

# Lesotho



## PHARMACEUTICAL COUNTRY PROFILE





# Lesotho Pharmaceutical Country Profile

Published by Ministry of Health and Social Welfare in collaboration with the World Health Organization

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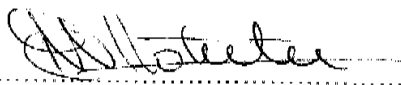
## Foreword

The 2011 Pharmaceutical Country Profile for Lesotho has been produced by the Ministry of Health and Social Welfare, in collaboration with the World Health Organization.

This document contains information on existing socio-economic and health-related conditions, resources; as well as on regulatory structures, processes and outcomes relating to the pharmaceutical sector in Lesotho. The sources of data for each piece of information are presented in the tables that can be found at the end of this document.

On behalf of the Ministry of Lesotho, I wish to express my appreciation to Masoko Ntsekhe from the Ministry of Health and Social Welfare for his contribution to the process of data collection and the development of this profile.

It is my hope that partners, researchers, policy-makers and all those who are interested in the Lesotho pharmaceutical sector will find this profile a useful tool to aid their activities.

Signature:   
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## Introduction

This Pharmaceutical Country Profile provides data on existing socio-economic and health-related conditions, resources, regulatory structures, processes and outcomes relating to the pharmaceutical sector of Lesotho. The aim of this document is to compile all relevant, existing information on the pharmaceutical sector and make it available to the public in a user-friendly format. In 2010, the country profiles project was piloted in 13 countries ([http://www.who.int/medicines/areas/coordination/coordination\\_assessment/en/index.html](http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html)). During 2011, the World Health Organization has supported all WHO Member States to develop similar comprehensive pharmaceutical country profiles.

The information is categorized in 9 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Medicines Trade and Production (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical procurement and distribution, (8) Selection and rational use, and (9) Household data/access. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available). This narrative profile is based on data derived from both the core and supplementary indicators. The tables in the annexes also present all data collected for each of the indicators in the original survey form. For each piece of information, the year and source of the data are indicated; these have been used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links have been provided to the source documents so that users can easily access these documents.

The selection of indicators for the profiles has involved all technical units working in the Essential Medicines Department of the World Health Organization (WHO), as well as experts from WHO Regional and Country Offices, Harvard Medical School, Oswaldo Cruz Foundation (known as Fiocruz), University of Utrecht, the



Austrian Federal Institute for Health Care and representatives from 13 pilot countries. The compiled data comes from international sources (e.g. the World Health Statistics<sup>1,2</sup>), surveys conducted in the previous years and country level information collected in 2011.

Data collection in all 193 member states has been conducted using a user-friendly electronic questionnaire that included a comprehensive instruction manual and glossary. Countries were requested not to conduct any additional surveys, but only to enter the results from previous surveys and to provide centrally available information. To facilitate the work of national counterparts, the questionnaires were pre-filled at WHO HQ using all publicly-available data and before being sent out to each country by the WHO Regional Office. A coordinator was nominated for each of the member states. The coordinator for Lesotho was Masoko Ntsekhe. More information about the Pharmaceutical Country Profile is available on WHO web site at:

[http://www.who.int/medicines/areas/coordination/coordination\\_assessment/en/index.html](http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html).

The completed questionnaires were then used to generate individual country profiles. In order to do this in a structured and efficient manner, a text template was developed. Experts from member states took part in the development of the profile and, once the final document was ready, an officer from the Ministry of Health certified the quality of the information and gave formal permission to publish the profile on the WHO web site.

This profile will be regularly updated by Ministry of Health and Social Welfare. Comments, suggestions or corrections may be sent to:

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## **Section 1 - Health and Demographic Data**

This section gives an overview of the demographics and health status of Lesotho.

### **1.1 Demographics and Socioeconomic Indicators**

The total population of Lesotho in 2006 was 1,881,661 with an annual population growth rate of 0.87%<sup>3</sup>. The annual GDP growth rate is 2.11%<sup>4</sup>. The GDP per capita was US\$ 1,209.67 (at the current exchange rate<sup>i</sup>).

39% of the population is under 15 years of age, and 7% of the population is over 60 years of age. The urban population currently stands at 25% of the total population. The fertility rate in Lesotho is 3.3 births per woman. 43.41% of the population is living with less than \$1.25/day (international PPP). The income share held by the lowest 20% of the population is 2.97% (as a % of national income). The adult literacy rate for the population over 15 years is 82%.

### **1.2 Mortality and Causes of Death**

The life expectancy at birth is 44 and 49 years for men and women respectively. The infant mortality rate (i.e. children under 1 year) is 63/1,000 live births. For children under the age of 5, the mortality rate is 79/1,000 live births. The maternal mortality rate is 960/100,000 live births.<sup>5</sup>

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<sup>i</sup> The exchange rate for calculation for NCU is 8.47, which is consistent with the timing of the collection of related NHA data.



The top 10 diseases causing mortality in Lesotho are:

Ministry of Health and Social Welfare Annual Joint Review Report 2010/11 (p.57); Lesotho Health Systems Assessment 20109 (p.7)

	<b>Disease</b>
1	HIV/AIDS
2	Lower respiratory infections
3	Diarrheal diseases
4	Cerebrovascular disease
5	Ischaemic heart disease
6	Perinatal conditions
7	Tuberculosis
8	Measles
9	Chronic obstructive pulmonary disease
10	Road traffic accidents

The top 10 diseases causing morbidity in Lesotho are:

Ministry of Health and Social Welfare Annual Joint Review Report 2010/11 (p.57); Lesotho Health Systems Assessment 20109 (p.7)

	<b>Disease</b>
1	Cough and colds
2	Heart disease
3	STI
4	Pneumonia
5	Tonsillitis
6	Conjunctivitis
7	HIV/AIDS
8	Diabetes
9	Bronchitis
10	Diarrhoea and gastroenteritis





The adult mortality rate for both sexes between 15 and 60 years is 685/1,000 population, while the neonatal mortality rate is 37/1,000 life births. The age-standardized mortality rate by non-communicable diseases is 581/100,000, 279/100,000 by cardiovascular diseases and 101/100,000 by cancer. The mortality rate for HIV/AIDS is 11000/100,000 and 27/100,000 for tuberculosis. There is no Malaria and therefore no mortality in Lesotho. The HIV/AIDS mortality is for the whole population and includes adults and children.

### **Key reference documents:**

World Health Organisation (WHO) (2008) "World Health Statistics 2008, WHO Press, Geneva.  
Available online: <http://www.who.int/whosis/whostat/2008en/index.html>.

The World Bank (2009), World Databank on "annual GDP growth for Lesotho (%)"  
Available online: <http://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG>; accessed September 2011



## Section 2 - Health Services

This section provides information regarding health expenditures and human resources for health in Lesotho. The contribution of the public and private sector to overall health expenditure is shown and the specific information on pharmaceutical expenditure is also presented. Data on human resources for health and for the pharmaceutical sector is provided as well.

### 2.1 Health Expenditures

In Lesotho, the total annual expenditure on health (THE) in 2011 was 1133 million Lesotho loti (M) (104.44 million US\$)<sup>6</sup>. The total annual health expenditure was 6.44% of the GDP. The total annual expenditure on health per capita was M 421.03 (US\$ 50.97)<sup>7</sup>.

The general government<sup>ii</sup> health expenditure (GGHE) in 2008, as reflected in the national health accounts (NHA) was 486.48 million M (58.90 million US\$). That is, 14% of the total expenditure on health, with a total annual per capita public expenditure on health of M 237.42 (US\$ 28.74). The government annual expenditure on health represents 56.39% of the total government budget. Private health expenditure covers the remaining 43.61% of the total health expenditure.

Of the total population, 0.8% is covered by a public health service, public health insurance or social insurance, or other sickness funds.

Total pharmaceutical expenditure (TPE) in Lesotho in 2011 was 173.7 million M (24.125 million US\$), which is a per capita pharmaceutical expenditure of 92.31 M (US\$ 12.83). The total pharmaceutical expenditure accounts for 9.88% of the GDP and makes up 15.33% of the total health expenditure Figure 1. Public expenditure on pharmaceuticals represents 13.4% of the total expenditure on

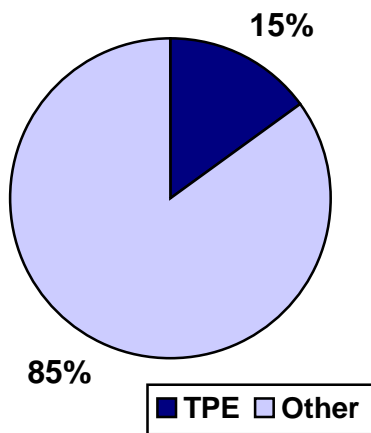
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<sup>ii</sup> According to the NHA definition, by "government expenditure" means all expenditure from public sources, like central government, local government, public insurance funds and parastatal companies.



pharmaceuticals (Figure 2), this converts into a per capita public expenditure on pharmaceuticals of 23.28 M (US\$ 2.75)<sup>8</sup>.

**FIGURE 1: Share of Total Pharmaceutical Expenditure as percentage of the Total Health Expenditure 2011**  
*THE in 2011 = 1,133 million M (104.44 million US\$)*



NDSO Annual Report (2011)

Private out-of-pocket expenditure as % of private health expenditure is 68.85%. Premiums for private prepaid health plans are 0.00% of total private health expenditure.

## 2.2 Health Personnel and Infrastructure

The health workforce is described in the table below and in Figure 3 and 4. There are 93 (0.49/10,000) licensed pharmacists<sup>iii</sup>, of which 30 (0.16/10,000) work in the public sector. There are 59 (0.32/10,000) pharmaceutical technicians and assistants (in all sectors). There are approximately twice as many pharmacy technicians as pharmacists.

<sup>iii</sup> According to Ms. Ramathebane, Lesotho Medical, Dental and Pharmacy Council

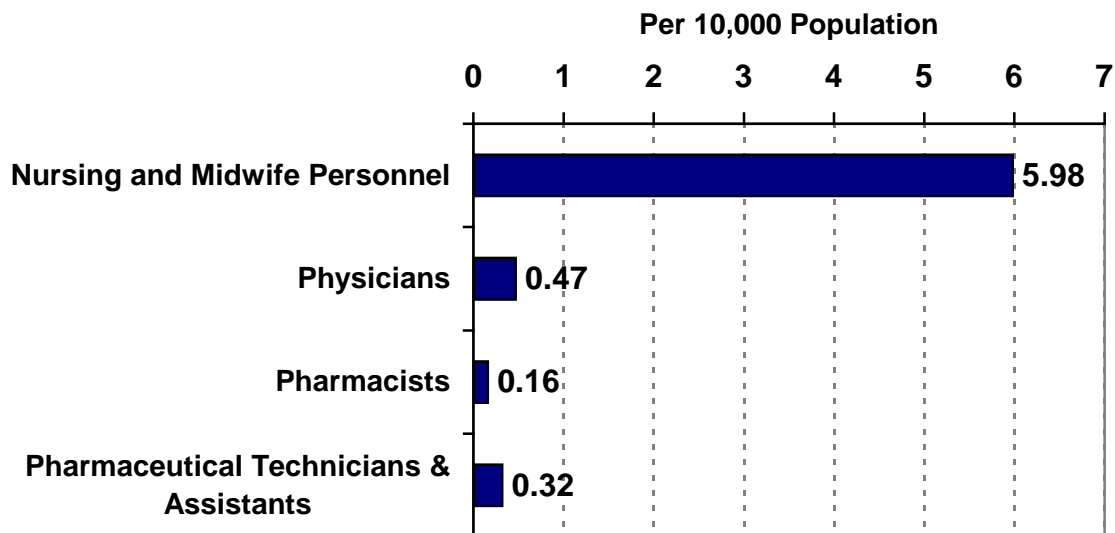


There are 89 (0.47/10,000) physicians and 1,123 (5.98/10,000) nursing and midwifery personnel in Lesotho. The ratio of doctors to pharmacists is 1.04 and the ratio of doctors to nurses and midwifery personnel is 0.08.

**Table 1: Human resources for health in Lesotho**

Human Resource	
Licensed pharmacists (all sectors)	93 (0.49/10,000) <sup>9</sup>
Pharmacists in the public sector (all sectors)	30 (0.16/10,000) <sup>10</sup>
Pharmaceutical technicians and assistants (all sectors)	59 (0.32/10,000) <sup>11</sup>
Physicians (all sectors)	89 (0.47/10,000)
Nursing and midwifery personnel (all sectors)	1,123 (5.98/10,000) <sup>12</sup>

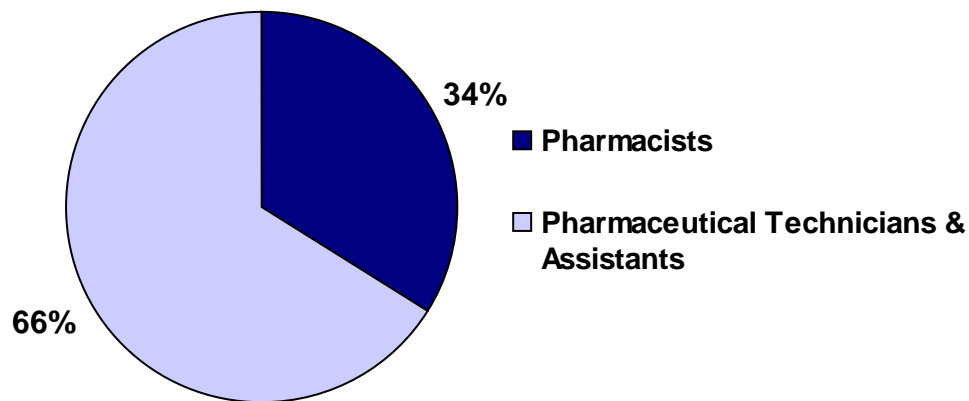
**Figure 3: The density of the Health Workforce 2009 in Lesotho (all sectors)**



WHS, 2009; Ministry of Health 2011



**Figure 4: Distribution of Pharmaceutical Personnel, Lesotho, 2003**



In Lesotho, there is a strategic plan for pharmaceutical human resource development in place<sup>13</sup>.

The health facility structure is described in Table 2. There are 21 hospitals, 1317 hospital beds and 195 primary health care units and centres in Lesotho.

**Table 2: Health centre and hospital statistics**

Infrastructure	
Hospitals	21 <sup>14</sup>
Hospital beds	1317 <sup>15</sup>
Primary health care units and centres	195 <sup>14</sup>

The annual starting salary for a newly registered pharmacist in the public sector is 111,156 M. The total number of pharmacists who graduated (as a first degree) in the past 2 years is 45. Accreditation requirements for pharmacy schools are in place. The pharmacy Curriculum is regularly reviewed.

**Key reference documents:**

World Health Organisation (WHO) (2009); "World Health Statistics 2009" WHO Press, Geneva. Available online: <http://www.who.int/whosis/whostat/2009n/index.html>.

Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011



## Section 3 - Policy Issues

This section addresses the main characteristics of the pharmaceutical policy in Lesotho. The many components of a national pharmaceutical policy are taken from the WHO publication “How to develop and implement national drug policy” (<http://apps.who.int/medicinedocs/en/d/Js2283e/>). Information about the capacity for manufacturing medicines and the legal provisions governing patents is also provided.

### 3.1 Policy Framework

In Lesotho, a National Health Policy (NHP) exists<sup>16</sup>. An associated National Health Policy implementation plan written in 2008 also exists ("3 Year Health and Sector Plan 2008/9-2010/11")<sup>17</sup>.

An official National Medicines Policy document exists in Lesotho. It was updated in 2005. A NMP implementation plan also exists which was most recently updated in 2005. Policies addressing pharmaceuticals exists, as detailed in Table 2. Pharmaceutical policy implementation is regularly monitored/assessed by the Monitoring and Evaluation Unit of Ministry of Health.

**Table 3: The group of policies cover<sup>18</sup>**

Aspect of policy	Covered
Selection of essential medicines	Yes
Medicines financing	Yes
Medicines pricing	Yes
Medicines Procurement	Yes
Medicines Distribution	Yes
Medicines Regulation	Yes
Pharmacovigilance	Yes
Rational use of medicines	Yes
Human Resource Development	Yes



Research	Yes
Monitoring and evaluation	Yes
Traditional Medicine	Yes

A policy relating to clinical laboratories exists and was most recently updated in 2008. An associated National clinical laboratory policy implementation plan, developed in 2008, also exists. Access to essential medicines/technologies as part of the fulfillment of the right to health, is not recognized in the constitution or national legislation<sup>19</sup>. There are official written guidelines on medicines donations<sup>20</sup>.

There is a national good governance policy in Lesotho<sup>21</sup>. This Good Governance policy is multisectoral. Various government ministries, non-governmental organizations, the business sector, political parties and United Nations agencies are responsible for implementing this policy.

No policy in place to manage and sanction conflict of interest issues in pharmaceutical affairs. There is associated formal code of conduct for public officials. A whistle-blowing mechanism that allows individuals to raise concerns about wrongdoing occurring in the pharmaceutical sector of Lesotho, exists<sup>22</sup>. Wrongdoings can be reported to the Anti-corruption unit through its Investigation Section (Police).

### **Key reference documents:**

South African Development Community (2009); "SADC survey", from WHO  
Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed September 2011

Ministry of Health and Social Welfare, "3 Year Health and Sector Plan 2008/9-2010/11"



## Section 4 – Medicines Trade and Production

### 4.1 Intellectual Property Laws and Medicines

Lesotho is a member of the World Trade Organization<sup>23</sup>. Legal provisions for granting patents to manufacturers exist. These cover pharmaceuticals.

Intellectual Property Rights are managed and enforced by the Office of the Registrar General, Law Office, Ministry of Law and Constitutional and Parliamentary Affairs<sup>24</sup>.

National Legislation has been modified to implement the TRIPS Agreement and contains TRIPS-specific flexibilities and safeguards<sup>25</sup>, presented in Table 4.

Lesotho is eligible for the transitional period to 2016.

**Table 4: TRIPS flexibilities and safeguards are present in the national law**

Flexibility and safeguards	Included
Compulsory licensing provisions that can be applied for reasons of public health	Yes
Bolar exceptions <sup>iv</sup>	No
Parallel importing provisions	Yes

<sup>iv</sup> Many countries use this provision of the TRIPS Agreement to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.

In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval (for example from public health authorities) without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision. *Article 30*

This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada - Patent Protection for Pharmaceutical Products")

[In: *WTO OMC Fact sheet: TRIPS and pharmaceutical patents*, can be found on line at: [http://www.wto.org/english/tratop\\_e/trips\\_e/tripsfactsheet\\_pharma\\_2006\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf)]





The country is engaged in capacity-strengthening initiatives to manage and apply Intellectual Property Rights in order to contribute to innovation and promote public health.

Although these do not include legal provisions yet, several sensitization meetings on intellectual property rights have been held in the country, organized by the Ministry of Trade and Industry<sup>26</sup>.

## **4.2 Manufacturing**

There are no licensed pharmaceutical manufacturers in Lesotho.

### **Key reference documents:**

South African Development Community (2009); "SADC survey", from WHO  
Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed  
September 2011



## Section 5 – Medicines Regulation

This section details the pharmaceutical regulatory framework, resources, governing institutions and practices in Lesotho.

### 5.1 Regulatory Framework

In Lesotho, there are no legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA).

### 5.2 Marketing Authorization (Registration)

In Lesotho, legal provisions do not require marketing authorization (registration) for all pharmaceutical products on the market.<sup>27</sup>

### 5.3 Regulatory Inspection

In Lesotho, legal provisions exist allowing for appointment of government pharmaceutical inspectors. Legal provisions exist, permitting inspectors to inspect premises where pharmaceutical activities are performed. Such inspections are not required by law but are a pre-requisite for the licensing of private facilities. Where inspections are legal requirements, these are not the same for public and private facilities. Inspections are carried out on a number of entities, outlined in Table 7, but are not carried out on a routine basis.

**Table 7: Local entities inspected for GMP compliance<sup>28</sup>**

Entity	Inspection
Private wholesalers	Yes
Retail distributors	Yes
Public pharmacies and stores	Yes
Pharmacies and dispensing points if health facilities	Yes



## 5.4 Import Control

Legal provisions do not exist, requiring authorization to import medicines. Laws do not exist that allow the sampling of imported products for testing.

Legal provisions do not exist, requiring importation of medicines through authorized ports of entry. Regulations or laws do not exist to allow for inspection of imported pharmaceutical products at authorized ports of entry<sup>29</sup>.

## 5.5 Licensing

In Lesotho, legal provisions do not exist, requiring manufacturers to be licensed. Legal provisions do not exist, requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP), because there is no manufacturing. Good Manufacturing Practices are not published by the government<sup>30</sup>.

Legal provisions exist, requiring wholesalers and distributors to be licensed. Legal provisions do not exist, requiring wholesalers and distributors to comply with Good Distributing Practices.

**Table 8: Legal provisions pertaining to licensing**

Entity requiring licensing	
Importers	No
Wholesalers	Yes
Distributors	Yes

Legal provisions exist, requiring pharmacists to be registered. Legal provisions exist, requiring private pharmacies to be licensed. National Good Pharmacy Practice Guidelines are not published by the government<sup>31</sup>. By law, a list of all licensed pharmaceutical facilities is not required to be published.



## 5.6 Market Control and Quality Control

In Lesotho, legal provisions do not exist for controlling the pharmaceutical market. A laboratory does not exist in Lesotho for Quality Control testing.

**Table 9: Reason for medicines testing<sup>32</sup>**

Medicines tested:	
For quality monitoring in the public sector <sup>v</sup>	No
For quality monitoring in the private sector <sup>vi</sup>	No
When there are complaints or problem reports	Yes
(for product registration)	[Yes/No]
For public procurement prequalification	Yes
For public program products prior to acceptance and/or distribution	Yes

Samples are not collected by government inspectors for undertaking post-marketing surveillance testing.

**[If samples are collected]**

In the past 2 years, [**<number>**] samples were taken for quality control testing. Of the samples tested, [**<number>**] (or [**<number>**] [**(calculate percentage = (5.06.05/5.06.07)\*100**)] %) failed to meet the quality standards. The results [**are/are not**] publicly available<sup>33</sup>.

## 5.7 Medicines Advertising and Promotion

In Lesotho, legal provisions do not exist to control the promotion and/or advertising of prescription medicines. Legal provisions do not prohibit direct advertising of prescription medicines to the public. Guidelines and Regulations do not exist for advertising and promotion of non-prescription medicines. There is

<sup>v</sup> Routine sampling in pharmacy stores and health facilities

<sup>vi</sup> Routine sampling in retail outlets



no national code of conduct concerning advertising and promotion of medicines by marketing authorization holders.

## 5.8 Clinical Trials

In Lesotho, legal provisions do not exist requiring authorization for conducting Clinical Trials by the MRA. There are no additional laws requiring the agreement by an ethics committee or institutional review board of the Clinical Trials to be performed. Clinical trials are not required to be entered into an international/national/regional registry, by law<sup>34</sup>.

Legal provisions do not exist for GMP compliance of investigational products. Sponsor investigators are not legally required to comply with Good Clinical Practices (GCP). National GCP regulations are not published by the Government. Legal provisions do not permit the inspection of facilities where clinical trials are performed.

## 5.9 Controlled Medicines

Lesotho is a signatory to a number of international conventions, detailed in Table 10.

**Table 10: International Conventions to which Lesotho is a signatory<sup>35</sup>**

Convention	Signatory
Single Convention on Narcotic Drugs, 1961	Yes
1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes
Convention on Psychotropic Substances 1971	Yes
United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes

Laws exist for the control of narcotic and psychotropic substances, and precursors (Drugs of Abuse Act, 2008). The annual consumption of Morphine is 0.003416 mg/capita.



The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have not been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need.

**Table 10S: Annual consumption of selected controlled substances in Lesotho<sup>36</sup>**

Controlled substance	Annual consumption (mg/capita)
Morphine	0.0034
Fentanyl	0.1822
Pethidine	0.8692

### 5.10 Pharmacovigilance

In Lesotho, there are no legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate. Legal provisions do not exist either requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA. Laws regarding the monitoring of Adverse Drug Reactions (ADR) do not exist in Lesotho<sup>37</sup>. A national pharmacovigilance centre linked to the MRA does not exist.

ADRs are monitored in at least one public health program (TB, HIV, AIDS).

A number of steps are being considered in order to enhance pharmacovigilance system. These include development of ADR forms that are not in use yet.

#### Key reference documents:

International Narcotics Control Board (2010)

Available online: [http://www.incb.org/incb/annual\\_report.html](http://www.incb.org/incb/annual_report.html); accessed September 2011

South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>;

accessed September 2011



## Section 6 - Medicines Financing

In this section, information is provided on the medicines financing mechanism in Lesotho, including the medicines coverage through public and private health insurance, use of user charges for medicines and the existence of public programmes providing free medicines. Policies and regulations affecting the pricing and availability of medicines (e.g. price control and taxes) are also discussed.

### 6.1 Medicines Coverage and Exemptions<sup>38</sup>

In Lesotho, concessions are made for certain groups to receive medicines free of charge (see Table 11). Furthermore, the public health system or social health insurance schemes provide medicines free of charge for particular conditions (see Table 12). However, there is no health insurance scheme in Lesotho.

**Table 11: Population groups provided with medicines free of charge**

Patient group	Covered
Patients who cannot afford them	Yes
Children under 5	Yes
Pregnant women	Yes
Elderly persons	Yes

**Table 12: Medications provided publicly, at no cost**

Conditions	Covered
All diseases in the EML	Yes
Any non-communicable diseases	Yes
Malaria	Yes/No
Tuberculosis	Yes
Sexually transmitted diseases	Yes
HIV/AIDS	Yes
Expanded Program on Immunization (EPI) vaccines for	Yes



children	
Contraceptives	Yes

Medicines are free at the health centre level. However at the hospital level they are provided with other services for a hugely subsidized all inclusive fee - medicines are not charged separately in any of the faculties.

## 6.2 Patients Fees and Copayments

Co-payments or fee requirements for consultations are levied at the point of delivery. However, there are no copayments or fee requirements imposed for medicines. Revenue from fees or from the sale of medicines is used to pay the salaries or supplement the income of public health personnel in the same facility.<sup>39</sup>

## 6.3 Pricing Regulation for the Private Sector<sup>vii</sup>

In Lesotho, there are no legal or regulatory provisions affecting pricing of medicines.

The government does not run an active national medicines price monitoring system for retail prices. Regulations do not exist mandating that retail medicine price information should be publicly accessible<sup>40</sup>.

## 6.4 Prices, Availability and Affordability of Key Medicines

Within the last five years no WHO/HAI pricing survey was conducted in Lesotho. Nevertheless, other surveys on medicines prices and availability have been conducted (Medicines Access Survey 2007 and 2010).

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<sup>vii</sup> This section does not include information pertaining to the non-profit voluntary sector





## 6.6 Duties and Taxes on Pharmaceuticals (Market)

Lesotho [imposes/does not impose] duties on imported active pharmaceutical ingredients (APIs) and duties on imported finished products are also imposed. Value-added tax or other taxes are imposed on finished pharmaceutical products. Provisions for tax exceptions or waivers for pharmaceuticals and health products are in place<sup>41</sup>. Taxes are applied to public sector medicines. Donations are exempted from taxes. The VAT on pharmaceutical products is 14%.

### Key reference documents:

South African Development Community (2009); "SADC survey", from WHO Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed September 2011



## **Section 7 - Pharmaceutical Procurement and Distribution in the Public Sector**

This section provides a short overview on the procurement and distribution of pharmaceuticals in the public sector of Lesotho.

### **7.1 Public Sector Procurement**

Public sector procurement in Lesotho is both centralized and decentralized. There is a National Procurement Agency, which procures on behalf of all public facilities. The facilities then procure from the National Agency as per need.

The public sector procurement is centralized under the responsibility of a procurement agency which is semi-autonomous government agency that procures all public goods<sup>42</sup>.

Public sector request for tender documents are publicly available, but public sector tender awards are not publicly available. Procurement is based on the prequalification of suppliers<sup>43</sup>. Information on where the supplier's goods are registered and sold is requested and whether the supplier's goods are registered in his own country. After assessment of the required documentation and testing of samples a decision is made whether to prequalify. There is a written public sector procurement policy. This policy was approved in 2009.

Legal provisions exist, that give priority to locally produce goods in public procurement. The key functions of the procurement unit and those of the tender committee are clearly separated. A process exists to ensure the quality of products that are publicly procured.

The quality assurance process includes the pre-qualification of products and suppliers. A list of pre-qualified suppliers and products is available. A list of samples tested during the procurement process and the results of quality testing are not available. The tender methods employed in public sector procurement include, international competitive tenders and direct purchasing.



## 7.2 Public Sector Distribution

The government supply system department in Lesotho has a Central Medical Store at National Level<sup>44</sup>. There are no public warehouses in the secondary tier of the public sector distribution. There are national guidelines on Good Distribution Practices (GDP). A licensing authority that issues GDP licenses does exist<sup>45</sup>. The licensing authority does not accredit public distribution facilities, but private sector facilities only.<sup>viii</sup>

A list of GDP certified wholesalers or distributors does not exist (SADC, 2009) in the public sector.

A number of processes are in place at the Central Medical Store as detailed in Table 14S.

**Table 14S: Processes employed by the Central Medical Store**

Process	
Forecasting of order quantities	Yes
Requisition/Stock orders	Yes
Preparation of picking/ Packing slips	Yes
Reports of stock on hand	Yes
Reports of outstanding order lines	Yes
Expiry dates management	Yes
Batch tracking	No
Reports of products out of stock	Yes

The percentage availability of key medicines at the Central Medical Store (CMS) is 82%. Routine procedure to track the expiry dates of medicines at the CMS exist. The Public CMS not ISO certified.<sup>46</sup>

<sup>viii</sup> According to Ministry of Health and Social Welfare, 2011



### 7.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers and distributors in the private sector. A list of GDP certified wholesalers and distributors does not exist in the private sector<sup>47</sup>.

#### **Key reference documents:**

South African Development Community (2009); "SADC survey", from WHO  
Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>;  
accessed September 2011



## **Section 8 - Selection and Rational Use of Medicines**

This section outlines the structures and policies governing the selection of essential medicines and promotion of rational drug in Lesotho.

### **8.1 National Structures**

A National Essential Medicines List (EML) exists.

The EML was lastly updated in 2006 and is publicly available.

There are currently 216 medicines on the EML. Selection of medicines for the EML is not undertaken through a written process. A mechanism aligning the EML with the Standard Treatment Guidelines (STGs) is in place<sup>48</sup>.

National Standard Treatment Guidelines (STGs) for the most common illnesses are produced/endorsed by the MoH in Lesotho.

These were last updated in 2006. Specific STGs cover primary care, secondary care and paediatric conditions (updated in 2006)<sup>49</sup>.

Of the public health facilities, 89% have a copy of the EML and 79% have a copy of the STGs.

There is no public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and consumers<sup>50</sup>. Public education campaigns on rational medicine use topics have not been conducted in the last two years. A survey on rational use of medicines has been conducted in the previous two years. There is no national programme or committee, involving government, civil society, and professional bodies, to monitor and promote rational use of medicines.

A written National Strategy for containing antimicrobial resistance does not exist<sup>51</sup>.



Lesotho's Essential Medicines List (EML) includes formulations specifically for children. Criteria for the selection of medicines to the EML are not explicitly documented. A national medicines formulary does exist.

A funded national intersectoral task force to coordinate the promotion of the appropriate use of antimicrobials and prevention of the spread of infection does not exist.

A national reference laboratory or other institution does not have the responsibility for coordinating epidemiological surveillance of antimicrobial resistance.

## **8.2 Prescribing**

Legal provisions exist to govern the licensing and prescribing practices of prescribers. Furthermore, legal provisions restricting dispensing by prescribers do not exist. Prescribers in the private sector dispense medicines.

There are no regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs). Where there are requirements for DTCs, more than half of general hospitals as well as regional/provincial hospitals have one. Mandatory continuing education that includes pharmaceutical issues is not required for doctors, nurses or paramedical staff.

Prescribing by INN name is obligatory in the public sector<sup>52</sup>. The average number of medicines prescribed per patient contact in public health facilities is 3. Of the medicines prescribed in the outpatient public health care facilities, 88 % are on the national EML. Of the patients treated in the outpatient public health care facilities, 53% receives antibiotics and 8% receive injections. Of prescribed drugs, 86.5% are dispensed to patients. Of medicines in public health facilities, 31.1% are adequately labelled.



**Table 16: Characteristics of medicines prescribing**

	%
% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	88
% of patients in outpatient public health care facilities receiving antibiotics (mean)	53
% of patients in outpatient public health care facilities receiving injections (mean)	8
% of prescribed drugs dispensed to patients (mean)	86.5
% of medicines adequately labeled in public health facilities (mean)	31.1

A professional association code of conduct which governs the professional behaviour of doctors exists. Similarly a professional association code of conduct governing the professional behaviour of nurses exists.

### 8.3 Dispensing

Legal provisions in Lesotho exist to govern dispensing practices of pharmaceutical personnel. The basic pharmacist training curriculum includes a spectrum of components as outlined in Table 17.

**Table 17: Core aspects of the pharmacist training curriculum<sup>53</sup>**

	Covered
The concept of EML	Yes
Use of STGS	Yes
Drug information	Yes
Clinical pharmacology	Yes
Medicines supply management	Yes



Mandatory continuing education that includes rational use of medicines is not required for pharmacists.

Substitution of generic equivalents at the point of dispensing is allowed in public and private sector facilities. Sometimes antibiotics are sold over-the-counter without a prescription. Injectable medicines are not sold over-the-counter without a prescription.<sup>54</sup>

A professional association code of conduct which governs the professional behaviour of pharmacists exists. In practice, nurses, pharmacists and personnel with less than one month of training do sometimes prescribe prescription-only medicines at the primary care level in the public sector (even though this may be contrary to regulations).

### **Key reference documents:**

South African Development Community (2009); "SADC survey", from WHO  
Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed  
September 2011  
Access to Medicines Survey - Lesotho, 2007 and 2010





## **List of key reference documents:**

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<sup>1</sup> World Health Organisation (WHO) (2010), "World Health Statistics 2010", WHO Press, Geneva. Available online: <http://www.who.int/whosis/whostat/2010/en/index.html>.

<sup>2</sup> World Health Organisation (WHO) (2009), "World Health Statistics 2009", WHO Press, Geneva. Available online: <http://www.who.int/whosis/whostat/2009/en/index.html>.

<sup>3</sup> Lesotho Health System Assessment, 2010

<sup>4</sup> The World Bank (2009), World Databank on "annual GDP growth for Lesotho (%)" Available online: <http://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG>; accessed September 2011

<sup>5</sup> World Health Organisation (WHO) (2010), "World Health Statistics 2008", WHO Press, Geneva. Available online: <http://www.who.int/whosis/whostat/en/>; accessed September 2011

<sup>6</sup> Annual Joint Review (AJR), 2011

<sup>7</sup> National Health Accounts (2008)

Available online: <http://www.who.int/nha/country/lso/en/>, accessed September 2011

<sup>8</sup> Lesotho Health System Assessment, 2010

<sup>9</sup> **Ms. Ramathebane, Lesotho Medical, Dental and Pharmacy Council, 2011**

<sup>10</sup> **Head count department of pharmacy, 2011**

<sup>11</sup> Global Health Atlas, 2003

<sup>12</sup> World Health Organisation (WHO) (2010)

Available online: <http://www.who.int/whosis/whostat/en/>; accessed September 2011

<sup>13</sup> Lesotho Health Sector, "Human Resources Development & Strategic Plan 2005-2025", 2005

<sup>14</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed September 2011

<sup>15</sup> World Health Organisation (WHO) (2009), "World Health Statistics 2009", WHO Press, Geneva. Available online: <http://www.who.int/whosis/whostat/2009/en/index.html>.

<sup>16</sup> South African Development Community (2004); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed September 2011

<sup>17</sup> Ministry of Health and Social Welfare, "3 Year Health and Sector Plan 2008/9-2010/11", 2008



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<sup>18</sup> South African Development Community (2004); "SADC survey", from WHO  
Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed  
September 2011

<sup>19</sup> Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011

<sup>20</sup> Ministry of Health and Social Welfare, Department of Pharmaceuticals, 2008

Available online: <http://www.health.gov.ls/>; accessed September 2011

<sup>21</sup> **Vision 2020, 2006**

<sup>22</sup> Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011

<sup>23</sup> World Trade Organization (2011), "Member Information on Lesotho and the WTO" - Lesotho is  
member of the WTO since May 1995.

Online available: <http://www.wto.org/>; accessed September 2011

<sup>24</sup> Industrial Property Order, 1989

<sup>25</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed  
September 2011

<sup>26</sup> Ministry of Trade and Industry, 2011

Available online: <http://www.trade.gov.ls/home/>

<sup>27</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed  
September 2011

<sup>28</sup> Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011

<sup>29</sup> Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011

<sup>30</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed  
September 2011



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<sup>31</sup> Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011

<sup>32</sup> Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011

<sup>33</sup> **INSERT reference for 5.06.06-5.06-08**

<sup>34</sup> Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011

<sup>35</sup> International § Control Board (2010)

Available online: [http://www.incb.org/incb/annual\\_report.html](http://www.incb.org/incb/annual_report.html); accessed September 2011

<sup>36</sup> International Narcotics Control Board (2010)

Available online: [http://www.incb.org/incb/annual\\_report.html](http://www.incb.org/incb/annual_report.html); accessed September 2011

<sup>37</sup> Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011

<sup>38</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed September 2011

<sup>39</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed September 2011

<sup>40</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed September 2011

<sup>41</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed September 2011

<sup>42</sup> Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011



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<sup>43</sup> South African Development Community (2009); "SADC survey", from WHO  
Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed  
September 2011

<sup>44</sup> **Supplement No.4 of 2<sup>nd</sup> March 2007**

<sup>45</sup> Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011

<sup>46</sup> Central Procurement Agency (NDSO), 2011

<sup>47</sup> Lesotho Medical, Dental and Pharmacy Order, 1970

<sup>48</sup> Lesotho Essential Medicines List, 2006

<sup>49</sup> Standard Treatment Guidelines Lesotho, 2006

<sup>50</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed  
September 2011

<sup>51</sup> Ministry of Health and Social Welfare, 2011

Available online: <http://www.health.gov.ls/>; accessed September 2011

<sup>52</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed  
September 2011

<sup>53</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed  
September 2011

<sup>54</sup> South African Development Community (2009); "SADC survey", from WHO

Available online: <http://apps.who.int/medicinedocs/en/m/abstract/Js17209e/>; accessed  
September 2011



Investing in our future

**The Global Fund**

To Fight AIDS, Tuberculosis and Malaria

# Pharmaceutical Sector Country Profile Questionnaire

**LESOTHO**

# The Pharmaceutical Sector Country Profile Survey

## 1. Background and Rationale:

Pharmaceutical Sector Country Profiles aim to increase the availability of quality information on structures, processes and outcomes of health and pharmaceutical sectors of countries. This information will be collected through a questionnaire and is meant to be used by country decision-makers, health and pharmaceutical experts, international partners and the public through databases and published country, regional and global reports.

The information is categorized in nine sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Medicines Policies, (4) Medicines Trade and Production, (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical Procurement and distribution, (8) Selection and Rational Use and (9) Household data/access.

Every four years since 1999, health officials from the 193 WHO Member States have been invited to complete a standardized questionnaire (named Level I) reporting on the status of the national pharmaceutical situation. Level I indicators assessed structures and processes related to the pharmaceutical situation of a country. They were used to carry out a rapid assessment that would highlight strengths and weaknesses of countries pharmaceutical situations. 156 countries responded to the 2007 level I survey and the results were stored and available in a global WHO database and used to develop a global report as well as a number of regional and sub-regional reports. The Pharmaceutical Sector Country Profile questionnaire described here will replace the Level I tool for the 2011 Member States' survey. The aim of this new approach is to build on the achievements and lessons learnt from the Level I tools and surveys and to improve the quality and scope of information (e.g, outcomes and results indicators) and enhance the involvement and ownership of countries in the development of profiles. The new tool has been piloted in the 15 countries of the Southern African Development Community in 2009 and in 13 countries across the world in 2010. The results of these pilots are available on-line at: [http://www.who.int/medicines/areas/coordination/coordination\\_assessment/en/index.html](http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html)

Another innovation of the 2011 survey is the collaboration between WHO and The Global Fund. In 2009, the Global Fund developed and introduced the Pharmaceutical and Health Product Management ("PHPM") Country Profile to gradually replace the Procurement and Supply Management ("PSM") Plan. In the course of 2010 both agencies have developed a joint Pharmaceutical Sector Country Profile questionnaire that includes key indicators of the

pharmaceutical sector and that will be used by both agencies as the sole tool for pharmaceutical sector data collection in countries. The information captured in the Pharmaceutical Sector Country Profile questionnaire will be used by the Global Fund during grant negotiations and signing, and will also support grant implementation. In addition to the Country Profile that provides an overview of countries' pharmaceutical sectors, the Global Fund will also use a second questionnaire that will focus in more detail on medicines procurement and supply.

## **2. What can Pharmaceutical Sector Country Profiles offer:**

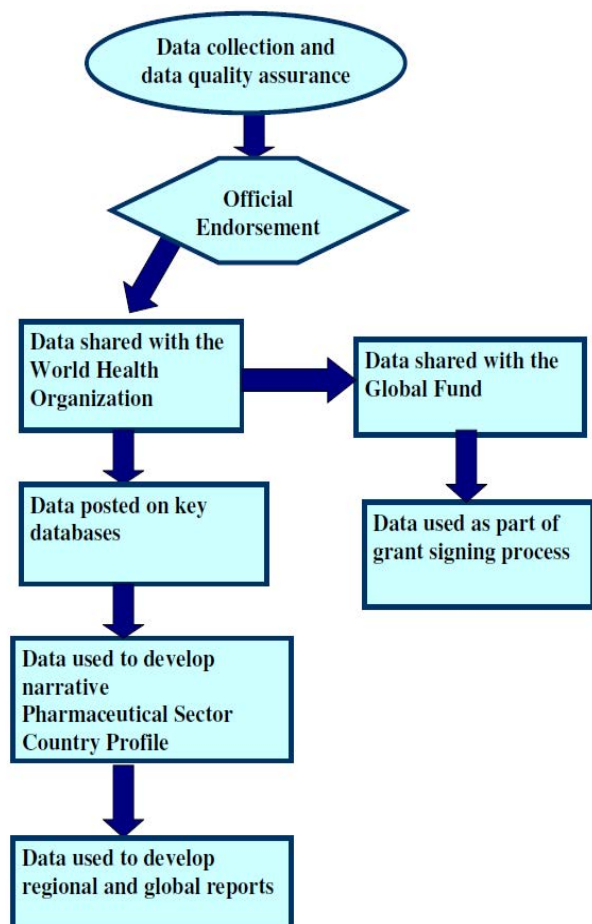
Completing this questionnaire will require the time of national experts and responsible officers but it is worthwhile as your country and your partners will benefit from it in a number of ways:

- I) The questionnaire offers a unique opportunity to consolidate, in one place, information that is available in different locations and institutions e.g. the National Medicines Regulatory Authority, Central Medical Stores, National Health Accounts, etc.
- II) The methodology proposed for filling in the questionnaire will ensure that good quality data are collected and that the source and date of information are known and reported.
- III) Data on structure, process and outcomes are collected, and the questionnaire has been pre-filled with data available in the public domain; indicators are divided into core and supplementary in order to make it easier to identify what is more important.
- IV) The data collected will highlight the strengths and weaknesses of the pharmaceutical sector and will be made available in a national database as official country information, for use by decision-makers, health and pharmaceutical experts, researchers and international partners and the public..
- V) The data collected could be transformed into a narrative report with robust data analysis and bibliographic references, that will summarize the medicines situation in the country.
- VI) Based on experiences from previous surveys, a detailed glossary of key definitions and a manual for use of the questionnaire have been developed and can be found at the end of the questionnaire.

### 3. The process of data collection and analysis:

**3.1 Data collection.** The Pharmaceutical Sector Country Profile questionnaire has already been filled in by WHO with reliable data available from global and country sources. We kindly ask you to review, to correct (if necessary) and to validate the information already included in the questionnaire, and also to fill in the gaps, based on reliable information available in your country.

In order to do this, we recommend that you involve the most appropriate respondents and responsible institutions to fill in the various components of the tool so that the questionnaire is completed within the given deadline, with good quality information. If during the data collection process, clarifications are needed, WHO Regional and Headquarters Offices will provide the necessary assistance and support, including for data quality issues.



**3.2 Official endorsement.** Once the questionnaire has been completed, the information contained in it should be officially endorsed and its disclosure authorized by a senior official in the Ministry of Health. This should be done by signing the formal endorsement form attached to the questionnaire. This will ensure that the quality of the information contained in the Pharmaceutical Sector Country Profile questionnaire is certified by the country.

**3.3 Data shared with the Global Fund.** Data collected from Global Fund priority countries will be shared with the Global Fund and it will be used as part of the Global Fund's own grant signing and implementation procedures.

**3.4 Data posted on key databases.** Data endorsed by the country will be posted on health databases (such as the WHO Global Health Observatory, <http://www.who.int/gho/en/>), making it available to decision-makers, health and medicines experts and researchers, international partners and the public.



**3.5 Development of narrative Pharmaceutical Sector Country Profiles.** Data provided within the country questionnaire can be used by the country to develop a narrative profile that will illustrate the national pharmaceutical sector. In order to do this, WHO has prepared a template profile (included in the CD-Rom shared with you) that can be easily used by countries and that will help presenting data in the form of tables, graphs and charts. Countries could seek support from WHO for the development of their narrative profile, which will be finalized and validated by the country that will own the copyright for it and will publish it as a national official document.

**3.6 Development of Regional and Global Reports.** The information provided by countries in the Pharmaceutical Sector Country Profile questionnaire will be analysed by WHO and used to produce regional and global reports on the pharmaceutical sector of countries in 2011. These reports will provide an overview of the progress made between 2007 and 2011, of the challenges that remain to be addressed and will include data analysis by technical areas, countries' income level and geographical location.

# Guidelines for countries on how to fill in the Pharmaceutical Sector Country Profile Questionnaire

## Please read these instructions carefully before starting data collection

1. Macros: the questionnaire has macros installed. A macro is a series of MS Word commands and instructions that are grouped together as a single command to accomplish a task automatically. For these macros to work properly, the macro security levels for MS Word on your computer should be set as 'low'. This can be easily adjusted by taking the following steps:

1. Open the Word document containing the instrument.
2. Go to 'Tools' > 'Macro' > 'Security'.
3. Click on the tab 'Security Level'.
4. Set the Security on 'Low' and click 'OK'.

After filling in the questionnaire, the setting should be restored to a higher level of security in order to protect your computer.

2. Core and supplementary indicators: the instrument consists of core and supplementary questions. Core questions cover the most important information, while supplementary questions deal with more specific information applicable to particular sections. Please note that core questions have been shaded with different coloured backgrounds for different sections of the instrument, while supplementary questions are all white. This should help you to distinguish between the different categories of indicators. Please try to fill in all the core questions for each section before moving to the supplementary ones. Remember that we are only asking you to collect information that is already available and you are not expected to conduct any additional survey(s).

3. Prefilled data: the answers to some of the questions have been prefilled by WHO HQ. Where this is the case, please verify this information as it may not be up-to-date. If you find that any of the prefilled responses are not correct, please change the value and document the source and year.

4. Calculated fields: for a few items, you will not be required to enter any value as these will be generated at WHO HQ using data entered into related fields. These fields have been clearly marked in red – please do not input any data into them or change data that are already in this field. For example, the per capita expenditure on health will be automatically calculated once the total health expenditure and population are entered into the questionnaire. This system is intended to improve the quality of answers and avoid you having to perform additional calculations. Calculated fields are protected and cannot be changed.

5. Possible answers:

*Checkbox 'Yes/No/Unknown':* tick one of the three options (only one answer is possible).

*Multiple choice checkbox:* tick any of the options that apply (multiple answers are sometimes possible).

*Percentage fields:* 0-100. Please use decimal points ('dots') for decimals (example: 98.11). Please do not use ranges (e.g. "3-5"). If you only have ranges, then use the median and otherwise the mean. In this instance, please detail what data you have used and what the range is in the comment boxes.

*Number fields:* unlimited number. Please use decimal points ('dots') for decimals (example: 29387.93). Please do not use ranges. If you only have ranges, then use the median and otherwise the mean. In this instance, please detail what data you have used and what the range is in the comment boxes.

6. Comments: comments fields allow the entry of free text to clarify or follow up on answers given. Please reference each comment by using the number of the question you are referring to (example: 2.01.02).

7. Year of data : year fields should be used to specify the year of the **data** used to answer the question. Only values between 1930 and 2011 will be accepted. Please use this column as follows:

- When the source refers directly to a specific document (for example: 'Medicines Act' or 'EML'), please put in the publication year of the document (note: only the year and not a specific date can be entered).
- When the source refers to a document that contains older data than the document itself, please put in the original year of the data. For example, when the total population for 2008 is extracted from the World Health Statistics 2010, please put 2008 in the 'year' column and 'World Health Statistics 2010' in the 'source' column.
- When the source of the information is not a document, but the informant himself/herself, please put in the current year.

**8. Source of data:** sources used for the answers given will be referenced in the narrative country profile and in the databases in which the information will be stored. Please specify your sources as clearly as possible by providing the name, year, and writer/publisher of the documents used. Also provide a web (URL) link to the documents, if available. If there is only a non-English version of the reference available, then please include it regardless of the language. Use the 'source' column to enter the name and year of the **source**, and use the "Comments and References" fields at the end of every section to list the sources. In case the source is not documented, then provide the name and title of the person and/or the entity they work for as a source of information. Examples are given below.

7.01.12S	Which of the following <u>tender</u> methods are used in public sector procurement		1996	DoH, 1996
7.01.12.01 S	National competitive tenders	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.12.02 S	International competitive tenders	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.12.03 S	Direct purchasing	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.13S	Comments and References	National Drug Policy for South Africa , published in 1996. Document availablilt at: <a href="http://www.doh.gov.za/docs/policy/drugsjan1996.pdf">http://www.doh.gov.za/docs/policy/drugsjan1996.pdf</a>		

**9. Documents:** you will see in the questionnaire that we would like you to collect and share a number of key country documents that we believe would greatly enrich the country’s profile content and these documents could be made available through countries and WHO web pages. Please attach the following documents, if available:

- National Medicines Policy (NMP);
- NMP implementation plan;
- National Medicines Act;
- National pharmaceutical Human Resources report or strategic plan;
- Latest report on the national pharmaceutical market (any source);
- Pharmacovigilance national centre report (including an Adverse Drug Reaction (ADR), analysis report produced in the last two years);
- National pharmaceutical legislation or regulation;
- Annual report of quality control laboratories;

- Annual report of national regulatory authority;
- Legal provisions on medicines price regulations;
- Medicines procurement policy;
- National Essential Medicines List (EML);
- National Standard Treatment Guidelines (STGs);
- National strategy for antimicrobial resistance;
- Any other medicines pricing/availability surveys, household surveys and rational use surveys, in addition to the ones used to prefill the instrument.

The last page of the questionnaire contains a table with the list of key documents to be attached. Please fill it in by indicating the exact title, publisher and year for each attachment as shown in the example below.

Document	Exact title	Author	Publisher	Year	File name
<b>Essential Medicines List</b>	National Medicines List	Ministry of Health	Ministry of Health	2009	EML.doc
<b>National Medicines Policy</b>	National Drug Policy	Federal Ministry of Health	Federal Ministry of Health	2005	NDP.pdf

These documents will be published on the WHO web site's medicines library (<http://apps.who.int/medicinedocs/en/>) and will therefore have to be endorsed by the Ministry of Health prior to being made publicly available. You can send us these documents by e-mail as attachments or you can upload them into a protected web site. Please use the table at the end of the instrument to report the title, year and author of the documents attached.

**10. Attaching files to the questionnaire:** please place all files to be attached in a single folder on your computer. Name the documents as follows: <short name of the document>.doc (example: EML.doc). Then compress (ZIP) the files and attach the compressed file with the completed instrument to the email. If the total file size of the compressed file exceeds 7 MB, you can upload the documents in a protected file server called MedNet, which is managed by WHO. The procedure for doing this is very simple and please contact Mr Enrico Cinnella in WHO HQ, Geneva, ([cinnellae@who.int](mailto:cinnellae@who.int)) to be granted access to MedNet and to receive instructions on how to upload files. You can also upload documents to the WHO Medicines Documentation server at <http://hinfo.humaninfo.ro/medicinedocs/>, though the documents will only appear on the Medicines Documentation site at the beginning of the following month.

**11. Manual for use of the questionnaire:** the manual contains detailed instructions on the questionnaire, on where to find information and how to answer questions.

Questions that may be particularly problematic are marked with the following icon:



**12. Glossary:** the glossary contains definitions for all key and/or problematic items in the instrument. It is highly recommended that you use the glossary, since exact definitions might differ between countries and institutions. The glossary is at the end of the file. When a question contains an item that is defined in the glossary, the terms will be marked in bold, underlined and written in blue font.

2.02 Health Personnel and Infrastructure				
Core questions <a href="#">(click for help)</a>				
			Year	Source
2.02.01	Total number of pharmacists licensed/registered to practice in your country			
2.02.02C	Pharmacists per 10,000 population			
2.02.03	Total number of pharmacists working in the public sector			
2.02.04	Total number of <u>pharmaceutical technicians and assistants</u>			
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes <input type="checkbox"/> No <input type="checkbox"/>		

definition of "pharmaceutical technicians and assistants" is in the glossary

Instructions are available for this specific question

**13. Respondents and acknowledgements:** at the beginning of every section there are fields available to fill in details about the respondent for that particular section. It is also possible to enter the details of multiple respondents. At the end of the instrument please add a list of contributors who should be acknowledged. Provide their names and the main organization(s) they work for.

**14. Endorsement of data:** A formal endorsement needs to be signed by a senior official in the Ministry of Health before the completed questionnaire is sent back to WHO. The endorsement form is included in the pack of CD-ROM documents you have received from WHO. Please present the endorsement form to a senior official in the Ministry of Health for signature, and for obtaining permission to use and publish the data.

15. Process of creating a country profile document: The data you will collect using this questionnaire can be used to develop a pharmaceutical sector country profile for the country. Examples of profiles are available on-line at [http://www.who.int/medicines/areas/coordination/coordination\\_assessment/en/index1.html](http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index1.html)

WHO has prepared a template profile (included in the CD) that can be easily used by countries and that will help presenting data in the form of tables, graphs and charts. Countries can use the generic template provided by WHO and add the information in the questionnaire. Below you can find an example of the template that shows how fields can be changed according to the specific responses provided by each country.

<b>3.2 Intellectual Property Laws and Medicines</b>	
Country X is/is not a member of the World Trade Organization. The country has/has no patent law. National Legislation has/has not been modified to implement the TRIPS Agreement. Country X is/is not eligible for the transitional period to 2016.	
The following (TRIPS) flexibilities and safeguards are present in the national law:	
Compulsory licensing provisions that can be applied for reasons of public health	Yes/No

In each section of the questionnaire you will find some comment boxes that you can use to expand on the answer to one or more questions. The text of these comments can also be included in the profile in order to present the country situation in more detail.

In the questionnaire you are also asked to indicate the source and date of each piece of information you provide; these should be used to develop bibliographic references for the profile.

If you prefer, WHO can develop the narrative profile and the Organization will then share the document with the country, which will own/maintain the copyright for it and will be able to publish it as a national document.

## Section 0 General Info

### 0.01 Contact Info

0.01.01	Country (precoded)	RV_Lesotho
0.01.02	Name coordinator	MASOKO NTSEKHE
0.01.03	Address (Street, City)	445 MANONG ROAD,HILLSVIEW,MASERU
0.01.04	Phone number	(266) 58929467
0.01.05	Email address	ntsekhem@health.gov.ls / masoko.ntsekhe@yahoo.com
0.01.06	Web address	www.health.gov.ls
0.01.07	Institution	MINISTRY OF HEALTH AND SOCIAL WELFARE



## Section 1 Health and Demographic data

### 1.00 Respondent Information Section 1

1.00.01	Name of person responsible for filling out Survey section 1	Masoko Ntsekhe
1.00.02	Phone number	(266) 58929467
1.00.03	Email address	ntsekhem@health.gov.ls
1.00.04	Other respondents for filling out this section	

### 1.01 Demographic and Socioeconomic Indicators

#### Core questions ([click here for help](#))

			Year	Source
1.01.01	<a href="#">Population</a> , total (,000)	1,881.661	2006	Bureau of Statistics Population Census
1.01.02	Population growth rate (Annual %)	0.87	2010	Lesotho Health Systems Assessment
1.01.03	Total <a href="#">Gross Domestic Product</a> (GDP) (millions US\$)	1,758.16	2009	World Bank data
1.01.04	GDP growth (Annual %)	2.11	2009	World Bank data
1.01.05C	<a href="#">GDP</a> per capita (US\$ current <a href="#">exchange rate</a> )	1,209.67		
1.01.06	Comments and References			

#### Supplementary questions ([click here for help](#))

			Year	Source
1.01.07S	Population < 15 years (% of total population)	39	2008	WHS

1.01.08S	Population > 60 years (% of total population)	7	2008	WHS
1.01.09S	Urban population (% of total population)	25	2008	WHS
1.01.10S	Fertility rate, total (Births per woman)	3.3	2008	WHS
1.01.11S	Population living with less than \$1.25/day (international PPP) (%)	43.41	2003	World Bank data
1.01.12S	Population living below nationally defined poverty line (%)	56.3	2003	World Bank data
1.01.13S	Income share held by lowest 20% of the population (% of national income)	2.97	2003	World Bank data
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	82	2008	WHS
1.01.15S	Comments and References			

## 1.02 Mortality and Causes of Death

### Core questions ([click here for help](#))

			Year	Source
1.02.01	<a href="#">Life expectancy at birth</a> for men (Years)	44	2008	WHS
1.02.02	Life expectancy at birth for women (Years)	49	2008	WHS
1.02.03	<a href="#">Infant mortality rate</a> , between birth and age 1 (/1,000 live births)	63	2008	WHS
1.02.04	<a href="#">Under 5 mortality rate</a> (/1,000 live births)	79	2008	WHS
1.02.05	<a href="#">Maternal mortality ratio</a> (/100,000 live births)	960	2005	WHS - interagency est

1.02.06	Please provide a list of top 10 diseases causing mortality			
1.02.06.01	Disease 1	HIV/AIDS		
1.02.06.02	Disease 2	Lower respiratory infections		
1.02.06.03	Disease 3	Diarrheal diseases		
1.02.06.04	Disease 4	Cerebrovascula disease		
1.02.06.05	Disease 5	Ischemic heart disease		
1.02.06.06	Disease 6	Perinatal conditions		
1.02.06.07	Disease 7	Tuberculosis		
1.02.06.08	Disease 8	Measles		
1.02.06.09	Disease 9	Chronic obstructive pulmonary disease		
1.02.06.10	Disease 10	Road traffic accidents		
1.02.07	Please provide a list of top 10 diseases causing morbidity			
1.02.07.01	Disease 1	Cough and colds		
1.02.07.02	Disease 2	Heart Disease		
1.02.07.03	Disease 3	STI		
1.02.07.04	Disease 4	Pneumonia		
1.02.07.05	Disease 5	Tonsillitis		
1.02.07.06	Disease 6	Conjunctivitis		
1.02.07.07	Disease 7	HIV/AIDS		
1.02.07.08	Disease 8	Diabetes		
1.02.07.09	Disease 9	Bronchitis		

1.02.07.10	Disease 10	Diarrhea and gastroenteritis		
1.02.08	Comments and References	References: Ministry of Health and Social Welfare Annual Joint Review Report 2010/11(p. 57) (1.02.07); Lesotho Health Systems Assessment 20109(p.7) (1.02.06)		
<b>Supplementary questions</b> ( <a href="#">click here for help</a> )				
			Year	Source
1.02.09S	Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	685	2008	WHS
1.02.10S	Neonatal mortality rate (/1,000 live births)	37	2008	WHS
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	581	2004	WHS
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	279	2009	WHS
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	101	2009	WHS
1.02.14S	<a href="#">Mortality rate</a> for HIV/AIDS (/100,000 population)	584.59	2011	Annual Joint Review, 2010/11
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	27	2008	WHS
1.02.16S	Mortality rate for Malaria (/100,000 population)			
1.02.17S	Comments and References	There is no malaria in Lesotho(1.02.16s). The HIV/AIDS mortality is per the whole population and includes adults and children(1.02.14s)		

## Section 2 Health Services

### 2.00 Respondent Information Section 2

2.00.01	Name of person responsible for filling out this section of the instrument	Masoko Ntsekhe
2.00.02	Phone number	(266) 58929467
2.00.03	Email address	ntsekhem@health.gov.ls; masoko.ntsekhe@yahoo.com
2.00.04	Other respondents for filling out this section	

### 2.01 Health Expenditures

#### Core questions ([click here for help](#))

			Year	Source
2.01.01.01	Total annual expenditure on health (millions NCU)	1,133	2011	AJR
2.01.01.02	Total annual expenditure on health (millions US\$ average exchange rate)	104.44	2008	NHA data
2.01.02C	Total health expenditure as % of <a href="#">Gross Domestic Product</a>	6.44		
2.01.03.01C	Total annual <a href="#">expenditure on health</a> per capita (NCU)	421.03		
2.01.03.02C	Total annual expenditure on health per capita (US\$ average exchange rate)	50.97		
2.01.04.01	<a href="#">General government annual expenditure</a> on health (millions NCU)	486.48	2008	NHA data
2.01.04.02	General government annual expenditure on health (millions US\$ average exchange rate)	58.90	2008	NHA data
2.01.05	Government annual expenditure on health as percentage of total government budget (% of total government budget)	14	2011	AJR

2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	56.39		
2.01.07.01C	Annual per capita government expenditure on health (NCU)	237.42		
2.01.07.02C	Annual per capita government expenditure on health (US\$ average exchange rate)	28.74		
2.01.08C	<a href="#">Private health expenditure</a> as % of total health expenditure (% of total expenditure on health)	43.61		
2.01.09	Population covered by a public health service or public health insurance or <a href="#">social health insurance</a> , or other <a href="#">sickness funds</a> of total population)	0.8	2011	AJR
2.01.10	Population covered by private health insurance (% of total population)			
2.01.11.01	Total pharmaceutical expenditure (millions NCU)	173.7	2011	NDSO Annual Report
2.01.11.02	Total pharmaceutical expenditure (millions US\$ current exchange rate)	24.125	2011	NDSO Annual Report
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	92.31		
2.01.12.02C	Total pharmaceutical expenditure per capita (US\$ current exchange rate)	12.83		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	9.88		
2.01.14C	Pharmaceutical expenditure as a % of <a href="#">Health Expenditure</a> (% of total health expenditure)	15.33		
2.01.15.01	Total public expenditure on	23.28	2010	HSA

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	pharmaceuticals (millions NCU)			
2.01.15.02	Total public expenditure on pharmaceuticals (millions US\$ current exchange rate)	2.75		
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	13.4		
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	12.37		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US\$ current exchange rate)	1.46		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)			
2.01.18.02	Total private expenditure on pharmaceuticals (millions US\$ current exchange rate)			
2.01.19	Comments and References	AJR: Annual Joint Review(2.01.09) HSA: Lesotho Health Systems Assessment(2.01.15.01) 13.4% (2.01.15.01) is in relation to the recurrent budget(2.01.15.01)		
<b>Supplementary questions (<a href="#">click for help</a>)</b>				
			Year	Source
2.01.20S	<a href="#">Social security</a> expenditure as % of government expenditure on health (% of government expenditure on health)			
2.01.21S	Market share of generic pharmaceuticals [ <a href="#">branded</a> and <a href="#">INN</a> ] by value (%)			
2.01.22S	Annual growth rate of total pharmaceuticals market value (%)			
2.01.23S	Annual growth rate of generic pharmaceuticals market value (%)			

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2.01.24S	Private <a href="#">out-of-pocket</a> expenditure as % of private health expenditure (% of private expenditure on health)	68.85	2008	NHA data
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	0.00	2008	NHA data
2.01.26S	Comments and References			

## 2.02 Health Personnel and Infrastructure

### Core questions [\(click for help\)](#)

			Year	Source
2.02.01	Total number of pharmacists licensed/registered to practice in your country	93	2011	Ms. Ramathebane - Lesotho Medical, Dental and Pharmacy Council
2.02.02C	Pharmacists per 10,000 population	0.49		
2.02.03	Total number of pharmacists working in the public sector	30	2011	Head count department of Pharmacy
2.02.04	Total number of <a href="#">pharmaceutical technicians and assistants</a>	59	2003	Global Health Atlas
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2005	Lesotho Health Sector Human Resources Development & Strategic Plan 2005-

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				2025
2.02.06	Total number of physicians	89	2009	WHS
2.02.07C	Physicians per 10,000 pop	0.47		
2.02.08	Total number of <a href="#">nursing and midwifery personnel</a>	1,123	2009	WHS
2.02.09C	Nurses and midwives per 10,000 pop	5.98		
2.02.10	Total number of hospitals	21	2009	SADC survey
2.02.11	Number of hospital beds per 10,000 pop	7	2009	WHS
2.02.12	Total number of primary health care units and centers	195	2009	SADC survey
2.02.13	Total number of licensed pharmacies			
2.02.14	Comments and References	Licensing is done by Ministry of Trade and licences have been issued to many people who do not qualify (2.02.13)		

**Supplementary questions ([click here for help](#))**

			Year	Source
2.02.15S	Starting annual salary for a newly registered <a href="#">pharmacist</a> in the public sector (NCU)	111,156.00	2008	Lesotho Government Revised Salary Structure for Civil Servants
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country	45	2010	Ministry of Health - Department of Pharmaceuticals graduate lists
2.02.17S	Are there <a href="#">accreditation</a> requirements	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2008	Ms. M. Tlali - Former

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	for pharmacy schools?			Head of Department of Pharmacy School
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	Ms. M. Tlali
2.02.19S	Comments and References			

## Section 3 Policy issues

### 3.00 Respondent Information Section 4

3.00.01	Name of person responsible for filling out this section of the instrument	Masoko Ntsekhe		
3.00.02	Phone number	(266) 58929467		
3.00.03	Email address	ntsekhem@health.gov.ls		
3.00.04	Other respondents for filling out this section			

### 3.01 Policy Framework

#### Core questions ([click here for help](#))

			Year	Source
3.01.01	<a href="#">National Health Policy</a> exists. If yes, please write year of the most recent document in the "year" field.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2004	SADC survey
3.01.02	<a href="#">National Health Policy Implementation plan</a> exists. If yes, please write the year of the most recent document in the "year"	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		Ministry of Health and Social Welfare - 3 Year Health and Sector Plan 2008/9-2010/11
3.01.03	Please provide comments on the Health policy and its implementation plan	The 2011 Health Policy draft available		
3.01.04	<a href="#">National Medicines Policy</a> official document exists. If yes, please write the year of the most recent document in the "year" field.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2005	SADC Survey
3.01.05	Group of policies addressing pharmaceuticals exist.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2004	Health Policy
3.01.06	National Medicines Policy covers the following components:	—		

3.01.06.01	Selection of <a href="#">Essential Medicines</a>	<input checked="" type="checkbox"/> Yes		
3.01.06.02	Medicines Financing	<input checked="" type="checkbox"/> Yes		
3.01.06.03	Medicines Pricing	<input checked="" type="checkbox"/> Yes		
3.01.06.04	Medicines <a href="#">Procurement</a>	<input checked="" type="checkbox"/> Yes		
3.01.06.05	Medicines <a href="#">Distribution</a>	<input checked="" type="checkbox"/> Yes		
3.01.06.06	Medicines <a href="#">Regulation</a>	<input checked="" type="checkbox"/> Yes		
3.01.06.07	<a href="#">Pharmacovigilance</a>	<input checked="" type="checkbox"/> Yes		
3.01.06.08	<a href="#">Rational Use of Medicines</a>	<input checked="" type="checkbox"/> Yes		
3.01.06.09	Human Resource Development	<input checked="" type="checkbox"/> Yes		
3.01.06.10	Research	<input checked="" type="checkbox"/> Yes		
3.01.06.11	Monitoring and Evaluation	<input checked="" type="checkbox"/> Yes		
3.01.06.12	<a href="#">Traditional Medicine</a>	<input checked="" type="checkbox"/> Yes		
3.01.07	National medicines policy implementation plan exists. If yes, please write year of the most recent document.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2005	SADC survey
3.01.08	Policy or group of policies on clinical laboratories exist. If yes, please write year of the most recent document in the "year" field	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2008	Ministry of Health Laboratory Department
3.01.09	National clinical laboratory policy implementation plan exists. If yes, please write year of the most recent document in the "year" field	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2008	Ministry of Health Laboratory Department
3.01.10	Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
3.01.11	There are official written guidelines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2008	Department of

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	on medicines donations.			Pharmaceuticals
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	AJR
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?	Monitoring and Evaluation Unit of Ministry of Health		
3.01.13	Is there a national <a href="#">good governance policy</a> ?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2006	Vision 2020
3.01.13.01	Multisectoral	<input checked="" type="checkbox"/> Yes	2006	Vision 2020
3.01.13.02	For the pharmaceutical sector	<input type="checkbox"/> Yes		
3.01.13.03	Which agencies are responsible?	Various government ministries, non-governmental organisations, business sector, political parties, united nations agencies		
3.01.14	A policy is in place to manage and sanction <a href="#">conflict of interest</a> issues in pharmaceutical affairs.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
3.01.15	There is a formal code of conduct for public officials.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2005	Lesotho Government Codes of Good Practice
3.01.16	Is there a <a href="#">whistle-blowing</a> mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
3.01.16.01	Please describe:	Wrongdoings can be reported to the Anti-corruption unit through its Investigations Section(Police)		
3.01.17	Comments and References			

## Section 4 Medicines Trade and Production

### 4.00 Respondent Information Section 4

4.00.01	Name of person responsible for filling out this section of the instrument	Masoko Ntsekhe
4.00.02	Phone number	(266) 58929467
4.00.03	Email address	ntsekhem@health.gov.ls
4.00.04	Other respondents for filling out this section	

### 4.01 Intellectual Property Laws and Medicines

#### Core questions ([click here for help](#))

		Year	Source
4.01.01	Country is a member of the World Trade Organization	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995 WTO
4.01.02	Legal provisions provide for granting of Patents on:		1989 Industrial Property Order 1989
4.01.02.01	<a href="#">Pharmaceuticals</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
4.01.02.02	Laboratory supplies	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
4.01.02.03	Medical supplies	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
4.01.02.04	Medical equipment	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
4.01.03.01	Please provide name and address of the institution responsible for managing and enforcing intellectual property rights	The Office of the Registrar General, Law Office, Ministry of Law and Constitutional and Parliamentary Affairs, P.O.Box 33, Maseru, Lesotho. 100	
4.01.03.02	Please provide <a href="#">URL</a>		

4.01.04	National Legislation has been modified to implement the <a href="#">TRIPS Agreement</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
4.01.05	Current laws contain (TRIPS) flexibilities and safeguards	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
4.01.06	Country is eligible for the transitional period to 2016	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	WTO
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?		2009	SADC Survey
4.01.07.01	<a href="#">Compulsory licensing</a> provisions that can be applied for reasons of public health	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
4.01.07.02	<a href="#">Bolar exception</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.08	Are <a href="#">parallel importing</a> provisions present in the national law?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
4.01.09	The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
4.01.10	Are there legal provisions for <a href="#">data exclusivity</a> for pharmaceuticals	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.11	Legal provisions exist for <a href="#">patent extension</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.12	Legal provisions exist for linkage between patent status and <a href="#">Marketing Authorization</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.13	Comments and References	Several sensitization meetings on intellectual property rights have been held in the country, one as recent as 28-30 <sup>th</sup> June, 2011. Organized by Ministry of Trade and Industry (4.01.09)		

## 4.02 Manufacturing

**Core questions ([click here for help](#))**

			Year	Source
4.02.01	Number of licensed pharmaceutical <a href="#">manufacturers</a> in the country	0	2009	SADC Survey
4.02.02	Country has manufacturing capacity			
4.02.02.01	R&D to discover new active substances	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
4.02.02.02	Production of pharmaceutical starting materials ( <a href="#">APIs</a> )	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
4.02.02.04	Repackaging of finished dosage forms	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)			
4.02.04	Comments and References	There is no pharmaceutical manufacturing. Small scale unlicensed cosmetics manufacturing mushrooming(4.02.02)		

**Supplementary questions ([click here for help](#))**

			Year	Source
4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%)			
4.02.06S	Number of multinational pharmaceutical companies manufacturing medicines locally	0		
4.02.07S	Number of manufacturers that are <a href="#">Good Manufacturing Practice</a> (GMP) certified	0		
4.02.08S	Comments and References			



## Section 5 Medicines Regulation

### 5.00 Respondent Information Section 4

5.00.01	Name of person responsible for filling out this section of the instrument	Masoko Ntsekhe
5.00.02	Phone number	(266) 58929467
5.00.03	Email address	ntsekhem@health.gov.ls
5.00.04	Other respondents for filling out this section	

### 5.01 Regulatory Framework

#### Core questions ([click here for help](#))

		Year	Source
5.01.01	Are there legal provisions establishing the powers and responsibilities of the <a href="#">Medicines Regulatory Authority</a> (MRA)?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009 SADC survey
5.01.02	There is a Medicines Regulatory Authority	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009 SADC survey
5.01.03	If yes, please provide name and address of the Medicines regulatory authority		
5.01.04	The Medicines Regulatory Authority is:		
5.01.04.01	Part of MoH	<input type="checkbox"/> Yes	
5.01.04.02	Semi autonomous agency	<input type="checkbox"/> Yes	
5.01.04.03	Other (please specify)		
5.01.05	What are the functions of the National Medicines Regulatory Authority?		

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5.01.05.01	<a href="#">Marketing authorization</a> / registration	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.02	Inspection	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.03	Import control	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.04	<a href="#">Licensing</a>	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.05	Market control	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.06	<a href="#">Quality control</a>	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.07	Medicines advertising and promotion	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.08	<a href="#">Clinical trials</a> control	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.09	<a href="#">Pharmacovigilance</a>	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.10	Other: (please explain)			
5.01.06	Number of the MRA permanent staff			
5.01.06.01	Date of response			
5.01.07	The MRA has its own website	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.07.01	- If yes, please provide MRA Web site address (URL)			
5.01.08	The MRA receives external technical assistance	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.08.01	If yes, please describe:			
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.09.01	- If yes, please specify			
5.01.10	An assessment of the medicines regulatory system has been conducted in the last five years.	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the	Yes <input type="checkbox"/> No <input type="checkbox"/>		

	government.			
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.13.01	- If yes, please specify			
5.01.14	Revenues derived from <a href="#">regulatory activities</a> are kept with the Regulatory Authority	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.15	The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.16	Comments and References			

## 5.02 Marketing Authorization (Registration)

### Core questions ([click here for help](#))

			Year	Source
5.02.01	Legal provisions require a <a href="#">Marketing Authorization</a> (registration) for all pharmaceutical products on the market	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
5.02.02	Are there any mechanism for exception/waiver of registration?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.02.03	Are there mechanisms for recognition of registration done by other countries	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.02.03.01	If yes, please explain:			
5.02.04	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of	Yes <input type="checkbox"/> No <input type="checkbox"/>		

	pharmaceutical products			
5.02.05	Information from the <a href="#">prequalification</a> programme managed by WHO is used for product registration	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.06	Number of pharmaceutical products registered in your country			
5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.07.01	If yes, how frequently updated			
5.02.07.02	If yes, please provide updated list or <a href="#">URL</a> *			
5.02.08	Medicines registration always includes the <a href="#">INN (International Non-proprietary Names)</a>	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.10	Comments and References			
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
5.02.11S	Legal provisions require Marketing Authorization holders to provide information about variations to the existing Marketing Authorization	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.12S	Legal provisions require publication of a <a href="#">Summary of Product Characteristics (SPCs)</a> of the medicines registered	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing	Yes <input type="checkbox"/> No <input type="checkbox"/>		

	authorization process			
5.02.14S	<a href="#">Certificate for Pharmaceutical Products</a> in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.15S	Legal provisions require declaration of potential <a href="#">conflict of interests</a> for the experts involved in the assessment and decision-making for registration	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing <a href="#">New Chemical Entity (NCE)</a> (US\$)			
5.02.18S	Registration fee - the Amount per application for a <a href="#">generic</a> pharmaceutical product (US\$)			
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)			
5.02.20S	Comments & References			

### 5.03 Regulatory Inspection

#### Core Questions([click here for help](#))

			Year	Source
5.03.01	Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1970	Public Health Order
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey

5.03.02.01	If yes, legal provisions exist requiring inspections to be performed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.03.03	Inspection is a pre-requisite for licensing of:			
5.03.03.01	Public facilities	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.03.03.02	Private facilities	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.04	Inspection requirements are the same for public and private facilities	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.03.05.02	Private <a href="#">wholesalers</a> are inspected	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.05.03	<a href="#">Retail distributors</a> are inspected	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.05.04	Public pharmacies and stores are inspected	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.05.05	Pharmacies and dispensing points of health facilities are inspected	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.05.06	Please provide details on frequency of inspections for the different categories of facilities	There is no routine inspection - inspection is more reactive.		
5.03.06	Comments and References			

## 5.04 Import Control

### Core Questions ([click here for help](#))

		Year	Source
5.04.01	Legal provisions exist requiring authorization to import medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
5.04.03	Legal provisions exist requiring importation of medicines through	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	

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	authorized ports of entry			
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.04.05	Comments and References			
<b>5.05 Licensing</b>				
			Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with <a href="#">Good manufacturing Practices (GMP)</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
5.05.02.01	If no, please explain	There is no manufacturing		
5.05.03	GMP requirements are published by the government.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
5.05.04	Legal provisions exist requiring importers to be licensed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with <a href="#">Good Distributing Practices</a>  <b>When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)</b>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.05.07	National Good Distribution Practice requirements are published by the government	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey

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5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1970	Lesotho Medical, Dental and Pharmacy Order
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1970	Lesotho Medical, Dental and Pharmacy Order
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.05.13	Comments and References			

## 5.06 Market Control and Quality Control

### Core Questions ([click here for help](#))

			Year	Source
5.06.01	Legal Provisions for regulating the pharmaceutical market exist	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.06.02.01	If yes, is the laboratory part of the <a href="#">MRA</a> ?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.06.02.02	Does the regulatory authority contract services elsewhere?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.06.02.03	If yes, please describe			
5.06.03	Is there any national laboratory accepted for collaboration with <a href="#">WHO</a>	No		

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	<a href="#">prequalification Programme</a> ? Please describe.			
5.06.04	Medicines are tested:			
5.06.04.01	For quality monitoring in the public sector (routine sampling in pharmacy stores and health facilities)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.06.04.02	For quality monitoring in private sector (routine sampling in retail outlets)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.06.04.03	When there are complaints or problem reports	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.06.04.04	For product registration	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.06.04.05	For public procurement prequalification	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.06.04.06	For public program products prior to acceptance and/or distribution	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.06.05	Samples are collected by government inspectors for undertaking <a href="#">post-marketing surveillance</a> testing	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.06.06	How many Quality Control samples were taken for testing in the last two years?	8	2011	Central Procurement Agency Quality Assurance Manager
5.06.07	Total number of samples tested in the last two years that failed to meet quality standards	0	2011	Central Procurement Agency Quality Assurance Manager
5.06.08	Results of quality testing in past two years are publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		

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5.06.09	Comments and References			
<b>5.07 Medicines Advertising and Promotion</b>				
<b>Core Questions (<a href="#">click here for help</a>)</b>				
			Year	Source
5.07.01	Legal provisions exist to control the promotion and/or advertising of prescription medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:			
5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
5.07.04	Legal provisions require a pre-approval for medicines advertisements and promotional materials	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
5.07.06	A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
5.07.06.01	If yes, the <a href="#">code of conduct</a> applies to domestic manufacturers only, multinational manufacturers only, or both			
	Domestic only	<input type="checkbox"/> Yes		
	Multinational only	<input type="checkbox"/> Yes		

Both		<input type="checkbox"/> Yes
5.07.06.02	If yes, adherence to the code is voluntary	Yes <input type="checkbox"/> No <input type="checkbox"/>
5.07.06.03	If yes, the code contains a formal process for complaints and sanctions	Yes <input type="checkbox"/> No <input type="checkbox"/>
5.07.06.04	If yes, list of complaints and sanctions for the last two years is publicly available	Yes <input type="checkbox"/> No <input type="checkbox"/>
5.07.07	Comments and References	

## 5.08 Clinical trials

### Core Questions ([click here for help](#))

		Year	Source
5.08.01	Legal provisions exist requiring authorization for conducting <a href="#">Clinical Trials</a> by the MRA	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
5.08.02	Legal provisions exist requiring the agreement by an <a href="#">ethics committee/ institutional review board</a> of the Clinical Trials to be performed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
5.08.04	Comments and References		

### Supplementary questions ([click here for help](#))

		Year	Source
5.08.05S	Legal provisions exist for GMP compliance of investigational products	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
5.08.06S	Legal provisions require sponsor, investigator to comply with <a href="#">Good</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	

	<a href="#">Clinical Practices (GCP)</a>			
5.08.07S	National GCP regulations are published by the Government.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.08.09S	Comments and References			

## 5.09 Controlled Medicines

### Core Questions ([click here for help](#))

			Date	Source
5.09.01	The country has adopted the following conventions:			
5.09.01.01	Single Convention on Narcotic Drugs, 1961	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1974	International Narcotics Control Board, 2010
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1974	International Narcotics Control Board, 2010
5.09.01.03	<a href="#">Convention on Psychotropic Substances</a> 1971	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1975	International Narcotics Control Board, 2010
5.09.01.04	United Nations <a href="#">Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances</a> , 1988	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995	International Narcotics Control Board, 2010
5.09.02	Laws for the control of narcotic and psychotropic substances, and	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2008	Drugs of Abuse Act

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	precursors exist			
5.09.03	Annual consumption of Morphine (mg/capita)	0.003416	2009	International Narcotics Control Board, 2010
5.09.04	Comments and References			
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
5.09.05S	The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.182183	2009	International Narcotics Control Board, 2010
5.09.07S	Annual consumption of Pethidine (mg/capita)	0.869204	2009	International Narcotics Control Board, 2010
5.09.08S	Annual consumption of Oxycodone (mg/capita)			
5.09.09S	Annual consumption of Hydrocodone (mg/capita)			
5.09.10S	Annual consumption of Phenobarbital (mg/capita)			
5.09.11S	Annual consumption of Methadone			

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	(mg/capita)			
5.09.12S	Comments and References	The products are not used in Lesotho(5.09.08-11)		
<b>5.10 Pharmacovigilance</b>				
<b>Core Questions (<a href="#">click here for help</a>)</b>				
			Year	Source
5.10.01	There are legal provision in the Medicines Act that provides for <a href="#">pharmacovigilance</a> activities as part of the MRA mandate	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.02	Legal provisions exist requiring the <a href="#">Marketing Authorization</a> holder to continuously monitor the safety of their products and report to the MRA	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.03	Legal provisions about monitoring <a href="#">Adverse Drug Reactions (ADR)</a> exist in your country	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time			
5.10.04.02	If a national pharmacovigilance center exists in your country, an analysis report has been published in the last two years.	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.04.03	If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.05	An official standardized form for reporting ADRs is used in your country	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.06	A national Adverse Drug Reactions	Yes <input type="checkbox"/> No <input type="checkbox"/>		

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	database exists in your country			
5.10.07	How many ADR reports are in the database?			
5.10.08	How many reports have been submitted in the last two years?			
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
5.10.09.01	If yes, number of reports sent in the last two years			
5.10.10	Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.11	Is there a clear communication strategy for routine communication and crises communication?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.12	In the absence of a national pharmacovigilance system, ADRs are monitored in at least one public health program (for example TB, HIV, AIDS)?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.10.13	Please describe how you intend to enhance the Pharmacovigilance system	ADRs are monitored for TB,HIV, AIDS		
5.10.14	Comments and References	ADR forms have been developed but not yet used(5.10.05)		
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
5.10.15S	Feedback is provided to reporters	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.16S	The ADR database is computerized	Yes <input type="checkbox"/> No <input type="checkbox"/>		

5.10.17S	<a href="#">Medication errors (MEs)</a> are reported	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.18S	How many MEs are there in the ADRs database?			
5.10.19S	There is a <a href="#">risk management plan</a> presented as part of product dossier submitted for Marketing Authorization?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.20S	In the past two years, who has reported ADRs?			
5.10.20.01S	Doctors	<input checked="" type="checkbox"/> Yes		
5.10.20.02S	Nurses	<input checked="" type="checkbox"/> Yes		
5.10.20.03S	Pharmacists	<input type="checkbox"/> Yes		
5.10.20.04S	Consumers	<input type="checkbox"/> Yes		
5.10.20.05S	Pharmaceutical Companies	<input type="checkbox"/> Yes		
5.10.20.06S	Others, please specify whom			
5.10.21S	Was there any regulatory decision based on local pharmacovigilance data in the last 2 years?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.22S	Are there training courses in pharmacovigilance?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.22.01S	If yes, how many people have been trained in the last two years?			
5.10.23S	Comments and References			



## Section 6 Medicines Financing

### 6.00 Respondent Information Section 5

6.00.01	Name of person responsible for filling out this section of the instrument	Masoko Ntsekhe
6.00.02	Phone number	(266)58929467
6.00.03	Email address	ntsekhem@health.gov.ls
6.00.04	Other respondents for this sections	

### 6.01 Medicines Coverage and Exemptions

#### Core Questions ([click here for help](#))

		Year	Source
6.01.01	Do the followings receive medicines free of charge:	2009	SADC Survey
6.01.01.01	Patients who cannot afford them	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.01.02	Children under 5	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.01.03	Pregnant women	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.01.04	Elderly persons	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.01.05	Please describe/explain your yes answers for questions above	Medicines are free at the health centre level. However at the hospital level they are provided with other services for a hugely subsidized all inclusive fee - medicines are not charged separately in any of the facilities.	
6.01.02	Is there a public health system or <a href="#">social health insurance</a> scheme or public programme providing medicines free of charge for :	2009	SADC Survey
6.01.02.01	All medicines included in the <a href="#">EML</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.02.02	Any non-communicable diseases	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.02.03	Malaria medicines	Yes <input type="checkbox"/> No <input type="checkbox"/>	
6.01.02.04	Tuberculosis medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	

6.01.02.05	Sexually transmitted diseases medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
6.01.02.06	HIV/AIDS medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
6.01.02.07	Expanded Program on Immunization (EPI) vaccines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
6.01.02.08	If others, please specify	Contraceptives, school health,
6.01.02.09	Please describe/explain your yes answers for questions above	Explained in 6.01.01.05 above.
6.01.03	Does a national health insurance, social insurance or other <a href="#">sickness fund</a> provide at least partial <a href="#">medicines coverage</a> ?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.01.03.01	Does it provide coverage for medicines that are on the EML for inpatients	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.01.03.02	Does it provide coverage for medicines that are on the EML for outpatients	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.01.03.03	Please describe the medicines benefit of public/ <a href="#">social insurance schemes</a>	
6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.01.04.01	If yes, is it required to provide coverage for medicines that are on the <a href="#">EML</a> ?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6.01.05	Comments and References	There is no Health insurance Scheme - discussions are on going on the subject

## 6.02 Patients Fees and Copayments

### Core Questions ([click here for help](#))

			Year	Source
6.02.01	In your health system, at the point of delivery, are there any <a href="#">co-</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC

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	<a href="#">payment</a> /fee requirements for consultations			Survey
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
6.02.03	In practice, (even though this may be contrary to regulations) is revenue from fees or sales of medicines sometimes used to pay the salaries or supplement the income of public health personnel in the same facility?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.02.03.01	Please describe the patient fees and copayments system			
6.02.04	Comments and References			

## 6.03 Pricing Regulation for the Private Sector

### Core Questions ([click here for help](#))

			Year	Source
6.03.01	Are there legal or regulatory provisions affecting pricing of medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
6.03.01.01	If yes, are the provisions aimed at <a href="#">Manufacturers</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
6.03.01.02	If yes, are the provisions aimed at <a href="#">Wholesalers</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
6.03.01.03	If yes, are the provisions aimed at <a href="#">Retailers</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
6.03.01.04	Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.)			
6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey

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6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
6.03.03.01	-if yes, please explain how the information is made publically available	
6.03.04	Comments and References	

## 6.04 Prices, Availability and Affordability

### Core Questions ([click here for help](#))

		Year	Source
6.04.01-04	<p>Please state if a medicines price survey using the WHO/HAI methodology has been conducted in the past 5 years in your country.</p> <p><b>If yes</b>, please indicate the year of the survey and use the results to fill in this table</p> <p><b>If no</b>, but other surveys on medicines prices and availability have been conducted, please do not use them to fill in this section, but rather use the comment box to write some of the results and attach the report to the questionnaire</p>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	

Basket Of key medicines				Public procurement	Public patient	Private patient		
	Availability (one or both of)	Mean (%)	Orig		6.04.01.01	6.04.01.03		
			LPG		6.04.01.02	6.04.01.04		
		Median (%)	Orig		6.04.02.01	6.04.02.03		

			LPG		6.04.02.02	6.04.02.04	
	Price	Median Price Ratio	Orig	6.04.03.01	6.04.03.03	6.04.03.05	
			LPG	6.04.03.02	6.04.03.04	6.04.03.06	
	Affordability Days' wages of the lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection	Number of days' wages	Orig		6.04.04.01	6.04.04.03	
			LPG		6.04.04.02	6.04.04.04	
6.04.05	Comments and References		Medicines Access Survey 2007 and Medicines Access Survey 2010				

## 6.05 Price Components and Affordability

### Core Questions ([click here for help](#))

		Year	Source
6.05.01	Please state if a survey of medicines price components has been conducted in the past 5 years in your country	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	
6.05.02	Median cumulative percentage <a href="#">mark-up</a> between Manufacturer Selling Price (MSP)/ Cost Insurance and Freight (CIF) price and final medicine price for a basket of key medicines in the public sector (Median % contribution)	20	
6.05.03	Median cumulative percentage mark-up between MSP/CIF price and final medicine price for a basket of key medicines in the private sector (Median % contribution)		

6.05.04	Comment and References	
<b>Supplementary questions (<a href="#">click here for help</a>)</b>		
6.05.05S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution)	
6.05.06S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the private sector (Median % contribution)	
6.05.07S	Median manufacturer selling price (CIF) as percent of final medicine price for a basket of key medicines (%)	
6.05.08S	Median wholesaler selling price as percent of final medicine price for a basket of key medicines (%)	
6.05.09S	Median pharmacist <a href="#">mark-up</a> or <a href="#">dispensing fee</a> as percent of retail price for a basket of key medicines (%)	
6.05.10S	Median percentage contribution of the <a href="#">wholesale mark-up</a> to final medicine price for a basket of key medicines (in the public and private sectors) (%)	
6.05.11S	Median percentage contribution of the <a href="#">retail mark-up</a> to final medicine price for a basket of key medicines (in the public and private sectors) (%)	
6.05.12S	Comment and References	The final price is based on the price from the supplier plus the mark-up(Source: Central Procurement Agency Procurement Manager)

## 6.06 Duties and Taxes on Pharmaceuticals (Market)

### Core Questions ([click here for help](#))

Pharmaceutical Sector Country Profile Questionnaire.

			Year	Source
6.06.01	There are <a href="#">duties</a> on imported <a href="#">active pharmaceutical ingredients (APIs)</a>	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6.06.02	There are duties on imported <a href="#">finished products</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
6.06.03	<a href="#">VAT (value-added tax)</a> or any other tax is levied on finished pharmaceuticals products	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist	Taxes are applied to public sector medicines. Donations are exempted from taxes.		
6.06.06	Comments and References			
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
6.06.07S	<a href="#">Duty</a> on imported active pharmaceutical ingredients, APIs (%)			
6.06.08S	Duty on imported finished products (%)			
6.06.09S	<a href="#">VAT</a> on pharmaceutical products (%)	14	2009	SADC Survey
6.06.10S	Comments and References			

## Section 7 Pharmaceutical procurement and distribution

### 7.00 Respondent Information Section 6

7.00.01	Name of person responsible for filling out this section of the instrument	Masoko Ntsekhe
7.00.02	Phone number	(266) 58929467
7.00.03	Email address	ntsekheM@health.gov.ls
7.00.04	Other respondents for filling out this section	

### 7.01 Public Sector Procurement

#### Core Questions ([click here for help](#))

		Date	Source
7.01.01	Public sector procurement is:		
7.01.01.01	Decentralized	<input type="checkbox"/>	Yes
7.01.01.02	Centralized and decentralized	<input checked="" type="checkbox"/>	Yes
7.01.01.03	Please describe	There is a National Procurement Agency which procures on behalf of all public facilities. The facilities then procure from the National Agency as per need.	
7.01.02	If public sector <a href="#">procurement</a> is wholly or partially centralized, it is under the responsibility of a <a href="#">procurement agency</a> which is:		
7.01.02.01	Part of MoH	Yes <input type="checkbox"/>	No <input type="checkbox"/>
7.01.02.02	Semi-Autonomous	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
7.01.02.03	Autonomous	Yes <input type="checkbox"/>	No <input type="checkbox"/>
7.01.02.04	A government procurement agency	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>



which procures all public goods				
7.01.03	Public sector requests for tender documents are publicly available	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
7.01.04	Public sector tender awards are publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
7.01.05	Procurement is based on prequalification of suppliers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.05.01	If yes, please describe how it works	Information on where the supplier's goods are registered and sold is requested and whether the supplier's goods are registered in his own country. After assessment of the required documentation and testing of samples a decision is made whether to prequalify.		
7.01.06	Comments and References			
Supplementary questions ( <a href="#">click here for help</a> )				
			Year	Source
7.01.07S	Is there a written public sector <a href="#">procurement</a> policy?. If yes, please write the year of approval in the "year" field	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	Public Procurement Regulations
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
7.01.10S	A process exists to ensure the quality of products procured	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
7.01.10.01S	If yes, the quality assurance process includes <a href="#">pre-qualification</a> of products and suppliers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.10.02S	If yes, explicit criteria and procedures exist for pre-	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		

	qualification of suppliers			
7.01.10.03S	If yes, a list of pre-qualified suppliers and products is publicly available	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.11S	List of samples tested during the procurement process and results of quality testing are available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
7.01.12S	Which of the following <a href="#">tender</a> methods are used in public sector procurement:			
7.01.12.01S	National competitive tenders	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.12.02S	International competitive tenders	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.12.03S	Direct purchasing	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.13S	Comments and References			

## 7.02 Public Sector Distribution

### Core Questions ([click here for help](#))

			Year	Source
7.02.01	The government supply system department has a Central Medical Store at National Level	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		2007 Supplement No. 4 of 2 <sup>nd</sup> March
7.02.02	Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	0		
7.02.03	There are national guidelines on <a href="#">Good Distribution Practices (GDP)</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		2009 SADC Survey
7.02.04	There is a licensing authority that issues GDP licenses	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.04.01	If a licensing authority exists, does it accredit public distribution	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		

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facilities?				
7.02.05	List of GDP certified warehouses in the public sector exists	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
7.02.06	List of GDP certified distributors in the public sector exists	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
7.02.07	Comments and References	Licensing Authority accredits private sector facilities only(7.02.04)		
Supplementary questions ( <a href="#">click here for help</a> )				
			Year	Source
7.02.08S	Which of the following processes is in place at the Central Medical Store:			NDSO Records
7.02.08.01S	Forecasting of order quantities	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.02S	Requisition/Stock orders	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.03S	Preparation of picking/packing slips	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.04S	Reports of stock on hand	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.05S	Reports of outstanding order lines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.06S	Expiry dates management	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.07S	Batch tracking	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
7.02.08.08S	Reports of products out of stock	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.09S	Percentage % availability of key medicines at the Central Medical Store	82		
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days			
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.12S	The Public Central Medical Store is GDP certified by a licensing	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		

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	authority			
7.02.13S	The Public Central Medical Store is <a href="#">ISO</a> certified	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.02.15S	The second tier public warehouses are ISO certified	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.02.16S	Comments and References	There are no second tier warehouses(7.02.14S). NDSO is the Central Procurement Agency		

### 7.03 Private Sector Distribution

#### Core Questions ([click here for help](#))

			Year	Source
7.03.01	Legal provisions exist for licensing wholesalers in the private sector	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1970	Lesotho medical, Dental and Pharmacy Order
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.03.03	List of <a href="#">GDP</a> certified wholesalers in the private sector exists	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
7.03.04	List of GDP certified distributors in the private sector exists	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
7.03.05	Comments and References			

## Section 8 Selection and rational use

### 8.00 Respondent Information Section 7

8.00.01	Name of person responsible for filling out this section of the instrument	Masoko Ntsekhe
8.00.02	Phone number	(266)58929467
8.00.03	Email address	ntsekhem@health.gov.ls
8.00.04	Other respondents for filling out this section	

### 8.01 National Structures

#### Core Questions ([click here for help](#))

			Year	Source
8.01.01	National <a href="#">essential medicines list (EML)</a> exists. If yes, please write year of last update of EML in the "year" field	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2005	Lesotho Essential Medicines List (updated)
8.01.01.01	If yes, number of medicines on the EML (no. of <a href="#">INN</a> )	216		
8.01.01.02	If yes, there is a written process for selecting medicines on the EML	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.01.01.03	If yes, the EML is publicly available	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.01.01.04	If yes, is there any mechanism in place to align the EML with the <a href="#">Standard Treatment Guidelines (STG)</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.01.02	National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2006	SADC Survey

8.01.03	STGs specific to Primary care exist. Please use the "year" field to write the year of last update of primary care guidelines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2006	STGs
8.01.04	STGs specific to Secondary care (hospitals) exists. Please use the "year" field to write the year of last update of secondary care STGs.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.01.05	STGs specific to Paediatric conditions exist. Please use the "year" field to write the year of last update of paediatric condition STGs	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2006	SADC Survey
8.01.06	% of public health facilities with copy of EML (mean)- Survey data	89	2010	Medicines Access Survey
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data	79	2010	Medicines Access Survey
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
8.01.09	Public education campaigns on <a href="#">rational medicine use</a> topics have been conducted in the previous two years	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	MSH/SPS
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.01.11	A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
8.01.12	A written National strategy exists to contain <a href="#">antimicrobial resistance</a> . If	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		

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	yes, please write year of last update of the strategy in the "year" field			
8.01.13	Comments and References	Antimicrobial Resistance has been included in the 2011 Health Policy draft. A study has been conducted by MSH to assess adherence to STGs on antibiotic prescribing(8.01.12).  Items in the EML have been extracted from the STGs(8.01.01.04)		
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
8.01.14S	The <a href="#">Essential Medicines List (EML)</a> includes formulations specific for children	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2006	EML
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
8.01.16.01S	If yes, <a href="#">conflict of interest</a> declarations are required from members of national EML committee	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.01.17S	National medicines formulary exists	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1980	SADC Survey
8.01.18S	Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of <a href="#">antimicrobial resistance</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.01.20S	Comments and References	A symposium will be held in July in preparation of the establishment		

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		of the intersectoral task force(8.01.18S)		
<b>8.02 Prescribing</b>				
<b>Core Questions (<a href="#">click here for help</a>)</b>				
			Year	Source
8.02.01	Legal provisions exist to govern the licensing and prescribing practices of <a href="#">prescriber</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
8.02.03	Do prescribers in the private sector dispense medicines?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
8.02.04	Regulations require hospitals to organize/develop <a href="#">Drug and Therapeutics Committees (DTCs)</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey
8.02.05	Do more than half of <a href="#">referral hospitals</a> have a DTC?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
8.02.06	Do more than half of <a href="#">general hospitals</a> have a DTC?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
8.02.07	Do more than half of regions/provinces have a DTC?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
8.02.08	The core medical training curriculum includes components on:		2009	SADC Survey
8.02.08.01	Concept of <a href="#">EML</a>	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.08.02	Use of <a href="#">STGs</a>	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.08.03	<a href="#">Pharmacovigilance</a>	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.08.04	Problem based pharmacotherapy	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.09	Mandatory continuing education that includes pharmaceutical issues is required for doctors (see	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	SADC Survey



	<a href="#">physician</a> )			
8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for <a href="#">nurses</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.02.12	Prescribing by <a href="#">INN</a> name is obligatory in:		2009	SADC Survey
8.02.12.01	Public sector	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.12.02	Private sector	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.02.13	Average number of medicines prescribed per patient contact in public health facilities (mean)	3.0	2010	Access to Medicines Survey
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	88	2010	Access to Medicines Survey
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)			
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)	53	2007	Access to Medicines Survey
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)	8	2007	Access to Medicines Survey
8.02.18	% of prescribed drugs dispensed to patients (mean)	86.5	2010	Access to Medicines Survey
8.02.19	% of medicines adequately labeled in public health facilities (mean)	31.1	2010	Access to Medicines Survey

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8.02.20	Comments and References	There is no medical training in Lesotho(8.02.08).		
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
8.02.21S	A professional association code of conduct exists governing professional behaviour of doctors	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)	72	2007	Access to Medicines Survey
8.02.24S	Comments and References	Nurses and Midwives Act Of 1998 which is currently under review(8.02.22S). 83% of diarrhea medicines in stock(8.02.23S).		

## 8.03 Dispensing

### Core Questions ([click here for help](#))

			Year	Source
8.03.01	Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.03.02	The basic pharmacist training curriculum includes components on:	2009 SADC Survey		
8.03.02.01	Concept of EML	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.03.02.02	Use of STGs	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.03.02.03	Drug Information	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.03.02.04	Clinical pharmacology	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.03.02.05	Medicines supply management	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.03.03	Mandatory continuing education that includes rational use of medicines is required for	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
		2009	SADC Survey	

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	pharmacists			
8.03.04	<a href="#">Generic substitution</a> at the point of dispensing in public sector facilities is allowed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
8.03.05	<a href="#">Generic substitution</a> at the point of dispensing in private sector facilities is allowed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes <a href="#">sold over-the-counter</a> without any prescription?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	2010	Retail Pharmacist
8.03.07	In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the-counter without any prescription?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	2009	SADC Survey
8.03.08	Comments and References			
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
8.03.09S	A professional association <a href="#">code of conduct</a> exists governing professional behaviour of pharmacists	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	SADC Survey
8.03.10S	In practice, (even though this may be contrary to regulations) do the following groups of staff <i>sometimes</i> prescribe <a href="#">prescription-only medicines</a> at the primary care level in the public sector?			
8.03.10.01S	Nurses	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
8.03.10.02S	Pharmacists	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
8.03.10.03S	Paramedics	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input checked="" type="checkbox"/>		
8.03.10.04S	Personnel with less than one month training	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		

8.03.11S	Comments and References	
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## Section 9 Household data/access

### 9.00 Respondent Information section 8

9.00.01	Name of person responsible for filling out this section of the instrument	Masoko Ntsekhe
9.00.02	Phone number	(266) 58929467
9.00.03	Email address	ntsekhem@health.gov.ls
9.00.04	Other respondents for filling out this section	

### 9.01 Data from Household Surveys

#### Core Questions ([click here for help](#))

		Year	Source
9.01.01	What household surveys have been undertaken in the past 5 years to assess access to medicines?	0	
9.01.02	Adults with acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)		
9.01.03	Adults with acute conditions not taking all medicines because they cannot afford them (%)		
9.01.04	Adults (from poor households) with an acute health condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)		
9.01.05	Adults (from poor households) with an acute condition in two-week recall period who did not take all medicines because they cannot afford them (%)		

9.01.06	Adults with chronic conditions taking all medicines prescribed by an authorized <a href="#">prescriber</a> (%)			
9.01.07	Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)			
9.01.08	Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)			
9.01.09	Children (from poor households) with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)			
9.01.10	Percentage of people who obtained the medicines prescribed in the 15 days before the interview (%)			
9.01.11	People who obtained prescribed medicines for free in the 15 days before the interview (%)			
9.01.12	Comments and References			
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
9.01.13S	Adults with acute conditions not taking all medicines because the medicines were not available (%)			
9.01.14S	Adults with chronic conditions not taking all medicines because they cannot afford them (%)			
9.01.15S	Adults with chronic conditions not taking all medicines because the medicines were not available (%)			
9.01.16S	Children with acute conditions taking all medicines prescribed by			

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	an authorized prescriber (%)			
9.01.17S	Children with acute conditions not taking all medicines because they cannot afford them (%)			
9.01.18S	Children with acute conditions not taking all medicines because the medicines were not available (%)			
9.01.19S	Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%)			
9.01.20S	Comments and References			

## Key Documents to be attached

Document	Exact title	Author	Publisher	Year	File name
National Medicines Policy (NMP)					
NMP implementation plan					
National Medicines Act					
National pharmaceutical human resources report or strategic plan					
Latest report on the national pharmaceutical market (any source)					
National Pharmacovigilance Centre report (including Adverse Drug Reaction, ADR, analysis report in the last two years)					
National pharmaceutical legislation for regulation					
Annual report of quality control laboratories					
Annual report of national regulatory authority					
Legal provisions on medicines price regulations					
Medicines procurement policy					
National Essential Medicines List (EML)					
National Standard Treatment Guidelines (STGs)					
National Strategy for anti-microbial resistance					
Any other medicines					



<b>pricing/availability surveys, household surveys, and rational use surveys than the ones used to prefill in the instrument.</b>					
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# **MANUAL and GLOSSARY**

## Instructions

### ***Section 1 - HEALTH and DEMOGRAPHIC DATA***

#### **1.01 - Demographic and Socioeconomic Indicators**

In this section, the answers to questions have been prefilled with data from the WHO and/or World Bank databases. Please verify that you agree with the responses provided. If you find that any of the prefilled responses is not accurate, please change the value, and document your source and which year the value is for.

If you have access to a value that is consistent with and similar to a prefilled value but more current, please change to the most recent value and document your source and which year the value corresponds to.

#### **Possible sources of information**

- MoH
- Ministry of Planning
- National Bureau of Statistics
- Useful websites:

<http://www.who.int/gho/en/> This website of WHO Global Health Observatory (GHO) provides recent and comprehensive health data on all WHO Member States. The data, selected on the basis of quality and availability, relevance to global health, and comparability across member nations, cover over 50 core health indicators, which are organized into six major areas: mortality and burden of disease, health service coverage, risk factors, health system inputs, differentials in health outcome and coverage, as well as basic socio-demographic statistics. These are published in the World Health Statistics that is released in May of each year.

<http://www.who.int/infobase/report.aspx> The WHO Global InfoBase is a data warehouse that collects stores and displays information on chronic diseases and their risk factors for all WHO member states.

<http://unstats.un.org/unsd/demographic/products/socind/default.htm> The UN social indicators covering a wide range of subject-matter fields are compiled by the Statistics Division, Department of Economic and Social Affairs of the United Nations Secretariat, from many national and international sources.

[http://siteresources.worldbank.org/INTWDR2009/Resources/4231006-1225840759068/WDR09\\_22\\_SWDIweb.pdf](http://siteresources.worldbank.org/INTWDR2009/Resources/4231006-1225840759068/WDR09_22_SWDIweb.pdf) The World Bank development report 2009 provides recent values for most country profile indicators.

<http://world-gazetteer.com/> The World Gazetteer provides a comprehensive set of population data and related statistics. Population data are arranged by country and include population figures and area size for administrative

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divisions, largest cities, towns and places as well as for metropolitan areas. Historical population data (census or estimates; mostly from last or last two censuses) are also provided.

## Core questions

### 1.01.01 [Population total](#) (thousands)

The answer to this question will be prefilled. The most accurate estimate of actual population size at a given time is usually obtained by national census. You may have access to a more recent estimate from the latest census data. If that is the case, you may change the value to the more recent one expressed in thousands, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

### 1.01.02 [Population growth rate](#) (annual percentage)

The answer to this question will be prefilled. The most accurate estimate of actual population size at a given time is usually obtained by national census. You may have access to a more recent estimate from the latest census data. If that is the case, you may change the value to the more recent one expressed in annual percentage, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

### 1.01.03 [GDP](#) (millions US\$)

The answer to this question will be prefilled. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in your national currency, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

### 1.01.04 [GDP growth](#) (annual percentage)

The answer to this question will be prefilled. You may have access to a more recent estimate  
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from a national source. If that is the case, you may change the value to the more recent one expressed in annual percentage, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

1.01.05 **GDP per capita (current US Dollar)**

The answer to this question will be prefilled. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in current US Dollar, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

## Supplementary questions

1.01.07 **Population under 15 years (% of total population)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed in % of total population, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

1.01.08 **Population over 60 years (% of total population)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed in % of total population, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**1.01.09 Urban population (% of total population)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed in % of total population, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**1.01.10 Total fertility rate (births per woman)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed in births per woman, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**1.01.11 Population living with less than \$1.25/day (international PPP\$)**

The answer to this question will be prefilled for some countries. If that is the case, you may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed in international PPP\$, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

In case this value is not prefilled and not available for your country, leave the field blank.

#### 1.01.12 Population living below nationally defined poverty line

The answer to this question will be prefilled for some countries. If that is the case, you may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed in % of population, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

In case this value is not prefilled and not available for your country, leave the field blank.

#### 1.01.13 Income share held by lowest 20% of the population (% of national income)

The answer to this question will be prefilled for some countries. If that is the case, you may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed in % of national income, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

In case this value is not prefilled and not available for your country, leave the field blank.

#### 1.01.14 Adult literacy rate, 15 + years (% of the population above 15 years)

The answer to this question will be prefilled for some countries. If that is the case, you may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed in % of population above 15 years, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

In case this value is not prefilled and not available for your country, leave the field blank.

## 1.02 - Life Expectancy, Morbidity and Causes of Death

In this section, the answers to questions have been prefilled with data from the WHO and/or World Bank databases. Please verify that you agree with the responses provided. If you find that any of the prefilled responses is not accurate, please change the value, and document your source and which year the value is for.

If you have access to a value that is consistent with and similar to a prefilled value but more current, please change to the most recent value and document your source and which year the value corresponds to.

### Possible sources of information

- MoH
- Ministry of Planning
- National Bureau of Statistics
- Useful websites, in addition to those listed in the previous section:

<http://www.who.int/healthinfo/bod/en/index.html> WHO Global Burden of Disease and Risk Factors database provides statistical estimates of mortality and burden of disease (DALYs) by cause for the world, regions and WHO Member States. Estimates of Healthy Life Expectancy (HALE) and Life Expectancy for WHO Member States; latest documentation, methods, results and projections for the Global Burden of Disease; manuals, resources and software for carrying out national burden of disease studies.

<http://www.measuredhs.com/aboutsurveys/start.cfm> Demographic and Health Surveys (DHS) support a range of data collection options tailored to fit specific monitoring and evaluation needs of host countries. **Demographic and Health Surveys (DHS)** provide data for a wide range of monitoring and impact evaluation indicators in the areas of population, health, and nutrition. **AIDS Indicator Surveys (AIS)** provide countries with a standardized tool to obtain indicators for the effective monitoring of national HIV/AIDS programs. **Service Provision Assessment (SPA) Surveys** provide information about the characteristics of health and family planning services available in a country. **Key Indicators Survey (KIS)** provides monitoring and evaluation data for population and health activities in small areas—regions, districts, catchment areas—that may be targeted by an individual project, although they can be used in nationally representative surveys as well. **Other Quantitative Surveys** include biomarker collection, geographic data collection, and benchmarking surveys.

### Core questions

#### 1.02.01 [Life expectancy](#) at birth (men)

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The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed in years, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

1.02.02 [Life expectancy](#) at birth (women)

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed in years, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

1.02.03 [Infant mortality](#) rate, between birth and age 1 (per 1,000 live births)

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed as the number of deaths between birth and age 1 per 1,000 live births, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

1.02.04 [Under 5 mortality](#) rate (per 1,000 live births)

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed as the number of deaths under 5 per 1,000 live births, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

1.02.05 **[Maternal mortality ratio](#) (per 100,000 live births)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed as the number of deaths per 100,000 live births, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

1.02.06 **Please provide a list of top 10 diseases causing mortality**

This information may be found from your national bureau of statistics. The level of disease specification will vary by country. Use the most specific and current list to answer the question. If available, please provide a URL of your source in the comments.

1.02.07 **Please provide a list of top 10 diseases causing morbidity**

This information may be found from your national bureau of statistics. The level of disease specification will vary by country. Use the most specific and current list to answer the question. If available, please provide a URL of your source in the comments.

## Supplementary questions

1.02.09 **Adult mortality rate (both sexes, 15 to 60 years, /1,000 population)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed as the total number of deaths between 15 and 60 years per 1,000 population, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**1.02.10 Neonatal mortality rate (/1,000 live births)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed as the number of deaths per 1,000 live births, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**1.02.11 Age-standardized mortality rate by non-communicable diseases (/100,000 population)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed as the number of deaths by non-communicable diseases per 100,000 population, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**1.02.12 Age-standardized mortality rate by cardiovascular diseases (/100,000 population)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed as the number of deaths by cardiovascular diseases per 100,000 population, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**1.02.13 Age-standardized mortality rate by cancer (/100,000 population)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed as the number of deaths by cancer per 100,000 population, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**1.02.14 Mortality rate by HIV/AIDS (/100,000 population)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed as the number of deaths by HIV/AIDS per 100,000 population, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**1.02.15 Mortality rate by tuberculosis (/100,000 population)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed as the number of deaths by tuberculosis per 100,000 population, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**1.02.16 Mortality rate by malaria (/100,000 population)**

The answer to this question will be prefilled. You may have access to a more recent estimate from your national bureau of statistics. If that is the case, you may change the value to the more recent one expressed as the number of deaths by malaria per 100,000 population, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

## **Section 2 - HEALTH SERVICES**

### **2.01 Health Expenditures**

The answers to some of the questions in this section have been prefilled. When that is the case, please verify that you agree with the responses provided. If you find that any of the prefilled responses is inaccurate, please change the value and document your source and year.

If a prefilled value is consistent with and similar to data from your national sources, but it is older, please change to the most recent value and document your source and year.

#### **Possible sources of information**

Ministry of Health

Ministry of Finances

Ministry of Planning

National Bureau of Statistics

Useful websites:

<http://www.who.int/nha/en/> WHO National Health Accounts (NHA) provides evidence to monitor trends in health spending for all sectors, public and private, different health care activities, providers, diseases, population groups and regions in a country, intended to help in developing national strategies for effective health financing and in raising additional funds for health. Information can be used to make financial projections of a country's health system requirements and compare their own experiences with the past or with those of other countries.

<http://www.who.int/macrohealth/en/> National Macroeconomic and Health Reports provide data on health status, health systems, health care financing, and an analysis of costs of health care and investment plan.

<http://unstats.un.org/unsd/snaama/introduction.asp> The Economic Statistics Branch of the United Nations Statistics Division maintains a National Accounts Statistics database of main national accounts aggregates. It is the product of a global cooperation effort between the United Nations Statistics Division, international statistical agencies and the national statistical services of more than 200 countries and is in accordance with the request of the Statistical Commission that the most recent available data on national accounts of as many countries and areas as possible be published and disseminated regularly.

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1\\_1\\_1\\_2\\_4](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1_1_1_2_4)

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## Manual for data collection

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Medicines Financing” where relevant documents can be found.

<http://apps.who.int/medicinedocs/en/d/Js6160e/6.html> This link gives direct access to Chapter 4 of the [WHO World Medicines Situation Report \(2004\)](#): ‘World Pharmaceutical Sales and Consumption’. This chapter presents medicines expenditures from many countries that are based on estimates of medicines consumption and analysis of sales data.

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## Core questions

### 2.01.01.01 Total annual [expenditure on health](#) (THE) in national currency (millions NCU)

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in millions NCU, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

### 2.01.01.02 Total annual [expenditure on health](#) (THE) (millions US\$)

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in current US Dollar, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical. If the more recent value is in NCU, it needs to be converted into \$US using the average [exchange rate](#) of the year data are available. Document the exchange rate used for the conversion.

### 2.01.02 Total [health expenditure](#) as a percentage of [GDP](#)

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

### 2.01.03.01 Total annual expenditure on health per capita (THE per capita) in national currency (NCU)

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the

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more recent one expressed in millions NCU, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical. If expressed in \$US, the more recent value needs to be converted into your national currency using the average [exchange rate](#) of the most recent year data are available. Document the exchange rate used for the conversion.

#### 2.01.03.02 **Total annual expenditure on health per capita (THE per capita) in national currency (US\$)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in millions NCU, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical. If expressed in \$US, the more recent value needs to be converted into your national currency using the average [exchange rate](#) of the most recent year data are available. Document the exchange rate used for the conversion.

#### 2.01.04.01 **[General government annual expenditure on health \(GGHE\)](#) in national currency (millions NCU)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in millions NCU, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical. If expressed in \$US, the more recent value needs to be converted into your national currency using the average [exchange rate](#) of the most recent year data are available. Document the exchange rate used for the conversion.

2.01.04.02 [General government annual expenditure on health](#) (GGHE) (millions US\$)

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in millions US\$, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical. If expressed in NCU, the more recent value needs to be converted into US\$ using the average [exchange rate](#) of the most recent year data are available. Document the exchange rate used for the conversion.

2.01.05 **Government annual expenditure on health as percentage of total government budget (% total government budget)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in percentage of total government budget, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

2.01.06 [Government annual expenditure on health](#) as percentage of total expenditure on health (% of total expenditure on health)

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

2.01.07.01 Annual per capita [government expenditure on health](#) in national currency (NCU)

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

2.01.07.02 Annual per capita [government expenditure on health](#) in US\$

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

2.01.08 [Private annual health expenditure](#) as a percentage of total health expenditure (% of total expenditures on health)

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

2.01.09 Population covered by a public health service or public health insurance or social health insurance, or other [sickness funds](#) (% of total population)

This value needs to be obtained from your government. It should be expressed as the percentage of total population. If a public health system exists in your country and everyone has access to it, the answer is 100%. If some groups are eligible for coverage from several sources, count people only once so that the response is not higher than 100%.

2.01.10 Population covered by private health insurance (% of total population)

This value needs to be obtained from your government. It should be expressed as the percentage of total population. Private health insurance includes for-profit and not-for-profit (community-based health insurance) insurance schemes.

#### 2.01.11.01 **Total pharmaceutical expenditure (TPE) in national currency (millions NCU)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in millions NCU, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical. If the more recent value is expressed in \$US, it needs to be converted into your national currency using the average [exchange rate](#) of the year most recent data are available. Document the exchange rate used for the conversion.

#### 2.01.11.02 **Total pharmaceutical expenditure (TPE) in US\$ (millions US\$)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in current US Dollar, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical. If the more recent value is expressed in your national currency, it needs to be converted into \$US using the average [exchange rate](#) of the year most recent data are available. Document the exchange rate used for the conversion.

#### 2.01.12.01 **Total pharmaceutical expenditure per capita in national currency (NCU)**

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

#### 2.01.12.02 **Total pharmaceutical expenditure per capita in US\$**

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The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

**2.01.13 Total pharmaceutical expenditure as a percentage of [GDP](#) (% of GDP)**

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

**2.01.14 Total pharmaceutical expenditure as a percentage of total health expenditure (% of total health expenditure)**

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

**2.01.15.01 Total public expenditure on pharmaceuticals in national currency (millions NCU)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in millions NCU, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical. If the more recent value is expressed in \$US, it needs to be converted into your national currency using the average [exchange rate](#) of the most recent year data are available. Document the exchange rate used for the conversion.

**2.01.15.02 Total public expenditure on pharmaceuticals in US\$ (millions US\$)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in current US Dollar, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical. If the more recent value is expressed in your national currency, it needs to be converted into \$US using the average [exchange rate](#) of the most recent year data are available. Document the exchange rate used for the conversion.

**2.01.16 Share of public expenditure on pharmaceuticals as a percentage of total expenditure on pharmaceuticals**

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

**2.01.17.01 Public expenditure on pharmaceuticals per capita in national currency (NCU)**

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

**2.01.17.02 Public expenditure on pharmaceuticals per capita in US\$**

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

#### 2.01.18.01 **Total private expenditure on pharmaceuticals in national currency (millions NCU)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in millions NCU, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical. If expressed in \$US, it needs to be converted into your national currency using the average [exchange rate](#) of the most recent year data are available. Document the exchange rate used for the conversion.

#### 2.01.18.02 **Total private expenditure on pharmaceuticals in US\$ (millions US\$)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in current US Dollar, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical. If expressed in your national currency, it needs to be converted into \$US using the average [exchange rate](#) of the most recent year data are available. Document the exchange rate used for the conversion.

### **Supplementary questions**

#### 2.01.20 **[Social security](#) expenditure as % of government expenditure on health**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in percentage of government health expenditure, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

#### 2.01.21 **Market share of [generic pharmaceuticals](#) [branded and INN] by value (%)**

This value represents the retail market share of all generics, including branded and INN generics. It is expressed as a percentage of the value of the entire pharmaceutical retail market in your country, including public and private markets as well as the reimbursement market if applicable.

#### 2.01.22 Annual growth rate of total pharmaceuticals market value (%)

This value may be obtained from your government or from the local association of manufacturers. Use the most recent year for which the value is available. Do not attempt to average values over several years.

#### 2.01.23 Annual growth rate of generic pharmaceuticals market value (%)

This value may be obtained from your government or from the local association of manufacturers. Use the most recent year for which the value is available. Do not attempt to average values over several years.

#### 2.01.24 Private [Out-of-pocket expenditure](#) as % of private health expenditure (% of total private health expenditure)

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in percentage of private health expenditure, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.



**2.01.25 Premiums for private prepaid health plans as % of total private health expenditure (% of total private health expenditure)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in percentage of total private health expenditures, and document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

## 2.02 Health Personnel and Infrastructure

The answers to some of the questions in this section have been prefilled. When that is the case, please verify that you agree with the responses provided. If you find that any of the prefilled responses is inaccurate, please change the value and document your source and year.

If a prefilled value is consistent with and similar to data from your national sources, but it is older, please change to the most recent value and document your source and year.

### Possible sources of information

Ministry of Health

Ministry of Finances

Ministry of Planning

National Bureau of Statistics

Useful websites:

<http://www.who.int/gho/en/> Global Health Observatory is an interactive database bringing together core health statistics for the 193 WHO Member States. It comprises more than 100 indicators, which can be accessed by way of a quick search, by major categories, or through user-defined tables. The data can be further filtered, tabulated, charted and downloaded. The data are also published annually in the World Health Statistics Report released in May.

<http://apps.who.int/globalatlas/default.asp> Global Health Atlas contains more detailed data on the health workforce of WHO member states.

<http://www.who.int/macrohealth/en/> National Macroeconomic and Health Reports provide data on health status, health systems, health personnel, health care financing, and an analysis of costs of health care and investment plan.

<http://unstats.un.org/unsd/snaama/introduction.asp> The Economic Statistics Branch of the United Nations Statistics Division maintains a National Accounts Statistics database of main national accounts aggregates. It is the product of a global cooperation effort between the United Nations Statistics Division, international statistical agencies and the national statistical services of more than 200 countries and is in accordance with the request of the Statistical Commission that the most recent available data on national accounts of as many countries and areas as possible be published and disseminated regularly.

### Core questions

Pharmaceutical Sector Country Profile Questionnaire.

2.02.01 **Total number of [pharmacists](#) licensed to practice in your country**

Some countries require pharmacists to renew regularly their license to practice. This question seeks to document the number of pharmacists with a legal and current authorization to practice. This number will be obtained from the Pharmacy Council, if it exists. Otherwise, you can consult the Ministry of Health. If you cannot obtain the number of licensed pharmacists, please use the number of registered pharmacists and specify this in the comment field

2.02.02 **Number of [pharmacists](#) per 10,000 population**

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

2.02.03 **Total number of [pharmacists](#) working in the [public sector](#)**

This number includes pharmacists working in public administration, public sector hospitals, other public facilities, public sector manufacturers, public sector wholesalers and public sector medical stores. It does not include pharmacists working in private pharmacies contracted by the government to deliver services for a fee. This number will be obtained from your government. Alternatively, it can be obtained from the Pharmacy Council, if it exists.

2.02.04 **Total number of [pharmaceutical technicians and assistants](#)**

This number will be obtained from the Pharmacy Council, if it exists. Otherwise, you can consult the Ministry of Health.

**2.02.05 A strategic plan for pharmaceutical human resource development is in place in your country**

Answer yes	If such a plan exists. If that is the case, please attach/upload a copy of the plan to your completed questionnaire and provide URL if available. If The development of human resources for the pharmaceutical sector is included in the Human Resources for Health plan, please answer yes and explain this in the comment field.
Answer no	Otherwise

**2.02.06 Total number of [physicians](#)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in absolute number, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**2.02.07 Number of [physicians](#) per 10,000 population**

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

2.02.08 **Total number of [nursing and midwifery personnel](#)**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in absolute number, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

2.02.09 **Number of [nursing and midwifery personnel](#) per 10,000 population**

The answer to this question will be automatically calculated from your answers to previous questions. You cannot edit this value directly by typing a different number: the value will change only if you change the answers used to calculate it.

2.02.10 **Total number of [hospitals](#) in your country**

This number will be obtained from your government.

2.02.11 **Total number of [hospitals](#) beds in your country**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in absolute number, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

2.02.12 **Total number of [primary health care units and centers](#) in your country**

The answer to this question will be prefilled for some countries. You may have access to a more recent estimate from a national source. If that is the case, you may change the value to the more recent one expressed in absolute number, document your source and the year the value corresponds to. Linking the value that you select with the source and year is critical.

**2.02.13 Total number of [licensed pharmacies](#) in your country**

This number will be obtained from the Pharmacy Council, if it exists. Otherwise, you can consult the Ministry of Health.

## Supplementary questions

**2.02.15 Starting net annual salary for a newly registered pharmacist in the [public sector](#) in national currency (NCU)**

This value expressed in national currency needs to be obtained from your government. It is related to net annual income.

**2.02.16 Total number of pharmacists who graduated (first degree) in the past two years**

For consistency purposes, collate this number for the two full years preceding this survey. If this data cannot be easily collected, you can provide the number of pharmacists that have registered in the past 2 years (use then the comment field to explain this)

2.02.17 Requirements for [accreditation](#) of pharmacy schools exist.

Answer yes	If pharmacy schools must be accredited to function.
Answer no	Otherwise

2.02.18 The Pharmacy Curriculum is regularly reviewed.

Answer yes	If the pharmacy curriculum is reviewed and updated on a regular basis.
Answer no	Otherwise

## **Section 3 - MEDICINES POLICIES**

The answers to some of the questions in this section have been prefilled. When that is the case, please verify that you agree with the responses provided. If you find that any of the prefilled responses is inaccurate, please change the value and document your source and year.

If a prefilled value is consistent with and similar to data from your national sources, but it is less current, please change to the most recent value and document your source and year.

### **3.01 Policy Framework**

#### **Possible sources of information**

- MoH
- National legislative proceedings
- Medicines Regulatory Agency, if it exists
- Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.1.2/clmd,50.html#hlCL1\\_1\\_1\\_1\\_2](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.1.2/clmd,50.html#hlCL1_1_1_1_2)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Medicines Policy” where several relevant documents can be found.

[http://apps.who.int/medicinedocs/en/cl/CL6.1.1.18.19/clmd,50.html#hlCL6\\_1\\_1\\_18\\_19](http://apps.who.int/medicinedocs/en/cl/CL6.1.1.18.19/clmd,50.html#hlCL6_1_1_18_19)

This link takes you in the WHO medicines library, directly to the key word “Right to Health” where several relevant documents can be found.

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.5/clmd,50.html#hlCL1\\_1\\_1\\_2\\_5](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.5/clmd,50.html#hlCL1_1_1_2_5)

This link takes you in the WHO medicines library, directly to the subject “Good Governance for Medicines” where several relevant documents can be found.

### **Core questions**

3.01.01 A [National Health Policy \(NHP\)](#) exists.

Pharmaceutical Sector Country Profile Questionnaire.



Answer yes	If a National Health Policy exists and if it is presented in a publicly available document. If that is the case, please write year of the most recent document in the “year” field and provide URL if available.
Answer no	Otherwise

3.01.02 A [National Health Policy](#) implementation plan exists.

Answer yes	If a National Health Policy implementation plan exists and if it is presented in a publicly available document. If that is the case, please write year of the most recent document in the “year” field provide URL if available. The implementation plan may be any strategic operation plan ensuring that the NHP in place is being implemented.
Answer no	Otherwise

3.01.03 Please insert comments on the Health Policy and its implementation plan

This is an optional text field for comments.
--

3.01.04 A [National Medicines Policy](#) (NMP) official document exists.

Answer yes	If a National Medicines Policy exists and if it is presented in an official and publicly available document. If that is the case, please write year of the most recent document in the “year” field and attach/upload a copy of the document to your completed questionnaire and provide URL if available.
Answer no	Otherwise

3.01.05 **A group of policies addressing pharmaceuticals exist.**

Answer yes	If a group of policies addressing pharmaceutical exist, even though they are not assembled into one National Medicines Policy single document. Please attach/upload a copy of the document to your completed questionnaire and provide URL if available.
Answer no	Otherwise

3.01.06.01 **Does the [National Medicines Policy](#) (NMP) or a policy cover the selection of Essential Medicines?**

Answer yes	If the selection of Essential Medicines is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.06.02 **Does the [National Medicines Policy](#) (NMP) or a policy cover medicines financing?**

Answer yes	If the medicines financing is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.06.03 **Does the [National Medicines Policy](#) (NMP) or a policy cover medicines pricing?**

Answer yes	If the medicines pricing is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.06.04 **Does the [National Medicines Policy](#) (NMP) or policy cover medicines procurement?**

Answer yes	If the medicines procurement is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.06.05 Does the [National Medicines Policy](#) (NMP) or policy cover medicines distribution?

Answer yes	If the medicines distribution is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.06.06 Does the [National Medicines Policy](#) (NMP) or policy cover medicines regulation?

Answer yes	If the medicines regulation is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.06.07 Does the [National Medicines Policy](#) (NMP) or a policy cover pharmacovigilance?

Answer yes	If pharmacovigilance is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.06.08 Does the [National Medicines Policy](#) (NMP) or a policy cover Rational Use of Medicines?

Answer yes	If Rational Use of Medicines is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.06.09 Does the [National Medicines Policy](#) (NMP) or a policy cover human resources development?

Answer yes	If human resource development is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.06.10 Does the [National Medicines Policy](#) (NMP) or a policy cover research?

Answer yes	If research is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.06.11 Does the [National Medicines Policy](#) (NMP) or a policy cover monitoring and evaluation?

Answer yes	If monitoring and evaluation is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.06.12 Does the [National Medicines Policy](#) (NMP) or a policy cover [traditional medicine](#)?

Answer yes	If traditional medicine is addressed in the NMP or in a separate policy.
Answer no	Otherwise

3.01.07 A [National Medicines Policy \(NMP\) Implementation Plan](#) exists.

Answer yes	If a National Medicines Policy Implementation Plan exists and if it is presented in a publicly available document. If that is the case, please write year of the most recent document in the “year” field, attach/upload a copy of the document to your completed questionnaire and provide URL if available. The implementation plan may be any strategic operation plan ensuring that the NMP in place is being implemented.
Answer no	Otherwise

3.01.08 A policy or group of policies on clinical laboratories exists.

Answer yes	If a policy or group of policies on clinical laboratories exist. If that is the case, please write year of the most recent document in the “year” field and provide URL if available.
Answer no	Otherwise

3.01.09 A national clinical laboratory policy implementation plan exists.

Answer yes	If a national clinical laboratory policy implementation plan exists and if it is presented in a publicly available document. If that is the case, please write year of the most recent document in the “year” field and provide URL if available. The implementation plan may be any strategic operation plan ensuring that the clinical laboratory policies in place are being implemented.
Answer no	Otherwise

3.01.10 Access to essential medicines/technologies is part of the fulfillment of the right to health, recognized in the Constitution or National Legislation.

Answer yes	If the constitution or national legislation specifically includes access to essential medicines/technologies as a part of fulfilling the right of citizens to health
Answer no	Otherwise

3.01.11 **Official written guidelines on [medicines donations](#) exist.**

Answer yes	If official guidelines on medicines donations are written in a publicly available document. If that is the case, provide URL if available.
Answer no	Otherwise

3.01.12 **Is pharmaceutical policy implementation being regularly monitored/assessed?**

Answer yes	If a concrete process of monitoring pharmaceutical policy implementation exists, leading to concrete outcomes. In order to be considered as regular, monitoring should take place at least on a quarterly basis.
Answer no	Otherwise

3.01.12.01 **If yes, who is responsible for pharmaceutical policy monitoring?**

Provide the function of the person(s) responsible for pharmaceutical policy monitoring
--

3.01.13 **Is there a national [good governance](#) policy?**

Answer yes	If such a policy exists, and is publicly available. If that is the case, provide a URL if available.
Answer no	Otherwise

3.01.13.01 & 3.01.13.02 If a national [good governance](#) policy exists, describe its scope: multisectoral or for the pharmaceutical sector?

3.01.13.01	Answer yes, if the policy covers all sectors of government
3.01.13.02	Answer yes, if there is a separate policy for the pharmaceutical sector

3.01.13.03 If a national [good governance](#) policy exists, which agencies are responsible?

If a national good governance policy exists, describe the government agencies responsible for its implementation.

3.01.14 A policy is in place to manage and sanction [conflict of interest](#) issues in pharmaceutical affairs.

Answer yes	If such a policy exists, and is publicly available. If that is the case, provide URL if available.
Answer no	Otherwise

3.01.15 There is a formal [code of conduct](#) for public officials.

Answer yes	If such a code exists. If such a code exists, provide URL if available.
Answer no	Otherwise

3.01.16 Is there a [whistle-blowing](#) mechanism allowing individuals to raise a concern about wrong doing occurring in the pharmaceutical sector of your country ([ombudsperson](#))?

Answer yes	If such a mechanism exists.
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Answer no	Otherwise
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3.01.16.01 **If such a whistle-blowing mechanism exists, please describe.**

Describe the structure and processes in place.
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## **Section 4 - MEDICINES TRADE AND PRODUCTION**

### **4.01 Intellectual Property Laws and Medicines**

The answers to some of the questions in this section have been prefilled. When that is the case, please verify that you agree with the responses provided. If you find that any of the prefilled responses is inaccurate, please change the value and document your source and year.

If a prefilled value is consistent with and similar to data from your national sources, but it is older, please change to the most recent value and document your source and year.

#### **Possible sources of information**

Ministry of Health

Ministry of Finances

Ministry of Trade

National Patent Office

Useful websites:

<http://www.who.int/phi/en/> This link takes you to the WHO webpage on the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) which posts recent information about the topic of intellectual property laws and medicines.

[http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) This link takes you to the WTO website directly on the WTO members list and international trade information by country.

[http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm00\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm) This link takes you to the WTO website directly on the [TRIPS and pharmaceutical patents fact sheet](#).

#### **Core questions**

4.01.01 **Country is a member of the World Trade Organization (WTO).**

Answer yes	If your country is an active member of the WTO
Answer no	If your country is not member of WTO or if it participates as an observer

[http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm)

Pharmaceutical Sector Country Profile Questionnaire.

4.01.02.01 Legal provisions for granting of pharmaceutical [patents](#) exist in your country.

Answer yes	If legal provisions are in place to grant patents on pharmaceutical products.
Answer no	Otherwise

4.01.02.02 Legal provisions for granting [patents](#) on laboratory supplies exist in your country.

Answer yes	If legal provisions are in place to grant patents on laboratory supplies.
Answer no	Otherwise

4.01.02.03 Legal provisions for granting [patents](#) on medical supplies exist in your country.

Answer yes	If legal provisions are in place to grant patents on medical supplies.
Answer no	Otherwise

4.01.02.04 Legal provisions for granting [patents](#) on medical equipment exist in your country.

Answer yes	If legal provisions are in place to grant patents on medical equipment.
Answer no	Otherwise

4.01.03.01 Please provide the name and address of the institution responsible for managing and enforcing intellectual property rights.

4.01.03.02 **Please provide URL if it exists.**

4.01.04 **National legislation has been modified to implement the [TRIPS Agreement](#).**

Answer yes	If national legislation has been modified to accommodate the TRIPS Agreement. If that is the case, provide URL where the legislation can be found if available.
Answer no	Otherwise

4.01.05 **If national legislation has been modified to implement the [TRIPS Agreement](#), current laws contain TRIPS flexibilities and safeguards.**

Answer yes	If laws have been modified to accommodate the TRIPS Agreement, they include flexibilities and safeguards such as compulsory licensing.
Answer no	Otherwise

4.01.06 **Your country is eligible for the transitional period to 2016.**

Answer yes	If your country is eligible for exemption on pharmaceutical patent protection for least developed country as agreed in the <a href="#">Doha Declaration on TRIPS and Public Health</a> .
Answer no	Otherwise

4.01.07.01 **The following TRIPS flexibility/safeguard is present in the national law: [compulsory licensing provisions](#) that can be applied for reasons of public health.**

Answer yes	If compulsory licensing provisions are included in national legislation. If that is the case, provide a URL where the current legislation can be found, if available.
Answer no	Otherwise

4.01.07.02 **The following TRIPS flexibility/safeguard is present in the national law: [Bolar exception](#).**

Answer yes	If the Bolar exception is included in national legislation. If that is the case, provide a URL where the current legislation can be found, if available.
Answer no	Otherwise

4.01.08 **[Parallel importing](#) provisions are present in the national law**

Answer yes	If parallel provisions are included in the national legislation. If that is the case, provide a URL where the current legislation can be found, if available.
Answer no	Otherwise

4.01.09 **Your country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health.**

Answer yes	If the country is engaged in such initiatives. If that is the case, provide a URL where the current legislation can be found, if available.
Answer no	Otherwise

4.01.10 **Legal provisions about [data exclusivity](#) exist for pharmaceuticals.**

Answer yes	If laws about data exclusivity exist. If that is the case, provide a URL where the current legislation can be found, if available.
Answer no	Otherwise

**4.01.11 Legal provisions for [patent](#) extension exist for pharmaceuticals.**

Answer yes	If such legal provisions exist. If that is the case, provide a URL where the current legislation can be found, if available.
Answer no	Otherwise

**4.01.12 Legal provisions for linkage between patent status and marketing authorization exist.**

Answer yes	If such legal provisions exist. If that is the case, provide a URL where the current legislation can be found, if available.
Answer no	Otherwise

## 4.02 Manufacturing

### Possible sources of information

Ministry of Health

Ministry of Finances

Ministry of Industry

Ministry of Trade

Medicines Regulatory Agency

Manufacturers Associations

IMS country reports

### Core questions

#### 4.02.01 Number of licensed pharmaceutical manufacturers in your country

This number includes local and multinational manufacturers that are registered by your government. It is recognized that this number may be difficult to obtain for large decentralized countries (i.e. India).

#### 4.02.02.01 Your country has capacity for Research and Development (R&D) to discover new active substances.

Answer yes	If your country has capacity for R&D to discover new active substances and research and development are currently taking place in your country
Answer no	Otherwise

#### 4.02.02.02 Your country has capacity for production of pharmaceutical starting materials, i.e. [Active Pharmaceutical Ingredients \(API\)](#)

Answer yes	If your country has capacity for production of APIs, and if APIs are being produced in your country.
Answer no	Otherwise

4.02.02.03 **Your country has capacity for producing formulations from pharmaceutical starting materials.** [API](#)

Answer yes	If your country has capacity for producing formulations starting from APIs produced elsewhere and if formulations are being produced in your country
Answer no	Otherwise

4.02.02.04 **Your country has capacity for repackaging finished dosage forms**

Answer yes	If your country has capacity for repackaging pharmaceutical products, and if repackaging plants exist in your country.
Answer no	Otherwise

4.02.03 **Percentage of market share by value produced by domestic manufacturers (%)**

This value may be obtained from your government and from the association of domestic manufacturers if it exists.

## Supplementary questions

**4.02.05 Percentage of market share by volume produced by domestic manufacturers (%)**

This value may be obtained from your government and from the association of domestic manufacturers if it exists. It may be difficult to obtain in some countries.

**4.02.06 Number of multinational pharmaceutical companies manufacturing medicines locally**

This value may be obtained from your government. It may be difficult to obtain in some countries.

**4.02.07 Number of manufacturers that are GMP certified**

This value may be obtained from your government. If it exists, the Medicines Regulatory Authority is likely to have this information.



## **Section 5 - MEDICINES REGULATION**

The answers to some of the questions in this section have been prefilled. When that is the case, please verify that you agree with the responses provided. If you find that any of the prefilled responses are not accurate, please change the value and document your source and year.

If a prefilled value is consistent with and similar to data from your national sources, but it is older, please change to the most recent value and document your source and year.

### **5.01 Regulatory Framework**

#### **Possible sources of information**

- MoH

- Medicines Regulatory Agency, if it exists

- Useful websites:

<http://apps.who.int/medicinedocs/en/cl/CL1.1.1.1.2/clmd,50.html> - hICL1 1 1 1 2

<http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.5/clmd,50.html#hICL1 1 1 5 5>

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Regulatory Support” where several relevant documents can be found.

<http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.5/clmd,50.html#hICL1 1 1 2 5>

This link takes you in the library, directly to the subject “Good Governance for Medicines” where several relevant documents can be found.

<http://www.ich.org/cache/compo/276-254-1.html> This link takes you to the official website of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) where ICH guidelines and several other relevant documents can be found.

#### **Core questions**

5.01.01 **Legal provisions establishing the powers and responsibilities of the national [medicines regulatory authority](#) exist.**

Pharmaceutical Sector Country Profile Questionnaire.

Answer yes	If such laws exist. If that is the case, upload/ attach a copy of the Medicines Act if it exists to your completed questionnaire.
Answer no	Otherwise

5.01.02 A national [medicines regulatory authority](#) exists.

Answer yes	If such authority exists.
Answer no	Otherwise

5.01.03 If a national [medicines regulatory authority](#) exists, provide name and address.

5.01.04 If a national medicines regulatory authority (MRA) exists, it is

5.01.04.01	Part of MoH: If employees of the national medicines regulatory authority are MoH employees and line items of the authority's budget are directly controlled by MoH, even if the authority is not physically located in MoH.
5.01.04.02	Semi-autonomous agency: If the national medicines regulatory authority is organized as a medicines regulatory agency in which staff are employed outside the regular government structure even if the government has influence through management committee.
5.01.04.03	Other: If it is not part of MoH, and not organized in semi-autonomous agency. If that is the case, please describe its structure.

5.01.05.01 **The functions of the medicines regulatory authority (MRA) include marketing authorization/registration.**

Answer yes	If that is the case, and provide its <a href="#">URL</a> .
Answer no	Otherwise

5.01.05.02 **The functions of the medicines regulatory authority (MRA) include inspection.**

Answer yes	If that is the case, and provide its <a href="#">URL</a> .
Answer no	Otherwise

5.01.05.03 **The functions of the medicines regulatory authority (MRA) include import control.**

Answer yes	If that is the case, and provide its <a href="#">URL</a> .
Answer no	Otherwise

5.01.05.04 **The functions of the medicines regulatory authority (MRA) include licensing.**

Answer yes	If that is the case, and provide its <a href="#">URL</a> .
Answer no	Otherwise

5.01.05.05 **The functions of the medicines regulatory authority (MRA) include market control.**

Answer yes	If that is the case, and provide its <a href="#">URL</a> .
Answer no	Otherwise

5.01.05.06 **The functions of the medicines regulatory authority (MRA) include quality control.**

Answer yes	If that is the case, and provide its <a href="#">URL</a> .
Answer no	Otherwise

5.01.05.07 **The functions of the medicines regulatory authority (MRA) include medicines advertising and promotion.**

Answer yes	If that is the case, and provide its <a href="#">URL</a> .
Answer no	Otherwise

5.01.05.08 **The functions of the medicines regulatory authority (MRA) include control of clinical trials.**

Answer yes	If that is the case, and provide its <a href="#">URL</a> .
Answer no	Otherwise

5.01.05.09 **The functions of the medicines regulatory authority (MRA) include pharmacovigilance.**

Answer yes	If that is the case, and provide its <a href="#">URL</a> .
Answer no	Otherwise

5.01.05.10 **The functions of the medicines regulatory authority (MRA) include other categories than listed in the above questions.**

Describe the function(s).
---------------------------

5.01.06 **If a national medicines regulatory authority (MRA) exists, what is the number of MRA permanent staff?**

Provide the number of permanent staff at the time you complete the questionnaire.

5.01.06.01 **Please indicate the date of your answer.**

In dd/mm/yyyy

5.01.07 **The medicines regulatory authority (MRA) has its own website.**

Answer yes	If it does. If that is the case, provide its <u>URL</u> under question 5.01.07.01.
Answer no	Otherwise

5.01.08 **If a national medicines regulatory authority (MRA) exists, it receives external assistance.**

Answer yes	If it does. If that is the case, describe external collaborations under question 5.01.08.01.
Answer no	Otherwise

5.01.09 **The medicines regulatory authority (MRA) is involved in harmonization/ collaboration initiatives.**

Answer yes	If your national MRA participates in initiatives to harmonize regulations related to medicines and if these initiatives involve other national MRAs in the region.
Answer no	Otherwise

5.01.09.01 **If the MRA is involved in harmonization/collaboration initiatives, specify which ones.**

Pharmaceutical Sector Country Profile Questionnaire.

Please describe the main harmonization initiatives in which your regulatory authority is involved. This includes sub-regional, regional, and international collaborations.

**5.01.10 An assessment of the national medicines regulatory system has been conducted in the last five years.**

Answer yes	If the national medicines regulatory system has been evaluated by an external agency in the last five years.
Answer no	Otherwise

**5.01.11 The Medicines Regulatory Authority gets funds from regular budget of the government.**

Answer yes	If the MRA budget is included in the government budget.
Answer no	Otherwise

**5.01.12 The Medicines Regulatory Authority is funded by the fees it receives for services provided.**

Answer yes	If the MRA is funded under a <u>fee-for-services</u> system.
Answer no	Otherwise

**5.01.13 The Medicines Regulatory Authority receives funds/support from other sources.**

Answer yes	If the MRA receives funds that are not in exchange for services, and do not come from the government budget (e.g. funds for development partners)
Answer no	Otherwise

**5.01.13.01 If the Medicines Regulatory Authority receives funds/support from other sources, please specify.**

Explain what the additional sources of funds are.

**5.01.14 Revenues derived from regulatory activities are kept with the MRA.**

Answer yes	If revenues generated by MRA (e.g. fees collected for services provided) are kept within the MRA.
Answer no	If revenues are returned to the government.

**5.01.15 The Medicines Regulatory Authority uses a computerized information management system to store and retrieve information on registration, inspections, etc.**

Answer yes	If the MRA uses an electronic information management system to process some of the regulatory information it receives and generates.
Answer no	Otherwise

## **5.02 Marketing Authorization (Registration)**

### **Possible sources of information**

- MoH

- Medicines Regulatory Agency, if it exists

- Useful websites:

<http://apps.who.int/medicinedocs/en/cl/CL1.1.1.1.2/clmd,50.html> - hlCL1 1 1 1 2

[http://apps.who.int/medicinedocs/en/cl/CL6.1.1.13.5/clmd,50.html#hlCL6\\_1\\_1\\_13\\_5](http://apps.who.int/medicinedocs/en/cl/CL6.1.1.13.5/clmd,50.html#hlCL6_1_1_13_5)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject "Marketing Authorization" where relevant documents can be found.

Pharmaceutical Sector Country Profile Questionnaire.

<http://apps.who.int/medicinedocs/en/m/abstract/Js16234e/> This address is a direct link to the “WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014” (2008). The WHO Medicines Regulatory Package is a collection of tools aimed at supporting the work and decision making processes of National Medicines Regulatory Authorities (NMRAs).

## Core questions

5.02.01 **Legal provisions require a [marketing authorization](#) (registration) for all pharmaceutical products on the market.**

Answer yes	If a marketing authorization has to be obtained for every pharmaceutical product before it is allowed in your country.
Answer no	Otherwise

5.02.02 **There are mechanisms for exception/waiver of pharmaceutical [marketing authorization](#) (registration).**

Answer yes	If marketing authorization does not need to be granted to market certain pharmaceutical products under certain circumstances.
Answer no	Otherwise



**5.02.03 There are mechanisms for recognition of registration granted by other countries.**

Answer yes	If marketing authorization granted by another country can be used for certain products under certain circumstances. If yes, explain in question 5.02.03.01 under which circumstances foreign registration is accepted in lieu of marketing authorization in your country.
Answer no	Otherwise

**5.02.04 Explicit and publicly available criteria exist for assessing applications for [marketing authorization \(registration\)](#) of pharmaceutical products.**

Answer yes	If such criteria exist and are available. If that is the case, provide the URL to the document describing these criteria if available.
Answer no	Otherwise

**5.02.05 Information from the prequalification program managed by WHO is used for product registration**

Answer yes	If information from the prequalification program managed by WHO is used for product registration.
Answer no	Otherwise

**5.02.06 Number of registered [pharmaceutical products](#) in your country**

Registered pharmaceutical products are those which have been approved by the national regulatory authority.

5.02.07 **Legal provisions require the MRA to make publicly available the list of registered [pharmaceutical products](#) with defined periodicity.**

Answer yes	If such legal provisions exist
Answer no	Otherwise

5.02.07.01 **If a list of registered [pharmaceutical products](#) is made publicly available at regular intervals, specify how often it is updated.**

Specify the actual time interval between the last and one before last updates.

5.02.07.02 **If a list of registered [pharmaceutical products](#) is published at regular intervals, please provide [URL](#) if it exists.**

5.02.08 **Medicines registration always includes the [INN \(International Non-proprietary Names\)](#).**

Answer yes	If the list of published registered medicines allows sorting names by INN.
Answer no	Otherwise

5.02.09 **Legal provisions require paying a fee for receiving medicine [marketing authorization](#) (registration) applications.**

Answer yes	If such laws exist. Provide the current fee amount in the supplementary questions
Answer no	Otherwise

## Supplementary questions

5.02.11 Legal provisions require [marketing authorization](#) holders to provide information about variations to the existing marketing authorization.

Answer yes	If legal provisions require marketing authorization holders to inform the MRA about product changes or new data affecting the existing marketing authorization.
Answer no	Otherwise

5.02.12 Legal provisions require publishing a [Summary of Product Characteristics \(SPC\)](#) of registered medicines.

Answer yes	If legal provisions require publishing the SPC of registered medicines.
Answer no	Otherwise

5.02.13 Legal provisions require the establishment of an expert committee involved in the marketing authorization process.

Answer yes	If legal provisions require the establishment of an expert committee to be involved decisions about marketing authorization.
Answer no	Otherwise

5.02.14 A [Certificate of Pharmaceutical Products](#) in accordance with the [WHO Certification Scheme](#) is required in the marketing authorization application.

Answer yes	If legal provisions require such a certificate in the marketing authorization application of a pharmaceutical product.
Answer no	Otherwise

5.02.15 Legal provisions require a declaration of potential conflict of interest from the experts involved in the assessment and decision making of registration.

Answer yes	If legal provisions require such declaration from the experts involved in marketing authorization.
Answer no	Otherwise

5.02.16 Legal provisions allow applicants to appeal against MRA decisions.

Answer yes	If such legal provisions exist.
Answer no	Otherwise

5.02.17 Value of the registration fee: the amount per application for a pharmaceutical product containing a [New Chemical Entity](#) (NCE) in US\$.

Provide the value of the registration fee in US\$. Use the exchange rate in effect at the time of completing the survey and provide the date and exchange rate in the comments field.

**5.02.18 Value of the registration fee: the amount per application for a generic pharmaceutical product in US\$.**

Provide the value of the registration fee in US\$. Use the exchange rate in effect at the time of completing the survey and provide the date and exchange rate in the comments field.

**5.02.19 Time limit for the assessment of a marketing authorization application (months).**

Please provide the time limit in months for the assessment of a marketing authorization application.

### 5.03 Regulatory Inspection

#### Possible sources of information

- MoH
- Medicines Regulatory Agency, if it exists
- Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.4/clmd,50.html#hlCL1\\_1\\_1\\_5\\_4](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.4/clmd,50.html#hlCL1_1_1_5_4)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Quality Assurance” where relevant documents can be found.

<http://apps.who.int/medicinedocs/documents/s14136e/s14136e.pdf>

This address is a direct link to the “WHO Quality assurance of pharmaceuticals A compendium of guidelines and related materials. Volume 2, 2nd updated edition. Good manufacturing practices and inspection”. This comprehensive document contains an entire section on inspections throughout the medicines supply chain.

#### Core questions

5.03.01 **Legal provisions exist allowing for appointment of government pharmaceutical inspectors.**

Answer yes	If legal provisions supporting the appointment of government inspectors of the pharmaceutical sector exist.
Answer no	Otherwise

5.03.02 **Legal provisions permitting inspectors to inspect premises where pharmaceutical activities are performed exist.**

Answer yes	If legal provisions supporting the inspection of premises where pharmaceutical activities are performed by government inspectors exist. If that is the case proceed to answer the following question.
Answer no	Otherwise and skip the next question.

Pharmaceutical Sector Country Profile Questionnaire.

**5.03.02.01 If yes, legal provisions requiring inspections to be performed exist.**

Answer yes	If legal provisions requiring inspection of premises where pharmaceutical activities to be performed by government inspectors exist.
Answer no	Otherwise and skip the next 3 questions.

**5.03.03.01 Inspection is a pre-requisite for licensing public facilities.**

Answer yes	If the licensing process requires at least one inspection to take place
Answer no	Otherwise

**5.03.03.02 Inspection is a pre-requisite for licensing private facilities.**

Answer yes	If the licensing process requires at least one inspection to take place
Answer no	Otherwise

**5.03.04 Inspection requirements for public and private facilities are the same.**

Answer yes	If inspection requirements exist and they are the same for public and private facilities.
Answer no	Otherwise

**5.03.05.01 Local manufacturers are inspected for GMP compliance.**

Answer yes	If this is a true statement. If it is, describe the frequency of inspections.
Answer no	Otherwise

**5.03.05.02 Private wholesalers are inspected.**

Answer yes	If this is a true statement. If it is, describe the frequency of inspections.
Answer no	Otherwise

**5.03.05.03 Retail pharmacies are inspected.**

Answer yes	If this is a true statement. If it is, describe the frequency of inspections.
Answer no	Otherwise

**5.03.05.04 Public pharmacies and stores are inspected.**

Answer yes	If this is a true statement. If it is, describe the frequency of inspections.
Answer no	Otherwise

**5.03.05.05 Pharmacies and dispensing points of health facilities are inspected.**

Answer yes	If this is a true statement. If it is, describe the frequency of inspections.
Answer no	Otherwise

**5.03.05.06 Please provide details on frequency of inspections for the different categories of facilities.**



Manual for data collection

Answer yes	If this is a true statement. If it is, describe the frequency of inspections.
Answer no	Otherwise

## 5.04 Import Control

### Possible sources of information

- MoH
- Medicines Regulatory Agency, if it exists
- Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.4/clmd,50.html#hlCL1\\_1\\_1\\_5\\_4](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.4/clmd,50.html#hlCL1_1_1_5_4)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Quality Assurance” where relevant documents can be found.

<http://apps.who.int/medicinedocs/en/m/abstract/Js16234e/> This address is a direct link to the “WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014” (2008). The WHO Medicines Regulatory Package is a collection of tools aimed at supporting the work and decision making processes of National Medicines Regulatory Authorities (NMRAs).

### Core questions

5.04.01 Legal provisions requiring authorization to [import](#) medicines exist.

Answer yes	If such legal provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.04.02 Legal provisions allowing the [sampling](#) of imported products for testing exist.

Answer yes	If such legal provisions exist. . If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.04.03 Legal provisions requiring importation of medicines through [authorized ports of entry](#) exist.

Pharmaceutical Sector Country Profile Questionnaire.

Answer yes	If such legal provisions exist. . If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

**5.04.04 Legal provisions allowing inspection of imported pharmaceutical products at authorized ports of entry exist**

Answer yes	If such legal provisions exist. . If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

## 5.05 Licensing

### Possible sources of information

- MoH

- Medicines Regulatory Agency, if it exists

- Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.4/clmd,50.html#hlCL1\\_1\\_1\\_5\\_4](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.4/clmd,50.html#hlCL1_1_1_5_4)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Quality Assurance” where relevant documents can be found.

<http://apps.who.int/medicinedocs/en/m/abstract/Js16234e/> This address is a direct link to the “WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014” (2008). The WHO Medicines Regulatory Package is a collection of tools aimed at supporting the work and decision making processes of National Medicines Regulatory Authorities (NMRAs).

### Core questions

5.05.01 **Legal provisions requiring manufacturers to be [licensed](#) exist.**

Answer yes	If there are legal provisions requiring any manufacturer operating in the country to be licensed. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise.

5.05.02 **Legal provisions requiring both domestic and international manufacturers to comply with [Good Manufacturing Practices \(GMP\)](#) exist.**

Answer yes	If such provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise and describe requirements if any under question 5.05.02.01

Pharmaceutical Sector Country Profile Questionnaire.

5.05.03 **GMP requirements are published by the government.**

Answer yes	If GMP requirements are defined in an official government publication. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.05.04 **Legal provisions requiring [importers](#) to be [licensed](#) exist.**

Answer yes	If such provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.05.05 **Legal provisions requiring [wholesalers](#) and distributors to be [licensed](#) exist.**

Answer yes	If such provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.05.06 **Legal provisions requiring [wholesalers](#) and distributors to comply with [Good Distribution Practices \(GDP\)](#) exist.**

Answer yes	If such provisions exist. If that is the case, provide URL to supporting documents if available.  <b>Related questions are asked in the procurement and distribution sections: please fill out all related questions at the same time.</b>
Answer no	Otherwise

5.05.07 National [Good Distribution Practices \(GDP\)](#) requirements are published by the government.

Answer yes	If GDP requirements are defined in an official government publication. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.05.08 Legal provisions requiring [pharmacists](#) to be registered exist.

Answer yes	If such provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.05.09 Legal provisions requiring private pharmacies to be [licensed](#) exist.

Answer yes	If such provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.05.10 Legal provisions requiring public pharmacies to be [licensed](#) exist.

Answer yes	If such provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.05.11 [National Good Pharmacy Practice Guidelines](#) are published by the government.

Answer yes	If Good Pharmacy Practices Guidelines are published by the government. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.05.12 **Legal provisions require the publication of the list of all licensed pharmaceutical facilities.**

Answer yes	If such provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

## 5.6 Market Control and Quality Control

### Possible sources of information

- MoH
- Medicines regulatory agency, if it exists
- Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL6.1.1.16.22/clmd,50.html#hlCL6\\_1\\_1\\_16\\_22](http://apps.who.int/medicinedocs/en/cl/CL6.1.1.16.22/clmd,50.html#hlCL6_1_1_16_22)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link brings you inside the library directly to the subject “Quality Assurance” with access to several relevant documents.

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.4/clmd,50.html#hlCL1\\_1\\_1\\_5\\_4](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.4/clmd,50.html#hlCL1_1_1_5_4)

This link takes you in the WHO medicines library, directly to the subject “Pharmacovigilance” where relevant documents can be found.

<http://apps.who.int/medicinedocs/en/m/abstract/Js16234e/> This address is a direct link to the “WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014” (2008). The WHO Medicines Regulatory Package is a collection of tools aimed at supporting the work and decision making processes of National Medicines Regulatory Authorities (NMRAs).

### Core questions

5.06.01 **Legal provisions for regulating the pharmaceutical market exist.**

Answer yes	If such legal provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.06.02 **A laboratory for [Quality Control](#) testing of pharmaceutical products exists in your country.**

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Answer yes	If a laboratory for QC testing of pharmaceutical products exists.
Answer no	Otherwise and skip the next question.

5.06.02.01 **If a laboratory for [Quality Control](#) testing of pharmaceutical products exists in your country, it is part of the MRA.**

Answer yes	If that is the case.
Answer no	Otherwise.

5.06.02.02 **Does the MRA contract [Quality Control](#) services elsewhere?**

Answer yes	If some or all QC testing is performed by a contracted laboratory. If that is the case, please describe under question 5.06.02.03.
Answer no	Otherwise

5.06.03 **Is there any national laboratory accepted for collaboration with WHO prequalification program.**

Answer yes	If that is the case.
Answer no	Otherwise

5.06.04.01 **Medicines are tested for quality monitoring in the [public sector](#).**

Answer yes	If routine sampling is performed in pharmacy stores and health facilities.
Answer no	Otherwise

5.06.04.02 Medicines are tested for quality monitoring in the [private sector](#).

Answer yes	If routine sampling is performed in pharmacy retail outlets.
Answer no	Otherwise

5.06.04.03 Medicines are tested for quality monitoring when there are complaints or reports of problems about product registration.

Answer yes	If complaints or reports of problems about product registration trigger medicines testing.
Answer no	Otherwise

5.06.04.04 Medicines are tested for quality monitoring when there are complaints or reports of problems about public procurement prequalification.

Answer yes	If complaints or reports of problems about public procurement prequalification trigger medicines testing.
Answer no	Otherwise

5.06.04.05 Medicines are tested for quality monitoring prior to acceptance and/or distribution of products included in public programs.

Answer yes	If acceptance and/or distribution of products included in public programs trigger medicines testing.
Answer no	Otherwise

5.06.05 **Samples** are collected by government inspectors for undertaking post-marketing surveillance testing.

Answer yes	If you have confirmation that samples of products on the market are collected by government inspectors.
Answer no	Otherwise

5.06.06 If **samples** collected by government inspectors are tested for post-marketing surveillance, please provide the number of samples taken for testing in the past two years.

For consistency purposes, provide the number of samples tested during the two full years preceding this survey.

5.06.07 If **samples** collected by government inspectors are tested for **post-marketing surveillance**, please provide the number of samples tested in the past two years that failed to meet quality standards.

For consistency purposes, provide the number of samples that failed during the two full years preceding this survey.

5.06.08 **Results of quality testing in the past two years are publicly available.**

Answer yes	If such a list is available. If that is the case, attach/upload a copy to your completed questionnaire.
Answer no	Otherwise



## 5.07 Medicines Advertising and Promotion

### Possible sources of information

- MoH
- Medicines Regulatory Agency, if it exists
- National Manufacturers Association if it exists
- Consumers Associations
- NGOs
- Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL6.1.1.16.45/clmd,50.html#hlCL6\\_1\\_1\\_16\\_45](http://apps.who.int/medicinedocs/en/cl/CL6.1.1.16.45/clmd,50.html#hlCL6_1_1_16_45)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Promotion” where relevant documents can be found.

<http://www.drugpromo.info/> This link gives access to a database of a wide range of materials that describe, analyze, report on or comment on any aspect of pharmaceutical promotion. This database is part of a WHO/Health Action International project on medicines promotion.

<http://apps.who.int/medicinedocs/pdf/s8109e/s8109e.pdf> This link gives direct access to a review of the WHO/HAI database “Drug promotion what we know, what we have yet to learn Reviews of materials in the WHO/HAI database on drug promotion”.

### Core questions

5.07.01 [Legal provisions](#) controlling the [promotion](#) and/or advertising of [prescription medicines](#) exist.

Answer yes	If such laws exist.
Answer no	Otherwise

5.07.02 **Who is responsible for regulating promotion and/or advertising of medicines?**

Pharmaceutical Sector Country Profile Questionnaire.

Provide the name of the agency or the function of the person responsible for regulating promotion and advertising of medicines
--

5.07.03 **Legal provisions prohibiting direct advertising of prescription medicines to the public exist.**

Answer yes	If such laws exist.
Answer no	Otherwise

5.07.04 **Legal provisions requiring pre-approval of medicines advertising and promotional materials exist.**

Answer yes	Pre-approval of medicines advertising and promotional materials means that the Medicines Regulatory Authority must review and approve these materials before they can be used in order to ensure their content is accurate and not misleading. Answer yes if such laws exist.
Answer no	Otherwise

5.07.05 **Guidelines/Regulations about advertising and promotion of non-prescription medicines exist.**

Answer yes	If such guidelines exist.
Answer no	Otherwise

5.07.06 **A national code of conduct about medicines advertising and promotion by holders of manufacturing authorization exists and is publicly available**

Answer yes	If such a <u>code of conduct</u> is in place and publicly available for inspection.
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Answer no	Otherwise
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5.07.06.01 If a national [code of conduct](#) about medicines advertising and promotion exists, to whom does it apply?

Select one of three possible answers:	Domestic manufacturers or Multinational manufacturers or Both
---------------------------------------	---

5.07.06.02 If a national [code of conduct](#) about medicines advertising and promotion exists, adherence to the code is voluntary.

Answer yes	If pharmaceutical manufacturers choose whether they want to adhere to the code.
Answer no	Otherwise

5.07.06.03 If a national [code of conduct](#) about medicines advertising and promotion exists, it contains a formal process for complaints and sanctions.

Answer yes	If there is a formal process for complaints and sanctions included in the code of conduct about medicines advertising and promotion by pharmaceutical manufacturers.
Answer no	Otherwise

5.07.06.04 If a national [code of conduct](#) about medicines advertising and promotion exists and it contains a formal process for complaints and sanctions, a list of complaints and sanctions for the past two years is publicly available.

Answer yes	If a list of complaints and sanctions related to non-adherence to the code of conduct about medicines advertising and promotion over the past two years is available.
Answer no	Otherwise



## 5.08 Clinical Trials

### **Possible sources of information**

- MoH
- Medicines Regulatory Agency, if it exists
- Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.6/clmd,50.html#hlCL1\\_1\\_1\\_5\\_6](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.5.6/clmd,50.html#hlCL1_1_1_5_6)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject "Safety and efficacy" where relevant documents can be found.

<http://apps.who.int/medicinedocs/documents/s14084e/s14084e.pdf> This link gives direct access to the WHO Handbook for Good Clinical Research Practice. This useful document is organized as a reference and educational tool to facilitate understanding and implementation of Good Clinical Practice (GCP) by:

- describing the clinical research process as it relates to health and medical products, and identifying and explaining each of the activities that are common to most trials and the parties who are ordinarily responsible for carrying them out;
- linking each of these processes to one or more principle(s) of GCP;
- explaining each GCP principle and providing guidance on how each principle is routinely applied and implemented;
- directing the reader to specific international guidelines or other references that provide more detailed advice on how to comply with GCP.

<http://apps.who.int/tdr/publications/training-guideline-publications/operational-guidelines-ethics-biomedical-research/pdf/ethics.pdf> This link gives direct access to the WHO Operational Guidelines for Ethics Committees That Review Biomedical Research.

### **Core questions**

Pharmaceutical Sector Country Profile Questionnaire.

5.08.01 [Legal provisions](#) requiring authorization by the [Medicines Regulatory Authority \(MRA\)](#) to conduct [clinical trials](#) exist.

Answer yes	If such legal provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.08.02 **Legal provisions requiring the agreement by an [ethics committee](#)/institutional review board of clinical trials to be performed exist.**

Answer yes	If such legal provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.08.03 **Legal provisions requiring the registration of clinical trials into an international, regional or national registry exist.**

Answer yes	If such legal provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

## Supplementary questions

5.08.05 **Legal provisions for [GMP](#) compliance of investigational products exist.**

Answer yes	If such legal provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.08.06 **Legal provisions require sponsors and investigators to comply with [Good Clinical Practices](#) (GCP).**

Answer yes	If such legal provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.08.07 **National [Good Clinical Practices](#) (GCP) regulations are published by the government.**

Answer yes	If such regulations are published and are available for inspection. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.08.08 **Legal provisions permit inspection of facilities where clinical trials are performed.**

Answer yes	If such provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

## 5.09 Controlled Medicines

The answers to some of the questions in this section have been prefilled. When that is the case, please verify that you agree with the responses provided. If you find that any of the prefilled responses are not accurate, please change the value and document your source and year.

If a prefilled value is consistent with and similar to data from your national sources, but it is older, please change to the most recent value and document your source and year.

### **Possible sources of information**

- MoH

- Useful websites:

<http://www.incb.org> This is the website of the International Narcotics Control Board (INCB), the independent and quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions. It was established in 1968 in accordance with the [Single Convention on Narcotic Drugs, 1961](#). Most of the information collected in this section can be found on the INCB website.

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2/clmd,50.html#hlCL1\\_1\\_1\\_2\\_3](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2/clmd,50.html#hlCL1_1_1_2_3)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link brings you inside the library directly to the subject “Controlled Medicines” with access to several relevant documents.

<http://www.painpolicy.wisc.edu> This is the website of the Pain & Policy Studies Group at the University of Wisconsin Carbon Cancer Center, a WHO collaborating Center which provides useful international resources.

### **Core questions**

5.09.01.01 **The country is a signatory to United Nations [Single Convention on Narcotic Drugs, 1961](#).**

The answer to this question will be prefilled for some countries. Please verify that you agree with the response provided. If you have information that differs, please provide it, and document your source and its year. Linking your response with source and year is critical.

5.09.01.02 **The country is a signatory to United Nations 1972 Protocol amending the [Single Convention on Narcotic Drugs, 1961](#).**

Pharmaceutical Sector Country Profile Questionnaire.

The answer to this question will be prefilled for some countries. Please verify that you agree with the response provided. If you have information that differs, please provide it, and document your source and its year. Linking your response with source and year is critical.

5.09.01.03 **The country is a signatory to United Nations [Convention on Psychotropic Substances 1971](#).**

The answer to this question will be prefilled for some countries. Please verify that you agree with the response provided. If you have information that differs, please provide it, and document your source and its year. Linking your response with source and year is critical.

5.09.01.04 **The country is a signatory to United Nations [Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988](#).**

The answer to this question will be prefilled for some countries. Please verify that you agree with the response provided. If you have information that differs, please provide it, and document your source and its year. Linking your response with source and year is critical.

5.09.02 **[Legal provisions](#) for the control of narcotic and psychotropic substances, and precursors exist.**

Answer yes	If there are national laws controlling narcotic and psychotropic substances. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.09.03 **Annual [consumption](#) of Morphine (mg/capita)**

The answer to this question will be prefilled for some countries. Please verify that you agree with the response provided. If you have information that differs, please provide it, and document your source and its year. Linking your response with source and year is critical.

## Supplementary questions

**5.09.05 The legal provisions and regulations for the control of narcotic and psychotropic substances and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need.**

Answer yes	If such a review has taken place.
Answer no	Otherwise

**5.09.05.01 If such a review has taken place, provide the year of review.**

Please provide year of the review

**5.09.06 Annual [consumption](#) of Fentanyl (mg/capita)**

The answer to this question will be prefilled for some countries. Please verify that you agree with the response provided. If you have information that differs, please provide it, and document your source and its year. Linking your response with source and year is critical.

**5.09.07 Annual [consumption](#) of Pethidine (mg/capita)**

The answer to this question will be prefilled for some countries. Please verify that you agree with the response provided. If you have information that differs, please provide it, and document your source and its year. Linking your response with source and year is critical.

5.09.08 Annual [consumption](#) of Oxycodone (mg/capita)

The answer to this question will be prefilled for some countries. Please verify that you agree with the response provided. If you have information that differs, please provide it, and document your source and its year. Linking your response with source and year is critical.

5.09.09 Annual [consumption](#) of Hydrocodone (mg/capita)

The answer to this question will be prefilled for some countries. Please verify that you agree with the response provided. If you have information that differs, please provide it, and document your source and its year. Linking your response with source and year is critical.

5.09.10 Annual [consumption](#) of Phenobarbital (mg/capita)

The answer to this question will be prefilled for some countries. Please verify that you agree with the response provided. If you have information that differs, please provide it, and document your source and its year. Linking your response with source and year is critical.

5.09.11 Annual [consumption](#) of Methadone (mg/capita)

The answer to this question will be prefilled for some countries. Please verify that you agree with the response provided. If you have information that differs, please provide it, and document your source and its year. Linking your response with source and year is critical.





## 5.10 [Pharmacovigilance](#)

### Possible sources of information

- MoH
- Medicines regulatory agency
- Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL6.1.1.16.22/clmd,50.html#hICL6\\_1\\_1\\_16\\_22](http://apps.who.int/medicinedocs/en/cl/CL6.1.1.16.22/clmd,50.html#hICL6_1_1_16_22)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link brings you inside the library directly to the subject “Pharmacovigilance” with access to several relevant documents.

<http://www.who-umc.org> This is the website of the Uppsala WHO Collaborating Center. Uppsala Monitoring Centre (the UMC) is the field-name of the WHO Collaborating Centre for International Drug Monitoring. It is responsible for the management of the WHO Program for International Drug Monitoring. The UMC is an independent centre of scientific excellence which offers a range of products and services, derived from the WHO global individual case safety report (ICSR) database, from healthcare providers and patients in member countries of the WHO Program. It provides essential resources for regulatory agencies, health professionals, researchers, and the pharmaceutical industry. Many of these resources can be found on the website.

### Core questions

#### 5.10.01 **Legal provisions provide for pharmacovigilance activities as part of the MRA mandate.**

Answer yes	See section 3.1 question 13.
Answer no	Otherwise

#### 5.10.02 **Legal provisions exist requiring the [Marketing Authorization](#) holder to continuously monitor the safety of their products and report to the MRA.**

Answer yes	If regulations require pharmaceutical companies to continuously monitor the safety of products for which they have received a marketing authorization. If that is the case, provide URL to supporting documents if available.
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Pharmaceutical Sector Country Profile Questionnaire.

Answer no	Otherwise
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5.10.03 Legal provisions about monitoring [Adverse Drug Reactions \(ADR\)](#) exist in your country.

Answer yes	If ADR monitoring is mandated by law in your country. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.10.04 A [national pharmacovigilance center](#) linked to the MRA exists in your country.

Answer yes	If at least one pharmacovigilance center is located in your country.
Answer no	Otherwise

5.10.04.01 If a [national pharmacovigilance center](#) exists in your country, how many staff does it employ full-time?

If a national pharmacovigilance center exists in your country, only count the number of people who work full time at all the locations of this center at the time you complete the questionnaire.

5.10.04.02 If a [national pharmacovigilance center](#) exists in your country, an analysis report has been published in the past two years.

Answer yes	It a national pharmacovigilance center exists, and has published an analysis of submitted ADRs in the past two years. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.10.04.03 If a national [pharmacovigilance center](#) exists in your country, it publishes an ADR bulletin.

Answer yes	It a national pharmacovigilance center exists, and produces a regular bulletin to inform health care professionals about current drug safety topics. If that is the case, provide web link to the bulletin if available.
Answer no	Otherwise

5.10.05 An official standardized [Adverse Drug Reactions \(ADR\)](#) form is to be used in your country.

Answer yes	If ADRs have to be reported on an official standardized form. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

5.10.06 A national [ADR database](#) exists in your country.

Answer yes	If ADRs are reported centrally and entered into a paper-based or electronic database.
Answer no	Otherwise

5.10.07 If a national [ADR database](#) exists in your country, how many ADR reports are in the database?

This number can be provided by the people maintaining the ADR database, usually at the national pharmacovigilance center. For consistency purposes, select the number of ADR submitted during the two full years preceding this survey.

5.10.08 If a national [ADR database](#) exists in your country, how many ADR reports have been received in the past two years?

This number can be provided by the people maintaining the ADR database, usually at the national pharmacovigilance center. For consistency purposes, select the number of ADR submitted during the two full years preceding this survey.

5.10.09 ADR reports are sent to the WHO [ADR database](#) in Uppsala.

Answer yes	If ADR reports are sent to the WHO ADR database regularly, regardless of the format used.
Answer no	Otherwise

5.10.09.01 If ADR reports are sent to the WHO [ADR database](#) in Uppsala, how many ADR reports have been sent in the past two years?

This number can be provided by the people maintaining the ADR database, usually at the national pharmacovigilance center. For consistency purposes, select the number of ADR submitted to the WHO Collaborating Center in Uppsala during the two full years preceding this survey.

5.10.10 In the absence of a national pharmacovigilance system, ADRs are monitored in at least one public health program.

Answer yes	If at least one public health program monitors ADRs. Examples of public health programs include those targeting TB, HIV, or AIDS.
Answer no	Otherwise

## Supplementary questions

5.10.12 If a national [ADR database](#) exists in your country, reporters receive feedback when they submit an ADR report.

Answer yes	If the center processing ADRs sends feedback to acknowledge the submission and to obtain missing information that is needed.
Answer no	Otherwise

5.10.13 If a national [ADR database](#) exists in your country, it is computerized.

Answer yes	If are ADR reports are entered in a national electronic database.
Answer no	Otherwise

5.10.14 If a national [ADR database](#) exists in your country, [medications errors](#) (ME) are reported.

Answer yes	If a national ADR data base exists in your country, and allows for reporting medications errors.
Answer no	Otherwise

5.10.15 If a national [ADR database](#) exists in your country, how many ME does it contain?

This number can be provided by the people maintaining the ADR database, usually at the national pharmacovigilance center. For consistency purposes, select the number of ME present in the database on the first day of the current year.

5.10.16 There is a [risk management plan](#) presented as part of product dossier submitted for marketing authorization.

Answer yes	If the marketing authorization application must include a risk management plan.
Answer no	Otherwise

5.10.17.01 In the past two years, physicians have reported ADRs.

Answer yes	If physicians have used the ADR reporting system in the past two years.
Answer no	Otherwise

5.10.17.02 In the past two years, nurses have reported ADRs.

Answer yes	If nurses have used the ADR reporting system in the past two years.
Answer no	Otherwise

5.10.17.03 In the past two years, pharmacists have reported ADRs.

Answer yes	If pharmacists have used the ADR reporting system in the past two years.
Answer no	Otherwise

5.10.17.04 In the past two years, consumers have reported ADRs.

Answer yes	If consumers have used the ADR reporting system in the past two years.
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Answer no	Otherwise
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**5.10.17.05 In the past two years, pharmaceutical companies have reported ADRs.**

Answer yes	If pharmaceutical companies have used the ADR reporting system in the past two years.
Answer no	Otherwise

**5.10.17.06 In the past two years, others have reported ADRs.**

If that is the case, specify who they are.

**5.10.18 In the past two years, at least one regulatory decision was based on local pharmacovigilance data.**

Answer yes	If you are aware of any regulatory decision that in the past 2 years has been taken based on data collected through the pharmacovigilance system regulatory decisions take into account pharmacovigilance data.
Answer no	Otherwise

**5.10.19 Training courses in pharmacovigilance exist.**

Answer yes	If such courses take place in your country on a regular basis. If they exist specify how many people have been trained in the past two years on question 5.10.19.01
Answer no	Otherwise

## **Section 6 - MEDICINES FINANCING**

The answers to some of the questions in this section have been prefilled. When that is the case, please verify that you agree with the responses provided. If you find that any of the prefilled responses are not accurate, please change the value and document your source and year.

If a prefilled value is consistent with and similar to data from your national sources, but it is older, please change to the most recent value and document your source and year.

### **6.01 Medicines Coverage and Exemptions**

#### **Possible sources of information**

Ministry of Health

Ministry of Finances

Ministry of Planning

National Bureau of Statistics

National Health Insurance or Social Health Insurance

Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1\\_1\\_1\\_2\\_4](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1_1_1_2_4)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Medicines Financing” where relevant documents can be found.

<http://siteresources.worldbank.org/INTHSD/Resources/topics/Health-Financing/HFRFull.pdf> This link gives access to the World Bank publication: [A practitioner’s guide: Health Financing Revisited](#) (2006) which provides useful information about different health insurance systems.

#### **Core questions**

Pharmaceutical Sector Country Profile Questionnaire.



**6.01.01.01 Patients who cannot afford medicines receive them free of charge.**

Answer yes	If public programs providing medicines without any charge to patients who have been identified as being unable to afford medicines are in place.
Answer no	Otherwise

**6.01.01.02 Children under 5 receive medicines free of charge.**

Answer yes	If public programs providing medicines without any charge to children below 5 years are in place.
Answer no	Otherwise

**6.01.01.03 Pregnant women receive medicines free of charge**

Answer yes	If public programs providing medicines without any charge to pregnant women are in place.
Answer no	Otherwise

**6.01.01.04 Elderly persons receive medicines free of charge.**

Answer yes	If public programs providing medicines without any charge to elderly people are in place.
Answer no	Otherwise

**6.01.01.05 If you answered yes to one of the questions above, describe public programs that provide free medicines**

And explain how they function.

**6.01.02.01 Is there a public health system or social health insurance scheme or public program providing all medicines on the EML free of charge?**

Answer yes	If all medicines on the EML are provided without any charge for all conditions.
Answer no	Otherwise

**6.01.02.02 Is there a public health system or social health insurance scheme or public program providing all medicines for at least one non-communicable disease free of charge?**

Answer yes	If medicines for at least one non-communicable disease are provided without any charge by a medicines program.
Answer no	Otherwise

**6.01.02.03 Is there a public health system or social health insurance scheme or public program providing antimalarials free of charge?**

Answer yes	If medicines for malaria are provided without any charge by a medicines program.
Answer no	Otherwise

**6.01.02.04 Is there a public health system or social health insurance scheme or public program providing medicines for tuberculosis free of charge?**

Answer yes	If medicines for tuberculosis are provided without any charge by a medicines program.
Answer no	Otherwise

**6.01.02.05 Is there a public health system or social health insurance scheme or public program providing medicines for sexually transmitted diseases free of charge?**

Answer yes	If medicines for sexually transmitted diseases are provided without any charge by a medicines program.
Answer no	Otherwise

**6.01.02.06 Is there a public health system or social health insurance scheme or public program providing medicines for HIV/AIDS free of charge?**

Answer yes	If medicines for HIV/AIDS are provided without any charge by a medicines program.
Answer no	Otherwise

6.01.02.07 **Is there a public health system or social health insurance scheme or public program providing EPI vaccines free of charge?**

Answer yes	If EPI vaccines are provided without any charge by a medicines program.
Answer no	Otherwise

6.01.02.08 **Is there a public health system or social health insurance scheme or public program providing medicines for diseases not listed above free of charge?**

Answer yes	If medicines for diseases not listed above are free for the population targeted by the medicines program providing free medicines. If that is the case, specify which disease.
Answer no	Otherwise

6.01.02.09 **If you answered yes to one of the questions about free medicines above, explain why.**

6.01.03 **A [National Health Insurance](#), or a [Social Health Insurance](#) or other sickness fund provides at least partial [medicines coverage](#).**

Answer yes	If a public health system is in place in your country, and its benefits cover at least part of the cost of medicines.
Answer no	Otherwise

6.01.03.01 A [National Health Insurance](#), or a [Social Health Insurance](#) or other sickness fund provides at least partial [medicines coverage](#) for medicines that are on the EML for [inpatients](#).

Answer yes	If a public health system is in place in your country, and its benefits cover at least part of the cost of essential medicines when patients are hospitalized.
Answer no	Otherwise

6.01.03.02 A public health service, a [National Health Insurance](#), [Social Health Insurance](#) or other sickness fund provides at least partial [medicines coverage](#) for medicines that are on the [EML](#) for [outpatients](#).

Answer yes	If a public health system is in place in your country, and its benefits cover at least part of the cost of essential medicines when patients are treated without being hospitalized.
Answer no	Otherwise

6.01.03.03 Please describe the [medicines benefits](#) of public insurance schemes.

If public insurance schemes exist in your country, describe the extent of medicines coverage.
---

6.01.04 Do private health insurance schemes provide any medicines coverage?

Answer yes	If private health insurance schemes offer such coverage.
Answer no	Otherwise

**6.01.04.01 If private health insurance schemes provide medicines coverage, they are required to provide at least partial medicines coverage for medicines that are on the EML.**

Answer yes	If there are legal provisions requiring private insurance to cover medicines on the national EML.
Answer no	Otherwise

## 6.02 Patients Fees and Copayments

### Possible sources of information

Ministry of Health

Ministry of Finances

Ministry of Planning

National Bureau of Statistics

National Health Insurance or Social Health Insurance

Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1\\_1\\_1\\_2\\_4](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1_1_1_2_4)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Medicines Financing” where relevant documents can be found.

[http://www.oecd.org/document/36/0,3343,en\\_2649\\_33929\\_41000996\\_1\\_1\\_1\\_37407,00.htm](http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.htm) This link gives access to an OECD Health Policy publication: “Pharmaceutical pricing policies in a global market”, which provides useful information on pricing policies and medicines reimbursement practices.

### Core questions

6. 02.01 **In your health system, are there any copayments/fee requirements at the point of delivery for consultations?**

Answer yes	If patients pay a fee to be treated when they are treated in a public health facility.
Answer no	Otherwise

**6.02.02 In your health system, are there any copayments/fee requirements at the point of delivery for medicines?**

Answer yes	If patients pay a fee to receive medicines when they are treated in a public health facility.
Answer no	Otherwise

**6.02.03 In practice, (even though this may be contrary to regulations) revenue from fees or from the sale of medicines is *sometimes* used to pay the salaries or supplement the income of public health personnel in the same facility.**

Answer yes	If a part or the entire amount that patients pay for medicines in public health care facilities are <i>sometimes</i> used to supplement the income of public health care workers.
Answer no	Otherwise

**6.02.04 Please describe/explain the patient fees and copayment system.**



## 6.03 Pricing Regulation in the Private Sector

In this section, private sector does not include non-profit voluntary sector.

### Possible sources of information

Ministry of Health

Ministry of Finances

Ministry of Planning

National Bureau of Statistics

Useful websites:

<http://www.haiweb.org/medicineprices/> This link takes you to the Health Action International website, directly in the medicines prices section where comprehensive information on medicines prices can be found, including the HAI survey manual: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2nd Edition\)](#)

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1\\_1\\_1\\_2\\_4](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1_1_1_2_4)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Medicines Financing” where relevant documents can be found.

[http://www.oecd.org/document/36/0,3343,en\\_2649\\_33929\\_41000996\\_1\\_1\\_1\\_37407,00.html](http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html) This link gives access to an OECD Health Policy publication: “Pharmaceutical pricing policies in a global market”, which provides useful information on pricing policies and medicines reimbursement practices.

### Core questions

6.03.01 **Legal or regulatory provisions for setting the price of medicines exist.**

Answer yes	If such legal provisions or regulations exist. If that is the case, attach/upload a copy to your completed questionnaire.
Answer no	Otherwise

Pharmaceutical Sector Country Profile Questionnaire.

6.03.01.01 **If legal or regulatory provisions for setting the price of medicines exist, they apply to manufacturers.**

Answer yes	If legal provisions or regulations exist to regulate the manufacturer exist price
Answer no	Otherwise

6.03.01.02 **If legal or regulatory provisions for setting the price of medicines exist, they apply to wholesalers**

Answer yes	If legal provisions or regulations exist to regulate the wholesale price or margin
Answer no	Otherwise

6.03.01.03 **If legal or regulatory provisions for setting the price of medicines exist, they apply to retailers.**

Answer yes	If legal provisions or regulations exist to regulate the retail price or margin. Retailers include pharmacies, drug stores and licensed drug sellers
Answer no	Otherwise

6.03.01.04 **Please describe/explain positive answers above: explain the scope of provisions i.e. generics vs. originator or subsets of medicines, EML, etc.**

6.03.02 **The government runs an active national medicines price monitoring system for retail prices.**

Answer yes	If such a monitoring system exists.
Answer no	Otherwise

**6.03.03 Regulations mandating retail medicine price information to be publicly accessible exist**

Answer yes	If such regulations exist.
Answer no	Otherwise

**6.03.03.01 If regulations mandating retail medicine price information to be publicly accessible exist, please explain how the information is made publicly available**

## 6.04 Prices, Availability, and Affordability

### Possible sources of information

Ministry of Health

Ministry of Finances

Ministry of Planning

Ministry of Trade

Useful websites:

<http://www.haiweb.org/medicineprices/> This link takes you to the Health Action International website, directly in the medicines prices section where comprehensive information on medicines prices can be found, including the HAI survey manual: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2nd Edition\)](#)

<http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English>

This link gives direct access to the international drug prices indicator guide published by Management Sciences for Health (MSH)

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1\\_1\\_1\\_2\\_4](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1_1_1_2_4)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Medicines Financing” where relevant documents can be found.

6.04.01 **Pease state if a medicines pricing survey using the WHO/HAI methodology has been conducted in the past 5 years in your country.**

Answer yes	If yes please indicate the year of the survey and use the results to fill in this table
Answer no	Otherwise. If no, and other surveys on medicines prices and availability have been conducted, please <i>do not</i> use them to fill in this section but rather use the comment box to write some of the results and attach the report to the questionnaire.

*The table will be prefilled by WHO with results of the WHO/HAI pricing survey if they exist.*

*If you are aware of similar data obtained with a different methodology, please describe in the comments and attach/upload a copy of the report to your completed questionnaire and provide URL, if available.*

## 6.05 Price Components and Affordability

### Possible sources of information

Ministry of Health

Ministry of Finances

Ministry of Planning

Ministry of Trade

Useful websites:

<http://www.haiweb.org/medicineprices/> This link takes you to the Health Action International website, directly in the medicines prices section where comprehensive information on medicines prices can be found, including the HAI survey manual: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2nd Edition\)](#)

<http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English>

This link gives direct access to the international drug prices indicator guide published by Management Sciences for Health (MSH)

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1\\_1\\_1\\_2\\_4](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.4/clmd,50.html#hlCL1_1_1_2_4)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Medicines Financing” where relevant documents can be found.

**6.05.01 Please state if a survey of medicines prices components has been conducted in the past 5 years in your country.**

Answer yes	If yes please indicate the year of the survey and use the results to fill in the questions below
Answer no	Otherwise.

**6.05.02 Median cumulative percentage mark-up between [MSP/CIF](#) price and final medicine price for a basket of key medicines in the [public sector](#).**

Pharmaceutical Sector Country Profile Questionnaire.

This value is one of the WHO/HAI survey results, expressed in median % contribution.

6.05.03 **Median cumulative percentage mark-up between [MSP/CIF](#) price and final medicine price for a basket of key medicines in the private sector.**

This value is one of the WHO/HAI survey results, expressed in median % contribution.

## Supplementary questions

6.05.05 **Median percentage contribution of [MSP/CIF](#) to final medicine price for a basket of key medicines in the [public sector](#).**

This value is one of the WHO/HAI survey results, expressed in median % contribution.

6.05.06 **Median percentage contribution of [MSP/CIF](#) to final medicine price for a basket of key medicines in the private sector.**

This value is one of the WHO/HAI survey results, expressed in median % contribution.

6.05.07 **Median [manufacturer selling price](#) as percent of final medicine price for a basket of key medicines.**

This value is one of the WHO/HAI survey results, expressed in median %.

6.05.08 **Median [wholesaler](#) selling price as percent of final medicine price for a basket of key medicines.**

This value is one of the WHO/HAI survey results, expressed in median %.

6.05.09 **Median pharmacist markup or [dispensing fee](#) as percent of retail price for a basket of key medicines.**

This value is one of the WHO/HAI survey results, expressed in median %.

6.05.10 **Median percentage contribution of [wholesaler's mark-up](#) to final medicine price for a basket of key medicines (in the public and private sectors).**

This value is one of the WHO/HAI survey results, expressed in median %.

6.05.11 **Median percentage contribution of [retailer's mark-up](#) to final medicine price for a basket of key medicines (in the public and private sectors).**

This value is one of the WHO/HAI survey results, expressed in median %.



## 6.06 Duties and Taxes on Pharmaceuticals (Market)

### Possible sources of information

Ministry of Health

Ministry of Finances

Ministry of Trade

Useful websites:

<http://www.haiweb.org/medicineprices/> This link takes you to the Health Action International website, directly in the medicines prices section where comprehensive information on medicines prices can be found, including the HAI survey manual: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2nd Edition\)](#)

### Core questions

6.06.01 There are **duties** on imported **active pharmaceutical ingredients (APIs)**.

Answer yes	If import tariffs are applied to imported raw materials for local production of medicines.
Answer no	Otherwise

6.06.02 There are **duties** on imported **finished products**.

Answer yes	If import tariffs are applied to imported finished products.
Answer no	Otherwise

6.06.03 There is a **VAT or any other taxes** on finished pharmaceutical products.

Answer yes	If VAT or any other national/regional taxes are applied at one or more stages of the distribution chain's intermediate stages.
Answer no	Otherwise

**6.06.04 There are provisions for exceptions or waivers for pharmaceuticals and health products.**

Answer yes	If tax exceptions or waivers for pharmaceuticals and health products exist.
Answer no	Otherwise

**6.06.05 Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist**

## Supplementary questions

**6.06.07 Amount of [duties](#) in percentage on [active pharmaceutical ingredients](#) (APIs).**

This value is one of the WHO/HAI survey results, expressed in %.

**6.06.08 Amount of [duties](#) in percentage on imported [finished products](#).**

This value is one of the WHO/HAI survey results, expressed in %.

**6.06.09 Amount of [VAT](#) in percentage on pharmaceutical products.**

This value is one of the WHO/HAI survey results, expressed in %.



## **Section 7 - PHARMACEUTICAL PROCUREMENT and DISTRIBUTION**

The answers to some of the questions in this section have been prefilled. When that is the case, please verify that you agree with the responses provided. If you find that any of the prefilled responses are not accurate, please change the value and document your source and year.

If a prefilled value is consistent with and similar to data from your national sources, but it is older, please change to the most recent value and document your source and year.

### **7.01 Pharmaceutical Procurement in the Public sector**

#### **Possible sources of information**

- MoH
- Government Procurement Agency
- Public hospitals and dispensaries
- Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.10/clmd,50.html#hlCL1\\_1\\_1\\_2\\_10](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.10/clmd,50.html#hlCL1_1_1_2_10)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject "Supply Management" where several relevant documents can be found.

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.6.1/clmd,50.html#hlCL1\\_1\\_1\\_6\\_1](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.6.1/clmd,50.html#hlCL1_1_1_6_1)

This link takes you into the WHO library, directly to the subject "Prequalification of Medicines" where several key documents on procurement can be found.

#### **Core questions**

7.01.01.01 Public sector procurement is decentralized.

Answer yes	If responsibility of procurement is left to administrative regions, provinces or districts, or to public facilities themselves
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Pharmaceutical Sector Country Profile Questionnaire.

Answer no	If a national <u>procurement agency</u> has overall responsibility over pharmaceutical procurement, even if some of this responsibility can be delegated to international procurement agencies for specific diseases (malaria, AIDS, TB) or to public facilities on specific occasions (stock outage....)
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7.01.01.02 **Public sector procurement is centralized and decentralized.**

Answer yes	If a national <u>procurement agency</u> has overall responsibility over pharmaceutical procurement, but some of the responsibility of procurement is left to administrative regions, provinces or districts, or to public facilities themselves.
Answer no	Otherwise

7.01.01.03 **Please describe/explain the public procurement process.**

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**7.01.02 If public sector procurement is wholly or partially centralized, it is under responsibility of a procurement agency which is:**

<p>7.01.02.01 <b>Part of MoH</b></p>	<p>If employees of the national <u>procurement agency</u> are MoH employees and line items of the agency’s budget are directly controlled by MoH, even if the agency is not physically located in MoH</p>
<p>7.01.02.02 <b>Semi-Autonomous</b></p>	<p>If the national <u>procurement agency</u> is an organization in which staff are not employed in government post, but in which the government maintains a role</p>
<p>7.01.02.03 <b>Autonomous</b></p>	<p>If the agency is separate from the government. It may be a for-profit or not-for-profit organization (<u>non-governmental organization</u>)</p>
<p>7.01.02.04 <b>A government agency which procures all public goods</b></p>	<p>If employees of the national <u>procurement agency</u> are government employees and items procured are for use in the public sector.</p>

**7.01.03 Public sector tenders (bids documents) are publicly available.**

<p>Answer yes</p>	<p>If public sector tenders (bid documents) are publicly available and you were able to access at least a few of them. If that is the case, provide URL to supporting documents if available.</p>
<p>Answer no</p>	<p>Otherwise</p>

**7.01.04 Public sector procurement awards are publicly available.**

<p>Answer yes</p>	<p>If public sector awards are publicly available and you were able to access at least a few of them</p>
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Answer no	Otherwise
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7.01.05 **Public sector procurements are based on [prequalification](#) of suppliers.**

Answer yes	If suppliers are prequalified to participate in public sector procurement.
Answer no	Otherwise

7.01.05.01 **Please describe/explain how prequalification of suppliers works.**

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## Supplementary questions

7.01.07 **A written policy for public sector procurement exists.**

Answer yes	If such a policy exists and is available for inspection. If that is the case, write the year of approval in the “year” field and provide URL to supporting documents if available.
Answer no	Otherwise

**7.01.08 There are legal provisions in public procurement giving priority to goods produced by local manufacturers.**

Answer yes	If provisions giving an advantage to goods produced locally exist. For example, if local manufacture have a preference provision in public sector tenders. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

**7.01.09 The key functions of the procurement unit and those of the tender committee are clearly separated.**

Answer yes	If there is no overlap in responsibilities between the procurement unit and the tender committee.
Answer no	Otherwise

**7.01.10 A process ensuring the quality of procured products exists.**

Answer yes	If there is quality monitoring and evaluation of procured products.
Answer no	Otherwise

**7.01.10.01 If a process ensuring the quality of products procured exists, it includes [pre-qualification](#) of products, manufacturing sites and suppliers.**

Answer yes	If the quality assurance process includes the three components: prequalification of products, manufacturing sites and suppliers.
Answer no	Otherwise



7.01.10.02 **If a process ensuring the quality of products procured exists, explicit criteria and procedures for pre-qualification of suppliers exist.**

Answer yes	If the QA process follows explicit criteria and procedures.
Answer no	Otherwise

7.01.10.03 **If a process ensuring the quality of products procured exists, a list of prequalified suppliers, manufacturing sites and products is publicly available.**

Answer yes	If such lists exist and are publicly available. If that is the case, provide URL to the list if available.
Answer no	Otherwise

7.01.11 **A list of samples tested during the [procurement](#) process and the results of the quality testing are publicly available.**

Answer yes	If both the list of samples tested and the results of the tests are publicly available. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

7.01.12.01 **National competitive [tenders](#) are used in public sector procurement.**

Answer yes	If at least part of public procurement is done through national competitive tenders.
Answer no	Otherwise

7.01.12.02 **International competitive [tenders](#) are used in public sector procurement.**

Answer yes	If at least part of public procurement is done through international competitive tenders.
Answer no	Otherwise

7.01.12.03 **Direct purchasing is a method used in public sector procurement.**

Answer yes	If at least part of public procurement is done through direct purchasing
Answer no	Otherwise

## 7.02 Pharmaceutical Distribution in the Public Sector

### Possible sources of information

- MoH
- Ministry of Trade
- Government Procurement Agency
- Central Medical Store
- Warehouses of administrative regions
- Public hospitals and dispensaries
- WHO mapping medicines supply and distribution project (ongoing).

### Core questions

7.02.01 **The government supply system department has a Central Medical Store at National Level.**

Answer yes	If procured medicines transit through a central medical store (CMS), even if the CMS is run by a private contractor.
Answer no	Otherwise

7.02.02 **Number of public warehouses in the secondary**

**tier of public distribution (State/Regional/Provincial)**

If there is one warehouse per administrative region, the answer will be the same as the number of administrative regions. If there is no second tier for public distribution, i.e. if the pharmaceutical is transported directly from the CMS to the dispensing location, answer 0.

7.02.03 **There are national guidelines on Good Distribution Practices (GDP).**

Answer yes	If GDP guidelines exist and are publicly available
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Pharmaceutical Sector Country Profile Questionnaire.

Answer no	Otherwise
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7.02.04 There is a [licensing](#) authority issuing GDP licenses.

Answer yes	If a licensing authority exists and is operational.
Answer no	Otherwise

7.02.04.01 If a [licensing](#) authority exists, does it accredit public distribution facilities?

Answer yes	If public distribution facilities are formally licensed to distribute pharmaceuticals.
Answer no	Otherwise

7.02.05 A list of GDP certified warehouses in the public sector exists.

Answer yes	If this list exists and is publicly available.
Answer no	Otherwise

7.02.06 A list of GDP certified distributors in the public sector exists.

Answer yes	If this list exists and is publicly available.
Answer no	Otherwise

## Supplementary questions

**7.02.08.01 A process of forecasting order quantities is in place in the Central Medical Store.**

Answer yes	If such a process is functioning in the Central Medical Store.
Answer no	Otherwise

**7.02.08.02 A process of requisition/stock orders is in place in the Central Medical Store.**

Answer yes	If such a process is functioning in the Central Medical Store.
Answer no	Otherwise

**7.02.08.03 A process of picking/packing slips is in place in the Central Medical Store.**

Answer yes	If such a process is functioning in the Central Medical Store.
Answer no	Otherwise

**7.02.08.04 A process of stock on hand is in place in the Central Medical Store.**

Answer yes	If such a process is functioning in the Central Medical Store.
Answer no	Otherwise

**7.02.08.05 A process of producing reports of outstanding order lines is in place in the Central Medical Store.**

Answer yes	If such a process is functioning in the Central Medical Store.
Answer no	Otherwise

**7.02.08.06 Expiry dates management is in place in the Central Medical Store.**

Answer yes	If such a process is functioning in the Central Medical Store.
Answer no	Otherwise

**7.02.08.07 A process of batch tracking is in place in the Central Medical Store.**

Answer yes	If such a process is functioning in the Central Medical Store.
Answer no	Otherwise

**7.02.08.08 A process of producing reports of products out of stock is in place in the Central Medical Store.**

Answer yes	If such a process is functioning in the Central Medical Store.
Answer no	Otherwise

**7.02.09 Percentage of availability of key medicines in the Central Medical Store**

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If that is the case, attach/upload a copy of the report to the completed questionnaire.

**7.02.10 Percentage of selected medicines with at least one stock out in the past year in the Central Medical Store**

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If that is the case, attach/upload a copy of the report to the completed questionnaire.

**7.02.11 A routine procedure to track the expiry dates of medicines exists in the Central Medical Store.**

Answer yes	If such a procedure exists in the Central Medical Store.
Answer no	Otherwise

**7.02.12 The Central Medical Store is [GDP](#) certified by a licensing authority.**

Answer yes	If the central medical store has a current certificate of compliance with GDP.
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Answer no	Otherwise
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7.02.13 The Central Medical Store is [ISO](#) certified.

Answer yes	If the central medical store is ISO certified.
Answer no	Otherwise

7.02.14 The second tier public warehouses are [GDP](#) certified by a licensing authority.

Answer yes	If the second tier public warehouses have current certificates of compliance with GDP.
Answer no	Otherwise

7.02.15 The second tier public warehouses are [ISO](#) certified.

Answer yes	If the second tier public warehouses are ISO certified.
Answer no	Otherwise



## 7.03 Pharmaceutical Distribution in the Private Sector

### Possible sources of information

- MoH
- Ministry of Trade
- Wholesalers Associations
- Pharmacists Associations

### Core questions

7.03.01 **Legal provisions exist for licensing wholesalers in the private sector.**

Answer yes	If legal provisions exist requiring private wholesalers to be licensed to distribute pharmaceuticals.
Answer no	Otherwise

7.03.02 **Legal provisions exist for licensing distributors in the private sector.**

Answer yes	If legal provisions exist requiring private distributors to be formally licensed to distribute pharmaceuticals.
Answer no	Otherwise

7.03.03 **A list of GDP certified wholesalers in the private sector exists.**

Answer yes	If this list exists and is publicly available.
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Pharmaceutical Sector Country Profile Questionnaire.

Answer no	Otherwise
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7.03.04 **A list of GDP certified distributors in the private sector exists.**

Answer yes	If this list exists and is publicly available.
Answer no	Otherwise

## **Section 8 - SELECTION AND RATIONAL USE OF MEDICINES**

The answers to some of the questions in this section have been prefilled. When that is the case, please verify that you agree with the responses provided. If you find that any of the prefilled responses are not accurate, please change the value and document your source and year.

If a prefilled value is consistent with and similar to data from your national sources, but it is older, please change to the most recent value and document your source and year.

### **8.01 National Structures**

#### **Possible sources of information**

- MoH
- Public hospitals and dispensaries
- Useful websites:

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.8/clmd,50.html#hlCL1\\_1\\_1\\_2\\_8](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.8/clmd,50.html#hlCL1_1_1_2_8)

WHO publications and documentation library contains over 500 medicines-related publications in English, French and Spanish, taken primarily from the wide range of technical information materials. This link takes you in the library, directly to the subject “Rational Use” where many relevant documents cited in the glossary can be found.

<http://www.inrud.org/> The International Network for Rational Use of Drugs (INRUD) was established in 1989 to design, test, and disseminate effective strategies to improve the way drugs are prescribed, dispensed, and used, with a particular emphasis on resource poor countries.

#### **Core questions**

8.01.01 A national [Essential Medicines List \(EML\)](#) exists.

Answer yes	If a national list of essential medicines exists. If yes, please write year of last update of EML in the “year” field. Upload/attach the document to your questionnaire and provide the URL if available.
Answer no	Otherwise

Pharmaceutical Sector Country Profile Questionnaire.

8.01.01.01 If a national [Essential Medicines List](#) (EML) exists, provide the number of medicines listed on the EML

If a national EML exists, provide the number of INN on the list.
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8.01.01.02 If a national [Essential Medicines List](#) (EML) exists, there is a written process for selecting medicines that are listed.

Answer yes	If there is a formal process to select medicines that are listed on the EML.
Answer no	Otherwise

8.01.01.03 If a national [Essential Medicines List](#) (EML) exists, it is publicly available.

Answer yes	If a national list of essential medicines exists and is publicly available.
Answer no	Otherwise

8.01.01.04 If a national [Essential Medicines List](#) (EML) exists, there is a mechanism in place to align the EML with the STGs.

Answer yes	If that is the case. Describe the mechanism in the comments.
Answer no	Otherwise

8.01.02 National [Standard Treatment Guidelines](#) (STGs) for most common illnesses are produced/endorsed by the MoH.

Answer yes	If a document summarizing recommended treatments for most commonly
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	occurring conditions in your country has been published or endorsed by the MoH. If yes, please write year of most recent update of STGs in the “year” field.
Answer no	Otherwise

8.01.03 [Standard Treatment Guidelines \(STGs\)](#) specific to primary care exist in your country

Answer yes	If national STGs specific to primary care conditions exist in your country. Please document the year of their latest update in the “year’ field. Primary care is the care provided at first point of contact between the patient and the health care system
Answer no	Otherwise

8.01.04 [Standard Treatment Guidelines \(STGs\)](#) specific to secondary care (hospitals) exist in your country

Answer yes	If national STGs specific to secondary care (hospitals) conditions exist in your country. Please document the year of their latest update in the “year’ field.
Answer no	Otherwise

8.01.05 If [Standard Treatment Guidelines \(STGs\)](#) specific to pediatric conditions exist in your country

Answer yes	If national STGs specific to pediatric conditions exist in your country. Please document the year of their latest update in the “year’ field.
Answer no	Otherwise

**8.01.06 Percentage of public health facilities with a copy of the [national EML](#).**

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If this is the case, document the mean percentage of public health facilities with a copy of the national EML as found in the survey, and the date of the survey. If possible, attach/upload a copy of the report to the completed questionnaire.

**8.01.07 Percentage of public health facilities with a copy of the national STGs.**

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If this is the case, document the mean percentage of public health facilities with a copy of the national STGs as found in the survey, and the date of the survey. If possible, attach/upload a copy of the report to the completed questionnaire.

**8.01.08 A public or independently funded national medicines information centre provides information on medicines to [prescribers](#), [dispensers](#), and consumers.**

Answer yes	Only if such a medicines information center exists, and it is either publicly funded or funded by private organizations that do not benefit financially from the sale of medicines.
Answer no	Otherwise

**8.01.09 Public education campaigns on [rational medicine use](#) topics have been conducted in the previous two years.**

Answer yes	Only if such campaigns occurred in the previous two years, and were free of medicines advertising.
Answer no	Otherwise

8.01.10 A national survey on [rational medicine use](#) has been conducted in the previous two years.

Answer yes	If the MoH has conducted a national audit of medicines prescribing and/or dispensing and/or use during the previous two years. If possible attach publicly available results.
Answer no	Otherwise

8.01.11 A national program or committee (involving government, [civil society](#), and professional bodies) exists to monitor and promote rational use of medicines.

Answer yes	If such a program or committee exists.
Answer no	Otherwise

8.01.12 A written national strategy exists to contain [antimicrobial resistance](#).

Answer yes	If a national written strategy to fight antimicrobial resistance exists. Please document the year of their latest update in the “year” field. If yes, attach/upload the document and provide URL if available.
Answer no	Otherwise

## Supplementary questions

8.01.14 **The EML includes formulations specific for children.**

Answer yes	If the EML includes formulations that are used specifically to treat pediatric conditions.
Answer no	Otherwise

8.01.15 **There are explicit and documented criteria for selection of medicines on the EML.**

Answer yes	If criteria to select medicines on the EML are explicit and documented.
Answer no	Otherwise

8.01.16 **There is a formal committee or other equivalent structure for the selection of products on the national EML.**

Answer yes	If a formal committee or other equivalent structure charged with selecting EM exists.
Answer no	Otherwise

8.01.17 **If there is a formal committee or other equivalent structure for the selection of products on the national EML, conflict of interest declarations are required from members of national EML committee.**

Answer yes	If such declarations are required from the EML committee members.
Answer no	Otherwise



8.01.18 A national medicines [formulary](#) exists.

Answer yes	If a manual containing clinically oriented summaries of pharmacological information about selected drugs has been produced at the national level.
Answer no	Otherwise

8.01.19 A funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection exists.

Answer yes	If such a task force exists.
Answer no	Otherwise

8.01.20 A national reference laboratory or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance

Answer yes	If a reference laboratory or other institution with such responsibility exists. Attach/upload its contact information.
Answer no	Otherwise

## 8.02 Prescribing

### Possible sources of information

- MoH
- Public hospitals and dispensaries
- Medical, nursing, and pharmacist schools
- Useful websites

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.8/clmd,50.html#hlCL1\\_1\\_1\\_2\\_8](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.8/clmd,50.html#hlCL1_1_1_2_8)

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<http://www.inrud.org/> The International Network for Rational Use of Drugs (INRUD) was established in 1989 to design, test, and disseminate effective strategies to improve the way drugs are prescribed, dispensed, and used, with a particular emphasis on resource poor countries.

### Core questions

8.02.01 Legal provisions to govern the licensing and prescribing practices of **prescribers** exist.

Answer yes	If such legal provisions exist. If yes, attach/upload a copy of the laws.
Answer no	Otherwise

8.02.02 Legal provisions to restrict **dispensing** by **prescribers** exist.

Answer yes	If such legal provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

Pharmaceutical Sector Country Profile Questionnaire.

8.02.03 Do [prescribers](#) in the private sector dispense medicines?

Answer yes	If such legal provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

8.02.04 Regulations require hospitals to organize/develop [Drug and Therapeutics Committees](#) (DTCs).

Answer yes	If such regulations exist. Attach/upload a copy of the regulations.
Answer no	Otherwise

8.02.05 Do more than half of the referral hospitals have [Drug and Therapeutics Committees](#) (DTCs).

Answer yes	If that is the case.
Answer no	Otherwise

8.02.06 Do more than half of the general hospitals have [Drug and Therapeutics Committees](#) (DTCs).

Answer yes	If that is the case.
Answer no	Otherwise

8.02.07 Do more than half of the regions/provinces have [Drug and Therapeutics Committees](#) (DTCs).

Answer yes	If such regulations exist.
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Answer no	Otherwise
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8.02.08.01 The core training of [physicians](#) includes a component on the [national EML](#).

Answer yes	If all medical students receive training on the national EML. This question can only be answered if a national EML exists.
Answer no	Otherwise

8.02.08.02 The core training of physicians includes a component on the use of [Standard Treatment Guidelines](#).

Answer yes	If all medical students receive training on the national STGs.  This question can only be answered if national STG exist.
Answer no	Otherwise

8.02.08.03 The core training of physicians includes a component on [pharmacovigilance](#).

Answer yes	If all medical students receive training on the pharmacovigilance. If possible, upload/attach a copy of the official curriculum.
Answer no	Otherwise

8.02.08.04 The core training of physicians includes a component on problem based pharmacotherapy.

Answer yes	If all medical students receive training on problem based pharmacotherapy.
Answer no	Otherwise

**8.02.09 Mandatory continuing education that includes pharmaceutical issues is required for physicians.**

Answer yes	Only if regulations require continuing education for physicians and if they specify that rational use of medicines be part of continuous education.
Answer no	Otherwise

**8.02.10 Mandatory continuing education that includes pharmaceutical issues is required for nurses.**

Answer yes	Only if regulations require continuing education for nurses and if they specify that rational use of medicines be part of continuous education.
Answer no	Otherwise

**8.02.11 Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff.**

Answer yes	Only if regulations require continuing education for paramedical staff and if they specify that rational use of medicines be part of continuous education.
Answer no	Otherwise

**8.02.12.01 Prescription by [INN name](#) is mandatory in the public sector.**

Answer yes	Only if regulations require prescribers in the public sector to refer medicines by their INN name when they write prescriptions.
Answer no	Otherwise

**8.02.12.02 Prescription by [INN name](#) is mandatory in the private sector.**

Answer yes	Only if regulations require prescribers in the private sector to refer medicines by their INN name when they write prescriptions.
Answer no	Otherwise

**8.02.13 Average (mean) number of medicines prescribed per patient contact in public health facilities.**

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If this is the case, document the mean number of medicines prescribed per patient contact in public health care facilities as found in the survey, and the date of the survey. If possible, attach/upload a copy of the report to the completed questionnaire.

**8.02.14 Mean percentage of medicines prescribed in public health care facilities that are on the [national EML](#).**

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If this is the case, document the mean percentage of medicines prescribed that are on the national EML as found in the survey, and the date of the survey. If possible, attach/upload a copy of the report to the completed questionnaire.

**8.02.15 Mean percentage of medicines that are prescribed by [INN name](#) in public health care facilities.**

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If this is the case, document the mean percentage of medicines that are prescribed by INN name as found in the survey, and the date of the survey. If possible, attach/upload a copy of the report to the completed questionnaire.

**8.02.16 Mean percentage of patients in public health care facilities receiving antibiotics.**

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If this is the case, document the mean percentage of patients receiving antibiotics in public health care facilities as found in the survey, and the date of the survey and. If possible, attach/upload a copy of the report to the completed questionnaire.

**8.02.17 Mean percentage of patients in public health care facilities receiving injections.**

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If this is the case, document the mean percentage of patients receiving injections in public health care facilities as found in the survey, and the date of the survey. If possible, attach/upload a copy of the report to the completed questionnaire.

**8.02.18 Mean percentage of prescribed medicines dispensed to patients.**

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If this is the case, document the mean percentage of prescribed medicines dispensed to patients as found in the survey, and the date of the survey. If possible, attach/upload a copy of the report to the completed questionnaire.

**8.02.19 Mean percentage of medicines adequately labeled in public health facilities.**

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If this is the case, document the mean percentage of medicines adequately labeled in public health facilities as found in the survey, and the date of the survey. If possible, attach/upload a copy of the report to the completed questionnaire.

## Supplementary questions

8.02.21 A professional association [code of conduct](#) governing professional behavior of physicians exists.

Answer yes	If such a code of conduct exists and is available for inspection
Answer no	Otherwise

8.02.22 A professional association [code of conduct](#) governing professional behavior of nurses exists.

Answer yes	If such a code of conduct exists and is available for inspection.
Answer no	Otherwise

8.02.23 Percentage of children with diarrhea treated with ORS

This question can only be answered if a [WHO Level II facility survey](#) or a similar assessment of rational use of medicines has been carried out in your country, and its results are available. If this is the case, document the mean percentage of children treated with ORS as found in the survey, and the date of the survey. If possible, attach/upload a copy of the report to the completed questionnaire.



## 8.03 Dispensing

### Possible sources of information

- MoH
- Public hospitals and dispensaries
- Medical, nursing, and pharmacist schools
- Useful websites

[http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.8/clmd,50.html#hlCL1\\_1\\_1\\_2\\_8](http://apps.who.int/medicinedocs/en/cl/CL1.1.1.2.8/clmd,50.html#hlCL1_1_1_2_8)

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<http://www.inrud.org/> The International Network for Rational Use of Drugs (INRUD) was established in 1989 to design, test, and disseminate effective strategies to improve the way drugs are prescribed, dispensed, and used, with a particular emphasis on resource poor countries.

### Core questions

8.03.01 **Legal provisions to govern dispensing practices of pharmaceutical personnel exist.**

Answer yes	If such legal provisions exist. If that is the case, provide URL to supporting documents if available.
Answer no	Otherwise

8.03.02.01 **The core training of pharmacists includes a component on the concept of [EML](#).**

Answer yes	If all pharmacy students receive training on the concept of EML.
Answer no	Otherwise

Pharmaceutical Sector Country Profile Questionnaire.

**8.03.02.02 The core training of pharmacists includes a component on use of [Standard Treatment Guidelines](#).**

Answer yes	If all pharmacy students receive training on use of STGs. This question can only be answered if national STG exist.
Answer no	Otherwise

**8.03.02.03 The core training of pharmacists includes a component on drug information.**

Answer yes	If all pharmacy students receive training on drug information.
Answer no	Otherwise

**8.03.02.04 The core training of pharmacists includes a component on clinical pharmacology.**

Answer yes	If all pharmacy students receive training on clinical pharmacology.
Answer no	Otherwise

**8.03.02.05 The core training of pharmacists includes a component on medicines supply management.**

Answer yes	If all pharmacy students receive training on medicines supply management.
Answer no	Otherwise

**8.03.03 Mandatory continuing education that includes rational use of medicines is required for pharmacists.**

Answer yes	Only if regulations require continuing education for pharmacists and if they specify that it includes rational use of medicines.
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Answer no	Otherwise
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8.03.04 **Substitution of generic equivalents at the point of dispensing facilities is allowed in public sector.**

Answer yes	If there are no regulations preventing generic substitution in the public sector.
Answer no	Otherwise

8.03.05 **Substitution of generic equivalents at the point of dispensing facilities is allowed in private sector.**

Answer yes	If there are no regulations preventing generic substitution in the private sector.
Answer no	Otherwise

8.03.06 **In practice, (even though this may be contrary to regulations) antibiotics are *sometimes* sold over-the-counter without a prescription.**

Answer yes	If consumers do not always need a prescription to buy antibiotics. This question does <b>not</b> ask whether it is allowed to sell antibiotics over the counter. It rather asks what the actual situation on the ground is.
Answer no	Otherwise

8.03.07 In practice, (even though this may be contrary to regulations) [injectable medicines](#) are sold over-the-counter without a prescription.

Answer yes	If consumers do not always need a prescription to buy injectable medicines. This question does <b>not</b> ask whether it is allowed to sell injections over the counter. It rather asks what the actual situation on the ground is.
Answer no	Otherwise

## Supplementary questions

8.03.09 A professional association [code of conduct](#) governing professional behavior of pharmacists exists.

Answer yes	If such a code of conduct exists.
Answer no	Otherwise

8.03.10.01 **In practice, (even though this may be contrary to regulations), nurses prescribe [prescription-only medicines](#) at the primary care level in the public sector.**

Answer yes	If, to the best of your knowledge, nurses prescribe prescription-only medicines at primary care public facilities. This question does <b>not</b> ask whether nurses are legally allowed to prescribe. It rather asks what the actual situation on the ground is.
Answer no	Otherwise

8.03.10.02 **In practice, (even though this may be contrary to regulations), pharmacists prescribe [prescription-only medicines](#) at the primary care level in the public sector.**

Answer yes	If, to the best of your knowledge, pharmacists prescribe prescription-only medicines at primary care public facilities. This question does <b>not</b> ask whether pharmacists are legally allowed to prescribe. It rather asks what the actual situation on the ground is.
Answer no	Otherwise

8.03.10.03 **In practice, (even though this may be contrary to regulations), paramedics prescribe [prescription-only medicines](#) at the primary care level in the public sector.**

Answer yes	If, to the best of your knowledge, paramedics prescribe prescription-only medicines at primary care public facilities. This question does <b>not</b> ask whether paramedics are legally allowed to prescribe. It rather asks what the actual situation on the ground is.
Answer no	Otherwise

8.03.10.04 **In practice, (even though this may be contrary to regulations), personnel with less than one month of training prescribe [prescription-only medicines](#) at the primary care level in the public sector.**

Manual for data collection

Answer yes	If, to the best of your knowledge, personnel with less than one month training prescribe prescription-only medicines at primary care public facilities. This question does <b>not</b> ask whether personnel with less than one month training are legally allowed to prescribe. It rather asks what the actual situation on the ground is.
Answer no	Otherwise

## **Section 9 - HOUSEHOLD DATA/ACCESS**

### **Possible sources of information**

*The following questions will be prefilled by WHO with results of the household medicines survey if they exist. If you are aware of similar data obtained with a different methodology, please describe in the comments and attach/upload a copy of the report to your completed questionnaire and provide URL, if available.*

### **Core questions**

**9.01.01 What household surveys have been undertaken in the past 5 years to assess access to medicines?**

List nationally representative household surveys that took place in the 5 years preceding this country profile questionnaire.

**9.01.02 Adults with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.03 Adults with acute conditions not taking all medicines because they cannot afford them (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household Pharmaceutical Sector Country Profile Questionnaire.

survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.04 Adults from poor households with an acute health condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.05 Adults from poor households with an acute health condition in two-week recall period who did not take all medicines because they cannot afford them (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.06 Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies



**9.01.07 Adults from poor households with chronic conditions not taking all medicines because they cannot afford them (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.08 Adults from poor households with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.09 Children (from poor households) with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.10 Percentage of people that obtained the medicines prescribed in the 15 days before the interview (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.11 People that obtained prescribed medicines for free in the 15 days before the interview**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

## **Supplementary questions**

**9.01.13 Adults with acute conditions not taking all medicines because the medicines were not available (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.14 Adults with chronic conditions not taking all medicines because they cannot afford them (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household

survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.15 Adults with chronic conditions not taking all medicines because they were not available (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.16 Children with acute conditions taking all medicines prescribed by an authorized prescriber (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.17 Children with acute conditions not taking all medicines because they cannot afford them (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.18 Children with acute conditions not taking all medicines because medicines were not available (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies

**9.01.19 Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%)**

This question refers to the WHO household surveys. If one of these surveys has been carried out in your country, and results are available, the answer has been prefilled. If a similar household survey has been conducted by the government or by another development partner, you can also use it to fill in this part of the profile, but please do not forget to attach it, so that we can compare the two methodologies



## Glossary

### ACCREDITATION

Accreditation is an evaluative process in which a health care organization undergoes an examination of its policies, procedures and performance by an external organization (accrediting body) to ensure that it is meeting predetermined standards.

For facilities, accreditation standards are usually defined in terms of physical plant, governing body, administration, and medical and other staff. Accreditation is often carried out by organizations created for the purpose of assuring the public of the quality of the accredited institution or program.

The State can recognize accreditation in lieu of, or as the basis for mandatory approvals.

Public or private payment programs often require accreditation as a condition of payment for covered services.

Accreditation may either be permanent or may be given for a specified period of time.

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### ACTIVE INGREDIENT

An Active Pharmaceutical Ingredient (API) is the chemical substance contained in a pharmaceutical, which is responsible for its therapeutic effect. Some pharmaceuticals contain more than one active ingredient (combination product).

[In: *OECD – Pharmaceutical Pricing Policies in a Global Market*, at:  
[http://www.oecd.org/document/36/0,3343,en\\_2649\\_33929\\_41000996\\_1\\_1\\_1\\_37407,00.html](http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html)]

### ADVERSE REACTION (ADVERSE DRUG REACTION, ADR)

An adverse drug reaction is a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function. (WHO, 1972)

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## Glossary

An adverse drug reaction, contrary to an adverse event, is characterized by the suspicion of a causal relationship between the medicine and the occurrence, i.e. judged as being at least possibly related to treatment by the reporting or a reviewing health professional.

[At: <http://www.who-umc.org/DynPage.aspx?id=13111&mn=1513>]

**Serious adverse reaction:** An adverse reaction which results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.

**Unexpected adverse reaction:** An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeq.at/index.aspx?alias=phisglossary>]

## ADR DATABASE

An ADR database is an ADR case management system which allows monitoring ADR occurrence and trends. The Uppsala Monitoring Center maintains a sophisticated WHO International ADR database called *Vigibase*.

## **ANTIMICROBIAL RESISTANCE**

Antimicrobial resistance corresponds to the emergence and spread of microbes that are resistant to cheap and effective first-choice, or "first-line" antimicrobial drugs. The bacterial infections which contribute most to human disease are also those in which emerging and microbial resistance is most evident: diarrheal diseases, respiratory tract infections, meningitis, sexually transmitted infections, and hospital-acquired infections. Some important examples include penicillin-resistant *Streptococcus pneumoniae*, vancomycin-resistant enterococci, methicillin-resistant *Staphylococcus aureus*, multi-resistant salmonellae, and multi-resistant *Mycobacterium tuberculosis*. The development of resistance to drugs commonly used to treat malaria is of particular concern, as is the emerging resistance to anti-HIV drugs.

[At: <http://www.who.int/mediacentre/factsheets/fs194/en/>]

## **AUDITING**

Auditing is an independent and objective activity designed to add value and improve an organization's operations by helping an organization to accomplish its objectives by using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

## **AUTHORIZED PORT-OF-ENTRY**

An authorized port-of-entry is a port where medicines may enter or leave a country under official supervision, i.e. where customs formalities may take place.

[From *Managing Drug Supply, Second Edition, Management Sciences for Health*. Available at [http://erc.msh.org/newpages/english/drugs/intro\\_pg.pdf](http://erc.msh.org/newpages/english/drugs/intro_pg.pdf)]

## **BOLAR EXCEPTION (PROVISION)**

Many countries use this provision of the TRIPS Agreement to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.

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## Glossary

In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval (for example from public health authorities) without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision. *Article 30*

This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada - Patent Protection for Pharmaceutical Products")

[In: [WTO OMC Fact sheet: TRIPS and pharmaceutical patents](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf), can be found on line at: [http://www.wto.org/english/tratop\\_e/trips\\_e/tripsfactsheet\\_pharma\\_2006\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf)]

### **BRAND NAME (INNOVATOR'S NAME, PROPRIETARY PRODUCT NAME, MEDICINE SPECIALITY PRODUCT NAME, MEDICINAL SPECIALITY PRODUCT NAME)**

Name given for marketing purposes to any ready-prepared medicine placed on the market under a special name and in a special pack. A brand name may be a protected trademark.

[In: [PHIS Glossary 2009](http://phis.goeg.at/index.aspx?alias=phisglossary), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### **CERTIFICATE OF PHARMACEUTICAL PRODUCT**

A WHO-type certificate of the form described in Guidelines for implementation of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce.

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

### **CIVIL SOCIETY**

*Civil society* are individuals and groups, organised or unorganised, who interact in the social, political and economic domains and who are regulated by formal and informal rules and laws. Civil society offers a dynamic, multilayered wealth of perspectives and values, seeking expression in the public sphere.

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## Glossary

[In: *Governance for sustainable human development, A UNDP policy document-Glossary of key terms. Can be found online at: <http://mirror.undp.org/magnet/policy/glossary.htm>*]

### **CIVIL SOCIETY ORGANIZATIONS**

*Civil society organisations* are the multitude of associations around which society voluntarily organises itself and which can represent a wide range of interests and ties, from ethnicity and religion, through shared professional, developmental and leisure pursuits, to issues such as environmental protection or human rights.

[In: *Governance for sustainable human development, A UNDP policy document-Glossary of key terms. Can be found online at: <http://mirror.undp.org/magnet/policy/glossary.htm>*]

### **CLINICAL TRIAL (CLINICAL STUDY)**

A clinical trial is any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, and/or identify any adverse reaction to, investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety.

Clinical trials are generally divided into Phases I-IV. It is not possible to draw clear distinctions between these phases, and different opinions about details and methodology do exist.

However, the individual phases, based on their purposes as related to the clinical development of pharmaceutical products, can be briefly defined as follows:

**Phase I.** These are the first trials of a new active ingredient or new formulations in humans, often carried out in healthy volunteers. Their purpose is to make a preliminary evaluation of safety, and an initial pharmacokinetic/ pharmacodynamic profile of the active ingredient.

**Phase II.** The purpose of these therapeutic pilot studies is to determine activity and to assess the short-term safety of the active ingredient in patients suffering from a disease or condition for which it is intended. The trials are preformed in a limited number of subjects and are often, at a later stage, of a comparative (e.g. placebo-controlled) design. This phase is also concerned with the determination of appropriate dose ranges/ regimens and (if possible) the clarification of dose-response relationships in order to provide an optimal background for the design of extensive therapeutic trials.

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**Phase III.** This phase involves trials in large (and possibly varied) patient groups for the purpose of determining the short- and long-term safety-efficacy balance of formulation(s) of the active ingredient, and assessing its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated, and special features of the product must be explored (e.g. clinically relevant drug interactions, factors leading to differences in effect, such as age). The trials should preferably be randomized double-blind, but other designs may be acceptable, e.g. long-term safety studies. In general, the conditions under which the trials are conducted should be as close as possible to the normal conditions of use.

**Phase IV.** In this phase studies are performed after the pharmaceutical product has been marketed. They are based on the product characteristics on which the marketing authorization was granted and normally take the form of post-marketing surveillance, and assessment of therapeutic value or treatment strategies. Although methods may differ, the same scientific and ethical standards should apply to Phase IV studies as are applied in premarketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc., are normally regarded as trials of new pharmaceutical products.

*[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]*

### **CODE OF CONDUCT (CODE OF BEHAVIOR)**

A code of conduct is a set of conventional principles and expectations that are considered binding on any person who is a member of a particular group.

*[At: <http://wordnet.princeton.edu/>]*

### **COMPULSORY LICENSE**

Compulsory license is a license granted by an administrative or judicial body to a third party to exploit an invention without the authorization of the patent holder. The type of license is commonly referred to as a non-voluntary license connoting the lack of consent to the patent holder.

*[The TRIPS rules on compulsory licensing are contained in article 31. from "Utilizing Trips Flexibilities for Public Health Protection through south-south Regional Frameworks", South Centre, <http://apps.who.int/medicinedocs/en/d/Js4968e/1.html#Js4968e.1>]*

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## **CONFLICT OF INTEREST**

A conflict of interest is a situation in which a public official's decisions are influenced by the official's personal interests.

[At: <http://wordnet.princeton.edu/>]

The common meaning of conflict of interest is a conflict between an individuals' private or personal interest and his or her duty. However, conflict of interest may also refer to a situation where an individual has several duties which conflict without involvement of any private or personal interest. Mitigating conflict of interest means eliminating a conclusive or a reasonable presumption of bias in decision-making processes.

[In *PAHO Governance Manual*]

## **CONTROLLED MEDICINES**

Narcotic medicines and psychotropic substances regulated by provisions of national medicines laws.

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

## **CONVENTION ON PSYCHOTROPIC SUBSTANCES, 1971**

This international treaty establishes an international control system for psychotropic substances. It responded to the diversification and expansion of the spectrum of drugs of abuse and introduced controls over a number of synthetic drugs according to their abuse potential on the one hand and their therapeutic value on the other.

[At: [http://www.incb.org/incb/convention\\_1971.html](http://www.incb.org/incb/convention_1971.html)]

**[CONVENTION AGAINST THE ILLICIT TRAFFIC IN NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES, 1988](#)**

This international treaty provides comprehensive measures against drug trafficking, including provisions against money laundering and the diversion of precursor chemicals. It provides for international cooperation through, for example, extradition of drug traffickers, controlled deliveries and transfer of proceedings.

[At: [http://www.incb.org/incb/convention\\_1988.html](http://www.incb.org/incb/convention_1988.html)]

**CONSUMPTION OF OPIOIDS**

The amounts of opioid/analgesics distributed legally in a country for medical purposes to those institutions and programs that are licensed to dispense to patients, such as hospitals, nursing homes, pharmacies, hospices and palliative care programs. In international drug control terminology, consumption does not refer to the amounts dispensed to or used by patients, but rather amounts distributed to the retail level.

[At: <http://www.painpolicy.wisc.edu/glossary.htm>]

**CO-PAYMENT**

Insured patient's contribution towards the cost of a medical service covered by the insurer. It can be expressed as a percentage of the total cost of the service (also known as co-insurance) or as a fixed amount.

[In: *OECD – Pharmaceutical Pricing Policies in a Global Market*, at:

[http://www.oecd.org/document/36/0,3343,en\\_2649\\_33929\\_41000996\\_1\\_1\\_1\\_37407,00.html](http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html)]

### **COST, INSURANCE, FREIGHT (CIF)**

CIF is a shipping term meaning that the seller must pay the costs, insurance and freight charges necessary to bring the goods to the port of destination.

[In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2<sup>nd</sup> Edition\)](#) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

### **COUNTERFEIT MEDICAL PRODUCT**

The term counterfeit medical product describes a product with a false representation of its identity and/or Source. This applies to the product, its container or other packaging or labeling information. Counterfeiting can apply to both branded and generic products.

Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging. Violations or disputes concerning patents must not be confused with counterfeiting of medical products.

Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit.

Substandard batches of or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### **DATA EXCLUSIVITY**

Data exclusivity is the protection of an originator pharmaceutical company's data preventing other parties from using these data for a commercial purpose. Concretely, this protection prevents generic product manufacturers from proceeding to clinical trials and health authorities from evaluating generic product market authorization applications during this period. In the European Union, this period was harmonized to eight years in 2004.

[In: *OECD – Pharmaceutical Pricing Policies in a Global Market*, at: [http://www.oecd.org/document/36/0,3343,en\\_2649\\_33929\\_41000996\\_1\\_1\\_1\\_37407,00.html](http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html)]

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### **DIRECT\_TO\_CONSUMER ADVERTISING**

Direct-to-consumer advertising (DTC advertising) usually refers to the marketing of medicines aimed directly toward the public, rather than healthcare professionals. Forms of DTC advertising include TV, print, and radio.

*[Adapted from: OECD – Pharmaceutical Pricing Policies in a Global Market, at:*

*[http://www.oecd.org/document/36/0,3343,en\\_2649\\_33929\\_41000996\\_1\\_1\\_1\\_37407,00.html](http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html)]*

### **DISPENSER**

A dispenser is a health care professional who is legally qualified to distribute medicines.

### **DISPENSING FEE**

Normally a dispensing fee is a fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up. The fee more accurately reflects the work involved in dispensing a prescription; a percentage mark-up makes profit dependent on the sale of expensive medicines.

*[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]*

### **DISTRIBUTION**

The division and movement of pharmaceutical products from the premises of the manufacturer of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

*[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]*

### **DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH**

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In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines.

They therefore adopted a separate declaration on TRIPS and Public Health. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They underscored countries' ability to use the flexibilities that are built into the TRIPS Agreement, including compulsory licensing and parallel importing. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016.

On one remaining question, they assigned further work to the TRIPS Council — to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries. (This is sometimes called the “Paragraph 6” issue, because it comes under that paragraph in the separate Doha declaration on TRIPS and public health.)

*[In: [WTO OMC Fact sheet: TRIPS and pharmaceutical patents](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf), can be found on line at: [http://www.wto.org/english/tratop\\_e/trips\\_e/tripsfactsheet\\_pharma\\_2006\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf)]*

## DRUG

See [pharmaceutical](#)

## DRUG AND THERAPEUTICS COMMITTEE

A drugs and therapeutics committee is a group of people established and officially approved by the health ministry and/or health facility management that promotes the safe and effective use of medicines in the area or facility under its jurisdiction.

*[In: [Drug and therapeutics committees, a practical guide](http://apps.who.int/medicinedocs/en/d/Js4882e/3.html) Geneva 2003, can be found online at: <http://apps.who.int/medicinedocs/en/d/Js4882e/3.html> ]*

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### **DUTY (IMPORT TARIFF)**

Import tariff may apply to all imported medicines or there may be a system to exempt certain products and purchases. The import tax or duty may or may not apply to raw materials for local production. It may be different for different products.

[In: *HAI/WHO Measuring medicine prices, availability, affordability and price components (2<sup>nd</sup> Edition)* and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

### **ESSENTIAL MEDICINES**

Essential medicines are defined by WHO as medicines that, "... satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility."

[At: [http://www.who.int/topics/essential\\_medicines/en/](http://www.who.int/topics/essential_medicines/en/)]

### **ETHICS COMMITTEE (EC, INSTITUTIONAL REVIEW BOARD, IRB)**

Ethics Committees (EC) ensure that biomedical research follows international guidelines, including the Declaration of Helsinki, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and the WHO and ICH Guidelines for Good Clinical Practice. The purpose of an EC in reviewing biomedical research is to contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants. A cardinal principle of research involving human participants is 'respect for the dignity of persons'. The goals of research, while important, should never be permitted to override the health, well-being, and care of research participants. ECs should also take into consideration the principle of justice. Justice requires that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account age, gender, economic status, culture, and ethnic considerations. ECs should provide independent, competent, and timely review of the ethics of proposed studies. In their composition, procedures, and decision-making, ECs need to have independence from political, institutional, professional, and market influences. They need similarly to demonstrate competence and efficiency in their work. ECs are responsible for carrying out the review of proposed research before the commencement of the research. They also need to ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision. ECs are responsible for acting in the full interest of potential research participants and concerned Pharmaceutical Sector Country Profile Questionnaire.

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communities, taking into account the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws.

[In: [Operational Guidelines for Ethics Committees That Review Biomedical Research](#) Geneva 2000, can be found online at: <http://apps.who.int/medicinedocs/en/d/Js6171e/2.3.html> <http://apps.who.int/tdr/publications/training-guideline-publications/operational-guidelines-ethics-biomedical-research/pdf/ethics.pdf>]

### **EXCHANGE RATE**

Several websites provide exchange rates and tools to express money values in \$US. For example, the following site automatically calculates average exchange rates for a given period of time (under currency tools)

<http://www.oanda.com/currency/historical-rates>

### **FEE FOR SERVICE**

Fee for service payments are payments to a services provider (for example a general practitioner, or a Medicines Regulatory Authority) for each act or service rendered.

[From: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### **FINISHED PRODUCT**

*A finished product is a product that has undergone all stages of production, including packaging in its final container and labeling.*

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

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## **FORMULARY**

A formulary is a manual containing clinically oriented summaries of pharmacological information about selected drugs. The manual may also include administrative and regulatory information pertaining to the prescribing and dispensing of drugs).

A national formulary generally concentrates on available and affordable medicines that are relevant to the treatment of diseases in a particular country. Formularies are also frequently created for different levels of health care, different sectors and for individual hospitals.

[In: [How to develop a national formulary based on the WHO model formulary, a practical guide](http://apps.who.int/medicinedocs/en/d/Js6171e/2.3.html) Geneva 2004, can be found online at: <http://apps.who.int/medicinedocs/en/d/Js6171e/2.3.html> ]

## **GENERAL HOSPITAL**

General hospitals are secondary care centers. Their main function is to provide a referral service for the primary health care centers and a direct service to the population under their jurisdiction. They usually offer acute medical, surgical, pediatric and obstetric services. They do not have a full range of specialty units such as oncology, cardiac or neurological surgery, although they may have 1-2 units providing sub-specialist tertiary care.

## **GENERIC**

A pharmaceutical product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.

The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form.

Generics can be classified in branded generics (generics with a specific trade name) and unbranded generics (which use the international non-proprietary name and the name of the company). [Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

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[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### **GENERIC SUBSTITUTION**

Generic substitution is the practice of substituting a pharmaceutical, whether marketed under a trade name or generic name (branded or unbranded generic), by a pharmaceutical, often a cheaper one, containing the same active ingredient(s).

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

### **GOOD CLINICAL PRACTICE**

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. [Source: ICH Guideline for Good Clinical Practice]

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### **GOOD DISTRIBUTION PRACTICE (GDP)**

Part of [quality assurance](#) which ensures that the quality of pharmaceuticals is maintained throughout the numerous activities occurring during the distribution process. A well-managed distribution system should achieve the following objectives: maintain a constant supply of drugs, keep pharmaceuticals in good condition through the distribution process, minimize pharmaceutical losses due to spoilage and expiry, maintain accurate inventory records, rationalize drug storage points, use available transportation resources as efficiently as possible, reduce theft and fraud, and provide information for forecasting pharmaceuticals needs.

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

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### **GOOD GOVERNANCE PROGRAM**

The Good Governance for Medicines (GGM) program is a World Health Organization (WHO) program, started in late 2004, in line with the WHO Global Medicines Strategy 2004-2007. Its goal is to reduce corruption in the pharmaceutical sector by the application

of transparent, accountable administrative procedures and by promoting ethical practices. Through this initiative, WHO's objective is to support countries in maintaining efficient health-care systems.

[In: [WHO Good Governance for Medicines Progress Report Geneva 2009](http://apps.who.int/medicinedocs/documents/s16218e/s16218e.pdf) can be found online at: <http://apps.who.int/medicinedocs/documents/s16218e/s16218e.pdf> ]

### **GOOD MANUFACTURING PRACTICE (GMP)**

Part of [quality assurance](#) which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

[In: [WHO A model quality assurance system for procurement agencies Geneva 2007](http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf), can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

### **GOOD PHARMACY PRACTICE**

Good Pharmacy Practice is the practice of pharmacy aimed at providing and promoting the best use of drugs and other health care services and products by patients and members of the public. It requires that the welfare of the patient is the pharmacist/s prime concern at all times.

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

### **GOVERNMENT HEALTH EXPENDITURE**

Government health expenditure is health expenditure incurred by public funds (state, regional and local government bodies and social security schemes).

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Private expenditure is the privately funded part of total health expenditure. Private sources of funds include out-of-pocket payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care.

[In: *PHIS Glossary 2009*, can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### **GROSS DOMESTIC PRODUCT (GDP)**

Gross domestic product (GDP) corresponds to the value of all goods and services provided in a country by residents and non-residents without regard to their allocation among domestic and foreign claims.

[At: [http://www.who.int/whosis/indicators/WHS09\\_IndicatorCompendium\\_20090701.pdf](http://www.who.int/whosis/indicators/WHS09_IndicatorCompendium_20090701.pdf)]

Gross domestic product is an aggregate measure of production equal to the sum of the gross values added of all resident institutional units engaged in production (plus any taxes, and minus any subsidies, on products not included in the value of their outputs). The sum of the final uses of goods and services (all uses except intermediate consumption) measured in purchasers' prices, less the value of imports of goods and services, or the sum of primary incomes distributed by resident producer units.

[At: <http://unstats.un.org/unsd/snaama/glossresults.asp?qID=5>]

### **GROSS NATIONAL INCOME (GNI)**

Gross national income (GNI) is the sum of value added by all resident producers plus any product taxes (less subsidies) not included in the valuation of output plus net receipts of primary income (compensation of employees and property income) from abroad.

[At: [http://www.who.int/whosis/indicators/WHS09\\_IndicatorCompendium\\_20090701.pdf](http://www.who.int/whosis/indicators/WHS09_IndicatorCompendium_20090701.pdf)]

Gross national income (GNI) is [GDP](#) less net taxes on production and imports, less compensation of employees and property income payable to the rest of the world plus the corresponding items receivable from the rest of the world (in other words, GDP less primary incomes payable to non-resident units plus primary incomes receivable from non-resident units). An alternative approach to measuring GNI at market prices is as the aggregate value of the balances

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of gross primary incomes for all sectors; (note that gross national income is identical to gross national product (GNP) as previously used in national accounts)

[At: <http://unstats.un.org/unsd/snaama/glossresults.asp?qID=8>]

## GUIDELINES FOR MEDICINES DONATIONS

In 1999 WHO published guidelines for drug donations based on four core principles. The first and paramount principle is that a drug donation should benefit the recipient to the maximum extent possible. This implies that all donations should be based on an expressed need and that unsolicited drug donations are to be discouraged. The second principle is that a donation should be made with full respect for the wishes and authority of the recipient, and be supportive of existing government health policies and administrative arrangements. The third principle is that there should be no double standards in quality: if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation. The fourth principle is that there should be effective communication between the donor and the recipient: donations should be based on an expressed need and should not be sent unannounced.

WHO advises that recipient countries formulate their own national guidelines for drug donations on the basis of international guidelines. These national guidelines should then be officially presented and explained to the donor community. Only after they have been presented and officially published can they be enforced.

[In: [WHO Drug donations guidelines.pdf](#) , can be found on line at:  
<http://apps.who.int/medicinedocs/pdf/whozip52e/whozip52e.pdf>]

## **HEALTH EXPENDITURE (HE, TOTAL HEALTH EXPENDITURE, THE)**

Health expenditure is defined as the sum of expenditure on activities that – through application of medical, paramedical, and nursing knowledge and technology – has the goals of:

- Promoting health and preventing disease;
- Curing illness and reducing premature mortality;
- Caring for persons affected by chronic illness who require nursing care;
- Caring for persons with health-related impairments, disability, and handicaps who require nursing care;
- Assisting patients to die with dignity;
- Providing and administering public health;
- Providing and administering health programs, health insurance and other funding arrangements.

Health expenditure includes expenditure on:

**Personal health** (curative care, rehabilitative care, long-term nursing care, ancillary services to health care, medical goods dispensed to out-patients) and expenditure on

**Collective health** (prevention and public health, administration and insurance).

Health expenditure can be separated in:

Public (government) expenditure: health expenditure incurred by public funds (state, regional and local government bodies and social security schemes).

Private expenditure: privately funded part of total health expenditure. Private sources of funds include out-of-pocket payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care.

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeq.at/index.aspx?alias=phisglossary>]

## **HEALTH INSURANCE**

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The term health insurance refers to all types of health insurance programs, including private, public, for profit and not-for-profit programs and organizations, particularly those which include the poor. Health insurance programs pool financial risks across populations and pay part of or all health care expenses for their defined population of members (and possibly dependents) from premiums contributed by individuals, employers, nongovernmental organizations and/or government.

*[In: Prescribing Cultures and Pharmaceutical Policy in the Asia-Pacific 2009 edited by Karen Eggleston, Walter H Shorestein Asia-Pacific Research Center Books.*

*Chapter 18: Insurance Systems in the Asia-Pacific Region: Improving Appropriate Use of and Access to Medicines by Anita Wagner and Dennis Ross-Degnan]*

## HOSPITAL

Licensed establishment primarily engaged in providing medical, diagnostic, and treatment services that include physician, nursing, and other health services to in-patients and the specialized accommodation services required by in-patients. Hospital provides in-patient health services, many of which can only be provided using the specialized facilities and equipment that form a significant and integral part of the production process. In some countries, health facilities need in addition a minimum size (such as number of beds) in order to be registered as a hospital.

Hospital may also provide out-patient services as a secondary activity.

Hospitals can be classified in general hospitals, mental health and substance abuse hospitals and specialty (other than mental health and substance abuse) hospitals.

A **general hospital** is a licensed establishments primarily engaged in providing diagnostic and medical treatment (both surgical and non-surgical) to in-patients with a wide variety of medical conditions. These establishments may provide other services, such as out-patient services, anatomical pathology services, diagnostic X-ray services, clinical laboratory services, operating room services for a variety of procedures, and pharmacy services.

A **mental health and substance abuse hospital** is a licensed establishment primarily engaged in providing diagnostic and medical treatment, and monitoring services to in-patients who suffer from mental illness or substance abuse disorders. The treatment often requires an extended stay in an in-patient setting including hostelling and nutritional facilities. Psychiatric, psychological, and social work services are available at the facility. These hospitals usually provide other services, such as out-patient care, clinical laboratory tests, diagnostic X-rays, and electroencephalography services.

A **specialty hospital** is a licensed establishment primarily engaged in providing diagnostic and medical treatment to in-patients with a specific type of disease or medical condition (other than mental health or substance abuse). Hospitals providing long-term care for the chronically ill and hospitals providing rehabilitation, and related services to physically challenged or disabled people are included in this item. These hospitals may provide other services, such as Pharmaceutical Sector Country Profile Questionnaire.

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out-patient services, diagnostic X-ray services, clinical laboratory services, operating room services, physical therapy services, educational and vocational services, and psychological and social work services.

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### **IMPORTER**

An importer is an individual or company or similar legal entity importing or seeking to import a pharmaceutical product. A “licensed” or “registered” importer is one who has been granted a license or registration status for the purpose. In addition to a general license or permit as an importer, some countries require an additional license to be issued by the national drug regulatory authority if pharmaceutical products are to be imported.

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

## INDICATOR

A parameter that aims to describe, in a few numbers as much detail as possible about a system, to help understand, compare, predict, improve, and innovate. Indicators serve two major functions: They reduce the number of measurements and parameters that normally would be required to give an accurate picture of a situation, and they facilitate the communication process for providing the reader with the results of measurement.

Structural, process and outcome indicators can be distinguished. Indicator data can either be quantitative or qualitative.

**Structural indicators:** These indicators provide qualitative information to assess the pharmaceutical system's capacity to achieve its policy objectives. They are intended to check whether the key structures/systems/mechanisms necessary to implement a pharmaceutical policy exist in the country (e.g. POM dispensaries)

**Process indicators:** Process indicators assess the degree to which activities necessary to attain the objectives are carried out and their progress over time (e.g. pricing policies).

**Outcome indicators:** These indicators measure the results achieved and the changes that can be attributed to the implementation of a policy (e.g. life expectancy).

[In: *PHIS Glossary 2009*, can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

## INFANT MORTALITY RATE

Infant mortality rate is the total number of infants dying before reaching the age of one year per 1,000 live births in a given year. It is an approximation of the number of deaths per 1,000 children born alive who die within one year of birth.

[At: <http://unstats.un.org/unsd/demographic/products/socind/health.htm#tech>]

## INJECTABLE MEDICINES

Sterile medicines intended for administration by bolus injection, perfusion or infusion by any of the following routes: intravenous, intramuscular, intra-thecal, intra-arterial, subcutaneous, intra-dermal, intra-ventricular, epidural, intra-vesicular, intra-vitreous, intra-pleural and intraocular.

An injectable medicine is **Ready-to-administer** when it requires no further dilution or reconstitution and is presented in the final container or device, ready for administration or connection to a needle or administration set. For example, an infusion in a bag with no additive required.

An injectable medicine is **Ready-to-use** when it requires no further dilution or reconstitution before transfer to an administration device. For example, a liquid with an ampoule, of the required concentration, that only needs to be drawn up into a syringe.

*[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]*

## IN-PATIENT CARE

An in-patient is a patient who is formally admitted (or “hospitalized”) to an institution for treatment and/or care and stays for a minimum of one night in the hospital or other institution providing in-patient care.

In-patient care is mainly delivered in hospitals, but partially also in nursing and residential care facilities or in establishments that are classified according to their focus of care under the ambulatory-care industry, but perform in-patient care as a secondary activity.

It should be noted that the term “in-patient” used in the OECD-SHA has a wider meaning compared to some national reporting systems where this term is limited to in-patient care in hospitals. Included are services delivered to in-patients in prison and army hospitals, tuberculosis hospitals, and sanatoriums.

In-patient care includes accommodation provided in combination with medical treatment when the latter is the predominant activity provided during the stay as an in-patient.

On the other hand, accommodation in institutions providing social services, where health care is an important but not predominant component should not be included in the health function. Examples might include institutions such as homes for disabled persons, nursing homes, and residential care for substance abuse patients.

[Source: OECD. A System of Health Accounts]

*[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]*

## **INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE (ICH)**

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines.

The objective of such harmonization is a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health.

[At: <http://www.ich.org/cache/compo/276-254-1.html>]

## **INTERNATIONAL NON-PROPRIETARY NAME (INN)**

INN is a unique name that is globally recognized and is public property. Since its inception, the aim of the INN system has been to provide health professionals with a unique and universally available designated name to identify each pharmaceutical substance. The existence of an international nomenclature for pharmaceutical substances, in the form of INN, is important for the clear identification, safe prescription and dispensing of medicines to patients, and for communication and exchange of information among health professionals and scientists worldwide.

As unique names, INNs have to be distinctive in sound and spelling, and should not be liable to confusion with other names in common use. To make INN universally available they are formally placed by WHO in the public domain, hence their designation as "non-proprietary". They can be used without any restriction whatsoever to identify pharmaceutical substances.

Another important feature of the INN system is that the names of pharmacologically-related substances demonstrate their relationship by using a common "stem". By the use of common stems the medical practitioner, the pharmacist, or anyone dealing with pharmaceutical products can recognize that the substance belongs to a group of substances having similar pharmacological activity.

Non-proprietary names are intended for use in pharmacopoeias, labeling, product information, advertising and other promotional material, medicine regulation and scientific literature, and as a basis for product names, e.g. for generics. Their use is normally required by national or, as in the case of the European Community, by international legislation.

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As a result of ongoing collaboration, national names such as British Approved Names (BAN), Dénominations Communes Françaises (DCF), Japanese Adopted Names (JAN) and United States Adopted Names (USAN) are nowadays, with rare exceptions, identical to the INN.

To avoid confusion, which could jeopardize the safety of patients, trade-marks cannot be derived from INN and, in particular, must not include their common stems.

[WHO Guidance on INN at: <http://www.who.int/medicines/services/inn/innguidance/en/index.html>]

## **INTERNATIONAL ORGANIZATION OF STANDARDISATION (ISO)**

ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards. ISO is a network of the national standards institutes of 159 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. ISO is a non-governmental organization that forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations. Therefore, ISO enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society.

Because "International Organization for Standardization" would have different acronyms in different languages ("IOS" in English, "OIN" in French for Organisation Internationale de normalisation), its founders decided to give it also a short, all-purpose name. They chose "ISO", derived from the Greek isos, meaning "equal". Whatever the country, whatever the language, the short form of the organization's name is always ISO.

[At: <http://www.iso.org/iso/about.htm>]

## **INTERNATIONAL REFERENCE PRICES**

In the WHO/HAI survey measuring prices, availability, affordability and price components of medicines, medicine prices are expressed as ratios relative to a standard set of reference prices to facilitate national and international comparisons. Median prices listed in MSH's International Drug Price Indicator Guide have been selected as the most useful standard since they are updated frequently, are always available and are relatively stable. These prices are recent procurement prices offered by both not-for-profit and for-profit suppliers to developing countries for multi-source products.

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How representative reference prices are generally depends on the number of suppliers quoting for each product. For example, if a medicine has a single, high supplier price, a low median price ratio (MPR) will be obtained, which can be misinterpreted as low national prices.

[From: [WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations: Guide for coordinators and data collectors](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf>]

### **LAW (LEGAL PROVISIONS)**

Laws define the roles, rights and obligations of all parties involved in the subject matter in general terms (see also [regulations](#) below).

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

### **LEGISLATION**

Legislation corresponds to the first stage of the legislative process, in which laws are passed by the legislative body of government with regard to a subject matter such as the control of pharmaceuticals. Laws define the roles, rights and obligations of all parties involved in the subject matter in general terms (see also [regulations](#) below).

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

### **LICENSE HOLDER**

A license holder is an individual or a corporate entity possessing a marketing authorization for a pharmaceutical product.

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

### **LICENSEE**

A licensee is an individual or corporate entity responsible for the information and publicity on, and the pharmacovigilance and surveillance of batches of, a pharmaceutical product and, if applicable for their withdrawal, whether or not that individual or corporate entity is the holder of the marketing authorization.

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

### **LICENSING SYSTEM**

National legal provisions on who should manufacture, import or supply pharmaceuticals products, what qualifications people in the supplying agency should have, and who should dispense and sell pharmaceutical products.

[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

### **LIFE EXPECTANCY AT BIRTH**

Life expectancy at birth is an estimate of the number of years to be lived by a female or male newborn, based on current age-specific mortality rates. Life expectancy at birth by sex gives a statistical summary of current differences in male and female mortality across all ages. In areas with high infant and child mortality rates, the indicator is strongly influenced by trends and differentials in infant and child mortality.

[At: <http://unstats.un.org/unsd/demographic/products/socind/health.htm#tech>]

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### **MANUFACTURE (MANUFACTURING)**

Manufacturing includes all operations of receipt of materials, production, packaging, repackaging, labeling, relabeling, quality control, release, storage and distribution of active pharmaceutical ingredients and related controls.

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### **MANUFACTURER**

A manufacturer is a natural or legal person with responsibility for manufacturing of a product.

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

A local manufacturer is a business entity whose legal ownership is based in the country.

### **MANUFACTURER'S SELLING PRICE (MSP, EX-FACTORY PRICE)**

Manufacturer's selling price is the price the manufacturer charges for a medicine.

[In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2<sup>nd</sup> Edition\)](#) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

Ex-factory price is the manufacturer's posted price, in some countries also referred to as list price. Discounts or other incentives offered by manufacturers result in an effective price that is lower than the ex-factory price.

[In: [OECD – Pharmaceutical Pricing Policies in a Global Market](#), at: [http://www.oecd.org/document/36/0,3343,en\\_2649\\_33929\\_4100996\\_1\\_1\\_1\\_37407,00.html](http://www.oecd.org/document/36/0,3343,en_2649_33929_4100996_1_1_1_37407,00.html)]

### **MARKETING AUTHORISATION (REGISTRATION)**

A legal document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using [INNs](#) or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. "The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence"). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization.

Once a product has been given marketing authorization, it is included on a list of authorized products – the register – and is often said to be "registered" or to "have registration". Market authorization may occasionally also be referred to as a "license" or "product license".

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

### **MATERNAL MORTALITY RATIO**

The maternal mortality ratio is the number of maternal deaths per 100,000 live births during a specified time period, usually 1 year.

Maternal death is the death of a woman while pregnant or within 42 days after termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

Complications during pregnancy and childbirth are a leading cause of death and disability among women of reproductive age in developing countries. The maternal mortality ratio represents the risk associated with each pregnancy, i.e. the obstetric risk. It is also a Millennium Development Goal Indicator for monitoring Goal 5, improving maternal health.

[Can be found online at: <http://www.who.int/whosis/indicators/compendium/2008/3mrf/en/>]

### **MARK-UP (DISTRIBUTION MARK-UP)**

The mark-up is the percentage of the purchasing price added on to get the selling price.

A mark-up is added on to the total cost incurred by the producer of a good in order to create a profit.

The wholesale mark-up is the gross profit of wholesalers, expressed as a percentage add-on to the ex-factory price.

The pharmacy mark-up is the gross profit of pharmacies expressed as a percentage add-on to the wholesale price (or pharmacy purchasing price).

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### **MEDIAN PRICE RATIO (MPR)**

In the WHO/HAI survey measuring medicine prices, availability, affordability and price components, medicine prices found are not expressed as currency units, but rather as ratios relative to a standard set of international reference prices:

$$\text{Medicine Price Ratio (MPR)} = \frac{\text{Median local unit price}}{\text{International reference unit price}}$$

The ratio is thus an expression of how much greater or less the local medicine price is than the international reference price, e.g. an MPR of 2 would mean that the local medicine price is twice that of the international reference price.

Median price ratios facilitate cross-country comparisons of medicine price data.

Since averages can be skewed by outlying values, median values are a better representation of the midpoint value. The magnitude of price variations is presented as the interquartile range. A quartile is a percentile rank that divides a distribution into four equal parts. The range of values containing the central half of the observations, that is, the range between the 25<sup>th</sup> and 75th percentiles, is the interquartile range.

[In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2<sup>nd</sup> Edition\)](#) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

## **MEDICATION ERROR**

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

[At: <http://www.nccmerp.org/aboutMedErrors.html>]

## **MEDICINE**

See [pharmaceutical](#)

## **MEDICINES COVERAGE (MEDICINES BENEFIT)**

Medicines coverage refers to the medicines benefits offered by a health insurance to its members. Medicines coverage may be complete if all medicines costs are paid or reimbursed by the health insurance. It may be partial if the insurance pays or reimburses part of the costs of medicines or if it excludes certain medicines from the benefits it offers to its members.

## **MEDICINES REGULATORY AUTHORITY**

A national body that *has the legal mandate to set objectives and* administer the full spectrum of medicines regulatory activities, including at least all of the following functions in conformity with national drug legislation:

- Marketing authorization of new products and variation of existing products;
- Quality control laboratory testing;
- Adverse drug reaction monitoring;
- Provision of medicine information and promotion of rational medicines use;

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- Good Manufacturing Practice (GMP) inspections and licensing of manufacturers, wholesalers and distribution channels;
- Enforcement operations;
- Monitoring of medicines utilization.

*[Adapted from: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medreqpack/interface/files/glossary.pdf>]*

### **MORTALITY RATE**

Mortality rate is an estimate of the proportion of a population that dies during a specified period. The numerator is the number of persons dying during the period; the denominator is the number in the population exposed to the risk of dying, usually estimated as the midyear population.

*[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]*

### **NARCOTIC DRUG**

is a legal term encompassing substances covered by the Single Convention on Narcotic Drugs, 1961, and the 1972 Protocol Amending that Convention, including opiates, opioids, as well as cocaine and marihuana.

*[At: [http://www.incb.org/incb/en/convention\\_1961.html](http://www.incb.org/incb/en/convention_1961.html)]*

### **NATIONAL ESSENTIAL MEDICINES LIST**

The list of [essential medicines](#) that has been defined, adopted, and published at country level. This list is normally used by all health facilities, including main hospitals.

To generate its own list of essential pharmaceuticals, each country may adapt the [WHO Model List of Essential Medicines](#) (EML) updated by the WHO's Expert Committee on the Selection and Use of Essential Medicines at two-year intervals.

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

### **NATIONAL HEALTH SERVICES SYSTEMS (NATIONAL HEALTH INSURANCE)**

National health services systems are characterized by three main features: their funding comes primarily from *government* general revenues, they provide medical coverage to the whole population, and they usually deliver health care through a network of public providers.

[In: World Bank [A practitioner's guide: Health Financing Revisited](#) (2006) and at: <http://siteresources.worldbank.org/INTHSD/Resources/topics/Health-Financing/HFRFull.pdf>]

### **NATIONAL HEALTH POLICY (NHP)**

A national health policy document is a written expression of the government's medium- to long-term goals and priorities for the health sector and the main strategies for attaining them.

[From WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations at: [http://www.who.int/medicines/publications/WHO\\_TCM\\_2007.2/en/](http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/)]

### **NATIONAL MEDICINES POLICY (NMP)**

A national drug policy is a commitment to a goal and a guide for action. It expresses and prioritizes the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors, and involves all the main actors in the pharmaceutical field. A national drug Pharmaceutical Sector Country Profile Questionnaire.

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policy, presented and printed as an official government statement, is important because it acts as a formal record of aspirations, aims, decisions and commitments. Without such a formal policy document there may be no general overview of what is needed; as a result, some government measures may conflict with others, because the various goals and responsibilities are not clearly defined and understood.

The policy document should be developed through a systematic process of consultation with all interested parties. In this process the objectives must be defined, priorities must be set, strategies must be developed and commitment built.

[In [How to develop and implement a national drug policy](http://apps.who.int/medicinedocs/en/d/Js2283e/#Js2283e) and at:  
<http://apps.who.int/medicinedocs/en/d/Js2283e/#Js2283e>]

### **NATIONAL MEDICINES POLICY IMPLEMENTATION PLAN**

A national medicines policy implementation plan is a written expression of the government plans to put into action the national medicines policy, setting activities, responsibilities, budget and timelines.

[From *WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations* at:  
[http://www.who.int/medicines/publications/WHO\\_TCM\\_2007.2/en/](http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/)]

### **NATIONAL [PHARMACOVIGILANCE](#) CENTER**

Organizations recognized by the governments to represent their country in the WHO program (usually the medicines regulatory agency). A single governmentally recognized centre (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyze and give advice on all information related to drug safety.

[At: <http://www.who-umc.org/DynPage.aspx?id=13111&mn=1513>]

### **NEW CHEMICAL ENTITY (NCE)**

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A new chemical entity (NCE) is a pharmaceutical that contains no active moiety, i.e. without any molecule or ion, but including those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the pharmaceutical substance. It is a chemical molecule developed by the innovator company in the early discovery stage, which after undergoing clinical trials could translate into a pharmaceutical that could be a cure for some disease.

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### **NON-GOVERNMENTAL ORGANIZATION (NGO, [CIVIL SOCIETY ORGANIZATION](#))**

A non-governmental organization (NGO) is a not-for-profit, voluntary citizens' group, which is organized on a local, national or international level to address issues in support of the public good. Task-oriented and made up of people with common interests, NGOs perform a variety of services and humanitarian functions, bring citizens' concerns to governments, monitor policy and program implementation, and encourage participation of civil society stakeholders at the community level. They provide analysis and expertise, serve as early warning mechanisms, and help monitor and implement international agreements. Some are organized around specific issues, such as human rights, the environment or health. Their relationship with offices and agencies of the United Nations (UN) system differs depending on their location and their mandate.

[United Nations definition at: <http://www.un.org/dpi/ngosection/criteria.asp>]

### **NURSE**

A nurse is a person who has completed a program of basic nursing education and is qualified and authorized in his/her country to practice nursing in all settings. Nursing professionals assist medical doctors in their tasks, deal with emergencies in their absence, and provide professional nursing care for the sick, injured, physically and mentally disabled, and others in need of such care, or they deliver or assist in the delivery of babies, provide antenatal and post-natal care and instruct parents in baby care.

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

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## **NURSING AND MIDWIFERY PROFESSIONALS**

Nursing and midwifery professionals are those who plan, provide and evaluate treatment, support and care services for people who are in need of such care due to effects of ageing, injury, illness or other physical or mental impairment, or potential risks to health including before, during and after childbirth. Occupations included in this category typically require knowledge and skills obtained as the result of study in nursing or midwifery at a higher educational institution. Examples of national occupations classified here are: nurse practitioner, clinical nurse, public health nurse, nurse anesthetist, professional nurse, and professional midwife.

*WHO reference?*

## **OMBUDSPERSON**

An ombudsman is a government appointee who investigates complaints by private persons against the government

[At: <http://wordnet.princeton.edu/>]

## **ORIGINATOR PHARMACEUTICAL PRODUCT/ORIGINATOR BRAND**

An originator brand is generally the product that was first authorized world wide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization: e.g. Valium. The originator product always has a brand name; this name may, however, vary across countries.

Some substances (e.g. prednisolone, izoniazid) are so old that no originator can be identified and the patent was probably never claimed.

[In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2<sup>nd</sup> Edition\)](http://www.haiweb.org/medicineprices/manual/documents.html) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

## **OUT-OF-POCKET PAYMENTS (OPP)**

Payments made by a health care consumer that are not reimbursed by a [third party payer](#).

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They include cost-sharing and informal payments to health care providers.

**Cost-sharing:** a provision of health insurance or third party payment that requires the individual who is covered to pay part of the cost of health care received. This is distinct from the payment of a health insurance premium, contribution or tax which is paid whether health care is received or not.

Cost-sharing can be in the form of deductibles, co-insurance or co-payments:

**Deductibles:** Amounts required to be paid by the insured under a health insurance contract, before any payment of benefits can take place. Deductibles are usually expressed in terms of an "annual" amount.

Once the deductible is reached, the insurers then pays up to 100% of approved amounts for covered services provided during the remainder of that benefit year.

**Co-payment:** cost-sharing in the form of a fixed amount to be paid for a service.

**Co-insurance:** cost-sharing in the form of a set proportion of the cost of a service.

[In: OECD. A System of Health Accounts at

[http://www.oecd.org/document/8/0,3343,en\\_2649\\_34631\\_2742536\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/8/0,3343,en_2649_34631_2742536_1_1_1_1,00.html)]

## OUT-PATIENT CARE

Out-patient care comprises medical and paramedical services delivered to out-patients. An out-patient is not formally admitted to the facility (e.g. physician's private office) and does not stay overnight. An out-patient is thus a person who goes to a health care facility for a consultation/treatment, and who leaves the facility within several hours of the start of the consultation without being "admitted" to the facility as a patient.

It should be noted that the term "out-patient" used in the OECD-System of Health Accounts has a wider meaning compared to some national reporting systems where this term is limited to care in out-patient wards of hospitals. In the SHA, all visitors to ambulatory care facilities that are not day cases or over-the-night cases are considered out-patients. [Source: OECD. A System of Health Accounts]

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

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### **OVER-THE-COUNTER MEDICINE (NON-PRESCRIPTION MEDICINE)**

Over-the-counter medicines are medicines that can be sold from licensed dealers without professional supervision and without prescription. These medicines are suitable for self-medication for minor disease and symptoms.

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

### **PARALLEL IMPORT**

Parallel or grey-market imports are not imports of counterfeit products or illegal copies. These are products marketed by the patent owner (or trademark- or copyright-owner, etc) or with the patent owner's permission in one country and imported into another country without the approval of the patent owner.

[In *National policy on traditional medicine and regulation of herbal medicines: report of a WHO global survey* and At: <http://apps.who.int/medicinedocs/en/d/Js7916e/3.html>]

### **PATENT**

Patents provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions.

A patent is not a permit to put a product on the market. A patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether the product is safe for consumers and whether it can be supplied. Patented pharmaceuticals still have to go through rigorous testing and approval before they can be put on the market.

[In: *WTO OMC Fact sheet: TRIPS and pharmaceutical patents*, can be found on line at: [http://www.wto.org/english/tratop\\_e/trips\\_e/tripsfactsheet\\_pharma\\_2006\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf)]

### **PHARMACEUTICAL (MEDICINE, DRUG)**

A pharmaceutical is any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. In this document, the terms drug, medicine, and pharmaceutical are used interchangeably.

[In: [WHO A model quality assurance system for procurement agencies](http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

### **PHARMACEUTICAL FORM**

The pharmaceutical form is the pharmaceutical-technological form in which an active substance is made available. Pharmaceutical may be administered in solid form (e.g. tablets, powers), in semi-liquid form (e.g. ointments, pastes), in liquid form (e.g. drops, injectables, infusions) or in gaseous form (inhalation).

[In: [OECD – Pharmaceutical Pricing Policies in a Global Market](http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html), at: [http://www.oecd.org/document/36/0,3343,en\\_2649\\_33929\\_41000996\\_1\\_1\\_1\\_37407,00.html](http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html)]

### **PHARMACEUTICAL PRODUCT**

A pharmaceutical product is a unique product defined by its active pharmaceutical ingredient, the strength of the active pharmaceutical ingredient, its pharmaceutical form and route of administration.

[In: [ICH Consensus Guideline Released for Consultation on 10 May 2005](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073307.pdf), at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073307.pdf>]

## PHARMACEUTICAL TECHNICIANS AND ASSISTANTS

Pharmaceutical technicians and assistants perform a variety of tasks associated with dispensing medicinal products under the guidance of a pharmacist or other health professional. Occupations included in this category typically require knowledge and skills obtained as the result of study in pharmacy services at a higher educational institution. Examples of national occupation titles classified here are: pharmaceutical technician, pharmaceutical assistant, dispensing technician.

*WHO reference?*

## PHARMACIST

Pharmacists are persons who have completed studies in pharmacy at university level (granted by adequate diploma) and who are licensed to practice pharmacy. They may be either salaried or self-employed pharmacists delivering services irrespectively of the place of service provision.

Services provided by pharmacists include: preparing and directing the preparation of medicines according to prescriptions of medical and dental practitioners, or establish formulae; checking prescriptions to ensure that recommended dosages are not exceeded, and that instructions are understood by patients – or persons administering the medicines – and advising on possible medicine incompatibility; dispensing medicines in hospitals or selling them in pharmacies.

[Source: adapted from EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

[In: *PHIS Glossary 2009*, can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

Pharmacists are those who store, preserve, compound, test, dispense and monitor medicinal products and therapies for optimizing human health. Occupations included in this category normally require completion of university-level training in theoretical and practical pharmacy, pharmaceutical chemistry or a related field. Examples of national occupation titles classified here are: hospital pharmacist, industrial pharmacist, retail pharmacist, dispensing chemist.

*WHO reference?*

**PHARMACY**

Pharmacies are premises which in accordance to the local legal provisions and definitions may operate as a facility in the provision of pharmacy services in the community or health facility setting.

*[In WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations at:  
[http://www.who.int/medicines/publications/WHO\\_TCM\\_2007.2/en/](http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/)]*

## PHARMACOVIGILANCE

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.

[In: [WHO The importance of pharmacovigilance](http://apps.who.int/medicinedocs/en/d/Js4893e/#Js4893e), can be found on line at: <http://apps.who.int/medicinedocs/en/d/Js4893e/#Js4893e>]

Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce risks and increase benefits from medicines. It is a key public health function.

Pharmacovigilance comprises:

- Collecting and managing data on the safety of medicines
- Looking at the data to detect signals (any new or changing safety issue)
- Evaluating the data and making decisions with regard to safety issues
- Acting to protect public health (including regulatory action)
- Communicating with stakeholders
- Auditing the outcomes of action taken and the key processes involved.

Those directly involved in pharmacovigilance include:

- Patients as the users of medicines
- Doctors, pharmacists, nurses and all other health care professionals working with medicines
- Regulatory authorities including the EMEA and those in the Member States responsible for monitoring the safety of medicines
- Pharmaceutical companies, and companies importing or distributing medicines

[Source: European Commission /Pharmaceutical / Pharmacovigilance available at: [http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance/pharmacovigilance\\_en.htm](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance/pharmacovigilance_en.htm)]

[In: [PHIS Glossary 2009](http://phis.goeq.at/index.aspx?alias=phisglossary), can be found on line at: <http://phis.goeq.at/index.aspx?alias=phisglossary>]

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### **PHYSICIAN (MEDICAL DOCTOR)**

A physician is a person who has completed studies in medicine at the university level (granted by adequate diploma) and who is licensed to practice.

To be legally licensed for the independent practice of medicine, (s)he must, in most cases, undergo additional postgraduate training in a hospital.

They may be either salaried or self-employed physicians delivering services irrespectively of the place of service provision.

Services provided by physicians include: conducting medical examination and making diagnosis, prescribing medication and giving treatment for diagnosed illnesses, disorders or injuries, giving specialized medical or surgical treatment for particular types of illnesses, disorders or injuries, giving advice on and applying preventive medicine methods and treatments.

[Source: EUROSTAT. Definitions and data collection specifications on health care statistics (non-expenditure data)]

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

Physicians (Medical Doctors) are those who study, diagnose, treat and prevent illness, disease, injury, and other physical and mental impairments in humans through application of the principles and procedures of modern medicine. Occupations included in this category require completion of a university-level degree in basic medical education plus postgraduate clinical training or equivalent.

*WHO reference?*

### **POST-MARKETING SURVEILLANCE**

Post-marketing surveillance is testing medicine samples to assess the quality of medicines that have already been licensed for public use.

[In WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations at: [http://www.who.int/medicines/publications/WHO\\_TCM\\_2007.2/en/](http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/)]

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### **POST-MARKETING SURVEILLANCE STUDY**

A post-marketing surveillance study is usually synonym of Phase IV study. (See [clinical trial](#)) In this phase studies are performed after the pharmaceutical product has been marketed. They are based on the product characteristics on which the marketing authorization was granted and normally take the form of post-marketing surveillance, and assessment of therapeutic value or treatment strategies. Although methods may differ, the same scientific and ethical standards should apply to Phase IV studies as are applied in premarketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc., are normally regarded as trials of new pharmaceutical products.

*[Adapted from: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]*

### **PREQUALIFICATION**

The activities undertaken in defining a product or service need, seeking expressions of interest from enterprises **to supply the product or service**, and examining the product or service offered against the specification and the facility where the product or service is prepared against common standards of [good manufacturing practice](#) (GMP). The examination of the product or service and of the facility where it is manufactured is performed by trained and qualified inspectors against common standards. Once the product is approved, and the facility is approved for the delivery of the specified product or service, other procurement agencies are informed of the decision. Prequalification is required for all pharmaceutical products regardless of their composition and place of manufacture/registration, but the amount and type of information requested from the supplier for assessment by the procurement agency may differ.

*[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]*

### **PRESCRIBER**

A prescriber is a health care professional who is legally qualified to write a [prescription](#).

## **PRESCRIPTION**

Is an order mostly in written form (~ receipt) by a qualified health care professional to a pharmacist or other therapist for a medicine or treatment to be provided to their patients. One prescription may contain several items. The maximum number of items on a receipt is in many countries regulated.

[In: *PHIS Glossary 2009*, can be found on line at: <http://phis.goeq.at/index.aspx?alias=phisglossary>]

## **PRESCRIPTION-ONLY MEDICINES**

Prescription-only medicines are medicines supplied only in licensed pharmacies on the presentation of signed prescriptions issued by a licensed and registered medical practitioner, licensed and/or registered dentist (for dental treatment only), and/or licensed and/or registered veterinarian (for animal treatment only), and the supply and dispensing of these medicines must be carried out by a pharmacist or under the supervision of a pharmacist. Prescription-only medicines are further subdivided into controlled medicines (narcotic medicines and psychotropic substances) and non-controlled medicines.

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at: <http://infocollections.org/medreqpack/interface/files/glossary.pdf>]

## **PRIMARY HEALTH CARE UNIT**

Primary health care units are units where primary health care is provided.

Primary health care is basic or general health care focused on the point at which a patient ideally first seeks assistance from the medical care system. Primary care is considered comprehensive when the primary provider takes responsibility for the overall coordination of the care of the patient's health problems, be they biological, behavioral, or social.

Such care is generally provided by physicians (general practitioners, family practitioners, internists, obstetricians and pediatricians) but in some countries is increasingly provided by other personnel such as nurse practitioners or physician assistants.

[In: *PHIS Glossary 2009*, can be found on line at: <http://phis.goeq.at/index.aspx?alias=phisglossary>]

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### **PRIVATE HEALTH EXPENDITURE**

Private expenditure: privately funded part of total health expenditure. Private sources of funds include out-of-pocket payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care.

By opposition, government (public) health expenditure is health expenditure incurred by public funds (state, regional and local government bodies and social security schemes).

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

### **PRIVATE SECTOR**

The private sector in a mixed economy is the part of the economy not under government control and that functions within the market; private enterprise.

[In: *Governance for sustainable human development, A UNDP policy document-Glossary of key terms. Can be found online at: <http://mirror.undp.org/magnet/policy/glossary.htm>*]

### **PROCUREMENT**

Procurement is the process of acquiring supplies, including those obtained by purchase, donation, and manufacture.

[In: *Managing Drug Supply Second Edition, Chapter 13, page 182 Management Sciences for Health, 1997*]

The process of purchasing or otherwise acquiring any pharmaceutical product, vaccine, or nutraceuticals for human use.

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

“There are many steps in the procurement process. No matter what model is used to manage the procurement and distribution system, efficient procedures should be in place to:

- Select the most cost-effective essential drugs to treat commonly encountered diseases;
- Quantify the needs;

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- Pre-select potential suppliers;
- Manage procurement and delivery;
- Ensure good product quality;
- Monitor the performance of suppliers and the procurement system.

Failure in any of these areas leads to lack of access to appropriate drugs and to waste.”

[In: [WHO A model quality assurance system for procurement agencies](http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

## PROCUREMENT AGENCY

A procurement agency is any organization purchasing or otherwise acquiring any pharmaceutical product, vaccine, or nutraceutical for human use.

[In: [WHO A model quality assurance system for procurement agencies](http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

## PROMOTION

Promotion refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.

[In: [C:\Documents and Settings\CVialle\Desktop\Country profile - Instructions and glossary 14 Sept 2010\WHO. A model quality assurance system for procurement agencies.pdf](http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf) [Criteria for Medicinal Drug Promotion](http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf) can be found online at: <http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf> ]

## PUBLIC SECTOR (CIVIL SERVICE)

Public sector is the part of the economy that is not privately owned, either because it is owned by the state or because it is subject to common ownership. This includes the national government, local authorities, national industries and public corporations.

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[In: *Governance for sustainable human development, A UNDP policy document-Glossary of key terms. Can be found online at: <http://mirror.undp.org/magnet/policy/glossary.htm>*]

### **PURCHASING POWER PARITY (PPP)**

Purchasing power parities are spatial deflators and currency converters, which eliminate the effects of the differences in price levels between countries, thus allowing volume comparisons of Gross Domestic Product (GDP) components and comparisons of price levels. PPPs are calculated in three stages: first for individual products, then for groups of products or basic headings and, finally, for groups of basic headings or aggregates. The PPPs for basic headings are unweighted averages of the PPPs for individual products. The PPPs for aggregates are weighted averages of the PPPs for basic headings. The weights used are the expenditures on the basic headings. PPPs at all stages are price relatives. They show how many units of currency A need to be spent in country A to obtain the same volume of a product or a basic heading or an aggregate that X units of currency B purchases in country B. In the case of a single product, the “same volume” means “identical volume”. But in the case of the complex assortment of goods and services that make up an aggregate such as GDP, the “same volume” does not mean an “identical basket of goods and services”. The composition of the basket will vary between countries according to their economic, social and cultural differences, but each basket will provide equivalent satisfaction or utility. PPPs are also referred to as “parity” or “parities”.

[In: *PHIS Glossary 2009*, can be found on line at: <http://phis.goeq.at/index.aspx?alias=phisglossary>]

### **QUALITY ASSURANCE**

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a pharmaceuticals. It is the totality of the arrangements made with the object of ensuring that pharmaceuticals are of the quality required for their intended use.

[In: *WHO A model quality assurance system for procurement agencies Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>*]

### **QUALITY CONTROL**

Quality control is the part of [Good Manufacturing Practices \(GMP\)](#) concerned with sampling, specifications, and testing and with the organization, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, or products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory operations but must be involved in all decisions concerning the quality of the product.

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[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

### **RATIONAL USE OF MEDICINES**

Rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

[In: [Promoting rational use of medicines: Core components](#) Geneva 2002, can be found online at: <http://apps.who.int/medicinedocs/pdf/h3011e/h3011e.pdf>]

### **REFERRAL HOSPITAL**

Referral hospitals are tertiary care centers. Their main function is to provide a referral service for secondary care centers (general hospitals) in all main subspecialties. In some cases, they may also provide secondary or even primary care. There are two categories of referral hospitals:

- Major hospitals offering a full range of services including specialty units
- Specialty hospitals dedicated to specific types of patients, e.g. children, or specific range of conditions, e.g. oncology.

### **REGULATIONS**

The second stage of the legislative process (the first stage being legislation, see above). Regulations are specifically designed to provide the legal machinery to achieve the administrative and technical goals of legislation.

[In: [WHO A model quality assurance system for procurement agencies](#) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

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## **REGULATORY INSPECTION**

A regulatory inspection is an officially conducted examination (i.e. review of quality assurance processes, personnel involved, any delegation of authority and audit) by relevant authorities at sites where pharmaceutical activities take place (i.e. manufacturing, wholesale, testing, distribution, clinical trials) to verify adherence to Good Practices

*[Adapted from: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medreqpack/interface/files/glossary.pdf>]*

## **REIMBURSEMENT LIST**

Reimbursement is the percentage of the reimbursement price (for a service or a medicine) which a third party payer pays. So 100% reimbursement means that the third party payer covers 100% of the reimbursement price / amount of a medicine or service except a possible prescription fee.

A reimbursement list is the list of medicines which a third party payer pays in part or completely.

*[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeq.at/index.aspx?alias=phisglossary>]*

## **REIMBURSEMENT CATEGORY (REIMBURSEMENT GROUP)**

Medicines eligible for reimbursement are often grouped according to selected characteristics, e.g. route of administration (oral, etc.), main indication (oncology, pediatric, etc.), ATC level, classification (hospital-only, etc.). In many countries different reimbursement rates are determined for different reimbursement categories.

*[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeq.at/index.aspx?alias=phisglossary>]*

## **RETAIL DISTRIBUTOR**

A retail distributor is a company that sells goods to consumers, e.g. a pharmacy or other medicines outlet. Many low- and middle- income countries have at least two different types of shops in which medicines can be purchased: pharmacies with a registered pharmacist and medicines stores, chemists or medicines outlets with paramedical or lay staff.

## **RETAIL MARK-UP**

The retail mark-up is the percentage that retailers (pharmacies) add to cover their costs, including their profit. These costs include those overhead costs that retailers incur in their practice, such as rent, staff salaries, repackaging and Pharmaceutical Sector Country Profile Questionnaire.

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loss, as well as profit. Retail mark-ups are not limited to the private sector: the public and other sectors can also use mark-ups to cover their costs.

Mark-ups can vary between products: imported and locally produced medicines often have different mark-ups. Pharmacies may also charge different mark-ups on originator brands and generically equivalent products. In some countries, for example, the mark-ups are higher on generic equivalents because, even with the markup, they are considered to be affordable.

**Maximum retail mark-up:** In some cases, the government applies a ceiling or maximum percentage limiting the mark-up that a retailer can add. However, it is also common to find that this mark-up is not enforced and much higher percentages can be found in practice.

**Regressive retail mark-up:** In some countries, there may be different maximum mark-ups for different price bands: this is called a 'regressive mark-up' and means that the mark-up decreases as the price of the medicine increases.

In countries where prices are not regulated or where regulations are not enforced, there might be great variation in retail mark-ups. If medicines are sold in the informal sector (medicine outlets), price variations can be even greater.

[In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2<sup>nd</sup> Edition\)](http://www.haiweb.org/medicineprices/manual/documents.html) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

## RISK MANAGEMENT PLAN

A Risk Management Plan is meant to document not only what is known about the safety of a medicine at that particular point in time, but also potential risks that require further elucidation, and how the pharmaceutical sponsor intends to investigate those risks. The sponsor is required to establish a plan for monitoring the new medicine when it is approved (a so-called Pharmacovigilance Plan) and consider whether there is a need for additional risk minimization activities (such as additional prescribing and educational material, restrictions on promotion of and access to the medicine) and outline these in a Risk Minimization Plan.

[Adapted from: *The Australian Prescriber* by the Australian Government at <http://www.australianprescriber.com/magazine/33/1/10/11/>]



## **SAMPLE**

A sample is a portion of a material collected according to a defined sampling procedure. The size of any sample should be sufficient to allow all anticipated test procedures to be carried out including all repetitions and retention samples. If the quantity of material available is not sufficient for the intended analyses and for the retention samples, the inspector should record that the sampled material is the available sample and the evaluation of the results should take account of the limitations that arise from the insufficient sample size.

*[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]*

## **SAMPLING**

Operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments, batch release. (See [sample](#) above)

*[In: WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]*

## **SICKNESS FUND**

A sickness fund is a single social health insurance institution. In some countries there are several sickness funds operating or even competing each other. Some sickness funds are operating on a regional basis whereas others are limited to specific professional groups like farmers or self employed persons.

*[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]*

## **[SINGLE CONVENTION ON NARCOTIC DRUGS, 1961](#)**

The adoption of this international treaty is regarded as a milestone in the history of international drug control. The Single Convention codified all existing multilateral treaties on drug control and extended the existing control systems to include the cultivation of plants that were grown as the raw material of narcotic drugs. The principal objectives of the Convention are to limit the possession, use, trade in, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes and to address drug trafficking through international cooperation

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to deter and discourage drug traffickers. The Convention also established the International Narcotics Control Board, merging the Permanent Central Board and the Drug Supervisory Board.

[At: [http://www.incb.org/incb/en/convention\\_1961.html](http://www.incb.org/incb/en/convention_1961.html)]

### **SOCIAL HEALTH INSURANCE (SHI)**

Social health insurance is a type of health care provision, often funded through insurance contributions by employers and employees as well as state subsidies. In many countries there are obligatory schemes for (employed) persons whose income does not exceed a certain amount/limit (= insurance obligation) in place. Social health insurance is often organized in different sickness funds - in some countries allowing the patient to select a sickness fund (Germany) whereas in others the membership is determined mandatory, e.g. depending on the type of occupation (e.g. Poland, Austria). In some social health insurance countries persons with higher income as well as self-employed persons may opt for substitutive private health insurance. In addition to social health insurance in some countries voluntary health insurance, covering e.g. out-of pocket payments or allowing for free choice of doctors, is very popular.

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

## **SOCIAL SECURITY**

Social security funds as defined by the National Health Accounts constitute special kinds of institutional units which may be found at any level of government - central, state or local. Social security schemes are social insurance schemes covering the community as whole or large sections of the community that are imposed and controlled by government units. They generally involve compulsory contributions by employees or employers or both, and the terms on which benefits are paid to recipients are determined by government units. The schemes cover a wide variety of programmes, providing benefits in cash or in kind for old age, invalidity or death, survivors, sickness and maternity, work injury, unemployment, family allowance, health care, etc. There is usually no direct link between the amount of the contribution paid by an individual and the risk to which that individual is exposed. Social security schemes have to be distinguished from pension schemes or other social insurance schemes which are determined by mutual agreement between individual employers and their employees, the benefits being linked to contributions.

*[In: Guide to Producing National Health Accounts, can be found on line at:*

*[http://www.who.int/nha/docs/English\\_PG.pdf](http://www.who.int/nha/docs/English_PG.pdf)*

## **STANDARD TREATMENT GUIDELINES (STG)**

STGs summarize recommended treatments for commonly occurring conditions. They should represent a consensus on what is regarded as the most appropriate treatment for each condition. The aim of providing such information is that treatments become standardized throughout a health system and that prescribing for the conditions covered is rationalized.

Widespread adoption and application of standardized treatments also make it possible to use these, together with morbidity and patient attendance data, as a basis for quantification of drug requirements.

STGs are useful to prescribers as ready reference texts for consultation during the course of daily clinical work and also as resource materials for basic and in-service prescriber training.

*[In: [Producing national drug and therapeutic information: The Malawi approach to developing standard treatment guidelines Geneva 1999](#) can be found online at: <http://apps.who.int/medicinedocs/pdf/whozip24e/whozip24e.pdf>]*

### **SUMMARY OF PRODUCT CHARACTERISTICS (SPC)**

Product information as approved by the Regulatory Authority. The SPC serves as the basis for production of information for health personnel as well as for consumer information on labels and leaflets of medicinal products and for control of advertising.

[In: *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014* at: <http://infocollections.org/medreqpack/interface/files/glossary.pdf>]

### **TENDER**

Tender is the procedure for procuring pharmaceuticals by seeking quotations from suppliers in response to a public request for quotations.

Competitive tender is a procedure which puts a number of suppliers into competition to obtain lower price. Asking potential suppliers to present their quotes in a standardized and comparable format ensures fair competition.

[In: *WHO A model quality assurance system for procurement agencies* Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf> ]

### **THIRD-PARTY PAYER**

A third-party payer is any entity, public or private, that pays or insures health or medical expenses on behalf of beneficiaries or recipients of the coverage.

[In: *OECD – Pharmaceutical Pricing Policies in a Global Market*, at: [http://www.oecd.org/document/36/0,3343,en\\_2649\\_33929\\_41000996\\_1\\_1\\_1\\_37407,00.html](http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html)]

**TOTAL POPULATION**

Total population is based on the de facto definition of population, which counts all residents regardless of legal status or citizenship--except for refugees not permanently settled in the country of asylum, who are generally considered part of the population of their country of origin.

*[Source: World Bank – Data and Statistics]*

## **TRADE-RELATED ASPECTS of INTELLECTUAL PROPERTY RIGHTS (TRIPS)**

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations. The agreement covers a wide range of subjects, from copyright and trademarks, to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only part of the agreement.

The balance works in three ways:

- Invention and creativity in themselves should provide social and technological benefits.

Intellectual property protection encourages inventors and creators because they can expect to earn some future benefits from their creativity. This encourages new inventions, such as new drugs, whose development costs can sometimes be extremely high, so private rights also bring social benefits.

- The way intellectual property is protected can also serve social goals. For example, patented inventions have to be disclosed, allowing others to study the invention even while its patent is being protected. This helps technological progress and technology dissemination and transfer. After a period, the protection expires, which means that the invention becomes available for others to use. All of this avoids "re-inventing the wheel".
- The TRIPS Agreement provides flexibility for governments to fine tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders' rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled. For pharmaceutical patents, the flexibility has been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. The enhancement was put into practice in 2003 with a decision enabling countries that cannot make medicines themselves, to import pharmaceuticals made under compulsory license. In 2005, members agreed to make this decision a permanent amendment to the TRIPS Agreement, which will take effect when two thirds of members accept it.

*[In: [WTO OMC Fact sheet: TRIPS and pharmaceutical patents](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf), can be found on line at:  
[http://www.wto.org/english/tratop\\_e/trips\\_e/tripsfactsheet\\_pharma\\_2006\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf)]*

## **TRADITIONAL MEDICINE (TM)**

Traditional medicine is the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illnesses.

**Herbal medicine:** plant derived material or preparations with therapeutic or other human health benefits, which contain either raw or processed ingredients from one or more plants. In some traditions, material of inorganic or animal origin may also be present.

**Complementary/alternative medicine (CAM):** often refers to a broad set of health care practices that are not part of a country's own tradition and are not integrated into the dominant health care system. Other terms sometimes used to describe these health care practices include "natural medicine", "nonconventional medicine" and "holistic medicine".

[In [National policy on traditional medicine and regulation of herbal medicines: report of a WHO global survey](#) and At: <http://apps.who.int/medicinedocs/en/d/Js7916e/3.html>]

## **UNDER 5 MORTALITY RATE**

Under-five mortality rate is defined as the probability of dying before reaching age 5 and is expressed as the number of deaths under age 5 per 1,000 live births.

[At: <http://unstats.un.org/unsd/demographic/products/socind/health.htm#tech>]

## **URL**

URL is the acronym of Universal Resource Locator which means the address of a web page on the World Wide Web.

## **VALUE ADDED TAX (VAT)**

VAT and GST can be levied on sales. These taxes vary from country to country, and also from state to state within a country. In many countries, medicines or certain sectors are exempted from VAT or GST; in other countries, VAT is collected at each stage of the supply chain. Each participant in the supply chain pays cost plus VAT, and then adds

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VAT to its selling price. The VAT is thus refunded to the participant so that the final purchaser is the only one who pays VAT.

In some countries, Goods and Services Tax (GST) and/or other national/regional taxes are charged on medicines.

[Adapted from: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2<sup>nd</sup> Edition\)](#) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

## WHOLESALE

All activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public.

Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned.

Wholesalers have a public service obligation: the obligation to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.

[Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

[In: [PHIS Glossary 2009](#), can be found on line at: <http://phis.goeg.at/index.aspx?alias=phisglossary>]

## WHOLESALE MARK-UP

The wholesale mark-up is the percentage added by the wholesaler or Central Medical Stores to cover overhead costs. These costs encompass overhead expenses such as rent, security, electricity, staff salaries and loss. In some situations, it includes costs to transport medicines to retailers. In the private sector, the markup also includes a profit margin; in the public and mission sector, the margin can provide capital for future investment or cover unforeseen increases in costs (e.g. inflation or devaluation).

If the medicines move through more than one wholesaler on their way to the patient, multiple wholesale mark-ups might be levied. This tends to happen as medicines move from central, urban areas to more rural ones.

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**Maximum wholesale mark-up:** In some countries, the government applies a ceiling or maximum percentage limiting the mark-up that a wholesaler can add. In some cases, this mark-up is not enforced and much higher percentages can be observed.

[In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2<sup>nd</sup> Edition\)](http://www.haiweb.org/medicineprices/manual/documents.html) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]

## WHO LEVEL II FACILITY SURVEY

Level II health facility indicators provide systematic data to measure outcomes on access (affordability and availability of key medicines and geographical accessibility of dispensing facilities) and rational use of quality medicines, including some indication of the quality of medicines at health facilities and pharmacies. Data on these indicators are collected through systematic surveys of public health facilities, public and private pharmacies and public warehouses. The results of country surveys can be used to indicate the extent to which the objectives set by the pharmaceutical sector - specifically the government and the national medicines policy - have been achieved. The results show the areas and gaps that should be addressed and which strategy can be prioritized for facilities, districts and countries.

[In: [WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations: Guide for coordinators and data collectors](http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf) Geneva 2007, can be found online at: <http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf>]

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## WHO CERTIFICATION SCHEME

The WHO Certification Scheme offers to importing countries information about:

- a) the status of the pharmaceutical product;
- b) the status of the manufacturer of the pharmaceutical product;
- c) the quality of individual batches of the exported pharmaceutical product;
- d) product information as approved in the country of export.

As at December 1994, the WHO Certification Scheme has been accepted by health authorities in 138 countries, both exporting and importing pharmaceuticals, which indicates their willingness to share the responsibility for the quality of drugs moving in international commerce.

[In: [Use of the WHO certification scheme on the quality of pharmaceutical products](#)

[moving in international commerce](#), can be found online at:  
<http://apps.who.int/medicinedocs/en/d/Jwhozip43e/4.2.html>]

## WHO PREQUALIFICATION PROGRAMME

Launched in 2001, partnered with UNAIDS, UNICEF and the UN Population Fund, and receiving support from the World Bank, the WHO [prequalification](#) program is tackling the quality problems commonly associated with medicines in the area of HIV/AIDS, Tuberculosis, Malaria and Reproductive Health Research. It provides a stringent assessment of pharmaceutical product dossiers, inspection of pharmaceutical manufacturing sites and of contract research organizations (CROs), prequalification of pharmaceutical quality control laboratories (QCLs), and advocacy for medicines of assured quality.

[In: WHO [Prequalification of Medicines Programme - Update for 2006](#), can be found on line at:  
<http://apps.who.int/medicinedocs/documents/s14150e/s14150e.pdf>]

## WHISTLE BLOWER

A whistle blower is an informant who exposes wrongdoing within an organization in the hope of stopping it.

[At: <http://wordnet.princeton.edu/>]

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