PHARMACEUTICAL SITUATION IN THE AMERICAS

Factbook on Level I Monitoring Indicators – 2007

Pan American Health Organization
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PHARMACEUTICAL SITUATION IN THE AMERICAS

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LIST OF ACRONYMS

ADRs:	Adverse drug reactions
AIDS:	Acquired Immune Deficiency Syndrome
AMRO:	WHO Regional Office for the Americas
AR:	Antimicrobial resistance
DTC:	Drug and Therapeutic Committee
EML:	Essential medicines list
FDA:	U.S. Food and Drug Administration
GLP:	Good laboratory practices
HIV:	Human Immunodeficiency Virus
INN:	International Nonproprietary Name
LDC:	Least-developed countries
MRA:	Medicines regulatory authority
NMP:	National medicine policy
NGO:	Non-governmental organization
OTC:	Over the counter
PSP:	Public sector procurement
R&D:	Research and development
RMU:	Rational medicine use
STGs:	Standard treatment guidelines
TRIPS:	Agreement on Trade-Related Aspects of Intellectual Property Rights
UMC:	Uppsala Monitoring Centre
UN:	United Nations
WHA:	World Health Assembly
WHO:	World Health Organization
WTO:	World Trade Organization

PREFACE

This Factbook of the Pharmaceutical Situation in the Americas of the Pan American Health Organization (PAHO) is part of an effort to collect, systematize, and make available information about the pharmaceutical situation in the countries of Americas. A previous publication on the Level I survey at the global level was conducted in 2003[1], and recently, in April 2010, was published the new version of the world survey with indicators of 2007[2]. In the Region of the Americas, two brochures were published with summarized information of 2003 and 2007.

The 2007 survey results presented in this document are part of the commitment of PAHO/WHO to perform regular monitoring, in order to determine whether there are enabling situations and environments in countries to realize the vision of people having access to the essential medicines they need; that such medicines are safe, effective, and of good quality; and that medicines are prescribed and used rationally.

As in the previous Factbook, this document aims to summarize and to provide an overview of the pharmaceutical situation in countries of the Region of the Americas that have contributed data through their health ministries. Information is presented by income level (e.g., medium and high). Data are presented as facts, with key findings following each table and figure.

We would appreciate any comments on and corrections of the data and information presented, which we can then use to further improve the process of data collection and information sharing.

It is hoped that the information presented in this Factbook can be a useful tool for policy makers, planners, and to a certain extent, researchers and others who need such data and information. We also hope that the data and information presented here can be used to identify gaps, define priorities and assist in setting targets, provide information for use in assessing the strengths and weaknesses of strategies, and shed light on national and institutional problems. This Factbook could also serve as a resource for international agencies and donors by supplying information to be used as baseline data, and possibly infer the potential impact of activities. In addition, professional groups and NGOs may find useful data within this Factbook to cite in their advocacy and information campaigns.

EXECUTIVE SUMMARY

World Health Organization pharmaceutical indicators

During the previous biennia, WHO's work on medicines has been guided by the WHO medicines strategies (WMS) 2000-2003 and 2004-2007. Both these strategies have emphasized the use of indicators to measure achievements and situations in countries, and to ascertain the impact of the WMS towards meeting pharmaceutical objectives. The WMS 2004-2007, approved as World Health Assembly Resolution WHA 54.11 (*WHO medicines strategy)*, has highlighted the challenges involved in medicines access and use in the twenty-first century. Resolution 54.11 acknowledged the four main objectives of WHO's medicines strategy; namely, to frame and implement policy; to ensure access; to ensure quality, safety, and efficacy; and to promote the rational use of medicines. The *WHO medicines strategy* 2004–2007 presents the strategies developed to help staff at WHO headquarters, its regions, and countries to work towards implementing this vision.

The WHO has continued to gather data and information on the pharmaceutical situations of the Member States using indicator-based tools to follow up on progress (or lack of progress) of pharmaceutical activities at the country level. Among the tools utilized is the Level I monitoring indicators on structures and processes of the pharmaceutical system in countries, which was used to gather the data presented in this Factbook.

This Factbook details the results of the 2007 assessment of Level I indicators for 31 countries of the Region of the Americas. Where possible, the results were compared with those from 2003.

National medicines policy (NMP)

The primary objectives of a NMP are to ensure: a) access – equitable availability and affordability of essential medicines; b) quality – that all medicines are safe, efficacious, and of high quality; and c) rational use – promote therapeutically sound and cost-effective use of medicines by health professionals and consumers. The functions and strategies of each component of the policy should be brought together in an implementation plan. Incorporation of the NMP into the national health system and strategies is necessary to ensure that the NMP goals and objectives are articulated in the national health plans, and to facilitate the efficient use of resources.

As of 2003, 16 countries had an official NMP, of which ten had an implementation plan. However, only nine countries managed to integrate a NMP into their National Health Policy. In 2007, of the 22 countries with a NMP, 13 had an implementation plan, and 16 NMPs were integrated into the National Health Policy (NHP).

Regulation of medicines

The regulation of medicines is a public policy that restricts the activities of the private sector in order to attain certain social goals set by the State. Such a policy includes all types of measures available to governments, whether legal, administrative, or technical, to ensure the safety, efficacy and quality of medicines, as well as the relevance and accuracy of product information. Medicines regulatory authorities (MRAs) are essential for ensuring stringent regulation of the manufacture, trade, and use of medicines in order to protect public health. A legal framework must be in place for the MRA to guarantee independent testing and assessment of the quality, efficacy, and safety of medicines.

In 2003, 21 countries reported having a legal framework in place for a medicines regulatory authority. By 2007, 28 countries had the requisite legal framework in place. Seventeen countries had legal provisions in 2003 governing the transparency of medicines, which increased to 20 countries by 2007. That same year, the number of countries with a publicly accessible MRA website increased from 10 to 19.

In 2003, 20 countries reported having a legal framework for the marketing authorization (MA) process. By 2007, 24 countries reported having such a framework. There was a significant increase in the median number of approved products in 2007 as compared with 2003 (11,571 v. 9,632, respectively). An increase in the number of countries using INN was also observed (from 20 to 24), as was the use of a computerized system (from 15 to 20), and the number of countries utilizing the WHO Certification Scheme (from 14 to 16).

In 2003, there were 22 countries with a legal provision in place for licensing the manufacturers, distributors, and importers of medicines. By 2007, the number of countries with such a legal provision had increased to 29. With respect to the licensing of prescribers, the number of countries with this type of legal provision had increased from 15 to 30 over the same period, while those with provisions for the licensing of pharmacies increased from 15 to 31.

The number of countries with a legal provision governing the inspection of manufacturers increased from 22 in 2003 to 24 by 2007. During this same period, the number of countries with legal provisions for the inspection of importers and wholesalers as well as distributors and pharmacies varied significantly, from 18 to 24, respectively.

In 2003, the median number of samples collected for quality control was 1,287 for 15 countries, and the median of those tested was 100%. The median percentage of products that failed testing was 3% of the samples tested. With regard to samples tested in 2006, the median tested revealed a slight decrease, although the median of those failing to meet standards was higher (4%).

With respect to pharmacovigilance, 13 countries reported monitoring adverse drug reactions (ADRs) in 2003; by 2007, this number had increased to 18, with 14 countries participating in the WHO Program for International Drug Monitoring.

The number of countries with a policy in place for the mandatory prescribing of generics in the public sector varied from 21 in 2003 to 23 in 2007; in the private sector, this varied from eight to 10 countries. With respect to permitting generic substitution over this same period, the number of countries increased from 21 to 27 in the public sector, and from 17 to 21 in the private sector.

Owing to the known impact of advertising and promotion of medicines on both prescribing behavior and patient demand, it is essential to regulate and monitor medicines promotion. In 2003, 21 countries reported having legislation governing medicines promotion and advertising; by 2007, 25 countries had such legislation.

Medicines supply systems

A well-coordinated medicines supply system helps to ensure that the funds available for the procurement of medicines are used effectively and efficiently. Failures in the supply system can lead to life-threatening medicines shortages and waste scarce resources. The existence of a large number of different partners with their own medicine supply strategy has led to a lack of coordination of supply systems, resulting in duplication, inefficiency, and increased workload, especially at the level of facilities. The selective priority diseases approach has resulted in neglect of other important conditions, such as chronic illnesses and common childhood diseases.

In 2003, the health ministry performed the procurement function in 19 countries and in 26 countries by 2007. The distribution function was performed by the health ministry in 12 countries in 2003 and in 18 countries by 2007. Procurement and distribution by an NGO were performed in two countries in 2003. In 2007, the procurement and distribution functions were performed by an NGO in four and two countries, respectively. The procurement function was performed by individual health institutions in 11 countries in both 2003 and 2007.

Seventeen countries in 2003 and 19 countries in 2007 used national competitive tendering, while the use of an international tender reflected a significant increase—from 11 in 2003 to 19 in 2007. The use of negotiation/direct procurement varied from 10 countries in 2003 to 19 in 2007. It was observed that countries used more than one procurement mechanism. In 2007, public sector procurement was limited to the essential medicines list (EML) in only 11countries.

Medicines financing

Access to specific treatments for high priority conditions has life-saving implications for individuals and major public health benefits for communities. A medicines pricing policy is also an important strategy, since the cost of medicines is one of the most important obstacles to access. If effectively implemented, pricing regulation and policies can provide a good basis for equitable access.

The number of countries where medicines for different diseases were free increased in 2007 in comparison to 2003. The number of countries where all medicines were free was 14 in 2003 and 17 in 2007. For malaria, the number of countries with free medicines in 2003 was 14 and in 2007, there were 18. For tuberculosis, 18 countries provided free medicines in 2003 and 24 by 2007. In 2003 and 2007, free medicines were available for sexually transmitted infections (STIs) in 15 and 17 countries, respectfully; for HIV/AIDS, this variation was significant, from 14 in 2003 to 24 in 2007.

In 2003, 15 countries reported providing medicines free of charge to those who could not afford them, as compared with 26 countries in 2007. The availability of free medicines for children under five years was reported by 16 countries in 2003 and by 26 countries in 2007. Free medicines for pregnant women varied from 15 countries in 2003 to 24 in 2007. The greatest variation was observed in the reporting of free medicines for the elderly, with seven countries providing these free of charge in 2003, as compared with 22 countries in 2007.

The number of countries that covered a portion of the population with public health insurance varied from 10 in 2003 to 20 in 2007, while countries that covered some of the population though private health insurance plans varied from 16 in 2003 to 24 in 2007.

Concerning the coverage of medicines, in 2003, four countries reported coverage by the public sector for all medicines, with six countries providing this coverage by 2007. There was only one country with no public-sector coverage of medicines in 2003 and four such countries by 2007.

There was a significant increase in the number of countries providing coverage of some medicines through private insurance (from 11 in 2003 to 18 in 2007); however, the number of countries covering all medicines through private insurance did not change over the period.

The number of countries reporting a policy on medicines pricing for the public sector increased from 10 in 2003 to 16 in 2007 and for the private sector from 10 in 2003 to 12 in 2007. Countries with a policy on medicines pricing for NGOs decreased from six in 2003 to four in 2007.

Production and trade

The region has low capacity for research and development (R&D) and for the production of pharmaceutical starting materials; although a slight improvement was observed from 2003 to 2007. In 2003, two countries reported having capacity for R&D and six countries by 2007. Regarding the production of pharmaceutical raw materials, four countries produced these materials in 2003 as compared to six in 2007. The number of countries that reported having capacity for formulation from raw materials increased from 19 in 2003 to 26 in 2007, and for repackaging of finished dosage forms the increase was from 18 countries in 2003 to 25 in 2007.

The protection of intellectual property rights (IPR) of medicines and other pharmaceutical products with patents has been extended and consolidated in the region with ratification by the majority of member states of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Several countries in the region changed their national legislation, making it compatible with the

abovementioned Agreement, some of them introducing the available TRIPS flexibilities.
In 2003, eight countries reported having their national legislation modified to implement the TRIPS Agreement, three countries were availing themselves of the provisions of TRIPS Article 65, while no country reported availing itself of provisions under TRIPS Article 66. In 2007, 17 countries reported having their legislation modified to implement the TRIPS Agreement, nine of which with provisions for TRIPS Article 65, one with provisions for TRIPS Article 66, and five with provisions for Paragraph 7 (in accordance with the Doha Declaration).

In 2003, only five countries had incorporated the provisions for parallel importation, while in 2007, eight countries had included this provision in their legislation. Regarding compulsory licensing, provisions were included in the legislation of six countries in 2003, which by 2007 had more than doubled to 13 countries. Five countries reported including the Bolar exception in 2003, which by 2007 had doubled to 10 countries.

Rational use of medicines

Rational use of medicines means 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." Over use, under use, and misuse of medicines may lead to unnecessary suffering and death and waste scarce resources. Some interventions found to be of value include a mandated multidisciplinary national body to coordinate policies on medicines use, standard treatment guidelines (STGs), essential medicines lists (EMLs), drug and therapeutics committees, and problem-based pharmacotherapy training.

There was a slight variation between 2003 and 2007 in the number of countries with an essential medicines list (EML), from 22 to 25. The median number of medicines comprising EMLs varied from 400 in 2003 to 512 in 2007. Similarly, the range between percentiles did not change significantly. The number of countries that last updated the list less than five years ago varied from 20 in 2003 to 24 in 2007.

Almost all countries with an EML used it in public procurement activities (21 in 2003 and 20 in 2007). Public sector insurance reimbursement for use of EML items varied from eight countries in 2003 to nine countries in 2007. The use of private insurance reimbursement was insignificant in both periods, increasing from two countries in 2003 to three countries in 2007.

There was a significant increase in the number of countries that reported having national standard treatment guidelines (STGs), from 13 in 2003 to 25 in 2007. For STGs at the hospital level, 10 countries reported their use in 2003 and 19 in 2007. For STGs at the primary health care level, 12 countries reported their use in 2003 and 23 in 2007.

In 2003, 19 countries reported having a national medicines formulary manual, whereas the corresponding figure for 2007 was 23 countries. In 2003, 17 countries reported that their national formularies covered only the EML, and in 2007 this decreased to 13 countries. The number of countries that reported having conducted the last update of their national medicines formulary within the past five years varied from 13 countries in 2003 to 16 in 2007.

Regarding the presence of concepts related to rational medicines use in health worker training programs, a significant variation was observed. In relation to EML concepts, these were reported to be present in physician education programs of eight countries in 2003 and in 15 by 2007. For nurses, the variation was from eight countries in 2003 to 15 in 2007. For pharmacists, it decreased slightly; from 15 countries in 2003 to 14 in 2007.

The availability of pharmacotherapy training for all categories of health workers had increased significantly in 2007 as compared to 2003. With regard to pharmacotherapy training for physicians, nine countries reported such training in 2003, while 15 included it by 2007; while the corresponding figures for nurses and for pharmacists over the period was one and 10 and six and 10, respectively.
In 2003, rational prescribing concepts were reported to be present in physician training programs in 10 countries, in the nursing programs in six countries, and in pharmacist programs in eight countries. By 2007, such concepts were reported to be present in physician training in 15 countries, and in nursing and pharmacist training in 11 countries.

With regard to public education campaigns, nine countries reported conducting public education on the use of antibiotics and five countries on the use of injections in 2003. By 2007, the number of countries reporting having carried out campaigns on the use of antibiotics increased to 10, and those reporting campaigns on the use of injections decreased to three.

Physicians account for most prescribing. However, nurses prescribe occasionally in a significant number of countries. In 2003, 12 countries reported having an independent medicines information center, which by 2007 had increased to 16 countries.

In 2003, 11 countries mandated the use of drug and therapeutic committees (DTCs) within the NMP; by 2007, DTCs were mandated in 15 countries.

In 2003, 10 countries reported having a national strategy for the control of adverse reactions (AR), 13 countries had a reference laboratory for AR surveillance, and seven countries reported having a national task force (NTF) as part of their AR control strategy. In 2007, countries reporting a national AR control strategy increased to 12 and those reporting a laboratory to conduct AR surveillance increased to 19; but countries with an NTF for AR decreased to six.

1. INTRODUCTION

1.1 Background

In 1975, the Twentieth World Health Assembly approved Resolution WHA 28.66, mandating WHO to help the Member States formulate national medicines policies and assist countries with the implementation of pharmaceutical strategies, such as selection of essential medicines, appropriate procurement of quality medicines, and training in various elements of pharmaceutical programs. This resolution marked the evolution of essential medicines programs in countries and the development of national medicines policies. The WHO Conference of Experts, held in Nairobi in 1985, recommended that WHO provide information on the medicines situation at the global and national levels.

The above-mentioned milestones have provided the impetus to develop tools and establish systems to collect and publish data on a regular basis. In 1988, *The World Drug Situation* was published. This document was updated in 2004 with the publication of *The World Medicines Situation*. Indicator tools were also developed and improved during this time.

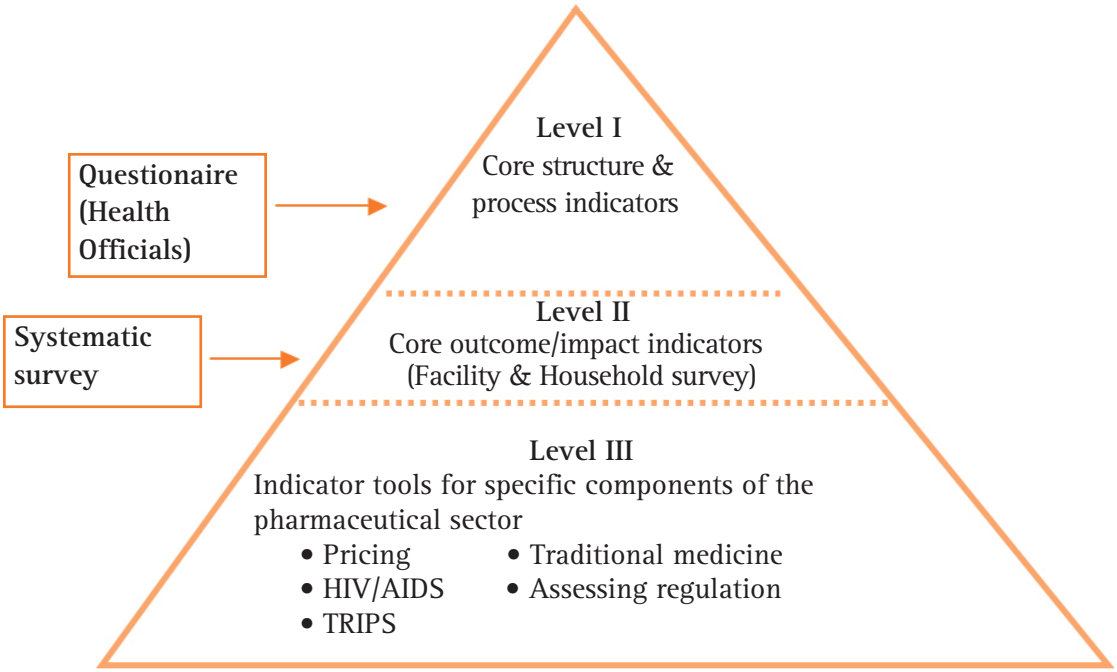
In the previous biennia, WHO's work on medicines has been guided by the (WMS) WHO medicines strategies 2000-2003 and 2004-2007. Both strategies have emphasized the use of indicators to measure the achievement and situation in countries, and to ascertain the impact of the WMS in achieving pharmaceutical objectives in countries. The WMS 2004-2007, approved as a resolution in WHA 54.11, has highlighted the challenges in medicines access and use in the twenty-first century. The WHA 54.11 WHO medicines strategy acknowledged the four main objectives of WHO's medicines strategy; namely, to frame and implement policy; to ensure access; to ensure quality, safety, and efficacy; and to promote rational medicines use. The WHO medicines strategy 2004–2007 presents the strategies developed to help staff at WHO headquarters, and in the regions and countries, to work towards implementing this vision.

WHO has continued to gather data and information on the pharmaceutical situations of the Member States, using indicator-based tools to follow up progress—or lack of progress—on pharmaceutical activities at the country level. Among the tools utilized is the Level I monitoring indicators on structures and processes of the pharmaceutical system in countries, which was used to gather the data presented in this Factbook. Monitoring the progress of efforts to improve the global medicines situation is a crucial part of the strategy.

1.2 Level I, II, and III Indicators

WHO has developed a three-tiered monitoring strategy to assess progress, compare situations between countries, and reassess and prioritize efforts based on the results. Figure 1 illustrates the three levels of the monitoring strategy. The WHO operational package for monitoring and assessing country pharmaceutical situation, specifically Level I and Level II indicators, has provided a practical indicator-based tool that can be regularly implemented without the need to invest large amounts of human or financial resources. The core indicators can be easily collected using standardized methodologies, small samples of data, and simple survey techniques.

Figure 1. WHO strategy for monitoring country pharmaceutical situations



Level I indicators assess the structures and processes related to medicines in a country. They can be used to reveal the achievements and weaknesses of individual pharmaceutical systems and to illustrate common sectoral strategies and approaches. They also enable rapid assessment of the implementation of various components of a country's pharmaceutical system. Every four years, health officials from WHO Member States are invited to complete a standardized questionnaire reporting on the status of national medicines policies and their components, including: legislation and regulations; quality control of medicines; essential medicines lists; supply systems; financing; access to medicines; production; rational use; and, trade and intellectual property (see Annex 2 for the Level I questionnaire and Annex 3 for a list of basic Level I indicators).

Level II indicators measure the degree of attainment or outcome of strategic pharmaceutical objectives. The description of each indicator, including calculations, is contained in the manual "WHO Operational Package for Monitoring and Assessing Country Pharmaceutical Situations"[3]

- Access is measured in terms of the availability and affordability of essential medicines.
- Quality is represented by the absence of expired stock on pharmacy shelves, and adequate handling and conservation conditions. Measuring quality by testing samples of pharmaceutical products was deemed too costly to be acceptable for most countries.
- Rational use is measured by examining prescribing and dispensing practices, and the implementation of strategies that have been shown to support rational use, such as standard treatment guidelines (STGs) and essential medicines lists (EMLs).

Countries calculate Level II indicators on the basis of data collected with standardized collection instruments at public health facilities, private pharmacies, and warehouses.

Level III indicators assess specific components of the pharmaceutical sector, health system, or national medicines policy in more depth. Examples include indicators for investigating the use of medicines in health facilities; medicines price surveys; and indicators to monitor the impact of the TRIPS Agreement

1.3 Countries Contributing Data and Structure for the Factbook

This Factbook details the results of the 2007 assessment of Level I indicators by 31 AMRO countries, including high- and middle-income countries:

Country	High-income	Middle-income
Antigua and Barbuda	√	
Argentina		√
Bahamas	√	
Barbados	√	
Belize		√
Bolivia		√
Brazil		√
Canada	√	
Chile		√
Colombia		√
Costa Rica		√
Dominican Republic		√
Ecuador		√
El Salvador		√

Continued

Continued

Country	High-income	Middle-income
Grenada		√
Guatemala		√
Guyana		√
Honduras		√
Jamaica		√
Mexico		√
Nicaragua		√
Panama		√
Paraguay		√
Peru		√
St. Kitts and Nevis		√
St. Lucia		√
St. Vincent and the Grenadines		√
Santa Lucía		√
Suriname		√
Trinidad and Tobago	√	
Uruguay		√

Data were collected in 2007. Most of the data for Level I indicators were gathered through the country's health ministry. Many WHO Member States submitted data in response to the Level I questionnaire. The WHO MedNet can be consulted to compare results over time and between countries (http://mednet.who.int/).

It is important to bear in mind that not all countries responding to the questionnaire answered all its questions. This sometimes resulted in questions with a small number of respondents.

Some problems were noted during data processing, owing to the nature of the questionnaires and the high volume of information from the 31 countries. Problems included limited knowledge of respondents; hence, the questionable accuracy and validity of some responses. Attempts were made to validate the data, insofar as possible, and to reflect them accurately in the survey report.

This Factbook summarizes data for the Level I structure and process indicators according to six categories: 1) national medicines policy; 2) regulatory system; 3) medicines supply system; 4) medicines financing; 5) production, trade, and intellectual property; and 6) rational medicines use. Each category includes a brief introduction, followed by tables that summarize the situation in 2007, and the key findings are highlighted after each table and figure. Insofar as possible, the data from 2007 was also compared with data from 2003, when 27 countries responded to the Level I questionnaire.

This Factbook does not attempt to analyze or address pharmaceutical policy issues, or to cover all key pharmaceutical components. It aims to provide the latest available information on pharmaceutical situations in various countries, and on the status of national medicines policies, as reflected by WHO Level I indicators. It is hoped that this information can be used as reference material by those who are interested in working on pharmaceutical sector issues at the country, sub-regional, and regional levels.

2. NATIONAL MEDICINES POLICY

The World Health Organization has noted that it takes a comprehensive and common framework to develop suitable policies that can tackle all of the interdependent problems and involve all stakeholders at the same time. Therefore, the WHO framework highly recommends that countries formulate and implement a national medicines policy (NMP) as a "commitment to a goal and a guide for action[4,5]. A NMP defines a framework for setting and monitoring medium- to long-term objectives in the public and private pharmaceutical sectors.

The primary objectives of a NMP are to ensure:

- access – equitable availability and affordability of essential medicines;
- quality: that all medicines are safe, efficacious, and of high quality; and
- rational use: to promote therapeutically sound and cost-effective use of medicines by health professionals and consumers.

The functions and strategies of each component of the policy should be brought together in an implementation plan. Incorporation of the NMP into the national health system and strategies is necessary to ensure that the NMP goals and objectives are articulated in the broader national health plans, and so that resources can be used efficiently.

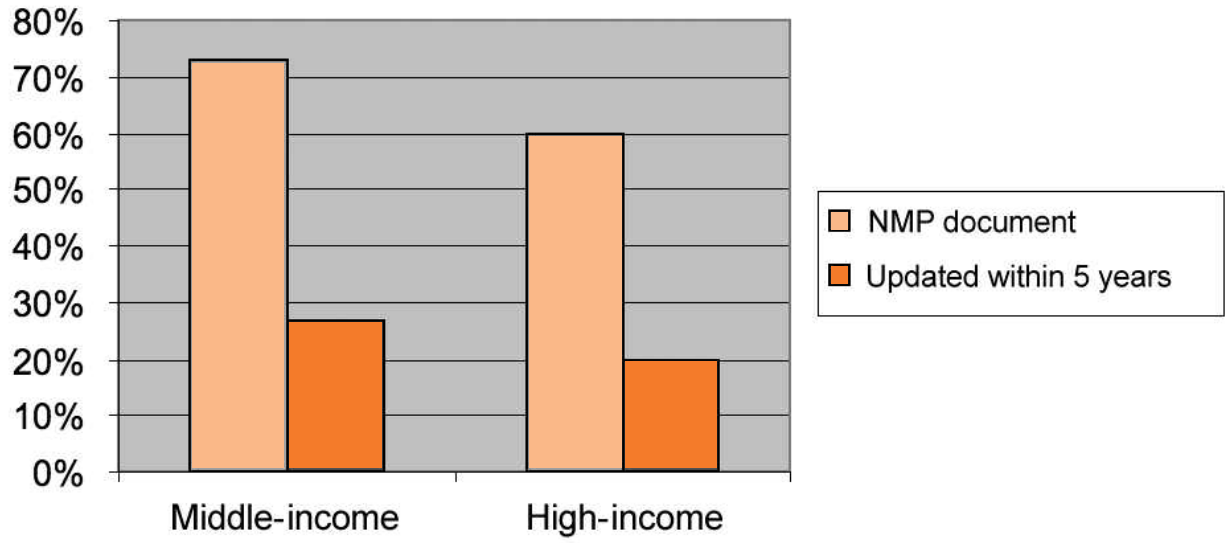
NMPs require regular review to evaluate whether objectives have been achieved and to track progress over time. Standardized indicators of the pharmaceutical situation allow countries to monitor and evaluate the impact of implementing a NMP.

Table 1. Status of national medicines policies (NMPs) in 2007

	Middle –income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Official NMP (or draft) document	19	73.1	3	60.0	22	71.0
Official NMP document updated within 5 years*	7	26.9	1	20.0	8	25.8
NMP implementation plan	11	57.9	2	50.0	16	66.7
NMP implementation plan updated within 5 years*	8	40.0	2	50.0	10	41.7
NMP integrated in NHP	15	75.0	1	25.0	16	66.7

* Assumes countries that did not provide dates had not updated their NMP document/NMP implementation plan within the last five years.

Figure 2. National medicines policies (NMP) in 2007



- Most of the countries have a NMP (official or draft) and most NMPs are official documents;
- Only about half of the countries have an implementation plan;
- Yet only a few of these policies and plans have been updated within the last 5 years.

In 2003, 16 countries had an official NMP, of which 10 had an implementation plan; the NMP was integrated into the national health policy in only nine countries. In 2007, of the 22 countries with a NMP, 13 had an implementation plan and 16 of them were integrated into the national health policy (NHP). The data here show a positive change in relation to the situation in 2003.

Table 2. Countries reporting recent indicator assessments

	Middle-income		High-income	
	Number of countries	%	Number of countries	%
Areas assessed within the last 5 years (2003-2007)				
Overall pharmaceutical situation	7	37.0	1	50.0
Rational use(prescription audit)	6	32.0	n.a.	n.a.
Access	8	47.0	n.a.	n.a.

n.a-not available

- Not all of the countries reported having assessed their pharmaceutical situation within the past 5 years.

3. REGULATORY SYSTEM

A legislative framework is required to implement and enforce pharmaceutical sector policies. Laws and regulations create a legal basis for control of public and private pharmaceutical activities, including administrative measures and sanctions in response to violations. Areas covered include the roles and responsibilities of the medicines regulatory authority; market approval and registration of medicines; regulation of premises where medicines can be handled; and the qualifications, rights, and responsibilities of medicine manufacturers, importers, exporters, distributors, prescribers, and dispensers.

3.1 Medicines Regulatory Authority (MRA)

Medicines regulatory authorities (MRAs) are essential to ensure stringent regulation of the manufacture, trade, and use of medicines in order to protect public health. A MRA establishes a legal framework to guarantee independent testing and assessment of the quality, efficacy, and safety of drugs. It should also ensure the integrity of the interactions between patients and dispensers once a prescription has been issued. To ensure this, the MRA should be following several mutually-reinforcing activities such as licensing, controlling, and monitoring.[6]

Table 3. Presence of medicines regulatory authority (MRA)

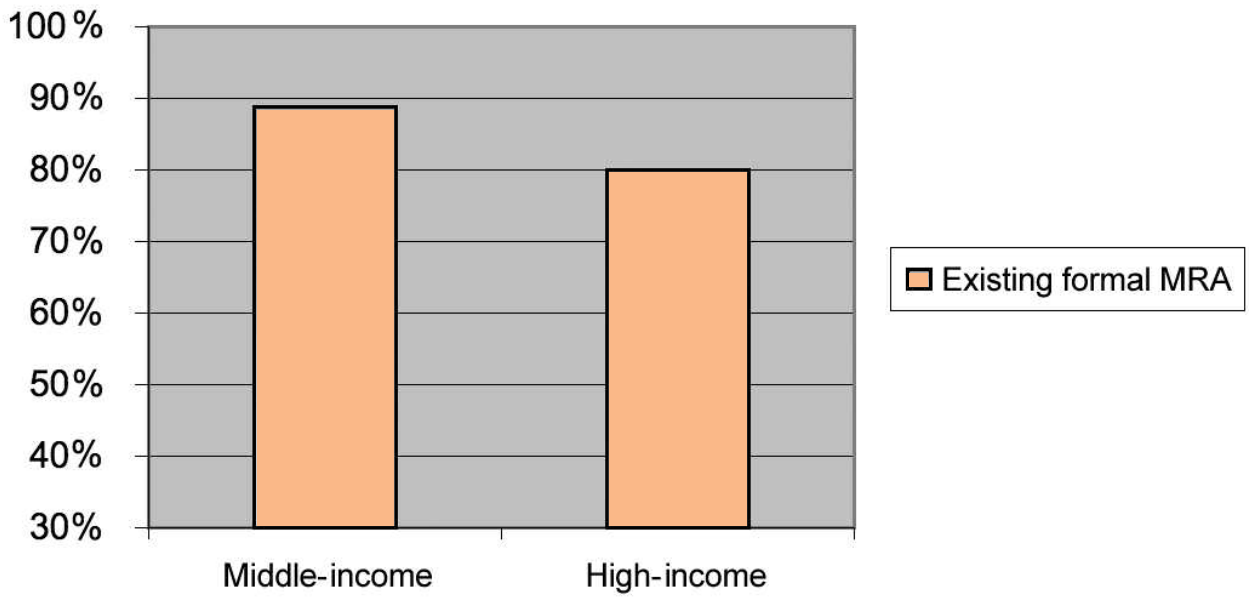
	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Legal provision for establishment of MRA	24	92.3	4	80.0	28	90.3
Existing formal medicines regulatory authority	23	88.5	4	80.0	27	87.1
Legal provision requiring transparency	17	70.8	3	75.0	20	71.4

Continued

Table 3. Continued

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
MRA involved in harmonization initiative	23	92.3	4	100.0	28	93.3
Publicly accessible MRA website	18	69.2	1	25.0	19	63.3
Sources of funding for MRA						
Government budget	24	96.0	5	100.0	29	96.7
Medicines registration fees	13	76.5	1	25.0	14	66.7
Other	6	60.0	1	33.3	7	53.8

Figure 3. Formal medicines regulatory authority



- Most of the countries report having legal provisions for the establishment of a MRA and a MRA involved in harmonization activities;
- Publicly accessible MRA websites and legal provisions requiring transparency are common;
- The source of funding for the MRA is primarily the government budget, but registration fees are also used in middle-income countries.

In 2003, 21 countries reported having legal provisions in place for a medicines regulatory authority (MRA), which increased to 28 countries by 2007. In 2003, 17 countries reporting having legal provisions requiring transparency, increasing to 20 by 2007, and the number of countries with a publicly accessible MRA website increased from 10 to 19.

BOX 1
Pan American Network on Drug Regulatory Harmonization (PANDRH)

PANDRH constitutes a continental forum that deals with drug regulatory harmonization. It includes the presence of all of the region's drug regulatory authorities, as well as representation of organizations for economic integration such as CARICOM, MERCOSUR, TLCA, the Latin American Association for Integration (ALADI), and the Andean Community; academics; representation of regional professional associations; and other interested groups from all the continent's sub-regions. The private sector is represented chiefly by the pharmaceutical industry. The Pan American Health Organization (PAHO/WHO) became PANDRH's Secretariat as facilitator of its various working groups.

PANDRH has four working/decision-making components: the Pan American Conference, the Steering Committee, the working groups, and the Secretariat. Each has functions established in the Network's standards and regulations.

To date, PANDRH has held five conferences and formed 12 working groups: Bioequivalence, Registration of Medicines, Good Manufacturing Practices, Good Laboratories Practice, Vaccines, Drug Promotion, Pharmacovigilance, Drug Counterfeiting, Good Clinical Practices, Medicines Classification, Herbal Products, and Pharmacopeia.

Website: www.paho.org/pandrh

3.2 Marketing authorization

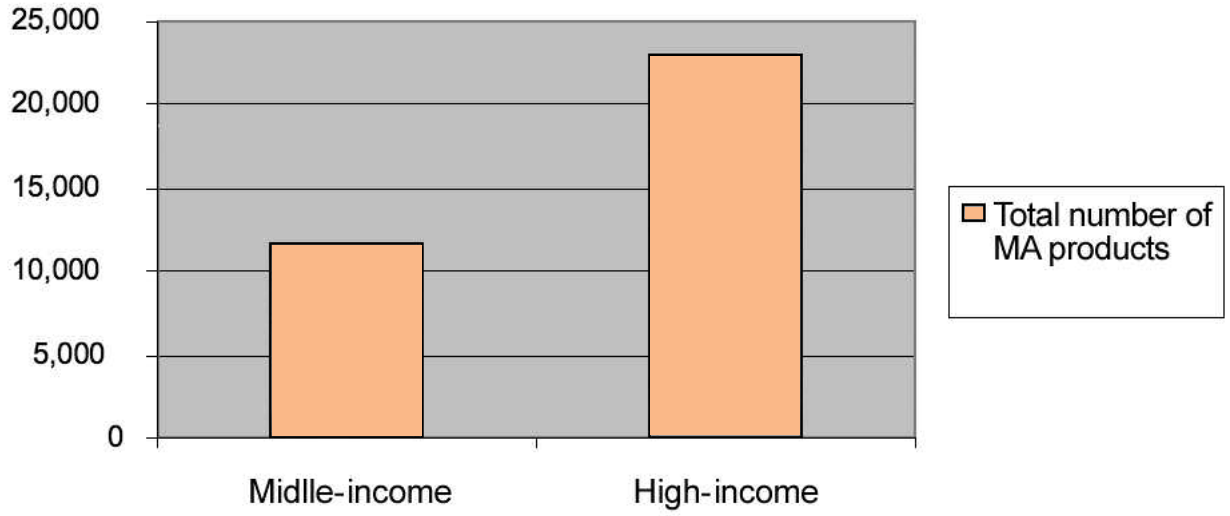
A marketing authorization (MA) is the permission granted by the MRA for a product to be put on the market. Product assessment and registration involves evaluating technical and administrative data submitted about a product. It aims to ensure that a pharmaceutical product has been adequately tested and evaluated for safety, efficacy, and quality, and that the product information provided by the manufacturer is accurate.[7]

It is recommended that the International Nonproprietary Name (INN) be used, as it can contribute to the harmonization and standardization of product names, thereby simplifying procurement; and the prescribing, distribution, and dispensing of medicines particularly across country borders, thereby decreasing the risk of mistakes due to confusing the names of medicines.

Table 4. Marketing authorization (MA)

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Provisions governing MA	21	80.8	3	60.0	24	77.4
MA list publicly available	16	66.7	2	40.0	18	68.1
Computerized system for registered products	19	76.0	1	25.0	20	69.0
WHO Certification Scheme part of MA	14	53.8	2	40.0	16	51.6
INN used in registration of medicines	21	80.8	3	60.0	24	77.4
Official registration committee	15	60.0	1	25.0	16	55.2
	Median (25th, 75th percentile)		Median (25th, 75th percentile)		Median (25th, 75th percentile)	
Total no. of MA products	11.074		23.000		11.571	
	5.997,75	16.448,75	23.000	23.000	6.499	16.849
	18		1		19	

Figure 4. Number of market-authorized products



- Most of the countries reported the presence of a comprehensive MA framework;
- MA list was not always publicly available;
- Use of the WHO Certification Scheme for MA was not common in the region, and the INN was frequently used;
- High-income countries seemed to have more market-authorized products, but there was a very high rate of non response

In 2003, 20 countries reported having MA legal provisions in place. In 2007, the number of countries with MA increased to 24. There was a significant increase in the median number of approved products in 2007 as compared with 2003 (11,571 v. 9,632).

Between 2003 and 2007, an increase in the number of countries was observed for the following: use of the INN (from 20 to 24); use of a computerized system (from 15 to 20); and use of the WHO Certification Scheme (from 14 to 16).

3.3 Licensing

Licensing is the authorization of facilities for conducting activities associated with manufacturing, storing, supplying, and dispensing medicines, as well as the prescribing and dispensing activities of medical professionals. Specifications regarding pharmaceutical premises, personnel, and procedures must be followed by pharmaceutical manufacturers, distributors, and retailers if they are to obtain and keep their operating licenses. Licensing is extremely crucial to ensuring the quality of medicines to be marketed.

Table 5. Legal provisions governing licensing

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Legal provisions governing:						
Manufacturers	24	92.3	5	100.0	29	93.5
Wholesalers & distributors	24	92.3	5	100.0	29	93.5
Medicine importers & exporters	24	92.3	3	100.0	27	93.1
Prescribers	25	96.2	5	100.0	30	96.8
Pharmacy	26	100.0	5	100.0	31	100.0

- Almost all of the countries reported having legal provisions in place governing medicine manufacturers, distributors/wholesalers, importers/exporters, prescribers and pharmacies.

In 2003, there were 22 countries with legal provisions in place for the licensing of medicine manufacturers, distributors, and importers. In 2007, the number of countries with legal provisions in these areas increased to 29. Regarding the licensing of prescribers, the number of countries with such legal provisions increased from 15 to 30, and regarding the licensing of pharmacies the variation was from 15 to 31.

3.4 Regulatory Inspection

Regulatory inspection is a tool that can be used to survey the quality and reliability of products and facilities prior to licensing or marketing authorization, and subsequently for surveillance and monitoring purposes.

Table 6. Regulatory inspection

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Legal provisions for the inspection of premises	25	96,2	4	80,0	29	93,5
Manufacturers						
Facilities inspection	20	80,0	4	80,0	24	80,0
Published national guidelines	18	90,0	1	50,0	19	86,4
Wholesalers/ distributors						
Facilities inspection	21	80,8	3	60,0	24	77,4
Published national guidelines	16	80,0	1	50,0	17	77,3
Importers/ exporters						
Facilities inspection	20	80,0	2	50,0	22	75,9
Published national guidelines	15	80,3	0	0,0	15	78,9
Retail distributors/ pharmacies						
Facilities inspection	21	84,0	3	60,0	24	82,8
Published national guidelines	18	90,0	0	0,0	18	85,7

- Most countries reported having legal provisions in place for the inspection of manufacturers, wholesalers/distributors, importers/exporters, and retail distributors/pharmacies;
- Most middle-income countries also had published national guidelines.

The number of countries with legal provisions in place for the inspection of manufacturers increased from 22 in 2003 to 24 in 2007. Regarding legal provisions for inspecting importers and wholesalers and for inspecting distributors and pharmacies, there was a significant variation from 18 to 24 countries.

3.5 Control of Narcotics and Psychotropic Substances

In order to globally counteract the illicit production of and trafficking in narcotics and psychotropic substances, which pose a great danger to public health, the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances was issued in 1988 to provide for legal measures against medicine trafficking. It is very important that countries implement legal provisions to control and monitor not only finished products, but also the precursors, chemicals, and solvents used for the production of narcotics and psychotropic substances.[9,10] The Convention further promotes strong international cooperation, as only a joint international approach can facilitate a decrease in the use, production, and illicit trade of these substances worldwide.

Table 7. Control of narcotics and psychotropic substances

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Legal provisions governing control of narcotics	26	100.0	5	100.0	31	100.0
Convention signatory	25	100.0	5	100.0	30	100.0

- All the countries reported having legal provisions in place for the control of narcotics, and all countries reported being signatories to the Convention of reference.

3.6 Quality Control

Quality control is important to ensure that patients receive medicines that are safe and effective. WHO recommends that the MRA of each country should have access to a quality control laboratory to test whether medicine samples meet the required quality criteria. WHO provides guidelines on establishing testing facilities.[11,12]

The results of the testing of samples of marketed drugs permit the regulatory authority to evaluate the actual quality of products used in the country, identify problems pertaining to medicines quality,vii and adopt adequate regulatory measures, such as product recalls, withdrawing a drug from the market, or other relevant action.

Table 8. Quality control

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Quality Control						
Quality assurance system in place	18	72.0	3	75.0	21	72.4
Samples tested for:						
Medicines registration	17	68.0	1	25.0	18	62.1
Post-marketing surveillance	19	79.2	1	33.3	20	74.1
Post-marketing surveillance Samples tested in:						
Government quality control laboratory	18	85.7	1	33.3	19	79.2
Local academic institutions	8	50.0	0	0.0	8	42.1
Private laboratory	5	35.7	2	66.7	7	41.2
Mini laboratories (e.g., district, regional)	3	23.1	0	0.0	3	18.8
Quality control laboratory in a third country	7	43.8	2	66.7	9	47.4
Quality control procedures for imported medicines	23	88.5	3	75.0	26	86.7
Legal procedures to recall or dispose of defective products	20	76.9	3	75.0	23	76.7
Quality testing in 2006	**Median (25th, 75th percentile)**		**Median (25th, 75th percentile)**		**Median (25th, 75th percentile)**	
Number of samples tested	1.401		166		812	
	448	1874	105	227	183	1.713
	15		2		17	
Number of samples that failed	63,5		9		45	
	18.8	93	6	12	12	91
	14		2		16	

- Most countries reported having a quality assurance system in place;
- A government quality control laboratory was most commonly used for testing in middle-income countries. High-income countries also resorted to private laboratories and third-country laboratories;
- Not all the countries had legal procedures in place to recall defective products;
- Middle-income countries tended to collect more samples, but this may be because the number of high-income countries was very small.

In 2003, the median number of samples collected was 1,287 for 15 countries, and the median number of tested samples was 100%. In 2006, the median number of collected samples decreased to 812.

BOX 2
EXTERNAL QUALITY CONTROL PROGRAM
OF OFFICIAL MEDICINE CONTROL LABORATORIES (EQCP)

The External Quality Control Program of Official Medicine Control Laboratories (EQCP) is a PAHO/WHO technical cooperation activity carried out in collaboration with the United States Pharmacopeia (USP), in conjunction with the Official Medicine Control Laboratories (OMCL) of PAHO Member States. The Program includes the development of quality tests utilizing pharmacopeia methods. Results and reports of the tests performed are evaluated by the USP. The evaluation makes it possible to:

- Formulate recommendations for participating laboratories, with a view to optimizing testing capacity and reporting;
- Identify areas requiring technical cooperation;
- Evaluate the quality of drugs used in priority programs; and
- Develop the concept of reference QC laboratories throughout the region.

Objectives:

- Strengthen the performance in quality control tests of the OMCL of the Americas;
- Increase communication and the sharing of information; and
- Harmonize methodologies to facilitate the acceptance/recognition among countries of the validity of the results obtained.

Continued

Box 2. Continued

Development of the EQCP

The EQCP comprises three phases:

Phase 1: Diagnostic study of the OMCL in those countries that agreed to participate in the Program. A questionnaire and the subsequent visit of an expert are utilized.

Phase 2: Tests of external control through the shipment of samples and corresponding standards, indicating the methodology to use and the form to report their results. It has as an objective to evaluate the performance of the laboratories participating in the development of the tests and in the reporting of results. The results are evaluated at the USP and reports with recommendations are sent to each laboratory on an individual basis. The criteria used by the USP for evaluating include weighing-in, equipment, precision, reproducibility, relative errors standard, data report and interpretation, limitations of the monograph, and familiarity with the USP methods. Twenty-three OMCL from 21 countries have been participating in the EQCP.

Phase 3: Training of human resources by implementing workshops and seminars on good laboratory practices (GLP) in countries that, according to the results, need more assistance to overcome their difficulties and improve their performance.

3.7 Pharmacovigilance

"Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems. Recently, its concerns have been widened to include: herbals, traditional and complementary medicines, blood products, biologicals, medical devices, and vaccines."

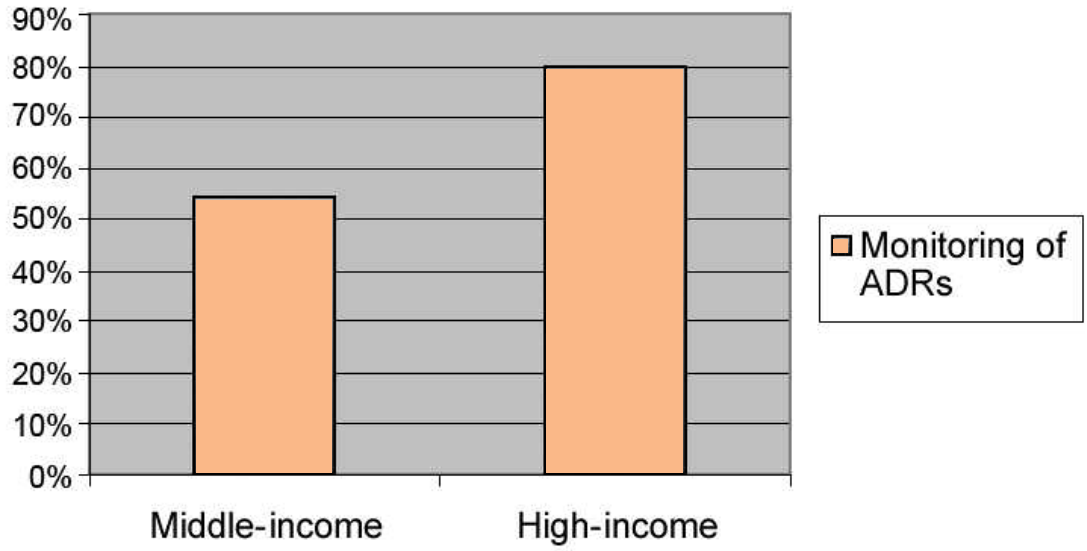
Adverse drug reactions (ADRs) are a common, though often enough preventable, cause of illnesses, disability, and even death. The system of pharmacovigilance is understood to be a tool to detect, assess, understand, and prevent ADRs. Every country should have a pharmacovigilance system in place to safeguard public health,[14,15] as part of the essential regulatory functions. One of its aims is to "contribute to the assessment of benefit, harm, effectiveness, and risk of medicines, encouraging their safe, rational, and more effective (including cost-effective) use.[13]

Since 1968, there has been a WHO Program for International Drug Monitoring, now coordinated by the Uppsala Monitoring Centre (UMC) in Uppsala, Sweden, with oversight by an international board. The principal function of the UMC is to manage the international database of ADR reports received from national centers. Most national contributing centers have easy electronic access to these reports. The UMC has established standardized reporting by all national centers and has facilitated communication between countries to promote rapid identification of signals. señales significativas.[12]

Table 9. Monitoring of adverse drug reactions (ADRs)

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Monitoring of ADRs	14	53.8	4	80.0	18	58.1
Local level	8	61.5	3	75.0	11	64.7
Regional level	6	50.0	2	50.0	8	50.0
Central level	13	92.9	3	75.0	16	88.9
International reporting of ADRs	11	45.8	3	60.0	14	48.3

Figure 5. Countries with monitoring of ADRs



- Only about one half of middle-income countries monitored ADRs, mostly at the central level;
- International reporting was done by half of the countries.

In 2003, 13 countries reported monitoring ADRs and this number increased in 2007 to 18, with 14 countries participating in the WHO International Program for Drug Monitoring.

3.8 Prevention and Combat of Counterfeit Medicines

A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both brand-name and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient, or with fake packaging.[16]

Counterfeit medicines represent an enormous public health challenge. In some countries this is a rare occurrence, while in others it is an everyday reality. Even one single case of counterfeit medicine is unacceptable because, in addition to putting patients at risk and undermining the public's confidence in their medicines, it also betrays the vulnerability of the pharmaceutical supply system and jeopardizes the credibility of national health and enforcement authorities.[17]

Table 10. Counterfeit medicines

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Laws or regulations on counterfeit medicines	16	61.5	4	80,0	20	64,5
Detect counterfeit medicines by reports from:						
national authorities	18	81.8	4	100.0	22	84.6
specific/ad hoc studies	19	90.5	2	66.7	21	87.5
pharmaceutical sector	23	95.8	4	100.0	27	96.4
civil society/NGOs	16	84.2	3	100.0	19	86.4

- About 60% of middle-income and more than three-quarters of high-income countries reported having laws, regulations, programs, or procedures for detecting and combating counterfeit medicines;
- All sources were used to detect counterfeit medicines, but the pharmaceutical sector was the most used.

3.9. Prescribing and Dispensing of Generic Medicines

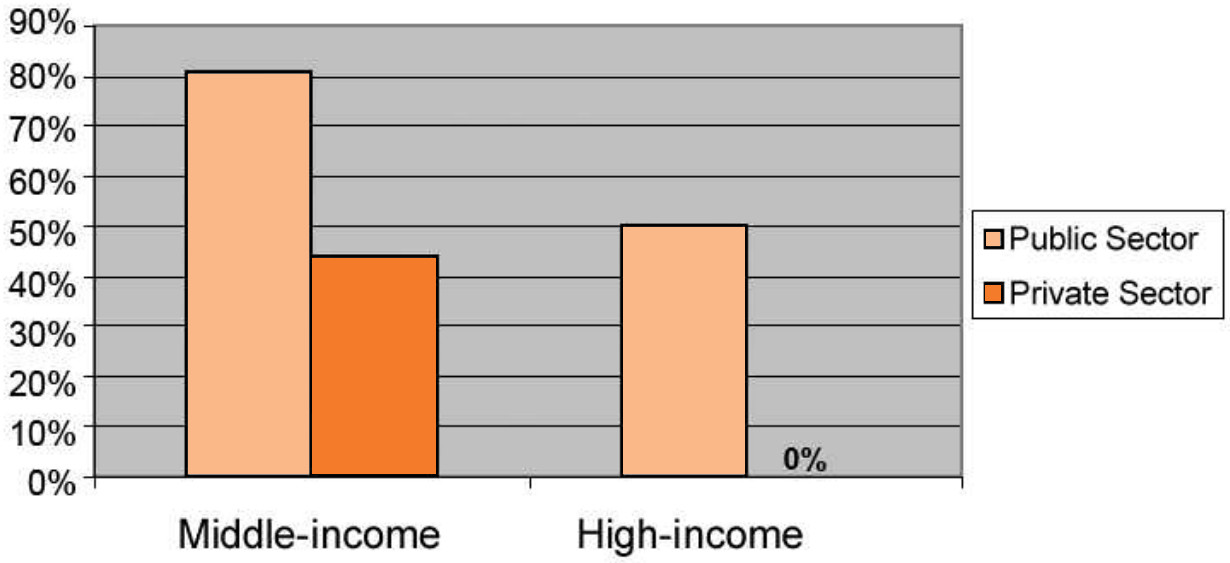
Selecting the best and safest medicine for an individual, out of a broad range of choices, requires a high level of expertise and considerable skill on the part of the prescriber or dispenser. Prescribing contra-indicated medications or the wrong dosage can have a major deleterious impact on the health of patients and even threaten their lives. Evaluating the eligibility of and providing education for prescribing and dispensing staff is therefore crucial in order to ensure appropriate and competent prescribing practices.[18]

The prescribers have an additional influence on whether to prescribe a branded medicine or, for the most part, the much less expensive generic variant. Cost effective prescribing can have a huge alleviating effect on the public health expenditure burden for countries. Establishing measures to promote or ensure generic prescribing can thus mean saving money, which can then be invested in other public health services.

Table 11. Legislation on prescribing and dispensing generic medicinesin the public and private sectors

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Prescribing generics mandatory in:						
Public sector	21	80.8	2	50.0	23	76.7
Private sector	10	43.5	0	0.0	10	37.0
Permitting generic substitution in:						
Public pharmacies	23	92.0	4	80.0	27	90.0
Private pharmacies	18	81.8	3	60.0	21	77.8
Incentives for dispensing of generics:						
Public pharmacies	6	24.0	2	40.0	8	26.7
Private pharmacies	5	21.7	1	25.0	6	22.2

Figure 6. Mandatory generic prescribing



- Most middle-income countries require generic prescribing in the public sector, but this was much less common for the private sector;
- Generic substitution was common in the public and private sectors of all countries;
- Incentives for generic dispensing were not very common.

The number of countries with a policy for mandatory prescribing of generics in the public sector varied from 21 in 2003 to 23 in 2007, and in the private sector from eight to 10 countries. With regard to permitting generic substitution, the number of countries increased from 21 in 2003 to 27 in 2007 in the public sector, and from 17 to 21 in the private sector.

BOX 3
GENERIC MEDICINES STRATEGY

The Pan American Health Organization/World Health Organization (PAHO/WHO) developed the "Guidelines for the Implementation Generic Medicines Strategies in Latin American and Caribbean Countries, for Improving Access to Medicines." This document was prepared by mandate of the Member States with the purpose of supporting countries in improving access to medicines.

A generics strategy is generally understood as a set of actions guided in a single direction that generates a framework of price competition in the medicines market.

The proposal considers the generic medicines strategies as part of the pharmaceutical policies, based in the concepts of essential medicines and quality assurance. The comprehensive nature of such strategies is sustained by the incorporation of all the recommended elements for the development of generic strategies.

The generic medicines strategies are an important element of pharmaceutical policies, which have shown their effectiveness in the improvement of accessibility because they generate competition in the pharmaceutical sector and contribute to price reduction, accordingly.

ELEMENTS OF A GENERIC MEDICINE STRATEGY

- Appropriate regulation that involves the aspects of registration, quality, prices, supply, prescribing, and dispensing.
- Promotion of the extended use of the "International Non-proprietary Name" (INN).
- Quality assurance of all marketed medicines.
- Establishment of economic incentives for supply and demand of generic medicines.
- Development of acceptance strategies for generic medicines among society and health professionals.
- Promotion of prescribing by generic name and responsible substitution.

GENERIC MEDICINES STRATEGIES AS A TOOL FOR PROMOTING RATIONAL USEl

Generic strategies can become an important tool in the promotion of rational use of medicines from different mechanisms, such as:

- Promotion and marketing of a generic list of medicines from the essential medicines list.
- Use of the INN in registration, on labels and inserts, in purchasing, in prescribing and dispensing, as well as in the process of information dissemination to health workers and the community in general.
- Regulation, evaluation, and authorization of publicity and advertisement of brands.

The above three considerations can guide efforts for the fulfillment of one of the central objectives of the pharmaceutical policies: avoiding wasteful use of therapeutic resources. Moreover, these considerations also help to diminish the possible distortion and confusion of information associated with commercial brand names.

3.10 Promotion and Advertising

Given the known impact of advertising and promotion of medicines on both prescribing behavior and patient demand, it is essential to regulate and monitor medicines promotion to ensure that it remains ethical. All promotional claims should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation, and in good taste.[19]

Table 12. Promotion and advertising

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Legislation on promotion/advertising	20	80.0	5	100.0	25	83.3
Responsible agency for regulating promotion/advertising:						
Industry	3	11.5	1	20.0	25	14.3
Government or national regulatory authority	19	73.1	3	60.0	22	78,6
Co-regulation	1	3.8	1	20.0	2	7.1
Government regulation including:						
Pre-approval for advertisement/promotion	16	80.0	0	0.0	16	72.7
Ban on public advertising	17	85.0	3	100.0	20	87.0
Guidelines on the advertising of over-the-counter (OTC) medicines	14	70.0	0	0.0	14	63.6
Civil society/NGOs taking an active part in monitoring promotional/advertising activities	8	33,3	2	66,7	10	37,0

- Most countries reported having legislation on promotion and advertisement of medicines;
- Government or the national regulatory authority was most often the responsible agency for regulating promotion and advertising in middle-income countries;
- Civil society/NGOs play a minor role in monitoring advertising in middle-income countries.

4. MEDICINES SUPPLY SYSTEM

A well-coordinated medicines supply system helps to ensure that funds available for the procurement of medicines are used effectively and efficiently. Failures in the supply system can lead to life-threatening medicines shortages and waste of scarce resources. Problems frequently result when an inefficient public medicines supply system is intended to serve an entire country and/or more efficient private sector supply systems only serve urban populations.

It can be assumed that there is a tendency for NGOs and private organizations in low-income countries to be involved in procurement and distribution, specifically in relation to aid programs and as a means to address capacity and infrastructure problems. The existence of a large number of different partners, with their own medicine supply strategy, has led to a lack of coordination of supply systems, resulting in duplication, inefficiency, and increased workload, especially at the level of facilities. The selective approach to priority diseases has resulted in neglect of other important conditions, such as chronic illnesses and common childhood diseases.[4]

The fragmentation and segmentation in the health care services, and consequently in management supply systems; the "verticalization" of public health programs (such as HIV/AIDS, tuberculosis, malaria, and others); and the involvement of multiple stakeholders can be observed in the region. In addition, the steering role of the health ministries in the health sector is weak, including the disarticulation with other institutions and actors in the health sector, such as social security. The consequence of all of this is duplication of efforts, loss of resources, and compromise in the quality of the services delivered.

Individual facility-based purchasing may be introduced with a view to improving the efficiency of medicines management by locating decisions about medicine purchasing closer to the point of use. However, the purchase of medicines by individual health institutions often lacks transparency, and may not benefit from the economies achieved by bulk purchasing and centralized tendering and procurement.

Table 13. Public sector procurement and distribution (PSP)

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
PSP pooled at national level	21	80.8	4	80.0	25	80.6
Responsible for PSP:						
Health ministry						
Procurement	23	92.0	3	75.0	26	89.7
Distribution	17	89.5	1	50.0	18	85.7
NGOs						
Procurement	4	28.6	0	0.0	4	25.0
Distribution	2	22.2	0	0.0	2	20.0
Private institution						
Procurement	1	7.1	1	50.0	2	12.5
Distribution	2	20.0	1	100.0	3	27.3
Individual health institution						
Procurement	10	55.6	1	33.3	11	52.4
Distribution	8	66.7	1	50.0	9	64.3

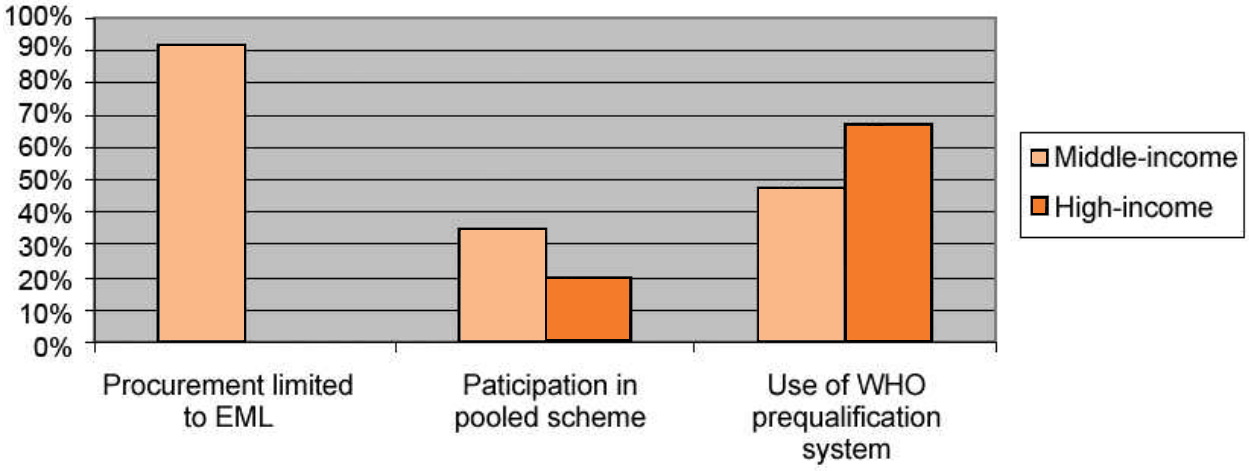
- Most countries have pooled procurement in the public sector at the national level;
- The health ministries were the main public sector procurement agencies, followed by individual health institutions. Private institutions played only a marginal role in middle-income countries. NGOs had a role in middle-income countries, but not in high-income countries;
- The health ministries were the main distribution agencies in both middle- and high-income countries;
- Non response rates were very high, especially for distribution.

In 2003, the health ministry performed the procurement function in 19 countries, increasing to 26 countries by 2007. The distribution function was performed by the health ministry in 12 countries in 2003, and in 18 countries by 2007. Procurement and distribution were performed by an NGO in two countries in 2003. In 2007, procurement was performed by an NGO in four countries and distribution in two countries. Procurement was performed by individual health institutions in 11 countries in both 2003 and 2007.

Table 14. Essential medicines list (EML) procurement and tender process for public sector procurement

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Public sector procurement limited to the EML	11	91,7	n.d.	n.d.	11	91.7
Provisions for medicines outside EML	13	52	0	0.0	3	46.4
Participation in pooled procurement scheme	9	37.5	1	20.0	10	34.5
Tender board overseeing public sector procurement	19	79.2	4	100.0	23	82.1
Separation of procurement office and tender committee	16	88.9	3	100.0	19	90.5
Use of WHO prequalification system	9	47.4	2	66.7	11	50.0
Type of tender						
National competitive tender	18	85.7	1	50.0	19	82.6
International competitive tender	16	69.6	3	100.0	19	73.1
Negotiation/direct purchasing	19	86.4	0	0.0	19	82.6
	Median (25th, 75th percentile)		Median (25th, 75th percentile)		Median (25th, 75th percentile)	
National competitive tender	80 0 9 | 2.5 11		45 22.5 | 67.5 2		80 0 | 90 13	
International competitive tender	3 0 | 15 11		55 32.5 | 77,5 2		3 0.5 | 15 13	
Negotiation/ direct purchasing	9,5 1.5 | 46.3 12		0 0 | 0 2		7 0 | 46.3 14	

Figure 7. Public sector procurement process



- In most middle-income countries, public sector procurement was limited to the EML, but there was a high rate of non response;
- In most countries, an independent tender board committee was overseeing public sector procurement;
- The WHO prequalification scheme was used in only a few middle-income countries and 30% took part in pooled procurement schemes;
- In most countries, national competitive tender and direct purchasing were used, while international competitive tender was less common.

Seventeen countries in 2003 and 19 countries in 2007 used national competitive tender, while countries that reported using an international competitive tender increased significantly; from 11 in 2003 to 19 in 2007. In addition, negotiation/direct purchasing varied from 10 in 2003 to 19 in 2007. However, it was observed that the countries used more than one procurement mechanism. In 2007, public sector procurement was limited to the essential medicines list (EML) in 11 countries.

BOX 4
STRATEGIC FUND

The Strategic Fund is a program of reimbursable procurement through which Pan American Health Organization/World Health Organization (PAHO/WHO) Member States and beneficiaries of the Global Fund against HIV/AIDS, Tuberculosis and Malaria (GFATM) can purchase strategic public health supplies, including medicines for the treatment of HIV, tuberculosis, malaria, and leishmaniasis, among others.

The Strategic Fund, also known as the Regional Revolving Fund for Strategic Public Health Supplies, was created by PAHO in September 2000 to promote the acquisition of high quality medicines and essential public health supplies at affordable prices in the Americas.

Origin

The Strategic Fund has been developed by the Secretariat of the PAHO/WHO at the request of Member States, and for the benefit of Member States (1999).

Participation

Participation in the Strategic Fund is open to all PAHO Member States and GFATM principal beneficiaries by signing a participation agreement with the Organization.
There are presently 20 countries in the region that have signed an agreement for participation.

The Strategic Fund's objectives are to:

- Facilitate the acquisition of Strategic Public Health Supplies by PAHO Member States at reduced cost by taking advantage of the potential savings offered by economies of scale;
- Further the continuous availability of public health supplies within PAHO Member States;
- Encourage Member States to improve planning capabilities and the use of public health supplies;
- Strengthen Member States' public health programs and the application of pertinent PAHO/WHO normative mandates.

Challenges Facing Member States in Access

The challenges facing Member States of the Pan America Health Organization, Regional Office of the World Health Organization in the Region of the Americas, in improving access to strategic public health supplies lie principally in important areas of selection of quality products, financing and procurement, cost containment, intellectual property regulation, and supply management.

Webpage: www.paho.org/strategicfund

5. MEDICINES FINANCING

In developing countries, expenditure on medicine accounts for 25-65 percent of total public and private health expenditure, and for 60-90 percent of out-of-pocket household expenditure on health.[20] Poor households are more likely to incur catastrophic expenditures (greater than 40 percent of income, after subsistence needs are met) when health services, including medicines, require payments, and when there is no prepayment or health insurance scheme.[21]

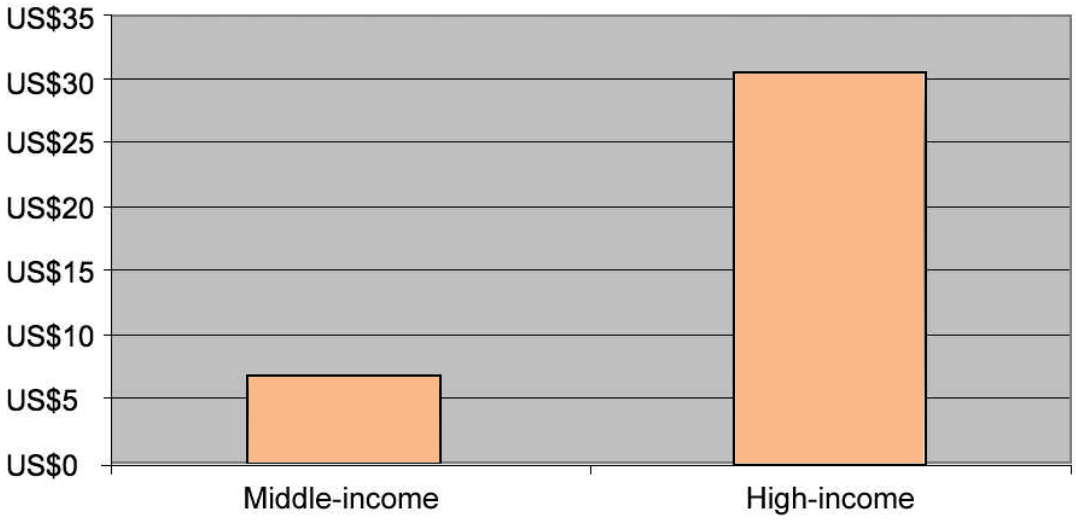
Increased public funding is important to achieve high public health impact and equitable access in most countries. Another strategy is the provision of medicines benefits through social health insurance and prepayment schemes.

Access to specific treatments for high priority conditions has life-saving implications for individuals and major public health benefits for communities. A medicines pricing policy is also an important strategy, since the price of medicine is one of the most important obstacles to access. Pricing regulation and policies can provide a good basis for equitable access, provided they are effectively enabled. Medicine prices can be inflated in current market environments. In recent years, WHO has put effort into developing a standardized methodology for surveying medicines prices and conducted numerous pricing surveys in WHO Regions.[22]

Table 15. Total per capita public expenditure for medicines in US$

	Country income level			
	Middle		High	
	Median (25th, 75th percentile)			
Per capita public expenditure for medicines in $US	US$ 6,80		US$ 30,50	
	US$ 3,90	US$ 14,40	US$ 29,90	US$ 154,70
	N=21		N=3	

Figure 8. Per capita public medicine expenditure in US$



- The per capita public or government expenditure on medicines was much higher in high-income as compared to middle-income countries; however, some countries gave very low values.

Table 16. Free provision of medicines in public health care facilities

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
National policy including some medicines free of charge	26	100.0	5	100.0	31	100.0
Types of free medicines:						
All medicines	14	66.7	3	100.0	17	70.8
Malaria medicines	16	84.2	2	100.0	18	85.7
Tuberculosis medicines	21	91.3	3	100.0	24	92.3
Sexually transmitted infections medicines	14	73.7	3	100.0	17	77.3
HIV/AIDS-related medicines	21	95.5	3	100.0	24	96.0
At least one vaccine	22	100.0	3	100.0	25	100.0

Continued

Table 16. Continued

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Patients receiving free medicines:						
Patients who cannot afford medicines	22	91.7	4	100.0	26	92.9
Children under 5 years of age	22	95.7	4	100.0	26	96.3
Older children	16	80.0	4	100.0	20	83.3
Pregnant women	20	87.0	4	100.0	24	88.9
Elderly	18	81.8	4	100.0	22	84.6

- All the countries reported providing some medicines free of charge, these most often being tuberculosis and HIV/AIDS-related medicines at the primary care level;
- High income countries were better able to subsidize access by providing free medicines, either for all conditions or for specific diseases;
- In practically all middle income countries, free medicines were provided to patients unable to afford them, to patients below 5 years of age, and to pregnant women.

In general, the number of countries where medicines for different diseases were provided to the population free of charge increased in 2007 as compared with 2003. The number of countries where all medicines were provided free of charge was 14 in 2003 and 17 in 2007. For malaria, the number of countries with medicines provided free of charge in 2003 was 14 and in 2007 it was 18. For tuberculosis, the variation was from 18 in 2003 to 24 in 2007. For sexually transmitted infections (STIs), the variation was from 15 to 17. For HIV/AIDS, the variation was significant, from 14 in 2003 to 24 in 2007.

In 2003, 15 countries reported that medicines were free for those who could not afford them, increasing to 26 countries by 2007. The reporting of availability of free medicines for children under five years varied from 16 countries in 2003 to 26 in 2007. The provision of free medicines for pregnant women varied from 15 countries in 2003 to 24 countries in 2007. The greatest variation was observed in the reporting of free medicines for the elderly, where availability varied from seven countries in 2003 to 22 in 2007.

Table 17. Fees for medicines

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Types of fees charged:						
Registration*/ consultation fees	22	100.0	5	100.0	27	100.0
Dispensing fees	2	8.7	1	20.0	3	10.7
Flat fees for medicines	4	18.2	1	20.0	5	18.5
Flat rate co-payments for medicines	4	17.4	1	20.0	5	17.9
Percentage co-payments for medicines	5	25.0	1	25.0	6	25.0
How often fees are used to pay salaries:						
Always	0	0.0	0	0.0	0	0
Frequently	0	0.0	0	0.0	0	0
Occasionally	3	13.6	0	0.0	3	11.5
Never	19	86.4	4	100.0	23	88.5

* It is possible that the way this is stated could cause misunderstanding, as registration is a regulatory action (normally charged) not related to consultation during medical visits; therefore, some countries reporting that all of the population is covered by public health insurance could have answered this question inaccurately.

- All the countries charged registration/consultation fees in primary care facilities. Dispensing fees and fees for medicines were less common, especially among middle-income countries;
- In most countries, fees from the sale of medicines were not used to pay salaries.

In 2003, the number of countries reporting that fees were never used for paying salaries was 12, but the rate of response was low. The corresponding figure for 2007 was 23 countries..

Table 18. Dispensing of medicines in the public and private sector

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Dispensing of medicines by prescribers						
Public Sector						
Always	0	0.0	0	0.0	0	0.0
Frequently	0	0.0	0	0.0	0	0.0
Occasionally	7	28.0	2	40.0	9	30.0
Never	18	72.0	3	60.0	21	70.0
Private Sector						
Always	0	0.0	0	0.0	0	0.0
Frequently	4	16.7	1	20.0	5	17.2
Occasionally	10	41.7	3	60.0	13	44.8
Never	10	41.7	1	20.0	11	37.9

- Public sector prescribers rarely, if ever, dispense medicines, while private prescribers were reported to be more likely to dispense.

Table 19. Health insurance and medicines coverage

		Middle-income		High-income		TOTAL	
		Number of countries	%	Number of countries	%	Number of countries	%
Population covered by health insurance							
All	Public sector	4	16.7	1	33.3	5	18.5
	Private Sector	1	4.5	1	25.0	2	7.7
Some	Public sector	18	75.0	2	66.7	20	74.1
	Private Sector	21	95.5	3	75.0	24	92.3
None	Sector público	2	8.3	0	0.0	2	7.4
	Sector privado	0	0.0	0	0.0	0	0.0
Medicines covered by health insurance							
All	Public sector	5	22.7	1	20.0	6	22.2
	Private Sector	3	15.8	1	33.3	4	18,2
Some	Public sector	15	68.2	2	40.0	17	63.0
	Private Sector	18	84.2	2	667	18	81.8
None	Public Sector	2	9.1	2	40.0	4	14.8
	Private Sector	0	0.0	0	0.0	0	0.0

- One-fifth of middle-income countries had public health insurance covering the entire population;
- Most countries had at least some people insured with either private or public insurance; Both public and private insurance usually offered coverage for at least some medicines.

The number of countries with some of the population covered by public health insurance varied from 10 in 2003 to 20 in 2007, while those with some of the population covered by private health insurance varied from 16 in 2003 to 24 in 2007.

In 2003, the number of countries that reported coverage of all medicines by the public sector was four and in 2007 there were six. One country reported having no public-sector medicines coverage in 2003 and four such countries in 2007. There was a substantial increase in the number of countries providing some medicines coverage through private insurance, from 11 in 2003 to 18 in 2007. The number of countries covering all medicines through private insurance showed no change between the two years sampled.

Table 20. Policies on medicines pricing covering different sectors

		Middle-income		High-income		TOTAL	
		Number of countries	%	Number of countries	%	Number of countries	%
Policy covering medicine prices	Public sector	14	53.8	2	50.0	16	53.3
	Private Sector	10	41.7	2	50.0	12	42.9
	NGO	4	21.1	0	0.0	4	18.2
If yes, which areas are covered?							
Maximum wholesale mark-up	Public sector	7	53.8	1	50.0	8	53.3
	Private Sector	7	70.0	1	50.0	8	66.7
	NGO	4	50.0	n.d.	n.d.	4	50.0
Maximum retail mark-up	Public sector	8	61.5	1	50.0	9	60.0
	Private Sector	10	90.9	1	33.3	11	70.6
	NGO	4	44.4	1	100.0	5	50.0
Duty on raw pharmaceutical materials	Public sector	4	30.8	1	50.0	5	33.3
	Private Sector	8	61.5	2	66.7	10	62.5
	NGO	4	50.0	0	0.0	4	444
Duty on finished pharmaceutical materials	Public sector	5	38.5	1	33.3	6	37.5
	Private Sector	10	76.9	2	50.0	12	70.6
	NGO	5	55.6	0	0.0	5	45.5

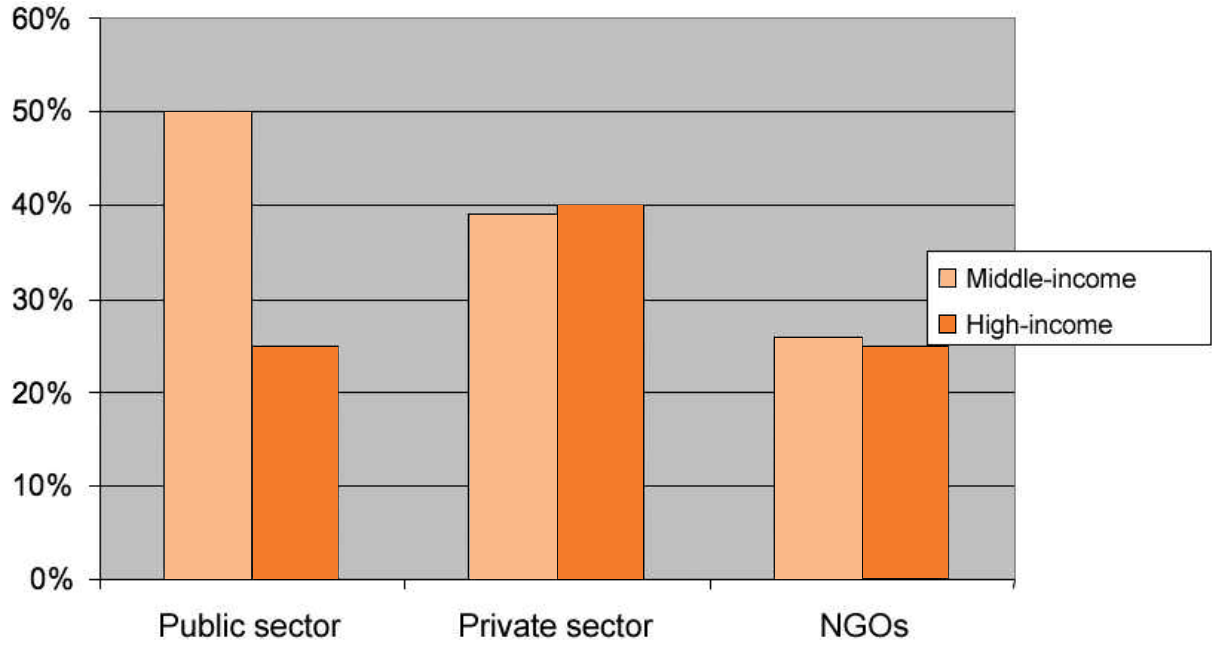
- Price regulation was being carried out by slightly more than half of the middle-income countries;
- Over half of the countries included maximum wholesale and retail mark-up policies in their public and private sector pricing policy;
- Duties on pharmaceutical materials were more common in the private sector than in the public sector.

The number of countries with a public sector policy on medicines pricing increased from 10 in 2003 to 16 in 2007, and for the private sector from 10 in 2003 to 12 in 2007. In the case of NGOs, however, the countries with a policy on medicines pricing decreased from six in 2003 to four in 2007.

Table 21. Monitoring, information, and guidelines on medicine prices and donations

		Middle-income		High-income		TOTAL	
		Number of countries	%	Number of countries	%	Number of countries	%
Monitoring system for prices	Public sector	13	50.0	1	25.0	14	46.7
	Private sector	9	39.1	2	40.0	11	39.3
	NGO	5	26.3	0	25.0	6	26.1
Regulations on accessibility of medicine price information	Public sector	7	28,0	1	50.0	9	31.0
	Private sector	3	14.3	2	40.0	5	19.2
	NGO	2	10.5	0	25.0	3	13.0
Guidelines on medicine donations	Public sector	19	73.1	1	100.0	24	77.4
	Private sector	10	52.6	2	66.7	12	54.5
	NGO	11	64.7	0	50.0	13	61.9

Figure 9. Retail price monitoring system



- Retail price monitoring systems had been set up in the public sector in about half of the middle-income countries, but they were less common for the private sector, and regulation on accessibility of information is even less common;
- Official published guidelines governing the donation of medicines were common in both middle- and high-income countries.

6. PRODUCTION, TRADE, AND INTELLECTUAL PROPERTY

Intellectual property rights (IPR) have an important impact on affordability and availability of medicines and thereby on public health. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) requires that WTO Members provide minimum standards of intellectual property protection, including patent protection. Patent protection grants exclusive rights to the patent holder for the use, manufacture, and sale of a medicine.

During the term of the patent, which can range from 15 to 20 years, the patent holder has a monopoly on the medicine, which prevents generic competition as a means of reducing prices. The more disadvantaged populations in developing countries cannot pay the same prices as those paid in wealthier countries for newer medicines. TRIPS-compliant mechanisms can be used to access lower-priced medicines.[23] It is important to consider adapting national legislation to incorporate all flexibilities available in the TRIPS Agreement (see below) to safeguard access to essential medicines for all.

It is crucial that countries assess the impact of the TRIPS Agreement and other international, regional, and bilateral trade agreements. WHO supports its Member States in the use of TRIPS flexibilities to enhance the affordability and availability of medicines. These safeguards also include setting the criteria for the patentability of pharmaceuticals, which adequately reflect public health concerns, legislative provisions for compulsory licensing, government use authorization, parallel importation, exceptions to exclusive patent rights, and other measures that promote generic competition and extension of the transition period.

There are variations in the manner with which the provision for such flexibilities have been incorporated into national legislation[24]; thus, there are limitations on the totality of the information on TRIPS flexibilities presented in the tables below. For example, provisions on parallel importation may exist in some countries, but there may be limitations that restrict parallel importation, such as when the explicit consent of the patent holder is required before parallel importation can take place. In such cases, the so-called flexibility is lost. In addition, there are essentially two kinds of parallel importation regimes: international exhaustion and regional exhaustion. When the international exhaustion regime is incorporated into national legislation, parallel importation of a product will be permitted into the country from anywhere else, whereas regional exhaustion (as for the whole of the European Union) would allow products to be imported only from within a particular regional grouping. There may,

therefore, be differences in the parallel importation provision, which will be important in determining whether or not the flexibilities are maintained.

Similar variations also exist in countries in terms of their legal provisions for compulsory licensing. While compulsory licensing provisions exist within most national legislation, such provisions may differ, for example, in terms of the various grounds on which compulsory licenses may be granted. It was agreed in the Doha Declaration, concerning the TRIPS Agreement and Public Health, that WTO Member States were free to determine the grounds on which compulsory licenses may be granted. However, this flexibility may not have yet been properly incorporated in all national legislation.

Article 65 of the TRIPS Agreement provides for four separate and different transition periods. The first transition period was in 1995, when developed country WTO Members had to implement the TRIPS Agreement, but developing country Members had to implement the basic TRIPS provision of most-favored-nation and national treatment. The second transition period was on 1 January 2000, at which time the developing countries were to implement the TRIPS Agreement. The third transition period is for centrally-planned economies, and finally the fourth transition period expired on January 1, 2005, at which time those countries that had delayed product patent protection for certain types of products and technology—such as pharmaceuticals—were required to provide such protection.

Some information on the local production of medicines aimed at improving access to high-quality, low-cost medicines, is also included below. A key challenge is to determine whether the circumstances for successful local production are being met, so that investment in local production is not at the expense of the cost or quality of medicines.

Table 22. National capacity for research and production of medicines

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Medicines production capability						
R&D of new active substances	5	20.8	1	20.0	6	20.7
Production of pharmaceutical raw materials	5	20.8	1	20.0	6	20.7
Formulation from raw materials	22	84.6	4	80.0	26	83.9
Repackaging of finished dosage forms	22	84.6	3	75.0	25	83.3

- Approximately 20 percent of countries had the capacity to research new substances and produce pharmaceutical raw materials;
- Most countries were capable of producing formulations from raw materials and to repackage finished dosage forms.

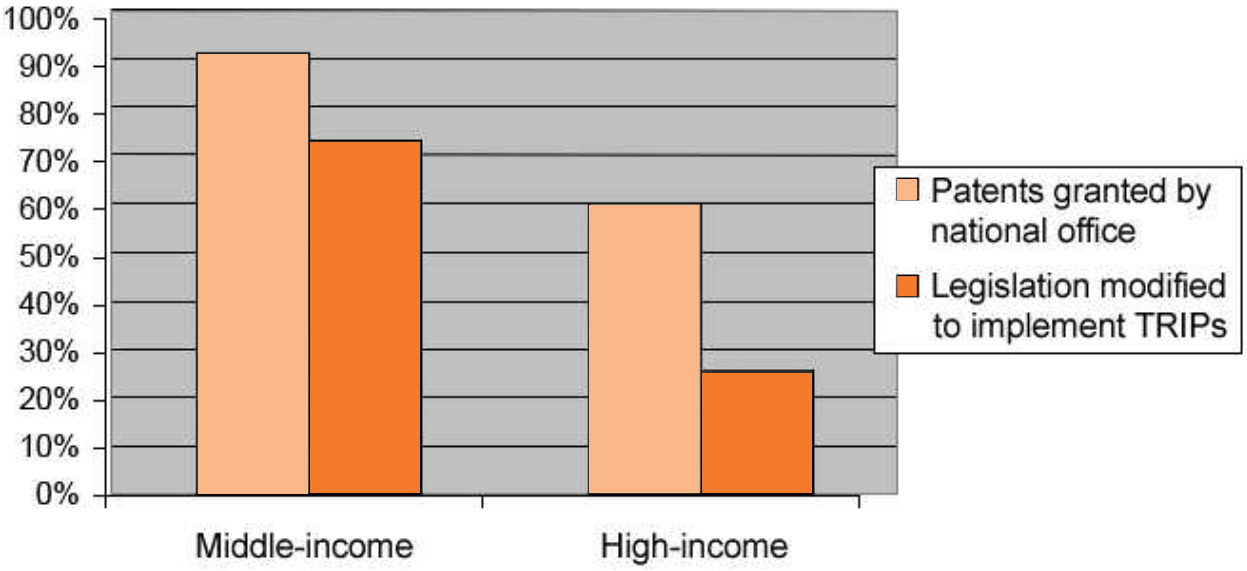
The region has low capacity for research and development (R&D) and for the production of pharmaceutical raw materials, but there was a slight improvement from 2003 to 2007. In 2003, two countries reported having capacity for R&D and in 2007 six countries reported having it. Regarding the production of pharmaceutical raw materials, the variation was from four in 2003 to six in 2007. The number of countries reporting having capacity for formulation from raw materials increased from 19 in 2003 to 26 in 2007, and for repackaging of finished dosage forms the number of countries increased from 18 in 2003 to 25 in 2007.

Table 23. Patent rights, trade, and the TRIPS flexibilities

		Middle-income		High-income		TOTAL	
		Number of countries	%	Number of countries	%	Number of countries	%
Patents granted by national office		20	53.8	22	71.0	23	85.2
National legislation modified to implement TRIPS		16	53.8	22	71.0	17	65.4
TRIPS Article 65		7	53.8	2	50.0	9	42.9
Less Developed Countries (LDCs): TRIPS Article 66		1	10.0	0	0.0	1	9.1
Doha declaration (Paragraph 7)		5	29.4	0	0.0	5	26.3
TRIPS implemented in national legislation							
Compulsorylicensing	Yes	11	52.4	2	40.0	13	50.0
Government use	Yes	9	47.4	2	40.0	11	47.8
Parallel importing provisions	Yes	8	38.1	0	0.0	8	43.5
Bolar exception	Yes	9	47.4	1	25.0	10	58.8

- Patents were granted by a national office in almost all of the middle-income and in over half of the high-income countries;
- About three-quarters of middle-income countries modified their legislation to implement TRIPS;
- The transitional period (especially Article 65) had been used by a significant proportion of countries;
- All of the four listed TRIPS flexibilities had been used by about 50 percent of middle-income countries, except parallel importing provisions, which fell below.

Figure 10. Intellectual property protection



In 2003, eight countries reported having modified their national legislation to implement the TRIPS Agreement; three countries were availing themselves of the provisions of Article 65 of TRIPS, and none reported availing themselves of Article 66 of TRIPS. In 2007, 17 countries reported having modified their legislation to implement the TRIPS Agreement, nine with provisions for TRIPS Article 65, one with provisions for TRIPS Article 66, and five with provisions for Paragraph 7 (according to the Doha Declaration).

In 2003, five countries had incorporated the provisions for parallel imports, although the response was very low. In 2007, eight countries reported the inclusion of this provision in their legislation. Compulsory licensing had been included in six countries in 2003, and in 2007 the number of countries with this legal provision had more than doubled to 13. With regard to the Bolar exception, five countries reported having included this provision in their legislation in 2003 and 10 by 2007.

7. ESSENTIAL MEDICINES AND RATIONAL USE

Rational use of medicines means 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"[25]. Over use, under use, and misuse of medicines may lead to unnecessary suffering and death, and to wastage of scarce resources. Examples of irrational use of medicines include:

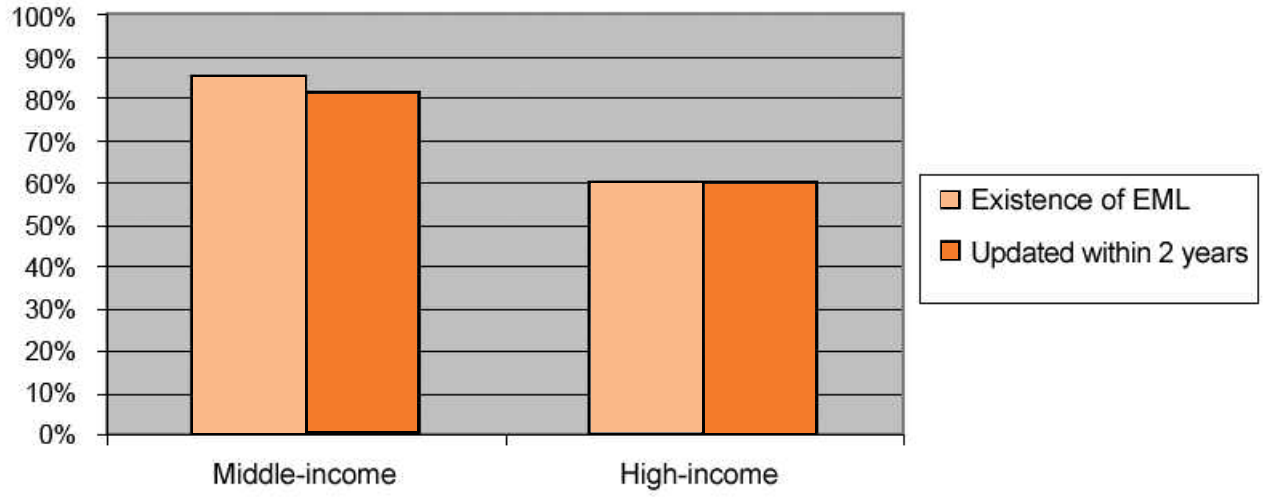
- Use of antibiotics for non-bacterial illnesses, thus contributing to increased antimicrobial resistance;
- Non-adherence to recommended dosing regimens, preventing desired therapeutic outcomes from being achieved, and potentially increasing antimicrobial resistance; and
- Use of expensive and frequently unsafe injections when less expensive oral formulations would be more appropriate, contributing to increased incidence of hepatitis B and C, and HIV.
- Many factors influence the use of medicines, and countries need to implement various strategies to improve rational use. Some policies, strategies, and interventions found to be of value include: creating a mandated multidisciplinary national body to coordinate policies on medicine use; standard treatment guidelines (STGs) for common conditions; using essential medicines lists (EMLs) to guide procurement and training; establishing drug and therapeutics committees to coordinate medicines selection and management in hospitals; implementing problem-based pharmacotherapy training in undergraduate curricula; mandating continuing in-service medical education as a licensure requirement; establishing effective supervision in health systems; using audit and feedback to inform clinicians and facilities about their practice; developing independent sources of information about medicines for providers and consumers; avoiding perverse financial incentives to overuse medicines; establishing and enforcing a sound regulatory framework; and guaranteeing sufficient government expenditure to ensure the availability of medicines and retain well-trained staff.2[6,27].

Table 24. Availability and status of essential medicines list (EML)

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Existence of EML*	22	84.6	3	60.0	25	80.6
EML updated within the last 5 years**	21	80.7	3	60.0	24	77.4
No separate pediatric EML	19	86.4	2	66.7	21	100.0
Use of EML in different sectors						
Public sector procurement	21	87.5	3	100.0	24	88.9
Public insurance reimbursement	8	40.0	1	50.0	9	40.9
Private insurance reimbursement	2	10.5	1	50.0	3	14.3
Committee for EML medicines selection	21	87.5	3	100.0	24	88.9
	Median (25th, 75th percentile)		Median (25th, 75th percentile)		Median (25th, 75th percentile)	
Number of medicines in EML	508		580		512	
	383	600	580	580	386	598
	21		1		N=22	
Pediatric formulations in national EML	58.5		n.d.		58.5	
	29.25	263.5	n.d.	n.d.	29.5	263.5
	10		0		10	

* Including all countries with EML (irrespective if year of update was indicated or not)
** It was here assumed that those countries not providing dates had not updated their EML within the last five years

Figure 11. Essential medicines list



- Most middle-income countries had an EML list. Almost all existing EMLs in the Region of the Americas have been updated within the last 5 years;
- EMLs were commonly used in public sector procurement across all countries. They were used for public insurance reimbursement in about half of the middle-income countries, but were rarely used for private insurance reimbursement;
- Almost all countries had a committee for EML medicine selection.

There was minimal variation in the number of countries with an EML between 2003 and 2007 (from 22 to 25). The median number of medicines in the EML varied from 400 in 2003 to 512 in 2007. However, the range between percentiles did not change significantly. The number of countries that updated their EML within the past five years varied from 20 in 2003 to 24 in 2007.

Almost all countries with an EML used it in public sector procurement (21 in 2003 and 24 in 2007). In public insurance reimbursement, the usage of the EML varied from eight countries in 2003 to nine countries in 2007. The use of the EML for private insurance reimbursement was insignificant in both periods, increasing from two countries in 2003 to three in 2007.

Table 25. Standard treatment guidelines and medicines formulary manual

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
National standard treatment guidelines	22	88.0	3	75.0	25	86.2
National standard treatment guidelines updated within the past 5 years*	11	44.0	1	25.0	12	41.4
Hospital level guidelines	16	66.7	3	75.0	19	67.9
Primary care guidelines	19	79.2	4	100.0	23	82.1
Standard treatment guidelines for key pediatric illnesses	16	80.0	3	75.0	19	79.2
Medicines formulary manual	20	76.9	3	75.0	23	76.7
Formulary updated within the last 5 years*	13	50.0	3	75.0	16	53.3
Covering only EML medicines	12	66.7	1	33.3	13	61.9

*It was here assumed that those countries that did provide a date had not updated their STGs/formulary within the past 5 years.

- Standard treatment guidelines (STGs) were available at the national level in most of the countries. Hospital and primary care guidelines were slightly less common;
- Yet, less than 50 percent of national guidelines had been updated within the past 5 years;
- Most of the countries had STGs for key pediatric illnesses;
- Medicines formulary manuals existed in almost 80 percent of countries, but usually contained only EML medicines.

There was a significant increase in the number of countries that reported having national standard treatment guidelines (STGs), from 13 in 2003 to 25 in 2007. For STGs at the hospital level, ten countries reported having these in 2003 and 19 in 2007, while at the primary health care level, 12 countries had them in 2003 and 23 in 2007.

Nineteen countries reported having a national formulary in 2003 and 23 countries by 2007. In 2003, 17 countries reported that their national formulary manuals covered only the EML and in 2007 this decreased to 13 countries. The number of countries that reported having the last update of the medicines national formulary within the past five years varied from 13 in 2003 to 16 in 2007.

Table 26. Types of basic medicines training available to health workers

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
EML concepts						
Physicians	12	54.5	3	100.0	15	60.0
Nurses	12	54.5	3	100.0	15	60.0
Pharmacists	11	52.4	3	100.0	14	58.3
Pharmacy assistants	7	30.4	1	25.0	8	29.6
Paramedical staff	5	31.3	1	50.0	6	33.3
STG concepts						
Physicians	12	60.0	1	50.0	12	59.1
Nurses	11	55.0	1	100.0	12	57.1
Pharmacists	7	38.9	1	50.0	8	40.0
Pharmacy assistants	5	23.8	0	0.0	5	21.7
Paramedical staff	5	33.3	1	100.0	6	37.5
Pharmacotherapy training						
Physicians	13	68.4	2	100.0	15	71.4
Nurses	8	47.1	2	100.0	10	52.6
Pharmacists	8	47.1	2	100.0	10	52.6
Pharmacy assistants	3	14.3	0	0.0	3	13.0
Paramedical staff	2	13.3	1	100.0	3	18.8
Rational prescribing concepts						
Physicians	13	65.0	2	100.0	15	68.2
Nurses	9	47.4	2	100.0	11	52.4
Pharmacists	9	47.4	2	100.0	11	52.4
Pharmacy assistants	3	13.0	0	0.0	3	12.0
Paramedical staff	3	18.8	1	100.0	4	23.5

- Physicians, nurses, and pharmacists were exposed to the concepts of EMLs, STGs, pharmacotherapy training, and rational prescribing in more than half of the countries;
- Pharmacy assistants and paramedical staff were exposed to the above-mentioned concepts to a lesser extent, especially to pharmacotherapy and rational prescribing.

Regarding the presence of rational medicine use concepts in the training of health workers, a significant variation was observed between 2003 and 2007. With respect to EML concepts, variations for physicians, nurses, pharmacists, pharmacy assistants, and paramedical staff were from eight to 15, from eight to 15, from 15 to 14, from four to eight, and from four to six countries, respectively.

Regarding countries that have training available on STG concepts, there was a significant increment in the case of nurses and pharmacists; from six to 12 for nurses and from five to eight for pharmacists. In 2007, STG concepts were reported to be present in physician training in 13 as opposed to 10 countries in 2003; of pharmacy assistants in five as opposed to two countries in 2003, and of paramedical staff in six as opposed to two countries in 2003.

The availability of training in pharmacotherapy showed a significant increase in 2007 for all categories of health workers. Pharmacotherapy training for physicians varied from nine countries in 2003 to 15 in 2007; for nurses from only one country in 2003 to 10 in 2007; for pharmacists from six countries in 2003 to 10 in 2007, and for both pharmacy assistants and paramedical staff from zero in 2003 to three countries in 2007.

Rational prescribing concepts were reported to be present in physicians' training in 10 countries in 2003; in nurses' training in six countries; and in pharmacists' training in eight countries. In 2007, these concepts were reported to be present in physicians' training in 15 countries, and in nurses' and pharmacists' training in 11 countries. Pharmacy assistants and paramedical staff had pharmacotherapy training in three and four countries, respectively.

Table 27. Education and information for health workers

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Education Programs:						
Physicians	8	34.8	2	50.0	10	37.0
Nurses, midwives & paramedical staff	6	25.0	2	50.0	8	28.6
Pharmacists	8	32.0	2	50.0	10	34.5
Pharmacy aides/assistants	1	4.3	1	33.3	2	7.7
Medicines Information center:						
Prescribers	14	56.0	2	40.0	16	53.3
Dispensers	14	56.0	2	40.0	16	53.3
Consumers	13	52.0	1	20.0	14	46.7
Education campaigns:						
Use of antibiotics	10	40.0	0	0.0	10	34.5
Use of injections	3	13.0	0	0.0	3	11.1

- Continuing education requirements were higher for physicians and pharmacists than for nurses; it was very low for pharmacy aides;
- Medicines information centers were available for access by prescribers, dispensers, and consumers in about 50% of countries;
- Education campaigns were more common for the use of antibiotics than for the use of injections.

Regarding the existence of an independent medicines information center, 12 countries reported having one in 2003 and 16 countries in 2007.

With respect to public education campaigns, nine countries reported such campaigns on the use of antibiotics and five on the use of injections in 2003. In 2007, 10 countries reported conducting campaigns on the use of antibiotics and three on the use of injections.

Table 28. Prescribing practices

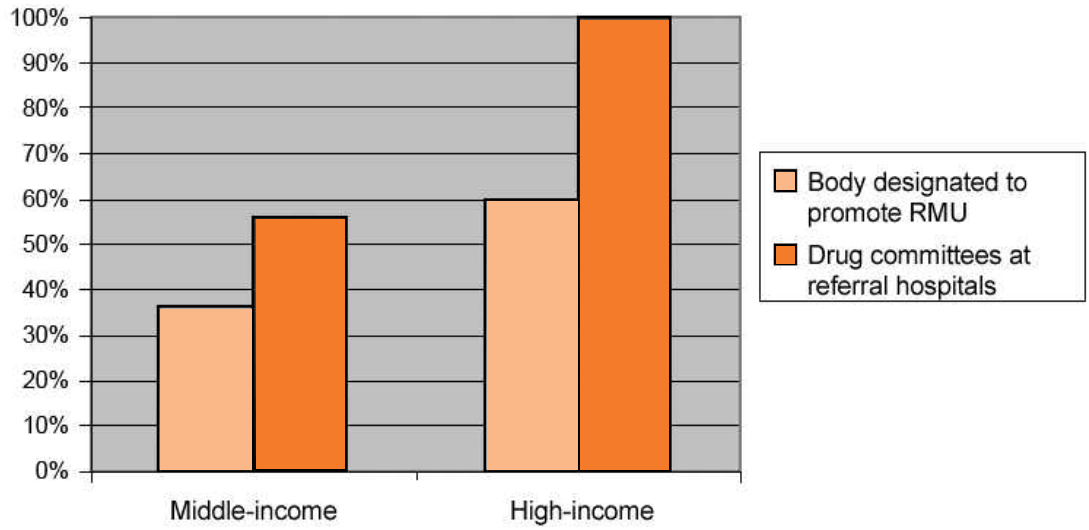
	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Prescription for medicines by:						
Physicians						
Always	16	61.5	3	60.0	19	61.3
Frequently	10	38.5	2	40.0	12	38.7
Occasionally	0	0.0	0	0.0	0	0.0
Never	0	0.0	0	0.0	0	0.0
Nurses, midwives & paramedical staff						
Always	1	4.0	0	0.0	1	3.3
Frequently	6	24.0	0	0.0	6	20.0
Occasionally	11	44.0	2	20.0	13	43.3
Never	7	28.0	3	80.0	10	33.3
Pharmacists/pharmacy aides/assistants						
Always	1	4.2	0	0.0	1	3.4
Frequently	3	12.5	0	0.0	3	10.3
Occasionally	1	4.2	1	20.0	2	6.9
Never	19	79.2	4	80.0	23	79.3
Personnel with < 1 month of training						
Always	0	0.0	0	0.0	0	0.0
Frequently	0	0.0	0	0.0	0	0.0
Occasionally	3	23.0	0	0.0	3	11.1
Never	20	87.0	4	100.0	24	88.9

- Most prescribing was done by doctors, whereas nurses had a much smaller role, and pharmacists were unlikely to prescribe;
- It was uncommon for personnel with less than one month of training to prescribe.

Table 29. Monitoring of rational medicine use (RMU)

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Body designated to promote RMU	9	36.0	3	60.0	12	40.0
Requirement for drugs and therapeutic committees (DTCs)	12	46.2	3	75.0	15	71.0
Availability of drugs and therapeutic committees						
Referral hospitals (in at least half)	14	56.0	2	100.0	16	59.3
General hospitals (in at least half)	14	56.0	2	66.7	16	57.1
Regions/provinces (in at least half)	10	43.5	1	50.0	11	44.0

Figure 12. Promoting rational use



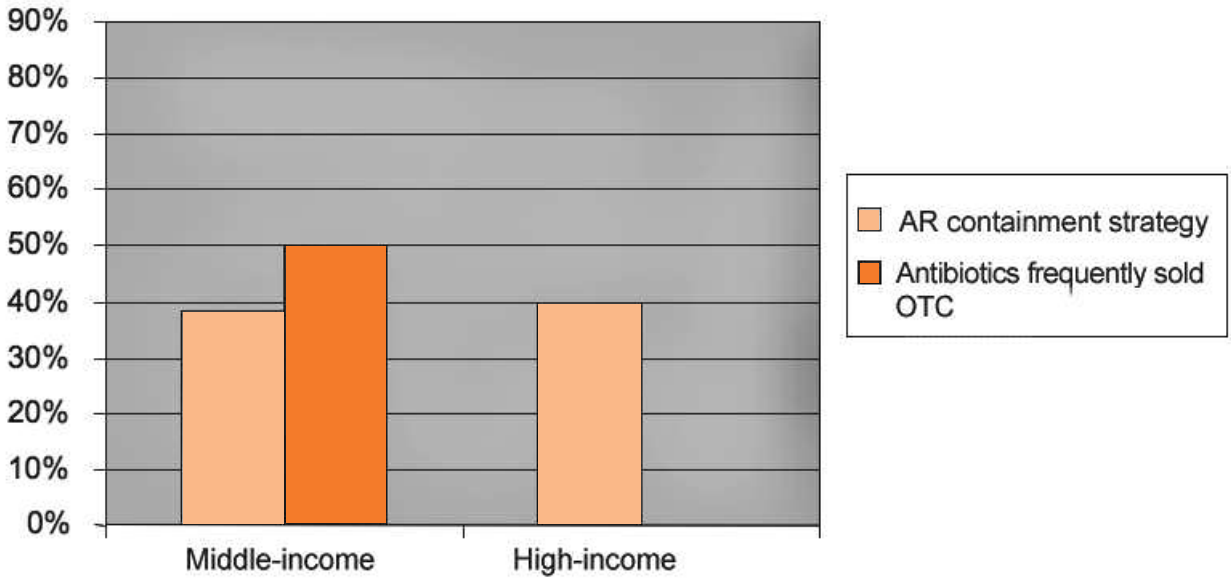
- Agencies for monitoring and promoting RMU were not common;
- Half of the countries had requirements for DTCs;
- DTCs were available in at least half of hospitals in more than 50 percent of the countries. This proportion was somewhat lower for DTCs in regions and provinces.

In 2003, 11 countries reported that DTCs were mandatory within the NMP: in 2007, DTC implementation was mandatory in 15 countries.

Table 30. Antimicrobial resistance (AR) and over-the-counter (OTC) sales

	Middle-income		High-income		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Antimicrobial resistance						
AR containment strategy	10	38.5	2	40.0	12	38.7
AR surveillance laboratory	16	61.5	3	60.0	19	61.3
Task force	5	20.0	1	25.0	6	20.7
Frequency of OTC sales						
Antibiotics						
Always	2	7.7	0	0	2	6.9
Frequently	13	50.0	0	0	13	44.8
Occasionally	6	23.1	2	66.7	8	27.6
Never	5	19.2	1	33.3	6	20.7
Injections						
Always	2	8.7	0	0	2	7.7
Frequently	7	30.4	1	33.3	8	30.8
Occasionally	10	43.5	1	33.3	11	42.3
Never	4	17.4	1	33.3	5	19.2

Figure 13. Controlling antimicrobial resistance



- Strategies for AR containment were in place in less than half of the countries. More than half of the countries had AR surveillance laboratories, but less than one quarter had an AR task force;
- Antibiotics were either always or frequently sold OTC in more than half of the countries. This was less likely for injections.

Regarding antimicrobial resistance control, in 2003 ten countries reported having a national AR control strategy, 13 countries had a reference laboratory for AR surveillance, and seven countries reported having an AR national task force. In 2007, the countries that reported having a National Strategy for AR control increased to 12, and those that reported having a laboratory for AR surveillance increased to 19; but the countries with an AR national task force decreased to six.

8. FINAL CONSIDERATIONS

The data collected and presented in this Factbook of Level I indicators are very valuable for the countries in the region. They are an ideal complement to the processes of NMP formulation and implementation. This Factbook can be useful to guide countries concerning the strategies and action required for achieving the objectives established in the NMP, as well as to redirect public policies related to finance, industry and technology, among others, to avoid a negative impact on the NMP.

In general, the information obtained shows significant progress in relation to the results from 2003 in the six areas of the pharmaceutical system assessed. Nevertheless, there are still challenges related to some specific aspects, as mentioned below.

There is a significant difference between the public expenditure per capita for medicines in developed and developing countries, and even among the developing countries. The median expenditure on medicines in the developed countries was US$30.50 per year, with values for the 25th and 75th percentiles of US$29.50 and US$154.70, respectively. At the same time, in the developing countries, the median expenditure was US$6.80 per year, with values for the 25th and 75th percentiles of US$3.90 and US$14.40, respectively. Even if the differences in healthcare and medicine costs among countries are taken into consideration, the variations in public expenditure per capita reflect great inequity and could explain the high out-of-pocket expenditure for medicines in the developing countries.

Health insurance coverage for medicines is one of the areas where less progress was achieved. Only 22.2% of the countries had public health insurance coverage for all medicines, compared with 18% with private health insurance coverage.

Almost every country uses INN and there is an acceptable percentage of countries with legal provisions for generic substitution in the pharmacies. Nevertheless, prescribing by generic name (INN) in the private sector is mandatory in only 37% of the countries.

Regarding pharmacovigilance, although an improvement is observed in 2007 in relation to 2003, the number of countries with pharmacovigilance systems and ADR reporting to UMC is less than 50%.

The limited capacity in the region for research and development (R&D) of new active ingredients was confirmed. Only 22.7% of the countries had capacity for R&D of new molecules and for producing raw materials. The Global Strategy on Innovation, Public Health and Intellectual Property, approved in the Sixty-first World Health Assembly in 2008, provides an opportunity for achieving programs in this important component of pharmaceutical policies.

In relation to RMU, important progress was achieved in the EML, national formulary manuals, DTC, and training of health professionals. On the other hand, some key aspects related to RMU are inconclusive, namely:

- The availability of objective information about rational use of medicines. There are medicines information centers in only 53.3 % of the countries, and only 34.5% of the countries carried out public information campaigns on the adequate use of antibiotics. This finding is very important as 44.8% of the countries advised that antibiotics are frequently sold without a prescription.
- The development of strategies for controlling antimicrobial resistance (AR). A small portion of the countries, on the order of 38.7%, reported having a national AR control strategy, and only 20.7% of the countries had an AR control task force.

Finally, it is important to recall that these results correspond to Level I (structure and process) indicators. They provide important information about resource availability for the development of the pharmaceutical sector in the countries of the Region of the Americas. Nevertheless, information about the impact of public policies is also required. This information can be obtained using Level II and III indicators.

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ANNEX 1

Glossary of terms used in the Questionnaire on Structures and Processes of Country Pharmaceutical Situation 2007

Access to essential medicines: The availability and affordability of essential medicines. To be accessible, medicines must 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, appropriately used and at a price the individual and the community can afford.

Accountability: Being required to account for one's conduct and actions, usually to an individual or group but ultimately to the public. Both individuals and organizations may be accountable.

Advertisement: A set of activities undertaken to advertise medicines. It is usually targeted to the general public and it is usually limited to over-the-counter medicines.

Appropriate use of medicines: 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.

Assessment/indicatory study: An assessment or indicator study is a survey undertaken to obtain evidence of the inputs, processes or outcomes of the current pharmaceutical situation or progress towards particular goals or objectives.

Civil society: Non-governmental non-profit organizations, networks and voluntary associations including charities, community groups, faith-based organisations, professional associations, academia and trade unions.

Clinical trial: Any investigation in human subjects intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of an investigational product or to identify any adverse reactions to an investigational product or to study absorption, distribution, metabolism, and excretion of an investigational product with the object of ascertaining its safety and efficacy. The terms clinical trial and clinical study are synonymous.

Compulsory licensing: This term is used when the judicial or administrative authority is allowed by law to grant a license, without permission from the holder, on various grounds of general interest (absence of working, public health, economic development, and national defence). "Working" of a patent is the execution of the invention in the country of registration.

Continuing education programmes: A continuing education programme is a programme based on regular workshops, seminars and/or in-service training which provides all prescribers and dispensers with refresher courses on drug issues.

Counterfeit medicines: A medicine, whether branded or generic, that is deliberately and fraudulently mislabelled with respect to identity and/or source or that has fake packaging. Counterfeit products may contain the correct ingredients or the wrong ingredients or may lack any, or sufficient, active ingredients.

Dispensing fee: Normally 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 handling a prescription; a percentage mark-up makes profit dependent on the sale of expensive medicines.

Dosage form: The form of the completed pharmaceutical product, e.g. tablet, capsule, injection, elixir, suppository

Drug: (see medicine)

Drugs and therapeutics committee: A drugs and therapeutics committee promotes the safe and effective use of medicines in the facility or area under its jurisdiction.

Essential Medicines List: An Essential Medicines List is a government-approved selective list of medicines or national reimbursement list.

Essential medicines: Essential medicines are those that satisfy the priority health care needs of the population.

Generic name: A non-propriety or approved name rather than a proprietary or brand name under which a generic drug is marketed. Generic drugs are pharmaceutical products usually intended to be interchangeable with the innovator product, which is usually manufactured without a license from the innovator company and marketed after the expiry of patent or other exclusivity rights. (see also INN)

Generic substitution: The practice of substituting a product, whether marketed under a trade name or generic name, by an equivalent product, usually a cheaper one, containing the same active ingredient(s).

Health insurance: Health insurance is any prepayment scheme for health care costs additional to but excluding subsidies funded through the Ministry of Health budget. The purpose of question 4.5 is to identify how much protection the population has against exposure to the cost of medicines at the time people are sick. Prepaid financing is the usual method for providing such protection. Public funding through the (prepaid) Ministry of Health budget is the most widespread form of prepayment. Question 4.6 attempts to identify additional prepayment protection (percentage of the population covered and degree of protection against medicine costs) such as private or employer-based health insurance, community prepayments schemes, social health insurance (health care funded through social security systems), etc.

INN (international non-proprietary name) or generic name: Common, generic names selected by designated experts to identify new pharmaceutical substances unambiguously. The selection process is based on a procedure and guiding principles adopted by the World Health Assembly. They are recommended for worldwide use, destined to be unique and public property (non-proprietary).

Legislation: Drug legislation describes the legal conditions under which pharmaceutical activities should be organised in line with the national medicines policy. It covers activities such as drug importation, distribution, production, registration and sales practices. It should clarify what is permissible and what is not in the field of pharmaceuticals as well as laying down who may manufacture or import drugs, and who may prescribe them. It concerns both public and private sectors.

Licensing: Licensing is a system that subjects all premises to evaluation against a set of requirements before a specific activity (e.g. manufacturing, storage etc.) is authorised to take place.

Manufacturing: All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products and the related controls.

Marketing authorization: An official 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.

Mark-up: A certain percentage added to a purchasing price to cover the cost and profit of the wholesaler or retailer.

Medicinal product: Any preparation for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient.

Medicine: Any dosage form containing a substance approved for the prevention and treatment of disease.

Medicines formulary manual: A formulary manual contains summary drug information.

Medicines information centre or service: A medicines information centre or service is an organization within or outside the ministry of health which collects and provides objective information on drugs to health personnel and the public. Objective information should be understood as information produced by independent scientific sources without any support from the pharmaceutical industry or private firms involved in the drug sector. The medicines information centre/service may perform additional tasks.

National medicines (drug) policy (NMP): A national medicines policies is an expression of the government's goals and priorities for the medium to long term for the pharmaceutical sector. It also 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 private sectors, and involves all the main actors in the pharmaceutical field.

NGO: Non-governmental non-profit organizations, networks and voluntary associations including charities, community groups, faith-based organisations, professional associations, academia and trade unions.

Parallel importing: Parallel importation is importation, without the consent of the patent-holder, of a patented product marketed in another country either by the patent-holder or with the patent-holder's consent. Parallel importation enables promotion of competition for the patented product by allowing importation of equivalent patented products marketed at lower prices in other countries.

Problem-based pharmacotherapy: Problem-based pharmacotherapy is a problem-based practical approach to teaching prescribing.

Promotion: A set of activities undertaken to promote prescription of prescription-only medicines. It is usually targeted to health providers only and it is usually forbidden to target the general public.

Public education campaigns: A public education campaign on rational use of medicines is any programme or campaign conducted at local or national level by the ministry of health, by a non-governmental organisation or by academia aimed at increased awareness of drug use issues and improvements in the use of drugs by the public, as long as the information provided is unbiased.

Rational medicines use: 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.

Registered products: Products that have been evaluated for quality, safety and efficacy and thence authorised for marketing.

Registration system: A system that subjects all products to evaluation of quality, safety and efficacy before they are authorised for marketing.

Regulatory authority: A Drug Regulatory Authority is designated by the State to ensure compliance with regulations applicable to drugs: issuing of marketing authorizations, authorizations of dispensaries, etc.

Retail distributors: A company that sells goods to consumers. In the pharmaceutical sector, the retailer is the pharmacy or any other medicine outlet. Many low- and middle- income countries have at least two different types of shops in which medicines can be purchases: pharmacies with a registered pharmacist and drug stores, chemists or medicine outlets with paramedical staff or lay people.

Standard Treatment Guidelines (STG): STGs are recommendations about how to treat a clinical condition.

Transitional period: TRIPS provides transitional periods during which countries are required to bring their national legislation and practices into conformity with its provisions. The latest dates for WTO Members were/are: 1996 for developed countries; 2000 for developing countries (as a general rule);

2005 for developing countries who had not introduced patents before joining the WTO; and 2006 for least-developed countries (extended to 2016 by the Doha Declaration). The TRIPS Agreement specifically recognizes the economic, financial, administrative and technological constraints of the least-developed countries. It therefore provides the possibility for further extension of the transitional period.

Transparency: Transparency means (1) defining policies and procedure in writing and publishing the written documentation, and (2) giving reasons for decisions to the affected party.

TRIPS Agreement (Agreement on Trade Related Aspects of Intellectual Property Rights)

Article 65: Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.
2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.
3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.
4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.
5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66: Least-Developed Country Members

1. In view of the special needs an requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other that Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.
2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

WHO Certification Scheme: The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce guarantees, through the issue of a WHO certificate, the quality of

pharmaceutical products entering international commerce. It is a simple administrative procedure that enables importing countries to obtain information on whether a product has been authorised to be placed on the market in the exporting country, and assurance that the manufacturer has been found to comply with WHO standards of good manufacturing practice. This system is particularly useful for countries with limited capacity for quality control of drugs.

Wholesaler: A company that buys goods from a manufacturer or importer and sells it to retailers. The number of wholesalers in the pharmaceutical sector varies between countries, from one state wholesaler to more than 500. The wholesaler may be an agent for one company only or deal with products from several companies. Manufacturers may also be wholesalers for their own products. In some countries, pharmacies may also have a wholesaler license.

ANNEX 2

Level I questionnaire 2007

Questionnaire on structures and processes of country pharmaceutical situations

Country:	Date (dd/mm/yyyy):
Name of coordinator/principal respondent:	E-mail address:
Position:	Postal address:

Questions	Responses	Explanations
1. NATIONAL MEDICINES (DRUGS) POLICY (NMP) Please consult the health ministry, medicines regulatory authority and/or medicine service in answering the questions in this section.		
1.1 Is there a National Medicines Policy (NMP) document? If no, skip to 1.4.	☐Yes ☐No ☐Don't Know	
a) If yes, is it an official or draft document?	☐Official ☐Draft ☐Don't Know	
b) What year was it last updated?	Year ____	
1.2 Is there an NMP implementation plan that sets activities, responsibilities, budget and timeline?	☐Yes ☐No ☐Don't Know	
a) If yes, when was it last updated?	Year ____	
1.3 Is the NMP integrated into or included in the published/official national health policy/plan?	☐Yes ☐No ☐Don't Know	
a) If yes, when was the national health policy/plan last updated?	Year ____	

Questions	Responses	Explanations
1.4 Has a national assessment/indicator study been conducted?	☐Yes ☐No ☐Don't Know	
a) If yes, which topics have been studied and when was the most recent study covering each topic conducted:		
Overall pharmaceutical situation:	☐Yes ☐No ☐DK Year ____	
Rational use/prescription audit:	☐Yes ☐No ☐DK Year ____	
Access (i.e. prices, affordability and/or availability) to medicines:	☐Yes ☐No ☐DK Year ____	
1.5 Is there a code of conduct that applies to public officials and staff involved in pharmaceutical related activities or posts, such as persons working in pharmaceutical services, medicines regulation, procurement and supply of medicines and other pharmaceutical divisions of the health ministry?	☐Yes ☐No ☐Don't Know	
2. REGULATORY SYSTEM Please consult the medicines regulatory authority in answering the questions in this section. Specific information regarding medicines tested for quality control purposes and monitoring of adverse drug reactions may need to be obtained from the quality control laboratory or the responsible agency/department.		
Regulatory authority		
2.1Are there legal provisions establishing the powers and responsibilities of the medicines regulatory authority?	☐Yes ☐No ☐Don't Know	
2.2 Is there an existing formal medicines regulatory authority?	☐Yes ☐No ☐Don't Know	

Questions	Responses	Explanations
2.3 What are the sources of funding for the medicines regulatory authority:		
Regular budget from the government:	☐Yes ☐No ☐Don't Know	
Fees from registration of medicines:	☐Yes ☐No ☐Don't Know	
Other:	☐Yes ☐No ☐Don't Know	
2.4Are there legal provisions requiring transparency and accountability and promoting a code of conduct in regulatory work?	☐Yes ☐No ☐Don't Know	
2.5 Is the medicines regulatory authority involved in regional/international harmonization initiatives?	☐Yes ☐No ☐Don't Know	
2.6 Is there a medicines regulatory authority website providing publicly accessible information on any of the following: legislation, regulatory procedures, prescribing information (such as indications, counterindications, side effects, etc.), authorised companies, and/or approved medicines?	☐Yes ☐No ☐Don't Know	
Marketing authorization		
2.7 Are there legal provisions for marketing authorization?	☐Yes ☐No ☐Don't Know	
2.8How many medicinal products have been approved to be marketed? *(count total number of unique dosage forms and strengths)*	Number _____	

Questions	Responses		Explanations
2.9 Is a list of all registered products publicly accessible?	☐Yes ☐No ☐Don't Know		
2.10 Is there a computerized registration system that facilitates retrieval of information on registered products?	☐Yes ☐No ☐Don't Know		
2.11 Is the WHO Certification Scheme certificate required as part of the marketing authorization process?	☐Yes ☐No ☐Don't Know		
2.12 Is INN used in the registration of medicines?	☐Yes ☐No ☐Don't Know		
2.13 Is there a functional formal committee responsible for assessing applications for registration of pharmaceutical products?	☐Yes ☐No ☐Don't Know		
Licensing			
2.14 Are there legal provisions for licensing of the following:			
Manufacturers:	☐Yes ☐No ☐Don't Know		
Wholesalers or distributors:	☐Yes ☐No ☐Don't Know		
Importers or exporters of medicines:	☐Yes ☐No ☐Don't Know		
Regulatory inspection			
2.15 Are there legal provisions to inspect premises and collect samples?	☐Yes ☐No ☐Don't Know		
2.16 Are the following types of facilities inspected to check compliance with applicable requirements and are there written national guidelines/checklists for the inspection:	Facilities inspected	Written national guidelines/checklists	
Manufacturers:	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
Wholesalers or distributors:	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
Importers/exporters:	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
Retail distributors/pharmacies:	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	

Questions	Responses	Explanations
Control of narcotics and stupefiants		
2.17 .Are there legal provisions for the control of narcotics, psychotropic substances and precursors?	☐Yes ☐No ☐Don't Know	
2.18 Is your country a signatory to the international convention on the control of narcotics, psychotropic substances and precursors?	☐Yes ☐No ☐Don't Know	
Quality control		
2.19 Is there a quality management system in place?	☐Yes ☐No ☐Don't Know	
2.20 Are medicine samples tested for the following regulatory purposes:		
Medicines registration:	☐Yes ☐No ☐Don't Know	
Post-marketing surveillance:	☐Yes ☐No ☐Don't Know	
2.21 In which of the following laboratories are samples tested:		
Government quality control laboratory:	☐Yes ☐No ☐Don't Know	
Local academic institutions:	☐Yes ☐No ☐Don't Know	
Private laboratory:	☐Yes ☐No ☐Don't Know	
Mini laboratories (district, regional):	☐Yes ☐No ☐Don't Know	
Quality control laboratory in another country:	☐Yes ☐No ☐Don't Know	
2.22 What is the total number of samples quality tested in 2006?	Number _____	
2.23 What is the total number of samples tested in 2006 that failed to meet quality standards?	Number _____	

Questions	Responses	Explanations
2.24 Are there regulatory procedures to ensure quality control of imported medicines?	☐Yes ☐No ☐Don't Know	
2.25 Are there legal procedures for the recall and disposal of defective products?	☐Yes ☐No ☐Don't Know	
Pharmacovigilance		
2.26 Are adverse drug reactions (ADR) monitored?	☐Yes ☐No ☐Don't Know	
a) If yes, at which of these health system levels are adverse drug reactions (ADR) monitored:		
Local level:	☐Yes ☐No ☐Don't Know	
Regional level:	☐Yes ☐No ☐Don't Know	
Central level:	☐Yes ☐No ☐Don't Know	
2.27 Does your country report ADRs to an international network or to the WHO Collaborating Centre for International Drug Monitoring?	☐Yes ☐No ☐Don't Know	
2.28 Are there any laws, regulations, programmes or procedures for detecting and combating counterfeit medicines?	☐Yes ☐No ☐Don't Know	
2.29 What sources of information are used to detect and combat counterfeit medicines:		
Reports from national authorities:	☐Yes ☐No ☐Don't Know	
Reports from specific/ad hoc studies:	☐Yes ☐No ☐Don't Know	
Reports from the pharmaceutical sector:	☐Yes ☐No ☐Don't Know	
Reports from civil society/NGOs:	☐Yes ☐No ☐Don't Know	

Questions	Responses	Explanations
Dispensing and prescribing		
2.30 Are there legal provisions for the following:		
Licensing and practice of prescribers:	☐Yes ☐No ☐Don't Know	
Licensing and practice of pharmacy:	☐Yes ☐No ☐Don't Know	
2.31 Is prescribing by generic name obligatory in the:		
Public sector:	☐Yes ☐No ☐Don't Know	
Private sector:	☐Yes ☐No ☐Don't Know	
2.32 Is generic substitution permitted at:		
Public pharmacies:	☐Yes ☐No ☐Don't Know	
Private pharmacies:	☐Yes ☐No ☐Don't Know	
2.33 Are there incentives to dispense generic medicines at:		
Public pharmacies:	☐Yes ☐No ☐Don't Know	
Private pharmacies:	☐Yes ☐No ☐Don't Know	
Promotion and advertising		
2.34 Are there provisions in the medicines legislation/regulations covering promotion and/or advertising of medicines?	☐Yes ☐No ☐Don't Know	
2.35 Who is responsible for regulating promotion and/or advertisement of medicines?	☐Yes ☐No ☐Don't Know	
a) If regulated by government, do regulations include any of the following:		

Questions	Responses		Explanations
Pre-approval for advertisement and/or promotional materials:	☐Yes ☐No ☐Don't Know		
Prohibition on advertising prescription medicines to the public:	☐Yes ☐No ☐Don't Know		
Guidelines on advertising of non-prescription medicines:	☐Yes ☐No ☐Don't Know		
2.36 Are civil society/NGOs included in surveillance of promotion and/or advertisement of medicines?	☐Yes ☐No ☐Don't Know		
3. MEDICINES SUPPLY SYSTEM Please consult the agency/department responsible for the procurement and supply of medicines in answering the questions in this section.			
3.1 Is public sector procurement pooled at the national level (i.e. there is centralised procurement for the regions/provinces)?	☐Yes ☐No ☐Don't Know		
3.2 Who is responsible for public sector medicines procurement and distribution:	Procurement	Distribution	
Ministry of Health:	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
Non-governmental organization (NGO):	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
Private institution contracted by the government:	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
Individual health institutions:	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
3.3 What type of tender process is used for public sector procurement and what is the percentage of the total cost for each:		Percentage of total cost	
National competitive tender:	☐Yes ☐No ☐ DK	____%	
International competitive tender:	☐Yes ☐No ☐DK	____%	
Negotiation/direct purchasing:	☐Yes ☐No ☐DK	____%	

Questions	Responses	Explanations
3.4 Is there a tender board/committee overseeing public sector procurement?	☐Yes ☐No ☐Don't Know	
a) If yes, are the key functions of the procurement office and those of the tender committee clearly separated?	☐Yes ☐No ☐Don't Know	
3.5 Does public sector medicines procurement use the WHO Prequalification system?	☐Yes ☐No ☐Don't Know	
3.6 Is public sector procurement limited to medicines on the Essential Medicines List (EML)?	☐Yes ☐No ☐Don't Know	
a) If yes, are there provisions for purchasing medicines not on the Essential Medicines List?	☐Yes ☐No ☐Don't Know	
3.7 Did your country participate in a pooled procurement scheme with at least one other country for at least one of the last two procurement cycles?	☐Yes ☐No ☐Don't Know	
4. MEDICINES FINANCING Please consult the budget/ finance division of the health ministry and/or the pharmaceutical supply group in answering the questions in this section. The hospital/health facility service and/or the national social and insurance services may also need to be consulted		
4.1What is the total public or government expenditure for medicines in US$ for the most recent year for which data are available?	US$ _____ Year _____	
4.2 Is there a national policy to provide at least some medicines free of charge (i.e. patients do not pay out-of-pocket for medicines) at public primary care facilities?	☐Yes ☐No ☐Don't Know	

Questions	Responses	Explanations
a) If yes, which of the following are free at public primary care facilities:		
All medicines:	☐Yes ☐No ☐Don't Know	
Malaria medicines:	☐Yes ☐No ☐Don't Know	
Tuberculosis medicines:	☐Yes ☐No ☐Don't Know	
Sexually transmitted diseases medicines:	☐Yes ☐No ☐Don't Know	
HIV/AIDS-related medicines:	☐Yes ☐No ☐Don't Know	
At least one vaccine:		
b) Which of the following types of patients receive medicines for free:		
Patients who cannot afford them:	☐Yes ☐No ☐Don't Know	
Children under 5 years of age:	☐Yes ☐No ☐Don't Know	
Older children:	☐Yes ☐No ☐Don't Know	
Pregnant women:	☐Yes ☐No ☐Don't Know	
Elderly persons:	☐Yes ☐No ☐Don't Know	
4.3 Which fees are commonly charged in public primary care facilities:		
Registration/consultation fees:	☐Yes ☐No ☐Don't Know	
Dispensing fees:	☐Yes ☐No ☐Don't Know	
Flat fees for medicines:	☐Yes ☐No ☐Don't Know	
Flat rate co-payments for medicines:	☐Yes ☐No ☐Don't Know	
Percentage co-payments for medicines:	☐Yes ☐No ☐Don't Know	
4.4 Is revenue from fees or the sale of medicines used to pay the salaries or supplement the income of public health personnel in the same facility?	☐Always ☐Frequently ☐Occasionally ☐Never ☐DK ☐Draft ☐Don't Know	

Questions	Responses			Explanations
4.9 Is a national medicine prices monitoring system for retail/patient prices in place?	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
4.10 Are there regulations mandating retail/patient medicine price information to be made publicly accessible?	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
4.11 Are there official written guidelines on medicine donations that provide rules and regulations for donors and provide guidance to the public, private and/or NGO sectors on accepting and handling donated medicines?	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
5. PRODUCTION AND TRADE Please consult the medicines regulatory authority, the patent office and/or the trade ministry in answering the questions in this section.				
5.1 What is the medicines production capability in the country:				
Research and development of new active substances:	☐Yes	☐No	☐Don't Know	
Production of pharmaceutical starting materials:	☐Yes	☐No	☐Don't Know	
Formulation from pharmaceutical starting materials:	☐Yes	☐No	☐Don't Know	
Repackaging of finished dosage forms:	☐Yes	☐No	☐Don't Know	
5.2 Are patents granted on pharmaceutical products by the national patent office?	☐Yes	☐No	☐Don't Know	

Questions	Responses			Explanations
4.5 Do prescribers dispense medicines?	*Public sector* ☐Always ☐Frequently ☐Occasionally ☐Never ☐DK	*Private sector* ☐ Always ☐Frequently ☐Occasionally ☐Never ☐DK		
4.6 What proportion of the population has health insurance?	☐All ☐Some ☐None ☐DK	☐All ☐Some ☐None ☐DK		
4.7 Are medicines covered by health insurance?	☐All ☐Some ☐None ☐DK	☐All ☐Some ☐None ☐DK		
4.8 Is there a policy covering medicine prices that applies to the public sector, the private sector, or non-governmental organisations?	Public sector ☐Yes ☐No ☐DK	Private sector ☐ Yes ☐ No ☐ DK	NGO ☐Yes ☐ No ☐ DK	
a) If yes, which of the following policies covering medicine prices apply:				
Maximum wholesale mark-up:	☐Yes ☐No ☐DK	☐Yes ☐ No ☐ DK	☐Yes ☐ No ☐DK	
Maximum retail mark-up:	☐ Yes ☐No ☐DK	☐Yes ☐No ☐DK	☐Yes ☐ No ☐DK	
Duty on imported raw pharmaceutical materials:	☐ Yes ☐No ☐DK	☐ Yes ☐ No ☐DK	☐ Yes ☐ No ☐DK	
Duty on imported finished pharmaceutical products:	☐ Yes ☐No ☐DK	☐ Yes ☐ No ☐ DK	☐ Yes ☐ No ☐DK	

Questions	Responses	Explanations
5.3 If your country is a member of the World Trade Organization (WTO), has national legislation been modified to implement the TRIPS Agreement?	☐Yes ☐No ☐Don't Know ☐Country not a member of WTO	
a) If a WTO member, has your country used the following available transitional periods to implement the TRIPS Agreement:		
Article 65:	☐Yes ☐No ☐Don't Know	
Article 66:	☐Yes ☐No ☐Don't Know ☐Country not an LDC	
Doha declaration (Article 7):	☐Yes ☐No ☐Don't Know	
5.4 Which of the following TRIPS flexibilities have been incorporated into national legislation as applies to pharmaceuticals: *CBD = Currently being discussed*		
Compulsory licensing provisions:	☐Yes ☐No ☐CBD ☐DK	
Government use:	☐Yes ☐No ☐CBD ☐DK	
Parallel importing provisions:	☐Yes ☐No ☐CBD ☐DK	
The Bolar exception:	☐Yes ☐No ☐CBD ☐DK	
6. RATIONAL USE OF MEDICINES Please consult the health ministry (hospital division), professional bodies and/or the education ministry in answering the questions in this section.		
6.1 Is there a national Essential Medicines List (EML)?	☐Yes ☐No ☐Don't Know	

Questions	Responses			Explanations
a) If yes, how many unique medicine formulations does the national EML contain?	Number _____			
b) How many paediatric formulations are included in the:				
National EML:	Number _____			
Separate Paediatric EML:	Number _____ ☐No separate paediatric EML			
c) When was the national EML last updated?	Year ____			
d) Is the national EML being used in the following:				
Public sector procurement:	☐Yes ☐No ☐Don't Know			
Public insurance reimbursement:	☐Yes ☐No ☐Don't Know			
Private insurance reimbursement:	☐Yes ☐No ☐Don't Know			
e) Is there a committee responsible for the selection of products on the national EML?	☐Yes ☐No ☐Don't Know			
6.2 Are the following types of standard treatment guidelines (STG) produced by the health ministry for major conditions?	*National STG* ☐ Yes ☐ No ☐ DK	*Hospital level STG* ☐ Yes ☐ No ☐ DK	*Primary care STG* ☐ Yes ☐ No ☐ DK	
a) If yes, when were the STGs last updated?	Year ____	Year ____	Year ____	
6.3 Are there standard treatment guidelines for key paediatric illnesses?	☐Yes ☐No ☐Don't Know			

Questions	Responses				Explanations
6.4 Is there a National Medicines Formulary Manual?	☐Yes ☐No ☐Don't Know				
a) If yes, when was it last published/reviewed?	Year ____				
b) Does it cover only medicines on the national EML?	☐Yes ☐No ☐Don't Know				
6.5 Are the following prescribing issues part of the basic curricula in most health training institutions for:	*Essential Medicines List (EML)*	*Standard Treatment Guidelines (STG)*	*Problem-based pharmaco-therapy*	*Rational presc-ribing*	
Doctors:	☐Yes ☐No ☐DK	☐Yes ☐No ☐ DK	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
Nurses:	☐Yes ☐No ☐DK	☐Yes ☐No ☐ DK	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
Pharmacists:	☐Yes ☐No ☐DK	☐Yes ☐No ☐ DK	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
Pharmacy assistants:	☐Yes ☐No ☐DK	☐Yes ☐No ☐ DK	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	
Paramedical staff	☐Yes ☐No ☐DK	☐Yes ☐No ☐ DK	☐Yes ☐No ☐DK	☐Yes ☐No ☐DK	

Questions	Responses	Explanations
6.6 Are there obligatory, non-commercially funded continuing education programs that include use of medicines for:		
Doctors:	☐Yes ☐No ☐Don't Know	
Nurses/midwives/paramedical staff:	☐Yes ☐No ☐Don't Know	
Pharmacists:	☐Yes ☐No ☐Don't Know	
Pharmacy aides/assistants:	☐Yes ☐No ☐Don't Know	
6.7 Is there a public or independently funded, nationally accessible (e.g. by phone) medicines information centre or service that provides information on demand to:		
Prescribers:	☐Yes ☐No ☐Don't Know	
Dispensers:	☐Yes ☐No ☐Don't Know	
Consumers:	☐Yes ☐No ☐Don't Know	
6.8 Have there been any public education campaigns about rational medicines use in the previous two years conducted by the health ministry, a non-governmental organisation, or academia on the following topics:		
Use of antibiotics:	☐Yes ☐No ☐Don't Know	
Use of injections:	☐Yes ☐No ☐Don't Know	
Other rational medicine use topics/issues:	☐Yes ☐No ☐Don't Know	

Questions	Responses	Explanations
6.9 How often do the following personnel prescribe prescription-only medicines at the primary health care level in the public sector:		
Doctors:	☐Always ☐Frequently ☐Occasionally	
Nurses/midwives/paramedical staff:	☐Always ☐Frequently ☐Occasionally ☐Never ☐DK	
Pharmacists/pharmacy aides/assistants:	☐Always ☐Frequently ☐Occasionally ☐Never ☐DK	
Personnel with <1 month formal health training:	☐Always ☐Frequently ☐Occasionally ☐Never ☐DK	
6.10 Is there a national programme and/or multidisciplinary body, involving government, civil society and professional bodies, which monitors and promotes the rational use of medicine?	☐Yes ☐No ☐Don't Know	
6.11 Is there a mandatory requirement to organize/develop drugs and therapeutics committees?	☐Yes ☐No ☐Don't Know	
6.12 What proportions of hospitals and regions have drugs and therapeutics committees:		
Referral hospitals:	☐All ☐Most ☐Half ☐Few ☐None ☐DK	
General hospitals:	☐All ☐Most ☐Half ☐Few ☐None ☐DK	
Regions/provinces:	☐All ☐Most ☐Half ☐Few ☐None ☐DK	

Questions	Responses	Explanations
6.13 Is there a national strategy to contain antimicrobial resistance?	☐Yes ☐No ☐Don't Know	
6.14 Is there a national reference laboratory to coordinate epidemiological surveillance of antimicrobial resistance?	☐Yes ☐No ☐Don't Know	
6.15 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 ☐No ☐Don't Know	
6.16 How frequently are the following types of medicines sold over the counter without any prescription:		
Antibiotics:	☐Always ☐Frequently ☐Occasionally	
Injections:	☐Always ☐Frequently ☐Occasionally	

List of respondents

Name	Position	Address	E mail	Section(s) completed

Comments about indicators and values

Item number	Comment

ANNEX 3

List of level I core indicators

No.	Indicator	Question
1	Existence of NMP document	1.1
2	Official updated NMP document	1.1
3	Updated NMP Implementation Plan	1.2
4	Regulatory Authority	2.2
5	Computerized Medicines Registration System	2.1
6	WHO Certification Scheme as part of the marketing authorization process	2.11
7	INNs in medicines registration	2.12
8	Legal provisions to inspect premises	2.15
9	Quality management system	2.19
10	Adverse Drug Reactions	2.26
11	Counterfeit Medicines	2.28
12	Permission of Generic Substitution in the public sector	2.32
13	Permission of Generic Substitution in the private sector	2.32
14	Regulations for advertisement and promotion of medicines	2.34
15	WHO prequalification system	3.5
16	Public sector procurement limited to national essential medicines list	3.6
17	Public spending on medicines per capita per year	4.1
18	National Policy providing at least some medicines free of charge	4.2
19	HIV/AIDS related medicines free at primary public health facilities	4.2a
20	Pregnant women receiving free medicines at primary health facilities	4.2b
21	Health insured population	4.6
22	Medicines covered by health insurance	4.7
23	Policy covering medicine prices in the private sector	4.8
24	TRIPS flexibilities incorporated into national legislation	5.4
25	National Essential Medicines List (EML) updated within the last 5 years	6.1a

No.	Indicator	Question
26	Standard treatment guidelines (STGs) updated in the last 5 years	6.2a
27	Essential Medicines concept part of basic curriculum in medicine /pharmacy	6.5
28	National medicines information centre for prescribers / dispensers	6.7a/b
29	National medicines information centre for consumers	6.7c
30	Proportion of hospitals / regions with DTCs	6.12c
31	National strategy to contain antimicrobial resistance	6.13

Pan American Health Organization
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