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Health Insurance Review & Assessment Service (HIRA).

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

The Health Insurance and Review Assessment (HIRA) is responsible for listing treatment materials for public insurance.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72625&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: National Evidence-based healthcare Collaborating Agency (NECA).

Website(s): https://www.neca.re.kr/eng/index.do

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

HTA is performed in a variety of health areas including medical technologies, devices, interventions, etc.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Korea Food & Drug Administration.

Website(s): https://www.mohw.go.kr
http://www.kimes.kr/eng/search/company_old_view.asp?ref_idx=598&lan=kor

Contact: Lim, Jai-gui Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Korea Institute of Nuclear Safety (KINS); Nuclear Safety and Security Commission.

Other agency's website: https://www.kins.re.kr/en
https://www.nssc.go.kr/en/index.do

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: https://www.mfds.go.kr/eng/wpge/m_39/denofile.do

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.pps.go.kr
National level procurement: Yes Website: http://www.pps.go.kr

Donations

Policy or guideline: Yes Website: https://www.kofih.org/projects/healthcare-resources-support/

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
National and public hospitals purcharse medical equipments according to the general procurement procedures.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1553	30.29
Computerized Tomography Scanner:[α]	1991	38.83
Positron Emission Tomography Scanner:[α]	195	3.8
Gamma camera or nuclear medicine:[α]	306	5.97
Mammograph:[α,*]	3179	421.87
Radiotherapy:[β]	218	4.25

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: https://www.mfds.go.kr/eng/wpge/m_55/de011038l001.do
https://emed.mfds.go.kr/#!CEAAB02F010
Contact name: — Contact email: —
Website with publically available technical specifications: https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=71809&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1
https://www.mfds.go.kr/eng/brd/m_40/down.do?brd_id=eng0011&seq=71809&data_tp=A&file_seq=2
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=71809&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1
https://www.mfds.go.kr/eng/brd/m_41/down.do?brd_id=eng0012&seq=70934&data_tp=A&file_seq=1
Use of management software: — Software name: —

Software comments (...Annex 1):
The inventories for medical devices are not managed by the government.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Mr. Jae Lee Kwang
Email: surreal@korea.kr

Name: Mr. Lim Jae-Gui
Email: guitar92@korea.kr

WHO Country officer(s):
Name: —
Email: —

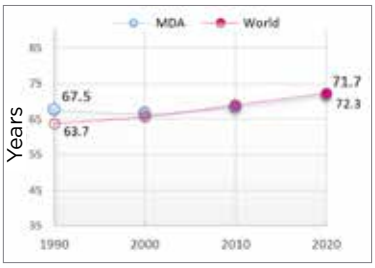
Name: —
Email: —

General comments (...Annex 1): Concerning the Infrastructure section: Korea Health Center is down to 29 beds.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Republic of Moldova

Country indicators - WHO country information

Population 000s (rank):[a]	4,034 (128)	Under-five mortality (per 1000 live births):[d]	14.47	UHC - Service coverage index (1-100):[h]	67
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	18.7% (3.6%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.75 (0.67): high	Global innovation index (rank):[j]	33 (59)
		ICT Development Index (rank):[g]	6.5 (59)	High-technology exports (% of manufacture exports):[k]	3.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://msmps.gov.md/en
https://amdm.gov.md/ro

Language(s): Rumanian and Russian

Ministry of health responsible for health technology policy implementation: Department of Medicines and Medical Devices.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

A special group of Agency of Medicines and Medical Devices organise the procurement of medical equipment from the state budget.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://amdm.gov.md/ro
http://lex.justice.md/UserFiles/File/2018/mo68-76md/an.53.docx

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: www.ms.gov.md/public/info/ghid
http://capcs.md/anunturi-licitatii-2020/
https://amdm.gov.md/ro/

Specific lists comments (...Annex 1):

Medical standards on diagnostic and treatment for pathological conditions in surgery, therapeutic profile for adults and children, have been developed. Also, development of guidelines is based on international recommendations for family

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

There are identified HTA activities but not a national unit per se.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Agency of Medicines and Medical Devices.

Website(s): https://msmps.gov.md/en/minister/organizare/subdiviziunile-ministerului/
https://amdm.gov.md

Contact: Mr. Aleksandr Coman Email: office@amed.md

National regulatory comments (...Annex 1):

The National Center of Public Health is ensuring the control of the rules of utilization of X-Ray equipment in all medical institutions of the country.

Name(s) of other regulatory agency eg. for radiation equipment etc.: The National Center of Public Health; National Agency for Regulation of Nuclear and Radiological Activities (Ministry of Ecology and Natural Resources).

Other agency's website: http://www.vertic.org/media/National%20Legislation/Moldova/MD_Statute_ANRANR_eng1.pdf

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified

Website: https://amdm.gov.md/ro/med-oborudovanie

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://msmps.gov.md/sites/default/files/legislatie/dokument_12.pdf
http://capcs.md/

National level procurement: Yes Website: http://capcs.md/

Donations

Policy or guideline: Yes Website: http://capcs.md/

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: https://msmps.gov.md/
https://amdm.gov.md/ro/

Medical device incorporation comments (...Annex 1):
Procurement guidelines: Government Decree No. 568 (10.09.09). Guidelines on technical specifications: Decree 190 from 25.06.2009 establishes standard specifications for biochemical and immunology test.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	5	1.43
Computerized Tomography Scanner:[α]	19	5.45
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	4	1.15
Mammograph:[α,*]	19	40.95
Radiotherapy:[β]	4	0.99

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Department of Medical Devices of the Agency of Medicines and Medical Devices. Unit website: http://lex.justice.md/md/375113/
http://www.simdm.amdm.gov.md/simdm/en_US/
https://amdm.gov.md/ro;

Contact name: Mr. Aleksandr Spynu Contact email: aspinu@gmail.com

Website with publically available technical specifications: https://amdm.gov.md/sites/default/files/attach/Catalog%20-ordinul%20nr.%20Rg04-000299%20din30.11.2020.xls

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: http://nomenclator.amdm.gov.md/
https://amdm.gov.md/sites/default/files/attach/Catalog%20-ordinul%20nr.%20Rg04-000299%20din30.11.2020.xls

Use of management software: Yes Software name: OpenMedis.

Software comments (...Annex 1):
It is not developed. A project to support management of medical equipment is being developed: openMedis.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 90

Contacts

National officer(s):

Name: —

Email: —

Name: Mr. Aleksandr Spynu

Email: aspinu@gmail.com

WHO Country officer(s):

Name: Dr. Miljana Grbic

Email: grbicm@who.int

Name: —

Email: —

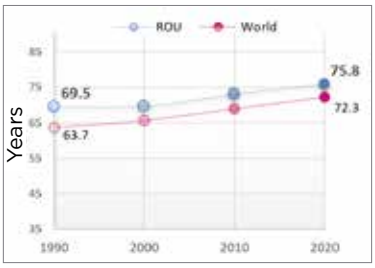
General comments (...Annex 1):

The strategy to develop Health System during the period 2005-2017 as well as the Plan of Action contains specific goals on strengthening the bases of technical material for healthcare.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Romania

Country indicators - WHO country information

Population 000s (rank):[a]	19,238 (60)	Under-five mortality (per 1000 live births):[d]	6.88	UHC - Service coverage index (1-100):[h]	71
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	13.4% (2.2%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.83 (0.73): very high	Global innovation index (rank):[j]	36 (46)
		ICT Development Index (rank):[g]	6.5 (58)	High-technology exports (% of manufacture exports):[k]	11.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: National Drugs Agency.

Website(s): http://ms.ro
http://www.insp.gov.ro
http://www.snspms.ro
https://www.anm.ro/en/medicamente-de-uz-uman/evaluare-tehnologii-medicale/

Contact: — Email: secretariat@anm.ro

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): Several national entities are in charge of performing HTA activities, each one focus in various areas (see corresponding links).

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: National Agency for Medicines and Medical Devices.

Website(s): https://www.anm.ro/dispozitive-medicale/anunturi-importante-dispozitive-medicale/
http://www.ms.ro/organizare/directia-politica-medicamentului-si-a-dispozitivelor-medicale/

Contact: Ms. Ana Maria Tanase Email: atanase@ms.ro

Name(s) of other regulatory agency eg. for radiation equipment etc.: Agentia Nationala a Medicamentului si a Dispozitivelor Medicale din Romania (ANM).

Other agency's website: http://www.cncan.ro/
https://www.anm.ro

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: —

Nomenclature comments (...Annex 1):

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.anm.ro/informatii-de-interes-public/programul-anual-al-achizitiilor-publice/

National level procurement: Yes Website: https://www.anm.ro/informatii-de-interes-public/bugetul-cu-sursa-de-finantare/
https://www.anm.ro/dispozitive-medicale/formulare-si-tarife/
https://www.anm.ro/informatii-de-interes-public/contractele-de-achizitii-publice/

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: https://www.anm.ro/dispozitive-medicale/eliberare-aviz-de-donatie/

Medical device incorporation comments (...Annex 1):

The procurement of high technologies devices is carried out at anational level. Go to the website and search for the corresponding documents.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	43	1.98
Computerized Tomography Scanner:[α]	118	5.44
Positron Emission Tomography Scanner:[α]	1	0.05
Gamma camera or nuclear medicine:[α]	25	1.15
Mammograph:[α,*]	112	41.84
Radiotherapy:[β]	69	3.59

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —

Unit/Department: Ministy of Health. Unit website: https://www.anm.ro/dispozitive-medicale/vigilenta/

Contact name: — Contact email: —

Website with publically available technical specifications: https://www.anm.ro/dispozitive-medicale/supraveghere-piata/

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)

Website: https://www.anm.ro/dispozitive-medicale/inregistrare-dispozitive-medicale-in-baza-nationala-de-date/

Use of management software: No Software name: —

Software comments (...Annex 1):

—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 1250

Contacts

National officer(s):

Name: —

Email: —

Name: Ms. Ioana Pertache

Email: pertache@ccss.ro

WHO Country officer(s):

Name: Dr. Andreea-Cassandra Butu

Email: butua@who.int

Name: —

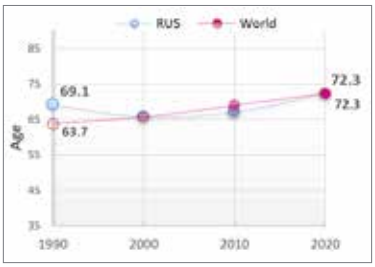
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Russian Federation

Country indicators

Population 000s (rank):[a]	145,934 (9)	Under-five mortality (per 1000 live births):[d]	5.8	UHC - Service coverage index (1-100):[h]	75
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs of NCDs (%):[e]	25.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	4.9% (0.6%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.82 (0.74): very high	Global innovation index (rank):[j]	35.6 (47)
		ICT Development Index (rank):[g]	7.1 (45)	High-technology exports (% of manufacture exports):[k]	13.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://roszdravnadzor.gov.ru/medproducts/documents/b40; https://minzdrav.gov.ru/documents; http://pravo.gov.ru/

Language(s): Russian

MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Department of Health Care and Health Development.

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://minzdrav.gov.ru/; http://www.medkirov.ru/licence/site/LSPA342E9

Website - IVD: https://roszdravnadzor.gov.ru/medproducts

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website(s): https://roszdravnadzor.gov.ru/medproducts/clinical; https://roszdravnadzor.gov.ru/medproducts/monitoring; https://minzdrav.gov.B4%D0%scope=pages&title_only=false; https://minzdrav.gov.ru/documents/8005-prikaz-ministerstva-zdravoohraneniya-100-ot-26-marta-1999-g (ambulatory specifications); https://minzdrav.gov.ru/documents/7418-svedeniya-o-vypolnenii-setevogo-grafika-realizatsii-prioritetnogo-natsionalnogo-proekta-zdorovie-na-1-dekabrya-2010-goda; https://minzdrav.gov.ru/search_only=false; https://minzdrav.gov.ru/search?order=relevapages&title_only=false

Approved devices lists comments (...Annex 1):
—

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

National unit/department that includes HTA for medical devices: Yes, Department of the Pharmaceutical and Medical Devices Market Development.

Website(s): https://minzdrav.gov.ru/documents

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
The HTA system development is inserted in the Russian Federation healthcare legislation. Currently, the procedure for a comprehensive assessment of drugs has been approved and is constantly being improved. However it is still at their start phase for medical devices and biomedical products.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Federal Service on Surveillance (Roszdravnadzor), Federal Agency for Technical Regulation and Metrology (Gosstandart), Federal Service for Supervision in the Area of Consumer Rights and Welfare Protection (Rospotrebnadoz).

Website(s): http://roszdravnadzor.ru/

Contact: — Email: interdep@rosminzdrav.ru

Name(s) of other regulatory agency eg. for radiation equipment etc.: Federal Environmental, Industrial and Nuclear Supervision Service of Russia; Ministry of Health of the Russian Federation.

Other agency's website: http://en.gosnadzor.gov.ru/; https://portal.egisz.rosminzdrav.ru/

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: https://roszdravnadzor.gov.ru/services/mi_reesetr

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://minzdrav.gov.ru/ministry/tenders/plan--ot-27-06-2016; https://minzdrav.gov.ru/ministry/tenders
National level procurement: No Website: https://minzdrav.gov.ru/ministry/tenders

Medical device incorporation comments (...Annex 1): —

Donations

Policy or guideline: Yes Website: https://minzdrav.gov.ru/documents/8014-federalnyy-zakon-1499-1-ot-28-iyunya-1991-g; https://minzdrav.gov.ru/ministry/tenders/pgz-2020

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://minzdrav.gov.ru; https://roszdravnadzor.gov.ru/en/medproducts/control; http://www.rosminzdrav.ru/documents/8185-federalnyy-zakon-ot-5-aprelya-2013-g-44-fz-o-kontraktnoy-sisteme-v-sfere-zakupok-tovarov-rabot-uslug-dlya-obespecheniya-gosudarstvennyh-i-munitsipalnyh-nuzhd

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	711	4.87
Computerized Tomography Scanner:[α]	1963	13.45
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	694	4.76

Healthcare facility[γ]	Total	Density per 100,000 population
Health posts:	n/a	n/a
Health centres:	n/a	n/a
General/district hospitals:	n/a	n/a
Specialized/regional/national hospitals:	n/a	n/a
Estimation % of health facilities with none or very limited oxygen supply:		n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Health Care and Health Development. Unit website: https://roszdravnadzor.gov.ru/
Contact name: Ms. Olga Krivonos Vladimirovna Contact email: KrivonosOV@rosminzdrav.ru
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: https://roszdravnadzor.gov.ru/services/misearch;
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Density of medical doctors (per 10 000 population):[ε] 44.4
Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Ms. Olga Krivonos Vladimirovna
Email: KrivonosOV@rosminzdrav.ru

WHO health products focal point:
Name: —
Email: —

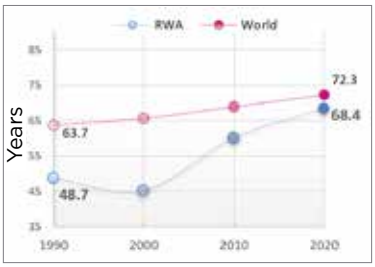
WHO Representative/WHO Liason Officer:
Name: Dr. Melita Vujnovic
Email: vujnovicm@who.int

General comments (...Annex 1): —

a UN POP WPP 2019 (2020 POP)
b WB FY21 2019
c UN POP WPP 2019 (1990-20 MOR)
d WHO GHO 2019
e WHO GHO 2016
f UN POP 2019
g ITU 2017
h WHO GHO 2017
i WHO GHO 2010-18
j WIPO 2020
k UN and WB 2017-19
δ Latest (2015-21):WHO HTA/HBP 2021 survey or WHO HTA 2015 survey or WHO 2021 survey
α Latest (2013-21):WHO GHO/2021 survey or OECD (2017-19)
β Latest (2013-21):WHO GHO/2021 survey or IAEA (2017-21)
γ Latest (2014-21):WHO GHO/2021 survey
ε WHO GHO 2010-18
n/a not applicable/not available

Rwanda

Country indicators - WHO country information

Population 000s (rank):[a]	12,952 (75)	Under-five mortality (per 1000 live births):[d]	40.47	UHC - Service coverage index (1-100):[h]	54
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	20.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.2% (0.1%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.54 (0.39): low	Global innovation index (rank):[j]	25.1 (91)
		ICT Development Index (rank):[g]	2.2 (153)	High-technology exports (% of manufacture exports):[k]	10.60%

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There are identified HTA activities which are specifically done in pharmaceutics for pricing and reimbursements as well as health economics; however, there is no national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Rwanda Food and Drugs Authority (Rwanda FDA)
Website(s): https://www.rwandafda.gov.rw/home
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: More than one system
Use: For various purposes
Website: —

Nomenclature comments (...Annex 1):
Rwanda has started to use Online Public Procurement, each device should have an unique identification code (mainly based on UMDNS). But it is challenging when dealing with different code nomenclature such as the sterilizer, autoclave or medical gases. Rwanda uses UMDNS for inventory and maintenance of medical equipment.

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	2	0.15

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 15

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Brian Clever Chirombo
Email: chirombob@who.int

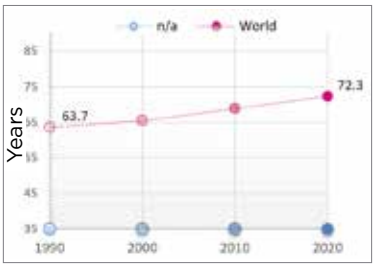
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Saint Kitts and Nevis

Country indicators - WHO country information

Population 000s (rank):[a]	53 (187)	Under-five mortality (per 1000 live births):[d]	14.99	UHC - Service coverage index (1-100):[h]	72
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	—	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (—): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	7.2 (37)	High-technology exports (% of manufacture exports):[k]	34.60%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Hospital management purchases devices directly from vendors.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	1	18.45
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	1	149.44
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Mr. Patrick Martin
Email: sknemo@yahoo.com

Name: —
Email: —

WHO Country officer(s):
Name: Dra. Amalia Del Riego
Email: delriegoa@paho.org

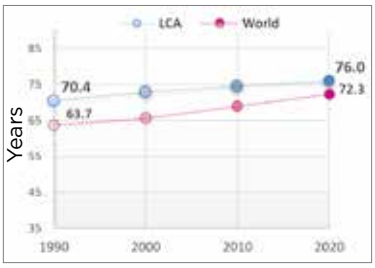
Name: Dr. Cecilia Acuñ
Email: acunamar@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Saint Lucia

Country indicators - WHO country information

Population 000s (rank):[a]	184 (176)	Under-five mortality (per 1000 live births):[d]	24.4	UHC - Service coverage index (1-100):[h]	72
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	17.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.76 (0.63): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	4.6 (104)	High-technology exports (% of manufacture exports):[k]	10.50%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): There is the Bureau of Standards which will do the regulatory activities.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The procurement at a national level is not for medical equipment, but for pharmaceuticals.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	2	10.97
Computerized Tomography Scanner:α	2	10.97
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	0	0
Mammograph:α,*	2	131.06
Radiotherapy:β	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
The medical equipment inventories of public hospitals exist. The functional status of such equipment is reflected in these lists. No PET scanners are available on the island. CT and MRI are available only in one private hospital facility.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):
Name: Mr. Protus Angus Jean Baptiste
Email: Mellow64@gmail.com

Name: —
Email: —

WHO Country officer(s):
Name: Dra. Amalia Del Riego
Email: delriegoa@paho.org

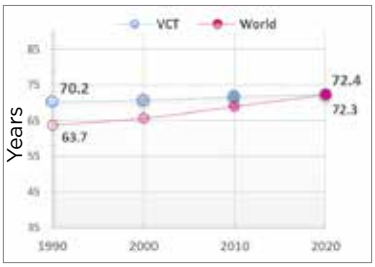
Name: Dr. Cecilia Acuñ
Email: acunamar@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Saint Vincent and the Grenadines

Country indicators - WHO country information

Population 000s (rank):[a]	111 (180)	Under-five mortality (per 1000 live births):[d]	14.12	UHC - Service coverage index (1-100):[h]	73
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	20.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.74 (—): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	5.5 (82)	High-technology exports (% of manufacture exports):[k]	9.90%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): http://health.gov.vc/health/index.php/health-information-system

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There are identified HTA activities but not a national unit. The development of one is in progress.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	0	0
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	2	229.86
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): No national inventory exists.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):

Name: Mr. Fitzroy T. Jones
Email: mcmh@gov.vc

Name: Mr. Pedro Richards
Email: pedradxray@yahoo.com

WHO Country officer(s):

Name: Dra. Amalia Del Riego
Email: delriegoa@paho.org

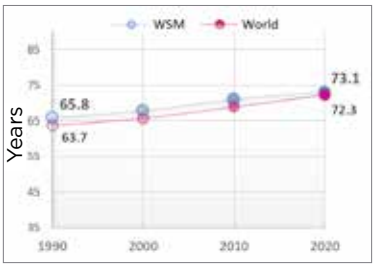
Name: Dr. Cecilia Acuña
Email: acunamar@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Samoa

Country indicators - WHO country information

Population 000s (rank):[a]	198 (175)	Under-five mortality (per 1000 live births):[d]	17.01	UHC - Service coverage index (1-100):[h]	53
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	31.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.72 (—): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	3.3 (127)	High-technology exports (% of manufacture exports):[k]	2.30%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Biomedical Engineering Unit.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.samoagovt.ws/tag/ministry-of-health/

Specific lists comments (...Annex 1): Please refer to Biomedical Engineering Unit Head, Mr. Galuafi Vaoga at email: biomed@nhs.gov.ws.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There are identified HTA activities but not a national unit. MoH together with National Health Services (NHS) intend to develop one, but it is still on progress.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of Health, Medical Equipment Management Committee.

Website(s): https://www.samoagovt.ws/tag/ministry-of-health/

Contact: Ms. Palanitina Toelupe Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: National Health Services Motootua Samoa, Government Apia Samoa.

Other agency's website: https://www.health.gov.ws/

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For procurement purposes
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: www.mof.gov.ws
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
For more information refer to the Biomed Engineering Unit.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	1	5.25
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	1	91.16
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Tupua Tamasese Meaole (TTM) Hospital Administrator. Unit website: —
Contact name: Ms. Kristy. T. Contact email: KristyT@nhs.gov.ws
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: Ms. Kristy. T.
Email: KristyT@nhs.gov.ws

WHO Country officer(s):
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

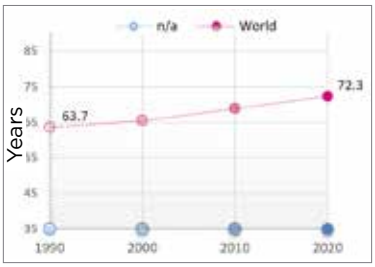
Name: —
Email: —

General comments (...Annex 1): Concerning the Infrastructure section: there are 18 General Practicioner Clinics in the Private sector.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

San Marino

Country indicators - WHO country information

Population 000s (rank):[a]	34 (189)	Under-five mortality (per 1000 live births):[d]	1.76	UHC - Service coverage index (1-100):[h]	82
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	—	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	— (—):	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.sanita.sm/on-line/home/authority-sanitaria.html

Language(s): Italiano

Ministry of health responsible for health technology policy implementation: Health Authority for Authorization, Accreditation and Quality of Health Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): http://www.sanita.sm/on-line/home.html

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There are identified HTA activities but not a national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Health Authority for Authorization, Accreditation and Quality of Health Services.

Website(s): http://www.sanita.sm/on-line/home/authority-sanitaria.html

Contact: Mr. Andrea Gualtieri. Email: andrea.gualtieri.authority@pa.sm

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	2	63.6
Computerized Tomography Scanner:[α]	1	31.8
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	1	229.11
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Health Authority for Authorization, Accreditation and Quality of Health Services. Unit website: http://www.sanita.sm/on-line/home/authority-sanitaria/vigilanza-e-gestione-del-rischio-clinico.html
Contact name: Mr. Andrea Gualtieri Contact email: andrea.gualtieri.authority@pa.sm
Website with publically available technical specifications: http://www.sanita.sm/on-line/home/authority-sanitaria/vigilanza-e-gestione-del-rischio-clinico.html
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Mr. Andrea Gualtieri
Email: andrea.gualtieri.authority@pa.sm

Name: —
Email: —

WHO Country officer(s):
Name: —
Email: —

Name: —
Email: —

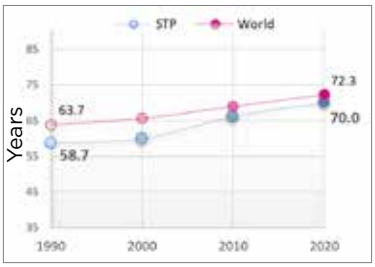
General comments (...Annex 1):

For specialized care and diagnostics, patients can be treated in italian hospitals that have agreements with San Marino.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Sao Tome and Principe

Country indicators - WHO country information

Population 000s (rank):[a]	219 (174)	Under-five mortality (per 1000 live births):[d]	16.14	UHC - Service coverage index (1-100):[h]	60
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.63 (0.52): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	3.1 (132)	High-technology exports (% of manufacture exports):[k]	17.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): Il n'existe pas au niveau national aucuen liste recomandant des technologies de sante.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): L'inventaire des equipments medicaux existant est caduque (2002) Apres cette date un nombre considerable des equipaments ont rentres en charge.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):

Name: Mr. Florentino Fernandes Dos Ramos
Email: frigao@hotmail.com

Name: —
Email: —

WHO Country officer(s):

Name: Dr. Anne Marie F. J. Ancia
Email: anciaa@who.int

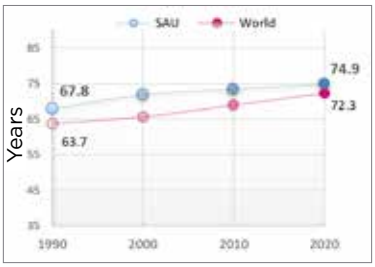
Name: Dr. Claudina Augusto da Cruz
Email: cruzc@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Saudi Arabia

Country indicators - WHO country information

Population 000s (rank):[a]	34,814 (41)	Under-five mortality (per 1000 live births):[d]	7.01	UHC - Service coverage index (1-100):[h]	73
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	20.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.85 (—): very high	Global innovation index (rank):[j]	30.9 (66)
		ICT Development Index (rank):[g]	6.7 (54)	High-technology exports (% of manufacture exports):[k]	0.60%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: http://www.sfda.gov.sa

Language(s): English

Ministry of health responsible for health technology policy implementation: General Supplies and Equipment Directorate.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: National Unified Procurement Company for Medical Supplies (NUPCO) & Saudi Food and Drug Administration (SFDA).

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1): Food and Drug Adminstration - Specification and Measurement Administration.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Saudi Food and Drug Authority.

Website(s): https://beta.sfda.gov.sa/sites/default/files/2020-03/MDS%E2%80%93G28.pdf

Contact: — Email: webmaster@sfda.gov.sa

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): The Ministry of Health supports the creation of a national entity for HTA in healthcare as part of the National Transformation Program. The new HTA entity will deal mainly with pharmaceutics but is intended to extends to other health products such as devices. Informed HTA decisions were rarely identified for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Directorates of Supplies and Equipment and Maintenance.

Website(s): http://www.sfda.gov.sa/ar/Pages/default.aspx

Contact: Mr. Mohamed Bani Al-Hathri and Mr. Abdel-Rahman Al-Zamel Email: Bani5442@hotmail.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: Saudi Food & Drug Authority.

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For regulatory and procurement purposes
Website: http://www.nupco.com

Nomenclature comments (...Annex 1):
A committee inside NUPCO has been established for that purpose and the work is in progress.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.nupco.com
National level procurement: Yes Website: http://www.nupco.com

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
National Unified Procurement Company for Medical Supplies (NUPCO).

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	28	0.97
Computerized Tomography Scanner:[α]	110	3.82
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	11	0.38
Mammograph:[α,*]	50	40.62
Radiotherapy:[β]	43	1.24

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Maintenance Directorate. Unit website: —
Contact name: Mr. Abdel-Rahman Al-Zamel Contact email: Abomohanad@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Bank Maintennace.

Software comments (...Annex 1):
For every hospital and health centre there is a maintenance-specialized company contracted to make the inventory and perform necessary maintenance activities for all medical devices within the facility. Also, there is a National inventory for high cost technologies (such as MRI, CT or PET scanners).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 300

Contacts

National officer(s):
Name: Mr. Mohamed Bani Al-Harthi
Email: Bani5442@hotmail.com

Name: Mr. Abdel-Rahman Al-Zamel
Email: Abomohanad@yahoo.com

WHO Country officer(s):
Name: Dr. Ibrahim Jawdat El-Ziq
Email: elziqi@who.int

Name: —
Email: —

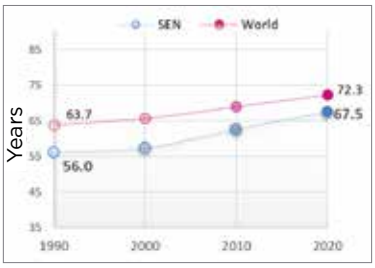
General comments (...Annex 1):

Concerning the HT national policy it is stated on the Medical Egypt Management Plan (Corporate).

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Senegal

Country indicators - WHO country information

Population 000s (rank):[a]	16,744 (69)	Under-five mortality (per 1000 live births):[d]	38.08	UHC - Service coverage index (1-100):[h]	49
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	19.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.3% (0.2%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.51 (0.35): low	Global innovation index (rank):[j]	23.7 (102)
		ICT Development Index (rank):[g]	2.7 (142)	High-technology exports (% of manufacture exports):[k]	0.90%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: http://www.sante.gouv.sn

Language(s): Français

Ministry of health responsible for health technology policy implementation: Direction des Infrastrutures, des Equipements et de la Maintenance.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Direction des Infrastrutures, des Equipements et de la Maintenance (DIEM).

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1): Il existe une liste standard de base pour toutes les structures sanitaires. Pour la plupart des acquisitions, les specifications techniques des équipements sont réalisées par la Direction des Equipements et de la Maintenance. Voir aussi les spécifications

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): http://www.sante.gouv.sn http://www.sante.gouv.sn/les-directions/la-direction-de-l%E2%80%99administration-g%C3%A9n%C3%A9rale-et-de-l%E2%80%99equipement

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: La Direction des Infrastructures, des Equipements et de la Maintenance (DIEM).

Website(s): http://www.sante.gouv.sn http://www.sante.gouv.sn/les-directions/la-direction-g%C3%A9n%C3%A9rale-de-la-sant%C3%A9-publique

Contact: Monsieur Amad Diouf Email: amadediouf@yahoo.fr

Name(s) of other regulatory agency eg. for radiation equipment etc.: Autorité de Radioprotection et de Surêté Nucléaire.

Other agency's website: http://www.sante.gouv.sn/les-services-rattaches/le-laboratoire-national-de-contr%C3%B4le-des-m%C3%A9dicaments

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For procurement purposes
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.sante.gouv.sn
National level procurement: — Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
On procéde à des appels d'offres nationaux et les representants des fabricants etrangers fournissent les équipements.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	4	0.24
Computerized Tomography Scanner:α	20	1.19
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	2	0.12
Mammograph:α,*	17	22.36
Radiotherapy:β	3	0.18

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department for Infrastructure, Equipment, and Maintenance (DIEM). Unit website: http://www.sante.gouv.sn/
Contact name: Monsieur Amad Diouf Contact email: amadediouf@yahoo.fr
Website with publically available technical specifications: http://www.sante.gouv.sn/les-directions/la-direction-de-la-pharmacie-et-du-m%C3%A9dicament
Number of regional/state offices/units: 4

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Système de gestion de la maintenance assistée par ordinateur (GMAO).

Software comments (...Annex 1):
On a une inventaire national des équipements médicaux (2009).

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 23

Contacts

National officer(s):

Name: Mr. Amad Diouf
Email: amadediouf@yahoo.fr

Name: Mme. Awa Ndiaye Diouf
Email: awandiayediouf@yahoo.fr

WHO Country officer(s):

Name: Dr. Lucile Imboua-Niava
Email: imboual@who.int

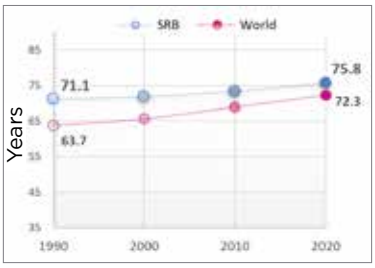
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Serbia

Country indicators - WHO country information

Population 000s (rank):[a]	8,737 (98)	Under-five mortality (per 1000 live births):[d]	5.63	UHC - Service coverage index (1-100):[h]	71
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	8.1% (0.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.81 (0.71): very high	Global innovation index (rank):[j]	34.3 (53)
		ICT Development Index (rank):[g]	6.6 (55)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.zdravlje.gov.rs/index.php?

Language(s): Serbian and English

Ministry of health responsible for health technology policy implementation: Committee for Health Technology Assessment.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Committee for Health Technology Assessment.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
Not available at the moment.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.zdravlje.gov.rs/ https://www.alims.gov.rs/eng/files/2018/11/Rulebook-on-Essential-Requirements-for-medical-devices.docx

Website - laboratories: https://www.zdravlje.gov.rs/tekst/341790/odeljenje-inspekcije-za-lekove-medicinska-sredstva-i-psihoaktivne-kontrolisane-supstance-i-prekursore.php

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):
There are no specific national standards nor recommended medical devices for specific procedures. And there are no lists recommending health techology for different diseases/situations.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Ministry of Health - Committee for health technology assessment.

Website(s): https://www.zdravlje.gov.rs/tekst/350554/pravilnik-o-blizim-uslovima-i-nacinu-vrsenja-procene-zdravstvenih-tehnologija.php https://www.zdravlje.gov.rs/tekst/333403/sektor-za-inspekcijske-poslove.php http://www.izjz-nis.org.rs/en/indexEN.html

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
It conducts centralized public procurement for health products including devices. HTA is in the law and with a centralized national unit either MoH sector for inspection affairs or Public Health Institute (NIS).

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Medicines and Medical Devices Agency (ALIMS).

Website(s): https://www.alims.gov.rs/eng/

Contact: Ms. Tatjana Sipetic Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: http://www.zdravlje.gov.rs

Nomenclature comments (...Annex 1):
National nomenclature is in the process of updating and amendment.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: https://www.zdravlje.gov.rs/

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Go to the website and search for the corresponding documents.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	59	6.2
Computerized Tomography Scanner:[α]	130	13.67
Positron Emission Tomography Scanner:[α]	2	0.21
Gamma camera or nuclear medicine:[α]	3	0.32
Mammograph:[α,*]	105	84.56
Radiotherapy:[β]	36	4.12

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: —

Software comments (...Annex 1):
The inventory was made, in 2000, according to methodology. In 2003, European Agency for Reconstruction commissioned a project performed by IPH Serbia, but the methodology was not included in the national Law on Health Records and Statistics and has not been adopted, so the inventory continued to be performed on annual basis based on the existing Law on Health Records and classification of medical equipment

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 300

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Fabio Scano
Email: scanof@who.int

Name: —
Email: —

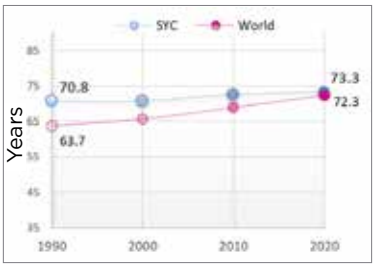
General comments (...Annex 1):

The Institute of Public Health of Serbia has a department for health technology assessment mainly responsible for updating nomenclature and type of technology.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Seychelles

Country indicators - WHO country information

Population 000s (rank):[a]	98 (182)	Under-five mortality (per 1000 live births):[d]	13.94	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.5% (1.6%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.8 (0.67): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	5 (90)	High-technology exports (% of manufacture exports):[k]	2.20%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: Yes, but it is only a recommendation

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

National regulatory comments (...Annex 1): —

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
It is a small committee that meets to discuss equipment request by the various units within the Ministry of Health. Please note that Seychelles has a small population and we do not purchase equipment on a big scale.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	10.77
Computerized Tomography Scanner:α	1	10.77
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	1	127.73
Radiotherapy:β	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ <10

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Teniin Gakuruh
Email: gakuruht@who.int

Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Sierra Leone

Country indicators - WHO country information

Population 000s (rank):[a]	7,977 (102)	Under-five mortality (per 1000 live births):[d]	107.83	UHC - Service coverage index (1-100):[h]	39
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	23.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	54.2% (22.2%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.45 (0.29): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	0.70%

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: —
Language(s): English
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Procurement Unit.
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
Lists for procurements are still being worked on not yet completed. However we do have public health emergency situations lists.

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Procurement Unit, Ministry of Health and Sanitation.
Website(s): http://www.health.gov.sl/home/
http://www.pharmacyboard.gov.sl/
Contact: Mr. Mohamed Kallon Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: For procurement purposes
Website: —

Nomenclature comments (...Annex 1):
The document is not available for the Facilities and Maintenance Unit.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Most of the equipment has been used and found incomplete, and this is the reason why its installation is difficult. Procurement of medical devices is carried out without involving the specialists.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	2	0.33
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	1	0.16
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Procurement Unit. Unit website: —
Contact name: Mr. Mohamed Kallon Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1):
The last inventory was done twelve years ago. Looking forward to start another one.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):

Name: —
Email: —

Name: Mr. Mohamed Kallon
Email: —

WHO Country officer(s):

Name: Dr. Evans Majani Liyosi
Email: liyosie@who.int

Name: —
Email: —

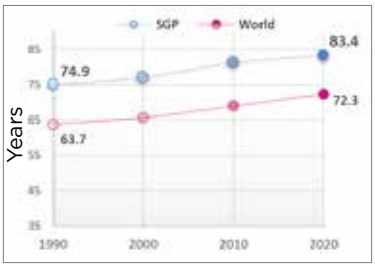
General comments (...Annex 1):

There is a limited number of technical personnel to meet the service demand. Most of the equipment supplied by donors are obsolete and out of order.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Singapore

Country indicators - WHO country information

Population 000s (rank):[a]	5,850 (112)	Under-five mortality (per 1000 live births):[d]	2.24	UHC - Service coverage index (1-100):[h]	86
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	9.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	9.0% (1.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.94 (0.81): very high	Global innovation index (rank):[j]	56.6 (8)
		ICT Development Index (rank):[g]	8.1 (18)	High-technology exports (% of manufacture exports):[k]	52.10%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.hsa.gov.sg/

Language(s): English

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Medical Devices Branch / Health Sciences Authority (HSA).

Website: http://eservice.hsa.gov.sg/medics/md/mdEnquiry.do?action=getAllDevices

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

A list is available in the form of the Singapore Medical Device Register (SMDR). This shows all approved medical devices in Singapore and provides information on them. It is not a list of recommended devices for procurement.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Health Technology Assessment Branch, and Agency for care effectiveness (ACE).

Website(s): https://www.ace-hta.gov.sg/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Medical Device Branch, Health Sciences Authority.

Website(s): https://www.hsa.gov.sg/medical-devices/

Contact: Ms. Joanna Koh Email: joanna_koh@hsa.gov.sg

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: https://www.hsa.gov.sg/medical-devices/registration/guides

Nomenclature comments (...Annex 1):
The Global Medical Device Nomenclature (GMDN) is used as an internal reference and it is not required for medical device product registration

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	42	7.76
Computerized Tomography Scanner:α	48	8.87
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	85	127.65
Radiotherapy:β	30	5.13

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: Health Technology Assessment Branch, Ministry of Health. Unit website: https://www.hsa.gov.sg/medical-devices
Contact name: Dr. Pwee Keng Ho Contact email: pwee_keng_ho@moh.gov.sg
Website with publically available technical specifications: https://www.hsa.gov.sg/medical-devices
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 600

Contacts

National officer(s):
Name: —
Email: —

Name: Dr. Pwee Keng Ho
Email: pwee_keng_ho@moh.gov.sg

WHO Country officer(s):
Name: —
Email: wpmyswr@who.int

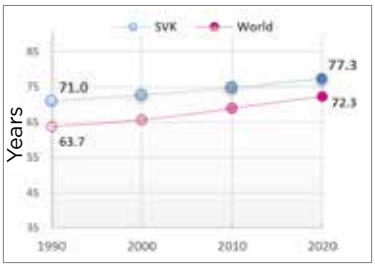
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Slovakia

Country indicators - WHO country information

Population 000s (rank):[a]	5,460 (116)	Under-five mortality (per 1000 live births):[d]	5.75	UHC - Service coverage index (1-100):[h]	77
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	15.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.8% (0.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.86 (0.81): very high	Global innovation index (rank):[j]	39.7 (39)
		ICT Development Index (rank):[g]	7.1 (46)	High-technology exports (% of manufacture exports):[k]	9.90%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: http://www.skmed.sk

Language(s): Slovak

Ministry of health responsible for health technology policy implementation: Department of Categorization Pricing and Drug Policy.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Ministry of Health.

Website: https://www.health.gov.sk/?zoznam-kategorizovanych-zdravotnickych-pomocok https://www.health.gov.sk/?zkszm

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): There is no list recomending health technology for above mentioned diseases/ situations.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2011/362/20210526 https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2011/363/20210413

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): The Working Group for Pharmacoeconomics, Clinical Outcomes and Health Technology Assessment of the Slovak Ministry of Health perform HTA, but not specifically for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: State Institute for Drug Control.

Website(s): https://www.sukl.sk/sk/zdravotnicke-pomocky-informacie?page_id=495

Contact: Ing. Ivan Bernát Email: pomocky@sukl.sk

Name(s) of other regulatory agency eg. for radiation equipment etc.: Nuclear Regulatory Authority of the Slovak Republic.

Other agency's website: https://www.ujd.gov.sk/ujd/www1.nsf/viewByKeyMenu/En-01

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: http://www.health.gov.sk

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	52	9.52
Computerized Tomography Scanner:α	100	18.32
Positron Emission Tomography Scanner:α	8	1.47
Gamma camera or nuclear medicine:α	30	5.49
Mammograph:α,*	100	135.44
Radiotherapy:β	37	6.78

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment

Website: —

Use of management software: Yes Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 63

Contacts

National officer(s):

Name: Dr. Branislav Jadud

Email: branislav.jadud@health.gov.sk

Name: —

Email: —

WHO Country officer(s):

Name: Dr. Tatul Hakobyan

Email: hakobyant@who.int

Name: —

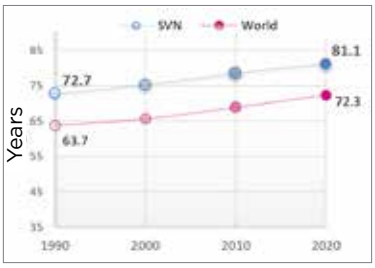
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Slovenia

Country indicators - WHO country information

Population 000s (rank):[a]	2,079 (145)	Under-five mortality (per 1000 live births):[d]	2.18	UHC - Service coverage index (1-100):[h]	80
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	11.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.9% (0.3%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.92 (0.88): very high	Global innovation index (rank):[j]	42.9 (32)
		ICT Development Index (rank):[g]	7.4 (33)	High-technology exports (% of manufacture exports):[k]	7.40%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http:/ / pisrs.si/ Pis.web/ pregledPredpisa?id=RESO102#

Language(s): Slovenian

Ministry of health responsible for health technology policy implementation: Directorate for healthcare economics

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia

Website: https://www.jazmp.si/en/regulation-of-activities/lists/

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.zdrzz.si/O_Zdruzenju/

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):
There are many boards (Slovenian Collegiate Boards) each responsible for one area of medicine. Those bodies produce recommendations on specific procedures where deemed necessary. Currently, recommendations are under

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: —

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
HTA framework is not done yet, but HTA processes are in an existing framework. HTA decision-taking is done by the following institutions: MoH, National Institute of Public Health, and the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP).

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Javna Agencija za zdravila in medicinske pripomocke / Agency for Medicinal Products and Medical Devicesof the Republic of Slovenia.

Website(s): http://www.jazmp.si/en/medical_devices/

Contact: Momir Radulovi_ Email: info@jazmp.si

Name(s) of other regulatory agency eg. for radiation equipment etc.: Slovenian Nuclear Safety Administration; Agency for Medicinal Products and and Medical Devices of the Republic of Slovenia.

Other agency's website: https://www.gov.si/en/state-authorities/bodies-within-ministries/slovenian-nuclear-safety-administration/

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: https://www.enarocanje.si/
https://simap.ted.europa.eu/cpv
https://webgate.ec.europa.eu/dyna2/emdn/

Nomenclature comments (...Annex 1):
As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: Yes Website: http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO7086

National level procurement: Yes Website: https://www.gov.si/drzavni-organi/ministrstva/ministrstvoza-zdravje/o-ministrstvu/direktorat-za-zdravstveno-ekonomiko/sektor-za-investicije-in-javna-narocila/

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
The name of the procurement policy is: Zakon o javnem naro_anj (ZJN-3)

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	26	12.51
Computerized Tomography Scanner:[α]	38	18.28
Positron Emission Tomography Scanner:[α]	3	1.44
Gamma camera or nuclear medicine:[α]	17	8.18
Mammograph:[α,*]	31	106.03
Radiotherapy:[β]	17	8.18

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No

Unit/Department: Division of Investments and Public Procurement. Unit website: https://www.gov.si/drzavni-organi/ministrstva/ministrstvo-za-zdravje/o-ministrstvu/direktorat-za-zdravstveno-ekonomiko/sektor-za-investicije-in-javna-narocila/

Contact name: Mr. Smiljan Mekicar Contact email: smiljan.mekicar@gov.si

Website with publically available technical specifications: https://www.enarocanje.si/

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment

Website: —

Use of management software: No Software name: —

Software comments (...Annex 1):
The inventories website is still in development and is not yet available to the public.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 174

Contacts

National officer(s):

Name: Mr. Smiljan Mekicar

Email: smiljan.mekicar@gov.si

Name: Momir Radulovi_

Email: info@jazmp.si

WHO Country officer(s):

Name: Dr. Aiga Rurane

Email: ruranea@who.int

Name: —

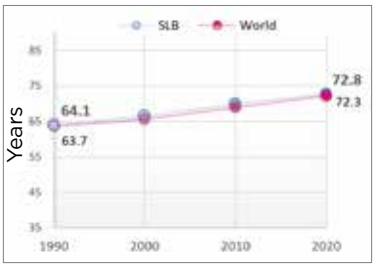
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Solomon Islands

Country indicators - WHO country information

Population 000s (rank):[a]	687 (161)	Under-five mortality (per 1000 live births):[d]	19.38	UHC - Service coverage index (1-100):[h]	50
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	39.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.57 (—): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	2.1 (157)	High-technology exports (% of manufacture exports):[k]	1.40%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Equipment Committee.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): Unfortunately, there are no such lists. Donation equipment have various brands.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There is no formalized HTA available and it relies heavily on other institutions assessment mechanisms, such as the WHO.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: Ministry of Health & Medical Services, Solomon Islands Government.

Website(s): https://solomons.gov.sb/ministry-of-health-medical-services/#division

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): The National Referral Hospital (NHR) performs most of the procurement, planning and allocation for the Provincial Hospital. There is a disposable procurement by the Ministry of Finance.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
There is virtually none of this currently in place.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The procurement Unit, Ministry of Health & Medical Service, has mainly to do with the finance but no with the technical aspect of the equipment. The Committee is Ad hoc and meets only to allocate equipment base on Departmental requests.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: Mr. Tenneth Dalipanda
Email: tdalipanda@moh.gov.sb

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Sevil Huseynova
Email: huseynovas@who.int

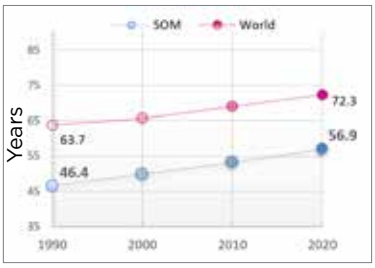
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Somalia

Country indicators - WHO country information

Population 000s (rank):[a]	15,893 (72)	Under-five mortality (per 1000 live births):[d]	114.62	UHC - Service coverage index (1-100):[h]	27
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	30.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	— (—):	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: —

Language(s): English

Ministry of health responsible for health technology policy implementation: National Medicines Regulatory Authority.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: National Medicines Regulatory Authority (NMRA): Department Medical Services.

Website(s): —

Contact: Mr. Saed Nuh Ahmed Email: saednux@gmail.com

Committee includes a biomedical or clinical engineer: No

HTA unit comments (...Annex 1): National Medicines Regulatory Authority (NMRA) under Department of Medical Services has an HTA role. However, even if the designated unit is present in the organigram is not yet well established. There are scarce HTA activities, but the plans are to expand, specially in pharmaceutics. The UHC country goal is in progress.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: National Medicines Regulatory Authority.

Website(s): https://moh.nomadilab.org/policy-planing/

Contact: Mr. Saed Nuh Ahmed Email: saednux@gmail.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministry of Health Somalia, Department of Public Health; Ministry of Energy & Water Resources.

Other agency's website: https://moh.nomadilab.org/1181-2/ https://moewr.gov.so/

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For regulatory purposes
Website: —

Nomenclature comments (...Annex 1):
The definition of medical devices is included in the national medicines law which is not yet ratified.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):
Name: Mr. Saed Nuh Ahmed
Email: saednux@gmail.com

Name: Mr. Hassan Elmi
Email: elmih@som.emro.who.int

WHO Country officer(s):
Name: Dr. Mamunur Md Sk Malik
Email: malikm@who.int

Name: Dr. Hassan Mohamed Elmi
Email: lmih@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

South Africa

Country indicators - WHO country information

Population 000s (rank):[a]	59,309 (25)	Under-five mortality (per 1000 live births):[d]	32.22	UHC - Service coverage index (1-100):[h]	67
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.4% (0.1%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.71 (0.47): high	Global innovation index (rank):[j]	32.7 (60)
		ICT Development Index (rank):[g]	5 (92)	High-technology exports (% of manufacture exports):[k]	5.50%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.sahpra.org.za/

Language(s): English

Ministry of health responsible for health technology policy implementation: Health Technology Directorate.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Health Technology.

Website: —

Nomenclature systems used for devices and tests: GMDN.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.sahpra.org.za/wp-content/uploads/2020/01/Classification_Medical_Devices_IVDs_Nov19_v2.pdf

Website - laboratories: https://www.sahpra.org.za/biological-products/

Nomenclature systems used for devices and tests: GMDN.

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Approved devices lists comments (...Annex 1):

There are no lists of the mentioned above. The list is only for the private sector funders (not the government). The National Department of Health is engaging with the private sector to establish a national system.

Health care facilities lists comments (...Annex 1):

Both UMNDS and GMDN have been used.

Specific lists comments (...Annex 1):

There are none of the cited lists mentioned above.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: National Health Technology Committee.

Website(s): http://www.health.gov.za/ https://www.gov.za/about-government/government-programmes/national-health-insurance-0?gclid=Cj0KCQjw4v2EBhCtARIsACan3nwMeUvMBkrHmKSJqw8W_oNCjOvApxawbfpSz6neNv26jGvTw0tyZyEaAk2PEALw_wcB#

Contact: Mr. Sam Bakhane Email: setlhare.bakhane@health.gov.za

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):

The institutionalization of a national HTA as part of the ongoing National Health Insurance (NHI) is in the process towards the National Department of Health (NDoH) and the Universal Health Care (UHC) goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: South African Health Products Regulatory Authority (SAHPRA).

Website(s): www.sahpra.org.za

Contact: Ms. Andrea Julsing Email: andrea.julsing@org.za

Name(s) of other regulatory agency eg. for radiation equipment etc.: Directorate of Radiation Control.

Other agency's website: www.sahpra.org.za https://nnr.co.za/ http://www.necsa.co.za/

National regulatory comments (...Annex 1):

The radiation control is now part of the tasks of the South African Health Products Regulatory Authority (SAHPRA).

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: For regulatory purposes

Website: —

Nomenclature comments (...Annex 1):
The regulator has adopted the use of GMDN which will be a nationally accepted nomenclature.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: www.treasury.gov.za
http://www.treasury.gov.za/legislation/pfma/Default.aspx
http://www.treasury.gov.za/legislation/pfma/Default.aspx

National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: www.treasury.gov.za

Medical device incorporation comments (...Annex 1):
The Office of the Chief Procurement Officer is in charge of the procurement of medical devices.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	12	0.2
Computerized Tomography Scanner:[α]	51	0.86
Positron Emission Tomography Scanner:[α]	3	0.05
Gamma camera or nuclear medicine:[α]	28	0.47
Mammograph:[α,*]	32	7.34
Radiotherapy:[β]	135	2.28

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Health Technology Policy. Unit website: —

Contact name: Mr. Sam Bakhane Contact email: setlhare.bakhane@health.gov.za

Website with publically available technical specifications: www.treasury.gov.za

Number of regional/state offices/units: 9

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: Yes Software name: —

Software comments (...Annex 1):
There are no national inventory nor management systems but some hospitals do have. Currently, we are compiling a national inventory and acquiring a system to be implemented at a national level. Thus, we are progressing to acquire the national system.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 300

Contacts

National officer(s):

Name: Mr. Sam Setlhare Bakhane
Email: setlhare.bakhane@health.gov.za

Name: Mr. S. du Plessis
Email: duples@fshealth.gov.za

WHO Country officer(s):

Name: Dr. Owen Laws Kaluwa
Email: kaluwao@who.int

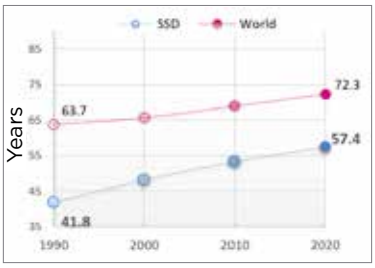
Name: Dr. Habib Somanje
Email: somanjeha@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

South Sudan

Country indicators - WHO country information

Population 000s (rank):[a]	11,194 (83)	Under-five mortality (per 1000 live births):[d]	97.86	UHC - Service coverage index (1-100):[h]	32
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.43 (0.28): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes
HTA unit/department includes the assessment of medical devices: —
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Olushayo Olu
Email: afwcosswho@who.int

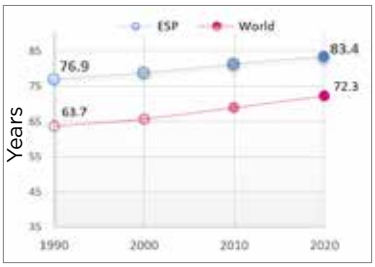
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Spain

Country indicators - WHO country information

Population 000s (rank):[a]	46,755 (30)	Under-five mortality (per 1000 live births):[d]	3.25	UHC - Service coverage index (1-100):[h]	86
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	9.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	5.7% (1.2%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.9 (0.78): very high	Global innovation index (rank):[j]	45.6 (30)
		ICT Development Index (rank):[g]	7.8 (27)	High-technology exports (% of manufacture exports):[k]	6.90%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: http://www.msps.es/organizacion/sns/planCalidadSNS/home.htm

Language(s): Español

Ministry of health responsible for health technology policy implementation: Agencia de la Calidad en el Sistema Nacional de Salud.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: Yes

Unit: Dirección General de Ordenación Profesional, Cohesión del Sistema Nacional de Salud y Alta Inspección.

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: No

Website - hospitals: —

Website - laboratories: https://www.aemps.gob.es/productos-sanitarios/productossanitarios_invitro/

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[5] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: AETS-ISCIII.

Website(s): https://www.aemps.gob.es/productos-sanitarios/vigilancia_productossanitarios/; https://eng.isciii.es/eng.isciii.es/Paginas/Inicio.html http://www.aetsa.org/; http://aquas.gencat.cat/ca/inici/; http://avalia-t.sergas.es http://www.bioef.org/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There is a network of Agencies for HTA and services of the National Health System. The HTA is for decision-making within the health system, as well as for medical products, including medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS).

Website(s): http://www.aemps.es

Contact: Ms. Carmen Abad Luna Email: cabad@aemps.es

Name(s) of other regulatory agency eg. for radiation equipment etc.: Consejo de Seguridad Nuclear; Ministerio para la Transición Ecológica y el Reto Demográfico.

Other agency's website: https://www.csn.es/home https://www.miteco.gob.es/en/

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: —

Nomenclature comments (...Annex 1):

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):

—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	805	17.22
Computerized Tomography Scanner:[α]	895	19.14
Positron Emission Tomography Scanner:[α]	84	1.8
Gamma camera or nuclear medicine:[α]	309	6.61
Mammograph:[α,*]	760	120.64
Radiotherapy:[β]	434	9.28

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: https://www.mscbs.gob.es/estadEstudios/estadisticas/sisInfSanSNS/tablasEstadisticas/InfAnualSNS2016/Informe_Anual_SNS_2016_completo.pdf

Use of management software: — Software name: —

Software comments (...Annex 1):

—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 1000

Contacts

National officer(s):

Name: Mr. Antonio Sarria-Santamera

Email: asarria@isciii.es

Name: —

Email: —

WHO Country officer(s):

Name: —

Email: —

Name: —

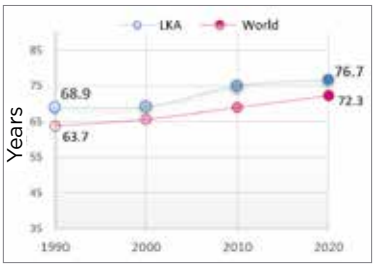
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Sri Lanka

Country indicators - WHO country information

Population 000s (rank):[a]	21,413 (57)	Under-five mortality (per 1000 live births):[d]	6.93	UHC - Service coverage index (1-100):[h]	67
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	13.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	5.4% (0.9%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (0.67): high	Global innovation index (rank):[j]	23.8 (101)
		ICT Development Index (rank):[g]	3.9 (117)	High-technology exports (% of manufacture exports):[k]	1.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: —

Website: https://nmra.gov.lk/index.php?option=com_devices&view=devices&Itemid=224&lang=en

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://nmra.gov.lk/images/PDF/Legislation/5e_nmdra_07.pdf http://www.health.gov.lk/moh_final/english/hospital_government.php?spid=24

Website - laboratories: https://nmra.gov.lk/index.php?option=com_devices&view=devices&Itemid=224&lang=en

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): The institutionalizing of an HTA as a mechanism for promoting health system integrity is in early stages.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Cosmetics, Devices and Drugs Authority.

Website(s): http://www.health.gov.lk

Contact: Dr. H. Beneragama Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: National Medicines Regulatory Authority.

Other agency's website: https://nmra.gov.lk/index.php?lang=en

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	9	0.42
Computerized Tomography Scanner:[α]	36	1.69
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	4	0.19
Mammograph:[α,*]	6	2.81
Radiotherapy:[β]	23	1.07

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Division of Biomedical Services. Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 3

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: Yes Software name: VH Temp.

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Mr. J.M.L.K. Jayathilake
Email: muditha j@hotmail.com

Name: Dr. Terance
Email: —

WHO Country officer(s):
Name: Dr. Alaka Singh
Email: singha@who.int

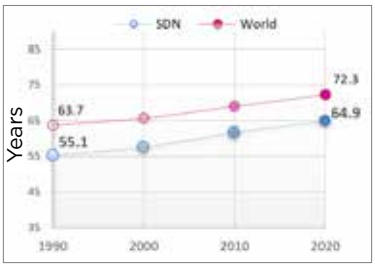
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Sudan

Country indicators - WHO country information

Population 000s (rank):[a]	43,849 (34)	Under-five mortality (per 1000 live births):[d]	56.58	UHC - Service coverage index (1-100):[h]	44
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.51 (0.33): low	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	2.6 (145)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): Arabic and English

Ministry of health responsible for health technology policy implementation: Health Development Unit.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.nmpb.gov.sd/en/lic_lap_pharm.php

Website - laboratories: http://www.nmpb.gov.sd/en/lic_lap_pharm.php

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

A Health Technology Management system (HTM) has been developed. However, there is not current HTA system in place, but it is a goal to pursue towards the Universal Health Care country goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: National Medicine and Poison Board.

Website(s): http://www.nmpb.gov.sd/

Contact: Dr. Mohamed Elhassan Mohamed Ahmed Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Sudanese Nuclear and Radiological Regulatory Authority; National Medicines and Poisons Board (NMPB).

Other agency's website: http://www.snrra.gov.sd/English/index.php http://www.nmpb.gov.sd/imp_device.php

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: For procurement purposes
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	12	0.32
Computerized Tomography Scanner:[α]	43	1.13
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	5	0.13
Mammograph:[α,*]	20	12.18
Radiotherapy:[β]	12	0.27

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Medical Engineering Unit/ Curative Medicine Department. Unit website: —
Contact name: Eng. Fatima Mohamed Fadol Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 7

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 365

Contacts

National officer(s):
Name: Mr. Mohamed Osman Hamid
Email: osmanhamid72@gmail.com

Name: Eng. Fatima Mohamed Fadol
Email: —

WHO Country officer(s):
Name: Dr. Nima Saeed Abid
Email: abidn@who.int

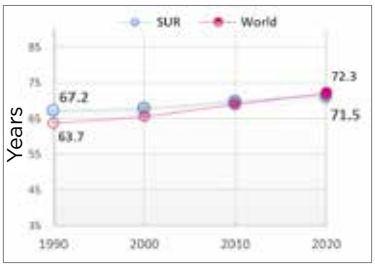
Name: Dr. Nahid Idris Salih Khalid
Email: salihn@sud.emro.who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Suriname

Country indicators - WHO country information

Population 000s (rank):[a]	587 (164)	Under-five mortality (per 1000 live births):[d]	17.57	UHC - Service coverage index (1-100):[h]	67
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	4.9% (1.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.74 (0.54): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	5.2 (88)	High-technology exports (% of manufacture exports):[k]	12.50%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: Ministry of Health.
Website(s): http://health.gov.sr/
Contact: Secretariat of the Director of Health Email: secdir.volksgezondheid@gov.sr
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	2	3.71
Computerized Tomography Scanner:[α]	4	7.42
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	4	93.6
Radiotherapy:[β]	3	5.11

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Mrs. Mellenie Kasanredjo
Email: mellenie.saimoen@gov.sr

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Karen Lewis-Bell
Email: lewisbek@paho.org

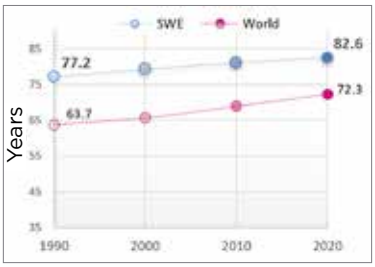
Name: Dr. Rosmond Adams
Email: adamsros@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Sweden

Country indicators - WHO country information

Population 000s (rank):[a]	10,099 (90)	Under-five mortality (per 1000 live births):[d]	2.64	UHC - Service coverage index (1-100):[h]	87
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	8.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.95 (0.88): very high	Global innovation index (rank):[j]	62.5 (2)
		ICT Development Index (rank):[g]	8.4 (11)	High-technology exports (% of manufacture exports):[k]	14.60%

National policy on health technology

Health technology (medical device) national policy: —

Policy is part of the National Health Program/Plan: —

Website: https://www.government.se/government-of-sweden/ministry-of-health-and-social-affairs/

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
The devices must bear the CE-mark.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):
There is an ongoing project in order to create such a national list. It is the Dental and Pharmaceutical Benefits Agency that is working with that.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: The Dental and Pharmaceutical Benefits Agency.

Website(s): https://www.tlv.se/medicinteknik.html
https://lakemedelsverket.se/english/
https://www.sbu.se/en/

Contact: Ms. Karin Melén Email: Karin.Melen@tvl.se

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
Network of HTA agencies such as: the Dental and Pharmaceutical Benefits Agency (TLV); Agency for the HTA and Assessment of Social Services (SBU), and Medical Products Agency. Alternative email: registrator@tlv.se.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Medical Products Agency.

Website(s): http://www.lakemedelsverket.se/english/

Contact: Ms. Malin Blixt Email: registrator@mpa.se

Name(s) of other regulatory agency eg. for radiation equipment etc.: Swedish Radiation Safety Authority.

Other agency's website: https://www.stralsakerhetsmyndigheten.se/en/

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on EMDN Use: For regulatory purposes

Website: —

Nomenclature comments (...Annex 1):

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):

The national law for procurement is based on the EU directive. Concerning procurement, it can be done at a country level or within a single hospital.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	130	12.87

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —

Website: —

Use of management software: Yes Software name: —

Software comments (...Annex 1):

—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 1137

Contacts

National officer(s):

Name: —

Email: —

Name: —

Email: —

WHO Country officer(s):

Name: —

Email: —

Name: —

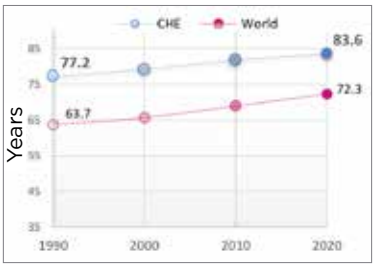
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Switzerland

Country indicators - WHO country information

Population 000s (rank):[a]	8,655 (100)	Under-five mortality (per 1000 live births):[d]	4	UHC - Service coverage index (1-100):[h]	87
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	7.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.96 (0.89): very high	Global innovation index (rank):[j]	66.1 (1)
		ICT Development Index (rank):[g]	8.7 (3)	High-technology exports (% of manufacture exports):[k]	12.90%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Swiss Federal Office of Public Health.

Website: https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung.html

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Reimbursement list for medical devices used by the patients themselves, and Reimbursement list for medical analyses are available on the corresponding website (see link).

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Health and Accident Insurance Directorate.

Website(s): http://www.snhta.ch/
https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherung-bezeichnung-der-leistungen/re-evaluation-hta.html
https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/heilmittel.html

Contact: — Email: ELGK-sekretariat@bag.admin.ch

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

There is the swiss network of HTA entities focusing in various areas. Some institutions are: Health Insurance Benefits, State Secretariat for Education, Research and Innovation, etc.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Swiss Agency for Therapeutic Products (Swissmedic).

Website(s): https://www.swissmedic.ch/swissmedic/en/home/

Contact: Dr. Karoline Mathys Badertscher Email: Karoline.Mathys@swissmedic.ch

Name(s) of other regulatory agency eg. for radiation equipment etc.: Swiss Federal Nuclear Safety Inspectorate (ENSI); Federal Office of Public Health (FOPH).

Other agency's website: https://www.ensi.ch/en/
https://www.bag.admin.ch/bag/en/home.html

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: More than one system
Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
Swissmedic uses GMDN (no country specific nomenclature), if manufacturers do not know the GMDN number, a UMDNS code may be given.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The medical devices must fulfil the requirements described in the European medical device directives. Legal basis (Swiss Medical devices ordinance): http://www.admin.ch/ch/d/sr/c812_213.html. The hospital / high cost technology planning is done at a national level. Coordinated planning of certain highly specialized areas of health care is in progress (see https://www.gdk-cds.ch/de/).

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	111	12.82

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: https://www.gdk-cds.ch/de/; https://www.gdk-cds.ch/fileadmin/docs/public/gdk/themen/spitalfinanzierung/GDK-UEbersicht_Spitallisten_Spitaltarife.pdf
Use of management software: — Software name: —

Software comments (...Annex 1):
Go to the gdk website and search for the 291.0.html documentation.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 120

Contacts

National officer(s):
Name: Mr. André Breisinger
Email: questions.devices@swissmedic.ch

Name: —
Email: —

WHO Country officer(s):
Name: —
Email: —

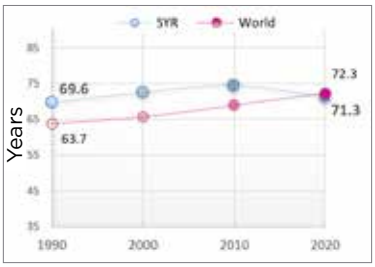
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Syrian Arab Republic

Country indicators - WHO country information

Population 000s (rank):[a]	17,501 (67)	Under-five mortality (per 1000 live births):[d]	22.4	UHC - Service coverage index (1-100):[h]	56
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	22.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.57 (—): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	3.3 (126)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: —

Policy is part of the National Health Program/Plan: —

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: —

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: —

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): It exists the Planning and International Collaboration Directorate which performed HTA activities, but it is not specifically for medical devices.

HTA unit/department includes the assessment of medical devices: —

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

National regulatory comments (...Annex 1): —

Presence of national authority responsible for regulating medical devices: —

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Syrian Atomic Energy Commission.

Other agency's website: http://www.aec.org.sy/

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	12	0.69

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Akjemal Magtymova
Email: magtymova@who.int

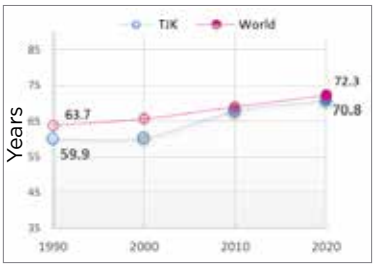
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Tajikistan

Country indicators - WHO country information

Population 000s (rank):[a]	9,538 (94)	Under-five mortality (per 1000 live births):[d]	32.28	UHC - Service coverage index (1-100):[h]	66
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	28.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.67 (0.58): medium	Global innovation index (rank):[j]	22.2 (109)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://adbmch.tj/en/home/
http://www.pharmnadzor.tj/index.html

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: Yes

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: —

Website - hospitals: http://ncl.tj/

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: —

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit comments (...Annex 1): —

HTA unit/department includes the assessment of medical devices: No

Unit/department: Medical Devices Unit.

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

National regulatory comments (...Annex 1): —

Name of regulatory agency: State Supervision Service for Pharmaceutical Activities of the Republic of Tajikistan; Agency of Standardization, Metrology, Certification and Trade Inspection under the Government of Republic of Tajikistan.

Website(s): https://adbmch.tj/en/home/
http://www.pharmnadzor.tj/
http://www.standard.tj/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Agency on Nuclear and Radiation Safety, National Academy of Sciences of Tajikistan.

Other agency's website: https://anrt.tj/en/research-institutes/division-of-physical-mathematical-chemical-geological-and-technical-sciences/agency-on-nuclear-and-radiation-safety

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: For procurement purposes

Website: https://portal.eaeunion.org/sites/odata/redesign/Pages/MedicalDeviceNomenclature.aspx

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —

National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	3	0.37
Computerized Tomography Scanner:[α]	9	1.1
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	5	12.59
Radiotherapy:[β]	2	0.21

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —

Unit/Department: Medical Devices Unit. Unit website: http://www.pharmnadzor.tj/

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: https://adbmch.tj/en/home/

Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):

Name: Mr. Salim Abdulazizov

Email: abdu_salim@mail.ru

Name: —

Email: —

WHO Country officer(s):

Name: Dr. Victor Stefan Olsavszky

Email: olsavszkyv@who.int

Name: —

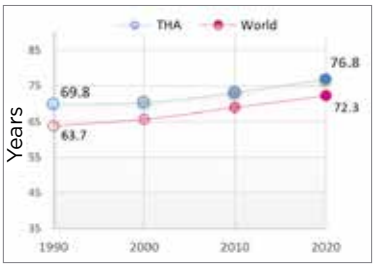
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Thailand

Country indicators - WHO country information

Population 000s (rank):[a]	69,800 (20)	Under-five mortality (per 1000 live births):[d]	8.65	UHC - Service coverage index (1-100):[h]	83
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	13.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.2% (0.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (0.65): high	Global innovation index (rank):[j]	36.7 (44)
		ICT Development Index (rank):[g]	5.7 (78)	High-technology exports (% of manufacture exports):[k]	23.60%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: https://www.moph.go.th/

Language(s): Thai

Ministry of health responsible for health technology policy implementation: Food and Drugs Administration.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: 1. National Health Security Office, 2.The Comptroller General's Department, 3.Social Security Office.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

There are lists of recommended procedures in organization level such as the procedure of the Physical Therapy Council. The approved medical devices list is only available for the reimbursements of the three health insurances, namely

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

There are lists of recommended procedures in organization level such as the procedure of the Physical Therapy Council.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Health Intervention and Technology Assessment Program (HITAP)

Website(s): https://www.hitap.net/en/organization/background

Contact: Dr. Pongpan Vongmanee Email: pongpan_v@fda.moph.go.th

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

HTA is focused on several health technologies and programs, including pharmaceuticals, medical devices, interventions, and disease prevention as well as to inform policy decisions.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Food and Drug Administration.

Website(s): https://www.moph.go.th/index.php/search
http://www.fda.moph.go.th/eng/medical/index.stm

Contact: Dr. Pongpan Vongmanee Email: pongpan_v@fda.moph.go.th

Name(s) of other regulatory agency eg. for radiation equipment etc.: Office of Atoms for Peace, Ministry of Science and Technology.

Other agency's website: https://most.go.th/main/en
http://www.nst.or.th/en/index.html

National regulatory comments (...Annex 1):

The Office of Atoms for Peace (OAP), within the Ministry of Science and Technology, is the responsible agency for strengthening regulatory control of sources that involve radioactive activities such as manufacturing, radiation processing, radiation application (medical, industrial, research, etc.), importation and exportation of radioactive sources and radioactive waste management under the Atomic Energy for Peace Law, BE2504 (1961) and the Nuclear Energy for Peace

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.moph.go.th/
National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: http://www.moph.go.th

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.moph.go.th/index.php/

Medical device incorporation comments (...Annex 1):
The procurement was performed by individividual agencies. For technical specifications go to the web site and find the law section, search for the corresponding documents.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	399	5.95
Positron Emission Tomography Scanner:[α]	5	0.07
Gamma camera or nuclear medicine:[α]	30	0.45
Mammograph:[α,*]	215	27.87
Radiotherapy:[β]	140	2.01

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 9

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: RMC2005.

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Mr. Chapon Ratanapan
Email: sonapan@fda.moph.go.th

Name: Dr. Orasa Kovindha
Email: kovindha@yahoo.com

WHO Country officer(s):
Name: Dr. Jos Vandelaer
Email: vandelaerjo@who.int

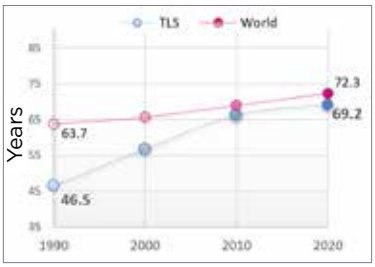
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Timor-Leste

Country indicators - WHO country information

Population 000s (rank):[a]	1,318 (152)	Under-five mortality (per 1000 live births):[d]	42.27	UHC - Service coverage index (1-100):[h]	53
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	20.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	2.9% (0.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.61 (0.44): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	3.6 (122)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1): There is the Standart Medical Equipment from Australia Advissor of Medical Equipment. See Clasification Minimum Standard equipment HP, CHC, DHC.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): The Inventory is from 2002-2009.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: —
Email: —

Name: Mr. Herculano da Silva
Email: egarggon_011105@yahoo.com

WHO Country officer(s):
Name: Dr. Arvind Mathur
Email: mathura@who.int

Name: —
Email: —

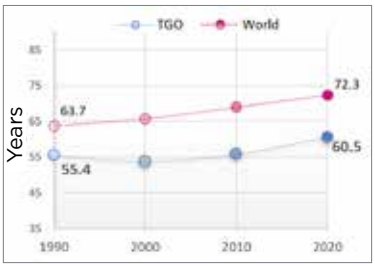
General comments (...Annex 1):

The Health Technology of medical equipment does not have standards for Medical Equipment yet.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Togo

Country indicators - WHO country information

Population 000s (rank):[a]	8,279 (101)	Under-five mortality (per 1000 live births):[d]	64.38	UHC - Service coverage index (1-100):[h]	44
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	23.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.52 (0.35): low	Global innovation index (rank):[j]	18.5 (125)
		ICT Development Index (rank):[g]	2.2 (156)	High-technology exports (% of manufacture exports):[k]	0.10%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Aucune organisation en charge de ces listes existe, malgré toutes les propositions formulées dans ce sens. Il ne semble pas avoir la volonté politique à évoluer dans ce sens.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —

HTA unit/department includes the assessment of medical devices: —

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

—

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
Le niveau du sous service chargé chargé des équipements est trop bas pour être lisible. Les supérieurs hiérarchique ne portent pas l'intérêt nécessaire pour la mise en oeuvre de la gestion qui s'impose pour les dispositifs médicaux.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
La politique suivi en terme d'achat de dispositif est celle du code des marchés publiques. L'achat ne se fait au niveau central que si l'Etat définit ponctuellement un programme d'intervention suite à une urgence nationale.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	1	0.15
Computerized Tomography Scanner:α	5	0.73
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	3	10.39
Radiotherapy:β	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Service de la Maintenance. Unit website: —
Contact name: Mr. Komlan Jean Edoh-kossi Contact email: kedohkos@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: 6

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
Bien que cela soit le point de départ de toute gestion en terme de maintenance des parcs biomédicaux, cette opération n'existe pas au plan national sauf par endroit mais aussi de façon sommaire . Les données ainsi consignées ne permettent pas de l'exploiter pour proposer des plans de renouvellement ou de developpement de parcs biomédicaux. En bref aucun inventaire digne de ce nom n'existe pas sur le plan national.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):
Name: —
Email: —

Name: Mr. Komlan Jean Edoh-kossi
Email: kedohkos@yahoo.fr

WHO Country officer(s):
Name: Dr. Fatoumata Binta T. Diallo
Email: diallof@who.int

Name: Dr. Minzah Pekele
Email: pekelem@who.int

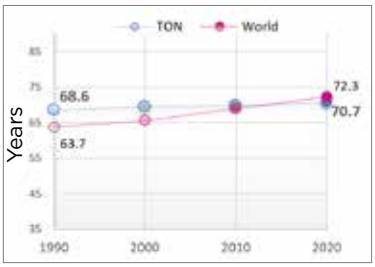
General comments (...Annex 1):

Compte tenue des difficultés que nous rencontrons pour la prise en compte adéquate des plateaux techniques dans nos formations sanitaires malgré les recommandations régionales pour une politique commune en matière de maintenance et la gestion durable des infrastructures sociales je veux bien croire que cette enquète nous ouvrira l' horizon de nouvelles politiques adptées à nos réalités.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Tonga

Country indicators - WHO country information

Population 000s (rank):[a]	106 (181)	Under-five mortality (per 1000 live births):[d]	11.41	UHC - Service coverage index (1-100):[h]	56
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.73 (—): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	4.3 (110)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Facility and Equipment Committee together with the Biomedical Engineering Unit of the Ministry of Health.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): There are no specific lists.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —

HTA unit/department includes the assessment of medical devices: —

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: Mr. Feleti Eke Email: feke@health.gov.to

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): Although there is no formal institution that oversees the implementation of any medical device regulation, there is the "Facility and Equipment Committee" of the Ministry of Health that oversees certain things such as the procurement of medical devices, the criteria of acceptance of donated equipment and the implementation of maintenance guidelines, etc.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	0	0
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	0	0
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Biomedical engineering. Unit website: —
Contact name: Mr. Feleti Eke Contact email: feke@health.gov.to
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Equipment Management Systems.

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):

Name: —
Email: —

Name: Mr. Feleti Eke
Email: feke@health.gov.to

WHO Country officer(s):

Name: Dr. Yutaro Setoya
Email: setoyay@who.int

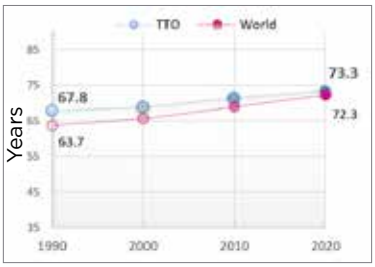
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Trinidad and Tobago

Country indicators - WHO country information

Population 000s (rank):[a]	1,399 (150)	Under-five mortality (per 1000 live births):[d]	16.6	UHC - Service coverage index (1-100):[h]	73
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	17.10%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.9% (1.9%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.8 (—): high	Global innovation index (rank):[j]	24.1 (98)
		ICT Development Index (rank):[g]	6 (68)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: http://www.health.gov.tt/

Language(s): English

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Ministry of Health.

Website: —

Nomenclature systems used for devices and tests: Other.

Approved devices lists comments (...Annex 1):

The nomenclature is part of the Computerized Maintenance Management System.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

Certification standards for equipment, e.g. European CE Marking and U.S. Food and Drug Administration.

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):

The list exists for point of care testing equipment, namely, Diagnostic Screening and Laboratory Testing. The medical equipment requirements for specific procedures are done by the respective inhouse Hospital Biomedical Department

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department:

Website(s): —

Contact: Mr. Kyron Lopez Email: kyron.lopez@health.gov.tt

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):

There are identified HTA activities at a national level. Furthermore a consultant is to be engaged to assists in the development of an HTA framework. Alternative contact for the Health Technology Management unit: pmu@health.gov.tt.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Chemistry Food and Drug Division.

Website(s): http://www.health.gov.tt
http://www.health.gov.tt/sitepages/default.aspx?id=93

Contact: Mr. Adrian Mc Cathy Email: adrianmccathy@health.gov.tt

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: More than one system
Use: For procurement purposes
Website: —

Nomenclature comments (...Annex 1):
Developed and in use as "Fixed Assest Inventory and Facilities Management". TMA Systems Maintenance Management Software (the nomenclature of medical devices are generally developed by the respective Regional Health Authorities for procurement purposes). The Ministry of Health of Trinidad and Tobago has established that no specific or official nomenclature system is used in this

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
There are guidelines based on the Regional Health Authorities (RHAs) internal policies and procedures on the procurement process and in particular for the need of the development of specifications. The Ministry of Health is presently moving towards standardising policies and procedures for all technical areas which would include the procurement of medical devices. Technical specifications are developed as part of all equipment procurement for public open tender. In general, there are recommended technical specifications used by each RHA for procurement of equipment as part of public tendering requirements. This is an area that the ministry is working with the RHAs towards standardising. For procurement information contact via mail to pmu@health.gov.tt (Project Management Unit).

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	7	5
Computerized Tomography Scanner:[α]	12	8.58
Positron Emission Tomography Scanner:[α]	1	0.71
Gamma camera or nuclear medicine:[α]	4	2.86
Mammograph:[α,*]	6	37.37
Radiotherapy:[β]	11	7.86

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Biomedical Department, North Central Regional Health Authority. Unit website: —
Contact name: Mr. Rusell Sooknanan Contact email: russel.sooknanan@ncrha.co.tt
Website with publically available technical specifications: —
Number of regional/state offices/units: 5

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (Diagnostic Imaging)
Website: —
Use of management software: Yes Software name: WebTMA.

Software comments (...Annex 1):
The inventories of other medical devices exist at each respective Regional Health Authorities (RHA) and for high-cost technologies such as diagnostic imaging.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 40

Contacts

National officer(s):
Name: Mr. Ronald Koylass
Email: Ronald.Koylass@health.gov.tt

Name: Mr. Rusell Sooknanan
Email: russel.sooknanan@ncrha.co.tt

WHO Country officer(s):
Name: Dr. Erica Lynette Wheeler
Email: wheelereri@paho.org

Name: Dr. Paul Edwards
Email: edwardsp@paho.org

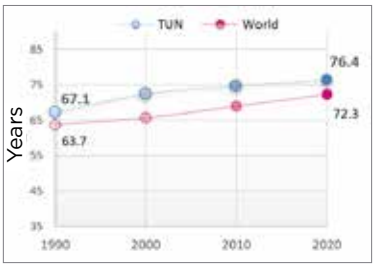
General comments (...Annex 1):

It is noted that several medical devices systems exist at the respective Regional Health Authorities (RHA) level. The MoH is currently working towards standardising these and in particular concerning the procurement guidelines for medical devices.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Tunisia

Country indicators - WHO country information

Population 000s (rank):[a]	11,819 (78)	Under-five mortality (per 1000 live births):[d]	16.62	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	15.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	18.4% (2.7%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.74 (0.6): high	Global innovation index (rank):[j]	31.2 (65)
		ICT Development Index (rank):[g]	4.8 (99)	High-technology exports (% of manufacture exports):[k]	6.90%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://www.santetunisie.tn/images/docs/pop-up3.html

Approved devices lists comments (...Annex 1):

L'acquisition et la mise en service des equipements lourds sont soumis a l'autorisation préalable du MoH pour les secteurs publique et privé et ce conformément aux critères et normes fixés par les arrêtés sus-indiqués. -Arrêté.

Health care facilities lists comments (...Annex 1):

—

Specific lists comments (...Annex 1):

L'acquisition et la mise en service des equipements lourds sont soumis a l'autorisation préalable du Ministère de la santé publique pour les secteurs publique et privé et ce conformément aux critères et normes fixés par les arrêtés

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: —

Website(s): https://www.ineas.tn/fr

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

INEAS is under the auspices of the MoH. It evaluates health technologies and provide rigorous evidence-based recommendations to decision-makers on pharmaceuticals and other technologies' uptake and use. As one internal policy trains it' s own staff, as well as HTA user's.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of Health.

Website(s): http://www.santetunisie.rns.tn/fr/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Centre National des Sciences et Technologies Nucléaires (CNSTN) et Centre National Chalbi Belkahia de Pharmacovigilance (CNPV).

Other agency's website: http://www.cnstn.rnrt.tn/radioprotection.php http://www.pharmacovigilance.rns.tn/

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
La nomenclature des dispositifs médicaux fait partie intégrante du Manuel des procédures de gestion de la maintenance biomédicale et hospitalière élaboré en 1996 et amélioré en 2007 par le Ministère de la santé publique qui a fait l'objet d'un arrêté.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: www.santetunisie.rns.tn

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
L'achat des dispositifs médicaux obéit en plus des procédures réglementaires (Reglément des marchés publics) d'unepart et passe par des commissions techniques spécialisés (commissions d'elaboration des cahiers des clauses techniques particulieres, fiches techniques, commissions de sélection, des commissions de réception provisoire et définitifs du matériel fiches techniques). Il n'ya pas de fiches techniques standard mais elles sont préparés au cas par cas en fonction du besoin (caractéristiques opérationnelles).

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	22	2
Computerized Tomography Scanner:[α]	98	8.91
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	13	1.18
Mammograph:[α,*]	21	22.58
Radiotherapy:[β]	29	2.45

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Agence Nationale de Contrôle Sanitaire et Environnemental des Produits.
Unit website: http://www.ancsep.rns.tn/
Contact name: Dir. General Contact email: ancsep.@rns.tn
Website with publically available technical specifications: http://www.santetunisie.rns.tn/fr/
Number of regional/state offices/units: 3

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: Yes Software name: G.M.B.H.

Software comments (...Annex 1):
Conformément au manuel des procédures de gestion de la maintenance chaque établissement de santé est dans l'obligation de tenir un inventaire technique des équipements et des infrastructures techniques, remplir la fiche d'identification et une fiche de santé (maintenance) par appareil. Un applicatif informatique dédiée a été développé à cet effet. Management Software: G.M.B.H. développé en local par le cetembh et le centre informatique du

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 20

Contacts

National officer(s):
Name: Mr. Fathi Amous
Email: fathi.amous@rns.tn

Name: Dir. General
Email: ancsep.@rns.tn

WHO Country officer(s):
Name: Dr. Yves Souteyrand
Email: souteyrandy@who.int

Name: Dr. Ramzi Ouhichi
Email: ouhichir@tun.emro.who.int

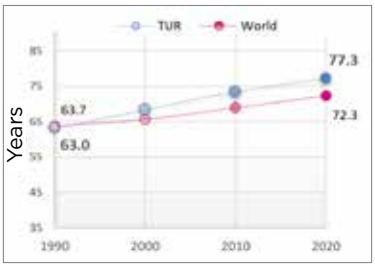
General comments (...Annex 1):

La structure publique de santé en Tunisie est composé de établissements publics de santé (CHU,H. Spécialisés) dans les sièges de faculté de médecine des hôpitaux régionaux des hôpitaux de circonscription des groupements de santé de base des centres de santé de base et des centres régionaux de médecine scolaire et universitaire en plus des trois hôpitaux militaires et un hôpital des forces de sécurité intérieure publics et six centres de d'hémodialyse et six polycliniques para-publique ne relevant pas du ministère de la santé le secteur privé

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Türkiye

Country indicators - WHO country information

Population 000s (rank):[a]	84,339 (17)	Under-five mortality (per 1000 live births):[d]	9.49	UHC - Service coverage index (1-100):[h]	79
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	15.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.2% (0.4%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.82 (0.68): very high	Global innovation index (rank):[j]	34.9 (51)
		ICT Development Index (rank):[g]	6.1 (67)	High-technology exports (% of manufacture exports):[k]	3.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Social Security Institution.

Website: https://www.saglik.gov.tr/TR,10550/turkiye-ilac-ve-tibbi-cihaz-kurumu.html

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=15023&MevzuatTur=7&MevzuatTertip=5

Website - laboratories: https://www.titck.gov.tr/dinamikmodul/85

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://www.saglik.gov.tr https://www.saglik.gov.tr/TR,10357/saglik-mevzuati.html

Approved devices lists comments (...Annex 1):

The Ministry of Health is closely involved in the decision making but the main responsible unit is the Social Security Institution of the Republic of Turkey. The directorate of Curative Services is the main responsible unit in the Ministry of Health

Health care facilities lists comments (...Annex 1):

—

Specific lists comments (...Annex 1):

These standards are not centrally organized and published. Each department has its own and they can be found in the second link under Saglik Mevzuati>Genelgeler, Tebligler, Yönergeler, Yönetmelikler>... Relevant departments

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: General Directorate of Curative Services.

Website(s): https://shgmargestddb.saglik.gov.tr/ https://www.saglik.gov.tr/

Contact: Mr. Irfan Sencan Email: irfan.sencan@saglik.gov.tr

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

Generic email of the HTA department shgm.argestd@saglik.gov.tr .

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Directorate of Pharmacy and Pharmaceuticals Department of Medical Device Services.

Website(s): https://www.titck.gov.tr/faaliyetalanlari/tibbicihaz

Contact: Mr. Bilgehan Karadayi Email: bilgehan.karadayi@iegm.gov.tr

Name(s) of other regulatory agency eg. for radiation equipment etc.: Nuclear Regulatory Authority (NDK); Turkish Medicines and Medical Devices Agency (TITCK).

Other agency's website: http://ndk.gov.tr/tr/ https://www.titck.gov.tr/faaliyetalanlari/tibbicihaz/tibbi-cihazda-klinik-arastirmalar

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: https://www.saglik.gov.tr/?_Dil=2

Nomenclature comments (...Annex 1):
Huab is the Turkish registry system for medical devices. Both GMDN and UNSPSC are used in this system. For reimbursement purposes another nomenclature mentioned in the corresponding link is also used.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.saglik.gov.tr/?_Dil=2
National level procurement: No Website: —

Donations

Policy or guideline: Yes Website: http://www.saglik.gov.tr/

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	915	10.85
Computerized Tomography Scanner:[α]	1211	14.36
Positron Emission Tomography Scanner:[α]	131	1.55
Gamma camera or nuclear medicine:[α]	299	3.55
Mammograph:[α,*]	966	120.72
Radiotherapy:[β]	300	3.56

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Directorate of Pharmacy and Pharmaceuticals. Unit website: https://www.hssgm.gov.tr/
Contact name: Mr. Saim Kerman Contact email: saim.kerman@iegm.gov.tr
Website with publically available technical specifications: https://www.hssgm.gov.tr/TuzuklerYonetmelikler
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: http://www.saglik.gov.tr/
Use of management software: — Software name: —

Software comments (...Annex 1):
Go to the previous website and search for sbhbt. However, the full online inventory databank, with restricted use to the authorities, is on the following site: http://sbu.saglik.gov.tr/sbhbf/

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 960

Contacts

National officer(s):
Name: —
Email: —

Name: Mr. Saim Kerman
Email: saim.kerman@iegm.gov.tr

WHO Country officer(s):
Name: Dr. Batyr Berdyklychev
Email: berdyklychevb@who.int

Name: —
Email: —

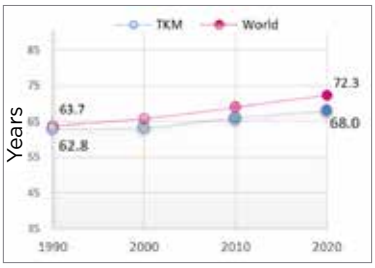
General comments (...Annex 1):

Concerning the medical equipment and structure section: there is a draft document (Health Statistics Yearbook) at the link: https://hsgm.saglik.gov.tr/tr/ , but it is not appropiate to use it as a reference since the original document will be available in the future. Some numbers can be variable because of the dynamic situation in Turkey. Especially for the last 5-7 years, the health technology situation is changing and developing rapidly.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Turkmenistan

Country indicators - WHO country information

Population 000s (rank):[a]	6,031 (111)	Under-five mortality (per 1000 live births):[d]	41.76	UHC - Service coverage index (1-100):[h]	73
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	27.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.72 (0.59): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: —

Policy is part of the National Health Program/Plan: —

Website: https://www.saglykhm.gov.tm/home

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: —

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): There is no systematic programme of health technology assessment, but an informed decision is mainly used for pharmaceutics but no for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —

Name of regulatory agency: Ministry of Health and Medical Industry of Turkmenistan.

Website(s): https://www.saglykhm.gov.tm/home

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	11	1.82

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: https://www.saglykhm.gov.tm/home
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr Egor Zaitsev
Email: zaitseve@who.int

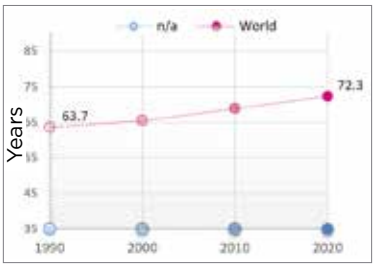
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Tuvalu

Country indicators - WHO country information

Population 000s (rank):[a]	12 (192)	Under-five mortality (per 1000 live births):[d]	22	UHC - Service coverage index (1-100):[h]	52
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	—	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	— (—):	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): English
Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - laboratories: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes
HTA unit/department includes the assessment of medical devices: No
Unit/department: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
National Drug and Therapeutic Committee (NDTC) has done HTA activities mainly in pharmaceutics; however, there is no a national HTA unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Ministry of Health.
Website(s): —
Contact: Director of Health Email: pphs@tuvalu.tv
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
Guidelines on Donations exist, they are nationally developed but they are not publicly available.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Biomedical Department of Princess Margaret Hospital. Unit website: —
Contact name: Mr. Nelson Morikao Vaguna Contact email: pphs@tuvalu.tv
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ —

Contacts

National officer(s):
Name: Mr. Nelson Morikao Vaguna
Email: wallabies.donny@gmail.com

Name: Mr. Natano Elisala
Email: pharmacyintuvalu@gmail.com

WHO Country officer(s):
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

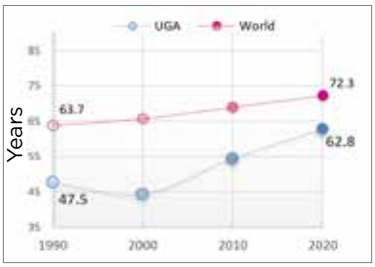
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Uganda

Country indicators - WHO country information

Population 000s (rank):[a]	45,741 (31)	Under-five mortality (per 1000 live births):[d]	43.32	UHC - Service coverage index (1-100):[h]	50
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	15.3% (3.8%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.54 (0.4): low	Global innovation index (rank):[j]	20.5 (114)
		ICT Development Index (rank):[g]	2.2 (152)	High-technology exports (% of manufacture exports):[k]	3.50%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.health.go.ug/

Language(s): English

Ministry of health responsible for health technology policy implementation: Health Infrastructure Department.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: National Advisory Commitee on Medical Equipment (NACME).

Website: www.health.go.ug

Nomenclature systems used for devices and tests: Nationally developed.

Approved devices lists comments (...Annex 1):
Usually we use the WHO recommendations. List of equipment by health care level is available in the website.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.nda.or.ug/medical-devices-guidelines/

Website - laboratories: https://www.nda.or.ug/drug-register-downloads/

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
Standard Medical Equipment list is under review.

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):
There are no national lists recommending health technology for specific procedures. We usually adhere to the World Health Organization recommendations.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —

HTA unit/department includes the assessment of medical devices: No

Unit/department: Health Infrastructure Division.

Website(s): http://www.health.go.ug

Contact: Eng. George Otim Odongcoo Email: otimodongcoo@gmail.com

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):
There are identified HTA activities but there is not a national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: National Drug Authority.

Website(s): https://www.nda.or.ug/

Contact: Mr. Gordon K. Sematiko Email: gsematiko@nda.or.ug

Name(s) of other regulatory agency eg. for radiation equipment etc.: Uganda National Bureau of Standards.

Other agency's website: https://www.nda.or.ug/medical-devices/

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For various purposes
Website: www.health.go.ug

Nomenclature comments (...Annex 1):
See the list of medical equipment by level, and the Standard Medical Equipment Lists and Specifications by healthcare level are under review (as in sample formats in the corresponding websites). The main uses of the nomenclature system are for procurement purposes, and inventory systems in healthcare facilities.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: www.ppda.go.ug
National level procurement: Yes Website: http://www.health.go.ug

Donations

Policy or guideline: Yes Website: http://www.health.go.ug

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
The Ministry acquires resources and procures in bulk; although for the last 2 years development funds for infrastructure have been directly allocated to regional referral hospitals which procure equipment with the guidance of the health infrastructure division and national advisory committee on medical equipment (NACME). The Public Procurement and Disposal of Public Assets Authority (within the MoH, specified website).

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	6	0.13
Computerized Tomography Scanner:α	20	0.44
Positron Emission Tomography Scanner:α	0	0
Gamma camera or nuclear medicine:α	3	0.07
Mammograph:α,*	5	3.3
Radiotherapy:β	4	0.09

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Health Infrastructure Department. Unit website: http://www.health.go.ug
http://mrh.igad.int/production/index_ug
Contact name: Eng. Sitra Mulepo Contact email: sitraik@hotmail.com
Website with publically available technical specifications: https://www.nda.or.ug/medical-devices/
Number of regional/state offices/units: 13

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: Yes Software name: New order for managing anything data (NOMAD) software.

Software comments (...Annex 1):
Currently, is being updated.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 500

Contacts

National officer(s):
Name: Mr. Sitra Mulepo C. S.
Email: sitraik@hotmail.com

Name: Eng. Sitra Mulepo
Email: sitraik@hotmail.com

WHO Country officer(s):
Name: Dr. Yonas Tegegn Woldemariam
Email: woldemariamt@who.int

Name: Mr. Joseph N. Mwoga
Email: mwogaj@who.int

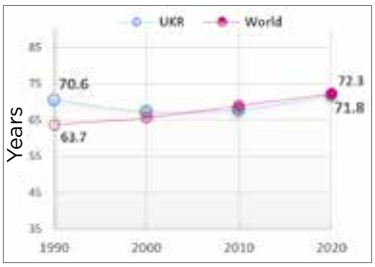
General comments (...Annex 1):

The policy guidelines on donations is at Chapter 5.1.5 of the medical equipment policy (see documentations). The Medical Equipment Policy is under review.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Ukraine

Country indicators - WHO country information

Population 000s (rank):[a]	43,734 (35)	Under-five mortality (per 1000 live births):[d]	8.11	UHC - Service coverage index (1-100):[h]	73
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	25.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	7.8% (0.9%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.78 (0.73): high	Global innovation index (rank):[j]	36.3 (45)
		ICT Development Index (rank):[g]	5.6 (79)	High-technology exports (% of manufacture exports):[k]	5.60%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: https://moz.gov.ua/uploads/0/691-strategiya.pdf; https://zakon.rada.gov.ua/laws/show/753-2013-%D0%BF#n11 https://zakon.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80#Text

Language(s): Ukranian

Ministry of health responsible for health technology policy implementation: Department of Regulatory Policy in the Treatment of Drugs and Products in the Health Care System of the Ministry of Health.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Department of Medical Care; the Department of Motherhood, and Childhood.

Website: https://moz.gov.ua/ministry-mandates/nakaz-moz-ukraini-vid-19072019--1645-pro-zatverdzhennja-rozpodilu-medichnogo-virobu-medichni-virobi-dlja-koronarografii-sudi

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
—

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://moz.gov.ua/dokumenti https://zakon.rada.gov.ua/rada/show/v0153282-98#Text

Website - laboratories: https://moz.gov.ua/dokumenti

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1):
There are many files, namely, the orders MSS. Orders of the Ministry of Health approval of protocols of care for various diseases.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: HTA Department State Expert Center (SEC), MoH.

Website(s): https://en.moz.gov.ua/ https://www.dec.gov.ua/

Contact: Ms Oresta Pinyazhko Email: pinyazhko@dec.gov.ua

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
In 2019 was established the national HTA within the MoH to power the National Essential Medicines List and to inform the National Benefits Package towards the Universal Health Care. The HTA is focused on a wide range of health products, interventions, but till now is rarely focused in medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: State Administration of Ukraine on Medicinal Products (SAUMP).

Website(s): https://en.moz.gov.ua/ https://www.dls.gov.ua/

Contact: Volodymyr Chekalin Email: Chekalin_VV@dls.gov.ua

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministry of Energy and Environment Protection of Ukraine

Other agency's website: https://mepr.gov.ua/en/

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified

Website: https://zakon.rada.gov.ua/rada/show/v0331282-01#Text
https://moz.gov.ua/article/ministry-mandates/nakaz-moz-ukraini-vid-28122019--2711-pro-zatverdzhennja-nomenklaturi-likarskih-zasobiv-ta-medichnih-virobiv-scho-zakupovuvatimutsja-za-naprjamami-vikoristannja-bjudzhetnih-koshtiv-u-2020-roci-za-bjudzhetnimi-programami-kpkvk-2301400

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: Yes Website: https://moz.gov.ua/zakupivli-likiv

Donations

Policy or guideline: Yes Website: https://en.moz.gov.ua/uploads/0/16-strategy_eng.pdf

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
Contact: Mr Ivan Zadvornykh, Email: ivanzadvornykh@gmail.com

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	198	4.53

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No

Unit/Department: Control of Monitoring and Maintenance of State Programs. Unit website: https://moz.gov.ua/ https://www.dls.gov.ua/

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: https://moz.gov.ua/derzhavnij-reestr-medichnoi-tehniki-ta-virobiv-medichnogo-priznachennja

Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 350

Contacts

National officer(s):

Name: Dr. Sergei Danilov
Email: sergdanilov@mail.ru

Name: Ms. Svetlana Zgonnik
Email: sz2212@gmail.com

WHO Country officer(s):

Name: Dr. Jarno Habicht
Email: habichtj@who.int

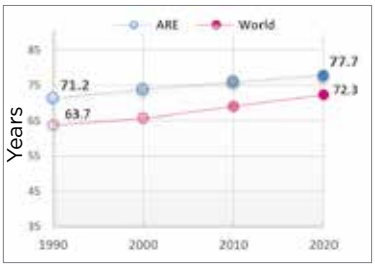
Name: Dr. Svitlana Pakhnutova
Email: pakhnutovas@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

United Arab Emirates

Country indicators - WHO country information

Population 000s (rank):[a]	9,890 (92)	Under-five mortality (per 1000 live births):[d]	6.57	UHC - Service coverage index (1-100):[h]	78
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	18.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.89 (—): very high	Global innovation index (rank):[j]	41.8 (34)
		ICT Development Index (rank):[g]	7.2 (40)	High-technology exports (% of manufacture exports):[k]	137.60%

National policy on health technology

Health technology (medical device) national policy: —

Policy is part of the National Health Program/Plan: —

Website: https://www.mohap.gov.ae/en/aboutus/Pages/PublicHealthPolicies.aspx

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: —

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://www.mohap.gov.ae/en/Pages/default.aspx https://www.doh.gov.ae/ https://www.dha.gov.ae/en/pages/dhahome.aspx

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): HTA activities have been identified within the MoH. It exists the Health Authority Abu Dhabi, the Dubai Health Authority and the Department of Health (DoH) but there is not a national unit. The main activities of the HTA are in health products pricing and reimbursement decisions. Also, the private sector is playing an increasing role in health care coverage.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —

Name of regulatory agency: Ministry of Health & Prevention.

Website(s): https://www.mohap.gov.ae/en/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Federal Authority for Nuclear Regulation (FANR) and Department of Health (DOH).

Other agency's website: https://www.fanr.gov.ae/; www.doh.gov.ae

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	7	0.71

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Rayana Ahmad Bou Haka
Email: emuaedesk@who.int

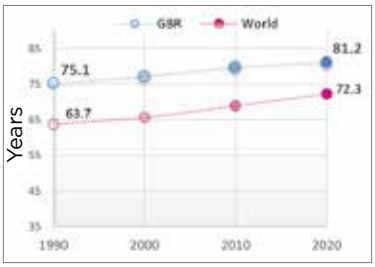
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

United Kingdom of Great Britain and Northern Ireland

Country indicators - WHO country information

Population 000s (rank):[a]	67,886 (21)	Under-five mortality (per 1000 live births):[d]	4.21	UHC - Service coverage index (1-100):[h]	88
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	10.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	1.6% (0.5%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.93 (0.86): very high	Global innovation index (rank):[j]	59.8 (4)
		ICT Development Index (rank):[g]	8.7 (5)	High-technology exports (% of manufacture exports):[k]	23.50%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

There is no approved list of medical devices for procurement. However we have lists for communicable and non communicable diseases, and public health emergency situations. Guidance is produced by NICE and CEP which was

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market http://guidance.nice.org.uk/IP?textonly=false; http://www.nice.org.uk/guidance/index.jsp?action=ByType&type=6&status=3&p=off. Also see www.dh.gsi.gov.uk/ce

Specific lists comments (...Annex 1):

The Centre for Evidence Based Purchasing (CEP) website is a portal containing over 600 and therefore too numerous for specific reference in this document. Please note CEP was disbanded end of March 2010 but the reports still apply to

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: National Institute for Health and Care Excellence (NICE).

Website(s): http://www.nice.org.uk/ http://awttc.org http://www.healthcareimprovementscotland.org

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

Evidence-based recommendations are developed in a wide range of areas: clinical guidelines, diagnostic technologies, interventional procedures, cost effectiveness, highly specialised, and medical technologies guidance.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: The Medicines and Healthcare products Regulatory Agency (MHRA).

Website(s): www.mhra.gov.uk; https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Contact: — Email: info@mhra.gov.uk

National regulatory comments (...Annex 1):

The Medicines and Healthcare products Regulatory Agency (MHRA) are the UK Competent Authority with respect to the safety, quality and performance placed on the market by manufacturers in the UK under the EU Medical Devices Directives.

Name(s) of other regulatory agency eg. for radiation equipment etc.: Office for Nuclear Regulation (ONR); Department for Business, Energy & Industrial Strategy, Health and Safety Executive, Office for Nuclear Regulation; Medicines and Healthcare products Regulatory Agency (MHRA).

Other agency's website: www.onr.org.uk https://www.gov.uk/guidance/regulatory-controls-for-radiation-protection-in-the-uk

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: Not specified

Website: http://www.mhra.gov.uk/Howweregulate/Devices/Registrationofmedicaldevices/index.htm; www.nhseclass.nhs.uk

Nomenclature comments (...Annex 1):
The Medicines and Healthcare products Regulatory Agency (MHRA) will be moving forward to use solely the GMDN with their system being phased out. The nomenclature used by the National Health System (NHS) for the procurement of medical devices is that used by the "Official Journal of the European Union" (OJEU) CPV codes. The NHS also has a national system known as "e-class" which

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market

National level procurement: Yes Website: http://www.supplychain.nhs.uk http://www.nhsnss.org

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe/essential-technical-requirements-for-ppe-medical-devices-further-information-for-health-and-social-care-providers

Medical device incorporation comments (...Annex 1):
Medical devices may be procured at a number of levels, either locally (NHS Trust level), regionally (collaborative procurement hub level) or nationally (NHS Supply chain). Also in Scotland, there is a system for National Procurement for the NHS.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	465	6.85

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1):
A recent amendment of the Medical Devices Directive has lifted the confidentiality requirement on information supplied by manufacturers to Competent Authorities under their obligation to register certain types of medical devices. The devices include low-risk class I, devices CE marked based on a self-declaration of conformity by the manufacturer, custom-made devices made according to a prescription from a healthcare professional

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 3500

Contacts

National officer(s):

Name: —

Email: —

WHO Country officer(s):

Name: —

Email: —

General comments (...Annex 1):

Concerning the HT national policy, it was provided the following document: http://www.president.gov.ua/docs/Programa_reform_FINAL_1.pdf; www.rada.gov.ua. The UK comprises 4 devolved administrations: England, Wales, Northern Ireland and Scotland. Each Administration is responsible for the delivery of its own healthcare system as well as collating and maintaining its own data. Therefore, there is no centrally held data that covers the whole of the UK. A range of initiatives around the more widespread use of clinically and cost-effective medical devices is underway. The work is in early stages but once fully operational should improve patients' access to the latest health technologies.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

United Republic of Tanzania

Country indicators - WHO country information

Population 000s (rank):[a]	59,734 (24)	Under-five mortality (per 1000 live births):[d]	48.87	UHC - Service coverage index (1-100):[h]	46
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	17.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	3.8% (1.2%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.53 (0.4): low	Global innovation index (rank):[j]	25.6 (88)
		ICT Development Index (rank):[g]	1.8 (165)	High-technology exports (% of manufacture exports):[k]	6.90%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: https://www.moh.go.tz/en/

Language(s): English

Ministry of health responsible for health technology policy implementation: Diagnostic Services, Healthcare Technical Services under Directorate of Curative Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Tanzania Food and Drugs Authority.

Website: https://www.tmda.go.tz/publications/39

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

Lists recommending health techonology for different categories of diseases is not available. The Ministry is however planning to develop it. Registration of medical devices in Tanzania has started in January 2010. Registration will be carried out

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):

Lists recommending health techonology for different categories of diseases are not available. However, the Ministry is planning to develop it.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

The institutionalizing of HTA for decision making and priority setting for guidelines, essential medicines list, and cost-effective treatments is in progress. The Tanzania HTA committee (THTAC) is essential in the progress towards the Universal Health Care country goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Tanzania Food and Drugs Authority (TFDA).

Website(s): https://www.tmda.go.tz/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Tanzania Atomic Energy Commission.

Other agency's website: https://taec.go.tz/inspection-information/

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: More than one system
Use: For various purposes
Website: —

Nomenclature comments (...Annex 1):
TMDA is using GMDN as the nomenclature system for the registration of medical devices in Tanzania. The main types of nomenclature used are GMDN and UMDNS. The main uses of the nomenclature system are for procurement purposes and inventory systems in healthcare facilities.

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://trade.business.go.tz/media/THE%20TANZANIA%20FOOD,%20DRUGS%20AND%20COSMETICS(%20medical%20device)%20regulation.pdf
National level procurement: Yes Website: https://www.moh.go.tz/en/departments/procurement

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Medical Store Department (MSD) is responsible for procuring pharmaceuticals and medical devices for the public but not for profit organization. It should also be noted that individual entities can also procure medical devices on their own as not all devices are covered by MSD. The private sector imports medical devices after obtaining approval from TFDA. The

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	4	0.07
Computerized Tomography Scanner:[α]	10	0.17
Positron Emission Tomography Scanner:[α]	1	0.02
Gamma camera or nuclear medicine:[α]	4	0.07
Mammograph:[α,*]	8	3.38
Radiotherapy:[β]	9	0.15

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Healthcare Technical Services. Unit website: —
Contact name: Mr. Valentino Mvanga Contact email: vmvanga@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 20

Contacts

National officer(s):
Name: Mr. Valentino Mvanga
Email: valentino.mvanga@afya.go.tz

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Tigest Ketsela Mengestu
Email: ketselat@who.int

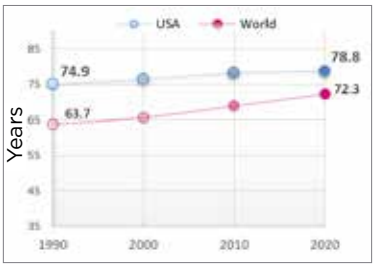
Name: Ms. Rose Shija Muhangwa
Email: shijar@who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

United States of America

Country indicators - WHO country information

Population 000s (rank):[a]	331,003 (3)	Under-five mortality (per 1000 live births):[d]	6.35	UHC - Service coverage index (1-100):[h]	83
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	13.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	4.8% (0.8%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.93 (0.81): very high	Global innovation index (rank):[j]	60.6 (3)
		ICT Development Index (rank):[g]	8.2 (16)	High-technology exports (% of manufacture exports):[k]	19.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: —

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): https://www.ahrq.gov/research/findings/ta/index.html

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

There is not a single body nor a national institution to evaluate health technologies. However, there is an extensive network of HTA institutions such as the Advisory Committee on Immunization Practices (ACIP), the Preventive Services Task Force (USPSTF), the Medicare Evidence Development & Coverage Advisory Committee (MedCAC), the Agency for Healthcare Research and Quality (AHRQ),

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH).

Website(s): http://www.fda.gov/MedicalDevices/default.htm

Contact: Dr. Jeffery Shuren Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: United States Nuclear Regulatory Commission (U.S. NRC); United States Environmental Protection Agency (EPA).

Other agency's website: https://www.nrc.gov/ https://www.epa.gov/radiation/radiation-regulations-and-laws

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on GMDN Use: Not specified

Website: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051637.htm
https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems

Nomenclature comments (...Annex 1):
1. Product Code. FDA- The Center for Devices and Radiological Health (CDRH) uses a nomenclature by assigning a 3-letter code to identify a device into a generic type or category. This nomenclature system is known as product code classification. The short name is ProCode.The Product Code Classification Database contains medical device names and associated information developed by the CDRH in support of its mission. This database contains device names and their associated product codes. The name

Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	13275	40.11
Computerized Tomography Scanner:[α]	14750	44.56
Positron Emission Tomography Scanner:[α]	1790	5.41
Gamma camera or nuclear medicine:[α]	16010	48.37
Mammograph:[α,*]	21421	521.55
Radiotherapy:[β]	4356	13.16

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —

Unit/Department: — Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 22000

Contacts

National officer(s):
Name: Ms. Tammie Bell
Email: Tammie.Bell2@fda.hhs.gov

Name: Mr. David E. Hohman
Email: —

WHO Country officer(s):
Name: Ms. Mary Lou Valdez
Email: valdezmar@paho.org

Name: —
Email: —

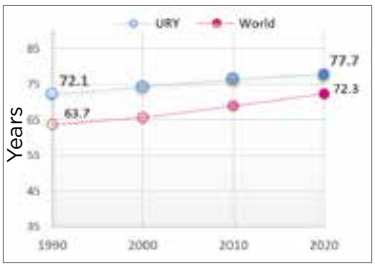
General comments (...Annex 1):

Unfortunately, we are only able to respond to numeric country statistics. As is often the case, they are too much difficulty for Federal States to answer; furthermore, is largely irrelevant for a system like ours that is so based on private sector.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Uruguay

Country indicators - WHO country information

Population 000s (rank):[a]	3,474 (131)	Under-five mortality (per 1000 live births):[d]	6.19	UHC - Service coverage index (1-100):[h]	79
World Bank income group:[b]	High	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.50%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.82 (0.71): very high	Global innovation index (rank):[j]	30.8 (69)
		ICT Development Index (rank):[g]	7.2 (42)	High-technology exports (% of manufacture exports):[k]	8.30%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://www.gub.uy/ministerio-salud-publica/

Language(s): Español

Ministry of health responsible for health technology policy implementation: Departamento de Evaluación de Tecnología.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Departamento de Evaluación de Tecnología.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):
Las listas aún no se encuentran disponibles públicamente.

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):
—

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Departamento de Evaluación de Tecnología, MoH.

Website(s): https://www.gub.uy/ministerio-salud-publica/evaluacion-tecnologia http://www.fnr.gub.uy/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
HTA is performed by the department of Health Assessment (MOH), and the National Resources Fund (FNR) in several areas concerning health products, and healthcare, including medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministerio de Salud Pública - Departamento de Evaluación de Tecnología.

Website(s): https://www.gub.uy/ministerio-salud-publica/evaluacion-tecnologia

Contact: Mr. Juan Manuel Jones Email: tecnologia@msp.gub.uy

Name(s) of other regulatory agency eg. for radiation equipment etc.: Autoridad Reguladora Nacional en Radioprotección (Ministerio de Industria, Energía y Minería).

Other agency's website: https://www.gub.uy/ministerio-industria-energia-mineria/institucional/estructura-del-organismo/autoridad-reguladora-nacional-radioproteccion

National regulatory comments (...Annex 1):
—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: For procurement purposes

Website: http://www.msp.gub.uy

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —

National level procurement: Yes Website: http://www.cocemi.com.uy/

Donations

Policy or guideline: Yes Website: https://www.gub.uy/tramites/donaciones-especiales

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):

Adquisiciones: Artículo 6º de la Ley Nº18211 Sistema Nacional Integrado de Salud. UCA: Un mecanismo para los prestadores públicos; COCEMI: Un mecanismo para algunos prestadores privados.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	10	2.94
Computerized Tomography Scanner:α	44	12.91
Positron Emission Tomography Scanner:α	1	0.29
Gamma camera or nuclear medicine:α	10	2.94
Mammograph:α,*	62	172.42
Radiotherapy:β	24	6.91

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Departamento de Evaluación de Tecnología. Unit website: —

Contact name: Mr. Juan Manuel Jones Contact email: jjones@msp.gub.uy

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment

Website: —

Use of management software: — Software name: —

Software comments (...Annex 1):

Realizado en 2008 y actualizado en 2010 para Tomógrafos y Equipos de Resonancia Magnética. El detalle de la información individual aún no se encuentra disponible en formato electrónico.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 10

Contacts

National officer(s):

Name: Dr. Juan Manuel Jones

Email: tecnologia@msp.gub.uy

Name: Mr. Juan Manuel Jones

Email: jjones@msp.gub.uy

WHO Country officer(s):

Name: Dr. Hernan J. Montenegro

Email: monteneher@paho.org

Name: Dr. Wilson Benia

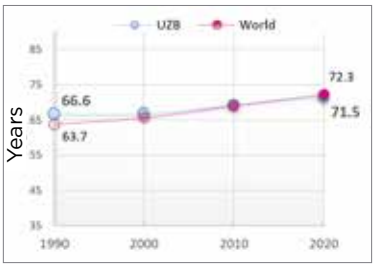
Email: beniaw@paho.org

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Uzbekistan

Country indicators - WHO country information

Population 000s (rank):[a]	33,469 (42)	Under-five mortality (per 1000 live births):[d]	13.95	UHC - Service coverage index (1-100):[h]	71
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	25.30%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.72 (—): high	Global innovation index (rank):[j]	24.5 (93)
		ICT Development Index (rank):[g]	4.9 (95)	High-technology exports (% of manufacture exports):[k]	0.70%

National policy on health technology

Health technology (medical device) national policy: —

Policy is part of the National Health Program/Plan: —

Website: https://www.uzpharm-control.uz/en/
http://ssv.uz/ru

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: —

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): http://tipme.uz/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
HTA activities are carried out mainly by the MoH, and the Evidence-Based Medicine Centre within the Tashkent Institute for Advanced Medical Education. HTA is done for various health topics: pharmaceutics, medical devices, and also the in pharmaceutics field but not specifically for medical devices, guidelines, etc.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of Health, General Directorate for the Quality Control of Medicines and Medical Equipment (GDQC).

Website(s): https://ssv.uz/

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: More than one system
Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	n/a	n/a
Computerized Tomography Scanner:[α]	n/a	n/a
Positron Emission Tomography Scanner:[α]	n/a	n/a
Gamma camera or nuclear medicine:[α]	n/a	n/a
Mammograph:[α,*]	n/a	n/a
Radiotherapy:[β]	9	0.27

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: https://www.uzpharm-control.uz/en/
Use of management software: — Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Lianne Kuppens
Email: kuppensl@who.int

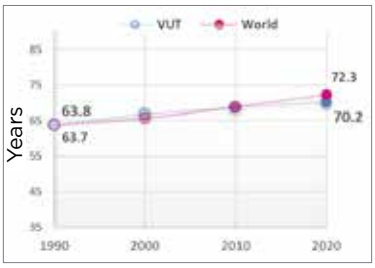
Name: —
Email: —

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Vanuatu

Country indicators - WHO country information

Population 000s (rank):[a]	307 (172)	Under-five mortality (per 1000 live births):[d]	24.93	UHC - Service coverage index (1-100):[h]	52
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	39.70%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.61 (—): medium	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	2.8 (141)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1): This list exists as part of another document -e.g. essential drug list or an inventory list of a health facility- but there is no separate nor specific document of the guideline on its own. No list exists for any of the conditions above (different diseases/

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For procurement purposes
Website: —

Nomenclature comments (...Annex 1):
When there is a plan to procure a medical device, only then is the technical nomenclature required.

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
—

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	0	0
Computerized Tomography Scanner:[α]	0	0
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	0	0
Mammograph:[α,*]	0	0
Radiotherapy:[β]	0	0

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
An updated complete list of medical equipment does not exist at national level; but at subnational levels and at facility level, health managers maintain their own inventory for various commodities including medical devices.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] <10

Contacts

National officer(s):
Name: Dr. Willie Tokon
Email: wtokon@vanuatu.gov.vu

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Eunyoung Ko
Email: koe@who.int

Name: —
Email: —

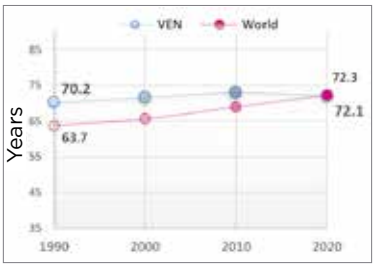
General comments (...Annex 1):

Vanuatu is a small island country in the Pacific region with a population of less than 350,000: this explains the low level of health facilities available.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Venezuela (Bolivarian Republic of)

Country indicators - WHO country information

Population 000s (rank):[a]	28,436 (50)	Under-five mortality (per 1000 live births):[d]	24.22	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	—	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	14.80%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.71 (0.59): high	Global innovation index (rank):[j]	— (—)
		ICT Development Index (rank):[g]	5.2 (86)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: —

Policy is part of the National Health Program/Plan: —

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Approved devices lists comments (...Annex 1): —

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Health care facilities lists comments (...Annex 1): —

Lists available: —

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Specific lists comments (...Annex 1): —

Lists available: —

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Comisión Nacional de Evaluación de Tecnología en Salud (CONETS).

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1): Las actividades de evaluación de tecnologías médicas se han desarrollado en el marco de la Comisión Nacional de Evaluación de Tecnología en Salud (CONETS) dentro del Ministerio del Poder Popular de la Salud.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Servicio Autónomo de Contraloría Sanitaria: Dirección de Regulación y Control de Materiales, Equipos, Establecimientos y Profesiones de Salud.

National regulatory comments (...Annex 1): —

Website(s): —

Contact: — Email: atencion@sacs.gob.ve

Name(s) of other regulatory agency eg. for radiation equipment etc.: Dirección de Regulación y Control de Materiales, Equipos, Establecimientos y Profesiones de Salud.

Other agency's website: http://sacs.gob.ve/site/index.php/advanced-stuff/direccion-de-regulacion-y-control-de-materiales-equipos-establecimientos-y-profesiones-de-salud

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: More than one system
Use: For various purposes
Website: https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database

Nomenclature comments (...Annex 1):
Does not have one specific nomenclature. For the certification of the medical device, the nomenclature used is the U.S FDA product classification.

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
Funindes (Univ. Simon Bolivar) is authorized by the Autonomous Service of the Sanitary Comptroller to carry out equipment analysis for subsequent sanitary registration.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	61	2.15

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: http://www.sacs.gob.ve/site/
Use of management software: — Software name: —

Software comments (...Annex 1):
—

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 60

Contacts

National officer(s):
Name: —
Email: —

Name: —
Email: —

WHO Country officer(s):
Name: Eco. Cristián Morales
Email: moralesc@paho.org

Name: Dr. Joel Caraballo
Email: carabaljoe@paho.org

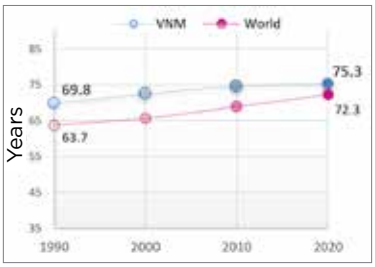
General comments (...Annex 1):

The most important problems of the hospitals in Venezuela were: the electrical system, the air conditioning and the vertical system (for 2001). In 2019 the most serious problems were water, sanitation and hygiene: 79% of hospitals reported failures in the drinking water service; most had the service intermittently, only two or three days a week. By 2011 there were 1,366 intensive care units. By 2019 there were 36 intensive care beds in Venezuela. Currently, MRI, CT, and Gamma Camera specialized service is not performed in Venezuelan hospitals. We

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Viet Nam

Country indicators - WHO country information

Population 000s (rank):[a]	97,339 (15)	Under-five mortality (per 1000 live births):[d]	20.94	UHC - Service coverage index (1-100):[h]	70
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	21.20%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	9.4% (1.9%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.7 (0.59): high	Global innovation index (rank):[j]	37.1 (42)
		ICT Development Index (rank):[g]	4.4 (108)	High-technology exports (% of manufacture exports):[k]	40.40%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): Vietnamese

Ministry of health responsible for health technology policy implementation: Department of Medical Equipment and Construction.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: https://www.moh.gov.vn/web/ministry-of-health/legal-documents

Website - laboratories: https://dav.gov.vn/procedures.html

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1): There are for all general procedures but they are not complete. We have enacted medical device list for procedures which shall be covered by medical insurance only.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Health Strategy and Policy Institute (HSPI).

Website(s): http://en.hspi.org.vn/vclen/trang-chu http://en.hspi.org.vn/vclen/Implementation-of-health-technology-assessment-in-Viet-Nam-t15990-8044.html

Contact: — Email: hspivietnam@hspi.org.vn

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): The HTA system has been developed by establishing nodal agencies within MoH, moving towards the Universal Health Care country goal. Priority-setting mechanisms and HTA processes are at a nascent stage. HTA is rarely applied to medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Department of Medical Equipment and Construction.

Website(s): http://www.nimec.gov.vn/

Contact: Mr. Nguyen Minh Tuan - General director Email: Ngmtuan_ttbvn@yahoo.com

Name(s) of other regulatory agency eg. for radiation equipment etc.: Institute of Medical Equipment and Construction.

Other agency's website: https://www.most.gov.vn/en/pages/OrganDetail.aspx?tochucID=2710

National regulatory comments (...Annex 1): Contact person: Hoang Mai Bui - Director of the Department of medical equipment verification and calibration.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: No Website: —
National level procurement: Yes Website: http://www.moh.gov.vn/

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:α	n/a	n/a
Computerized Tomography Scanner:α	n/a	n/a
Positron Emission Tomography Scanner:α	n/a	n/a
Gamma camera or nuclear medicine:α	n/a	n/a
Mammograph:α,*	n/a	n/a
Radiotherapy:β	47	0.48

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Medical Equipment and Construction. Unit website: —
Contact name: Mr. Nguyen Minh Tuan - General director Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:γ 1000

Contacts

National officer(s):
Name: —
Email: —

Name: Mr. Nguyen Minh Tuan - General director
Email: —

WHO Country officer(s):
Name: Dr. Kidong Park
Email: parkk@who.int

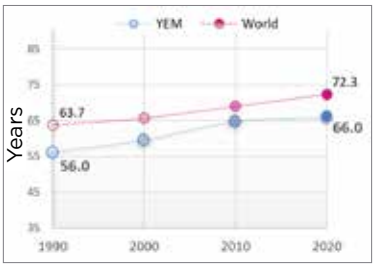
Name: Dr. Socorro Escalante
Email: escalantes@wpro.who.int

General comments (...Annex 1): —

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Yemen

Country indicators - WHO country information

Population 000s (rank):[a]	29,826 (48)	Under-five mortality (per 1000 live births):[d]	59.58	UHC - Service coverage index (1-100):[h]	44
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	27.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	15.8% (4.2%)
Life expectancy at birth (years):[c] 		Human Development Index (inequality adjusted HDI): rank:[f]	0.47 (0.32): low	Global innovation index (rank):[j]	13.6 (131)
		ICT Development Index (rank):[g]	— (—)	High-technology exports (% of manufacture exports):[k]	—

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): There is a need of financial, technical support and cooperation to put national standards or lists of recommended medical devices for specific procedures. For different diseases/situations there are no existing lists; MOPH must do that by

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] —

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: Ministry of Industry & The Supreme board for Drugs & Medical Appliance.

Website(s): www.sbd-ye.org; www.moit.gov.ye

Contact: Dr. Alhakmi Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministry of industry & The Supreme board for Drugs & Medical Appliance.

Other agency's website: www.moit.gov.ye

https://gnssn.iaea.org/main/ANNuR/Activity%20Documents%20%20Public/Training%20Course%20on%20knowledge%20safety%20networks/Knowledge%20safety%20Network-Yemen%20.pdf

National regulatory comments (...Annex 1): There are Authorities only for the registration of agents for medical equipment.

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
—

Medical device incorporation

Procurement

Policy or guideline: Yes Website: www.htb.gov.ye
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: http://moh.gov.ye/en/home.aspx

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
There are many procurements carried out at a national level but non-uniform standards by the health Governorate Office, local governorates authority, general hospitals authority, police health service, and army health service; and there are procurements carried out at a national level like Unicef, UNFPA, Emro, etc.

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	28	1.15
Computerized Tomography Scanner:[α]	88	3.61
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	3	0.12
Mammograph:[α,*]	18	17.62
Radiotherapy:[β]	1	0.03

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: The General Directorate of Medical Equipment and Maintenance. Unit website: —
Contact name: Mr. Faisal Ali Mujamal Contact email: eng- alfaisal@hotmail.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 6

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1):
The MOPH is working in its action plan state to complete the database for medical equipment. In the case of some hospitals, the inventory is done directly by them.

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 150

Contacts

National officer(s):
Name: Mr. Faisal Ali Mujamal
Email: eng- alfaisal@hotmail.com

Name: —
Email: —

WHO Country officer(s):
Name: Dr. Adham Rashad Ismail Abdel Moneim
Email: ismaila@who.int

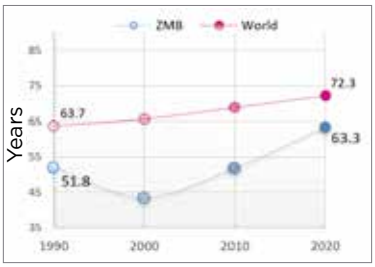
Name: —
Email: —

General comments (...Annex 1): There was a deficiency about maintenance and calibrations of medical devices.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Zambia

Country indicators - WHO country information

Population 000s (rank):[a]	18,384 (64)	Under-five mortality (per 1000 live births):[d]	61.38	UHC - Service coverage index (1-100):[h]	55
World Bank income group:[b]	Low	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	24.60%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	0.3% (0.0%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.58 (0.4): medium	Global innovation index (rank):[j]	19.4 (122)
		ICT Development Index (rank):[g]	2.5 (146)	High-technology exports (% of manufacture exports):[k]	2.30%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: Medical Equipment Unit.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Minsitry of Health, Directorate of Clinical Care and Diagnostic Services-Medical Equipment Unit.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1):

The MoH has developed the Standard Equipment Lists (SEL) for District facilities such as Health Posts, Health Centres and Level One Hospitals). The SEL are not yet done, because the Basic Health Care Package, which is the blueprint for health

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

—

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] Yes

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

Evidence-informed healthcare priority setting via HTA is at early stages. Currently, HTA is being used by the MoH to build the Health Benefits Package.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of Health-Directorate of Clinical Care and Daignostic services-Medical Equipment Unit.

Website(s): http://www.moh.gov.zm

Contact: Dr. Zuma Munkombwe Email: zmunkombwe@pra.gov.zm

Name(s) of other regulatory agency eg. for radiation equipment etc.: Zambia Medicines Regulatory Authority (ZAMRA).

Other agency's website: http://www.zamra.co.zm/

National regulatory comments (...Annex 1):

—

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: For regulatory and procurement purposes

Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: https://www.moh.gov.zm/docs/reports/Medical%20Equipment%20Management%20Guidelines.pdf

National level procurement: Yes Website: http://www.parliament.gov.zm/sites/default/files/documents/acts/The%20Zambia%20Medicines%20and%20Medical%20Supplies%20Agency.%20Act%20No.%209.pdf

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: —

Website: —

Medical device incorporation comments (...Annex 1):

This is in reference to the guidelines on procurement, donations, replacement of equipment at end of the lifespan. The Ministry of Health procures, under Mandate from ZPPA; the Ministry of Health develops the list, quantities and specifications. Public Procurement Authority sets the framework for the procurement mostly International Competetive Bidding. These are provided

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	1	0.07
Computerized Tomography Scanner:[α]	3	0.21
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	1	0.07
Mammograph:[α,*]	2	4.56
Radiotherapy:[β]	5	0.27

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Medical Equipment Unit. Unit website: —

Contact name: — Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 9

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: Yes Software name: ECRI and other nationally developed.

Software comments (...Annex 1):

The national data bank for equipment is in its infancy; the data was collected three years ago during a project that was funded by the Japan International Cooperation Agency (JICA). Currently, this data will be upgraded this year. The information captured includes Equipment Description, Model, Maker, Serial Number, Location, Functional Status, Age of Equipment. There are however hard copies at the facility level which maintenance units

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] 18

Contacts

National officer(s):

Name: Mr. Fales Mwamba

Email: Mwamba@moh.gov.zm

Name: Mr. Chipalo Kaliki

Email: ckaliki@moh.gov.zm

WHO Country officer(s):

Name: Dr. Nathan Nsubuga Bakyaita

Email: bakyaitan@who.int

Name: —

Email: —

General comments (...Annex 1):

The WHO used to run training programs for maintenance technicians but stopped long ago, this has affected this field. There is a need for the WHO to come in strongly in support of maintenance of Medical equipment. The main problems in developing countries are lack of skilled manpower, inadequate budgets for maintenance, lack of proper maintenance facilities equipped with tools, test and calibration equipment, lack of supportive policies. Coupled with a lack of local agents for the

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
d WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Zimbabwe

Country indicators - WHO country information

Population 000s (rank):[a]	14,863 (73)	Under-five mortality (per 1000 live births):[d]	53.89	UHC - Service coverage index (1-100):[h]	55
World Bank income group:[b]	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	28.40%	UHC - Population with household spending >10% (>25%) of corresponding income (%):[i]	— (—)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[f]	0.57 (0.44): medium	Global innovation index (rank):[j]	20 (120)
		ICT Development Index (rank):[g]	2.9 (136)	High-technology exports (% of manufacture exports):[k]	5.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

Ministry of health responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Hospital Equipment Unit.

Website: —

Nomenclature systems used for devices and tests: —

Approved devices lists comments (...Annex 1): —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1): —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[δ] No

HTA unit/department includes the assessment of medical devices: No

Unit/department: —

Website(s): —

Contact: Mr. Martin Nhorivo Email: mnhorivo@yahoo.co.uk

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
It has been started the building capacity and the HTA will be a fundamental tool to achieve the Universal Health Care goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency's website: —

National regulatory comments (...Annex 1): —

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: —

Nomenclature comments (...Annex 1): —

Medical device incorporation

Procurement

Policy or guideline: Yes Website: —
National level procurement: Yes Website: —

Donations

Policy or guideline: Yes Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1): —

Medical equipment

Medical equipment	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[α]	4	0.28
Computerized Tomography Scanner:[α]	6	0.42
Positron Emission Tomography Scanner:[α]	0	0
Gamma camera or nuclear medicine:[α]	4	0.28
Mammograph:[α,*]	4	6.89
Radiotherapy:[β]	10	0.67

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Hospital Equipment Unit. Unit website: —
Contact name: Mr. Martin Nhorivo Contact email: mnhorivo@yahoo.co.uk
Website with publically available technical specifications: —
Number of regional/state offices/units: 8

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Software comments (...Annex 1): —

Medical devices workforce

Number of biomedical/clinical engineers professionals in the country:[γ] —

Contacts

National officer(s):

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Name: Mr. Martin Nhorivo
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WHO Country officer(s):

Name: Dr. Alex Gasasira
Email: gasasiraa@who.int

Name: Dr. Stanley M. Midzi
Email: midzis@who.int

General comments (...Annex 1):

The country health technology policy document was initiated in 2007 with funding from the US. This is currently being formulated into a policy document for diagnostic imaging and medical devices.

a UN:WPP 2019, POP (data year: 2020)
b WB: FY23 (data year: 2021)
c UN:WPP 2019, MORT (data year: 1990-2020)
d UN-IGME, SDG 3.2.1 (data year: 2020)
e WHO: GHO, SDG 3.4.1 (data year: 2019)
f UNDP: HDR 2019/20, HDI and IHDI (data year: 2019)
g ITU: IDI 2017 (data year: 2017)
h WHO: GHO, SDG 3.8.1 (data year: 2019)
i WHO: GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO: GII (data year: 2020)
k UN-WB: HtE (data year: latest 2017-19)
δ WHO: HTA&HBP 20/21 survey, HTA 2015, CSoMD21 (data year: latest 2015 or 2021)
α WHO: GHO, ME; OECD, HE; CSoMD21 (data year: latest 2013-21)
β WHO: GHO, RU; IAEA: DIRAC; CSoMD21 (data year: latest 2013-21)
γ WHO: GHO, HW; CSoMD21 (data year: latest 2017-2021)
n/a not applicable/not available

Annex 1

Additional comments

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Afghanistan	EMR	—	—	—	The National HTA unit is not yet established.
Albania	EUR	—	—	—	There is not yet an HTA national unit but it has been acknowledged at a political level by the MoH. There is a centralized system for managing health products pricing and reimbursement via the Ministry of Health, the National Agency for Drugs and Device, and the Drug Price Commission.
Algeria	AFR	—	—	—	Adopted EMA (European Medicines Agency) and ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH HTA is focused on pharmaceutics but not in medical devices.
Andorra	EUR	—	—	—	There are identified HTA activities but not a national unit.
Angola	AFR	—	—	—	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Afghanistan	—	—	—	—	Concerning the HT national policy, it can be found the following document, within the provided website: ley-18211-dec-5-2007 SNIS.pdf.
Albania	—	This italian nomenclature system CIVAB comes with the Inventory system called CLINGO.	It exists the National Policy for management of medical devices in Albania. The procurement of medical devices at national levels is done partially.	The inventory system is called CLINGO. The National Biomedical Centre manages the system. Each hospital (13 regional hospitals are involved) is in charge of adding their own data. It doesn't cover all the hospitals and other public health institutions.	Concerning the HT national policy, it was provided the following document:|http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_albania.pdf
Algeria	—	—	—	—	—
Andorra	—	—	—	—	—
Angola	June 4, 2021: With Presidential Decree 136/21 the extinction of the Direcção Nacional de Medicamentos e Equipamentos is announced and the Regulatory Agency for Medicines and Health Technologies (ARMED) is created, which will have its headquarters in Luanda, Angola and will be supervised by the Ministry of Health.	—	—	—	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Antigua and Barbuda	AMR	—	—	—	—
Argentina	AMR	Existe una base de datos que contiene a las tecnologías sanitarias (denominados productos médicos) registradas y disponibles en el sitio -ver tercera liga web- (accesible con colocar nombre génerico de producto (por ej: apósito) o con su identificación (Nº de PM).	Cirugía, diagnóstico por imágenes, laboratorio, terapia intensiva.	Actualmente existen lineamientos para la elaboración de guías. Disponible en la segunda página web proporcionada.	In 2018, by Ministerial Resolution of Health No. 623, the National Commission for the Evaluation of Health Technologies (CONETEC) was created within the scope of the Ministry of Health, dependent on its General Coordination Unit. Other national agencies that prepare HTA reports: National Directorate for Quality and Regulation, Ministry of Health of the Nation https://www.argentina.gob.ar/salud/calidadatencionmedica National Administration of Medicines, Food and Medical Technology – ANMAT https://www.argentina.gob.ar/anmat • HTA programs at the subnational level: Argentina has several subnational Ministries of Health that have STD Directorates or Committees that carry out HTA reports: City of Buenos Aires and the Provinces of Buenos Aires, Neuquén, Santa Fe, Río Negro and Mendoza. • Other agencies that prepare HTA reports in the country: - Argentine Network for Health Technology Assessment (RedArETS) whose member nodes are: Ministry of Health of the City of Buenos Aires, Ministry of Health of the Province of Buenos Aires, Ministry of Health of the Province of Mendoza, Ministry of Health of the Province of Neuquén, Ministry of Health of the Province of Río Negro,

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Antigua and Barbuda	—	—	—	—	—
Argentina	—	The Administración Nacional de Medicamentos Alimentos y Tecnología Médica (ANMAT), reported the use of the Universal Medical Device Nomenclature System (UMDNS) for regulatory purposes of the medical devices in this country	For procurement of medical devices at national level we use the: "lista licitaciones".	—	The MoH wants to push awareness/surveillance about health technology quality, technical specifications, etc.

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Argentina continued					Ministry of Health of the Province of Santa Fe, Superintendence of Health Services, El Cruce Hospital, Higher School of Health - FBCB / Universidad Nacional del Litoral, Universidad Nacional del Sur, University Center for Studies in Health, Economy and Welfare of the National University of Comahue, University Center of Pharmacology of the National University of La Plata, Heart Institute of Corrientes, National Cancer Institute, National Directorate for Quality in Health Services and Regulation Sanitary of the Ministry of Health of the Nation. - Institute of Clinical and Health Effectiveness (IECS) - University Center of Pharmacology of the National University of La Plata (CUFAR – UNLP) - Institute of Medicine for Social Security and Technological Evaluation (IMSSET – UBA). - ISALUD University (ISALUD) - A recent study surveyed and identified 39 institutions that carry out some type of HTA report in Argentina.
Armenia	EUR	—	—	—	Informing decisions of the cited institutions are not specifically HTA. Alternative email: info@healthpiu.arm.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Argentina continued					
Armenia	"National Institute of Metrology"; National Institute of Standards"; "ArmAtomInspection"; and "Scientific Center of Drug and Medical Technology Expertise".	—	The technical specifications are developed by the Health Project Implementation Unit (HPIU) biomedical engineer in cooperation with international consultants.	—	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Australia	WPR	Australian Register of Therapeutic Goods (ARTG) – marketing approval and used to guide procurement in national and state/territory processes •Prostheses List of implanted medical devices for private patients - reimbursement •National hearing program aids, devices and appliances – reimbursement •National diabetes service scheme – subsidisation diabetes devices including continuous glucose monitoring devices •National stoma appliance scheme •Veterans rehabilitation and appliance schedule of devices and reimbursement •National Disability Insurance Scheme list of devices and appliances	—	—	The Therapeutic Goods Administration (TGA), the Medical Services Advisory Committee (MSAC), the Pharmaceutical Advisory Committee (PBAC), and the Prostheses List Advisory Committee (PLAC) perform Health Technology Assessment (HTA) processes to provide advice to the Australian Government Department of Health.
Austria	EUR	—	—	Österreichischer Strukturplan Gesundheit (up mentioned link) and various guidelines of the medical societies, internal guidelines of the hospitals, etc. Also, there is the Austrian Influenza Pandemic Plan.	Only for the hospital benefit catalogue there is a national HTA process in place, but not for drugs. It is expected that it will be a process in place in the next 1-2 years.
Azerbaijan	EUR	—	—	—	The HTA activities in pharmaceutics are not specifically for medical devices.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Australia	—	The use of GMDN is a legal mandatory requirement for devices supplied in Australia, including IVDs.	—	The National Product Catalogue provides an inventory input to a number of hospital procurement and equipment managements systems. Also, various systems are used by public and private hospitals	Australia's health system policy and delivery is at both a national and state/territory level All medical devices must be included in the Australian Register of Therapeutic Goods
Austria	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	The procurement is done with internal guidelines of the Hauptverband, insurance funds, hospitals, Bundesbeschaffungs GmbH, etc.	There are various software for the maintenance and inspection of medical devices in the hospital. Additionally, there is the implementation of a National Plan for high-cost technologies called: "Großgeräteplan".	—
Azerbaijan	—	—	The Procurement guidelines are under development. For donations guidelines the WHO are the ones used. The corresponding technical specifications are under the responsibility of the Innovation and Supply Centre.	—	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Bahamas	AMR	—	—	There are no lists recommending health technology for any of the above.	—
Bahrain	EMR	—	—	—	There are identified HTA activities but not a national unit.
Bangladesh	SEAR	—	—	—	
Barbados	AMR	—	—	—	HTA activities have been identified, but there is not a national unit.
Belarus	EUR	Documents: N° "2007 " and N° "458" in the specified website.	—	—	In BELCMT there are not informing decisions specifically for medical devices.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Bahamas	—	—	The Public Hospitals Authority, the corporate entity of the Ministry of Health, is responsible for managing the three Public Hospitals within the Bahamas. It uses the services of the ECRI Institute to assist in the procurement of medical devices.	—	—
Bahrain	—	It is needed the GMDN code for registration of medical devices, as well as the HS code.	—	—	—
Bangladesh	Ms. S. M. Sabrina Yesmin is the Assistant Director of DGDA.	—	Technical specifications are not publically available.	Central Medical Stores Depot, Tejgaon, Dhaka-1208. Dhaka has all the data in this regards.	—
Barbados	—	—	Procurement queries, comments, and information should be addresses to the Chief Supply Officer (email: joness@gob.bb).	There is not a national inventory but the Queen Elizabeth Hospital Engineering Services maintains an inventory of high-cost technologies and medical equipment; thus, there is an institutional inventory there. Also, all the polyclinics keep institutional inventory for medical equipment only. The institutional inventories at the hospital and the polyclinics are audited annually. Additionally, the Equipment management software is currently being installed at the Queen Elizabeth Hospital.	Concerning the Healthcare Infrastructure section: there are many single and grouped medical centres|and general practice clinics/offices which perform primary care that includes emergency services. Some medical centres of the private sector perform secondary care services as well.
Belarus	—	State register of medical equipment and medical supplies of Belarus.	Public procurement of medical devices and their specifications for each procurement procedure can be found in our website.	Go to website (first link) and find the document titled "mfindr".	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Belgium	EUR	Ces listes existent indirectement par le remboursement de certains dispositifs médicaux et/ou le remboursement de certains tests cliniques effectués. Les dispositifs médicaux implantables et invasifs à long terme doivent se trouver dans ce listing de l'INAMI pour pouvoir être facturés par l'hôpital aux patients.La liste est disponible sur internet via le lien signalé. Approvement for reimbursement by type of IVD device or analysis, not a product-specific list.	—	Ces listes existent indirectement par le remboursement de certains dispositifs médicaux et/ou le remboursement de certains tests cliniques effectués.	The assestment includes pre-market clinical evaluation of innovative high-risk medical devices.
Belize	AMR	—	Policy Analysis & Planning Unit, Ministry of Health.	There is no information about which lists are available.	HTA activities have been identified, but there is not a specific national unit.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Belgium	Agence Fédérale de Contrôle Nucléaire en ce qui concerne les dispositifs médicaux repris sous le point 3 de l'annexe XIII de l'Arrêté royal du 18/03/1999, qui veille au contrôle et à l'application du Règlement Général de la Protection de la population, des travailleurs et de l'environnement contre le danger des Rayonnements Ionisants (le RGPRI: AR du 20 juillet 2001), dans lequel sont stipulées des conditions /exigences en ce qui concerne les dispositifs médicaux relevant de sa compétence3. SPF Economie, P.M.E, Classes Moyennes et Energie: Les Directions Générales Energie, Qualité & Sécurité et Contrôle & Médiation sont compétents pour le contrôle des dispositifs médicaux tombant dans la catégorie 2 de l'annexe XIII de l'AR du 18/03/1999 relatif aux dispositifs médicaux. Anne. VanNerom@iph.fgov.be, T ++32 (0) 2 642 50 40 2.	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	Dans chaque Arrêté royal d'application se trouvent des exigences par rapport à la distribution et/ou la délivrance des dispositifs médicaux (docs: coord_tcm291-26685.pdf and tcm291-27069.pdf).|Décision de la Commission 2002/364/ EC portant spécifications techniques communes des dispositifs médicaux de diagnostique in vitro.	—	L'Agence fédérale de Contrôle nucléaire (AFCN) est en train de réviser les inventaires des dispositifs médicaux émettant des rayonnements ionisants présents en Belgique. Cet inventiare provient en partie de données fournies par les Organismes Agréés (AV Controlatom, TechniTest, ...). COCIR (European Coordination Committee of the Radiological, Electromedical and Medical IT Industries) peut également fournir des informations utiles sur les dispositifs d'imagerie diagnostique médicale en incluant l'âge de l'équipement (age profile). Rappelons que l'OECD a aussi mené une enquête avec des questions similaires, organisation à laquelle les données ont été mentionnées par l'AFCN.
Belize	—	—	The NEMC is trying to standardize equipment, and has suggested to set up a procurement committee. There is no follow up.	The NEMC is in the process of updating the Inventory, only for the public health facilities. The Karl Heusner Memorial Hospital (KHMH) has its own Inventory System.	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Benin	AFR	—	—	—	Ilya la Direction de la programmation et de la prospective (DPP) et Direction des hôpitaux (fait HTA), mais n'est pas specifiquement pour des dispositifs médicaux.
Bhutan	SEAR	We have a list for each level of health centre used for annual identification for non drug items which includes equipments but we have not uploaded it in a website.	—	At present we do not have national lists of recommended medical devices but we are developing a standard list of Equipment and non-drug items for each level of health facilities in Bhutan (national, regional, district hospital, Basic health unit I and Basic health unit II). The standard list of equipment will be based on the standard services that will be provided at each level of the health centre. The standard list is available since 2012.	HTA is focused on pharmaceutics and vaccines but not in medical devices.
Bolivia (Plurination-al State of)	AMR	There is a national medical devices list (LINADIME) and it is not based in any of the internationally recognized nomenclature.	Norma de caracterización de establecimientos de salud de primer nivel, La Paz, Bolivia, 2008.	Ver el Manual para la aplicacion de las prestaciones de seguros públicos de salud, La Paz, Bolivia.	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Benin	—	La nomenclature CNEH: Centre National d'Expertise Hospitalière Nomenclature (from France) est utilisée de façon informelle dans certains de nos hôpitaux.	—	—	—
Bhutan	The Medical Devices regulation is currently being drafted	Adapted nomenclature from GMDN	The procurement of MD is conducted by the Medical Supplies Procurement Division.	The Biomedical Engineering Division under the Department of Medical Services has maintained an Inventory of equipment above 25,000 rupees only.	Concerning the Infrastructure section: there is 1 National Referral Hospital with 350 beds, 2 Regional referral hospitals with 150 beds each, 10 district hospitals with 60 to 40 beds. 12 district hospitals with 20 beds. Out of 192 health posts, 18 are Basic Health Unit grade I with 10 beds, and the remaining 174 health centres with 2 to 5 beds are Basic Health Unit grade II.
Bolivia (Plurination-al State of)	Unidad de Seguros Públicos de Salud - Dante Ergueta tel. 591-22495053; Unidad de Servicios de Salud - Javier Luna Orozco tel. 591- 22495053.	—	Se cuenta con la propuesta de la norma "Pliego de especificaciones técnicas para la adquisición de dispositivos médicos" DBC. La adquisicion se realiza a través de los gobiernos municipales (Ley del Medicamento 1737, Reglamento a la ley del Medicamento 25235).	El inventario de equipos y la aplicación del plan para la adquisición de equipo médico solo se realizó para los departamentos de Oruro, Beni y Pando.	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Bosnia and Herzegovina	EUR	There are the lists of medical devices for procurement regarding the each general hospital as well as clinical centres (situation analysis of health care institutions). At the primary health care level, there is a list of medical equipments that is necessary for family medicine.	The Rulebook on Normative Standards for Establishment of Health Institutions.	There are documents that regulate the necessary knowledge, skills, procedures and equipment (definition of medical technology) which are used by those group of diseases. Also, there are Guides for specific medical conditions, and there are adequate contingency plans for responding for public health threats as needed. The Rulebook on National Standards for Establishment of Health Institutions, Standards for Primary Care and Hospitals.	The HTA is acknowledged in decentralized legislation, and present at a national level.
Botswana	AFR	—	Documents are in constant revision and update.	—	It is needed to strengthen the research to improve the HTA capacity.
Brazil	AMR	Lists for diseases are Health Attention Secretariat (SAS) unit competence. Other lists are not available for the moment.	—	Competencia de la Health Attention Secretariat (SAS).	HTA for medical devices, medicines, interventions, etc. There exist several agencies (see third link).
Brunei Darussalam	WPR	—	—	—	It is a established system for setting healthcare priorities, which involves HTA.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Bosnia and Herzegovina	For the Republika Srpska: Regarding the procurement of various medical devices, the company that generally provides the medical device must ensure capable suppliers who can implement a proper assessment and who can carry out the certification of medical devices.	The nomenclature is based on GMDN and EDMA codes; the instructions request manufacturer and representative of manufactures to use GMDN or EDMA codes for making generic names. This country have free access to the GMDN base, and found a new version of EDMA codes on the internet.	Responsible authority in both entities. Ministry of Health of Republika Srpska is responsible for the procurement of high-cost technologies while the Health Care Institutions can provide procurement of other medical equipment.	—	—
Botswana	There is a drug regulatory unit. It has a draft for an Act that will regulate medicines and medical devices.	—	—	There is the Medical Equipment Asset Register which was completed in December 2009. The Custom Solution is being implemented; the contract was signed on May 19th 2010.	Concerning the Infrastructure section: there are 800 clinics, healthposts and mobile clinics.
Brazil	—	Anvisa started working to internalize the GMDN. So far, 100 of Anvisa's technical names are compatible with GMDN. Anvisa also works in the implementation of the Unique Device Identification (UDI) in Brazil. Anvisa is currently preparing a draft proposal in a working group with the participation of the private sector, which was sent to the Public Consultation (2021).	In the given website search for the corresponding documents in procurement field. There are Lists of OPM, Procedures and Protocols.	Even though there is no standardized software for the medical equipment management in Brazil, some hospitals and other health facilities have developed and implemented their own. Besides that, the Post Market Surveillance of Medical Devices Unit of ANVISA, the Brazilian Regulatory Authority, intends to develop a software to address the main needs related to medical electrical equipment management (information related to the history of the medical equipment).	—
Brunei Darussalam	—	—	—	—	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Bulgaria	EUR	—	—	—	It exists a limited number of trained HTA experts. Relevant health economic education is available at several universities in the region, and HTA experts or health economists work as consultants for the government (more info see third link).
Burkina Faso	AFR	—	—	—	—
Burundi	AFR	Nous avons des listes préétablies suivant le type de catégories conformes aux normes en vigueur au MoH.	Nous avons également de la documentation sur la normalisation des équipements par structures de soins.	Lists available for communicable and non communicable diseases, injuries, and public health | emergency situations.	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Bulgaria	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	Only for the devices which are supplied through a centralized procedure accomplished by the Ministry of Health.	—	—
Burkina Faso	The RPNS within the NRA is in the process of institutionalization.	—	Les achats se font selon plusieurs procédures en fonction de la source de financement (les projets font des appels d'offres de façon indépendante, les hôpitaux exécutent en interne une partie du budget achat, les achats groupés au niveau national sont en train d'être expérimentés par la CAMEG: Centrale d'Achat des Médicaments Génériques); des apels d'offres internationaux sont quelque fois lancés par les projets.	Inventaire technique au niveau national a été fait par la DGIEM en 2003 avec l'appui de la GTZ; un inventaire non technique a été fait par la DAF en 2007 suivant une procédure du Ministère de l'Economie et des Finances. La mise à jour de ces inventaires n'est pas effective. Il y a les deux types d'inventaire: national fonctionnel pour certain équipement médicale et non-fonctionnel pour d'autres.	Concerning the HT national policy, a 2010 version was provided. Concerning the Section Infrastructure: There are 3 CHU and 1 Hôpital national.
Burundi	—	—	Procédé aux achats/Système d'appel d'offres ouvert national/international.|Il existe des entreprises nationales spécialisées dans la vente de ces produits.	—	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Cambodia	WPR	—	a) Medical Equipment Standard list for CPA referral Hospitals; |b) Medical Equipment Standard list for Minimum Package of activity (MPA) (Health Centre).	—	It has been started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities.
Cameroon	AFR	—	—	—	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Cambodia	—	The Hospital Service Bureau has developed standard medical equipment nomenclature for public hospitals in Cambodia and it has been utilized for medical equipment management and maintenance.	Procurement: Health Sector Support Program (HSSP2) is the implementation project team under the direction of Health Sector Strategic Plan (HSP2) of the Ministry of Health.|Medical Equipment standard list for CPA1,2,3 referral hospitals.	The software was originally developed by the Ministry of Health (MoH). The Department of Hospital service is managing inventories for medical equipment of four National hospitals and 18 CPA3 level hospitals. The Controlled medical equipment requires management (monitoring), maintenance and repair.	—
Cameroon	Il existe un organisme chargé de la réglementation concernant les équipements qui émettent les rayonnements ionisants. l'Agence Nationale de Radioprotection. Contact: Dr. SimoAugustin, e-mail: augsimo@yahoo.fr. |We added a website link that directs the user to an NRPA presentation.	—	Procurement: Il existe des directives générales concernant tous les marchés publics. Les hôpitaux et autres formations disposent aussi de budgets propores pour l'achat de dispositifs médicaux.	Les bailleurs de fonds réalisent des inventaires dans leurs zones d'intervention, mais il n'existe pas d'inventaire national.	L'étude devrait inclure la formation dans le domaine. Le Cameroun dispose d'un cycle de formation de techniciens en maintenance hospitalière qui fonctionne depuis deux ans dans trois lycées techniques, le diplôme de sortie délivré au bout de trois ans est l'équivalent du bacccalauréat. Il existe également des cycles de formation dans le domaine en enseignement supérieur.

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Canada	AMR	Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level.	—	Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level.	There are several HTA agencies, mainly regional.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Canada	In addition, for radiation emitting medical devices, there is Health Canada, Healthy Environments and Consumer Safety Branch, Consumer and Clinical Radiation Protection Bureau (http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/psp-psp/ccrpb-bpcrpcc-eng.php). Contact Person: Narine Martel, Director, Consumer and Clinical Radiation Protection Bureau.	Canada uses both: Preferred Name Codes (based on US FDA Panel Codes) and GMDN. Not publicly available.	Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level.	Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level. While there are no national inventories, the Canadian Institute for Health Information produces regular reports on selected imaging technologies in Canada. The most recent report is available at:|https://www.cihi.ca/en .	In several survey's sections (e.g. section health policy), we were not able to reflect the shared governance approach that Canada has evolved towards as several as the key organisations, namely, the Canadian Agency for Drugs and Technologies in Health are neither national nor provincial but entities whose governance and financing is shared among the Deputy Minister of Health of Canada's 14 jurisdictions (e.g. Federal, 10 provinces and 3 Territories). In addition, the survey did not allow for the identification of existing provincial capacities which would have resulted in having to fill 13 separate surveys to accurately reflect Canada's reality. Concerning HT national policy, it was provided the following document:|http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_canada.pdf .

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Cabo Verde	AFR	Standards: CARTA SANITÁRIA DE CABO VERDE (1999).	Standards: CARTA SANITÁRIA DE CABO VERDE (1999).	No, it is done according to the needs and the procedures of our action plan for the next years.	HTA is focused on pharmaceutics but not in medical devices.
Central African Republic	AFR	En concernant acquisition il ya une longue durée entre la commande et la réception.	—	Arrêté du ministre de la santé publique et de la population. Profil des participants: Médecin, chirurgiens, techniciens de santé, techniciens bio médicaux. Date de révision: Mars 2010.	—
Chad	AFR	It is needed to revise the list	—	—	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Cabo Verde	There is a department in charge of medical devices, but there is no legislation nor registration of medical devices yet.	—	—	There is no national inventory of medical equipment. There's a plan to do it soon.	In conclusion, there is a need to organize the park of medical devices. We would like to make a national inventory for medical equipment, assess the needs, and organizing technical guidelines for procurement to elaborate a clear plan of medical devices management. We think it is time to develop legislation for medical devices.
Central African Republic	No.	—	Achat groupé par les parténaires, passation de marché. Longue durée entre la commande et la réception.	Réalisée par la direction des infrastructures sanitaires. Il y a les deux types d'inventaire: national fonctionnel pour certain équipement médicale et non- fonctionnel pour d'autres.	Concerning the HT national policy it is stated in the following document POLITINACIONALSAUDE_ VERSÃOVALIDADA 2020.
Chad	—	—	There is a need to update the guideline.	—	The lack of a national policy in matters of health technology does not allow access to information on medical devices that could support the action plan with regards to training of users, specialists and maintenance technicians.

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Chile	AMR	Existen 8 listas de los dispositivos médicos que están bajo control obligatorio en el país: Guantes de examinación, Guantes quirúrgicos, Preservativos masculinos y femeninos de látex y sintéticos, Agujas hipodérmicas, Jeringas hipodérmicas de un solo uso, Jeringas con agujas hipodérmicas y Desfibriladores Externos Automáticos Portátiles. Se encuentran disponibles en la dirección proporcionada:|https://www.ispch.cl/andid/listado-de-dispositivos-medicos-establecimientos-y-empresas/dispositivos-medicos-con-registro-sanitario/	—	No se dispone de las listas de tecnologías sanitarias de este apartado.	—
China	WPR	—	—	—	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Chile	—	—	http://www.minsal.cl	—	Concerning the Infrastructure section: Los 21 centros de salud están incorporados en los 100 hospitales distritales/rurales. Los Centros de Referencia de Salud (CRS) = 7 considera a los Hospitales de Chile denominados de Mediana Complejidad y que se ubican en la región metropolitana y demás regiones del país. |Tambien existen también los hospitales de Chile denominados de Alta Complejidad. Se ubican en la región metropolitana y demás regiones del país. Estos hospitales tienen la calidad de "Establecimientos Auto-gestionados en red", incluyendo los base de regiones y los Institutos de especialidades, que se concentran en la Región Metropolitana. |En lo que concierne a los Centros de Salud de atención ambulatoria de especialidades. Son 5 de la Región Metropolitana y dos ubicados en regiones del norte y sur del país.
China	—	—	—	—	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Colombia	AMR	No existe un listado oficial. El acuerdo No.008 de La Comisión de Regulación en Salud (CRES) establece que los dispositivos médicos usados en los procedimientos listados son reembolsados dentro del Plan de Beneficios en Salud.	—	—	The INVIMA (Instituto Nacional de Vigilancia en Medicamentos y alimentos) and the IETS (Instituto de Evaluación Tecnológica en Salud) perform HTA.
Comoros	AFR	—	—	—	—
Congo	AFR	—	—	—	—
Cook Islands	WPR	—	—	—	There are identified HTA activities but not a national unit.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Colombia	El INVIMA tiene dos dependencias relacionadas, la Subdirección de Registros Sanitarios que tiene un grupo funcional específico de dispositivos médicos y se encarga de la evaluación y autorización pre-mercado de los dispositivos médicos; y la Subdirección de Insumos para la Salud que se encarga de la vigilancia posmercado y de auditar sistemas de calidad de los fabricantes y condicion de calidad de los importadores de los dispositivos médicos en Colombia. También existe la Dirección de Dispositivos Médicos y otras Tecnologías.	Nationally developed. It is in the phase of implementation.	—	Actualmente no hay inventario nacional, se ha intentado elaborar mediante el catastro de equipamiento físico. En la normatividad vigente, el Decreto 4725 de 2005, establece que los equipos biomédicos de tecnología controlada deben contar con registro sanitario o con permiso de comercialización en Colombia.	Actualmente se tiene reglamentado y en fase de implementación el Programa Nacional de Tecnovigilancia Post-mercado liderado por el Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) (importantes para la gestión y manejo de los dispositivos médicos), también es importante establecer normas sobre los productos importados (que son la mayoria). Otros temas relevantes son la trazabilidad y el manejo de los dispositivos médicos en el territorio nacional, al igual que el manejo y la aprobación de los equipos repotenciados, su control y uso (este mercado necesita formas alternativas de control, la definición de los requisitos para su uso, etc.).
Comoros	Inspection Général de la Santé.	—	La Evaluación de Tecnologías se reglamentó en el año 2011 mediante la Ley 1438, la cual será competencia del Instituto Nacional de Evaluación de Tecnologías que está en proceso de creación.	—	—
Congo	—	La Nomenclature officiel n'existe pas. Mais sinon, on utilise ce qui peut etre à la portée de la main et selon les circonstances.	L'achat des dispositifs médicaux est décentralisé. il peut se faire au niveau national comme à l'étranger.	—	—
Cook Islands	—	—	—	—	—

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Costa Rica	AMR	—	—	Existen protocolos y procedimientos para las enfermedades y situaciones de emergencias en mención, pero no existen listas de dispositivos médicos como tales.	Two entities perform HTA: Caja Costarricense de Seguro Social (CCSS) and DDCTS. The extension of the HTA entities is at subnational level, not at national level.
Côte d'Ivoire	AFR	Les listes d'acquisition provient du Plan National de développement Sanitaire PNDS.	Document de travail de la Direction des Infraestructures, de l'Equipement et de la Maintenance (DIEM): ListeTypeEquip CHR_HG_CSU_ CSR .	Les procédures et directives sont dans le mannuel de directives à l'attention du personnel des des établissemnts de soins. il n'existe pas de liste spécifique à un domaine ou un programme de santé.	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Costa Rica	El Ministerio de Salud tiene a su cargo el registro y control del equipo y material biomédico mediante el Reglamento Nº 34482-S para el uso, registro, clasificación, importación y control de equipo y material biomédico. El Sistema Integrado de Compras Públicas sigue la regulacion vigente para hacer sus respectivas compras de productos de salud.	The GMDN has been adapted to the national needs.	La Caja Costarricense de Seguro Social brinda cobertura universal a la población y es el mayor proveedor de servicios de salud del país, tanto en hospitales, clínicas y áreas de salud, por lo que se considera que hace la adquisición a nivel nacional. También hay adquisiciones en el sector privado de dispositivos médicos en menor escala; de esta última no se tiene acceso al inventario.	El Ministerio de Salud cuenta con la base de datos de los productos de equipo y material biomédico registrados para el país. Para cualquier adquisición dentro del país es necesario contar con su registro, pero no es del tipo inventario pues no se contabiliza; el registro tiene cinco años de vigencia. En el caso de la CCSS (ver|https://www.ccss.sa.cr/) se tiene un inventario por establecimiento (en los tres niveles de atención) tanto a nivel hospitalario como en clínicas y áreas de salud. Del sector privado se ha reportado que cuentan con inventarios de equipos por institución, sin embargo no se tiene acceso a ese inventario pues se maneja como información discrecional en algunos de los casos y es difícil de monitorearlo en su totalidad. En el Ministerio de Salud para el registro de equipo y material biomédico se utiliza el programa Visual Basic 6.0, Base de datos SQL Server 2005; mientras que en la Caja Costarricense de Seguro Social se utiliza el programa ACCESS para la gestión del equipo médico.	Es díficil que las instituciones den cierta información que consideran es confidencial, por el ejemplo: el acceso a sus inventarios de equipo. En el caso de la Caja Costarricense de Seguro Social, que es el mayor prestador de servicios de salud del país, se pudo obtener dicha información con las autoridades correspondientes, pero resulta complicado.
Côte d'Ivoire	—	—	Il s'agit du Guide de la Direction des Marchés Publics.	La base nationale de données n'est pas fonctionnelle.	—

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Croatia	EUR	—	—	In 2007 the Ministry of Health and Social Welfare issued Ordinance on the organization and work procedures of the Ministry of Health and Social Welfare's Crisis Headquarters (http://narodne-novine.nn.hr/clanci/sluzbeni/2007_05_46_1563.html) which determines organization scheme and work procedure of the Ministry of Health and Social Welfare's Crisis Headquarters as well as actions of other health care institutions and private health workers in case of major crisis. Major crisis is described as any event which constitutes a serious threat to health of a certain community and results (or might result) in large number of victims who cannot be taken care of by usual work organization of public and private health care institutions or private health workers.	HTA is focused on pharmaceutics, not specifically in medical devices. HTA has three partners: the MoH, Health Insurance Fond (HIF) and Croatian Institute of Public Health (CIPH). However systematic use of HTA to support healthcare decision-making is in still in process, but expected over the next years.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Croatia	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	Ministry of Health and Social Welfare currently conducts joined procurement of several groups of medical devices for more than 20 hospitals in the Republic of Croatia. The procurement procedure is managed by the expert divisions within the Ministry in collaboration with all hospitals included in the Procurement Plan and top medical experts for every group of the equipment. Due to continuous advancement in medical devices technology, a special commission is formed before every procurement procedure. The commission defines the required technical specifications of the device based on the most recent available data.	The Ministry of Health and Social Welfare has a national informal and internal inventory for medical devices in all public health institutions. This inventory is used mainly for analytical purposes and planning strategies within the Ministry. In 2008 Croatian National Institute of Public Health, as part of a pilot project under EUROSTAT guidelines, made an inventory of 10 most expensive medical devices (MRI, Computed Tomography, Linear Accelerator, etc.).	—

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Cuba	AMR	—	Existe un listado de modelo de equipamiento médico destinado para cada nivel de atención. No está refrendado en ninguna web (no disponible).	Cada especialidad médica tiene establecidas normas y programas a través de las recomendaciones de los grupos nacionales y apoyo del Consejo de Sociedades Científicas. En cuanto a las listas para diferentes enfermedades y/o situaciones no están refrendadas en ninguna web (no disponible).	It also exists the Department of Innovation and Evaluation of Health Technologies attached to the National Directorate of Science and Technology of the Ministry of Public Health (MINSAP). Evaluations are made mainly for pharmaceutics not for medical devices.
Cyprus	EUR	—	—	—	Pharmaceutical Services within the Ministry of Health performs HTA evaluation of pharmaceutics.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Cuba	En el caso de los medios de diagnóstico in vitro, estos son regulados y atendidos en el Centro de Control estatal de Medicamentos, Equipos y Dispositivos Medicos (CCEEM).	It is use the SUCNEM, a nationally developed nomenclature, based on the Universal Medical Device Nomenclature System (UMDNS) and the Global Medical Device Nomenclature (GMDN)	Basado en la política de salud, los equipos médicos deben contar con el Registro Sanitario para su utilización en el Sistema Nacional de Salud (see: www.bvscuba.sld.cu) y en la Gaceta Oficial de la República de Cuba (www.gacetaoficial.cu). Para el proceso de importación se realiza una evaluación entre las autoridades competentes donde se efectúa previamente un análisis entre asistencia médica y electromedicina. La fichas técnicas para facilitar el proceso de adquisición no están publicadas.	El Programa de Informatización de la Salud se encuentra en fase de desarrollo. There are 3 types of inventory for medical equipment: National for high cost technologies (such as MRI, CT or PET scanners), National for medical equipment and National functional for medical equipment.	En términos de aclaración general indicamos que en Cuba, como es conocido, el Sistema de Salud tiene características de ser único, centralizado, público, gratuito y universal, refrendado en la Constitución de la República. La demanda de equipos médicos se realiza sobre la base de requirimientos acorde al desarrollo científico-técnico mundial y de los índices de consumo para los insumos y obedece a las políticas sanitarias establecidas. Con relación al 3.3.1 las Directrices se basan en la Resolución del Ministerio del Comercio Exterior No. 15 del 2006, no obstante se conocen las Directrices de la Organización Mundíal de la Salud.
Cyprus	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	Procurement guidelines apply to the Public Sector only.	—	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Czechia	EUR	—	—	—	There are HTA activities in pharmaceutics, not specifically for medical devices.
Democratic People's Republic of Korea	SEAR	—	—	—	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Czechia	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	—	—	—
Democratic People's Republic of Korea	—	—	—	—	—

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Democratic Republic of the Congo	AFR	Il existe des listes de materiel dressé au niveau periphérique approuvé (district sanitaire). Pour le niceu intermediaires et niveau tertiaire cette liste est en élaboration.	—	—	—
Denmark	EUR	—	—	In the case of lists for different diseases and situations, there are some more general plans, but no specific medical devices recommended.	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Democratic Republic of the Congo	La Direction des laboratoirs de Sante veuille surtout au respect des normes de autres equipements des laboratoires et des services d'imagerie medicales. Tandis la Direction des Equipements et Materiels Medicaux s'occupes des autres materiel medicaux et non medicaux . Un autre organisme non du ressort de la santé, c'est le Comite National de Protection Contre les Rayonments Ionisants (CNPRI) qui s'occupe essentiellement des equipements émettant des rayonnements non seulement médicaux mais tout. Il faut dire qu'il y a manque notoire des textes qui doivent réglementer tout ceci . C'est avec les quelques notions appris par ici et par là qu'on essaye de faire tant qu'on peut . Sinon, le secteur est très peu reglementé ou carrément non reglementé.	La nomenclature officielle n'existe pas. Tout ce qui est à portée de main et selon les circonstances est utilisé.	En R.D.Congo, les achats se font à tous les niveaux. L'Etat n'a pas pu reglementer ce secteur les achats se font à tous les niveaux et surtout les bailleurs de fonds pour leurs programmes spécifiques qu'ils appuient. Le directives à ce niveau sont fonction d'un appel offre, c'est en ce moment que celui qui lance l'offre dresse un certains critères des dispositifs qu'il veut acquerir.	On est dans le processus de creér de pool de maintenance avec des ingenieurs sanitaires et de rehabiliter les ateliers qui existent . Il y a un programme de formation des ingenieurs et des utilisateurs.	En tant pays post-conflit, dans le processus de l'organisation de son système national de santé, le gouvernement dispose déjà d'une strategie de renforcement du système de santé qui est une strategie sectorielle. Ensuite, le pays vient de se doter d'un plan stragegique de développement sanitaire pour 5 ans avec un cadre des dépenses à moyen terme ou toutes ces technologies sont planifiées.
Denmark	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	—	The National Institute of Radiation Protection is in charge. The inventory covers all x-ray equipment, equipment for nuclear medicine and radiation therapy.	The National Board of Health is issuing some Health Technolgy Assessments, including but not limited to medical devices. Only a minority of technologies are handled, so this is regarded as being outside the scope of the Policy section.

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Djibouti	EMR	—	—	—	The development of the HTA unit is in progress, as well as the human resources to fill the workforce gap within the MoH.
Dominica	AMR	—	—	—	HTA activities have been identified, but there is not a specific national unit.
Dominican Republic	AMR	—	—	—	—
Ecuador	AMR	—	Estatuto del MSP; Licenciamiento por Area en el I y II nivel.	Reglamento para el registro y control sanitario de dispositivos médicos; reactivos bioquímicos y de diagnóstico y productos dentales. Reg. Oficial 573 del 20 de abril de 2009.	There are HTA activities for health products, not specified for medical devices.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Djibouti	—	—	—	—	—
Dominica	—	—	—	The Software is currently awaiting for the setting-up.	A manual exists in draft form to govern issues related to medical devices. It is still supposed to have a final review to begin the process of it's adoption and implementation.
Dominican Republic	La Ley General de Salud 42-01 y el Reglamento de Medicamentos Decreto 246-06 son el marco legal que fundamenta el accionar del Viceministerio de Garantía de la Calidad.	No existe una nomenclatura oficial. Sin embargo, existe una propuesta que data del año 2006 que respondió a un proyecto de mantenimiento preventivo de equipos médicos.	En cuanto a la adquisición solo existen recomendaciones dadas en fichas técnicas y de acuerdo a la complejidad del establecimiento.	—	—
Ecuador	Eco. Ruth Lucio, Coordinadora Nacional de Desarrollo Estratégico en Salud Dirección Nacional de Vigilancia y Control Sanitario en lo relativo a Publicidad y vigilancia. Dr. Liliana Sacoto es la Directora Nacional. Asi como la Dra. Amelia Prieto del Instituto Nacional de Higiene y Medicina Tropical.	For MD traceability purposes will be taken as a reference the Universal Medical Devices Nomenclature System (UMDNS) developed by Emergency Care Research Institute (ECRI). In case that UMDNS does not have a specific code for a MD, it will be taken as an alternative nomenclature, the Global Medical Devices Nomenclature developed by GMDN Agency.	Las políticas de adquisición están en proceso de implementación por la Dirección de Inteligencia y Economía de la salud. |Programa Mi hospital: Adquisición de equipos para 8 hospitales declarados en emergencia sanitaria.	Se está actualizando el inventario de los Hospitales declarados en emergencia. Hay "National inventory only for high cost technologies (such as MRI, CT or PET scanners)" tambien.	La regulación y el control de la publicidad de dispositivos médicos se realiza mediante el "Reglamento para la publicidad y promoción de medicamentos en General, Productos Naturales procesados de uso medicinal, medicamentos homeopáticos y dispositivos médicos". Reg. Oficial 416, acuerdo ministerial 179 del 30 de marzo de 2011.

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Egypt	EMR	—	Were counted by the sector ministry and therapeutic medicine, the National Information Center Ministry	—	A pharmacoeconomics unit was officially established in 2011 under the Central Administration of Pharmaceutical Affairs within the Ministry of Health, but HTA is not obligatory for pricing or reimbursement. However, the recent universal health insurance law from 2018 mandates the representation of health economists in the governing boards of the new Universal Health Insurance Authority and the health care provider body.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Egypt	—	Used in the database of geographical information system health.	Management of medical equipment and hospital management. Curative medicine sector and management of medical devices.	Database of geographical information system health.	Concerning the Infrastructure section: the proposed names are not totally compatible with ours. Thus, the number of units is under the Ministry of Health only and is not confined to Tfsalia to the private sector in 2010.

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
El Salvador	AMR	—	Norma técnica para el diseño y equipamiento de Casas de Salud.	Tomadas de la pagina web del MINSAL (ver link proporcionado). Norma técnica para radiología diagnóstica e intervencionista; Norma técnica para uso de fuentes radiactivas en braquiterapia; Norma técnica para la operación de equipos de teleterapia; Norma técnica uso de fuentes radiactivas no selladas en medicina nuclear; Norma de procedimientos de control de calidad para equipos de rayos-x de uso en diagnóstico medico y dental; Norma técnica sobre anestesiología P.I; Norma técnica sobre anestesiología P.II.	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
El Salvador	El departamento está a cargo del Dr. Rivera, Director de Regulación y Legislación en Salud del Ministerio de Salud.	El catálogo desarrollado es de equipo médico en general y sólo es para fines de compra. No existe distinción o clasificación de equipos de tecnología médica por su aplicación o incidencia en la salud del paciente.	—	Para el control de equipos con fuente de radiaciones ionizantes, la Dirección de Regulación a través de la Unidad Reguladora de Radiaciones Ionizantes (UNRA) tiene el inventario de los equipos como TC, Rayos X, Angiografía, Gamma Cámara, etc. Autorizados a nivel nacional en la actualidad, se remitirá el listado actualizado a la fecha a la OMS.	Las respuestas proporcionadas corresponden exclusivamente a la información disponible en la Unidad de Proyectos del Ministerio de Salud Pública y Asistencia Social. Agradecemos permitirnos participar de tan importante encuesta que nos permite establecer un enlace que estamos seguros contribuirá a mejorar nuestra gestión en la planificación, evaluación, adquisición y mantenimiento de los dispositivos médicos de nuestro sistema nacional de salud; así como a contribuir en el desarrollo de una política nacional de tecnología sanitaria en El Salvador. Este trabajo servirá de referencia mundial en materia de tecnologías sanitarias, en particular en lo que se refiere a políticas, gestión, regulación y uso de dispositivos médicos. Esta encuesta se convertirá en la información de base para las actividades con que se llevarán a la práctica las intervenciones que prevea la OMS en respuesta a las peticiones de los Estados Miembros, de acuerdo con lo establecido en la resolución sobre las tecnologías sanitarias aprobada en 2007 (WHA60.29). Nos ponemos a su total disposición.

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Equatorial Guinea	AFR	—	—	—	There are identified HTA activities but not a national unit.
Eritrea	AFR	—	Ministry of Health, Department of Regulatory Services, Medicine and Medical Devices Control Division.	—	—
Estonia	EUR	The list about reimbursed medical devices used in outpatient conditions is available on web-site (second link) Medical devices used in inpatient conditions are financed though the prices of healthcare services (these prices include also costs of workforce, area, etc). List of healthcare sevices is available on web-site (third link).	—	Recommended medical devices for specific procedures are described in diagnostic (and treatment) guidelines. They are composed and/or approved by specialists organizations.	The HTA for medical products, mainly pharmaceutics, and treatments. There is mention of medical equipment too.
Eswatini	AFR	—	—	The list is still being developed by the Emergency Preparedness Group.	There is no HTA national unit per se. However, and adaptive HTA has been used to inform in areas such as benefits package in health interventions prioritisations packages.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Equatorial Guinea	—	—	—	—	—
Eritrea	—	Official nomenclature system for medical devices is currently on the process of development.	—	National medical devices inventory on the six zones has started in 2008 and, currently, it is in the process of finalization (only one zone is partially remaining).	—
Estonia	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	The procurement of medical devices is regulated by the Public procurement law, as well as all other commodities (see specified website: riigiteataja).	—	—
Eswatini	—	—	The National guidelines on procurement are yet to be developed. The unit together with the bio-medical department forms a committee that recommends purchasing the needed equipment or rather requested equipment.	Though this inventory is still under development, we have only covered hospitals and health centres and will proceed to clinics (health posts for Swaziland).	Concerning the Infrastructure section: In Swaziland Health Centres may have more than 20 beds. The referral levels are being defined by the ongoing essential health care package that is being developed.

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Ethiopia	AFR	We have capital and routine medical device list with technical specification categorized with health facility level.	The list of healthcare facilities is currently in progress.	A revision has started for each. It is use the WHO guidelines and other documents.	An HTA unit is not yet established. Within the FMoH the Pharmaceutical and Medical Device Directorate and HEFA team are primary driving forces to generate and promote HTA based evidence. The HEFA team is tasked with spearheading the application of evidence-based health care decision making by organizing available evidence, costing interventions, and defining effectiveness measures of the different health programs and then supporting policymakers at the national and regional levels.
Fiji	WPR	The biomedical catalogue for procurement can be obtained by the Fiji Health Sector Improvement Program (FHSIP).	CSN & CSP lists can be obtained from ministry of health, HQ.	CSN & CSP. Can be obtained from Ministry of Health, HQ.	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Ethiopia	Radiation & Protection Authority.	Nationally developed and adapted from both UMDN and GMDN. This nomenclature is done by EPSA, ESDA and FMoH in collaboration with skateholders. The nomenclature is mainly use for procurement and regulatory purposes. Established the Public Infrastructure Directorate are now started inventory to identify the type, source and status of the devices.	The Plan, Monitoring and Evaluation Directorate (PMED), within Federal Ministry ofHealth (FMOH) is in charge of the procurement.	AAU, Tikur Anbesa specialized Hospital update medical Inventory and Equipment history file in 2013.	Concerning National policy on health technology: National Medical device strategy under development (draft) and National Medical device directive (final draft) will approved within 3 or 4 months. Concerning the HT national policy, it is stated in the corresponding National Health Policy document. Concerning the Infrastructure section: the targets of the government are to expand the current infrastructure capacity.
Fiji	Also, supported by the divisional biomedical engineering units.	—	Mainly standardization of all medical equipment as per the national biomedical catalogue. Also, supported by the Ministry of Health central procurement centre at Fiji Pharmaceutical Services.	BME Equipment Inventory. The inventory has more than 8,600 items.	—

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Finland	EUR	—	—	—	—
France	EUR	La liste des dispositifs médicaux et prestations pris en charge par l'assurance maladie est accessible à l'adresse donnée en ameli (chercher fournisseurs-de-biens-medicaux/ exercer-au-quotidien/liste-des-produits-et-prestations-lpp/liste-des-produits-et-prestations-lpp/).	—	—	There are three commissions: La commission de la transparence (CT); la commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (CNEDIMTS), and la commission évaluation économique et de santé publique (CEESP).
Gabon	AFR	—	—	—	HTA activities have been identified, but there is not a specific national unit per se. Currently, the HTA unit is in progress towards the Universal Health Care (UHC) country goal.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Finland	—	Finland CA will implement the European Medical Device Nomenclature (EMDN) used by manufacturers/ARs when registering their medical devices in the EUDAMED database. The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland.|Also, some other commercial nomenclature systems are used in healthcare organizations and health technology companies.|Healthcare organizations use these nomenclatures in, for example, public procurement, product information retrieval, ERP, and cost accounting.	—	—	—
France	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	—	—	Dans cette enquete, nous avons mentionnées la HAS et l'ANSM qui sont deux agences qui sont chargées: |HAS: Agence d'évaluation des dispositifs médicaux |ANSM : Agence nationale de sécurité du médicament qui est chargée de la sécurité sanitaire des dispositifs médicaux.
Gabon	—	—	—	—	—

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Gambia	AFR	—	—	—	HTA activities have been identified, but there is not a specific National unit. Currently, the HTA unit is in progress towards the Universal Health Care (UHC) country goal.
Georgia	EUR	—	—	Governmental decree #153, 2007.	State Regulation Agency for Medical Activities is in charge of HTA but not for medical devices.
Germany	EUR	—	—	—	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Gambia	—	The Medical Research Council (UK) unit "the Gambia" (refer to specified link) uses the UMDNS system via the ECRI Health Devices Sourcebook (ECRI website). Note that this is not used by the Ministry of Health.	—	Recently inventories have been compiled for the National Laboratory Services. However, those for Hospital/ Clinical equipment are not available yet. The Medical Research Council (UK) the Gambia has a full inventory of its biomedical equipment. It is comprised of 1,500 devices including minor clinical equipment, high-cost diagnostic and research laboratory equipment. We use a proprietary equipment management program from Phoenix Data Systems Inc. called AIMS (www.goaims.com).	Concerning the Infrastructure section: the private sector section correspond to the responses for the Medical Research Council (UK) the Gambia; Concerning HT nactional policy we provide the following doc.: Medical Equipment and Devices Policy 2010 March. doc. Concerning Section Infrastructure: We have 3 CHU and 1 Hôpital national.
Georgia	Georgian National Agency For Standards, Technical Regulations and Metrology is responsible for standartization and metrology as well as calibration and accreditation of facilities, providing inspection of medical devices.	According to Georgian legislation, Georgia recognizes international or national (according on a list of certain countries) certficates of medical devices there.	—	Nuclear and Radiation Safety Service, Ministry of Environment and Natural Resources.	—
Germany	There are more than 30 regional Competent Authorities.	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	—	—	Germany does not complete the whole survey because of their federal system, which will imply to make the whole survey in their 16 states. Regarding the Regulations section: they follow the EU system, other matters are state´s competency.

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Ghana	AFR	The standard list serves as a guide. The actual procurement is based on the need of health facility, availability of utilities, and availability of professional user staff.	—	—	There are identified HTA activities but there is not a national unit per se. HTA structures (Steering Committee, Technical Working Group and Secretariat) in the MOH have been set up| and a national HTA strategy developed and yet to be launched. In progress towards the Universal Health Care country goal.
Greece	EUR	—	—	—	Various HTA institutions are performing a variety of domains including medical devices.
Grenada	AMR	The list can be requested from the management of the Hospital services. However there is no web to guideline because was never used as a policy of the MoH.	—	No lists available.	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Ghana	The Radiation Protection Institute is responsible for the regulation of equipment with radiation sources such as X-Ray machines.	—	The Ghana National Procurement law as well as the Ministry of Health (MoH). Depending on the value of the procurement package, the health facilities are allowed to procure sometimes, the unit of the MoH also procures some of the capital equipment especially from other projects. All procurement of medical devices is carried out with the technical support of the Clinical Engineering Department of the Ghana Health Service or the Biomedical Engineering Unit of the MoH.	Most inventories are held at a regional and an institutional level. We are yet to acquire the software for the management of the inventory at the national level.	There is no written nor published national health technology policy yet but there are policies available that have been established by the systems and structures unit for health technology in Ghana. Ghana Health Service has drafted its operational policy for healthcare equipment and needs to be finalized.
Greece	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	The EU Directive for public procurement and national specific legislation for health procurement (law 3580/2007). A part of procurement of medical devices is carried out at a national level, by the Health Procurement Committee.	"Praxis", was developed by the Institute of Biomedical Technology (INBIT), and it is a specific one. Also, it is used the Asset Management Software.	—
Grenada	—	A system was develop but it was not supported by management. There is no URL because this software was locally developed.	There are procurement guideliness but they are not implemented or followed. The procurement of medical devices are carried out at a national level by the Central Medical Stores Unit (CMS). No specific devices have been selected but the needed assessment was done.	The inventory for all medical equipment in the island can be found in the Biomedical Engineering Department, General Hospital. The system was locally developed, installed and called The Medical Device Management System Software.	—

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Guatemala	AMR	—	—	Ver: Norma Técnica Vigente para inscripción sanitaria de dispositivos médicos. Específicamente la Normativa 37.	HTA activities have been identified, but there is not a specific national unit. Currently, the HTA unit is in progress towards the Universal Health Care (UHC) country goal. There are the following units: Planificación Estratégica (SIGSA), Observatorio en Salud Reproductiva (OPSOMS/ OSAR) y Sistema Informático de Gestión (SIGES).
Guinea	AFR	—	—	Les Normes ont été définies pour les formations sanitaires de base (postes, centres de santé), les Centres de santé améliorés, les Hôpitaux préfectoraux / districts sanitaires et les Hôpitaux Régionaux. Ces normes ne sont pas disponibles pour toutes les unités fonctionnelles des hôpitaux nationaux.	—
Guinea-Bissau	AFR	—	—	—	—
Guyana	AMR	—	—	—	—
Haïti	AMR	—	—	—	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Guatemala	—	La Clasificación In Vivo y según Clase se encuentra contemplada en el Anexo de la Norma Técnica No. 37.	The procurement is done, at general level, by the Sistema de Adquisiciones del Estado de Guatemala.	No se utiliza ninguno.	—
Guinea	—	—	For procurement or donnations: nous procédons par appel d'offres national ou international.	L'inventaire disponible n'est pas exhaustif en ce qui concerne tous les dispositifs medicaux actuellement utilisés	—
Guinea-Bissau	—	—	—	Inventário Nacional de Equipamentos Médicos: Trabalho curso e dados parciais para o sul do País.	—
Guyana	—	—	—	There are inventories for X-ray equipment. One public corporation uses an assets software to carry out the same function.	—
Haïti	—	—	—	Il n'existe pas encore une liste d'inventaire technique national pour les equipements medicaux.	Concerning the Infrastructure section: les centres de santé sont dotés de 10 lits.

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Honduras	AMR	—	—	—	HTA activities have been identified, but there is not a specific national unit.

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Honduras	—	El Reglamento para el Control Sanitario de Productos, Servicios y Establecimientos de Interés Sanitario, establece una nomenclatura con fines de Registro.	Ley de Contratación del Estado y Reglamento de Ley de Contratación del Estado (more information under|https:// www.arsa.gob.hn/). Cada uno de los Programas de Salud dependientes de la Dirección antes mencionada o entes cooperantes realizan compras de dispositivos médicos para proveer a nivel nacional, como pueden ser pruebas de laboratorio y anticonceptivos. El Programa de Equipamiento se elabora por demanda y por complejidad.	El inventario es por Objeto de Gasto. Existe el SIAFI que es un sistema informático para fines de presupuesto, el cual actualmente se encuentra en proceso de ampliación ya que permitirá la gestión del equipamiento en todas sus fases.	—

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Hungary	EUR	—	—	The uploaded Ministerial Decree lays down the minimum requirements for the provision of healthcare services. The criteria are equally specified for healthcare facilities (1.2.1) and specific procedures. The document has been uploaded only once. The decree is only available in Hungarian. The assigned URLs contain protocols for pandemic situation according to the National Influenza Pandemic Preparedness Plan (second link). Also, see the Decree 60_2003 on minimum requirements of healthcare services.	There are HTA activities for health products, rarely for medical devices.
Iceland	EUR	Only CE marked medical devices are approved.	—	—	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Hungary	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	For procurement guidelines see the "Decree of the Minister of Welfare" (No. 9/1993 NM) on the specific aspects of the financing of healthcare insurance services.|In respect of certain medical devices procured at a national level over a certain amount, procurement is carried out by the Central Services Directorate General of the Prime Minister's Office. In the remaining cases, hospitals procure medical devices subject to itemized accounting individually and the National Health Insurance fund reimburses a certain level of the costs (see the list in the corresponding website, but with exception of pacemakers, heart valves, cochlear implants).	Under high-cost (amounts exceeding EUR 400). Unfortunately, the real state is not a public registry. The access is ensured only for data providers, manufacturers and conformity assessment bodies. Most of the public institutions use the software CT-EcoSTAT.	Concerning the HT policies: "Safety and Partnership Program" -the health program adopted by the Hungarian government on July 9th, 2008 - the acceptance of medical devices and health technologies into the social insurance scheme was defined in the context of improvement of insurance tasks until 2010. |Concerning the HT units section: it has been listed units that are subordinated bodies but not within the Ministry of Health. Therefore, we found it appropriate to mention them. |Concerning the procurement of certain medical devices: it is performed centrally by the Central Services Directorate General of the Prime Minister's Office. In respect of certain medical devices procured at a national level and exceeding a certain amount, the procurement is carried out by the Central Services Directorate General of the Prime Minister's Office.
Iceland	According to Directives 93/42, 90/385 and 98/79.	—	—	—	—

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India	SEAR	—	—	—	HTAIN performs the evaluation and appropriateness and the cost-effectiveness of the available and new health technologies. It includes interventions, drugs, and medical equipment. It has 12 research regional hubs and several technical partners around the country.
Indonesia	SEAR	—	—	We do not have lists for different diseases/situations, but we use WHO recommendations.	It has been started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities. Social Security Management Agency for the Health Sector (BPJS) is focus on HTA for health products. Komite Penilaian Teknologi Kesehatan (Komite PTK) performs economic HTA (not for medical equipment). HTA for medical equipment is rarely performed.
Iran (Islamic Republic of)	EMR	—	—	—	The HTA office under the umbrella of the Ministry of Health and Education (MOHME) was established in 2008, it produces HTA over health products and medical equipment.

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India	Notified medical devices are regulated under the Drugs and Cosmetics Act and Rules under the 14 rule of medical devices as notified under the corresponding Act.	—	—	—	—
Indonesia	—	It is used a Harmonization System code (HS) at the moment. After harmonization GMDN will be used.	We follow the Presidential Decree No. 80 for general procurement. Both, yes and no. Yes, for vertical public hospitals, procurement conducted at national level. No, since re-centralization, procurement of medical devices at province/ district's hospital conducted at local level (province and district level); see yanmed on the website.	Inventories are still ongoing.	—
Iran (Islamic Republic of)	—	—	—	—	—

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Iraq	EMR	The lists of medical equipments have been announced on annual basis.	—	—	It has been adopted the EMA (European Medicines Agency) and the ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH, HTA is focused on pharmaceutics not in medical devices.
Ireland	EUR	There are also several National Framework Agreement contracts for the supply of medical devices and equipment. List of reimbursable devices from Primary Care Reimbursement Service (PCRS). List of reimbursable devices from PCRS is available at pcrs website under -> online services -> list of reimbursable items.	—	—	Additional HTA contact: laura_ dooley@health.gov.ie

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Iraq	The company KIMADIA is responsible for the bulk purchase of medicines, drugs, medical supplies and equipment for whole Iraq on behalf of the MoH. The regulations are pertaining to the procurement aspects.	The MoH is working on adapting a national nomenclature system and linking it to the UMDNS.	The company provides storage, distribution and marketing of medicines and supplies for all Iraq where it is the sole importer of the public sector as well as developing the basic rules for setting the prices for each class of drugs, chemicals and medical supplies to ensure the right price to the citizens and pharmacies and the relevant authorities. Works as well as the allocation of quantities of medicine (drugs and emergency life-saving drugs) as well as the necessary supplies to be used in exceptional emergency circumstances. In addition, to cover part of the needs of the health institutions of medicine and supplies is through national production.	The Ministry of Health at a central level keeps updated records on monthly basis for the functional status of the high-cost technologies. 2- World Health Organization is supporting the procurement of 3 CMMS (from GE - Asset Plus) for three Central Maintenance Repair shops in Baghdad, Erbil and AL-Muthanna Provinces. 3- The Inventories for 6 provinces out of 18 are completed and 6 provinces will be supported to carry out a functional inventory for their medical equipment during the current biennium 2010/11. Finally, MS Excel is been used at the hospitals where inventory was carried out.	Data were obtained from the annual report from 2010, issued by the Department of Planning and Human Resource Development at the MoH Iraq.
Ireland	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	Portfolio & Category Management approach involves the development of medical devices/equipment procurement strategies at a national level and the facilitation of regional and local decision making consistent with these strategies and accompanying procedures. Go to the website and search for: services/Publications/ corporate/procurementpolicy. pdf. Health Service Executive (HSE).	There are no national inventories available to date. Inventories of medical equipment (including functional inventories) are maintained at a local level. Often there are separate asset management and medical equipment management inventories. There is an initiative to compile this data into regional/national inventories in the near future. There is no common software but a variety of systems are employed including HEX, SAP, MS Access.	Concerning the Infrastructure section: the breakdown of infrastructures does not match to our public sector. We have 7 Hospital Groups.

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Israel	EUR	List for procurement/reimbursement It is part of the National Insurance Law.	—	It is in the Israeli legislation.	The HTA within the MoH, as well as research centers such as the Israeli Center for Technology Assessment in Health Care (ICTAHC).

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Israel	Contact person: Avi Kravel within the Medical Devices department.	—	Technical specifications are available only in hardcopy.	—	All the divisions and departments mentioned in this survey are part of the Medical Technology Administration of the Minisrty of Health in Israel. The Administration is in charge of the regulation, licencing and policy making regarding all medical technologies in Israel (including medical devices).

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Italy	EUR	Documents are available at the websites. Documents are often updated, and many of them under revision.	—	—	Agenzia Nazionale per i Servizi Sanitari Regionali (AGENAS) performs HTA for medical devices, and Italian medicines agency (AIFA) mainly in pharmaceutics and related. HTA is also performed in research institutes such as PoliclinicoGemelli (last link).

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Italy	Addresse and contact of the Medical Devices Directorate: Via Molise 2, 00187 Roma, Italy. Tel. +390647051.	CND Classificazione Nazionale dei Dispositivi Medici (correlated with GMDN). CND was nationally developped, and it is the base for EMDN. As mentioned on several occasions in the past, a map of correspondence between the GMDN nomenclature and the Italian CND classification has been created since 2007 to allow manufacturers to register in the Italian database of medical devices. This map is subject to ongoing maintenance even today at the request of manufacturers. This map was introduced at the beginning because the GMDN code was originally the mandatory registration key in the Italian system. Subsequently, the mandatory use of the GMND code was removed at the request of the manufacturers, due to the difficulty of using it and, in many cases, due to its unavailability. In any case, the possibility of using the GMDN code and its connection with the CND is still allowed, but it appears that, despite this possibility of use, the GMDN code is rarely used in the registration in the Italian system.|A new version of the Italian medical device nomenclature (CND) will be published within the next months. Because the CND has been chosen as the basis of the EMDN nomenclature, a huge update has been done to create the European nomenclature.	Go to the website and look for: dispositivi/dispomed.jsp documents.	—	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Italy cont...					
Jamaica	AMR	—	—	Not available at present.	At the moment, the country does not have an official process for collecting evidence and preparing HTA reports as an input for making health coverage decisions, but they are interested in working towards it..
Japan	WPR	New medical devices which begin to be reimbursed have been published by the Central Social Insurance Medical Council.	—	—	There are a medical technology evaluation team, an expert committee for insurance care materials, an expert committee on drug prices (within the MoH: first link). Also, the National Institute of Public Health performs economic health evaluation (second link).

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Italy cont...		All the updates have been acquired in the new version of the CND, that has been approved by the Italian Technical Committee on 21st December 2020.|One of the most important inputs for the CND update was the comparison with GMDN and so an alignment between the first level of the CND 2018 version and GMDN (dataset 01/05/2019) has been done. A list of GMDN codes not covered by CND has been defined and then used to create some new codes in CND. In the Meeting of the Medical Device Nomenclature Working Group-04, OCTOBER 2019 of the European Commission, the state of the art of mapping between CND and GMDN was a point of the agenda. Any further other mapping activities must be agreed upon with the European Commission in line with the provisions of the project itself.			
Jamaica	—	—	The procurement is done at regional and hospital levels.	—	Concerning the HT national policy is stated in the document Ritza 04.
Japan	—	Japanese Medical Device Nomenclature was developed from the GMDN 2003 version.	—	—	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Jordan	EMR	The list is not published. It is within the updated document of the study department.	—	We have a list but for a specific departments, it is not published. It is only updated and kept in the Study & Project Department. In the near future it will be published the Essential list at our website.	Structured HTA capacity_building is being developed and implemented in the Department of the Pharmacy Center for Drug Policy and Technology Assessment (CDPTA), King Hussein Cancer Center (third link). Jordan started a hospital-level HTA at King Hussein Cancer Center (KHCC). The CDPTA at KHCC is responsible for conducting HTAs, their assessments are appraised by the Pharmacy and Therapeutic (P&T) Committee and HTA results are currently utilized to support formulary listing decisions.
Kazakhstan	EUR	For list of approved medical devices for procurement we have the Medical State Register of Lekarstennyh.	—	—	Additional HTA contact: Zaid Zholdassov: zholdassov_z@rcrz.kz. The HTA is focused on pharmaceutics, sometimes performed for medical devices.
Kenya	AFR	Lists are developed locally and available in hard copy only. Lists for procedures only cover surgical procedures.	—	It only covers surgical procedures which are locally developed. No available.	The development of HTA framework for health products is in progress.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Jordan	It also exists the Energy & Minerals Regulatory Commission.	This country will support the WHO standard nomenclature for medical devices. Until now, its nomenclature is based on UMDNS for management in the CMMS system, and the government procurement department uses UNSPSC nomenclature for procurement purposes.	The procurement is done at a national level by Ministry of Health. Some manufacturers have guidelines and technical specificatios such as: ECRI, AAMI, HTM (See:|http://dbe.gov.jo). Although the list is not published neither available online, it's within the updated document of the study department.	—	Concerning medical equipment management section: we have around 700 type medical equipment tech., spec., updated only in tenders are published; and we have 30 medical equipment, workshops MOH Hospitals.
Kazakhstan	National center of examination of drugs (RGP), medical devices and medical equipment nazancheniya (MH RK).	Medical State Register of lekarstennyh.	The procurement is done at a national level with the register of procurement of medical equipment. We have the National Register of medical devices.	Medical State Register of lekarstennyh.	Concerning the Infrastructure section: the division for 20 beds on health centres is not applicable for the Kazakhstan centres network.
Kenya	Kenya has demonstrated its commitment to improve the national legal and regulatory framework for radiation safety. Currenty, The Radiation Protection Board (RPB) regulates such activities in Kenya, including those with sealed and unsealed radioactive sources as well as X-ray and other radiation-emitting devices.	The GMDN is used for regulatory purposes	The procurement at a national level is specifically done at the Ministry of Health. Guidelines for donations: IEC 60601, ISO 13485, Directive 93/42/EEC.	Locally developed.	The corresponding technical specifications, as well as donation guidelines are available upon request in soft copy (not pdf versions).

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Kiribati	WPR	We do not have a standard list in place but we do overseas and local procurement for specific medical devices needed for MoH; e.g., in 2009 overseas procurement for medical devices was made through medical healthcare prioritization according to doctors and head nurses. The selection and orders of medical devices were made to medical suppliers (such as South Austral and Braun) taking into account quality, affordability and critical need to meet quality health care services and patient's safety and satisfaction.	—	We do not have a standard list in place but we do overseas and local procurement for specific medical devices needed for MoH; e.g., in 2009 overseas procurement for medical devices was made through medical healthcare prioritization according to doctors and head nurses. The selection and orders of medical devices were made to medical suppliers (such as South Austral and Braun) taking into account quality, affordability and critical need to meet quality health care services and patient's safety and satisfaction. In 2010 (8/3/2010) we received some medical devices. Kiribati outbreak manual for public health nurses and curative: national pandemic guidelines, national disaster guideline.	—
Kuwait	EMR	—	—	—	It has been started the institutionalizing of HTA within the MoH, with activities such as the building capacity.

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Kiribati	—	—	The donations are second-hand medical devices from churches (LDS & CCatholics); such as defibrillator, computer, patient monitor-propaq, dressing trolleys.	We have the inventory record and monitoring system with medical stores/clinical wards/community health centres. In the case there is no inventory for specific medical equipment we refer to overseas medical supplier for assistance and good advices. In some cases there is inventory only for high cost technologies (such as MRI, CT or PET scanners).	Medical devices components such as tools, knowledge, skills, repair and maintenance are very crucial and essential therefore Kiribati is very fortunate to be part of this surveillance thus is the only way to maintain our QA/QI (quality assurance and quality improvement) to achieve MoH objectives (utilization of quality medical/nursing care to all Kiribati individual patient/client to provide patient's safety, quality health care services and patient' satisfaction). We would appreciate being advised in ongoing training especially for nurses.
Kuwait	—	—	—	—	—

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Kyrgyzstan	EUR	Standards: The law on the Health Care institutions. We have lists for communicable diseases, and public health emergency situations, as well as clinical protocols. The register of registered medical equipment is made at the website of the Department of Drug Provision and Medical Equipment MoH of the Kyrgyz Republic.	Equipment timesheets are available, but without the use of nomenclature.	Clinical protocols.	—
Lao People's Democratic Republic	WPR	—	—	—	It has been started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities. There are identified HTA activities but not national unit. The creation of a national health insurance authority towards the UHC goal is in progress.
Latvia	EUR	—	—	Regulation of Cabinet of Ministers No. 60.	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Kyrgyzstan	—	The nomenclature is used for various purposes: regulation, procurement, in-vitro diagnostics lists and inventory.	Kyrgyz Republic National Health Care Reform Program "Manas taalimi". Procurements are carry out through the National (budget) or donor projects.	The National Register for Medical Equipment and the National Functional Register for Medical Equipment. The National Functional Register for the Medical Equipment is a database for medical facilities of the public health institutions; meanwhile, the National Register of the Medical Equipment is a national list of pharmaceuticals and medical equipment authorized and registered for utilization in the Kyrgyz Republic. A database is employed for material and technical facilities and medical facilities of public health institutions.	—
Lao People's Democratic Republic	There is the political will to strenghten the Nuclear and radiation safety and security, as well as the corresponding legal framework (as seen in the 2020-2025 plan).	—	The procurement at a national level is only for sophisticate and high-value equipment.	In the whole country, the inventories are ongoing .	—
Latvia	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	The procurement of national devices at a national level started from the year 2010.	—	—

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Lebanon	EMR	—	—	—	The HTA is at initial stages to inform health policy and products. National strategy will incorporate several actors: MoH, National Social Security Funds, General Security, etc.
Lesotho	AFR	—	—	—	—
Liberia	AFR	Lists of standards and lists are: "Basic Package of Health Services" which contains a list of the equipment at the "annexe". However, the list is subject to revision. The WHO guidelines are being used for donations. The process has been initiated for the adaptation of the guidelines.	—	The list of equipment can be found in the index of the following document Basic Package of Health Services. However, the list is subject to revision.	—
Libya	EMR	There are national standards lists but they are not written. There are lists for Sundries Hospital consumable- Diagnostics Laboratory 37/3.	—	There are national standards lists but are not written. It exists also lists for interventions, and emergencies. See the following file: General_terms_and_conditions_ for_medicines_and_medical_ consumables_and_equipment.	—

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Lebanon	It controls the importation of all radiological devices (x-ray devices, tracers for nuclear medicine, etc.).	The Ministry of Health is planning to acquire the Global Medical Devices Nomenclature system to adopt it and use it for regulatory and procurement purposes.	The procurement of medical equipment for public hospitals is done by the Council for Development and Reconstruction in coordination with the Ministry of Public Health. A procurement procedure and bidding documents are used and adapted according to the specific project and considering the government rules for procurement. No guidelines exist in the private sector that is dominating the health sector (80% of beds are private).	The Ministry of Health has acquired a GIS licence to establish a database which will include the available high-cost technologies.	—
Lesotho	—	—	—	—	—
Liberia	Currently, there is a National Drug Regulatory Authority that is in the process of institutonalization.	No comments as the nomenclature does not exist.	The procurements are based on the WHO guidelines and they are mainly organized through partners.	The functional inventory of medical equipment is ongoing. The focus is to take inventory of all equipment in the Public Health facilties.	—
Libya	The Medical Supply Organization (MSO) is responsible for the procurement of medical appliances for the public sector.	For the medical equipment list, it is used a nomenclature based on the UMDNS. The nomenclature is used for inventory systems of healthcare facilities and lists.	In regards to the technical specifications of medical devices, we depend mainly on the technical committees which consist of experts in medicine, pharmacy and biomedical engineer. These committees set up decrees issued by the Secretariat of Health.	The last version is from 2006.	This is the first time for us to participate in this survey. Our standards and policies are under development and/or being updated. Many issues in this survey are available but still not documented. "General_terms_and_ conditions_for_medicines_ and_medical_consumables_ and_equipment"

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Lithuania	EUR	Licensing regulations for health care facilities. General and specific requirements for institutional health care services. There is a list of medical devices that are mandatory for specialized and surgical health care services. Public Procurement Office operating under the Ministry of Economy, compiles the list of drugs and medical supplies, annually. The list is approved by the Minister of Health. The items included in this list are procured in a centralized way. The procurement expenses are disbursed from the National Health Insurance Fund Budget. The National Health Insurance Fund under the Ministry of Health is responsible for public procurement of the items of the list, mentioned above.	—	These are lists of indications and reimbursement regulations for expensive health technology examination techniques (e.g. CT, MRI) and diagnostic procedures (e.g. diagnostic interventional procedures). Only available in lithuanian language. General and specific requirements for institutional health care services. There is a list of medical devices that are mandatory for specialized and surgical health care services. There are no separate lists of communicable or non-communicable diseases.	—
Luxembourg	EUR	—	—	Contenues notamment dans le plan pandémie grippale qui n'est pas sur l'internet public.	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Lithuania	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	Guidelines for procurement of expensive health technologies (i.e. MRI, CT etc.). Guidelines are in the Lithuanian language only. There are basic requirements for technical specification of medical devices that are procured in a public centralized way.	The State Health Care Accreditation Agency, under the Ministry of Health, is responsible for the management of national data regarding expensive health technologies (i.e. MRI, CT, etc.).	—
Luxembourg	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	—	Software choisi par chaque hôpital individuellement.	—

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Madagascar	AFR	—	—	—	—
Malawi	AFR	The standard list provided is for health centres, community hospitals and district hospitals. The standard list for central hospitals is being developed and will be published very soon (file names: "jica" and "customer", respectively).	—	—	—

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Madagascar	—	Nomenclature nationale pour la comptabilité matière du patrimoine de l'Etat (codification pour l'inventaire technique).	Specifications techniques pour: Matériels et équipements pour les Centres de Santé de base; matériels et équipements de laboratoire pour les Centres Hospitaliiers de Districts de niveau 2; matériels et équipements biomédicaux et hospitaliers pour les Centres Hospitaliers de Districts de niveau 2.	Inventaire effectué en 2007 avec le projet CRESAN 2 (55 Centre Hospitalier de District de niveau 1 (CHD1), 29 Centres Hopsitaliers de Districts de niveau 2 (CHD2), 18 Centres Hospitalier de Référence Régionale (CHRR), 10 Centre Hospitalier Universitaire (CHU) et Etablissements Sanitaires. Mise à jour en cours.	Formation en maintenance biomedicale a Madagascar: Depuis 1980, la multiplication des établissements hospitaliers et l'avenement des nouvelles technologies au service de santé ont induit une arrivée massive et diversifiée d'appareillages biomédicaux et ont fait apparaître le problème crucial de leur maintenance. La dernière action de recyclage (formation continue) des techniciens date de 2001.
Malawi	Radiation protection and nuclear safety is done via AERA and it is in process of institutionalization.	—	There are the following pdf files: the "Public Procurement Act (2003)", the "Desk Instructions", and the "Procurement Regulations".	The inventory is in a database known as "Planning and Management of Assests in Health Sector (PLAMAHS)" and is not yet online.	—

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Malaysia	WPR	The corresponding lists are only prepared based on the needs.	—	There is no standardized list. It is based on needs.	Malaysian Health Technology Assessment Section (MaHTAS) of the MoH performs HTA for health products including medical devices.
Maldives	SEAR	—	—	—	—

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Malaysia	The Medical Device Act 2012 (Act 737) has come into force on June 30th 2013, while the effective date for its subsidiary legislations, the Medical Device Regulations (MDR) 2012 was on July 1th 2013. Act 737 provides two and one years, respectively, of a transition period for the industry to submit applications for medical device registration and establishment licensing before the law is fully enforced. It exists a separate unit for the regulation of radiological equipment (i.e. within the Ministry of Energy): Radiation Health and Safety Section, Engineering Services Division, Ministry of Health Malaysia:|https://radia.moh.gov.my/. The Atomic Energy Licensing Act 1984 (Act 304) provides the regulation and control of irradiating apparatus.	—	Depending on the types of Medical Devices. Some are procured at a national level, some at the state level and some at the hospital level.	—	—
Maldives	—	—	The procurement is done at a national level as well as for government health facilities.	—	—

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Mali	AFR	Il n'existe pas de normes nationales pour des procedures spécifiques, en général elles sont traitées au cas par cas. Non, comme décrit précedemment, il n'existe pas de liste spécifique de dispositifs médicaux pour les cas cités. La liste de dispositifs médicaux approuvée est en fait par niveau de structures sanitaires. A ce jour nous disposons de listes standard d'équipements pour les structures de base (CSCOM - centre de santé communautaire) et les structures de première référence (CSREF - centre de santé de référence) que nous utilisons dans nos différents dossiers d'appel d'offres d'acquisition de dispositifs pour celles ci. Pour les hôpitaux nous essayons d'harmoniser , car les structures diffèrent un peu ,en fonction de la population, de l'éloignement et de la position géographique.	—	Il n'existe pas de normes nationales pour des procedures spécifiques , en général elles sont traitées au cas par cas. Pour diverses maladies et situations Il n'existe pas de liste spécifique de dispositifs médicaux pour les cas cités.	The HTA is at initial stages to inform health policy and products but not for medical equipment.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Mali	—	Il existe dans le document de la comptabilité matière une rubrique nomenclature sommaire ou les différents produits sont classés par catégories, mais c'est un domaine très important qui mérite une action.	Guidelines for procurement: existe un document de projet de politique nationale en matière d'équipements et d'infrastructures sanitaires qui traite ces cas , mais il reste à être validé. Jusqu'à l'adoption de la loi hospitalière. La DFM était le seul organe d'achat de dispositifs médicaux. Vue que cette loi accorde un statut particulier à certaines structures sanitaires notamment l'autonomie de gestion, mais aussi dans le cadre de la décentralisation il y a le transfert de compétences entre le Ministère de la Santé et les collectivités territoriales, de sorte que ces structures peuvent acheter indépendamment	Chaque année le Ministère de la santé à travers la DFM organise des inventaires mixtes dans lesquels| participent comptables matières et techniciens biomédicaux, dans toutes les structures sanitaires du pays [centres de santé communautaire (cscom) , centre de santé de référence (csréf) et hôpitaux régionaux (HR).Ensuite les differentes fiches sont compilées et informatisés au niveau de la division comptabilité matières.	Concerning the Infrastructure section: nous n'avons pas encore une politique nationale pour les équipements mais nous y travaillons, nous avons tenu deux ateliers: l'un pour l'élaboration des élements de la politique et l'autre pour la rédaction du document de politique. Le document attend sa validation lors d'un atelier national pour être soumis à l'Assemblée Nationale. Concerning the Section Infrastructure: la Division établissements sanitaires et réglementation (DESR) à la Direction Nationale de la Santé s'occupe également des établissements privés de santé mais ne dispose pas de données à jour (2010) sur leur nombre exact.

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Malta	EUR	—	—	—	Office of the Chief Medical Officer is in charge to perform HTA, mainly in pharmaceutics.
Marshall Islands	WPR	—	—	—	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Malta	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	Procurement at national level: there is a strong collaboration between the two. For capital expenditure for new technologies it is usually the department, for others it is usually coordinated by the hospital itself.	The name of the Software is Clingo from the company Carestream Health Italia SRL.	The Ministry of Health has started to provide emphasis on new health technology and its assessment. Over the last 2 years, it has been developed a short form and guidelines for the completion of all the requests for the implementation of new health technologies and services. Together, the Director Generals for Strategy & Sustainability, and Healthcare Services have met three times a year to evaluate the proposals received. It is envisaged that a health technology evaluation unit will be developed in the short term.
Marshall Islands	—	—	—	Inventory is not available.	—

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Mauritania	AFR	—	—	Il existent des paquets d'activités par niveau des soins de la pyramide sanitaire.	—

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Mauritania	Direction de la Medecine Hospitaliere qui a l'attribution de élabore et suit la reglementation et les normes hospitaliere, et prépare l'autorisation d'ouvertue a titre privé des cliniques et des cabinets de soins infirmier. Inspection General de la Santé (IGS) a l'attribution de verifier la gestion des activités de l'ensembles des services du departement et des organes sous tutelles, et leurs conformité aux lois et reglement en vigeur cf voir organigramme du ministere de la sante qui se trouve dans le site web du ministere.	—	Il existe un plan de passation des Marchés (search for the document admin07 in the specified website). Il existe le Centrale d'Achat des Médicaments, Equipements et Consommables Médicaux (CAMEC) en ce qui concerne la procuration des equipments medicaux:|http://www.camec.mr/	Un inventaire technique national etait diponible dans une base de donnée informatisée (GMAO) qui est malheusement deectueuse depuis 2004, et qui n'a jamais été actualisé au niveau national.	Le suivi de la maintenance des équipements est une mission confiée à la Direction des Infrastructures, du Matériel et de la Maintenance (DIMM) et mis en œuvre par le service de la Maintenance.|Le service de la maintenance comprend deux divisions :- Division de la maintenance des infrastructures;- Division de la maintenance des équipements et des matériels. Le service de la maintenance dispose d'un plateau technique composé, au niveau central de 7. techniciens biomédicaux, de 2 ingénieurs biomédicaux et d'un ingénieur électrotechnicien, au niveau périphérique de : 5 unités régionale, qui assurent une maintenance de proximité. La qualité du service est insuffisante dans la quasi-totalité des structures de maintenance lié à la perception même de la composante maintenance, qui n'est généralement pas prise en compte lors de l'élaboration des projets et de certaines défaillances au niveau du développement des compétences (formations spécialisées, stages de perfectionnement pour les experts etc.) et autres moyens (financier, outillages etc.) pour l'exécution des activités de maintenance (préventive, curative etc.).

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Mauritius	AFR	Some lists are available for certain specific conditions e.g pandemic, fogging, sprayers, etc. (an specific Plan is in preparation), there are no specific lists for non-comunicable nor communicable diseases. It must be pointed out that the Ministry does not accept all donations except from friendly countries.	—	Some lists are available for certain specific conditions e.g Pandemic, fogging, sprayers, etc. There is no specific list for Communicable Diseases but a PLAN is in preparation.	—
Mexico	AMR	See "cuadro básico". The list is under new policies.	The lists are updated constantly.	—	—
Micronesia (Federated States of)	WPR	—	—	There are no lists available.	The unit of Budget and Planning with the department of finance and administration (DOFA) performs economic analysis, however, there is no HTA for medical products.

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Mauritius	Radiation Protection Authority for Radiation.	We import all our devices.	Central Procurement Board has a policy. However, there is an equipment committee which looks after procurement of equipment spare parts. For public sectorn procurement is done at a level of the Ministry of Health and the central procurement board. Private equipment is done by direct purchase. In the public sector, we recommend certification based on the FDA, CE and TUV approved systems.	Each hospital has a separate inventory. Concerning Software there is one developed locally which is currently on trial. E-health is in preparation.	Concerning the HT national police it is stated in following document: politique santé.
Mexico	—	The nomenclature system is established and organized in charts for health technologies that can be used in public/ social health services. As for the government administration for 2018-2024, the charts will be organized as a compendium and it is in the process of depuration.	There are some recommendations for this topic, but they are not policies. The specifications are only recomendations.	Subsistema de Información de Equipamiento, Recursos Humanos e Infraestructura para la Atención a la Salud (Subsystem of Equipment, Human Resources and Infraestructure in Health). There are not only one, in general these are made in each one of the units for their particular needs.	—
Micronesia (Federated States of)	—	—	Medical devices may be purchased by the National Department of Health & Social Affairs, or the State Health Services. At a national level purchases are made by the coordinator of the program receving the grant or funds for the purchase in consultation with the department to receive the device (e.g. manager of state hospital radiography department, or chief of ancillary services). Guidelines are only for competitive quotes or bidding processes.	The National Department of Health and Social Affairs, as well as state health services, keep assets registries for fixed assets over $1,000. Medical Devices will be included on these registers. Individual units (e.g. state laboratory) should have a functional inventory of devices/equipment.	There is limited expertise in the country. There are no qualified radiographers nor pathologists. Only 3 over 30 laboratory technicians have a bachelors degree in medical laboratory science.

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Monaco	EUR	—	—	There are "Plans d'urgence".	La Direction de l'Action Sanitaire pourrait commander évaluations des technologies de Santé.
Mongolia	WPR	—	—	—	—
Montenegro	EUR	There is a list of medical devices (based on the opinion of a team of doctors) that are provided or reimbursed to the patient by the Health Insurance Fond. The list is created as a result of different indications mostly for treatment, alleviation or compensation for an injury or disability. There is the Law on Protection of Population against Communicable Diseases. Also, we have a national strategy for an emergency which is involved as a part of the public health emergencies policy (see link).	—	There are no national standards for medical devices, but Competent Authority, in accordance with the law on medical devices recognize appropriate international standards (EC, ISO). There is the Law on Protection of Population against Communicable Diseases. Also, we have National strategy for emergency situation, which involves part about public health emergency situations (see link). The lists are published in Montenegrin language.	There is no HTA framework yet, but positive political will.
Morocco	EMR	Des listes standardisées de dispositifs médicaux pour différents établissements de soins sont établies au niveau de la DEM.	—	Concernant les points "b" et "c" des listes sont établies au niveau de la DEM. La DELM prend en charge les points "a" et "b" aussi (see comments of other lists).	Adopted EMA (European Medicines Agency) and ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH, HTA is focused on pharmaceutics but not in medical devices.
Mozambique	AFR	—	—	—	The Department of Health Information (DIS), Ministry of Health (MISAU), performs HTA for technologies related to prevention and control of diseases, but no specifically for medical devices.
Myanmar	SEAR	—	—	—	It has started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Monaco	—	Directive 93/42/CEE.	Procurement guidelines: marquage CE requis.	Pas d'inventaire.	—
Mongolia	—	—	—	—	—
Montenegro	—	"Register (notification) of medical devices" that contains information on medical devices which are available for use in Montenegro has just recently been set up. As it is at the start of its operations, it will use GMDN as a referent nomenclature system and based on this, it will be developed a system that will be in Montenegrin language so that all users can use it properly and they will have information what is on Montenegrin market as well.	The procurements of medical devices for public health institutions are in conformity with Law on public procurements. We recognize international standards in accordance with a law on medical devices.	There are no specific national inventories but every year the Government of Montenegro provides a specific amount of money that can be used in special cases (public health emergency etc.).	Concerning the Infrastructure section: We would like to inform you that we have specialized hospitals for only one speciality as psychiatric, orthopaedic and lungs diseases. We have 3 institutions like this.
Morocco	—	Nomenclature basée sur l'ECRI et le CNEH.	Un projet de mise en place d'une stratégie Nationale en matière de gestion des T.S est en cours. Les spécifications techniques sont établies selon les besoins des utilisateurs (grands projets de CHUs) et standardisées pour chaque type d'établissement de soins.	La majorité des inventaires des régions sont sur support papier et non encore informatisé. L'alimentation de la base de données du progiciel de gestion des dispositifs médicaux est en cours.	—
Mozambique	—	—	—	—	—
Myanmar	—	—	The Procurement and Distribution Division, Department of Medical Services is in charge of procurement at a national level.	In some cases, there is an inventory only for high cost technologies (such as MRI, CT or PET scanners).	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Namibia	AFR	—	—	—	MoH uses HTA for both regulatory and coverage purposes. Not performed for medical devices. However, an HTA has yet to be elevated to the national agenda. There is a written HTA. guideline, and formal identification of technologies for HTA.
Nauru	WPR	—	—	SPC assist us with our supplies for the Pandemic preparedness but we do not have a list as most of these are consumables.	—
Nepal	SEAR	—	—	—	There are identified HTA activities but not national unit per se. However, there is research in the health unit within the MoH. The HTA under the government umbrella is in progress and a requirement to reach the Universal Health Care country goal.
Netherlands	EUR	The health insurance scheme takes care of the reimbursement of extramural medical devices in the Netherlands. The reimbursement of medical devices is function orientated.	—	In the Netherlands, the professional has to decide, recommend or indicate a medical device. The cupola of the professionals can publish a guideline for specific procedures. There is no national policy on diseases or situations.	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Namibia	According to the Atomic Energy and Radiation Protection Act No. 5 of 2005.	—	There are guidelines for Implementation of the National Health care Technology Policy & Medical Equipment Management. Since finances have been decentralised, each of the 13 political regions is responsible for budgeting and procuring medical equipment for the health facilities in that region. Advise on budgeting and tender specifications can be obtained from MEM at a National Level.	Medical Equipment Management System Software (MEMS).	—
Nauru	—	—	The procurement for the medical devices is based on the Hospital's Senior Management Team decision and the availability of the fund.	We keep an asset register at the Administration Office and the Pharmaceutical Store which include all the medical equipment in the hospital.	—
Nepal	—	—	We follow the Public Procurement Act and the regulation of Nepal for procurement of medical devices also. Also, it is partially carried out at national level procurement of medical devices.	Working on to develop national inventories.	—
Netherlands	For vigilance and post market surveillance (more info in the medische-hulpmiddelen corresponding link).	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	There is the Commission decision of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices.	The Netherlands has no national inventory for medical devices.	—

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New Zealand	WPR	Under New Zealand law there is no approval system for medical devices and hence no pre-market scrutiny of their safety and performance. There is a legal requirement for the sponsor (importer/exporter/ supplier) of a medical device (with some exceptions) to notify the device to a database maintained by Medsafe within 30 working days of becoming the sponsor for the device.	—	—	National Health Committee performs HTA in several areas, but not for medical devices.
Nicaragua	AMR	—	—	The Ministry of Health does not have lists recommending health technology for different diseases or situations.	There are identified HTA activities but not a national unit.
Niger	AFR	—	—	—	—

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New Zealand	—	—	National requirements apply only to procurement of electro-medical devices through a set of AS/NZ standards such as AS/NZ3551:2004 which are mandated under a national law. Government publishes standards that are applicable to some devices.	—	The definition of medical device used in NZ law (the Medicines Act 1981) is not currently aligned with the GHTF approach. Consequently, some products that are regarded as devices in other countries are currently regulated as medicines in NZ. Examples include pregnancy tests, condoms with spermicide, IUCDs with copper and nasal irrigation solutions.
Nicaragua	—	For various reasons, there is not an official nomenclature system used for medical devices.	The procurement department works as a team with the Health Services Department, the Sanitary Regulations Department and the Acquisition Unit of the Ministry of Health.	This inventory was carried out for the maintenance unit (CEMED). The last update was in 2009.	Our Ministry of Health is doing big efforts to normalize and regulate the procurement of medical devices, but we do require training for our personnel to perform a better job. We also have limitations in providing maintenance to the acquired equipment.
Niger	—	Il ya plusieurs types de codification testés. Les premières se sont inspirées du code CNEH (code national pour l'équipement hospitalier) français. Il n'ya pas de codification unique retenue au niveau national.	Toutes les acquisitions réalisées dans le cadre des projets et programmes passent par la DIES. Mais certaines (ONG et associations caritaives) ne passent pas.	Il ya eu plusieurs tentatives d'installation de logiciel de GMAO (Gestion de la Maintenance Assistée par Ordinateur) dont Gestmat (par la Société Deloitte et Touch Consulting) et OPTIM (par le Bureau BEEM Engineering France). Aucun logiciel n'est totalement fonctionnel en ce moment.	Le Niger dispose d'une stratégie nationale de maintenance adoptée depuis avril 2008.

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Nigeria	AFR	—	—	—	Three organisms perform HTA at a national level: The Agency for Food and Drugs Administration and Control (NAFDAC),|Nigeria Institute for Pharmaceutical Research and Development (NIPRD) and the National Health Insurance Scheme.|(NHIS). The action plan 2018-2021 of the MoH states the progress to a National Quality Review & Health Technology Assessment Systems to determine which health interventions are cost effective including medical devices (see fourth link). HTA is a pliar for UHC's goal.
Niue	WPR	—	—	—	—
North Macedonia	EUR	The reimbursement is performed by the National Health Insurance Fund, the list of medical devices that are reimbursed are posted on the "fzo website". In public health facilities the procurement is currently going through a public competition with those medical devices that have entered the register of medical devices.	—	—	There is not an HTA national unit yet per se but it has been acknowledged at a political level by the MoH. There are HTA activities for the selection of specific medicines. It exists a Centralized System for external price referencing and decentralized procurement prices of non-prescription medicines and devices.
Norway	EUR	A few devices - those being reimbursed via the blue prescription system i- are listed. Lists are made by The Norwegian Labour and Welfare Administration, refer to the procurement of medical devices at national level section.	—	—	The system has two levels; a national level where decisions based on HTAs are made by the four regional health authorities in concert, and a local/"hospital-level" where decisions are made based on the mini-HTAs performed locally in each hospital. Pharmaceutics have to pass always by the national level. The Norwegian Knowledge Centre for the Health Services (member of the NIPH since 2016) do HTAs on selected procedures and devices upon request.

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Nigeria	—	—	—	—	—
Niue	—	—	—	—	—
North Macedonia	—	The GMDN code is being recognized.	—	—	—
Norway	The Directorate of Health, Department of medical devices and medicinal products is the Competent Authority for medical devices in Norway, it has the tasks of the competent authority as they are given in the European directives for medical devices. These tasks, however, are not identical with those listed under the corresponding ones of this survey.	The use of GMDN is not imposed by law.	Only procurement of devices being reimbursed via the blue prescription system is carried out at a national level, by The Norwegian Labour and Welfare Administration.	—	Concerning the HT national policy, it was provided the following document: plan van aanpak patientveiligheid medische technologie. pdf.|Concerning the infrastructure section: As of 01.01.2009: 11 885 beds in specialised healthcare. 117 of these are in the private sector.

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Oman	EMR	—	—	Medical devices for specific procedures, whenever required, are prepared or modified based on the requirement from end users. Available at Directorate of Medical Technologies.	Drug control, bulk procurement and distribution of drugs are managed by MoH. There are identified HTA activities but there is no national unit per se.
Pakistan	EMR	—	—	The provinces develop their lists of equipment based on their health facilities, the available funds, and according to the Priced Vocabulary of Medical Stores (PVMS) (Available). World Health Organization Pakistan share such lists with the Ministry of Health at time of emergency.	—
Palau	WPR	—	—	—	—
Panama	AMR	Available at the specified website.	—	—	HTA activities are performed in the MoH, Caja de Seguro Social (CSS), and institutions such as the Instituto Conmemorativo Gorgas de Estudios de la Salud (1928) (GORGAS). HTA is performed in several areas: pharmaceutics, interventions, cost-effectiveness, etc. In the ministry of health, they perform some kind of HTA processes for the List of Essentials Medicines, in the CONAMEP (Comisión Nacional de Medicamentos de Panamá)
Papua New Guinea	WPR	—	—	—	The 2011 initiative undertaken to establish a national e-health strategic framework and committee, as first steps. There are identified HTA activities but not national unit. The Universal Health Care country goal is in progress.

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Oman	—	—	The procurement guidelines are available at the Directorate of Medical Technologies.	Available at the Directorate of Medical Technologies.	—
Pakistan	The WHO country team helped the Ministry of Health in drafting rules for regulations of medical devices, but they are not applicable after the 18th amendment.	—	The procurement service rules 2003 (KPK) issued by the finance department. The procurement is carried out at a provincial level and identified by SPRA etc. There is a National inventory for medical equipment.	A national inventory was previously maintained but now is at a province/region level, it is in pipeline.	After the 18th amendment and devolution of the MoH, no person nor authority can provide information, the WHO as convening body of health systems in Pakistan collected the information separately from all regions/ provinces then the information was compiled by the WHO focal person of health technologies.
Palau	—	—	—	—	—
Panama	—	El sistema UMDNS ha sido adoptado en la legislación. Su implementación está aún en proceso.	La Caja de Seguro Social hace sus procesos de adquisición de forma independiente del Ministerio de Salud pero sujeto al sistema de Fichas Técnicas Nacionales en cuyas confecciones también participa.	—	—
Papua New Guinea	—	—	—	—	—

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Paraguay	AMR	—	—	—	HTA activities identified, but not proven at national or subnational level.
Peru	AMR	—	—	There are National Standards or list of recommended medical devices for specific procedures but it is managed by protocolos of care at the Hospital, Health Center or Specialty Hospital. For a), b) and c) there are protocolos of care at level of hospitals. d) No. There aren´t . There are contingency plans at levels of hospitals. Public health emergency situations (pandemic, acts of terrorism, natural disasters, contamination, etc.).	Three institutions perform HTA: Ministry of Health-DIGEMID; National Institute of Health (INS) and the Institute of Health Technology Assessment and Research (IETSI-ESSALUD). Besides this 3 institutions, there is one more: INEN- Instituto Nacional de Enfermedades Neoplásicas, that perform HTA too. Moreover, in 2020, by Ministerial Resolution No. 190-2020, the National Network for Health Technology Assessment (RENETSA) was formed, made up of: - INS - DIGEMID - The Social Health Insurance (ESSALUD), through the Institute for the Evaluation of Technologies in Health and Research (IETSI) The INS, through the CETS, will lead the National Network for Health Technology Assessment – RENETSA, which brings together public entities and academic institutions that carry out health technology assessment in the country. Contact: INS Nora Reyes Puma nreyes@ins.gob.pe DIGEMID JENNER IVÁN SOLIS RICRA isolis@minsa.gob.pe

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Paraguay	—	Se está elaborando un plan para proceder con la instalación de un sistema de nomenclatura.	Procurement guidelines: se inició la elaboración de directrices.	—	Concerning the HT national policy, it was provided the following document: DECRETO EJECUTIVO 468.pdf
Peru	—	Ley Nº29459-D.S and the D.S. Nº 016-2011-SA.	—	There are any kind of inventories for medical devices available in the country.	—

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Philippines	WPR	The lists are limited to diagnostics, no interventional equipment noted (ie, ECMO, DaVinci, etc.)	—	This is part of the requirements for the licensing of health facilities. The given URL is for general surgery. The indicated website can be browsed for other recommended medical devices for other procedures.	HTAC has one biomedical engineer and one medical physicist.
Poland	EUR	The polish competent authority for medical devices is the Office for Registration of Medicinal products, Medical devices and Biocidal products, which keeps the register of medical devices in a database; it is only used for market surveillance and vigilance purposes. On polish market can be placed all CE - marked medical devices according to current EU regulatory framework and directives (90/385/EEC; 93/42/ EC; 98/79/EC).	There are no lists, but basic (minimal) requirements regarding the necessary medical devices that are a part of the health benefit package regulations and are created concerning the type of facility (including specialisation) and with clear-cut requirements on specialised health care services.	There are no lists, but basic (minimal) requirements regarding the necessary medical devices that are a part of the health benefit package regulations and are created concerning the type of facility (including specialisation) and with clear-cut requirements on specialised health care services.	AOTMiT evaluates pharmaceutical and non-pharmaceutical technologies including medical devices assessment. The Agency for Health Technology Assessment and Tariff System evaluates pharmaceutical and non-pharmaceutical technologies including medical devices assessment.
Portugal	EUR	—	—	—	Functions of Infarmed: Research, assessment, registration, monitoring and supervision of health products. Clinical research evaluation, assessment and registration of CE marked medical devices, notification of health care products and market supervision activities.

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Philippines	—	The Philippines will be using the Nomenclature that will be decided by the member states of the ASEAN who are working on the harmonization of medical device regulation in the region, where medical device nomenclature is one of the concerns.	The procurement for a medical device is part of the National Procurements system of the Philippine Government (see website). Procurement of medical devices can be done at a national level, at a regional level and local government units.	—	—
Poland	The Ministry of Health is the national regulatory authority in the area of the health system and The Office for registration of Medicinal Products, Medical Devices and Biocidal Products is the polish competent authority responsible for cooperation with European Commission in the medical device regulatory area. Another regulatory agency is the Market Surveillance, Vigilance system, Clinical trial registration and Inspection, Cooperation with the European Commission and other Competent Authorities.	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	—	—	—
Portugal	—	The Directorate-General of Health/Ministry of Health of this country pointed out that the official nomenclature system for medical devices and IVDs for registry purposes is based on the European Medical Device Nomenclature (EMDN).	Go to the website and search for the "contratoseaquisicoes" documents.	—	—

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Qatar	EMR	There are functional inventory of medical devices for procurement and/ or reimbursement in HMC hospitals. HMC disciplines occupies functional inventory of medical devices for prompt delivery of patient care services. Emergency prepardness policy reference.	—	HMC disciplines occupies functional inventory of medical devices for prompt delivery of patient care services. It exists the emergency prepardness policy reference (including lists) too.	There are identified HTA activities. HTA consultancy is required for building high-level infrastructure and there is the formation of an HTA workforce but there is not a national unit. Drugs pricing falls on External Reference Pricing stated in the national objectives towards Universal Health Care (UHC) implementation goal.
Republic of Korea	WPR	The Health Insurance and Review Assessment (HIRA) is responsible for listing treatment materials for public insurance.	—	—	HTA is performed in a variety of health areas including medical technologies, devices, interventions, etc.
Republic of Moldova	EUR	A special group of Agency of Medicines and Medical Devices organise the procurement of medical equipment from the state budget.	—	Medical standards on diagnostic and treatment for pathological conditions in surgery, therapeutic profile for adults and children, have been developed. Also, development of guidelines is based on international recommendations for family physicians and blood transfusion agencies.	There are identified HTA activities but not a national unit per se.

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Qatar	If ever a private agency, hospital or clinic needs a specific product they should approach the Medical Licensing which in turn seeks technical evaluation (such as specification, safety, compliance, etc.) from the Bio-Medical Engineering to import the product to the country. Bio-Eng does verify FDA, CE and/ or equivalent compliance on medical device/ equipment for safety, especially for Hamad Medical Corporation (HMC) hospitals.	This is used for planning of medical equipment for new / upcoming projects.	The specification compliance on safety and clinical requisites is regularly updated. The Hamad Medical Corporation (HMC) Materials Management and Tender committee take over the procurement activities of Medical and Non-Medical Equipment/ items for HMC hospitals, and the ministry upon request, as deem necessary. Specification of equipment formulated in cooperation with end-user prepared by Bio-eng.	Maintained GE AssetPlus for the functional inventory of Medical equipment for the Hamad Medical Corporation (HMC), hospitals and Public Health Care Centers.	List of accredited HMC hospitals: Hamad General Hospital, Women's Hospital, Rumailah Hospital, Al Amal Hospital, and Al Khor Hospital. Emergency Medical Services (EMS), Pediatric Emergency, Trauma Centers, Orthopedic Center, Dental and School Health, Home Healthcare, Primary Health Centers, Skilled Nursing Facility. Upcoming projects: Qatar Heart Center, New Children's Hospital, Al-Wakra Hospital. Please visit the Hamad Medical Corporation website (www.hamad.qa) and the Qatar Supreme Council of Health website (https://www.moph.gov.qa/) for more details.
Republic of Korea	—	—	National and public hospitals purcharse medical equipments according to the general procurement procedures.	The inventories for medical devices are not managed by the government.	Concerning the Infrastructure section: Korea Health Center is down to 29 beds.
Republic of Moldova	The National Center of Public Health is ensuring the control of the rules of utilization of X-Ray equipment in all medical institutions of the country.	—	Procurement guidelines: Government Decree No. 568 (10.09.09). Guidelines on technical specifications: Decree 190 from 25.06.2009 establishes standard specifications for biochemical and immunology test.	It is not developed. A project to support management of medical equipment is being developed: openMedis.	The strategy to develop Health System during the period 2005-2017 as well as the Plan of Action contains specific goals on strengthening the bases of technical material for healthcare.

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Romania	EUR	—	—	—	Several national entities are in charge of performing HTA activities, each one focus in various areas (see corresponding links).
Russian Federation	EUR	—	—	—	The HTA system development is inserted in the Russian Federation healthcare legislation. Currently, the procedure for a comprehensive assessment of drugs has been approved and is constantly being improved. However it is still at their start phase for medical devices and biomedical products.
Rwanda	AFR	—	—	—	There are identified HTA activities which are specifically done in pharmaceutics for pricing and reimbursements as well as health economics; however, there is no national unit.
Saint Kitts and Nevis	AMR	—	—	—	—

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Romania	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	The procurement of high technologies devices is carried out at anational level. Go to the website and search for the corresponding documents.	—	—
Russian Federation	—	—	—	—	—
Rwanda	—	Rwanda has started to use Online Public Procurement, each device should have an unique identification code (mainly based on UMDNS). But it is challenging when dealing with different code nomenclature such as the sterilizer, autoclave or medical gases. Rwanda uses UMDNS for inventory and maintenance of medical equipment.	—	—	—
Saint Kitts and Nevis	—	—	Hospital management purchases devices directly from vendors.	—	—

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Saint Lucia	AMR	—	—	—	—
Saint Vincent and the Grenadines	AMR	—	—	—	There are identified HTA activities but not a national unit. The development of one is in progress.
Samoa	WPR	—	—	Please refer to Biomedical Engineering Unit Head, Mr. Galuafi Vaoga at email: biomed@nhs.gov.ws.	There are identified HTA activities but not a national unit. MoH together with National Health Services (NHS) intend to develop one, but it is still on progress.
San Marino	EUR	—	—	—	There are identified HTA activities but not a national unit.
Sao Tome and Principe	AFR	—	—	Il n'existe pas au niveau national aucuen liste recomandant des technologies de sante.	—
Saudi Arabia	EMR	—	—	Food and Drug Adminstration - Specification and Measurement Administration.	The Ministry of Health supports the creation of a national entity for HTA in healthcare as part of the National Transformation Program. The new HTA entity will deal mainly with pharmaceutics but is intended to extends to other health products such as devices. Informed HTA decisions were rarely identified for medical devices.

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Saint Lucia	There is the Bureau of Standards which will do the regulatory activities.	—	The procurement at a national level is not for medical equipment, but for pharmaceuticals.	The medical equipment inventories of public hospitals exist. The functional status of such equipment is reflected in these lists. No PET scanners are available on the island. CT and MRI are available only in one private hospital facility.	—
Saint Vincent and the Grenadines	—	—	—	No national inventory exists.	—
Samoa	—	—	For more information refer to the Biomed Engineering Unit.	—	Concerning the Infrastructure section: there are 18 General Practicioner Clinics in the Private sector.
San Marino	—	—	—	—	For specialized care and diagnostics, patients can be treated in italian hospitals that have agreements with San Marino.
Sao Tome and Principe	—	—	—	L'inventaire des equipments medicaux existant est caduque (2002) Apres cette date un nombre considerable des equipaments ont rentres en charge.	—
Saudi Arabia	—	A committee inside NUPCO has been established for that purpose and the work is in progress.	National Unified Procurement Company for Medical Supplies (NUPCO).	For every hospital and health centre there is a maintenance-specialized company contracted to make the inventory and perform necessary maintenance activities for all medical devices within the facility. Also, there is a National inventory for high cost technologies (such as MRI, CT or PET scanners).	Concerning the HT national policy it is stated on the Medical Egypt Management Plan (Corporate).

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Senegal	AFR	—	—	Il existe une liste standard de base pour toutes les structures sanitaires. Pour la plupart des acquisitions, les specifications techniques des équipements sont réalisées par la Direction des Equipements et de la Maintenance. Voir aussi les spécifications techniques des équipements médicaux.	—
Serbia	EUR	Not available at the moment.	—	There are no specific national standards nor recommended medical devices for specific procedures. And there are no lists recommending health techology for different diseases/situations.	It conducts centralized public procurement for health products including devices. HTA is in the law and with a centralized national unit either MoH sector for inspection affairs or Public Health Institute (NIS).
Seychelles	AFR	—	—	—	—

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Senegal	—	—	On procéde à des appels d'offres nationaux et les representants des fabricants etrangers fournissent les équipements.	On a une inventaire national des équipements médicaux (2009).	—
Serbia	—	National nomenclature is in the process of updating and amendment.	Go to the website and search for the corresponding documents.	The inventory was made, in 2000, according to methodology. In 2003, European Agency for Reconstruction commissioned a project performed by IPH Serbia, but the methodology was not included in the national Law on Health Records and Statistics and has not been adopted, so the inventory continued to be performed on annual basis based on the existing Law on Health Records and classification of medical equipment (1980's). The inventory is not available.	The Institute of Public Health of Serbia has a department for health technology assessment mainly responsible for updating nomenclature and type of technology.
Seychelles	—	—	"It is a small committee that meets to discuss equipment request by the various units within the Ministry of Health. Please note that Seychelles has a small population and we do not purchase equipment on a big scale.	"	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Sierra Leone	AFR	Lists for procurements are still being worked on not yet completed. However we do have public health emergency situations lists.	—	—	—
Singapore	WPR	A list is available in the form of the Singapore Medical Device Register (SMDR). This shows all approved medical devices in Singapore and provides information on them. It is not a list of recommended devices for procurement.	—	—	—
Slovakia	EUR	—	—	There is no list recomending health technology for above mentioned diseases/situations.	The Working Group for Pharmacoeconomics, Clinical Outcomes and Health Technology Assessment of the Slovak Ministry of Health perform HTA, but not specifically for medical devices.
Slovenia	EUR	—	—	There are many boards (Slovenian Collegiate Boards) each responsible for one area of medicine. Those bodies produce recommendations on specific procedures where deemed necessary. Currently, recommendations are under development at the Ministry of Health.	HTA framework is not done yet, but HTA processes are in an existing framework. HTA decision-taking is done by the following institutions: MoH, National Institute of Public Health, and the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP).

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Sierra Leone	—	The document is not available for the Facilities and Maintenance Unit.	Most of the equipment has been used and found incomplete, and this is the reason why its installation is difficult. Procurement of medical devices is carried out without involving the specialists.	The last inventory was done twelve years ago. Looking forward to start another one.	There is a limited number of technical personnel to meet the service demand. Most of the equipment supplied by donors are obsolete and out of order.
Singapore	—	The Global Medical Device Nomenclature (GMDN) is used as an internal reference and it is not required for medical device product registration	—	—	—
Slovakia	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	—	—	—
Slovenia	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	The name of the procurement policy is: Zakon o javnem naro anj (ZJN-3)	The inventories website is still in development and is not yet available to the public.	—

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Solomon Islands	WPR	—	—	Unfortunately, there are no such lists. Donation equipment have various brands.	There is no formalized HTA available and it relies heavily on other institutions assessment mechanisms, such as the WHO.
Somalia	EMR	—	—	—	National Medicines Regulatory Authority (NMRA) under Department of Medical Services has an HTA role. However, even if the designated unit is present in the organigram is not yet well established. There are scarce HTA activities, but the plans are to expand, specially in pharmaceutics. The UHC country goal is in progress.
South Africa	AFR	There are no lists of the mentioned above. The list is only for the private sector funders (not the government). The National Department of Health is engaging with the private sector to establish a national system.	Both UMNDS and GMDN have been used.	There are none of the cited lists mentioned above.	The institutionalization of a national HTA as part of the ongoing National Health Insurance (NHI) is in the process towards the National Department of Health (NDoH) and the Universal Health Care (UHC) goal.
South Sudan	AFR	—	—	—	—
Spain	EUR	—	—	—	There is a network of Agencies for HTA and services of the National Health System. The HTA is for decision-making within the health system, as well as for medical products, including medical devices.
Sri Lanka	SEAR	—	—	—	The institutionalizing of an HTA as a mechanism for promoting health system integrity is in early stages.

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Solomon Islands	The National Referral Hospital (NHR) performs most of the procurement, planning and allocation for the Provincial Hospital. There is a disposable procurement by the Ministry of Finance.	There is virtually none of this currently in place.	The procurement Unit, Ministry of Health & Medical Service, has mainly to do with the finance but no with the technical aspect of the equipment. The Committee is Ad hoc and meets only to allocate equipment base on Departmental requests.	—	—
Somalia	—	The definition of medical devices is included in the national medicines law which is not yet ratified.	—	—	—
South Africa	The radiation control is now part of the tasks of the South African Health Products Regulatory Authority (SAHPRA).	The regulator has adopted the use of GMDN which will be a nationally accepted nomenclature.	The Office of the Chief Procurement Officer is in charge of the procurement of medical devices.	There are no national inventory nor management systems but some hospitals do have. Currently, we are compiling a national inventory and acquiring a system to be implemented at a national level. Thus, we are progressing to acquire the national system.	—
South Sudan	—	—	—	—	—
Spain	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	—	—	—
Sri Lanka	—	—	—	—	—

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Sudan	EMR	—	—	—	A Health Technology Management system (HTM) has been developed. However, there is not current HTA system in place, but it is a goal to pursue towards the Universal Health Care country goal.
Suriname	AMR	—	—	—	—
Sweden	EUR	The devices must bear the CE-mark.	—	There is an ongoing project in order to create such a national list. It is the Dental and Pharmaceutical Benefits Agency that is working with that.	Network of HTA agencies such as: the Dental and Pharmaceutical Benefits Agency (TLV); Agency for the HTA and Assessment of Social Services (SBU), and Medical Products Agency. Alternative email: registrator@tlv.se.
Switzerland	EUR	Reimbursement list for medical devices used by the patients themselves, and Reimbursement list for medical analyses are available on the corresponding website (see link).	—	—	There is the swiss network of HTA entities focusing in various areas. Some institutions are: Health Insurance Benefits, State Secretariat for Education, Research and Innovation, etc.
Syrian Arab Republic	EMR	—	—	—	It exists the Planning and International Collaboration Directorate which performed HTA activities, but it is not specifically for medical devices.
Tajikistan	EUR	—	—	—	—

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Sudan	—	—	—	—	—
Suriname	—	—	—	—	—
Sweden	—	As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)	The national law for procurement is based on the EU directive. Concerning procurement, it can be done at a country level or within a single hospital.	—	—
Switzerland	—	Swissmedic uses GMDN (no country specific nomenclature), if manufacturers do not know the GMDN number, a UMDNS code may be given.	The medical devices must fulfil the requirements described in the European medical device directives. Legal basis (Swiss Medical devices ordinance):|http://www.admin.ch/ch/d/sr/c812_213.html. The hospital / high cost technology planning is done at a national level. Coordinated planning of certain highly specialized areas of health care is in progress (see|https://www.gdk-cds.ch/de/).	Go to the gdk website and search for the 291.0.html documentation.	—
Syrian Arab Republic	—	—	—	—	—
Tajikistan	—	—	—	—	—

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Thailand	SEAR	There are lists of recommended procedures in organization level such as the procedure of the Physical Therapy Council. The approved medical devices list is only available for the reimbursements of the three health insurances, namely the National Health Security Office, the Comptroller General's Department, and the Social Security Office.	—	There are lists of recommended procedures in organization level such as the procedure of the Physical Therapy Council.	HTA is focused on several health technologies and programs, including pharmaceuticals, medical devices, interventions, and disease prevention as well as to inform policy decisions.
Timor-Leste	SEAR	—	—	There is the Standart Medical Equipment from Australia Advissor of Medical Equipment. See Clasification Minimum Standard equipment HP, CHC, DHC.	—

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Thailand	The Office of Atoms for Peace (OAP), within the Ministry of Science and Technology, is the responsible agency for strengthening regulatory control of sources that involve radioactive activities such as manufacturing, radiation processing, radiation application (medical, industrial, research, etc.), importation and exportation of radioactive sources and radioactive waste management under the Atomic Energy for Peace Law, BE2504 (1961) and the Nuclear Energy for Peace Law, BE 2559. It also guarantees the safety of users and the public against radiation and nuclear use by regulating the use of nuclear energy and by educating the public.	—	The procurement was performed by individividual agencies. For technical specifications go to the web site and find the law section, search for the corresponding documents.	—	—
Timor-Leste	—	—	—	The Inventory is from 2002-2009.	The Health Technology of medical equipment does not have standards for Medical Equipment yet.

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Togo	AFR	Aucune organisation en charge de ces listes existe, malgré toutes les propositions formulées dans ce sens. Il ne semble pas avoir la volonté politique à évoluer dans ce sens.	—	—	—
Tonga	WPR	—	—	There are no specific lists.	—

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Togo	—	Le niveau du sous service chargé chargé des équipements est trop bas pour être lisible. Les supérieurs hiérarchique ne portent pas l'intérêt nécessaire pour la mise en oeuvre de la gestion qui s'impose pour les dispositifs médicaux.	La politique suivi en terme d'achat de dispositif est celle du code des marchés publiques. L'achat ne se fait au niveau central que si l'Etat définit ponctuellement un programme d'intervention suite à une urgence nationale.	Bien que cela soit le point de départ de toute gestion en terme de maintenance des parcs biomédicaux, cette opération n'existe pas au plan national sauf par endroit mais aussi de façon sommaire . Les données ainsi consignées ne permettent pas de l'exploiter pour proposer des plans de renouvellement ou de developpement de parcs biomédicaux. En bref aucun inventaire digne de ce nom n'existe pas sur le plan national.	Compte tenue des difficultés que nous rencontrons pour la prise en compte adéquate des plateaux techniques dans nos formations sanitaires malgré les recommandations régionales pour une politique commune en matière de maintenance et la gestion durable des infrastructures sociales je veux bien croire que cette enquête nous ouvrira l' horizon de nouvelles politiques adptées à nos réalités.
Tonga	Although there is no formal institution that oversees the implementation of any medical device regulation, there is the "Facility and Equipment Committee" of the Ministry of Health that oversees certain things such as the procurement of medical devices, the criteria of acceptance of donated equipment and the implementation of maintenance guidelines, etc.	—	—	—	—

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Trinidad and Tobago	AMR	The nomenclature is part of the Computerized Maintenance Management System.	Certification standards for equipment, e.g. European CE Marking and U.S. Food and Drug Administration.	The list exists for point of care testing equipment, namely, Diagnostic Screening and Laboratory Testing. The medical equipment requirements for specific procedures are done by the respective inhouse Hospital Biomedical Department and the clinicians. The American Hospital Association guidelines are used as a reference. Also, the Ministry has established requirements for Diagnostic Laboratory Point of Care Testing.	There are identified HTA activities at a national level. Furthermore a consultant is to be engaged to assists in the development of an HTA framework. Alternative contact for the Health Technology Management unit: pmu@health.gov.tt.

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Trinidad and Tobago	—	Developed and in use as "Fixed Assest Inventory and Facilities Management". TMA Systems Maintenance Management Software (the nomenclature of medical devices are generally developed by the respective Regional Health Authorities for procurement purposes). The Ministry of Health of Trinidad and Tobago has established that no specific or official nomenclature system is used in this country, but the nomenclature codes given by manufacturers	There are guidelines based on the Regional Health Authorities (RHAs) internal policies and procedures on the procurement process and in particular for the need of the development of specifications. The Ministry of Health is presently moving towards standardising policies and procedures for all technical areas which would include the procurement of medical devices. Technical specifications are developed as part of all equipment procurement for public open tender. In general, there are recommended technical specifications used by each RHA for procurement of equipment as part of public tendering requirements. This is an area that the ministry is working with the RHAs towards standardising. For procurement information contact via mail to pmu@health.gov.tt (Project Management Unit).	The inventories of other medical devices exist at each respective Regional Health Authorities (RHA) and for high-cost technologies such as diagnostic imaging.	It is noted that several medical devices systems exist at the respective Regional Health Authorities (RHA) level. The MoH is currently working towards standardising these and in particular concerning the procurement guidelines for medical devices.

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Tunisia	EMR	L'acquisition et la mise en service des equipements lourds sont soumis a l'autorisation préalable du MoH pour les secteurs publique et privé et ce conformément aux critères et normes fixés par les arrêtés sus-indiqués. -Arrêté. Dune manière générale la liste de matériel découle de l'activité préconisée sans liste préetaéblie. Seules les produits non conformes aux spécifications techniques fixés par les cahiers de charges (CCTP) des appels d'offres ou dont le contrôle technique à l'importation non concluant et ceux qui ne sont pas autorisés a être mis sur le marché dans leurs pays d'origine ne sont pas autorisés a etre mis sur le marché Tunisien.	—	L'acquisition et la mise en service des equipements lourds sont soumis a l'autorisation préalable du Ministère de la santé publique pour les secteurs publique et privé et ce conformément aux critères et normes fixés par les arrêtés sus-indiqués.-Arrêtés du 22/6/2000 et du 7/3/2003. Dune manière générale la liste de matériel découle de l'activité préconisée sans liste préetaéblie.	INEAS is under the auspices of the MoH. It evaluates health technologies and provide rigorous evidence-based recommendations to decision-makers on pharmaceuticals and other technologies' uptake and use. As one internal policy trains it' s own staff, as well as HTA user's.

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Tunisia	—	La nomenclature des dispositifs médicaux fait partie intégrante du Manuel des procédures de gestion de la maintenance biomédicale et hospitalière élaboré en 1996 et amélioré en 2007 par le Ministère de la santé publique qui a fait l'objet d'un arrêté.	L'achat des dispositifs médicaux obéit en plus des procédures réglementaires (Reglément des marchés publics) d'unepart et passe par des commissions techniques spécialisés (commissions d'elaboration des cahiers des clauses techniques particulieres, fiches techniques, commissions de sélection, des commissions de réception provisoire et définitifs du matériel fiches techniques). Il n'ya pas de fiches techniques standard mais elles sont préparés au cas par cas en fonction du besoin (caractéristiques opérationnelles).	Conformément au manuel des procédures de gestion de la maintenance chaque établissement de santé est dans l'obligation de tenir un inventaire technique des équipements et des infrastructures techniques, remplir la fiche d'identification et une fiche de santé (maintenance) par appareil. Un applicatif informatique dédiée a été développé à cet effet. Management Software: G.M.B.H. développé en local par le cetembh et le centre informatique du msp.	La structure publique de santé en Tunisie est composé de établissements publics de santé (CHU,H. Spécialisés) dans les sièges de faculté de médecine des hôpitaux régionaux des hôpitaux de circonscription des groupements de santé de base des centres de santé de base et des centres régionaux de médecine scolaire et universitaire en plus des trois hôpitaux militaires et un hôpital des forces de sécurité intérieure publics et six centres de d'hémodialyse et six polycliniques para-publique ne relevant pas du ministère de la santé le secteur privé compte 3371 unités réparties entre cliniques, cabinets dentaires, officines, cabinets de radiologie, centres d'imagerie médicale laboratoires et centres d'hémodialyse.

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Türkiye	EUR	The Ministry of Health is closely involved in the decision making but the main responsible unit is the Social Security Institution of the Republic of Turkey. The directorate of Curative Services is the main responsible unit in the Ministry of Health but other directorates also give their opinion on the subject. There is the new version (2010) of the relevant document. Specific lists can be reached by opening EKLER Appendix (see in website).	—	These standards are not centrally organized and published. Each department has its own and they can be found in the second link under Saglik Mevzuati>Genelgeler, Tebligler, Yönergeler, Yönetmelikler>... Relevant departments and headlines. Each directorate and department has its relevant health technology reference documents (guidelines, circulars, regulatory statute etc) in its links on the website.	Generic email of the HTA department shgm.argestd@saglik.gov.tr .
Turkmeni-stan	EUR	—	—	—	There is no systematic programme of health technology assessment, but an informed decision is mainly used for pharmaceutics but no for medical devices.
Tuvalu	WPR	—	—	—	National Drug and Therapeutic Committee (NDTC) has done HTA activities mainly in pharmaceutics; however, there is no a national HTA unit.
Uganda	AFR	Usually we use the WHO recommendations. List of equipment by health care level is available in the website.	Standard Medical Equipment list is under review.	There are no national lists recommending health technology for specific procedures. We usually adhere to the World Health Organization recommendations.	There are identified HTA activities but there is not a national unit.

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Türkiye	—	Huab is the Turkish registry system for medical devices. Both GMDN and UNSPSC are used in this system. For reimbursement purposes another nomenclature mentioned in the corresponding link is also used.	—	Go to the previous website and search for sbhbt. However, the full online inventory databank, with restricted use to the authorities, is on the following site:|http://sbu.saglik.gov.tr/sbhbf/	Concerning the medical equipment and structure section: there is a draft document (Health Statistics Yearbook) at the link:|https://hsgm.saglik.gov.tr/tr/ , but it is not appropiate to use it as a reference since the original document will be available in the future. Some numbers can be variable because of the dynamic situation in Turkey. Especially for the last 5-7 years, the health technology situation is changing and developing rapidly.
Turkmeni-stan	—	—	—	—	—
Tuvalu	—	—	Guidelines on Donations exist, they are nationally developed but they are not publicly available.	—	—
Uganda	—	See the list of medical equipment by level, and the Standard Medical Equipment Lists and Specifications by healthcare level are under review (as in sample formats in the corresponding websites). The main uses of the nomenclature system are for procurement purposes, and inventory systems in healthcare facilities.	The Ministry acquires resources and procures in bulk; although for the last 2 years development funds for infrastructure have been directly allocated to regional referral hospitals which procure equipment with the guidance of the health infrastructure division and national advisory committee on medical equipment (NACME). The Public Procurement and Disposal of Public Assets Authority (within the MoH, specified website).	Currently, is being updated.	The policy guidelines on donations is at Chapter 5.1.5 of the medical equipment policy (see documentations). The Medical Equipment Policy is under review.

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Ukraine	EUR	—	—	There are many files, namely, the orders MSS. Orders of the Ministry of Health approval of protocols of care for various diseases.	In 2019 was established the national HTA within the MoH to power the National Essential Medicines List and to inform the National Benefits Package towards the Universal Health Care. The HTA is focused on a wide range of health products, interventions, but till now is rarely focused in medical devices.
United Arab Emirates	EMR	—	—	—	HTA activities have been identified within the MoH. It exists the Health Authority Abu Dhabi, the Dubai Health Authority and the Department of Health (DoH) but there is not a national unit. The main activities of the HTA are in health products pricing and reimbursement decisions. Also, the private sector is playing an increasing role in health care coverage.

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Ukraine	—	—	Contact: Mr Ivan Zadvornykh, Email: ivanzadvornykh@gmail.com	—	—
United Arab Emirates	—	—	—	—	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
United Kingdom of Great Britain and Northern Ireland	EUR	There is no approved list of medical devices for procurement. However we have lists for communicable and non communicable diseases, and public health emergency situations. Guidance is produced by NICE and CEP which was disbanded 31 March 2010. NHS Supply Chain provides a catalogue of products that can be purchased by the NHS which are approved by way of meeting EU directives.	—	The Centre for Evidence Based Purchasing (CEP) website is a portal containing over 600 and therefore too numerous for specific reference in this document. Please note CEP was disbanded end of March 2010 but the reports still apply to clinical professionals UK wide. Also, NICE Interventional Procedures (IP) Programme develops guidance on interventional (mainly surgical) procedures, and approx two-thirds of these involve a medical device or devices developed specifically for the procedure (see second link). In addition to the IP guidance referenced the previous lists, NICE has produced guidance on use of devices in the following non-communicable high burden diseases: ICDs, drug-eluting stents, endovascular stent grafts for AAA, inhaler devices for asthma and insulin pumps (see third link). The website is a portal containing the full set of reports most of which will be relevant to either a, b, or c. They are too numerous to mention here please also see comments of previous lists.	Evidence-based recommendations are developed in a wide range of areas: clinical guidelines, diagnostic technologies, interventional procedures, cost effectiveness, highly specialised, and medical technologies guidance.

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United Kingdom of Great Britain and Northern Ireland	The Medicines and Healthcare products Regulatory Agency (MHRA) are the UK Competent Authority with respect to the safety, quality and performance placed on the market by manufacturers in the UK under the EU Medical Devices Directives. Trading Standards Departments based in local authorities also have enforcement responsibility in respect of medical devices available over the counter direct to the public.	The Medicines and Healthcare products Regulatory Agency (MHRA) will be moving forward to use solely the GMDN with their system being phased out. The nomenclature used by the National Health System (NHS) for the procurement of medical devices is that used by the "Official Journal of the European Union" (OJEU) CPV codes. The NHS also has a national system known as "e-class" which is a classification system for products and services.	Medical devices may be procured at a number of levels, either locally (NHS Trust level), regionally (collaborative procurement hub level) or nationally (NHS Supply chain). Also in Scotland, there is a system for National Procurement for the NHS.	A recent amendment of the Medical Devices Directive has lifted the confidentiality requirement on information supplied by manufacturers to Competent Authorities under their obligation to register certain types of medical devices. The devices include low-risk class I, devices CE marked based on a self-declaration of conformity by the manufacturer, custom-made devices made according to a prescription from a healthcare professional for an individual patient, assembled procedure packs, re-usable sterile devices and in vitro diagnostic devices. EU member states including the UK are currently working on how these registers can be published. Higher risk devices are CE marked based on a conformity assessment conducted by a third party certification organisation designated as competent to undertake this function by an EU member state. CE marking denotes that the device meets safety, quality and performance requirements accepted across Europe and allows access to member states markets without further restrictions. In addition, there also two national implant registries in operation. One for hip and knee implants covering England &Wales.	Concerning the HT national policy, it was provided the following document:|http://www.president.gov.ua/docs/Programa_reform_FINAL_1.pdf; www.rada.gov.ua. The UK comprises 4 devolved administrations: England, Wales, Northern Ireland and Scotland. Each Administration is responsible for the delivery of its own healthcare system as well as collating and maintaining its own data. Therefore, there is no centrally held data that covers the whole of the UK. A range of initiatives around the more widespread use of clinically and cost-effective medical devices is underway. The work is in early stages but once fully operational should improve patients' access to the latest health technologies.

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
UK cont...					
United Republic of Tanzania	AFR	Lists recommending health techonology for different categories of diseases is not available. The Ministry is however planning to develop it. Registration of medical devices in Tanzania has started in January 2010. Registration will be carried out phasewise and 1st phase involves single use devices. The first phase involves limited number of devices in particular single use devices. Prior to the start of first phase of registration applicants were requested to notify they are dealing with and the list of notified devices is used as a basis for approval during the transition period. The guideline for registration can be accessed at the tfda website.	—	Lists recommending health techonology for different categories of diseases are not available. However, the Ministry is planning to develop it.	The institutionalizing of HTA for decision making and priority setting for guidelines, essential medicines list, and cost-effective treatments is in progress. The Tanzania HTA committee (THTAC) is essential in the progress towards the Universal Health Care country goal.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
UK cont...				The other for pacemakers for the whole of the UK. Both record information on individual devices, who they were implanted in and when both the original implant and any revision procedure were undertaken. Both Registries produce annual reports which contain all this data apart of course from individual patients names and other personal details.	
United Republic of Tanzania	—	TMDA is using GMDN as the nomenclature system for the registration of medical devices in Tanzania. The main types of nomenclature used are GMDN and UMDNS. The main uses of the nomenclature system are for procurement purposes and inventory systems in healthcare facilities.	Medical Store Department (MSD) is responsible for procuring pharmaceuticals and medical devices for the public but not for profit organization. It should also be noted that individual entities can also procure medical devices on their own as not all devices are covered by MSD. The private sector imports medical devices after obtaining approval from TFDA. The list of recommendations is not available. However, the guidelines for registration recommend the use of ISO standards and national standards if available.	—	—

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United States of America	AMR	—	—	—	There is not a single body nor a national institution to evaluate health technologies. However, there is an extensive network of HTA institutions such as the Advisory Committee on Immunization Practices (ACIP), the Preventive Services Task Force (USPSTF), the Medicare Evidence Development & Coverage Advisory Committee (MedCAC), the Agency for Healthcare Research and Quality (AHRQ), etc.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
United States of America	—	1. Product Code. FDA- The Center for Devices and Radiological Health (CDRH) uses a nomenclature by assigning a 3-letter code to identify a device into a generic type or category. This nomenclature system is known as product code classification. The short name is ProCode.The Product Code Classification Database contains medical device names and associated information developed by the CDRH in support of its mission. This database contains device names and their associated product codes. The name and product code identify the generic category of a device for the FDA. The Product Code assigned to a device is based upon the medical device product classification designated under 21 Code of Federal Regulations (CFR) Parts 862-892.2. Problem code FDA-CDRH also has a nomenclature for CDRH Event Problem Codes for Medical Devices used in reporting adverse device events. The adverse event vocabulary codes were developed in cooperation with the National Cancer Institute Enterprise Vocabulary Service (NCI-EVS); see the second link.	—	—	Unfortunately, we are only able to respond to numeric country statistics. As is often the case, they are too much difficulty for Federal States to answer; furthermore, is largely irrelevant for a system like ours that is so based on private sector.

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Uruguay	AMR	Las listas aún no se encuentran disponibles públicamente.	—	—	HTA is performed by the department of Health Assessment (MOH), and the National Resources Fund (FNR) in several areas concerning health products, and healthcare, including medical devices.
Uzbekistan	EUR	—	—	—	HTA activities are carried out mainly by the MoH, and the Evidence-Based Medicine Centre within the Tashkent Institute for Advanced Medical Education. HTA is done for various health topics: pharmaceutics, medical devices, and also the in pharmaceutics field but not specifically for medical devices, guidelines, etc. However, a national HTA is still in progress as well as unified national mechanisms for developing and implementing clinical standards, guidelines and protocols.
Vanuatu	WPR	—	—	This list exists as part of another document -e.g. essential drug list or an inventory list of a health facility- but there is no separate nor specific document of the guideline on its own. No list exists for any of the conditions above (different diseases/situations).	—

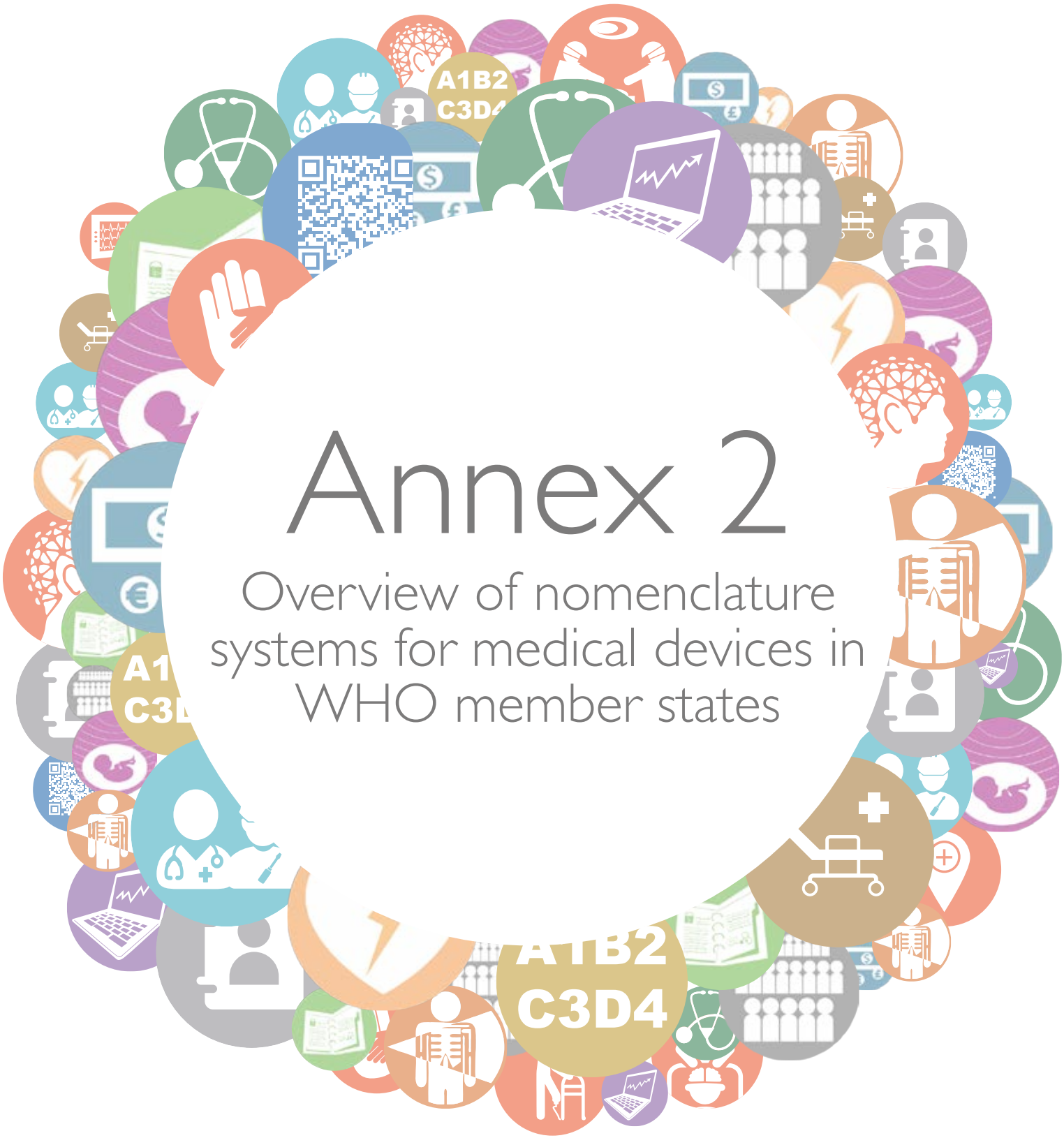
Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Uruguay	—	—	Adquisiciones: Artículo 6º de la Ley Nº18211 Sistema Nacional Integrado de Salud. UCA: Un mecanismo para los prestadores públicos; COCEMI: Un mecanismo para algunos prestadores privados.	Realizado en 2008 y actualizado en 2010 para Tomógrafos y Equipos de Resonancia Magnética. El detalle de la información individual aún no se encuentra disponible en formato electrónico.	—
Uzbekistan	—	—	—	—	—
Vanuatu	—	When there is a plan to procure a medical device, only then is the technical nomenclature required.	—	An updated complete list of medical equipment does not exist at national level; but at subnational levels and at facility level, health managers maintain their own inventory for various commodities including medical devices.	Vanuatu is a small island country in the Pacific region with a population of less than 350,000: this explains the low level of health facilities available.

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Venezuela (Bolivarian Republic of)	AMR	—	—	—	Las actividades de evaluación de tecnologías médicas se han desarrollado en el marco de la Comisión Nacional de Evaluación de Tecnología en Salud (CONETS) dentro del Ministerio del Poder Popular de la Salud.
Viet Nam	WPR	—	—	There are for all general procedures but they are not complete. We have enacted medical device list for procedures which shall be covered by medical insurance only.	The HTA system has been developed by establishing nodal agencies within MoH, moving towards the Universal Health Care country goal. Priority-setting mechanisms and HTA processes are at a nascent stage. HTA is rarely applied to medical devices.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Venezuela (Bolivarian Republic of)	—	Does not have one specific nomenclature. For the certification of the medical device, the nomenclature used is the U.S FDA product classification.	Funindes (Univ. Simon Bolivar) is authorized by the Autonomous Service of the Sanitary Comptroller to carry out equipment analysis for subsequent sanitary registration.	—	The most important problems of the hospitals in Venezuela were: the electrical system, the air conditioning and the vertical system (for 2001). In 2019 the most serious problems were water, sanitation and hygiene: 79% of hospitals reported failures in the drinking water service; most had the service intermittently, only two or three days a week. By 2011 there were 1,366 intensive care units. By 2019 there were 36 intensive care beds in Venezuela. Currently, MRI, CT, and Gamma Camera specialized service is not performed in Venezuelan hospitals. |We as Funindes USB are authorized by the Autonomous Service of the Sanitary Controller, it is authorized to carry out equipment analysis for subsequent sanitary registration: see Paper Quality Certification of Medical Devices in Venezuela (https://globalce.org/index.php/GlobalCE/article/view/83).
Viet Nam	Contact person: Hoang Mai Bui - Director of the Department of medical equipment verification and calibration.	—	—	—	—

Country	WHO region	National list of approved priority/ essential medical devices, (including IVDs), for procurement or reimbursement	National list for different types of healthcare facilities (hospitals, laboratories, etc)	National list for specific clinical interventions/ emergencies	National health technology assessment unit
Yemen	EMR	—	—	There is a need of financial, technical support and cooperation to put national standards or lists of recommended medical devices for specific procedures. For different diseases/situations there are no existing lists; MOPH must do that by cooperation of specialist administrations.	—
Zambia	AFR	The MoH has developed the Standard Equipment Lists (SEL) for District facilities such as Health Posts, Health Centres and Level One Hospitals). The SEL are not yet done, because the Basic Health Care Package, which is the blueprint for health service delivery in Zambia, has neither been developed.	—	—	Evidence-informed healthcare priority setting via HTA is at early stages. Currently, HTA is being used by the MoH to build the Health Benefits Package.
Zimbabwe	AFR	—	—	—	It has been started the building capacity and the HTA will be a fundamental tool to achieve the Universal Health Care goal.

Country	National regulatory authority	Medical device nomenclature system	Medical Device incorporation: procurement/donations/ technical specifications:	Inventories and medical equipment management software comments:	General Comments
Yemen	There are Authorities only for the registration of agents for medical equipment.	—	There are many procurements carried out at a national level but non-uniform standards by the health Governorate Office, local governorates authority, general hospitals authority, police health service, and army health service; and there are procurements carried out at a national level like Unicef, UNFPA, Emro, etc.	The MOPH is working in its action plan state to complete the database for medical equipment. In the case of some hospitals, the inventory is done directly by them.	There was a deficiency about maintenance and calibrations of medical devices.
Zambia	—	—	This is in reference to the guidelines on procurement, donations, replacement of equipment at end of the lifespan. The Ministry of Health procures, under Mandate from ZPPA; the Ministry of Health develops the list, quantities and specifications. Public Procurement Authority sets the framework for the procurement mostly International Competetive Bidding. These are provided by the Medical equipment Unit but the developed SEL for the District facilities have specifications as well which are part of the planning documents used by the facilities for planning.	The national data bank for equipment is in its infancy; the data was collected three years ago during a project that was funded by the Japan International Cooperation Agency (JICA). Currently, this data will be upgraded this year. The information captured includes Equipment Description, Model, Maker, Serial Number, Location, Functional Status, Age of Equipment. There are however hard copies at the facility level which maintenance units use. This needs to be computerised and accessible from anywhere which is not the case now. There is no software for equipment management but have tried ECRI and another software developed by a professional in Holland.	The WHO used to run training programs for maintenance technicians but stopped long ago, this has affected this field. There is a need for the WHO to come in strongly in support of maintenance of Medical equipment. The main problems in developing countries are lack of skilled manpower, inadequate budgets for maintenance, lack of proper maintenance facilities equipped with tools, test and calibration equipment, lack of supportive policies. Coupled with a lack of local agents for the supply of equipment the traders take advantage and dump equipment which tomorrow will need services.|
Zimbabwe	—	—	—	—	The country health technology policy document was initiated in 2007 with funding from the US. This is currently being formulated into a policy document for diagnostic imaging and medical devices.



Annex 2

Overview of nomenclature systems for medical devices in WHO member states

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For a long time, the need of a common Medical Devices nomenclature available for all WHO member countries has been acknowledged and recently during the COVID-19 pandemic its absence has been painfully felt.

The objective of this work is to present and summarize the information available concerning the existence and use of nomenclatures in the world.

Analysis of the Nomenclature Systems

The Country Survey of Medical Devices (2020) as well as the Nomenclature consultations (2021-2022) are of particular interest in the context of our research since both of them covered several cross-cutting themes concerning medical devices and collected a significant amount of data during different periods .

Its latest updated versions (2020-2022), in which 180 countries took part, comprises data summarized in the Global Atlas of Medical Devices 2022 regarding the key points of our research that are listed as follows:

- countries that reported to have an official nomenclature system;
- type of medical devices nomenclature system reported as official;
- purpose of use of the medical devices nomenclature reported as official;
- variability of the parameters mentioned above by Region.

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More than a half of the responding member states, i.e., 99 (51%) have an official nomenclature system for medical devices, and 81 (42%) did not have an official one. A total of 14 countries (7%) did not participate in the survey (see Fig. 1).

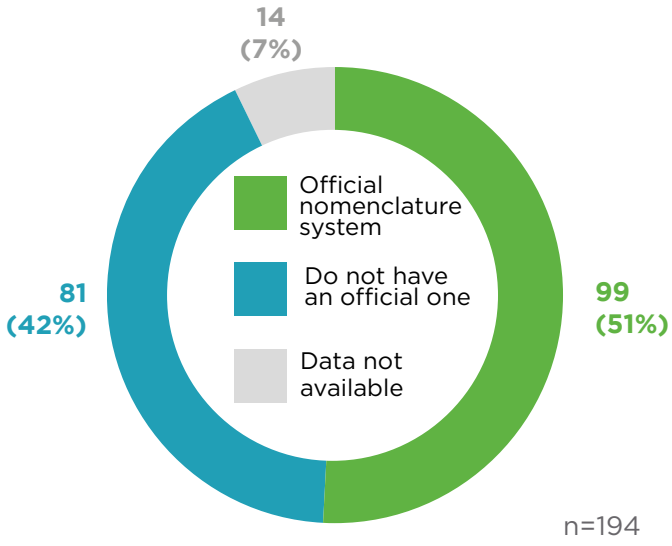

Figure 1. Existence of an official nomenclature system for medical devices (data from the 2020 Country survey and the 2021-2022 Nomenclature consultations)

In addition, 105 member states use, at least, one nomenclature system with the following types: 18% a Nationally developed nomenclature system, 9% use the Universal Medical Device Nomenclature System (UMDNS), 8% use the Global Medical Device Nomenclature (GMDN), 5% use more than one system and 15% uses the European Medical Device Nomenclature (EMDN) (see Fig. 2).

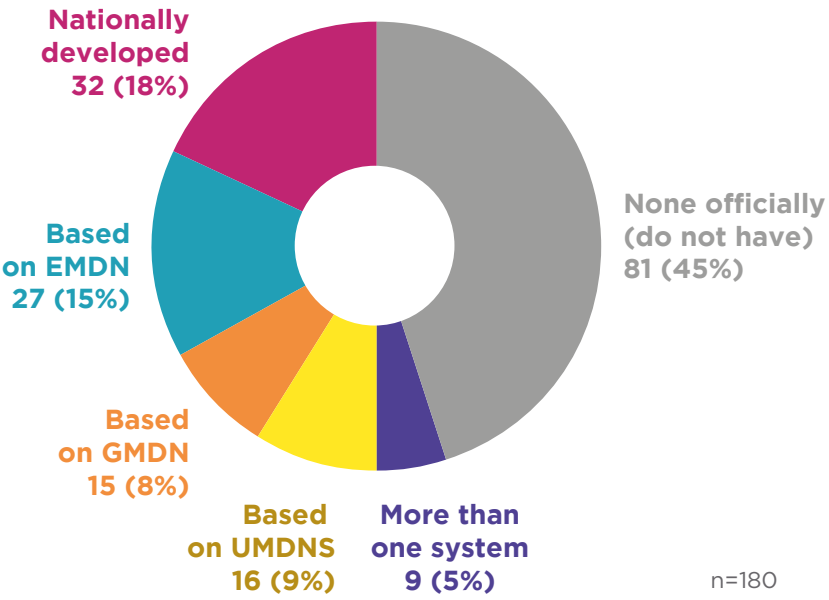

Figure 2. Type of an official nomenclature system for medical devices (data from the 2020 Country survey and the 2021-2022 Nomenclature consultations)

The majority of countries that reported having an official nomenclature for their medical devices did not specify a purpose of use, i.e., 34 (34%). While regulatory purposes, in particular 28 of 42 countries from the European Region (EUR), was the most reported purpose of use. To a lesser extent, procurement purposes and various purposes were reported i.e. 12 (12%) and 11 (11%), respectively, for all countries in all regions (see Fig. 3).

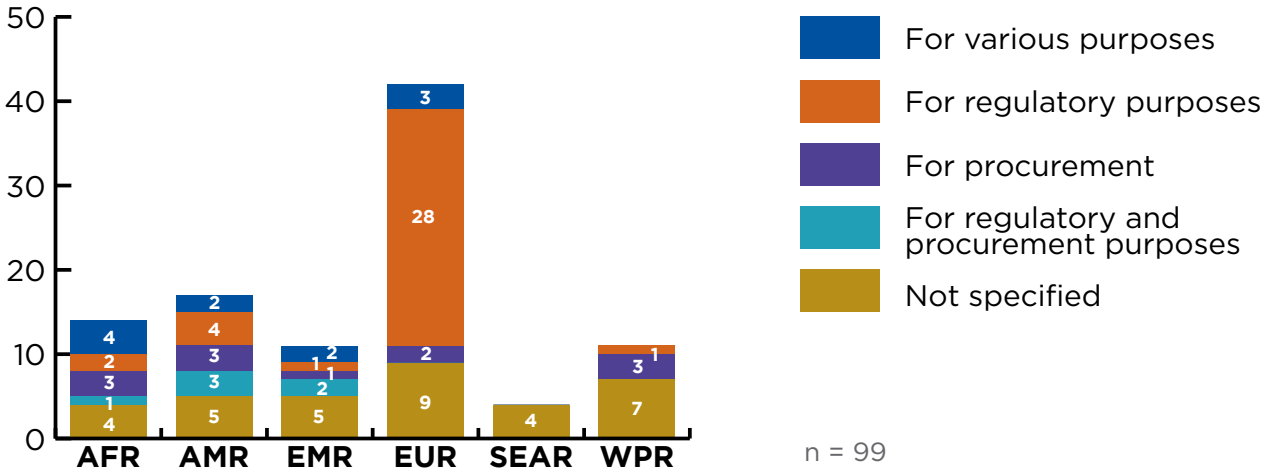

Figure 3. Nomenclature system purpose of use by WHO regions (data from the 2020 Country survey and the 2021-2022 Nomenclature consultations)

Desk Review

Methodology

We collected and compared information about whether state members of the WHO had a nomenclature system in place and publicly available through the web, as well as the type and use of the nomenclature. There were three main sources of information:

- Country answers, comments and websites shared by the member countries (explained in the Sources section).
- Desk Review
  - » Search for webpages
  - » Search for studies such as journal articles, reports, and thesis using Medline and Google scholar

The Desk Review search was conducted during the months of February, March and April 2021, with a final update made in December 2021. The following search string was used in Google and Medline search engines:

```
COUNTRY NAME AND ("NOMENCLATURE" OR "CLASSIFICATION" OR "REGULATION"
OR "SYSTEM") AND ("MEDICAL DEVICES" OR "MEDICAL EQUIPMENT")
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If no relevant hits were found in English, a reviewer would translate to the country's official language. When reviewers did not yet find an answer, they tried synonyms, and then proceeded by searching and reading anything related to laws and commercial sites on medical devices in order to find the appropriate wording for the search terms in the target language and adjust the search accordingly. In many cases, they also looked for clues into the Ministry of Health website, searched for dedicated agencies and eventually for procedures regarding import of medical equipment.

World Health Organization

The topic of the medical devices nomenclature, has been addressed by the WHO Executive Board and the World Health Assembly from 2018 to 2022. In 2007 the WHA60.29[1] resolution on health technologies addressed needs for norms and standards for Medical devices. In 2018 WHO proposed the principles for a nomenclature system, stating that it should be available as a public good, with transparent governance and methodology, and be able to be referenced in systems, among other conditions. The WHA75 report of the director general includes the activities been done by WHO in the previous 3 years, including multiple consultations with stakeholders, nomenclature agencies, and a mapping pilot process.

In May 2022, a decision was taken by the World Health Assembly WHA75(25) to integrate available information related to medical devices, including terms, codes and definitions, in the web-based database and clearinghouse established in line with resolution WHA60.29 (2007) and now available as the Medical Devices Information System (MEDEVIS); and to link this to other WHO platforms, such as the International Classification of Diseases (ICD-11), to serve as a reference to stakeholders and Member States; (2) to submit a substantive report on progress made in implementing this decision to the Executive Board at its 152nd session in January 2023 and its 156th session in January 2025.

More information on the process can be found at WHO medical devices Nomenclature page[2].

1 https://apps.who.int/gb/ebwha/pdf_files/WHASSA_WHA60-Rec1/E/cover-intro-60-en.pdf?search=WHA60.29=true#WHA60.29

2 https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75(25)-en.pdf

International and regional agreements

In addition to country-by-country analysis we also examined the regulation of medical devices, in particular in terms of nomenclature systems, at the international and regional level.

Various countries as well as corporations use the United Nations Standard Products and Services Code (UNSPSC) alongside the Harmonized Commodity Description and Coding Systems (HS) to trade products, including medical devices.

European Union

The member states of the European Union use different nomenclature systems of medical devices (for more details by country, please, consult Annex 2 - Findings by country), however, the EU has currently adopted a common nomenclature system - the European Medical Device Nomenclature - (FAQ on EMDN) that will be based primarily on Classificazione Nazionale Dispositivi medici (CND).

As a Regulatory requirement in the European Union, set by the publication to the Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), the EMDN[3] (European Medical Device Nomenclature) is the nomenclature that manufacturers shall use for the registration of medical devices in EUDAMED[4], where it is associated to each Unique Device Identifier - Device Identifier (UDI-DI)[5].

According to the Global Atlas of Medical Devices 2022, all 27 countries of the European Union reported the use of EMDN i.e., around 15% of the countries in the world.

The Southern Common Market (MERCOSUR)

MERCOSUR has developed the Mercosur Common Nomenclature (MCN) that is based on the Harmonized Commodity Description and Coding System developed by the World Customs Organization (WCO). The MCN provides information concerning a wide range of products including medical devices.

The member countries of MERCOSUR agreed to use the MCN in terms of importing and exporting commodities, however, some of the countries use nationally developed or other types of nomenclature systems, for more detailed information about each member of MERCOSUR, please, consult Annex 2 - Findings by country.

Association of Southeast Asian Nations (ASEAN)

One of the key documents that addresses several issues concerning medical devices regulation within ASEAN is the ASEAN Medical Device Directive (AMDD). The AMDD includes provisions under which the member states committed themselves to harmonize the sphere of medical devices regulation to facilitate trade and cooperation.

3 EMDN - Article 26 of Regulation (EU) 2017/745 on medical devices (MDR) and Article 23 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR).

4 EUDAMED - Article 33 of Regulation (EU) 2017/745 on medical devices (MDR) and Article 30 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR).

5 UDI System - Article 27 of Regulation (EU) 2017/745 on medical devices (MDR) and Article 24 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR).

United States-Mexico-Canada Agreement (USMCA)

Although the USA, Canada, Mexico within the United States-Mexico-Canada Agreement (USMCA) are advancing towards more integrated environment in terms of regulatory framework convergence (the USITC document), in particular developing the same risk-based classification of medical devices, countries do not use a common nomenclature system of medical devices.

African Medical Devices Forum (AMDF)

The African Medical Devices Forum (AMDF), under the auspices of the African Union, serves as a platform for enhancing integration and regulatory framework convergence in the context of medical devices. African Medical Devices Forum

Asian Harmonization Working Party (AHWP)

Global Harmonization Working Party (formerly known as the Asian harmonization working party: the AHWP) with members from Asia, Africa, Middle East and South America facilitates the process of regulatory framework convergence.

Related links below:

Playbook for Implementation of a Medical Device Regulatory Framework
Requirements of Medical Devices Nomenclature for the AHWP (2010)
Asian Harmonization Working Party (AHWP)

International Medical Device Regulators Forum (IMDRF)

The International Medical Device Regulators Forum (IMDRF) "is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence."

IMDRF Adverse Events Working Group developed a nomenclature for the adverse events reporting, including terminology and codes (see the IMDRF Terminologies for Categorized Adverse Event Reporting).

IMDRF strategic plan for 2021-2025 can be found here.

Comparison of desk review (2021) versus the Country survey (2020) and Nomenclature consultations (2021-2022)

The Country survey (2020) and the Nomenclature consultations (2021-2022) collected data about 180 countries, and the desk review (2021) gathered information about four more, bringing the total number of countries that we have information about to 184. Nevertheless, the nomenclature system status of 10 countries remains unknown. Although some gaps in the data provided by the member states on the Country survey (2020) and the Nomenclature consultations (2021-2022) were covered through the web and literature search of the desk review, the difference between both data sets can also provide some insight about the accessibility of such information, either public or through the country itself.

For example, both the Country survey (2020) and the Nomenclature consultations (2021-2022) and the desk review showed that more than a third of the respondent members *do not have an official nomenclature* coding structure for the proper management of their medical devices. There is a 10% difference between the former, i.e., 45% (81 countries) and 35% (64 countries) for the last.

The same percentage difference, 10%, was shown concerning a specific t*ype of official nomenclature* usage, i.e., 58% from the Country survey (2020) and the Nomenclature consultations (2021-2022) and 65% found in the desk review.

For more than one system, there is a difference of 27% between what member countries indicated through their responses, i.e., 9 countries (5%) versus 58 countries (32%) found through the desk review.

The *UMDNS* showed a use difference of 2% (9% from the Country survey (2020) and the Nomenclature consultations (2021-2022) versus 7% from the desk review), corresponding to 16 and 12 countries, respectively; the *nationally developed* nomenclature showed a difference of 1% (Country survey (2020) and the Nomenclature consultations (2021-2022): 18% vs. desk review: 17%; corresponding to 32 and 31 countries, respectively); and a percentage difference of 13% was found between the countries that use the *EMDN*, i.e., 27 respondent countries (15%) versus 4 countries (2%) whose information was found through the desk review.

Finally, the countries whose nomenclature is based on the *GMDN* showed no percentage difference between the data from the Country survey (2020) and the Nomenclature consultations (2021-2022) and the desk review (2021), i.e., both of them with 15 countries (8%).

Regarding the *official nomenclature system purpose of use*, and comparing the results between the data obtained through the Country survey (2020) and the Nomenclature consultations (2021-2022) and the desk review (2021), the following was obtained:

The *not specified* purpose of use corresponds to the largest percentage of countries in both the Country survey (2020) and the Nomenclature consultations (2021-2022) and the desk review (2021), i.e., 34% (34) and 40% (38), respectively. This can be explained by the difficulty of specifying the various uses of the nomenclature system of medical devices within a country's health system.

Between the number of the responding country members Country survey (2020) and the Nomenclature consultations (2021-2022) and the gathered information (desk-review), the South-East Asia Region (SEAR) and the Western Pacific Region (WPR) exhibited a difference of no more than two countries and a similar distribution for their assorted nomenclature system purposes.

Concerning specific purposes of nomenclature systems, all WHO Regions showed a comparable number of countries using their nomenclature for *procurement purposes* and both *regulatory and procurement purposes*, respectively 18 from the Country survey (2020) and the Nomenclature consultations (2021-2022) and 19 from the desk review. However, in comparison to the preceding, a greater number of the member countries stated the *various purposes* of use for their nomenclature system, at least in the case of the desk review (23 versus the 11 from the Country survey (2020) and the Nomenclature consultations (2021-2022)).

In comparison to other specific uses, most of the WHO regions have been found to mainly use three specific purposes of use for their medical devices: *regulatory, procurement,* or both *regulatory and procurement purposes*: 54% from the Country survey (2020) and the Nomenclature consultations (2021-2022) and 32% from the desk review, for example: the African Region Country survey (2020) and the Nomenclature consultations (2021-2022): 6 countries and the desk review: 4 countries; the European Region (EUR) Country survey (2020) and the Nomenclature consultations (2021-2022): 30 countries and the desk review: 8 countries; the WPR Country survey (2020) and the Nomenclature consultations (2021-2022): 4 countries and the desk review: 5 countries; the Americas Region (AMR) and the Eastern Mediterranean Region (EMR) Country survey (2020) and the Nomenclature consultations (2021-2022) and desk review, with 10 and 4 countries, respectively. The SEAR Country survey (2020) and the Nomenclature consultations (2021-2022), as well as the desk review, found no evidence of any of the nomenclature-specified purposes mentioned above.

If contrasted to what was identified in the desk review, the *regulatory purpose* for medical devices has been enlarged and specified as the number of country members in the EUR adopting the *EMDN* has grown, i.e., 36 (36%) from the Country survey (2020) and the Nomenclature consultations (2021-2022) versus 12 (13%) found in the desk review.

Many of the differences can be explained by the following:

- It is important to note that the Country survey (2020) and the Nomenclature consultations (2021-2022) responses, despite being from different time periods, had a recent and significant participation from the responding member states during the 2021–2022 period. This participation derived, particularly, in the Executive Board, and World health assembly discussion and information sessions on nomenclature of medical devices.
- The existence of a nomenclature system, type, and use is a continuous and rapidly evolving area of medical devices that depends on many factors, such as legislation, commerce, management, political will, economy, etc.
- As previously shown the specific purposes for the use of the nomenclature system, if any, are rarely mentioned such as the following: for reimbursement purposes; for national essential lists; for inventory systems in healthcare facilities. This may be explained due to lack of visibility of any or specific purposes within the Health system and the absence of centralized information concerning the different areas involved in Health technology.

Findings by country

The desk review (2021) findings by country concern qualitative national information. And, as stated in the Methodology, the medical devices surveys, from previous years until now, included comments related to the nomenclature system of the member states. Although, some of them have been updated with the latest Country Survey (2020) and the Nomenclature consultations (2021-2022) data and its qualitative analysis.

Concerning regional nomenclature agreements, the information can be found in the dedicated International Agreements section.

Below, please find the list of member states with no comments about nomenclature type or use, and a section with the countries that provided the corresponding comments (including them).

Countries without comments referring to nomenclature

No qualitative information was found during the desk review (nor sent during Country Survey (2020) or the Nomenclature consultations (2021-2022)) about the nomenclature type, and use of the following 51 member states:

Afghanistan
Algeria
Andorra
Antigua and Barbuda
Bahamas
Barbados
Belize
Burkina Faso
Burundi
Cameroon
Cabo Verde
Central African Republic
Chad
Chile
Comoros
Côte d'Ivoire
Democratic People's Republic of Korea
Gabon
Guinea-Bissau
Haiti
Kuwait
Lesotho
Liberia
Malawi
Marshall Islands
Mauritania
Mauritius
Micronesia (Federated States of)
Mongolia
Mozambique
Myanmar
Nauru
Niue
Pakistan
Palau
Papua New Guinea
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Samoa
San Marino
Seychelles
Solomon Islands
Somalia
Suriname
Swaziland (Eswatini)
Tonga
Turkmenistan
Tuvalu
Vanuatu
Vietnam

Countries with comments referring to nomenclature

The following section includes the corresponding information from 143 member states that have submitted comments to Country Survey (2020) and/or the Nomenclature consultations (2021-2022), as well as the information retrieved in the 2021 desk review consultation.

Albania

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

This Italian nomenclature system CIVAB comes with the Inventory system called CLINGO.

Desk review up to December 2021

The registration list for medical devices in Albania and the codes that appeared belong to CIVAB nomenclature. Nomenclature is used mainly for registration and inventory purposes.

https://www.humatem.org/telecharger_document_base_documentaire/88
http://akbpm.gov.al/shperndarja-e-barnave-dhe-pajisjet-mjekesore/

Angola

Desk review up to December 2021

Access to the information is restricted since user accounts and passwords are required to access the website of the Ministry of Health.

Argentina

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

The Administración Nacional de Medicamentos Alimentos y Tecnología Médica (ANMAT), reported the use of the Universal Medical Device Nomenclature System (UMDNS) for regulatory purposes of the medical devices in this country[6].

Desk review up to December 2021

Medical equipment research in the national inventory revealed that identification codes and technical names of medical equipment are similar to the ones that are used in UMDNS.

[When searching for medical equipment in the national inventory, identification codes and technical names are UMDNS.]

https://helena.anmat.gob.ar/uploads/pdfs/dc_17612_30714838411_8533.pdf?rnd=ade6bf84-fed4-48cb-b11f-c7b913a302ea

6 Answered to the September 2021 Survey for the GAMD 2021 Update.

Armenia

Desk review up to December 2021

Armenia uses a nomenclature that was developed within the Eurasian Economic Union (see first link, paragraph 8, an official website). The Eurasian Economic Commission (EEC) and the GMDN Agency signed the Memorandum of Understanding (2nd link) to support the harmonization of Eurasian Economic Union's (EAEU) medical device nomenclature with the GMDN. The common market of medical products within the Eurasian Economic Union (EAEU) begins to function in full in 2022.

https://portal.eaeunion.org/sites/odata/redesign/Pages/MedicalDeviceNomenclature.aspx
http://www.eurasiancommission.org/en/nae/news/Pages/19-03-2019-3V.aspx
https://www.e-draft.am/projects/222/about
http://www.pharm.am/index.php/ru/2015-06-03-16-27-43/3571-2017-11-28-13-33-46

Australia

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

The use of GMDN is a legally mandatory requirement for devices supplied in Australia, including IVDs.

Desk review up to December 2021

The Therapeutic Goods Administration site (Australian Regulatory Agency) states the use of GMDN, for medical devices including IVDs.

https://www.tga.gov.au/global-medical-device-nomenclature-gmdn
https://www.tga.gov.au/sites/default/files/ivd-gmdncodes.pdf

After publication of the first draft of this Overview, the Therapeutic Goods Administration (the responsible agency for regulating medical devices in this country) pointed out that the nomenclature used in Australia for medical devices, including IVDs, is the Global Medical Device Nomenclature System (GMDN), which is a legal and mandatory requirement for the devices supplied in this country.[7]

Austria

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

2020

The Austrian Medical Devices Register uses the UMDNS and the EDMA Code.

https://goeg.at/Medizinprodukteregister

Desk review up to December 2021

The Austrian Medical Devices Register uses the UMDNS, GMDN and EDMA Code for IVDs. In the future, the CND/EMDN will be used as part of the European Commission Standard.

https://goeg.at/Medizinprodukteregister
https://medizinprodukteregister.at/Nomenklaturen

7 Commented by email to the publication of the Draft Nomenclature Overview

Azerbaijan

Desk review up to December 2021

State registration of medical devices is not carried out by the government. For import of medical products and medical equipment, it is necessary to obtain a confirmation letter regarding the classification of an imported product, and then obtain a hygienic certificate from the Republican Center for Hygiene and Epidemiology of the Republic of Azerbaijan.

http://www.pharma.az/

Bahrain

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The GMDN code is required for registration of medical devices, as well as the HS code.

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/guidelines/MDR_Guideline_Medical%20Device%20Registration_%20Ver%206.0.pdf

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Medical%20Device%20Registration%20Form%20%2020%20Dec%202020.pdf

https://www.gmdnagency.org/Services/Members#N

Desk review up to December 2021

According to the 19 sub-section of the Registration Guideline for medical devices (from the National Health Regulatory Authority), for registration purposes, it is needed the GMDN and the HS code. In some cases, it might be required to fulfil the classification criteria issued by the NHRA Medical Devices Regulations department (it should be provided).

Bangladesh

Desk review up to December 2021

A medical equipment price list can be found on the website of the Directorate General of Drug Administration, but naming systems are not provided.

https://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/registered-medical-device-list

Belarus

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

State register of medical equipment and medical supplies of Belarus.

https://www.rceth.by/Documents/3mz3prN132420141216.pdf

Desk review up to December 2021

Country uses the EEU's nomenclature system alongside the nationally developed one. The Eurasian Economic Commission (EEC) and the GMDN Agency signed the Memorandum of Understanding (2nd link) to support the harmonization of Eurasian Economic Union's (EAEU) medical device nomenclature with the GMDN.

https://www.rceth.by/Documents/3mz3prN132420141216.pdf
https://pravo.by/document/?guid=3871&p0=F91800087
http://www.eurasiancommission.org/en/nae/news/Pages/19-03-2019-3V.aspx

Belgium

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

2020

The GMDN code is used during the notification of the placing on the market of class I medical devices, it is also used in the form for the transmission of material vigilance incidents. This code is also used for the registration of diagnostic medical devices in vitro in the European database Eudamed; in Belgium, several agencies are involved in the evaluation and regulation of devices.

(Original in French) *Le code GMDN est utilisé lors de la notification de mise sur le marché des dispositifs médicaux de classe I, il est également utilisé dans le formulaire de transmission des incidents en matériovigilance. Ce code est également utilisé pour l'enregistrement des dispositifs médicaux de diagnostique in vitro dans la base de données européennes Eudamed; in Belgium, several agencies are involved in the evaluation and regulation of devices.*

https://kce.fgov.be/en
https://www.famhp.be/en

Desk review up to December 2021

The country uses the GMDN, and as it is a member of the EU it will be used in parallel with CND/EMDN.

https://ec.europa.eu/health/sites/health/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf

Benin

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The CNEH nomenclature is used informally in some of the country's hospitals.
(Original in French) *La nomenclature CNEH est utilisée de façon informelle dans certains de nos hôpitaux.*

http://www.sante.gouv.bj/

Desk review up to December 2021

The adoption of national and / or international nomenclatures for the identification of infrastructure, biomedical equipment and care structures is an important prerequisite for the establishment of harmonized management of health assets across the country.

(Original in French) *L'adoption de nomenclatures nationales et/ou internationales pour l'identification des infrastructures, des équipements biomédicaux et des structures de soins est un préalable important pour la mise en place d'une gestion harmonisée du patrimoine sanitaire à travers le pays.*

http ://www.sante.gouv.bj/
https ://www.jhia-online.org/index.php/jhia/article/download/179/110/664

Bhutan

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

Adapted nomenclature from the GMDN.

Desk review up to December 2021

There is a national medical devices list that is based on the nationally developed nomenclature.

http://www.moh.gov.bt/national-medical-devices-list/

Bolivia (Plurinational State of)

Desk review up to December 2021

Country uses the UMDNS as well as the Mercosur Common Nomenclature (MCN).

http://www.agemed.gob.bo/
https://www.mercosur.int/bolivia-ingresa-al-mercosur/
There is a national medical devices list (LINADIME) and it is not based in any of the internationally recognized nomenclature
https://www.agemed.gob.bo/archivo_uso_racional/linadime/R.A.LINADIME.pdf

Bosnia and Herzegovina

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The nomenclature is based on GMDN and EDMA codes; the instructions request manufacturer and representative of manufactures to use GMDN or EDMA codes for making generic names. This country have free access to the GMDN base, and found a new version of EDMA codes on the internet.

Desk review up to December 2021

The nomenclature is based on the GMDN and the EDMA codes.

http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-lijekovima-i-medicinskim-sredstvima

Botswana

Desk review up to December 2021

Country uses the UMDNS.

https://www.bomra.co.bw/index.php/bomra-downloads/guidelines-manuals

Brazil

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

Anvisa started working to internalize the GMDN. So far, 100 of Anvisa's technical names are compatible with GMDN. Anvisa also works in the implementation of the Unique Device Identification (UDI) in Brazil. Anvisa is currently preparing a draft proposal in a working group with the participation of the private sector, which was sent to the Public Consultation (2021).

https://www.anvisa.gov.br/datavisa/nomestecnicosggtps/consulta_ggtps.asp
www.anvisa.gov.br

Desk review up to December 2021

Brazil's regulatory agency uses the GMDN system. For importation the Mercosur Common Nomenclature is used.

https://www.gov.br/anvisa/pt-br

Brunei Darussalam

Desk review up to December 2021

The UMDNS is used for regulatory purposes (see second link). Country is a Member of the Asian Harmonization Working Party (AHWP). Within the AHWP efforts are being made to start developing a unified medical devices nomenclature system for regulatory purposes.

http://www.ahwp.info/index.php/node/57
https://www.dgra.de/media/pdf/studium/masterthesis/master_matthies_c.pdf

Bulgaria

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

2020

Uses GMDN and UMDNS.

https://www.mh.government.bg/en/
https://www.bda.bg/en/information-for-companies/122-medical-devices-announcements-category

Desk review up to December 2021

It uses the GMDN and the UMDNS, and as a member of the EU it will use the CND/EMDN.

https://www.mh.government.bg/en/
https://www.bda.bg/en/information-for-companies/122-medical-devices-announcements-category

Cambodia

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The Hospital Service Bureau has developed standard medical equipment nomenclature for public hospitals in Cambodia and it has been utilized for medical equipment management and maintenance.

Canada

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

Not publically available. Used internally for coding products in the database. Preferred Name Codes are based on US FDA Panel Codes.

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-global-medical-device-nomenclature.html

Desk review up to December 2021

Health Canada is initiating the transition from its current medical device categorization method to the Global Medical Device Nomenclature (GMDN) to improve the availability, access to, and quality of information available on medical devices in Canada (see first link).

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-global-medical-device-nomenclature.html

After the publication of the first draft of this Overview, the Directorate of Medical Devices/Health Canada specified that two types of nomenclatures for medical devices coexist in this country: the Global Medical Device Nomenclature System (GMDN) and preferred name codes. In addition, it was clarified that although Canada continues to accept PNC and encourage manufacturers to use the GMDN, it has never been the intention to use any other nomenclature other than those mentioned above, nor to develop a national one.[8]

8 Commented by email to the publication of the first Draft Nomenclature Overview

China

Desk review up to December 2021

Based on the UMDNS (China has plans to develop a uniquely identifiable database for medical equipment).

http://english.nmpa.gov.cn/2019-12/10/c_456290.htm

Colombia

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

Nationally developed. It is in the phase of implementation.

https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/resolucion-2535-de-2013.pdf
https://www.invima.gov.co/

Desk review up to December 2021

Currently, the country is in resolutions to generate a interoperable semantic standard.

https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/analisis-estandar-semantico-dispositivos-medicos.pdf

Democratic Republic of the Congo

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The official nomenclature does not exist. This country uses "whatever is at hand an according to its circumstances".

(Original in French) *La nomenclature officielle n'existe pas. Tout ce qui est à portée de main et selon les circonstances est utilisé.*

Congo

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

Via the "Questions for Biomedical / Clinical Engineers" survey, the private HTM-Consulting pointed out the coexistence of many nomenclature systems within this country, as there is not a specific one in official use. As reported by the private agency, this situation has caused errors and mismatches regarding the purchase of specific medical devices.[9]

Cook Islands

Desk review up to December 2021

Regulated by MOH

https://www.health.gov.ck/policies-guidelines/

9 Answered to the August 2021 Survey "Questions for Biomedical / Clinical Engineers"

Costa Rica

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The GMDN has been adapted to the national needs.

https://www.ministeriodesalud.go.cr/index.php/acceso-a-sistemas-de-informacion

Desk review up to December 2021

Costa Rica has a national nomenclature system for classifying medical equipment.

http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=62959&nValor3=99850&strTipM=TC

Croatia

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

Desk review up to December 2021

Croatia uses the GMDN nomenclature for the national registration of medical equipment. As an EU member, it will adopt the use of CND/EMDN too.

https://www.halmed.hr/Medicinski-proizvodi/Upute-za-podnositelje-zahtjeva-41/Proizvodnja-medicinskih-proizvoda/

Cuba

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

The Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (CECMED) reported the coexistence and use for procurement purposes of two nomenclature systems: the SUCNEM, a nationally developed nomenclature, based on the Universal Medical Device Nomenclature System (UMDNS) and the Global Medical Device Nomenclature (GMDN)[10].

https://www.cecmed.cu/
http://www.electromedicina.sld.cu

Desk review up to December 2021

Cuba has its system for classifying medical equipment: SUCNEM, which is based on the UMDNS. Additionally, the country uses the GMDN.

https://www.cecmed.cu/registro/equipos-medicos
http://cencomed.sld.cu/socbio2007/trabajos/pdf/conferencias/aguiar/viernes/mesa2/dulce.pdf

Cyprus

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

10 Answered to the September 2021 Survey for the GAMD 2021 Update.

Czechia

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN)

2020

The GMDN and UMDNS remain the historically used nomenclatures. Three national specific systems (categorizations) of medical devices are used for reimbursement and statistical purposes. The GMDN remains a comprehensively recognized system for the registration and notification of medical devices in the Czechia. GMDN codes are used in the Register of Medical Devices (RZPRO) administered by the State Institute for Drug Control (SUKL) for regulatory purposes, adverse events reporting, safety corrective measures, and information on clinical trials.

Desk review up to December 2021

It is used by the UMDNS for registration, and other types of medical device nomenclature for reimbursement purposes. As a EU member it will adopt the use of CND/EMDN too.

https://www.niszp.cz/en/registration-and-notification

Denmark

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

Desk review up to December 2021

The use of the GMDN system is in the law, but soon it will be used in alongside the CND/EMDN, as the EU nomenclature.

https://laegemiddelstyrelsen.dk/en/devices/

Djibouti

Desk review up to December 2021

Regulated by MOH

https://sante.gouv.dj/reglements

Dominica

Desk review up to December 2021

No change. Neither in the web portal of the government nor the Ministry of Health, Wellness and New Health Investment (the latest is in development) there's no information about nomenclature of medical devices.

http://health.gov.dm/

Dominican Republic

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

There is no official nomenclature. However, there is a proposal dating from 2006 that responded to a project for preventive maintenance of medical equipment.

(Original in Spanish) *No existe una nomenclatura oficial. Sin embargo, existe una propuesta que data del año 2006 que respondió a un proyecto de mantenimiento preventivo de equipos médicos.*

Desk review up to December 2021

There is no official nomenclature system. The access to the Dirección General de Medicamentos, Alimentos y Productos Sanitarios have only three windows of information about the process and certification of medical devices, medicines and cosmetics; none of them is available for public navigation as a supplier registration and password are needed; the only available classification (but not nomenclature system) of medical devices is in the Oficial Decret No. 246-06, Book 2, chapter 1, articles 11 to 20.

https://digemaps.msp.gob.do/menu/

Ecuador

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

For MD traceability purposes will be taken as a reference the Universal Medical Devices Nomenclature System (UMDNS) developed by Emergency Care Research Institute (ECRI). In case that UMDNS does not have a specific code for a MD, it will be taken as an alternative nomenclature, the Global Medical Devices Nomenclature developed by GMDN Agency.

https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/01/Resoluci%C3%B3n_ARCSA-026-YMIH-Dispositivos-M%C3%A9dicos.pdf

Egypt

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

Used in the database of geographical information system health.

https://www.edaegypt.gov.eg/

Desk review up to December 2021

Medical devices registration requires use of a nomenclature (not specified, link 2).

https://www.edaegypt.gov.eg/
https://www.wikiprocedure.com/index.php/Egypt_-Register_with_Central_Administration_of_Pharmaceutical_Affairs_(CAPA)

El Salvador

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

The catalog developed is for medical equipment in general and is for purchase purposes only. There is no distinction or classification of medical technology equipment based on its application or impact on the health of the patient

(Original in Spanish) *El catálogo desarrollado es de equipo médico en general y sólo es para fines de compra. No existe distinción o clasificación de equipos de tecnología médica por su aplicación o incidencia en la salud del paciente.*

Desk review up to December 2021

In the Dirección Nacional de Medicamentos is available the guide for medical devices registration. It includes the classification of medical devices (see link).

https://www.transparencia.gob.sv/institutions/h-zacamil/documents/207883/download

Equatorial Guinea

Desk review up to December 2021

Regulated by MOH

Eritrea

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

Official nomenclature system for medical devices is currently in the process of development.

https://shabait.com/

Estonia

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

Desk review up to December 2021

It uses the MSA code (nationally developed) although it also uses the GMDN, both for various purposes such as regulation and procurement.

https://msa.sm.ee/eng/search/
https://msa.sm.ee/ctrl/en/Fail/laadi_alla_mall/96968
https://haigekassa.ee/en/people/medical-devices
https://www.terviseamet.ee/en/medical-devices-2/regulatory-controls-medical-devices

Ethiopia

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

Nationally developed and based on both the UMDN and the GMDN. This nomenclature was developed by EPSA, ESDA and FMoH in collaboration with stakeholders. The nomenclature is mainly used for procurement and regulatory purposes. The Established Public Infrastructure Directorate is now starting an inventory to identify the type, source and status of the devices.

www.fmhaca.gov.et
https://epsa.gov.et/featured-services/procurement-list/

Desk review up to December 2021

The Guideline for Registration of Medical Devices includes the medical devices' essential safety and performance requirements, and risk classification I to IV. As well as a nationally developed nomenclature as stated in the Ethiopian Food and Drug Administration (first link and third link). The second link shows the registration form for medical devices.

http://www.fmhaca.gov.et/publication/guidelines-for-registration-of-medical-devices-or-supplies/
https://www.eris.efda.gov.et/public/registration

Fiji

Desk review up to December 2021

There is no specific nomenclature system. The procurement, management, inventory and registration use the generic name or the trade name of the product (according to the 2013 policy).

http://www.health.gov.fj/wp-content/uploads/2018/02/Fiji-National-Medicinal-Products-Policy-2013.pdf

Finland

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

Finland CA will implement the European Medical Device Nomenclature (EMDN) used by manufacturers/ ARs when registering their medical devices in the EUDAMED database. The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland.

https://www.fimea.fi/web/en/medical-devices

Desk review up to December 2021

The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland.

https://www.fimea.fi/web/en/medical-devices
https://www.fimea.fi/documents/160140/764068/english_Publications_Forms_IVDD_manufacturers_formulaire.pdf/0d7e0ec9-072e-c61b-934d-2fa178875ddf?t=1577451373998

France

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

2020

The classification of the provisions of medical devices is provided for in Article R. 5211-7 of the Public Health Code. The rules are specified in the order of March 15, 2010 amending the order of April 20, 2006 setting the classification rules for medical devices.

(Original in French) *La classification des dispositions des dispositifs médicaux est prévue à l'article R. 5211-7 du code de la santé publique. Les règles sont précisées dans l'arrêté du 15 mars 2010 modifiant l'arrêté du 20 avril 2006 fixant les règles de classification des dispositifs médicaux.*

http://www.legifrance.gouv.fr/affichCode.do;jsessionid=3DA99E555F0AB933E0B91227088DB46C.djo04v_3?idSectionTA=LEGISCTA000006190738&cidTexte=LEGITEXT000006072665&dateTexte=20100330

Desk review up to December 2021

It is used as a nomenclature based on the GMDN (for procurement and commercialization), and as it is in the EU it will be used in parallel with the EMDN (for different purposes such as regulation, registration, procurement, surveillance, etc.).

https://www.legifrance.gouv.fr/codes/id/LEGISCTA000006190738/
https://www.ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/DM-classes-IIa-IIb-III-et-DMIA-Communication-et-liste/(offset)/6#paragraph_25854

After publication of the first draft of this Overview, the Hôpitaux de Haute-Savoie/AFIB have expresed the use, for more than 30 years, of the CNEH code nomenclature system (developed by the Center

National d'Expertise Hospitalière) for the identification and management of any biomedical devices and medical infrastructures in this country. This nomenclature in French language, is publicly available. In addition, the inventory and management software system for medical devices (CMMS) uses the CNEH codes to identify any medical device. It has also been specified that the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), formerly the AFSSAPS, is the agency in charge of giving marketing authorizations for CE-marked medical devices, which in no case takes into consideration the use of the GMDN nor the UMDN for classifying or identifying any medical device.[11]

Gambia

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The Medical Research Council (UK) in Gambia (refer to specific link) uses the UMDNS system via the ECRI Health Devices Sourcebook (ECRI website). Note that this is not used by the Ministry of Health.

http://www.mrc.gm/

Georgia

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

According to Georgian legislation, Georgia recognizes international or national (according to a list of certain countries) certificates of medical devices there.

https://matsne.gov.ge/ru

Desk review up to December 2021

The Law of Medicines and Pharmaceutical Activities (which includes the regulation of medical goods or medical devices) proposes three groups on the classification of pharmaceutical products (article 11, superindex 2) for advertising and retailing purposes. But there is no nomenclature system for medical devices.

https://matsne.gov.ge/ru/document/download/29836/21/en/pdf

Germany

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

2020

At the German Institute for Medical Documentation and Information (DIMDI) German manufacturers or an authorised representative of non-EU manufacturers have to register their products themselves. The database is served by DIMDI and today uses UMDNS.

http://www.dimdi.de

11 Answered to the August 2021 Survey "Questions for Biomedical / Clinical Engineers" and commented by email to the publication of the first Draft Nomenclature Overview.

Desk review up to December 2021

According to the information of the regulatory agency of Medical devices (BfARM) and the Ministry of Health two systems are used: UMDS (for medical devices in general) and EMDN for IVD. Although it is announced that both of them will be replaced (in May 2021) with the EMDN (European Nomenclature system for medical devices) which itself is based on the Italian CND system.

https://www.dimdi.de/dynamic/de/medizinprodukte/bezeichnungssysteme/

Ghana

Desk review up to December 2021

According to the "Guideline for registration of medical devices", the GMDN will be required for registration just in case it is previously coded. The nomenclature is used for registration purposes.

https://fdaghana.gov.gh/images/stories/pdfs/downloads/GUIDELINES%20FOR%20THE%20REGISTRATION%20OF%20MEDICAL%20DEVICES-REVIEWED.pdf

Greece

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

2020

A specific technical committee is responsible for the correlation of Nomenclature, Classification and Codification of Medical Devices.

https://www.gmdnagency.org/

Desk review up to December 2021

A specific technical committee is responsible for the correlation of the nomenclature, the classification and codification of medical devices.s The novel EMDN which is based on CND nomenclature will be introduced soon as the official EU's system. The National regulatory authority is the National Organization for Medicines in charge of medical products and devices.

https://www.eunethta.eu/eof/

Grenada

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

A system was developed but was not supported by management. There is no URL because this software was locally developed.

Desk review up to December 2021

The Ministry of Health website is not available for this country, nor the "Biomedical unit", which is responsible for the identification, procurement and maintenance of the medical equipment at the Hospitals and the Community Health facilities; nevertheless, the Strategic Plan for Health 2016-2025 is available and provides an in in which it is mentioned the lack of material and human resources.

http://www.gov.gd/moh/ced/mofa/sites/moh/files/grenada_health_sector_strategic_plan_2016-2015_approved.pdf

Guatemala

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

The In Vivo Classification, according to class, is contemplated in the Annex of the Technical Norm No. 37.

(Original in Spanish) *La Clasificación In Vivo y según Clase se encuentra contemplada en el Anexo de la Norma Técnica No. 37.*

https://www.mspas.gob.gt/
https://medicamentos.mspas.gob.gt/

Desk review up to December 2021

In accordance to the "Norma Técnica 37 versión 5-2016 Para la inscripción sanitaria de dispositivos médicos" the nomenclature system use for regulation, surveillance and control of medical devices has been nationally developed.

https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/normas-tecnicas?download=262%3Ainscripcion-sanitaria-de-dispositivos-medicos&start=40

Guinea

Desk review up to December 2021

In the Medicines and Cosmetics Regulation 2002 Act it is indicated that medicinal products for importation, manufacture, processing or packing should be done with the generic, official or approved non-proprietary name found in official pharmacopoeias or formularies alongside the brand name.

https://wipolex.wipo.int/en/text/199156

Guyana

Desk review up to December 2021

There is no official nomenclature for medical devices. The Regulation Agency (GAFDD) is in charge of the registration of devices.

https://gafdd.gy/inspectorate/#

Honduras

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The Regulation for the Sanitary Control of Products, Services and Establishments of Sanitary Interest, establishes a nomenclature for registration purposes.

(Original in Spanish) *El Reglamento para el Control Sanitario de Productos, Servicios y Establecimientos de Interés Sanitario, establece una nomenclatura con fines de Registro.*

http://www.salud.gob.hn/site/

Desk review up to December 2021

The 'Reglamento de control sanitario 2005' proposes a nomenclature system for sanitary license (art. 133/ unidad III) and for registration (art. 159, unidad V).

https://arsa.gob.hn/public/archivos/Reglamentocontrolsanitario62005.pdf

Hungary

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

2020

The coding is not available on the Internet.

Desk review up to December 2021

A national nomenclature system (and classification) has been developed for medical devices on "4/2009. (III. 17.) Decree"; also, the acceptance of another nomenclature system such as the "Global device name" for registration of products (see: "Annex II"). Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

https://net.jogtar.hu/jogszabaly?docid=A0900004.EUM&celpara=#xcelparam
https://net.jogtar.hu/jogszabaly?docid=a0300008.esc

Iceland

Desk review up to December 2021

It uses a nomenclature system for registration (see link). Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

https://www.ima.is/medical_devices/about_medical_devices/

India

Desk review up to December 2021

Regulated by the Central Drugs Standard Control Organization: CDSCO.

https://cdsco.gov.in/opencms/opencms/en/Home/

Indonesia

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

It uses a Harmonization System code (HS) at the moment. After harmonization, GMDN will be used.

Desk review up to December 2021

There are classification guidelines and a policy for the distribution of medical devices and IVDs. The nomenclature systems mentioned in the regulation documents are the Harmonization System code (HS) and the GMDN (see two links).

http://regalkes.kemkes.go.id/informasi_alkes/Pedoman%20Klasifikasi.pdf
http://regalkes.kemkes.go.id/informasi_alkes/PMK_No_62.pdf

Iran (Islamic Republic of)

Desk review up to December 2021

Regulated by IMDR (first link). For its registration, any medical device needs a declaration of conformity as stated in GHTF STED which is accepted in the report in one of the following nomenclatures: National developed classification (IRC Code: Iran Registration Code); EU classification or US-FDA classification. However, in order to fulfil the whole documentation, the UMDNS classification is used.

http://imed.ir/
http://www.imed.ir/uploads/forms/documents/73a82691-3330-4eef-a1d1-36c769376672.pdf
http://imed.ir/ExtendedModules/Document/UI/DownloadFile.aspx?FileCode=a2ab141c-cd93-4904-8108-56f912e9e6bb&fileid=411

Iraq

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The MoH is working on adapting a national nomenclature system and linking it to the UMDNS.

https://kimadia.iq/en

Desk review up to December 2021

No official nomenclature system, but several such as UMDNS are accepted. The State Company for Provision of Medicines and Medical Appliances (KIMADIA) oversees imported medical devices. oversees imported medical devices. Tecmoh registers all medical devices in Iraq.

https://kimadia.iq/assets/files/1613646335_67-2021-2-%D8%A7%D8%B3%D8%B9%D8%A7%D8%B1-%D8%A7%D9%84%D9%85%D9%81%D8%A7%D8%AA%D8%AD%D8%A9-%D8%A7%D9%84%D9%85%D8%B1%D9%82%D9%85%D8%A9_1613646335.pdf

https://www.facebook.com/Iraqi-Pharmacovigilance-Center-IPhvC-%D8%A7%D9%84%D9%85%D8%B1%D9%83%D8%B2-%D8%A7%D9%84%D8%B9%D8%B1%D8%A7%D9%82%D9%8A-%D9%84%D9%84%D8%B1%D8%B5%D8%AF-%D8%A7%D9%84%D8%AF%D9%88%D8%A7%D8%A6%D9%8A-159782860751953/?hc_ref=ARSHWx4DaLIQXMMMAOzGGWzuyBljp90GRSRgwilptidc_P7hppyjNAGTkdxXOsm7KlQ&fref=nf&__tn__=kC-R

Ireland

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

Desk review up to December 2021

For registration of medical devices, it is recommended to use the GMND nomenclature system (see link 1), even if other nomenclatures are also accepted. Although as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/aut-g0054-guide-to-registration-of-persons-responsible-for-placing-medical-devices-on-the-market-v2.pdf?sfvrsn=10

Israel

Desk review up to December 2021

There is no official nomenclature, but the use of several nomenclatures is accepted, such as UMDNS, for the registration of medical technologies (regulated by the Division of Medical Equipment (see first link)). Risk Classification often uses the same as EC states. As in agreement with EC states, it may use the EMDN (European Nomenclature system for medical devices) too. The risk classification for medical devices used is divided into the following classes: I, IIa, IIb, and III (Decreto Legislativo 24 febbraio 1997, Art. 8). [From (Samadi)]

https://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/MLD/Pages/default.aspx
https://medicaldevices.health.gov.il/

Italy

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

CND Classificazione Nazionale dei Dispositivi Medici (correlated with GMDN). CND was nationally developped, and it is the base for EMDN. As mentioned on several occasions in the past, a map of correspondence between the GMDN nomenclature and the Italian CND classification has been created since 2007 to allow manufacturers to register in the Italian database of medical devices. This map is subject to ongoing maintenance even today at the request of manufacturers. This map was introduced at the beginning because the GMDN code was originally the mandatory registration key in the Italian system. Subsequently, the mandatory use of the GMND code was removed at the request of the manufacturers, due to the difficulty of using it and, in many cases, due to its unavailability. In any case, the possibility of using the GMDN code and its connection with the CND is still allowed, but it appears that, despite this possibility of use, the GMDN code is rarely used in the registration in the Italian system. A new version of the Italian medical device nomenclature (CND) will be published within the next months. Because the CND has been chosen as the basis of the EMDN nomenclature, a huge update has been done to create the European nomenclature. All the updates have been acquired in the new version of the CND, that has been approved by the Italian Technical Committee on 21st December 2020.|One of the most important inputs for the CND update was the comparison with GMDN and so an alignment between the first level of the CND 2018 version and GMDN (dataset 01/05/2019) has been done. A list of GMDN codes not covered by CND has been defined and then used to create some new codes in CND. In the Meeting of the Medical Device Nomenclature Working Group-04, OCTOBER 2019 of the European Commission, the state of the art of mapping between CND and GMDN was a point of the agenda. Any further other mapping activities must be agreed upon with the European Commission in line with the provisions of the project itself.

http://www.salute.gov.it/imgs/C_17_pagineAree_328_listaFile_itemName_15_file.pdf
http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html

Desk review up to December 2021

The Italian classification system (CND Classificazione Nazionale dei Dispositivi Medici) has been correlated to the GMDN nomenclature, as well as it will be the basis for the future EMDN (European Nomenclature system for medical devices) too, that will be the one used soon for EC states.

http://www.salute.gov.it/imgs/C_17_pagineAree_328_listaFile_itemName_15_file.pdf
http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html

Jamaica

Desk review up to December 2021

There is the Standards & Regulations Division within the MoH. However, there is not mentioned a specific nomenclature for registration of medical devices, nor for risk classification.

https://www.moh.gov.jm/divisions-agencies/divisions/standards-and-regulation-division/guidelines-forms-lists/
https://moh.gov.jm/wp-content/uploads/2015/12/Ven-List-2015.pdf

Japan

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

Japanese Medical Device Nomenclature was developed from the GMDN 2003 version.

https://www.std.pmda.go.jp/stdDB/index_en.html

Desk review up to December 2021

It uses a national nomenclature system called Japanese Medical device nomenclature (JMDN) - see PMDA regulatory agency link for more details

https://www.std.pmda.go.jp/stdDB/index_en.html
https://www.std.pmda.go.jp/stdDB/Data_en/InfData/Infetc/JMDN_en.pdf
https://www.pmda.go.jp/english/index.html

Jordan

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

This country will support the WHO standard nomenclature for medical devices. Until now, its nomenclature is based on UMDNS for management in the CMMS system, and the government procurement department uses UNSPSC nomenclature for procurement purposes.

http://www.jfda.jo/Default.aspx

Desk review up to December 2021

Jordan relies on the EU directives to classify its devices, namely, the Medical Devices Directives 93/42/EEC and the Active Implantable MDD 90/385/EEC and the Medical Devices Importation Directives, Art. 2.

http://www.jfda.jo/Pages/viewpage.aspx?pageID=153

Kazakhstan

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

Medical State Register of lekarstennyh.

https://www.ndda.kz/category/nomenklatura_men_izd

Desk review up to December 2021

It uses a nationally developed nomenclature system that is harmonized with the GMDN.

https://www.ndda.kz/category/nomenklatura_men_izd
http://nmirk.dari.kz/

Kenya

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

The GMDN is used for regulatory purposes.

https://www.gmdnagency.org

Desk review up to December 2021

The nomenclature is used for registration purposes. The following systems are allowed for registration purposes: nationally developed, GMDN, UDI and UMDNS; as stated in the guidelines, at least, one system must be used for registration of medical devices or IVDs (see link 1) alongside the risk classification for medical devices A-D (see link 2).

https://pharmacyboardkenya.org/files/?file=Final%20Guidelines%20for%20Medical%20Devices%20and%20IVDs.pdf
https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

Kiribati

Desk review up to December 2021

The Medical Equipment Management Committee within the MoH is in charge of the registration of medical equipment. There is no specific nomenclature used nor a risk classification system.

Kyrgyzstan

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The nomenclature is used for various purposes: regulation, procurement, in-vitro diagnostics lists and inventory.

http://cbd.minjust.gov.kg/act/view/ru-ru/1197
http://cbd.minjust.gov.kg/act/view/ru-ru/111673
http://www.pharm.kg/ru/about

Lao People's Democratic Republic

Desk review up to December 2021

No change as no nomenclature system is mentioned on any guidelines, policy, rules or acts; in this country, it is used the generic name of medical products or the active ingredients officially recognized

by the World Health Organization which are used worldwide and have no copyright owner, according to "Law on drugs and medical products (Amended)(2011); Medical Devices risk classification A- D (law on Drugs and Medical Products, Art. 11.).

http://www.fdd.gov.la/download/contents_documents/2019-07-05_100305am_Law%20on%20Medical%20Products%20(Eng).pdf

Latvia

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

Desk review up to December 2021

According to art. 119,3. from "Procedimientos de registro, evaluación de la conformidad, distribución, operación y supervisión técnica de dispositivos médicos": the GMDN is accepted for registration purposes. However, this country is not registered as a member of GMND agency.

http://www.zva.gov.lv
https://www.gmdnagency.org/
https://likumi.lv/ta/id/295401-medicinisko-iericu-registracijas-atbilstibas-novertesanas-izplatisanas-ekspluatacijas-un-tehniskas-uzraudzibas-kartiba

Lebanon

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The Ministry of Health is planning to acquire the Global Medical Devices Nomenclature system to adopt it and use it for regulatory and procurement purposes.

https://www.moph.gov.lb/userfiles/files/HealthCareSystem/Medical%20Technology/Laws%20and%20Regulations/karar%201506-2014.pdf

Desk review up to December 2021

There is no official nomenclature for medical devices, but GMND is accepted as stated in the "Minister Decision No. 1506 date 1/9/2014" page 1 (see link).

https://www.moph.gov.lb/userfiles/files/HealthCareSystem/Medical%20Technology/Laws%20and%20Regulations/karar%201506-2014.pdf

Libya

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

For the medical equipment list it is used a nomenclature based on UMDNS. Nomenclature is used for inventory systems in healthcare facilities and lists.

http://www.mhtc.ly
https://seha.ly/en

Desk review up to December 2021

It is accepted the use of various nomenclature systems of medical devices for procurement and donations (see link 2).

http://seha.ly/en/laws-regulations
https://mhtc.ly/docs/GeneralConditions/Generalcondition.pdf

Lithuania

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

Desk review up to December 2021

Medical devices are divided into classes I-III according to their risk (MS 102, 17-19). The State Health Care Accreditation Agency, MoH, is in charge of regulation. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too (see link 2).

https://vaspvt.gov.lt/node/78
http://vaspvt.taduliz.lt/node/44
https://vaspvt.gov.lt/node/1166

Luxembourg

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

Desk review up to December 2021

Although as part of the EC this country will use the European Nomenclature system for medical devices.

https://sante.public.lu/fr/support/recherche/index.php?~=do&from=search&s=desc%28score%29&r%5B0%5D=f%2Fsection%2Flegislation&res_length=20&q=dispositifs+m%C3%A9dicaux#main

Madagascar

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

National nomenclature for the material accounting of State assets (codification for the technical inventory).

(Original in French) *Nomenclature nationale pour la comptabilité matière du patrimoine de l'Etat (codification pour l'inventaire technique).*

http://www.agmed.mg/

Desk review up to December 2021

There is a nationally developed nomenclature. The regulation is in charge of L'Agence du Médicament de Madagascar (AGMED).

http://www.agmed.mg/PDF/SI/doss/ARRETE-14993_2013_MSANP-modalit%C3%A9s_fabrication_information_au_public_vente_dispositifs_m%C3%A9dicaux.pdf

Malaysia

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

For medical devices registration it is used the HS Code (Harmonized Tariff Nomenclature and Coding System) as well as the GMDN code (see link).

https://portal.mda.gov.my/documents/guideline-documents/30-guidelines-on-medical-device-registration-under-act-737-mda-gl-md-01-june-2014-2nd-edition/file.html

Maldives

Desk review up to December 2021

There is a project to develop a national nomenclature system based on the UMDNS (see: Situation analysis report, Link 3).

http://health.gov.mv/

https://www.facebook.com/mfdamv-102808298333472/

https://www.researchgate.net/publication/260766912_Situation_Analysis_on_medical_equipment_in_Maldives#fullTextFileContent

Mali

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

There is a summary nomenclature section in the stock accounting document where the different products are classified by category, but this is a very important area that deserves action.

(Original in French) *Il existe dans le document de la comptabilité matière une rubrique nomenclature sommaire ou les différents produits sont classés par catégories, mais c'est un domaine très important qui mérite une action.*

Desk review up to December 2021

http://www.cnop.sante.gov.ml/docs/LISTE%20AMO%20DANS%20LE%20SECTEUR%20%20PHARMACEUTIQUE%20PRIVE%20-%20%20Edition%202018.pdf

Malta

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

Mexico

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

The nomenclature system is established and organized in charts for health technologies that can be used in public/social health services. As for the government administration for 2018-2024, the charts will be organized as a compendium and it is in the process of depuration.

2020

The nomenclature system is established and organized in charts for health technologies that can be used in public/social health services. As for the government administration for 2018-2024, the charts will be organized now as a compendium and it is in the process of depuration. https://www.gob.mx/cms/uploads/attachment/file/512087/NOM-241-SSA1-2012.pdf

http://www.csg.gob.mx/descargas/pdf/priorizacion/cuadro-basico/iyem/catalogo/2017/EDICION_2017_TOMO_II_EQUIPO_MEDICO_-_link.pdf

http://www.csg.gob.mx/descargas/pdf/priorizacion/cuadro-basico/iyem/catalogo/2017/EDICION_2017_TOMO_I_INSTRUMENTAL_-_link.pdf

http://www.csg.gob.mx/descargas/pdf/priorizacion/cuadro-basico/iyem/catalogo/2017/EDICION_2017_TOMO_ANEXO_SET_QUIRURGICOS.pdf

http://www.csg.gob.mx/descargas/pdf/priorizacion/cuadro-basico/aux_diag/catalogo/2017/EDICION_2017_CByC-AUX_DE_DIAGNOST.pdf

http://www.csg.gob.mx/images/priorizacion/cuadro-basico/osteo-endo/catalogos/EDICION_2017_MATERIAL_DE_OSTESxNTESIS_Y_ENDOPRxTESIS.pdf

https://www.gob.mx/cms/uploads/attachment/file/512083/NOM-229-SSA1-2002.pdf

https://www.gob.mx/cms/uploads/attachment/file/512207/NOM-137-SSA1-2008.pdf

https://www.dof.gob.mx/nota_detalle.php?codigo=5562796&fecha=14/06/2019&print=true

Desk review up to December 2021

https://www.gob.mx/cofepris

http://www.csg.gob.mx/contenidos/priorizacion/cuadro-basico.html

Monaco

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

Directive 93/42/CEE.

https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-et-de-l-Aide-Sociales

Desk review up to December 2021

There is a nationally developed nomenclature for medical devices. Medical devices and IVDs are grouped by risk category: class I-III (arrêté ministériel n. 2003-581, Sec. I, Art. 1er). The Direction de l`Action Sanitaire et Sociale within the MoH is in charge of the regulation of medical devices.

https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-et-de-l-Aide-Sociales

Montenegro

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

“Register (notification) of medical devices” that contains information on medical devices which are available for use in Montenegro has just recently been set up. As it is at the start of its operations, it will use GMDN as a referent nomenclature system and based on this, it will be developed a system that will be in Montenegrin language so that all users can use it properly and they will have information what is on Montenegrin market as well.

https://www.calims.me/Portal/faces/dinamickeStrane?_Loop=4618826366059702&paramPut=+%3E+Medical+Devices+%3E+Definitions+and+Classification&paramRender=2&paramS=70&_adf.ctrl-state=wn7tyvskh_894

Desk review up to December 2021

It has recently developed a nomenclature system of medical devices based on GMDN.

https://www.calims.me/Portal/faces/dinamickeStrane?_frLoop=4618826366059702&paramPut=+%3E+Medical+Devices+%3E+Definitions+and+Classification&paramRender=2&paramS=70&_adf.ctrl-state=wn7tyvskh_894

Morocco

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

Nomenclature based on ECRI and CNEH.
(Original in French) *Nomenclature basée sur l’ECRI et le CNEH.*

http://dmp.sante.gov.ma/classification?rlc=587d5c&tirt=Dispositifs%20m%C3%A9dicaux&id=8

Desk review up to December 2021

It is based on the UMDNS.

http://dmp.sante.gov.ma/classification?rlc=587d5c&tirt=Dispositifs%20m%C3%A9dicaux&id=8

Namibia

Desk review up to December 2021

Many nomenclatures are accepted as stated in the second link

https://www.rrfa.co.za/wp-content/uploads/2012/11/NAM-Medicines-Registration-Guidelines.pdf
http://www.nmrc.com.na/

Nepal

Desk review up to December 2021

A national nomenclature system is based on the GMDN and the UMDNS.

https://www.dda.gov.np/
https://www.dda.gov.np/content/health-technology-product-an-medical-device-directive-2074

Via the "Questions for Biomedical / Clinical Engineers" survey, the IFMBE-Clinical Engineering Division (CED) explained that the lack of mandatory guidelines or official documents demanding the use of one specific nomenclature system, as well as the coexistence of many nomenclatures in different government health facilities in Nepal, has led to wrong procurements and mismanagement of medical device inventories.[12]

Netherlands

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

Desk review up to December 2021

There is a national nomenclature system based on the GMDN. Although, as a part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

https://www.rijksoverheid.nl/ministeries/ministerie-van-volksgezondheid-welzijn-en-sport
https://www.igj.nl/
https://www.rivm.nl/medische-hulpmiddelen
http://www.igz.nl/english/medical_devices/

New Zealand

Desk review up to December 2021

New Zealand uses a nomenclature based on the GMDN. The Global Medical Device Nomenclature (GMDN) codes are required to identify types of medical devices notified to the WAND database.

https://www.medsafe.govt.nz/regulatory/DevicesNew/1Definition.asp

12 Answered to the August 2021 Survey "Questions for Biomedical / Clinical Engineers"

Nicaragua

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

For various reasons there is not an official nomenclature system used for medical devices.

Desk review up to December 2021

Nicaragua has its own nomenclature system based on the GMDN.

http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/

Niger

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

There are several types of codification tested. The first were inspired by the French CNEH code (national code for hospital equipment). There is not a single codification adopted at the national level.

(Original in French) *Il y a plusieurs types de codification testés. Les premières se sont inspirées du code CNEH (code national pour l'équipement hospitalier) français. Il n'y a pas de codification unique retenue au niveau national.*

Nigeria

Desk review up to December 2021

There is no official nomenclature system. Medical devices are regulated by the National Agency for Food and Drug, Administration and Control (NAFDAC). Compliance with the classification of the country where the device is manufactured (link 2).

https://www.nafdac.gov.ng/drugs/
https://www.sciencedirect.com/science/article/pii/S2211883718300303#tbl0010
https://www.nafdac.gov.ng/

North Macedonia

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The GMDN code is being recognized.

Desk review up to December 2021

There is a nationally developed nomenclature but it is allowed the co-existence of several nomenclatures such as GMDN.

https://lekovi.zdravstvo.gov.mk/medicaldevices
http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-za-lekovi-i-medicinski-pomagala.pdf

Norway

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

The use of GMDN is not imposed by law.

Desk review up to December 2021

Norway uses a nomenclature system based on the GMDN. However, as a part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

https://legemiddelverket.no/English

Oman

Desk review up to December 2021

The GMDN is used for regulatory purposes. However, UMDNS and GMDN are both accepted nomenclature systems.

https://www.moh.gov.om/documents/16539/0/11%2B5++Listing+Guidance.pdf/9a6f51f7-b7b1-f209-2015-b3fd56d37b2c

Panama

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The UMDNS system has been adopted into legislation. Its implementation is still in process.

(Original in Spanish) *El sistema UMDNS ha sido adoptado en la legislación. Su implementación está aún en proceso.*

http://www.minsa.gob.pa/

http://minsa.b-cdn.net/sites/default/files/normatividad/decreto_468_de_2007_para_publicar_en_gaceta_2.pdf

Desk review up to December 2021

Panama is now in the process of adopting both the GMDN and the UMDNS for regulation purposes.

http://www.minsa.gob.pa/direccion/direccion-nacional-de-farmacia-y-drogas

Paraguay

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

A plan is being developed to proceed with the installation of a nomenclature system.

(Original in Spanish) *Se está elaborando un plan para proceder con la instalación de un sistema de nomenclatura.*

Desk review up to December 2021

The national regulatory authority is the Dirección de Vigilancia Sanitaria del Ministerio de Salud Pública y Bienestar Social.

https://www.mspbs.gov.py/monitoreo-insumos-medicamentos.html

Peru

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

Ley Nº29459-D.S and the D.S. Nº 016-2011-SA.

http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Publicaciones/DocumentosConsulta/P08_234-2017-05-04.PDF;
http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Normatividad/2020/DS_036-2020-SA.pdf
https://www.gmdnagency.org/

Desk review up to December 2021

According to the form DMEB-002 published on the official website, Peru uses the GMDN in the private sector, although the use of UMDNS or other systems is legally accepted (Ley Nº29459-D.S and the D.S. Nº 016-2011-SA). The national regulatory authority is the Dirección de Vigilancia Sanitaria del Ministerio de Salud Pública y Bienestar Social. Advance Scientific del Perú.

http://www.digemid.minsa.gob.pe

Philippines

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The Philippines will be using the Nomenclature that will be decided by the member states of the ASEAN who are working on the harmonization of medical device regulation in the region, where medical device nomenclature is one of the concerns.

Desk review up to December 2021

The national regulatory authority is the Bureau of Health Devices and Technology (BHDT), Department of Health.

https://doh.gov.ph/node/266

Poland

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

2020

The GMDN code is mentioned as a basic medical device nomenclature system in Polish legislation: Act of 20 May 2010 on Medical Devices; however, the use of other nomenclatures is allowed. Poland is part of the EU medical device regulatory framework so a new obligation from the European Commission in the area of medical device nomenclature and Eudamed will be implemented, e.g. adopting the European Medical Device Nomenclature (EMDN) when available.

Nevertheless, according to the EC statement, this nomenclature will still share some features with the GMDN code.

https://ec.europa.eu/health/sites/health/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf

Desk review up to December 2021

In the private sector, Poland uses a nomenclature system of medical devices based on the GMDN. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too. The national regulatory authority is the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products.

http://www.urpl.gov.pl/en/office
https://ec.europa.eu/health/sites/health/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf

Portugal

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

The Directorate-General of Health/Ministry of Health of this country pointed out that the official nomenclature system for medical devices and IVDs for registry purposes is based on the European Medical Device Nomenclature (EMDN).[13]

https://www.infarmed.pt/web/infarmed/pesquisa-dispositivos

Desk review up to December 2021

In the private sector Portugal uses a nomenclature system of medical devices based on GMDN. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too. The national regulatory authority is the National Authority of Medicines and Health Products (INFARMEDC, IP).

https://www.infarmed.pt/

Qatar

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

This is used for planning medical equipment for new / upcoming projects.

https://www.ecri.org/solutions/umdns/

Desk review up to December 2021

Medical devices are regulated by the MOHP but registered by the Ministry of Economy and Commerce (MEC). It uses the UMDNS for planning for new/upcoming projects, but the GMDN is also accepted. The national regulatory authority is the Medical Device Registration Unit, Pharmacy & Drug Control, Supreme Council of Health.

https://www.mfds.go.kr/eng/index.do

Republic of Korea

Desk review up to December 2021

Undefined nomenclature but uses medical devices classification and medical devices are regulated by the Korean Food and Drug Administration (KFDA).

https://www.mfds.go.kr/eng/wpge/m_39/denofile.do
https://www.mfds.go.kr/eng/index.do
https://www.mfds.go.kr/eng/brd/m_61/view.do?seq=74

13 Answered to the September 2021 Survey for the GAMD 2021 Update

Republic of Moldova

Desk review up to December 2021

It uses its own developed nomenclature that, nevertheless, is harmonized with the EU's regulation. The nomenclature is based on the GMDN (as seen in the second link, second page point 3c) but the use of other nomenclature is accepted too. The national regulatory authority is the agenţia medicamentului şi dispozitivelor medicale.

http://nomenclator.amdm.gov.md
https://amdm.gov.md/ro

Romania

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

Desk review up to December 2021

There is the European regulatory provision on medical devices Regulated by ANM (see first link) and a national database of medical devices. There is also an own nomenclature system. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

https://www.anm.ro/en/
https://www.anm.ro/nomenclator-dm/
https://www.anm.ro/en/dispozitive-medicale/regulamentele-europene-privind-dispozitivele-medicale/

Russian Federation

Desk review up to December 2021

There is an own developed nomenclature system but according to the fact that the state is a member of the EEU, which signed an agreement with the GMDN about nomenclature systems harmonization. The common market of medical products within the Eurasian Economic Union (EAEU) begins to function in full in 2022.

https://roszdravnadzor.gov.ru/services/mi_reesetr

Rwanda

Desk review up to December 2021

It uses the GMDN to register medical devices (see first link page 24).

http://www.rwandafda.gov.rw/web/guidelines/Guidelines_for_Regsitration_of_Medical_Devices.pdf

Via the "Questions for Biomedical / Clinical Engineers" survey, the Nabel HealthCare Engineering Ltd. pointed out the main use of the Universal Medical Device Nomenclature System (UMDNS) for Rwanda's medical devices, as well as the coexistence of many nomenclatures for specific procedures. Also, it has been expressed that even with the progress that this country has made in collaboration with the ECRI Institute, there are major challenges caused by the many identification codes used for medical devices.[14]

14 Answered to the August 2021 Survey "Questions for Biomedical / Clinical Engineers"

Sao Tome and Principe

Desk review up to December 2021

Regulated by the Central de Aprovisionamiento de Medicamentos:CAME (see link).

http://ms.gov.st/?p=57

Saudi Arabia

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

A committee inside NUPCO has been established for that purpose and the work is in progress.

http://www.nupco.com

Desk review up to December 2021

Medical devices are regulated by the MOH (first link) via the unit NUPCO (second link) which manages tenders for medical devices. Medical devices are Regulated by the Saudi Food and Drug Authority (third link). Private industry uses the GMDN.

https://www.moh.gov.sa/
https://www.nupco.com/
https://udi.sfda.gov.sa

Senegal

Desk review up to December 2021

Private industry uses the GMDN. The national regulatory authority is the Direction des Infrastructures, d'équipement et de la Maintenance.

https://sante.sec.gouv.sn/les-directions/la-direction-des-infrastructures-des-equipements-et-de-la-maintenance

Serbia

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

National nomenclature is in the process of updating and amendment.

http://www.zdravlje.gov.rs

Desk review up to December 2021

The national regulatory authority is the Medicines and Medical Devices Agency (ALIMS) which assures the use of the official nomenclature.

https://www.zdravlje.gov.rs/tekst/335365/medicinska-sredstva.php

Sierra Leone

Desk review up to December 2021

Medical devices are regulated by a national regulatory authority which is the Pharmacy Board (PBSL). The GMDN is used for registration of medical devices, and it is regularly used by the private industry.

http://www.pharmacyboard.gov.sl/

Singapore

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The Global Medical Device Nomenclature (GMDN) is used as an internal reference and it is not required for medical device product registration

Desk review up to December 2021

The GMDN is used for internal reference but not for the registration of medical products. In addition, since the country is a member of ASEAN, other nomenclature systems are also used. The national regulatory authority is the Health Science Authority.

https://www.hsa.gov.sg/medical-devices

Slovakia

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

Desk review up to December 2021

Regulated by the MoH, it uses the SNOMED system. The national regulatory authority is the Ministry of Health.

https://www.health.gov.sk/Titulka

Slovenia

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

2020

When medical devices are being produced by the manufacturers of medical devices with their registered place of business in the Republic of Slovenia, are notified to the national competent authority, GMDN code should be submitted, if available.

http://www.jazmp.si
https://simap.ted.europa.eu/cpv

Desk review up to December 2021

No changes. The official information is regulated by the JAZMP. The private industry uses the GMDN. The national regulatory authority is the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia.

https://www.jazmp.si/

South Africa

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The regulator has adopted the use of GMDN which will be a nationally accepted nomenclature.

Desk review up to December 2021

There are many co-existent nomenclatures. In many hospitals UMDNS is used. According to the country's legislature the GMDN can be used for special equipment, and IVDs (see first/second link). For medium and high-risk devices, it is obligatory to use the GMDN for manufacturing, importing, exporting and distribution (see first/second link). South Africa, for example, regulates medical devices according to 3 distinct pieces of legislation and guidelines most closely resembling those of the IMDRF founding members (see link 3). The national regulatory authority is the South African Health Products Regulatory Authority.

https://www.sahpra.org.za/wp-content/uploads/2019/09/20180201_SAHPRA-Registration_Medical-Devices_Call-up-plan_v1.pdf
https://www.sahpra.org.za/wp-content/uploads/2020/01/Classification_Medical_Devices_IVDs_Nov19_v2.pdf
https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

South Sudan

Desk review up to December 2021

There is no official nomenclature system in South Sudan (first link 1st paragraph from the beginning of page 6: The South Sudanese Drug and Food Control Authority Act, 2012). One of the nomenclatures that may be used for the registration of medical devices is the one developed by US-FDA (second link: registration requirement's section).

https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf
https://www.wikiprocedure.com/index.php/Sudan_-_Registration_of_medical_device_and_In_Vitro_devices_(IVDs)

Spain

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

2020

The code UMDNS has been used, but will be replaced by GMDN when the Spanish version is available.

(Original in Spanish) *Se ha utilizado el código UMDNS, pero se sustituirá por GMDN cuando esté disponible la versión en español.*

Desk review up to December 2021

It uses the UMDNS as the main nomenclature system. The GMDN is used for the regulation of medical devices in the private sector. Both GMDN and UMDNS are proposed on the official website (AEMPS). Uses the CIMA for medicine (see 2nd link). Regularly, private industry uses the GMDN system. The national regulatory authority is the Agencia Española de medicamentos y productos sanitarios.

https://www.aemps.gob.es/
https://cima.aemps.es/cima/publico/home.html

Sri Lanka

Desk review up to December 2021

Medical devices are regulated by the National Medicines Regulatory Authority (NMRA).

https://nmra.gov.lk/index.php?lang=en

Sudan

Desk review up to December 2021

It uses the UMDNS system, and since 2011 it has officially recommended the use of the GMDN. There is a risk-based classification system (link 4).

https://fmoh.gov.sd/
https://fmoh.gov.sd/Health-policy/Sudan%20HTA&M%20Policy_final.pdf
https://fmoh.gov.sd/index.php/files/index/93
https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

Syrian Arab Republic

Desk review up to December 2021

Medical devices are regulated by the MOH (see link). There is no specific information about the nomenclature system used.

http://www.moh.gov.sy/

Sweden

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

As per regulation 2017/45 on medical devices and Regulation (EU) 2017/746, the EU Member States Competent Authorities of MD representatives (of both the national MoH and the national agencies) of the MDCG, have opted for the publicly available, accessible and transparent nomenclature named European Medical Device Nomenclature (EMDN).

2020

The change from GMDN to EMDN will take place with regards to the implementation of the new EU regulation on medical devices that shall be applied from the 26th of May, 2021.

Desk review up to December 2021

For medical substances registration use SNOMED CT

https://www.lakemedelsverket.se/en/e-tjanster-och-hjalpmedel/substans-och-produktregister/national-substance-register-for-medicinal-products-nsl#hmainbody1

Switzerland

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

Swissmedic uses GMDN (no country specific nomenclature); if manufacturers do not know the GMDN number, a UMDNS code may be given.

Desk review up to December 2021

Both UMDNS and GMDN are used (the preference is given to GMDN, however, if manufacturers do not know GMDN, then UMDNS is used). Currently, there is a transition to EMDN (based on CND), as well as the corresponding mapping with the GMDN. The national regulatory authority is the Swiss Agency for Therapeutic Products, Swissmedic.

https://www.bag.admin.ch/dam/bag/en/dokumente/biomed/forschung-am-menschen/mdr-eu-berichterstattung/mdr-eu-berichterstattung-feb-20.pdf.download.pdf/20200217%20MDR%20IVDR%20Reporting%20BAG%20February.pdf
https://www.bag.admin.ch/bag/en/home.html

Tajikistan

Desk review up to December 2021

It uses the EAEU nomenclature, and the GMDN nomenclature, as well as others. The nomenclature of the manufactured drugs and medical products is determined by the manufacturers themselves as the official website states. The national regulatory authority is the Ministry of Health and Social Protection of the Population of the Republic of Tajikistan.

https://portal.eaeunion.org/sites/odata/redesign/Pages/MedicalDeviceNomenclature.aspx
https://www.wipo.int/edocs/lexdocs/laws/ru/tj/tj036ru.pdf

Thailand

Desk review up to December 2021

In Thailand, the sphere of medical devices is regulated by the Thai-FDA in cooperation with the Association of Southeast Asian Nations (ASEAN) that works together with the AHWP Asian on the harmonization of medical devices regulation. The GMDN is used for the regulation of medical devices in the private industry.

https://www.fda.moph.go.th/sites/fda_en/SitePages/Medical.aspx?IDitem=index
https://asiaactual.com/blog/thailand-implements-new-medical-device-regulations/

Timor-Leste

Desk review up to December 2021

There is an ongoing project for a nomenclature for MD, however there is scarce information.

http://timor-leste.gov.tl/?lang=en

Togo

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The level of the sub-service responsible for the equipment is too low to be read. The hierarchical superiors do not show the necessary interest for the implementation of the management which is essential for medical devices.

(Original in French)*: Le niveau du sous service chargé chargé des équipements est trop bas pour être lisible. Les supérieurs hiérarchique ne portent pas l'intérêt nécessaire pour la mise en oeuvre de la gestion qui s'impose pour les dispositifs médicaux.*

Desk review up to December 2021

https://www.wahooas.org/web-ooas/

Trinidad and Tobago

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

Developed and in use as "Fixed Asset Inventory and Facilities Management". TMA Systems Maintenance Management Software (the nomenclature of medical devices are generally developed by the respective Regional Health Authorities for procurement purposes).

Via the "Questions for Biomedical / Clinical Engineers" survey, the Ministry of Health of Trinidad and Tobago has established that no specific or official nomenclature system is used in this country, but the nomenclature codes given by manufacturers.[15]

Tunisia

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

The nomenclature of medical devices is an integral part of the Manual of biomedical and hospital maintenance management procedures drawn up in 1996 and improved in 2007 by the Ministry of Public Health, which was the subject of an order.

(Original in French) *La nomenclature des dispositifs médicaux fait partie intégrante du Manuel des procédures de gestion de la maintenance biomédicale et hospitalière élaboré en 1996 et amélioré en 2007 par le Ministère de la santé publique qui a fait l'objet d'un arrêté.*

Desk review up to December 2021

It uses a nationally developed nomenclature system, as well as the GMDN for the regulation of medical devices in the private sector.

http://www.dpm.tn/

Türkiye

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

Huab (see second link) is the Turkish registry system for medical devices. Both GMDN and UNSPSC are used in this system. For reimbursement purposes another nomenclature mentioned in the corresponding link is also used.

https://www.saglik.gov.tr/?_Dil=2
http://www.huap.org.tr/ubb/

Desk review up to December 2021

It uses a nomenclature system that is based on the UNSPSC and GMDN, however, they are adapted to national needs. Türkiye y is in the process of using the EU regulation. The national regulatory authority is the Turkish Medicines and Medical Devices Agency, Ministry of Health.

https://www.gs1.org/docs/healthcare/events/220610/8_Turkey_Goksin.pdf
https://www.ispartaeo.org.tr/haber-9
https://www.saglik.gov.tr/TR/

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Uganda

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

See the list of medical equipment by level, and the Standard Medical Equipment Lists and Specifications by healthcare level are under review (as in sample formats in the corresponding websites). The main uses of the nomenclature system are for procurement purposes, and inventory systems in healthcare facilities.

www.health.go.ug

Desk review up to December 2021

There exists a regulatory framework for medical devices registration, importation and use (link 3). However, Risk-based classification does not exist, and the application of the MD regulation is still limited (link 4).

https://www.health.go.ug/download-attachment/ivZtalade9SPz4To_dbsBqwckPflb2S57yGgoi0lTo8
https://www.health.go.ug/download-attachment/wxVPCk1sDLk3NnNJiYkpYY-ohGwUXSeQMm7srliHbMM
https://www.nda.or.ug/medical-devices/#1603100276960-871cf845-bab3
https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

Ukraine

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

https://zakon.rada.gov.ua/rada/show/v0331282-01#Text
https://moz.gov.ua/article/ministry-mandates/nakaz-moz-ukraini-vid-28122019--2711-pro-zatverdzhennja-nomenklaturi-likarskih-zasobiv-ta-medichnih-virobiv-scho-zakupovuvatimutsja-za-naprjamami-vikoristannja-bjudzhetnih-koshtiv-u-2020-roci-za-bjudzhetnimi-programami-kpkvk-2301400

Desk review up to December 2021

The incorporation of the GMDN is in progress. The national regulatory authority is the State Administration of Ukraine on Medicinal Products (SMDC).

https://www.dls.gov.ua/en/state-service-of-ukraine-on-medicines-and-drugs-control/regulation/

United Kingdom of Great Britain and Northern Ireland

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

The Medicines and Healthcare products Regulatory Agency (MHRA) will be moving forward to use solely the GMDN with their system being phased out. The nomenclature used by the National Health System (NHS) for the procurement of medical devices is that used by the “Official Journal of the European Union” (OJEU) CPV codes. The NHS also has a national system known as “e-class” which is a classification system for products and services.

http://www.mhra.gov.uk/Howweregulate/Devices/Registrationofmedicaldevices/index.htm
www.nhseclass.nhs.uk

Desk review up to December 2021

The MHRA will be moving forward to solely use the GMDN with its previous system being phased out. The nomenclature used by the NHS is for the procurement of medical devices that are used by the “Official Journal of the European Union” (OJEU) CPV codes. Also, the NHS has a national system known as “e-class” which is a classification system for products and services. The national regulatory authority is the Medicines & Healthcare products Regulatory Agency (MHRA).

https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#history
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949074/Device_Registration_Reference_Guide_January_2021_Migrated_and_Re-registered_and_New_accounts_Final_v1.pdf
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

United Republic of Tanzania

Country survey (2020) and Nomenclature consultations (2021-2022)

2020

TMDA is using GMDN as the nomenclature system for the registration of medical devices in Tanzania. The main types of nomenclature used are GMDN and UMDNS. The main uses of the nomenclature system are for procurement purposes and inventory systems in healthcare facilities.

http://www.gmdnagency.org

Desk review up to December 2021

It has been used by the GMDN since 2015, but there is no access to the nomenclature code from the official website. It is obligatory to use a nomenclature system as it has been stated in the guidelines for the registration of medical devices.

https://www.tmda.go.tz/publications/24
https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

United Arab Emirates

Desk review up to December 2021

There is a nationally developed nomenclature but it is allowed the co-existence of several nomenclatures (often suggested by the importer -see first two links-). Regulated by the MOH (see links).

https://www.mohap.gov.ae/Files/MOH_OpenData/562/MoH-UAE-Registred-MD-2-2-2014.pdf
https://www.mohap.gov.ae/Files/MOH_Service/373/09%20Classification%20of%20a%20ProductEN.pdf
https://www.mohap.gov.ae/en/services/issuing-a-permission-to-import-medical-equipment

United States of America

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

1. Product Code. FDA- The Center for Devices and Radiological Health (CDRH) uses a nomenclature by assigning a 3-letter code to identify a device into a generic type or category. This nomenclature system is known as product code classification. The short name is ProCode. The Product Code Classification Database contains medical device names and associated information developed by the CDRH in support of its mission. This database contains device names and their associated product codes. The name and product code identify the generic category of a device for the FDA. The Product Code assigned to a device is based upon the medical device product classification designated under 21 Code of Federal Regulations (CFR) Parts 862-892.2. Problem code FDA-CDRH also has a nomenclature for CDRH Event Problem Codes for Medical Devices used in reporting adverse device events. The adverse event vocabulary codes were developed in cooperation with the National Cancer Institute Enterprise Vocabulary Service (NCI-EVS); see the second link.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051637.htm
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/default.htm

Desk review up to December 2021

https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database

Via the "Questions for Biomedical / Clinical Engineers" survey, the U.S. Food and Drug Administration has specified that, besides their product codes for medical device classification, the Global Medical Devices Nomenclature (GMDN) is the official nomenclature used in the UDI system and for all medical device requirements in this country.[16]

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Uruguay

Desk review up to December 2021

UMDN is commonly used in the Mercosur bloc.

https://www.gub.uy/ministerio-salud-publica/home

Uzbekistan

Desk review up to December 2021

It uses its own nomenclature system (see first link). Used nomenclature correlates with one used by the EU (second link).

https://data.gov.uz/uz/datasets/3514?dp-1-sort=G1

Venezuela (Bolivarian Republic of)

Country survey (2020) and Nomenclature consultations (2021-2022)

2021-2022

Does not have one specific nomenclature. For the certification of the medical device, the nomenclature used is the U.S FDA product classification.

https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database

Via the "Questions for Biomedical / Clinical Engineers" survey, the Simon Bolivar University informed that it has defined the U.S. Food and Drug Administration product codes as the official nomenclature system used for medical devices in this country. Also, this institution has developed the "Quality Certification Process for Medical Equipment", which has been authorized by the Ministry of Health of Venezuela.[17]

https://www.legiscomex.com/BancoMedios/Documentos%20PDF/res_614.pdf

Yemen

Desk review up to December 2021

Regulated by the Supreme Board for Medicines & Medical Appliances (SBDMA)/ MoPHP.

www.sbd-ye.org

Zambia

Desk review up to December 2021

Regulated by the Zambia Medicines Regulatory Authority (ZAMRA).

https://www.zamra.co.zm

Zimbabwe

Desk review up to December 2021

Regulated by the Medicines Control Authority of Zimbabwe (MCAZ).

https://www.mcaz.co.zw

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Conclusion

As presented in this report, there are various nomenclature systems (EMDN, GMDN, nationally developed, and UMDNS) used around the world for different purposes. Nevertheless, less than one-half of the world does not have an official nomenclature to manage medical devices, and more than half have at least one of the four types mentioned above. This situation has been continuously evolving in the past ten years, with promising signals of more countries acquiring an official nomenclature and also signals of multiple nomenclatures being used for different purposes around the world. Several efforts are currently in place to harmonize not only the heterogeneous regulatory framework worldwide, but more specifically a international nomenclature system. Until now, these efforts have not been achieved due mainly to a lack of agreement between the main stakeholders and member states. As indicated before, the nomenclature system of medical devices is a cross-cutting issue that interrelates the national health system with other areas such as the economy, commerce, and health service provision within a country as well as with other countries due to globalization and regional agreements between countries.

However, we observe a positive trend of countries strengthening their regulatory frameworks, harmonizing their procedures, and adopting an official medical device nomenclature. To the extent that the health system is strengthened, it will facilitate the provision of services to achieve faster a universal health coverage.

Other limitations: More often than not, several regulations and agreements may be in use in a country for different purposes but also for a single purpose. For instance, it is possible to have more than one agreement regarding imports and exports depending on the destination or origin of merchandise. As a consequence, sometimes there may be more than one answer to the questions we ask.

It is a milestone achivement that the World health assembly approved In May 2022, the co-existance of various nomenclature systems in WHO platforms for reference to be available, accessible to all Member States, towards standardization.

Acknowledgements

This overview was commissioned by WHO and conducted by Ricardo X. Martinez Martinez, Lucero López Pérez, Lucía Jiménez Martínez, Juan J. López Pérez, Artem A. Shchepilov, Sebastián Losada Espinosa, David López Pérez. Many thanks to Eunice Lourenço Nobre da Conceição for her valuable comments and additions.

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