Access to safe, effective and quality-assured health products and technologies

Roadmap for WHO action 2025–2030

World Health Organization

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Preface

Health products and technologies are essential for prevention, diagnosis, treatment, monitoring, rehabilitation, and palliative care. They save lives and improve well-being, playing an integral role in achieving universal health coverage. Yet, all too often, these products are unavailable or unaffordable to those who need them most. Despite progress, challenges in delivering these tools persist, particularly in low- and middle-income countries.

Advancement on universal health coverage has stagnated and people continue to be pushed further into poverty due to out-of-pocket health spending. Inequalities remain a fundamental challenge, disproportionately affecting those living in poverty, conflict zones, older persons, individuals with disabilities, women, children, and other vulnerable and marginalized groups. Persistent issues such as substandard and falsified medical products, shortages and stockouts and insufficient data for decision-making and measuring progress present significant challenges that we must address collectively.

The challenges for improving access to safe, effective, and quality-assured health products and technologies are well known. They include a lack of research addressing public health needs, insufficient regulatory capacity in countries, ineffective policies for selecting and prioritizing, inadequate financing and reimbursement, and supply chain inefficiencies. These barriers are complex, requiring concerted effort and collaboration from many different stakeholders.

A changing world demands renewed investments in research and development for innovative health solutions and concerted efforts to ensure timely and equitable access both in and outside of emergency situations. Innovations are most powerful when they reduce inequalities and respond to public health needs rather than becoming another reason people are left further behind.

The World Health Organization (WHO) is committed to improving access to safe, effective, and quality-assured health products and technologies. The Access to Medicines and Health Products Division leads critical regulatory and policy support to Member States in this regard. WHO's expertise and leadership are indispensable in delivering the complex and wide-ranging support needed to address the myriad challenges within the health product and technology ecosystem.

WHO is widely recognized for its leadership in driving the public health agenda and convening global experts and stakeholders to leverage collective knowledge. Its combination of global reach, technical authority, networks for information exchange, and cross-sectoral collaboration capabilities gives WHO an unparalleled position in leading work on access to safe, effective and quality-assured health products and technologies globally. Valued for its consideration of implementation realities and grounded in a unique understanding of diverse contexts and national priorities, WHO is mandated and trusted by Member States to develop authoritative, evidence-based guidance, to deliver capacity building and to establish and manage global platforms.

The Access to safe, effective and quality-assured health products and technologies: roadmap for WHO action 2025–2030 provides a comprehensive outline of WHO's unique role and approach in increasing access to these vital health products and technologies. Our goal is to support Member States to reach Sustainable Development Goal targets for achieving universal health coverage, including financial risk protection, access to quality essential health-care services, and access to safe, effective, quality, and affordable health products and technologies.

We must expand collaborative approaches to close the gaps in unmet needs for health products and technologies. I am grateful to the support of our many partners and stakeholders and extend my heartfelt appreciation to all colleagues for their invaluable efforts and tremendous contributions. Together, we can build a healthier future for all. Let us reaffirm and renew our political commitment to accelerate the implementation of the 2030 Agenda for Sustainable Development, including enhancing efforts to ensure access to safe, effective, quality-assured essential medicines and other health products.

Dr Yukiko Nakatani

Assistant Director-General
Access to Medicines and Health Products (May 2023 to June 2025)
Health Systems (from June 2025)

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Abbreviations

APIs	Active pharmaceutical Ingredients
ATC	Anatomical Therapeutic Chemical Classification
COVID	Coronavirus disease
CRP	Collaborative Registration Procedure
DDD	Defined daily dose
FPP	Finished pharmaceutical product
GBT	Global Benchmarking Tool
GPW	General Programme of Work
INN	International Nonproprietary Names
MeDevIS	Medical Devices Information System
ML	Maturity level
mRNA	messenger ribonucleic acid
NRA	National Regulatory Authority
PHC	Primary health care
R&D	Research and development
SDG	Sustainable Development Goals
TRIPs	Trade-Related Aspects of Intellectual Property Rights
UHC	Universal health coverage
WHA	World Health Assembly
WHO	World Health Organization

Executive summary

Access to safe, effective and quality-assured health products and technologies is crucial for achieving universal health coverage and primary health care goals. The continued growth of the aging population; increasing burden of noncommunicable diseases; growing burden of mental health issues; climate change; shifting patterns of vector borne diseases, fungal disease and waterborne diseases; antimicrobial resistance; and new infectious hazards create an ongoing need for equitable access to safe, effective and quality-assured health products and technologies, and renewed investments in research and development for innovative health products and technologies.

The coronavirus pandemic exposed the inequalities in access to health products, highlighting the need for longer-term strategies to strengthen access to health products and technologies outside of and in emergency situations. While technological and scientific advances present an opportunity to increase access to health products and technologies, the risk of increasing inequality due to higher prices for new health products and technologies; the persisting problem of substandard and falsified medical products; a lack of skilled workforce in many low- and middle-income countries; and a lack of data for decision-making and for measuring progress present significant challenges.

In 2019, WHO underwent reform to better meet the United Nations Sustainable Development Goals and its own "triple billion" targets as described in the 13th General Programme of Work. A new structure was established and the Access to Medicines and Health Products Division was recognized as the leading division in Headquarters in supporting Member States to improve access to safe, effective and quality-assured health products and technologies. Certain roles such as the establishment of priority or essential lists, technical specifications, regulatory guidance and standards, regulatory strengthening, the issuance of nonproprietary names, and prequalification are unique to the Division.

The Access to safe, effective and quality-assured health products and technologies: roadmap for WHO action 2025–2030 outlines to Member States, and other stakeholders WHO's unique role and approach for increasing access to safe, effective and quality-assured health products and technologies in order to reach Sustainable Development Goal targets for achieving universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all. WHO's expertise and leadership are essential for delivering the complex and wide-ranging support needed to address the many challenges in the health product and technology ecosystem.

The roadmap highlights how the work of WHO aligns with and contributes to WHO's 14th General Programme of Work, particularly Strategic objective 3: Advance the primary health care approach and essential health system capacities for universal health coverage. The roadmap outlines WHO's 5 programmatic priority areas for access to safe, effective and quality-assured health products and technologies and elaborates the priorities within each area:

- **Programmatic area 1** • Research, development and production;
- **Programmatic area 2** • Safety, efficacy, and quality assurance;

- **Programmatic area 3** • Policy and prioritization;
- **Programmatic area 4** • Procurement and supply chain management, provision and use; and
- **Programmatic area 5** • Cross-cutting.

This year marks the 50th anniversary of the first mention of the concept of essential medicines by the World Health Assembly, a well-recognized and transformational public health concept. The anniversary offers an opportunity to reaffirm and renew political commitment to accelerate the implementation of the 2030 Agenda for Sustainable Development including enhancing efforts to ensure access to safe, effective, quality-assured essential medicines and other health products and technologies.

Improving the affordability, availability, accessibility, acceptability and assured quality of health products and technologies requires the collaboration of stakeholders; strong, effective, and reliable regulatory, legal and policy frameworks; adequate health-care financing; and a trained and capable health workforce. Going forward WHO will continue to adapt approaches to keep pace with the ever-evolving health landscape and to address new challenges and to make the most of new opportunities.

About the roadmap

The Access to safe, effective and quality-assured health products and technologies: roadmap for WHO action 2025–2030 (hereafter called the roadmap 2025–2030) was developed following the positive response from stakeholders to the Roadmap for access to medicines, vaccines and health product 2019–2023 (hereafter called the roadmap 2019–2023) *(1)*. The aim of the roadmap 2025–2030 is to share information on WHO's comprehensive work on access to health products and technologies with Member States and other stakeholders involved in supporting access to safe, effective and quality-assured health products and technologies. The document summarizes WHO's work on health products and technologies across the organization and shows how the work aligns with and contributes to global health goals, WHO's General Programme of Work (GPW) and other strategies and frameworks.

The roadmap 2025–2030 builds on the roadmap 2019–2023, considering the lessons learnt from implementation of the roadmap 2019–2023, from the WHO transformation and from the coronavirus (COVID-19) pandemic. As with the previous version, the roadmap 2025–2030 outlines WHO's approach for increasing access to safe, effective and quality-assured health products and technologies for the period in order to reach sustainable development goal (SDG) targets for achieving universal health coverage (UHC), including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

The roadmap 2025–2030 covers the various dimensions of access in the health product and technology ecosystem. The scope includes equitable access during outside of and in pandemic and public health emergency situations. Areas that fall outside the scope of this document include the health system components of leadership and governance, service delivery, health systems financing, health workforce and health information systems (covered under WHO's work on strengthening health systems); development of clinical guidelines and recommendations (covered under the strategies of the specific disease programmes within WHO); and traditional medicines (see Global Traditional Medicine Strategy 2025–2034 *(2)*). Digital health technologies used for diagnosis, treatment and assistive care are included as they are considered as medical devices or assistive products, but other digital technologies are outside the scope of this roadmap. Some aspects of work on antimicrobial resistance are covered in the roadmap otherwise see: the WHO strategic and operational priorities to address drug-resistant bacterial infections in the human health sector 2025–2035 *(3)*.

The roadmap 2025–2030 is aligned with the GPW14 and contributes to its overarching goal to promote, provide and protect health and wellbeing for all people, everywhere.S The roadmap is guided by the World Health Assembly and Regional Committee resolutions and strategies presented in the roadmap 2019–2023 and updated in Annex 1. The document does not provide an operational plan as this is developed at the regional or departmental level and articulated through regional or departmental strategies and the WHO Programme Budget. The roadmap 2025–2030 was developed under the leadership of the WHO Access to Medicines and Health Products Division and with broad consultations with WHO Departments, Regional and Country Offices, Member States and other key stakeholders. Key terms as used in the roadmap are explained in Annex 2.

Introduction

Access to safe, effective and quality-assured health products and technologies is a fundamental element in achieving the right of every human being to the enjoyment of the highest attainable standard of health without distinction of race, religion, political belief, economic or any other social condition *(4)*. Health products and technologies are critical to achieve every health target in the SDGs, are essential to all disease management strategies and to save lives in emergency and pandemic situations. They are used across the life course for prevention, diagnosis, treatment, rehabilitation, pain relief and palliative care. As such, access to health products and technologies is considered essential for reaching universal health coverage and primary health care (PHC) goals. It is also a critical component of strategies to ensure resilient health systems to prevent, prepare for, detect, adapt to, respond to and recover from public health threats while also ensuring the maintenance of health services in all contexts, including in fragile, conflict and violence settings.

When WHO declared COVID-19 a public health emergency of international concern on 30 January 2020, achieving timely and equitable access to safe, effective and quality-assured health products and technologies became central to the response. The pandemic exposed the inequalities in access which persist in the face of ongoing crises and create new and urgent demands for health care. The pandemic highlighted the need for longer-term strategies to strengthen equitable access to health products and technologies required for emergency response and for ensuring uninterrupted and sustainable provision of health products and technologies outside and in emergency situations *(5)*.

The constant evolution of demographic, epidemiologic, environmental and economic changes places new burdens on health outcomes and the needs for health products and technologies to address those burdens. Emerging resistance to key treatments results in an ongoing need for research and development (R&D) and timely, affordable access to new products. The aging population continues to grow and with it, noncommunicable diseases, many of which require long term treatments and care. There is a growing burden of mental health, unfinished communicable disease agendas, antimicrobial resistance and new infectious hazards. The changing climate is shifting patterns for vector-borne diseases such as malaria and dengue, fungal disease and waterborne diseases such as cholera. The needs for health products and technologies will change as the patterns, timing, duration and endemicity of these diseases change. New awareness on the effects of plastic in health systems and of health care waste on people's health and that of the environment calls for urgent attention to more sustainable design and use of health products and technologies.

Despite progress, safe, effective and quality-assured health products and technologies are still not reaching those who need them in many countries (Box 1). Improving access to health products and technologies is a multidimensional challenge involving numerous stakeholders, complex and interdependent processes, competing interests and complex regulatory, legal and policy frameworks. The cost of health products and technologies remains unaffordable for many countries or contributes to high out-of-pocket expenditure for patients. The entry of sub-standard and falsified medical products into the global supply chain is an ever-present challenge. Many low- and middle-income countries lack the skilled workforce required to ensure safety, efficacy and quality; for manufacturing and production, for managing supply chains and for

adequate provision to the patient. Challenges to ensure access are further complicated by a lack of data for national decision making and for measuring progress on national and global interventions.

Box 1

Access challenges for health products and technologies

2 billion people are experiencing hardship due to out-of-pocket health spending, a majority of which includes spending on health products *(6)*.

The global estimated spend on substandard and falsified medicines is estimated at $30.5 billion in low- and middle-income countries *(7)*.

The proportion of health facilities with a core set of relevant essential medicines available and affordable on a sustainable basis in 28 low- and lower-middle-income countries between 2004–2019 ranges from 0% to 41% *(8)*.

2.5 billion people globally need one or more assistive product *(9)*.

In 2023, vaccination coverage was below the 90% Immunisation Agenda 2030 (IA2030) target for several important vaccines across the life course *(10)*.

Technological and scientific advances, such as artificial intelligence, digital health, robotics, and new materials, for example offer opportunities for the development and delivery of health products and technologies and new approaches to address public health needs. Emerging technologies and advanced therapies also offer opportunities to improve health outcomes. New approaches to manufacturing and technology transfer established during COVID-19 can be scaled up and expanded to address other disease areas. The establishment of the concept of maturity levels (ML) for National Regulatory Authorities (NRAs) offers a framework for enhanced regulatory oversight and reliance and also strengthens regulatory capacity to ensure the quality of health products and technologies.

50 years ago, the essential medicines concept was introduced to the World Health assembly. The concept was recognized as a major transformational public health concept that revolutionized how governments can promote the availability, accessibility, affordability, quality, and rational use of medicines. The anniversary offers an opportunity to reaffirm and renew political commitment to accelerate the implementation of the 2030 Agenda for Sustainable Development including enhancing efforts to ensure access to safe, effective, quality-assured essential medicines and other health products and technologies.

WHO's unique role in improving access to safe, effective, quality-assured health products and technologies

More people, everywhere, attain the highest possible standard of health

WHO supports Member States to improve access to quality-assured health products and technologies critical for the achievement of UHC, PHC and health security goals and emergency preparedness and response. WHO's work on access to health products and technologies builds on the work done under WHO's GPW13 and contributes to all GPW14 goals to promote, provide and protect health (Fig. 1).

The key strategic objective for the access work is under the GPW14 Provide goal 3: *to advance the primary health care approach and essential health system capacities for universal health coverage*. Access to health products and technologies is part of the joint outcome 3.2: *health and care workforce, health financing and access to quality-assured health products substantially improved*; and the output 3.2.3 *WHO supports countries to implement measures for better access to, and use of, safe, effective and quality-assured health products*.

Fig. 1 Access to quality-assured health products and technologies within the GPW14

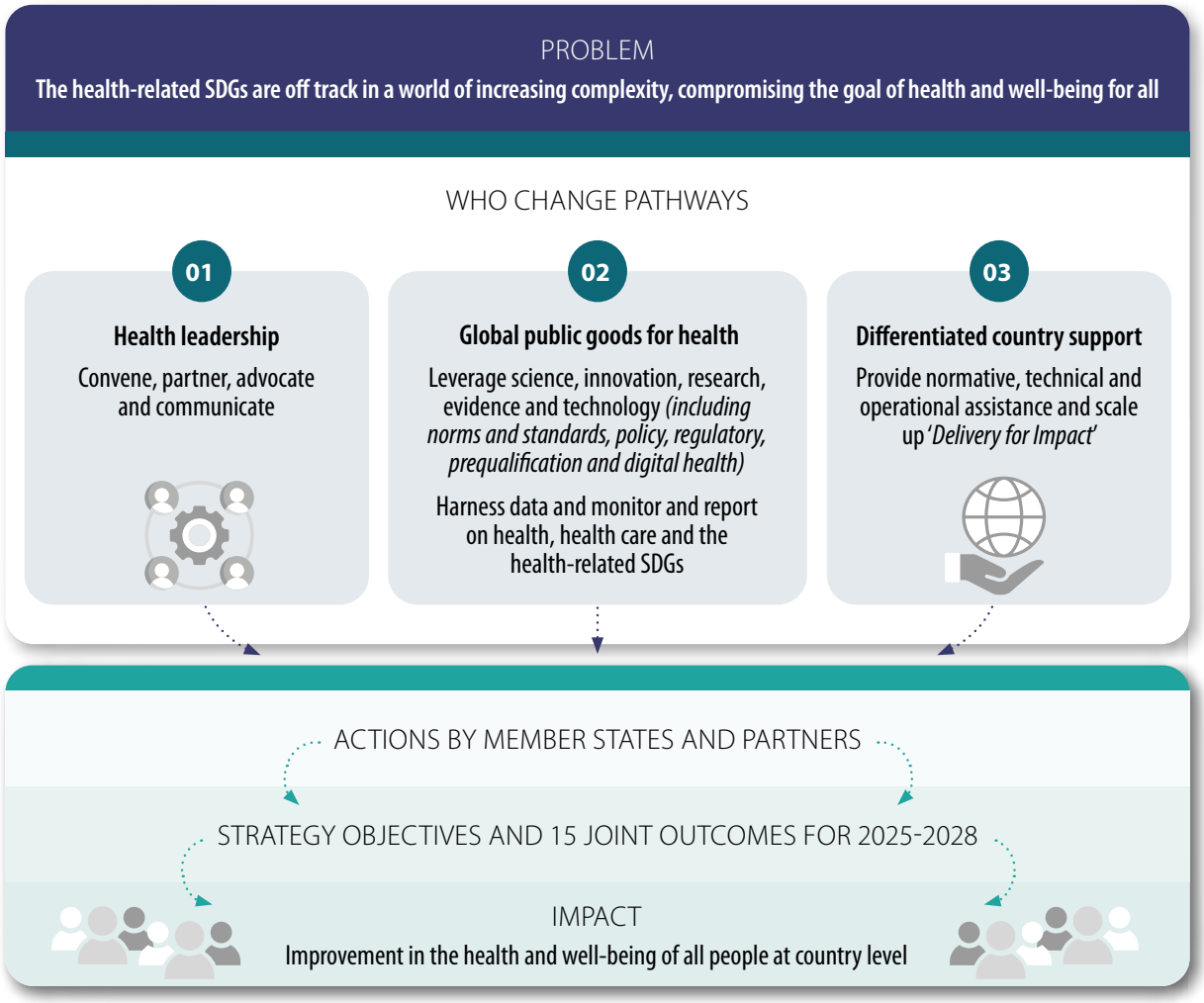
IMPACT	More people, everywhere, attain the highest possible standard of health and well-being
OVERARCHING GOAL	To promote, provide and protect health and well-being for all people everywhere
STRATEGIC OBJECTIVE	Advance PHC approach and essential health system capacities for UHC
JOINT OUTCOME	3.2 Health and care workforce, health financing and **access to quality-assured health products substantially improved**
GPW14 OUTPUT	3.2.3 WHO supports countries to implement measures for better access to, and use of, safe, effective and quality-assured health products

WHO's work on health products and technologies also contributes to other strategic objectives including improved access to quality services for noncommunicable diseases, mental health conditions and communicable diseases, addressing antimicrobial resistance and improving equity in access for sexual, reproductive, maternal, newborn, child, adolescents and older person health and immunization coverage. WHO's work on access to health products and technologies is also critical for access to medical countermeasures under the protect goal, by ensuring timely access to safe, effective and quality-assured health products and technologies.

A broad scope of work

WHO's mandate in supporting Member States to improve access to safe, effective and quality-assured health products and technologies is firmly established in the WHO constitution (Article 2) *(11)*. WHO's role as a leader, developer and provider of norms and standards and provider of technical support is outlined in the GPW14 (Fig. 2). The mandate to provide leadership, global public goods and country support for access to safe, effective and quality-assured health products and technologies has continued to expand in response to the numerous World Health Assembly and Regional Committee resolutions outlined in Annex 1.

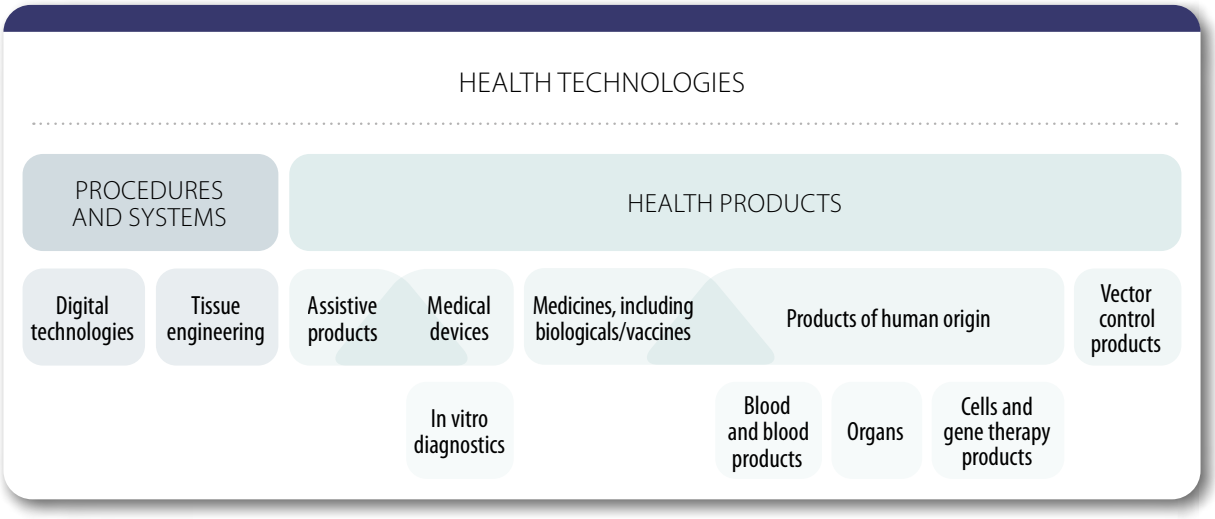
Fig. 2 GPW 14 theory of change



Source: A Global Health Strategy for 2025–2028, advancing equity and resilience in a turbulent world, Fourteenth General Programme of Work *(12)*.

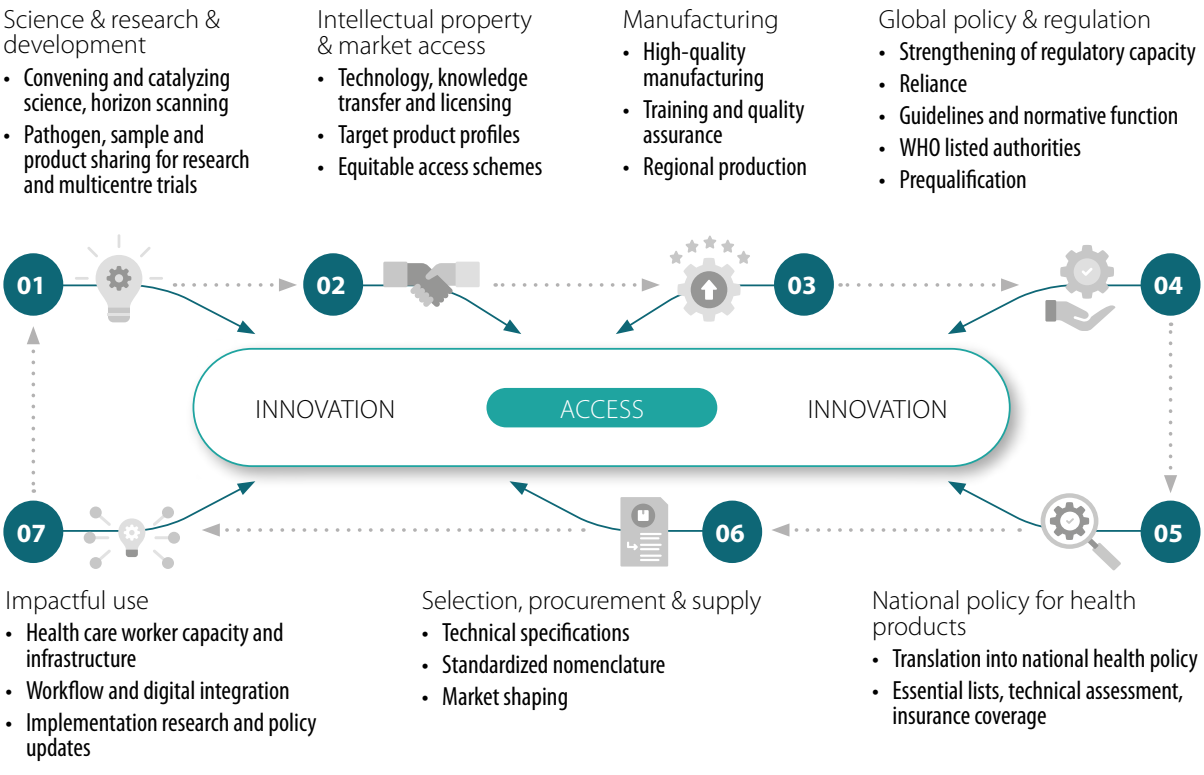
WHO supports Member States for access to a range of health technologies including procedures and systems and a range of health products such as medicines, vaccines, medical devices, including in vitro diagnostics, assistive products, blood, and other products of human origin, as well as vector control products (Fig. 3).

Fig. 3 Types of health products and technologies within the mandates provided to WHO



WHO's stewardship role in driving innovation forward and translating science into products and programmes is outlined in WHO's All for Health, Health for All Investment case 2025–2028 (Fig. 4) *(13)*. The role cuts across the global ecosystem from priority-setting to supporting Member States to access innovation in a timely manner.

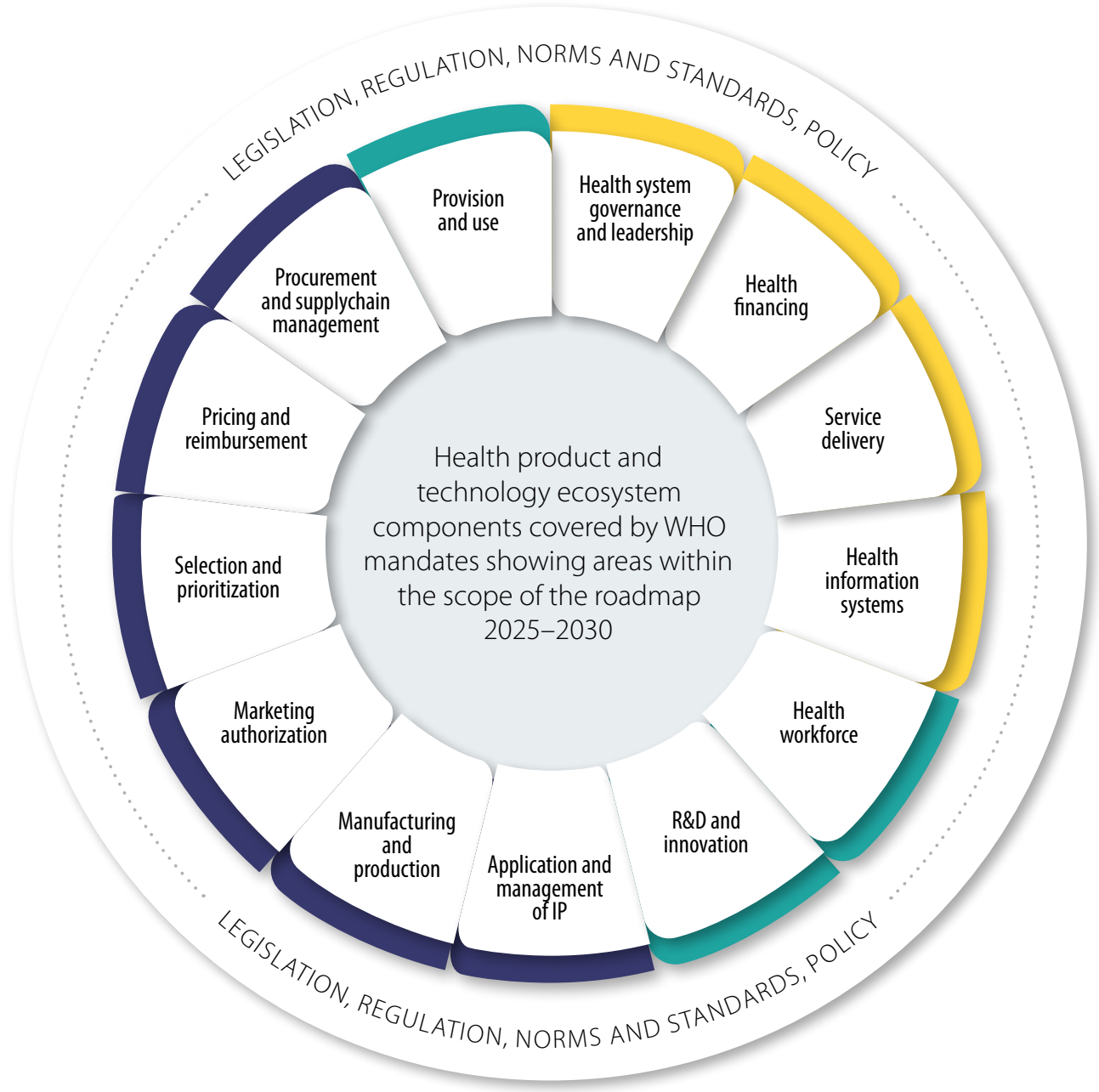
Fig. 4 WHO end-to end role in accelerating access to life-saving innovation



Source: All for Health, Health for All Investment case 2025–2028 *(13)*.

WHO's mandate covers both innovative products and products that have been on markets for many years. Comprehensive support is provided to Member States on the entire health product ecosystem (Fig. 5) from the health system building blocks of governance, financing, service delivery, health information systems and workforce to the value chain components including R&D to manufacturing, procurement and supply chain management, to provision and use.

Fig. 5 Health product and technology ecosystem components covered by WHO mandates showing areas within the scope of the roadmap 2025–2030



In addition to providing support for access to health products and technologies in peacetime, WHO supports Member States for equitable access to health products and technologies that are used to prevent or manage epidemic and pandemic diseases (medical countermeasures). The multilateral discussions through the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, as well as the work of the Working Group on amendments to the International Health Regulations will further guide WHO's work in this area including on the interim networked mechanism to enhance collaboration for timely and equitable access to medical countermeasures against pandemic threats, the network-of-networks approach (i-MCM-Net) *(14)*.

Unique and cross-cutting roles

In 2019, WHO underwent reform to better meet the United Nations Sustainable Development Goals and its own "triple billion" targets as described in the GPW13: 1 billion more people benefitting from universal health coverage; 1 billion more people better protected from health emergencies; and 1 billion more people enjoying better health and well-being. A new structure was established to increase alignment between Headquarters and Regional and Country offices and to be more effective and efficient as the world's leading authority on public health. The Access to Medicines and Health Products Division was recognized as the leading division in WHO Headquarters in supporting Member States to improve access to safe, effective and quality-assured health products and technologies (Fig. 5). Certain roles such as the establishment of priority or essential lists, technical specifications, regulatory guidance and standards, regulatory strengthening, the issuance of nonproprietary names, and prequalification are unique to the Division. Some other areas of work are cross-cutting in nature such as antimicrobial resistance, emergency preparedness and response, and specific disease areas. Selected examples of outputs resulting from these cross-cutting collaborations are shown in Box 2.

Box 2

Examples of cross-cutting collaborative outputs

- Application of parallel, coordinated, and independent evaluation procedures for health products that are eligible for prequalification and require WHO recommendations on their use
- Global Accelerator for Paediatric Formulations (GAP-f)
- Global hepatitis report 2024: action for access in low- and middle-income countries
- Improving access to medicines for neurological disorders
- Improving the health and wellbeing of people living with neglected tropical diseases through rehabilitation and assistive technology: thematic brief
- Interim Medical Countermeasures Network (i-MCM-Net)
- Keeping the 100-year-old promise: making insulin access universal
- mRNA vaccine technology transfer hub
- Regulatory guidance for assessment and management of applications for marketing authorization of oxytocin
- Universal Health Coverage compendium
- WHO AWaRe (Access, Watch, Reserve) antibiotic book
- WHO Diagnotic Task Force

Guided by experts

WHO's normative work on access to health products and technologies is guided by numerous expert and advisory committees. An Expert Committee is the highest official advisory body to the Director-General of WHO as well as to all the Organization's Member States and is established by the WHO World Health Assembly (WHA) or by an Executive Board decision. WHO also brings together individual experts to provide scientific, technical and/or strategic advice through strategy advisory groups. Box 3 shows a non-exhaustive list of expert and advisory committees advising on health products and technologies.

Box 3

Non-exhaustive list of WHO expert and advisory committees advising on health products and technologies

- Advisory Committee on Safety of Medicinal Products
- Advisory Group for Blood Regulation, Availability and Safety
- Expert Committee on Biological Standardization
- Expert Committee on Drug Dependence
- Expert Committee on Selection and Use of Medicines
- Expert Committee on Specifications for Pharmaceutical Preparations
- Global Advisory Committee on Vaccine Safety
- Immunization and vaccines related implementation research advisory committee
- International Nonproprietary Names Expert Group
- Product Development for Vaccines Advisory Committee
- Strategic Advisory Group of Experts on Immunization
- Strategic Advisory Group of Experts on In Vitro Diagnostics
- Strategic and Technical Advisory Group on Medical Devices
- Strategic Technical Advisory Group on Antimicrobial Resistance
- Technical Advisory Group on Assistive Technology
- Technical Advisory Group on Local Production and Technology Transfer of Health Products
- Technical Advisory Group on Market Access for Vaccines
- Technical Advisory Group on Pricing Policies for Medicines
- Technical Advisory Group on the Use of Digital Technologies to Enhance Access to Assistive Technologies
- Technical Advisory Group on WHO Listed Authorities
- WHO Advisory Group on Drug Statistic Methodology

Working with stakeholders at the global, regional and national levels

Numerous stakeholders throughout the ecosystem have a role in access to safe, effective and quality-assured health products and technologies. Academia, private sector entities and other partners are conducting research and manufacturing health products and technologies. Regulatory authorities are responsible for ensuring safety, efficacy and quality assurance. Ministries of health are responsible for developing and implementing national policies on health products and technologies, working with other ministries where relevant. A range of health care professionals are involved in provision and use, including for example procurement personnel, biomedical engineers, doctors, nurses, pathologists, pharmacists, physical therapists, rehabilitation personnel and community health workers. WHO's normative guidance and technical assistance on health products and technologies reach all of these stakeholders.

Technical collaborations across the globe

WHO benefits from technical collaboration with partners and stakeholders across the globe including WHO collaborating centres and non-State actors in official relations with WHO and benefits from valuable technical expertise and support from secondments and from the energy and new ideas of junior professional officers.

Progress on the roadmap 2019–2023

During the period 2019–2023, WHO work was critical for enabling timely access to quality-assured COVID-19 medical countermeasures (vaccines, treatments and medical devices, including diagnostics), while delivering on the numerous milestones outlined in the roadmap 2019–2023. This was a remarkable achievement considering the acute demands for timely access to health products and technologies for COVID-19 while simultaneously managing the constraints for the working environment that the pandemic created. Progress on WHO's work on access to health products and technologies for the period 2019–2023 has been reported in the WHO Results Report 2020–2021 and the WHO Results Report 2022–2023. Progress has also been reported in several departmental annual reports *(15, 16)* and in progress reports presented to the World Health Assembly and to the Regional Committees (Annex 1). Selected highlights from the 2022–2023 report are shown in Box 4.

Box 4

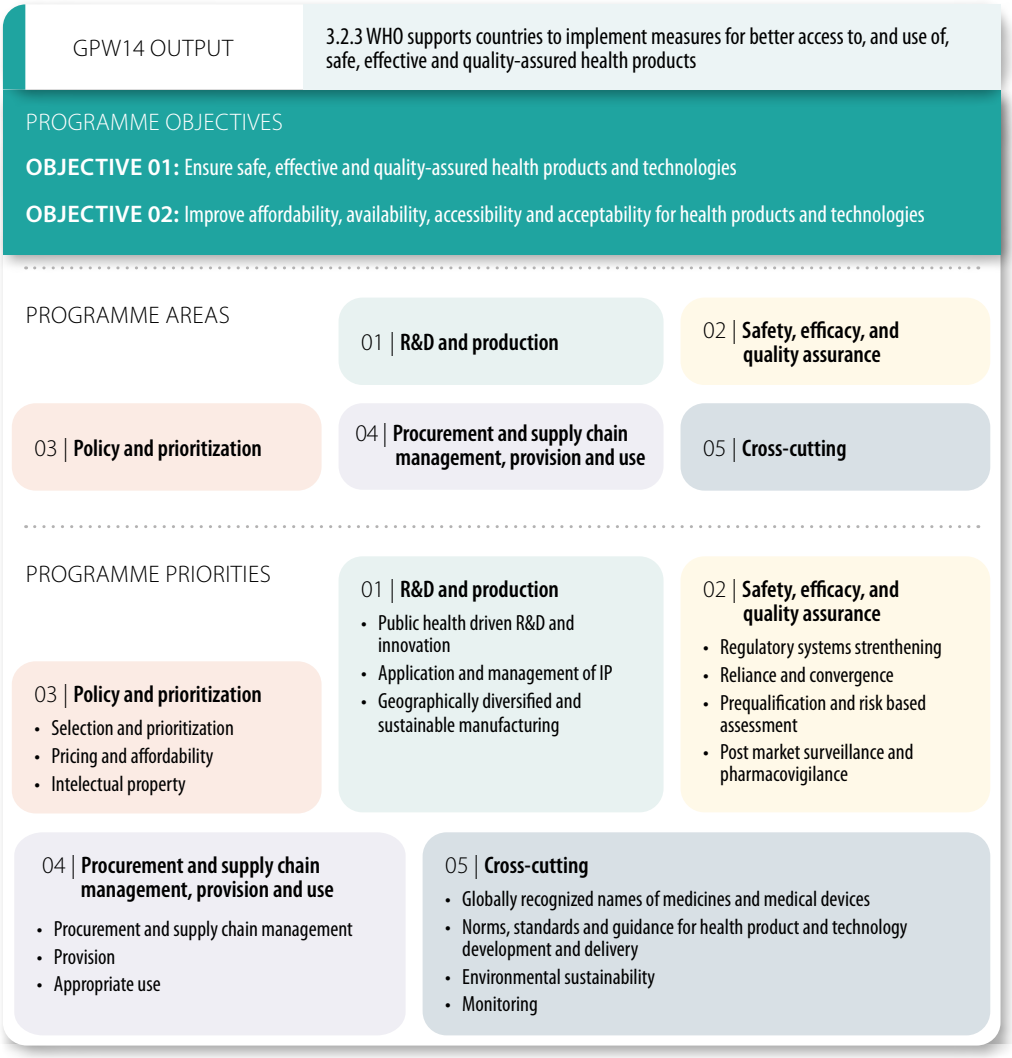
Highlights from WHO Results Report 2022–2023

- 58 national regulatory authorities achieved stable and well-functioning regulatory systems commensurate with ML3 or ML4 for at least one product type.
- 340-400 million more patients have access thanks to resources freed up by prequalification.
- Over 500 incident reports of suspected substandard and falsified medical products were received in 2023.
- 12,000 globally recognized (generic) names for pharmaceutical substances have been issued contributing to safety, efficacy and affordability.
- 92 countries initiated a national priority medical devices list, including essential in vitro diagnostics.
- 62 million persons were protected for life from yellow fever via campaigns and an additional 17.4 million children protected via routine immunization in Africa in 2023.
- Administration of more than 800 million vaccinations against polio in more than 30 countries in 2023.

Strategy for ensuring equitable, affordable access to safe, effective and quality-assured health products and technologies

WHO's work on access to safe, effective, quality-assured health products and technologies is structured around 2 interlinked programmatic objectives: ensure safe, effective and quality-assured health products and technologies; and improve affordability, availability, accessibility and acceptability for health products and technologies (Fig. 6). To reach these objectives WHO has 5 key programme areas including R&D and production; safety, efficacy and quality assurance; policy and prioritization; procurement and supply chain management, provision and use; and cross-cutting areas. Priorities within the programme areas reflect both ongoing core work of the organization and new areas of focus. The programmatic priorities reflect the full scope of WHO's work on health products and technologies and are further detailed in Annex 3 along with their outputs and outcomes. Note that the outcomes in this roadmap are named as intermediate outcomes as they lead to the GPW outcome: access to quality-assured health products and technologies substantially improved.

Fig. 6 Programme objectives, areas and priorities



Programme area 1
R&D and production of health products and technologies

Innovative health products and technologies for both infectious and noncommunicable diseases are still needed to address global public health problems, but much of the R&D pipeline still focuses on high-income country concerns and is driven by financial return *(17)*. Design and development of new products that take into consideration low- and middle-income settings from the outset can better address public health needs. Patent protection provides an incentive for R&D leading to innovation but, may also pose challenges for accessing affordable alternatives. Capacity is limited in many countries to apply and manage intellectual property rules in a manner that maximizes innovation and promotes access that is consistent with the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and other World Trade Organization's instruments. Low manufacturing capacity and capability in geographically diverse regions can contribute to poor access to health products and technologies that can be exacerbated in times of public health emergencies, such as was experienced during the COVID-19 pandemic. Country capacity to assess ecosystems and feasibility to locally produce safe, effective and quality-assured products and technologies and to secure tech transfer is low in many countries.

WHO's priorities under this programme area include:

- public health driven R&D and innovation;
- geographically diversified and sustainable manufacturing; and
- application and management of intellectual property rules.

WHO work in this area will contribute to better research prioritization for both pandemic preparedness and response as well as other public health priorities. It will also contribute to a better understanding of health products and technologies that are needed for public health goals and allow stakeholders to anticipate innovative technologies. Building capacity in countries will lead to more equitable R&D based on country needs. In line with the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property, the work will encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and technologies that is consistent with the provisions in the TRIPS Agreement and other international instruments.

WHO work on geographic diversification of sustainable production enables improved translation and absorption of R&D. Partners will be able to secure technology through access sharing mechanisms and scale up production. In the right settings, the work has the potential to improve affordability and enhance acceptability of specific health products and technologies. The work will contribute to sustainable production of health products and technologies and support the response to shortages. New products will address unmet needs in low- and middle-income countries and contribute to generate revenues that will sustain the investment both outside of and in pandemic and emergency situations. The work in this area leverages the strengths of complementary models.

WHO is widely recognized for its leadership in driving the public health agenda and convening global experts and stakeholders to leverage collective knowledge. Notable leadership initiatives in this programme area include R&D Blueprints, R&D Consortia, the WHO-WIPO-WTO Trilateral Technical Assistance Platform and the World Local Production Forum. WHO is uniquely positioned to support countries and regions in developing quality, sustainable, and scalable local production to bridge access gaps and strengthen health security.

Programme area 2
Safety, efficacy and quality-assurance

As of December 2024, 69% of national regulatory authorities worldwide lacked the resources and capacity to perform all regulatory functions well (ML1 and ML2) according to assessment with the WHO Global Benchmarking Tool. Gaps in effective and efficient regulation compromise safety, quality, and efficacy/performance and can also delay availability of health products and technologies. Strong regulatory capacity is essential for regulatory oversight before investing in local production of health products and technologies. In previous public health emergencies, it was observed that poor regulatory practices delayed access to life-saving quality-assured products in many countries. Country capacity for authorization of health products is needed to avoid such barriers including the use of reliance mechanisms and work-sharing as well as strengthened pharmacovigilance systems.

The priorities under this programme area include:

- regulatory systems strengthening;
- reliance and convergence of regulatory requirements, standards and guidelines;
- prequalification and risk-based assessment (including emergency use listing); and
- post market surveillance and pharmacovigilance.

Increasing regulatory preparedness and response to pandemics and public health emergencies cuts across these priorities.

WHO's work in this area contributes to strengthened regulatory capacity in low-resource settings, optimal use of limited resources and timely assessment and registration of new products. The work fosters greater collaboration; convergence of regulatory requirements, standards and guidelines; and harmonization amongst national and regional authorities. National regulatory authorities can make use of work carried out by trustworthy authorities and WHO to save resources and accelerate registration through confidential sharing of information. Information sharing and networking foster trust and confidence among national laboratories and regulatory bodies, thereby enhancing reliance and mutual recognition, which are especially crucial during emergencies when the speed of regulatory responses is vital. The WHO Listed Authority initiative globally recognizes regulatory authorities operating at highest level of performance and promotes reliance on the outputs and decisions of WHO Listed Authorities. Capacity building and technical assistance enhance national control laboratories' abilities to ensure medical product quality, a crucial support for resource-limited Member States. This is complemented by the harmonization of laboratory testing and batch release processes, which streamline operations by reducing redundancy and speeding up product availability.

WHO Prequalification is a unique platform for an efficient and harmonized quality assessment of products of public health importance, such as medicines (including active pharmaceutical ingredients (APIs)), vaccines, medical devices, including in vitro diagnostics and vector control products and contributes to diversification of quality-assured sources. Prequalification facilitates procurement decisions, expediting availability of health products and technologies outside of and in emergency situations and increases knowledge and skills for producing and approving safe, effective and quality-assured health products and technologies. Prequalification ensures compliance with WHO requirements on quality, safety and effectiveness/performance across the product lifecycle, including through the assessment of product variations and changes. To ensure that health products and technologies in supply chains are of assured quality or meet equivalence standards, it is essential to implement robust, agile, and risk-based approaches in regulatory market surveillance, vigilance, and control. WHO's work in this area contributes to improved quality, safety and efficacy/performance of health products and technologies; quality of care; and global health security.

WHO is uniquely mandated and trusted by Member States to support countries in strengthening their regulatory systems, including during emergencies. WHO leads this work globally, utilizing the Global Benchmarking Tool to perform gap analyses, guiding regulatory authorities on how to address gaps, and in measuring regulatory system maturity. The WHO Prequalification program is a globally recognized quality assurance mechanism for public health priority products, aiding in harmonized, evidence-based procurement decisions. In emergencies, WHO employs well-established risk-based assessment mechanisms. Recognized for its neutrality and technical expertise, WHO excels in capacity building and enhancing laboratory capabilities, while fostering international trust and cooperation among health regulators, crucial for both routine operations and emergency responses.

WHO is uniquely mandated to manage global platforms in support of strengthened regulatory systems. These include a centralized incident reporting platform, the WHO Global Surveillance and Monitoring System for facilitating coordinated responses to substandard and falsified medical products and the Programme for International Drug Monitoring, a unique and confidential global platform for Member States to exchange and review safety data on medicinal products. The combination of global reach, technical authority, networks for information exchange, and cross-sectoral collaboration capabilities gives WHO an unparalleled position in strengthening regulatory systems to combat dangerous medical products and to provide advice on safety of medicinal products.

Programme area 3
Policy and prioritization

Universal health coverage means that all people have access to the full range of quality health services they need, when and where they need them, without financial hardship. Many countries lack equitable access to safe, effective and quality-assured health products and technologies that are affordable, available, accessible and acceptable for those that need them. The high cost of some innovative and emerging technologies may threaten the financial sustainability of healthcare systems, even in high-income countries. In the absence of insurance coverage, the high cost of health products and technologies is a significant barrier to equitable access and quality care, especially in low and middle-income countries where many patients pay out of pocket and face impoverishing or catastrophic health expenditures. The evidence-based selection and prioritization of health products and technologies for procurement and reimbursement is important for governments to address the health needs of a population yet poses a key challenge for many countries. Prioritization that is informed by scientific evidence and that is transparent needs to feed into national guidelines, financing schemes, procurement processes and provision and use.

The priorities under this programme area include:

- selection and prioritization; and
- pricing and affordability.

WHO supports Member States with guidance on assessing and addressing national needs for health products and technologies to assure their availability, particularly in low-resource settings. WHO's work focuses on supporting countries in evidence informed deliberative processes for the selection of priority health products and technologies for public funding or community or social health insurance within the principles of UHC. This work is based in principles and practices of health technology assessment and considers a range of criteria, including effectiveness, cost-effectiveness, budget impacts, ethical principles, and fair choices. Guidance on pricing and use and support for improved transparency of markets aims to maximize the use of limited resources and reduce inequities due to out-of-pocket expenditure.

WHO work in this area contributes to evidence informed, legitimate and transparent assessment and prioritization of health products and technologies to support countries to select and prioritize according to the national context including for emergency and humanitarian situations. The work supports the defining health benefit packages *(18)*, making fair choices *(19)*, procurement and reimbursement decision-making, development and implementation of national policies and equity in access and sustainable use of health products and technologies.

The work promotes policies that can increase the uptake of generics and biosimilars for better affordability and that can expand access for specific populations such as children and pregnant women as well as and people living in long-term care facilities, hospice institutes or receiving home-based care. WHO work contributes to access to appropriately controlled psychoactive substances. The work increases the ability of governments to prevent harm from psychoactive substances while also contributing to improved access to internationally controlled medicines for medical purposes. The work contributes to increased transparency on market information including supply, demand and price information to reduce information asymmetries in markets, identify access barriers and identify opportunities for action. It also contributes to increased coherence of trade policies with public health objectives, expedited customs' treatment of vaccines in emergencies, facilitation of application of preferential tariffs, and enhanced access to more granular "vaccine-flows" data.

WHO is widely recognized for its expertise in developing authoritative, evidence-based policy guidance to inform countries' adaptation of WHO recommendations to ensure equitable access to affordable

medicines and health technologies in the specific country context. The WHO Model Essential Medicines List is recognized as transformational public health guidance, supporting countries, particularly low- and middle-income countries, to select those medicines that meet priority public health needs. Since 2016, WHO has expanded the concept to three further health product priority lists including, the Priority Assistive Products List, the Priority Medical Devices List, and the Essential In Vitro Diagnostic List. Other notable policy guidance includes the vaccine position papers which provide global vaccine and immunization recommendations for diseases that have an international public health impact. Key mandates are provided to WHO to support Member States in this programme area including, within the International Drug Control Conventions to advise the Commission on Narcotic Drugs (CND) on psychoactive substances that are needed for medical and scientific purposes. Notable leadership activities under this programme area include the WHO Fair Pricing Forum.

Programme area 4
Procurement and supply chain management, provision and use

Once health products and technologies have been prioritized, they need to be included in national treatment and use guidelines, included in benefits packages, procured in the right amounts managed, provided and used appropriately. Challenges in procurement include a lack of capacity for identifying the right products to procure, inadequate forecasting and inefficient practices that can impact availability and affordability of health products and technologies. Supply chain management challenges include a lack of capacity and a lack of modernized infrastructure. Other challenges include a lack capacity for installation, maintenance and repair of medical devices; a lack of adequate management of blood, organ and tissue supply; and low awareness, limited physical access, inadequate product range, workforce capacity gaps, inadequate policy, insufficient funding, fragmentation and sociodemographic obstacles for assistive technology.

Programme priorities include:

- procurement and supply chain management; and
- provision and use.

WHO supports Member States with tools for efficient procurement and supply chain management; performance assessment; monitoring of stockouts and shortages; guidance on market shaping; and technical specifications for procurement. Training and guidance are provided for management, prescribing, provision and use of health products and on their safe disposal.

WHO work in this area contributes to country capacity to monitor and improve performance of supply chain of health products and technologies, including outside of and in emergency and crisis situations as well as collaborative approaches to strategic procurement. Technical specifications assist decision making for procurement and assists appropriate us of medical devices and of assistive products. The work supports healthcare workers and users to manage and use these products leading to better quality care for patients including for improved prescribing, dispensing and use of medicines; improved management and use of medical devices; improved provision of assistive products through an integrated service delivery approach including training on the use of assistive; improved quality and management of blood services; improved management and use of vector control products; and improved management and use of vaccines.

WHO's guidance on procurement and supply chain management and use of health products and technologies is recognized as trust-worthy, evidence-based and free from conflict of interest. It is valued for its consideration of implementation realities and is grounded in unique understanding of diverse contexts and national priorities. In the area of access to and use of safe, effective and quality-assured medical devices and assistive products, this guidance is particularly critical as work in these areas is relatively new in many countries.

Programme area 5
Cross-cutting

There are a number of areas that cut across different areas of the ecosystem. WHO's priorities in this area include:

- globally recognized names of medicines and medical devices;
- norms, standards and guidance for health product and technology development and delivery;
- information for decision making; and
- environmental sustainability.

Globally recognized names of medicines and medical devices

Globally recognized names are important so that medicines and medical devices can be consistently identified throughout the ecosystem from R&D to procurement to prescribing, dispensing and use. WHO is constitutionally mandated and uniquely positioned to make transparent recommendations on globally harmonized names that are freely accessible to all stakeholders. Globally recognized names for medicines and for medical devices improve uniformity and understanding of medicines and medical devices and support pharmacovigilance, traceability in supply chains and monitoring of medicines and other health products and technologies.

Without a universal nomenclature system, medicines, biologicals and biological substances lack consistent identification, hindering clear communication, rational use, and affordable healthcare and can lead to potential medication errors, increased healthcare costs and barriers to international pharmaceutical trade and collaborations. Globally recognized names of medicines through the WHO International Nonproprietary Names (INN) system offer better affordability through improved use of generic medicines. The Anatomical Therapeutic Chemical (ATC) classification system and the Defined Daily Dose (DDD) as a measuring unit have become the gold standard for international drug utilization research contributing to improved quality of care.

Multiple nomenclature systems for medical devices contribute to duplication of efforts and have the potential to create challenges for procurement, management and use of medical devices. To address this challenge, WHO established, the first global open access clearing house for information on medical devices, the Medical Devices Information System (MeDevIS), providing consistent terms, codes and definitions of medical devices that are freely accessible by all stakeholders.

Norms, standards and guidance for health product and technology development and delivery

Norms and standards for pharmaceuticals and biologicals include written guidelines or recommendations and physical standards used for quality control. These are important for facilitating production and registration of medicines; establishing the basis for the WHO prequalification process; promoting competition of generics and biosimilars; and contributing to the availability and affordability of quality medicines. Good practice guidelines are used throughout the health product and technology ecosystem. Many countries around the world do not have the capacity to develop and implement the harmonized standards needed for the development of safe, effective and quality-assured health products and technologies leading to poor quality, unaffordable or unsafe products. WHO's work in this area contributes to consistently produced and distributed health products and technologies according to international quality standards and better regulatory oversight. The work on norms and standards contribute to a decrease in the regulatory burden and fosters greater collaboration, convergence and harmonization amongst national and regional regulatory authorities.

WHO's constitutional mandate and impartial, evidence-based consensus process enables it to develop robust and transparent international standards for a broad range of medicines, vaccines, biotherapeutic products, blood products, medical devices, including in vitro diagnostics, and cell and gene therapy products, providing the basis for national regulation. They also serve as the only accessible public standards filling the gaps where other standards fall short. This is particularly important for global priority public health areas and low- and middle-income country needs. WHO's international standards on pharmaceuticals and biologicals underpin other WHO programmes, including WHO prequalification, immunization, regulatory systems strengthening, polio eradication, influenza, public health emergencies, as well as other UN agencies programmes, while WHO recommendations on controlled substances are used by the UN drug policymaking body, the Commission on Narcotic Drugs.

Information for decision-making

Availability of data across the ecosystem is important for decision making and monitoring of progress. Many low- and middle-income countries lack the required capacity, resources, information management systems, infrastructure or skilled personnel to collect, analyse or report data on health product technology needs, capacity and performance. Improved data supports countries in policy development and decision making and provides information to partners and stakeholders for needs identification. WHO is uniquely positioned to collect data on country level need, unmet need and satisfaction through its broad reach and trusted status with Member States. WHO support through the development of robust and cost-effective data collection tools and technical support to gather, analyse and report on data is critical, particularly in low- and middle-income countries. WHO monitors stockouts and shortages, consolidates data on met and unmet needs for assistive technology, collects and analyses information on blood and blood product safety, tracks adverse outcomes related to the clinical use of human organs, blood, tissues, and cells, for example.

Environmental sustainability

Climate change and environmental degradation have emerged as major threats to human health with the rise in global temperatures and increasing chemical pollution in the environment. The health sector contributes to the emissions of greenhouse gases and the generation of waste. The production and distribution of health products contribute to those emissions. The use of plastics in health care products especially in single-use products contributes to growing volumes of waste and potentially negative impacts on human and environmental health. WHO's work in this area supports more environmentally sound delivery, management and disposal of health products and technologies. The work is interlinked with action on climate and health and is cross-cutting over all other areas of the roadmap.

Financing the roadmap

WHO's budget for work on access to safe, effective and quality-assured health products and technologies is published in the WHO Programme Budget for each biennium *(20)*. WHO's work on access to health products and technologies is funded from: Member States' assessed contributions (membership dues) and voluntary contributions from Member States, United Nations organizations, intergovernmental organizations, professional associations and other non-State actors. In addition, fees raised through the INN programme and the Prequalification programme contribute to the funding for these areas.

Measuring progress on access to medicines and other health products[1]

Outcome indicators

Measuring access to health products and technologies has in the past proven to be a limitation in the capacity to assess outcomes and to monitor progress on improving access in countries *(21)*. Efforts are underway to improve measurement of outcomes and to refine indicators at the output level.

The SDG indicator 3.b.3 was previously defined as: *the proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis (22)*. Data on this indicator posed challenges for collection and thus was not regularly collected in countries *(23)*. In 2024 the Inter-Agency and Expert Group on Sustainable Development Goal Indicators undertook a review and identified the need to modify the indicator. A new indicator has been proposed and will be presented to the 56th session of the UN Statistical Commission *(24, 25)*. The new proposed indicator, the *health products access index* (described below) will not require additional data collection in countries and will recognize other health products in addition to medicines.

The GPW13 used *the proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis* to measure the outcome, *improved access to essential medicines, vaccines, diagnostics and devices for primary health care*. Due to the challenges with this as described above, progress on the GPW13 outcome was not adequately measured. Thus, for the GPW14 joint outcome 3.2 Health and care workforce, health financing and **access to quality-assured health products substantially improved**, WHO has proposed 2 key indicators to measure progress on health products and technologies *(26)*. These include:

1. The *health products access index* (Table A4.1).
2. *Improved regulatory systems for targeted health products* (Table A4.2).

The proposed metadata for measuring these indicators is shown in Annex 4. Both indicators will not require additional data collection in countries, but rather rely on existing data that is collected routinely. These proposed GPW14 indicators will align with the roadmap programmatic objectives and will allow better monitoring of progress on the roadmap. The proposed baselines and targets for these indicators will be presented at the Seventy-eighth WHA (Table 1).

[1] Excluding vaccines

Table 1 Proposed targets and baselines for GPW14 outcome 3.2 specific to access to quality-assured health products (to be finalized at the Seventy-eighth World Health Assembly)

Indicator	Baseline	Target for 2028
Health product access index	72 (median)	2 points over baseline
Improved regulatory systems for targeted health products	63.6%	65.7%

Output indicators

WHO's Programme Budget *(20)* outlines the priorities of the Organization, defines the targets to be delivered, and allows monitoring of their achievement on a biennial basis. This roadmap covers the outputs within the scope of the GPW13 through 2025 (Table 2) and the GPW14 Programme Budget from 2026 to 2027 (Table 3).

Table 2 2024–2025 output indicators

Output	Indicator
1.3.1 Provision of authoritative guidance and standards on quality, safety and efficacy of health products, including through prequalification services, essential medicines and diagnostics lists	IND1. Number of norms/standards and guidance documents published, including updates on essential medicines and diagnostics list
1.3.2 Improved and more equitable access to health products through global market shaping and supporting countries to monitor and ensure efficient and transparent procurement and supply systems	IND1. Number of countries updating/developing/implementing medicines pricing policies and monitoring systems
	IND2. Number of countries initiating a national priority medical devices list, including essential in vitro diagnostics
	IND3. Number of countries that have established a national Priority Assistive Products List
1.3.3 Country and regional regulatory capacity strengthened, and supply of quality-assured and safe health products improved	IND1. Number of products prequalified annually
	IND2. Number of countries with improved regulatory systems
	IND3. Number of countries with well-functioning regulatory status (NRA ML3)
	IND4. Number of countries with a risk-based approach for regulating in vitro diagnostic medical devices
	IND5. Number of countries with improved regulatory preparedness for public health emergencies

Table 3 2026–2027 proposed output indicators (to be finalized at the Seventy-eighth World Health Assembly)

GPW14 Output statement	Output indicator proposed
3.2.3 WHO supports countries to implement measures for better access to and use of safe, effective, and quality-assured health products	IND1. Number of in-country registrations of prequalified products and SRA/WLA approved products registered under the Collaborative Registration Procedure or other facilitated reliance pathway in case of emergency
	IND2. Number of Member States with established institutional development plan to improve regulatory capacity for health products based on the assessment using WHO Global Benchmarking Tool
	IND3. Number of countries with a list of essential medicines (or reimbursed medicines) developed centrally, updated within the last 5 years and grounded in the concept of the WHO Model List of Essential Medicines

Other measurements of progress

The output indicators described above capture only a proportion of WHO's work on access to safe, effective and quality-assured health products. Other measure for outcomes, outputs and key performance indicators are reported in in various departmental and project reports, such as those reported in the Regulation and Prequalification Department's Annual Reports *(15, 16)*.

Going forward

Going forward WHO will continue to adapt approaches to keep pace with the ever-evolving health landscape, to address new challenges and to make the most of new opportunities. The use of artificial intelligence and digital technologies, emerging technologies and product innovation will present new possibilities to meet public health needs but also put new requirements for quality assurance and create risk of increasing inequities due to higher prices for new products and increasing complexity. New challenges for access to medicines and health products, such as those posed by climate and environmental concerns or emerging health threats, require innovative solutions, global collaboration and strengthened health systems response.

Some ongoing challenges may need further strengthening and resourcing to be able to address them and to meet the needs of Member States, such as access to generic and biosimilar medicines. Better monitoring of the impact of actions at global, regional and country level will support decision making and identification of gaps and interventions that support improved access to safe, effective and quality-assured health products and technologies.

Opportunities exist to build on WHO leadership, convening power and expertise. WHO's leadership on the concept of WHO listed Authorities or the essential medicines concept for example can support renewed commitments for medicines and other health products and technologies. Access depends on the collaboration of stakeholders and WHO is uniquely positioned to build on existing networks and to create new partnerships.

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Annex 1
Mandates and strategies since 2019 pertaining to health products and technologies[2]

Resolutions

WHA

2024	WHA77.4	Increasing availability, ethical access and oversight of transplantation of human cells, tissues and organs
2023	WHA76.6	Strengthening rehabilitation in health systems
2023	WHA76.5	Strengthening diagnostics capacity
2023	WHA76.3	Increasing access to medical oxygen
2022	WHA75.14	Global strategy and plan of action on public health, innovation and intellectual property
2021	WHA74.8	The highest attainable standard of health for persons with disabilities
2021	WHA74.6	Strengthening local production of medicines and other health technologies to improve access
2020	WHA73.1	COVID-19 response
2019	WHA72.8	Improving the transparency of markets for medicines, vaccines, and other health products

Regional Committee for Africa

2023	AFR/RC73/WP2	Regional strategy on diagnostic and laboratory services and systems, 2023–2032 for the WHO African Region

Directing Council of the Pan American Health Organization

2022	CDSS2.R1	Update on monkeypox in the Region of the Americas and access to vaccines
2021	CD59.R3	Increasing production capacity for essential medicines and health technologies
2020	CDSS1.R1	Update on the COVID-19 pandemic in the Region of the Americas, COVAX preparedness, and equitable access to COVID-19 vaccines open configuration options
2019	CD57.R11	Strategy and plan of action on donation and equitable access to organ, tissue and cell transplants 2019–2030

Regional Committee for Eastern Mediterranean

2020	EM/RC67/R.2	Regional strategy to improve access to medicines and vaccines in the Eastern Mediterranean Region, 2020–2030, including lessons from the COVID-19 pandemic

Regional Committee for Europe

2022	EUR/RC72/R3	The WHO European framework for action to achieve the highest attainable standard of health for persons with disabilities 2022–2030

[2] Resolutions and reports on antimicrobial resistance, immunization, UHC, PHC, health systems, emergency preparedness, non-communicable and communicable disease, infection prevention and control, maternal, newborn and childcare with elements pertaining to health products are not included in this list.

Regional Committee for South-East Asia

2018	SEA/RC71/R2	Delhi declaration on improving access to essential medical products in the region and beyond

Regional Committee for Western Pacific

2017	WPR/RC68.R7	Regulatory strengthening, convergence and cooperation for medicines and the health workforce

Governing body reports

WHA

2022	A75/11 Add.1	Standardization of medical devices nomenclature international classification, coding and nomenclature of medical devices, report by the Director-General
2022	A75/40	Availability, safety and quality of blood products, report by the Director-General
2022	A75/41	Human organ and tissue transplantation, report by the Director-General
2022	A75/43	Public health dimension of the world drug problem, report by the Director-General
2022	EB150 (11)	Global strategy and plan of action on public health, innovation and intellectual property
2021	EB148/10	Global strategy and plan of action on public health, innovation and intellectual property
2019	A72/22	Member State Mechanism on Substandard and Falsified Medical Products, report by the Director-General
2019	A72/17	Access to medicines and vaccines, report by the Director-General
2018	A71/21	Improving access to assistive technology, report by the Director-General

Other Governing Body Reports

2024	EB154(7)	Increasing availability, ethical access and oversight of transplantation of human cells, tissues and organ

Regional Committee for Africa

2023	AFR/RC73/7	Regional strategy on diagnostic and laboratory services and systems, 2023–2032 for the WHO African Region
2021	AFR/RC71/11	Framework for improving access to assistive technology in the WHO African Region
2021	AFR/RC71/INF. DOC/5	Progress report on the implementation of the regional strategy on regulation of medical products in the African Region, 2016–2025
2020	AFR/RC70/12	Status of human organ and tissue donation and transplantation in the WHO African Region

Directing Council of the Pan American Health Organization Health Organization

2024	CD61/INF/9	Access and rational use of strategic and high-cost medicines and other health technologies: final report
2023	CE172/INF/10	Progress reports on technical matters: B. Strategy and plan of action on donation and equitable access to organ, tissue, and cell transplants 2019–2030
2022	CSP30/11	Policy to strengthen national regulatory systems for medicines and other health technologies
2020	CD58/INF/8	Plan of action for universal access to safe blood: final report
2020	CD58/INF/14	Progress reports on technical matters: strengthening national regulatory authorities for medicines and biologicals

Regional Committee for Eastern Mediterranean

2022	EM/RC69/INF. DOC.5	Progress report on the regional strategy to improve access to medicines and vaccines in the Eastern Mediterranean Region, 2020–2030, including lessons from the COVID-19 pandemic

Regional Committee for Europe

2022	EUR/RC72/ INF./8	Oslo Medicines Initiative Statement by WHO/Europe
2022	EUR/RC72/7	The WHO European framework for action to achieve the highest attainable standard of health for persons with disabilities 2022–2030
2020	EUR/RC70/Inf. Doc./6	Better access to effective, novel and affordable medicines: a new vision for collaboration between the public and private sector

Regional strategies

Regional Committee for Africa

2024	AFR/RC74/6	Framework for strengthening local production of medicines, vaccines, and other health technologies in the WHO African Region 2025–2035

Directing Council of the Pan American Health Organization Health Organization

2022	CE170/17	Policy to strengthen national regulatory systems for medicines and other health technologies
2021	CD59/8	Increasing production capacity for essential medicines and health technologies

Regional Committee for Eastern Mediterranean

2024	EM/RC71/A	Regional flagship initiative 1: Expanding equitable access to medical products
2020	EM/RC67/6	Regional strategy to improve access to medicines and vaccines in the Eastern Mediterranean, 2020–2030, including lessons from the COVID-19 pandemic
2020	EM/RC67/R.1(D) - Annex 2	Strategic action framework to improve access to assistive technology in the Eastern Mediterranean Region

Annex 2
Explanation of terms as used in the roadmap 2025–2030

The definitions given below are **provided for the purposes of this document** and are drawn from WHO guidelines, fact sheets and health topics and from the literature.

Access	Indicates that within a health system a medicine or other health product or technology is affordable, available, accessible and acceptable; of assured quality and safety; and is delivered and used appropriately.
Assistive product	Any external product (including devices, equipment, instruments or software), the primary purpose of which is to maintain or improve an individual's functioning and independence, and thereby promote their well-being. Assistive products are also used to prevent impairments and secondary health conditions *(1)*. Assistive products include a large and diverse range of products that may be physical or digital, and support individual's function in cognition, communication, hearing, mobility, self-care and vision. Common examples include hearing aids, wheelchairs, spectacles, prostheses, and memory or communication devices, noting that some of these are also classified as medical devices, i.e. hearing aids.
Assistive technology	The application of organized knowledge and skills related to assistive products, including systems and services. Assistive technology is a subset of health technology *(2)*.
Biological products	Biological products can be defined according to their source material and method of manufacture. Biological products are derived from cells, tissues or microorganisms and reflect the inherent variability characteristic of living materials *(3)*.
Blood products	A blood product is any therapeutic substance derived from human blood, including whole blood and other blood components for transfusion and plasma-derived medicinal products *(4)*.
Controlled medicines	Pharmaceuticals with an identified or emergent clinical application whose active principles are listed under one of the three international drug control conventions (definition is under review) *(5)*.
Collaborative registration procedure (CRP)	A reliance and collaboration mechanism to facilitate and accelerate the assessment and registration of medical products in participating countries. Through CRP, NRAs can access product assessment and inspection reports from stringent regulatory authorities, WHO Listed Authorities or WHO Prequalification, allowing for a faster, verification-based or abridged review process to make their own decision *(6)*.
Diagnostics	Includes medical devices used for the diagnosis, screening, monitoring, prediction, staging or surveillance of diseases or health conditions, both in vitro and non-in vitro type *(7)*. Noting that the non-in vitro type includes imaging, electrophysiology, and medical devices that provide information (diagnostics definition is being updated in 2025).
Essential medicine	Essential medicines are those that effectively and safely treat the priority healthcare needs of the population. They are selected by taking into consideration public health relevance, evidence of benefits and harms, and with consideration of costs, affordability and other relevant factors *(8)*.

Essential in vitro diagnostics	Includes those in vitro diagnostic medical devices, intended for examination of specimens derived from the human body, that satisfy the priority health care needs of the population and are selected with due regard to disease prevalence, public health relevance, evidence of efficacy/performance and accuracy and comparative cost effectiveness *(9)*.
Equity	Equity is the absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other dimensions of inequality (e.g. sex, gender, ethnicity, disability, or sexual orientation) *(10)*.
Global benchmarking tool	The primary means by which WHO assesses regulatory systems for the regulation of health products.
Health products	Products to be used for a health purpose such as prevention, diagnosis or treatment of disease, disorders or conditions, pain, palliative and family care and rehabilitation *(12)*. Health products encompass medicines; vaccines; medical devices, including in vitro diagnostics; assistive products; blood products; other products of human origin; and vector control products *(13)*.
Health technologies	Refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives *(14)*.
In vitro diagnostic	A medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. (Note: in vitro diagnostics include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles, and are used, for the following purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status) *(11)*.
Local production	"Local" refers to the geographical location (i.e. occurring in the country or region) and "production" – in regard to pharmaceuticals for example – refers to all activities along the pharmaceutical manufacturing value chain *(15)*.
Maturity level	Maturity of regulatory systems is divided into four levels, characterized as follows: • ML1: regulatory systems in which some elements of regulatory systems exist; • ML2: evolving national regulatory systems that partially perform essential regulatory functions; • ML3: stable, well-functioning and integrated regulatory systems; and • ML4: regulatory systems operating at advanced level of performance and continuous improvement *(16)*.
Medical countermeasure	Health products that are used to prevent or manage epidemic and pandemic diseases *(17)*.

Medical device	Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose *(18)*. Medical devices include products used for prevention, diagnosis, treatment, monitoring, rehabilitation and palliation which do not have a pharmacological function. Medical devices range from bandages to complex diagnostic imaging devices. There are an estimated 2 million kinds of medical devices in the world *(19)*.
Medicine	Any substance or combination of substances marketed or manufactured to be marketed for treating or preventing disease in human beings, or with a view to making a medical diagnosis in human beings, or to restoring, correcting or modifying physiological functions in human beings *(20)*.
Norms and standards for safety, efficacy and quality-assurance of pharmaceuticals and biologicals	Include written standards (also referred to as recommendations and guidelines) as well as measurement standards. • Written standards for safety, efficacy and quality-assurance provide guidance for prequalification and national requirements for manufacturing and regulation of pharmaceutical and biological products *(21)*. • Measurement standards for safety, efficacy and quality-assurance serve as reference sources for comparison against which results from laboratories, regardless of location or methods employed, can be standardized and compared *(22)*.
Pharmacovigilance	Is defined by WHO as "the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible medicine-related problems *(23)*.
Preferred product characteristics	Prospective, strategic documents describing an ideal product class often at the early stage of development or seeking to stimulate innovation in a new area *(24)*.
Prequalification	WHO recommendation on the quality, safety, and efficacy of health products (and also including performance in the case of diagnostics and programmatic suitability in the case of vaccines) that will enable UN agencies or Member States to procure quality-assured health products or to facilitate national marketing authorization.
Primary health care	A whole-of-society approach to health that aims to maximize the level and distribution of health and well-being through three components: (a) primary care and essential public health functions as the core of integrated health services; (b) multisectoral policy and action; and (c) empowered people and communities *(25)*.
Products of human origin	Encompass all biological materials that are derived wholly or in part from the human body (living or deceased persons) and are intended for clinical application. They are used either as raw or processed materials, such as: organs for transplantation; blood and plasma products; ocular and musculoskeletal or other types of tissue; haematopoietic or other types of cells; ova and sperm used in assisted reproductive treatments; and breast milk used to treat premature infants *(26)*.

Reliance	The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others *(27)*.
Target product profiles	Outline the desired 'profile' or characteristics of a target product that is aimed at a particular disease or diseases. TPPs state intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics. TPPs are used when a pipeline develops, and more specific targets and minimum performance characteristics are able to be described with a much narrower specific description *(28)*.
Technology transfer	A logical procedure that controls the transfer of any product, platform technology or process, including product or process knowledge, together with its documentation and professional expertise. Technology transfer may involve development, manufacturing or testing sites *(29)*.
Vaccine	A preparation containing antigens capable of inducing an active immune response for the prevention, amelioration or treatment of infectious diseases.
Vector control product	A product that prevents transmission of vector-borne diseases such as malaria, dengue, leishmaniasis, dengue, and Zika by acting on the organism or that which transmits the disease to humans.
WHO listed authority	A regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process.

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Annex 3
Programme priorities

Programme area 1: R&D and production of health products and technologies

Public health driven R&D and innovation

WHO output	Intermediate outcome
• Monitoring and tracking the pipeline for health technology • WHO Foresight and horizon scanning • Global Observatory on Health R&D • International Clinical Trials Registry Platform	• Improved prioritization and planning
• Coordinated Scientific Advice to product developers and manufacturers • Paediatric Antiretroviral Drug Optimization processes • Novel R&D financing mechanisms such	• Streamlined health product development • Generation of appropriate evidence for policy and quality reviews
• Target product profiles • Preferred product characteristics • Guidance on trial design • Calls for innovative technologies • R&D blueprints • Identifying priority pathogens for R&D	• R&D that addresses the public health needs
• Establishment of R&D health technology consortia such as the regional collaborative network of R&D institutions and manufacturers to develop commercially viable messenger ribonucleic acid (mRNA) products for unmet needs	• Identification of disease targets for R&D based on regional and country needs and priorities

Geographically diversified and sustainable manufacturing

WHO output	Intermediate outcome
• World Local Production Forum • Regional, multilateral and bilateral partnerships and collaborations on local production • WHO Biomanufacturing Workforce Training Initiative • Private sector Engagement Forum • Global database on manufacturing capacity, capability and scalability • Network of inter-connected health technology development consortia, with the mRNA vaccine consortia serving as the first example and expansion to other health products and technologies over time	• Improved coordination of, collaboration on, and synergy of production in geographically diverse locations
• Local production ecosystem assessments • Prioritization and selection of health technologies and products, including platform technologies for geo-diversified production • Model strategy for strengthening local production	• Demand driven public health business cases

WHO output	Intermediate outcome
• Support to secure tech transfer and other access sharing mechanisms through partners • Support for technology transfers agreements and capability to manufacturing partners for sustainable production of prioritized health technologies and products over the full value chain	• Implementation strategies tailored to technology recipient needs • Strengthened geographically diversified production and scalable manufacturing of prioritized health technologies and products
• Training and capacity building including, for example the Virtual cGMP Training Marathon and the Week of Quality	• Strengthened geographically diversified production and scalable manufacturing of prioritized health technologies and products

Application and management of intellectual property

WHO output	Intermediate outcome
• Progress reports on the implementation of the GSPA-PHI	• Implementation of the Global Strategy on Public Health Innovation and Intellectual
• Technical assistance to Member States upon request and in line with the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property • Joint workshops, technical briefings and patent landscapes • Collaboration with other international organizations, including the Trilateral collaboration with WIPO and WTO for joint technical assistance	• Increased capacity in countries to apply and manage intellectual property rules in a manner that maximizes innovation and promotes access to health products and technologies that is consistent with the provisions in the TRIPs Agreement and other WTO instruments

Programme area 2: Safety, efficacy and quality-assurance

Regulatory systems strengthening

WHO output	Intermediate outcome
• Assessment with the Global Benchmarking Tool • Support for elaboration and implementation of Institutional Development Plans • Determination of maturity levels • Coalition of interested parties	• Strengthened national and regional regulatory capacity
• Support to NRAs for new and emerging health products and technologies where applicable	• Strengthened capacity of NRAs to regulate new and emerging health products and technologies
• Support to national control laboratories to enhance testing capacity of health products and technologies in accordance with WHO and international standards • Listing of prequalified and contracted laboratories	• Strengthened national control laboratory capacity

Reliance and convergence (on regulatory requirements, standards and guidelines)

WHO output	Intermediate outcome
• Framework for WHO Listed Authority • Performance evaluation and designation of regulatory authorities as a WHO Listed Authority	• Strengthened performance of national and regional regulatory authorities

• Global and regional regulatory harmonization and convergence initiatives and networks further developed • Support and harmonization of regional regulatory systems • Expanded list of WHO national quality control laboratories for biologicals and pharmaceuticals	• Effective networks for regulatory system strengthening
• CRP between WHO and NRAs in the assessment and accelerated national registration of WHO prequalified pharmaceutical products • Support to regional joint assessments	• Strengthened collaboration on market authorization

Prequalification and product risk-based assessment

WHO output	Intermediate outcome
• Prequalified medicines, APIs, finished pharmaceutical products (FPPs), biotherapeutic products, vaccines, medical devices, including in vitro diagnostics and vector control products	• Ensured quality, safety and efficacy/ performance and programmatic suitability of health products and technologies
• Emergency use listed medicines (APIs, FPPs and biotherapeutic products), vaccines and in vitro diagnostics • Expert Review Panel listing of in vitro diagnostics and medicines	• Fast tracked health product quality assurance in emergencies
• Information sessions, training workshops, scientific advice to manufacturers, and hands-on training for regulators • Platform, via prequalification assessment sessions, for co-working and experience sharing among regulators of varying maturity levels • Guidance on product assessment • Technical specifications and performance evaluation protocols for in vitro diagnostics	• Strengthened capacity for product assessment

Post-market surveillance, control and pharmacovigilance

WHO output	Intermediate outcome
• WHO Global System for Monitoring and Surveillance of Substandard and Falsified Medical Products • Support provided to countries for improving detection capacity and access to reliable laboratory testing facilities • Support countries develop and implement action plans for prevention, detection and response to substandard and falsified medical products	• Substandard and falsified products detected, prevented and responded to
• WHO Programme for International Drug Monitoring • WHO global database of individual case safety reports (VigiBase) • Recommendations on safety provided to WHO disease programmes	• Improved sharing of pharmacovigilance know-how and information • National pharmacovigilance systems supported to detect, assess and prevent adverse events due to medicines and vaccines • Disease treatment, prevention and immunization policies based on evidence

Programme area 3: Policy and prioritization

Selection and prioritization

WHO output	Intermediate outcome
• Model List of Essential Medicines • Model List of Essential in vitro Diagnostic • Priority List of Medical devices • Priority List of Assistive Products • MeDevIS	• Improved evidence-based selection of health products and technologies outside of and in emergency situations
• Support for inclusion of internationally controlled medicines in essential health services and benefit packages • Support for improved global distribution networks for internationally controlled medicines • Policy guidance for controlled medicines • Recommendations to UN on which psychoactive drugs have medical value	• Improved access to internationally controlled medicines for medical purposes

Pricing and affordability

WHO output	Intermediate outcome
• WHO guidelines and training on pharmaceutical pricing policies • Policy briefs on country pharmaceutical pricing policies • WHO pharmaceutical pricing policy webinar series	• Enhanced knowledge and competencies in implementing WHO recommendations, enabling informed decisions on pharmaceutical pricing
• Fair Pricing Forum • Medicine prices and other market information sources • Assessment of evidence on impact of national initiatives to improve transparency of markets, including price information sharing • Market Information for Access to Vaccines (MI4A) Initiative • Global Vaccine Market Reports • Trilateral collaboration with WCO and WTO to introduce vaccine categories within the Harmonized Commodity Description and Coding System • Report on national and regional transparency initiatives • Price and Market Intelligence Tool and Quarterly Brief in Selected Therapeutic Areas	• Improved transparency on vaccine and medicine markets to promote affordability and reduce price asymmetries

Programme area 4: Procurement and supply chain management, provision and use

Procurement and supply chain management

WHO output	Intermediate outcome
• Tools and platforms for improving efficient procurement of health products and technologies • Support to countries and regions to develop and implement regional strategies and plans of action for setting up pooled procurement mechanisms • Market shaping initiatives such as the Square Group vaccine market shaping partnership • Collaboration with key global partners on market shaping • Roadmaps and assessments to identify market and procurement barriers and opportunities that impact access to vaccines and agree on coordinated action • Patent landscapes of key products and technologies	• Strengthened capacity for efficient procurement • Collaborative approaches to strategic procurement • Increased affordability
• Pharmaceutical supply chain management tool • Technical guidelines for safe disposal and waste management of health products and technologies in and after emergencies • Equitable allocation mechanisms for emergencies • Guidance on quality assurance practices in the supply chain • Support for performance assessments • Monitoring of vaccine stockouts and shortages collected by countries and made available in the WHO Immunization Data portal	• Strengthened country capacity to monitor and improve performance of supply chains
• Technical specifications for procurement of medical devices including in vitro diagnostics • Technical specifications for procurement of assistive products and procurement guidance	• Enhanced availability of trusted information required for procurement
• Training and guidance on management of medical devices	Improved management and use of medical devices

Provision and use

WHO output	Intermediate outcome
Medicines • Clinical treatment guidelines • Antibiotic Access, Watch and Reserve (AWaRe)) Categorization • Good Pharmacy Practice promoted	• Improved prescribing, dispensing and use of medicines
Medical devices • Recommendations on use of in vitro diagnostics • Training and guidance on medical devices • Operational manuals for specific health products and technologies	• Improved management and use of medical devices

WHO output	Intermediate outcome
Assistive products • Training and guidance on minimum requirements for access to assistive products • Online training tools on assistive technology provision, targeting primary health care personnel • Provisioning models • Support for needs assessment	• Improved provision of assistive products through an integrated service delivery approach including training on the use of assistive products
Blood and blood products • Policy guidance • Educational modules on clinical use of blood • WHO Achilles Project to assist Member States in improving blood systems	• Improved quality and management of blood services
Vector control products • Indoor residual spraying manual • Larval source management manual	• Improved management and use of vector control products
Vaccines • WHO Vaccine Position Papers	• Improved management and use of vaccines

Programme area 5: Cross-cutting

Globally recognized names of medicines and medical devices

WHO output	Intermediate outcome
• Selection and publication of INN; School of INN • ATC/DDD methodology • Coalition of Member States using ATC-DDD • Web repository of ATC and DDD • Harmonization of medical devices nomenclature • MeDevIS	• Improved patient safety • Rational/appropriate use • Better affordability • Reduced barriers to international trade

Norms, standards and guidance for quality assurance of health product and technology development and delivery

WHO output	Intermediate outcome
• International reference preparations • International standards • International Pharmacopoeia • Regulatory guidelines and tools	• Strengthened regulatory oversight • Health products and technologies produced and distributed according to international quality standards

Non exhaustive list of guidance: • Recommendations for the preparation, characterization, and establishment of pharmaceutical and biological reference standards • Guidelines on Good Manufacturing Practice • Guidelines on import procedures for medical products • Good Storage and Distribution Practices • Inspection practices • Quality assurance for procurement • Guidance on blood systems	• Good practice for quality assurance in the development and delivery of health products and technologies

Information for decision-making

WHO output	Intermediate outcome
• Assistive Technology Assessment toolkit • Assessment tool for measuring country capacity in establishing organ transplantation • Self-assessment tool for blood supply system • Monitoring of vector control • Guidance and tools on antimicrobial surveillance and medicines consumption and use • Framework for the use of procurement and supply chain assessment data and information • Monitoring of vaccine stockouts and shortages collected by countries and made available in the WHO Immunization Data portal	• Improved information on health products and technologies available for decision making
• Harmful psychoactive substances placed under international control	• Improved monitoring of harmful psychoactive substances

Environmental sustainability

WHO output	Intermediate outcome
• Technical specifications for health products and technologies that include sustainability considerations • Guidance to countries on waste management • Decommissioning/disposal of medical devices	• Improved environmental sustainability of health products and technologies
• Regulatory green highway (Accelerated review of health products and technologies that are environmentally sustainable)	• Accelerated access to environmentally sustainable health products and technologies
• Digitalization of regulatory procedures	• Environmental efficiencies in regulatory procedures

Annex 4
GPW14 Proposed outcome indicators

Table A4.1 Health product access index

Rationale	Access to health products (medicines, vaccines, medical devices including diagnostics, assistive products, blood and other products of human origin) diagnostics and other health products) is a core element of providing quality health services that people need. The health product access index is designed to summarize data from existing essential health service coverage indicators to reduce duplication and reporting burden.
Mandate (WHA resolution, SDG)	WHA60.29, WHA67.22, WHA71.8, WHA76.5 SDG target 3.8: achieve universal health coverage, including financial risk protection, access to quality essential healthcare services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all.
Definition	Health services coverage indicators, that involve the use of any or a combination of health products are selected as tracer indicators to construct the health product access index. The index is computed with geometric means, using the mean scores calculated for each tracer indicator group (or category of product) that is linked to the use of different health products. The index is reported on a unitless scale of 0 to 100, with 100 being the optimal value
Numerator	The country score is calculated using existing national information for each tracer indicator.
Denominator	The denominator will depend on actual number of tracer indicators per category of product used for the calculation of the overall country score.
Preferred data sources	Facility reporting system, Health facility surveys, Household surveys, Administrative data
Other data sources	Official country response to the different types WHO surveys.
Disaggregation	Full disaggregation of the index may not be possible as not all tracer indicators have data that allow for disaggregation.
Frequency of data collection	Annual. As the reporting frequency for selected tracer indicators may not be every year, extrapolation from existing time series data may be used to compute values for the missing year(s).
Limitations	These tracer indicators are meant to be indicative of access to health products and, not a complete or exhaustive list of all health products required to deliver essential health services, under universal health coverage. The 19 tracer indicators were selected because they are well-established, with available data widely reported by countries (or expected to become widely available soon). Therefore, the index can be computed with existing data sources and does not require initiating new data collection.
Data type	Index
Related links	https://www.who.int/data/gho/data/indicators/indicator-details/GHO/uhc-index-of-service-coverage

Source: WHO Results Framework: Outcome Indicators Fourteenth General Programme of Work *(1)*.

Table A4.2 Improved regulatory systems for targeted health products (medicines, vaccines, medical devices including diagnostics)

Rationale	National Regulatory Authorities are the gatekeepers of the supply of medicines and other health products, mandated to ensure their quality, safety, and efficacy. They work within a legal framework and set of regulatory functions spanning the product lifecycle, from clinical trials oversight, marketing authorization and registration, licensing establishments, regulatory inspections, testing products, post-marketing surveillance, and safety monitoring. However, many countries still lack this basic building block of a well-functioning health system Resolution WHA67.20 emphasized the WHO mandate and requested both WHO and Member States to invest more in this area and to address all health products and technologies, particularly in low and middle-income countries. According to WHO database on regulatory systems strengthening activities, about 70% of member states have suboptimal regulatory systems, and especially the low- and middle-income countries. The situation in these countries can be extremely challenging. NRAs are often overburdened and under-staffed, with fragmented structures or insufficient legal and regulatory frameworks resulting into infiltration on the market of substandard and falsified (SF) medical products. SF medical products undermine public health goals, causes deaths, promotes antimicrobial resistance, erodes public confidence on health care services and workforce.
Mandate (WHA resolution, SDG)	WHA67.20 on Regulatory Systems Strengthening for medical products (2014)
Definition	Improved regulatory capacity measured against GBT indicators and implementation of recommendations according to their Institutional Development Plans for each of the health product streams (medicines, vaccines, medical devices and in vitro diagnostics)
Numerator	Maturity level achieved per product stream
Denominator	The highest maturity level achievable as per GBT as per product
Preferred data sources	Benchmarking reports and implementation of Institutional Development Plans (IDPs) according to WHO GBT
Other data sources	N/A
Disaggregation	N/A
Frequency of data collection	Annually
Limitations	Readiness of countries to invest in regulatory systems strengthening based on international good regulatory practices
Data type	Numerical or % implementation of GBT indicators
Related links	WHO global benchmarking tool for evaluation of national regulatory system of medical products (revision VI) Manual for benchmarking of the national regulatory system of medical products and formulation of institutional development plans (who.int) Evaluating and publicly designating regulatory authorities as WHO listed authorities Operational guidance for evaluating and publicly designating regulatory authorities as WHO listed authorities Manual for the performance evaluation of regulatory authorities seeking the designation as WHO listed authorities

Source: WHO Results Framework: Outcome Indicators Fourteenth General Programme of Work *(1)*.

Reference

1. Metadata WHO Results Framework: Outcome Indicators Fourteenth General Programme of Work (GPW14). Geneva: World Health Organization; 2024. (https://cdn.who.int/media/docs/default-source/documents/ddi/gpw14-results-framework_outcome-indicators_metadata.pdf, accessed 29 April 2025).