The Pharmaceutical Situation in the Americas

Level I Monitoring Indicators - 2007

Washington DC, October 2009

Pan American Health Organization
Regional Office of the World Health Organization

CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF BOXES

ACKNOWLEDGEMENTS

The publication of the Fact Book of the AMRO/PAHO was possible due to the collaboration of the National Authorities who provided the data in response to the Level I Questionnaire of the Pharmaceutical Situation.

This initiative was fully supported by the Medicine Programme Coordination (MPC) of the Essential Medicines and Pharmaceutical Policies Department of WHO and the Project of Essential Medicines and Biologicals of the Technology, Healthcare and Research Area (THR) of the Pan American Health Organization.

Edelisa D. Carandang coordinated and supervised the overall process of pharmaceutical indicators data collection and the analysis. The collection of the Level I data in the Americas was coordinated initially by the PAHO Associate Expert Jaume Vidal and then by the PAHO Advisor Regional on Pharmaceutical Policies, Nelly Marin Jaramillo, and relied on the collaboration of the advisors of Medicines and Health Systems and Services of the PAHO sub region and country offices of the region.

Edelisa D. Carandang, Gilles Bernard Forte and Enrico Cinnella (WHO) were responsible for the systematization, for designing the framework and preparing the draft of the document and Nelly Marin (PAHO/WHO Headquarter Office) and Adriana Ivama (PAHO/WHO Caribbean Office) were responsible for organizing and editing the publication. The final revision was conducted by Nelly Marin, Adriana Ivama and Valerie Kerr.

James Fitzgerald was responsible for the final revision of the document.

We would like to acknowledge the efforts of all our colleagues who made this publication possible.

ABBREVIATIONS

ADRs: Adverse drug reactions

AIDS: Acquired Immunodeficiency Syndrome

AMRO/PAHO: Americas Regional Office

AR: Antimicrobial resistance

DTC: Drug and Therapeutic Committee

EML: Essential Medicines List

FDA: Food and Drug Administration

GLP: Good Laboratory Practices

HIV: Human Immunodeficiency Virus

INN: International Nonproprietary Name

LDC: Least Developed Countries

MOH: Ministry of Health

MRA: Medicines Regulatory Authority

NMP: National Medicine Policy

NGO: Non-Governmental Organization

OTC: Over the counter

PSP: Public sector procurement

RA: Regulatory Authority

R&D: Research and Development

RMU: Rational Medicine Use

STGs: Standard Treatment Guidelines

TB: Tuberculosis

TPE: Total public expenditure for medicines

TRIPS: 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 Fact Book of the Americas Region (AMRO) is part of an effort to collect, systematize and make available information about the pharmaceutical situation in the Latin American and Caribbean countries. A previous publication on the Level I survey at the global level was done in 2003[i], and in the Region a folder was published with summarized information. The 2007 survey results presented in this document are part of the commitment to do regular monitoring to ascertain that there are enabling situations and environments in countries to realize the vision of people having access to the essential medicines they need; that the medicines are safe, effective and of good quality; and that the medicines are prescribed and used rationally.

As in the previous Fact Book, this document aims to summarize and to provide a picture of the pharmaceutical situation of countries in the Americas region that have provided data through their Ministry of Health. Information is presented by level of income (Middle and High). Data are presented as facts, with key finding after each table and figure.

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

It is hoped that the information presented in this Fact Book 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, set priorities and assist in setting targets, provide information in assessing the strengths and weaknesses of strategies, and elucidate national and institutional problems. This Fact Book could also inform international agencies and donors by supplying information that can be used as baseline data, and possibly infer the potential impact of activities. In addition, professional groups and nongovernmental organizations (NGOs) may find useful data to cite in their advocacy and information campaigns.

SUMMARY OF KEY POINTS

World Health Organization (WHO) Pharmaceutical Indicators

In the previous biennia, WHO's work on medicines has been guided by the WHO medicines strategies (WMS) 2000-03 and 2004-07. Both strategies have emphasized the use of indicators to measure achievements and situations in countries, and to ascertain the impact of the WMS in achieving pharmaceutical objectives. The WMS 2004-07, approved as a resolution in WHA 54.11, has highlighted the challenges in medicines access and use in the 21st century. The WHA 54.11 WHO medicines strategy acknowledged 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 use of medicines. The *WHO medicines strategy* 2004–2007 presents the strategies developed to help staff at WHO headquarters, the regions and countries to work towards realizing this vision.

The WHO has continued to gather data and information on pharmaceutical situations of member states using indicator-based tools to follow up progress or non progress of pharmaceutical activities in countries. 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 data in this Fact Book.

The present Fact Book details the results of the 2007 assessment of Level I indicators by 31 countries in 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.

In 2003, sixteen countries had an **Official NMP**, of which ten 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 sixteen of them were integrated into the National Health Policy (NHP).

Regulation of Medicines

Regulation of medicines is a public policy that restricts private sector activities in order to attain social goals set by the State. It includes the totality of measures – legal, administrative and technical – which governments take 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 to ensure stringent regulation of the manufacture, trade and use of medicines in order to protect public health. It is necessary to have a legal framework for the MRA to guarantee independent testing and assessment of the quality, efficacy and safety of medicines.

In 2003, twenty-one countries mentioned having legal provision for a **Medicines Regulatory Authority (MRA),** and in 2007 the number of countries increased to twenty-eight. The number of countries (17) that mentioned having legal provision requiring transparency, in 2003, increased to 20 in 2007, and the number of countries with a publicly accessible MRA website increased from 10 to 19.

In 2003, twenty countries mentioned having legal provision for **marketing authorization** (MA). 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 compared with 2003 (11,571 vs. 9,632). 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 legal provision for **licensing** manufacturers, distributors and importers of medicines. In 2007, the number of countries with legal provision in these areas increased to 29. Regarding the licensing of prescribers, the number of countries with legal provision increased from 15 to 30, and regarding licensing of pharmacies, the variation was from 15 to 31.

The number of countries with legal provision for **inspection** of manufacturers reflected an increase from 2003 (22) to 2007 (24). Regarding the legal provision for inspecting importers and wholesalers, and for inspecting distributors and pharmacies, there was a significant variation from 18 to 24.

In 2003, the median of collected samples for **quality control** was 1,287 for 15 countries and the median of those tested was 100%. The median of products that failed testing represented 3% of samples tested. In relation to the samples tested in 2006, the median of the samples tested showed a slight decrease but the median of those failing to meet the standards was higher (4%).

Regarding **Pharmacovigilance,** in 2003, thirteen countries reported monitoring ADRs and the number increased in 2007 to eighteen, with fourteen countries participating in the WHO International Programme for Drug Monitoring.

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; in the private sector this varied from eight to 10 countries. With regards to permitting generic substitution, the number of

countries increased from 21 to 27 in the public sector and from 17 to 21 in the private sector.

Given the known impact of **advertising and promotion of medicines** on both prescribing behaviour and patient demand, it is essential to regulate and monitor medicines promotion. In 2003, twenty-one countries reported having legislation for promotion and advertisement, and in 2007 the number of countries increased to twenty-five.

Medicines Supply Systems

A well-coordinated medicines supply system helps to ensure that funds available for medicines purchases are used effectively and efficiently. Failures in the supply system can lead to life-threatening medicines shortages and waste of 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 facility level. The selective priority diseases approach has resulted in neglect of other important conditions (e.g. chronic diseases, common diseases in children).

In 2003, the Ministry of Health performed **the procurement** function in 19 countries and in 2007 in 26 countries. **The distribution** function was performed by the Ministry of Health in 12 countries in 2003 and in 18 countries in 2007. Procurement and distribution by a NGO were performed in 2 countries in 2003. In 2007, the procurement and distribution functions were performed by a NGO in four countries 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 nineteen countries in 2007 used national competitive tendering, while the use of an international tender reflected a significant increase (a variation from 11 in 2003 to 19 in 2007). The use of negotiation/direct purchasing 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 the community. A medicines pricing policy is also an important strategy, since the cost of medicines is one of the most important obstacles to access. Pricing regulation and policies can provide a good basis for equitable access, if they are effectively implemented.

In general, the number of countries where medicines for different diseases were free increased in 2007 compared with 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**, the

variation was from 18 countries in 2003 to 24 in 2007. For **sexually transmitted diseases** (STDs), the variation was from 15 to 17 countries. For **HIV/AIDS,** the variation was significant, from 14 in 2003 to 24 in 2007.

In 2003, fifteen countries reported that medicines were free for those who could not afford them, compared with 26 countries in 2007. The availability of free medicines for children under 5 years was reported by 16 countries in 2003 and,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 elderly persons, where the availability varied from 7 to 22 countries.

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

With regards to the coverage of medicines, in 2003, four countries reported **coverage by the public sector** for all medicines and in 2007 there were six such countries. There was only one country with no coverage of medicines in the public sector in 2003 and four countries in 2007.

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

The number of countries with 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. The 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 in 2007 six countries reported having it. Regarding the production of pharmaceutical starting materials, the variation was from four countries in 2003 to six in 2007. The number of countries that reported having capacity for formulation from starting 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 flexibilities.

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

In 2003, a minimal number of countries (5) 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, and in 2007 the countries with such legal provision more than doubled (13 countries). For the **Bolar exception, five** countries reported having included it in their legislation in 2003 and the inclusion of this provision doubled in 2007 (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 of scarce resources. Some interventions found to be of value include: a mandated multi-disciplinary national body to coordinate policies on medicine 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 for medicines comprising the EML 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 (21 in 2003 and 20 in 2007). Public sector insurance reimbursement for the usage 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 a **National Standard Treatment Guidelines (STG)**, from 13 in 2003 to 25 in 2007. For STGs at the hospital level, there were 10 countries in 2003 and 19 in 2007. For STGs at the primary health care level, there were 12 countries in 2003 and 23 in 2007.

In 2003, there were 19 countries that reported having a **National Medicines Formulary Manual** and 23 countries in 2007. In 2003, seventeen countries mentioned that their national formularies covered only the EML and in 2007 this decreased to thirteen countries. The number of countries that reported having conducted the last update of

the medicines national formulary in less than five years varied from 13 in 2003 to 16 in 2007.

Regarding the presence of the **concepts related to Rational Medicines Use (RMU)** in the training program of health workers, a great variation was observed. In relation to EML concepts, these were reported to be present in the education programs of doctors in 8 countries in 2003 and in 15 in 2007. For nurses, the variation was from 8 countries in 2003 to 15 in 2007. For pharmacists, it decreased slightly from 15 countries in 2003 to 14 in 2007.

The availability of **training on pharmacotherapy** for all categories of health workers saw a significant increase in 2007 when compared with 2003. In the case of doctors, it varied from 9 countries in 2003 to 15 in 2007; for nurses, the variation was from 1 country in 2003 to 10 countries in 2007; and for pharmacists the variation was from 6 countries in 2003 to 10 countries in 2007.

In 2003, rational prescribing concepts were reported to be present in doctors' training programs in 10 countries, in the nurses' programs in 6 countries, and in the pharmacists' program in 8 countries. In 2007, these concepts were reported to be present in the doctor's training in 15 countries, and in nurses' and pharmacists' training in 11 countries..

In relation to having public education campaigns, in 2003, nine countries reported conducting public education on the use of antibiotics and five countries on the use of injections. In 2007, the countries that related having campaigns on the use of antibiotics increased to ten and the countries with campaigns on the use of injections decreased to three.

Most of the **prescribing** is done by doctors. However, nurses prescribe occasionally in a significant number of countries. In 2003, twelve countries reported having an **Independent Medicines Information Centre,** with the number of countries increasing to 16 in 2007.

In 2003, there were 11 countries where **Drug and Therapeutic Committees (DTCs)** were mandated within the NMP; whereas, in 2007, the DTC implementation was mandated in 15 countries.

In 2003, ten countries reported having a **National Strategy on AR control**, 13 countries had a reference laboratory for AR surveillance and 7 countries reported having a National Task Force (NTF) for AR Strategy. In 2007, the countries that reported having a National Strategy for AR control increased to 12 and the countries that reported having a laboratory for AR surveillance increased to 19; but the countries with a NTF for AR decreased to 6.

1. INTRODUCTION

1.1 Background

In 1975, the Twentieth World Health Assembly passed the WHA 28.66 resolution, which mandated the World Health Organization (WHO) to help Member States to formulate national medicines policies and to assist countries to implement pharmaceutical strategies, such as selection of essential medicines, appropriate procurement of quality medicines, and training in various elements of pharmaceutical programmes. The resolution marked the evolution of essential medicines programmes in countries and the development of national medicines policies. The conference of experts, held in Nairobi in 1985, requested that WHO provide information on the medicines situation at the global and national levels.

The above milestones have provided the impetus to develop tools and establish systems to collect and publish data regularly. In 1988, *The World Drug Situation* was published. This 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 2000-03 and 2004-07. 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 2004-07, approved as a resolution in WHA 54.11, has highlighted the challenges in medicines access and use in the 21st 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 use of medicines. 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 realizing this vision.

The World Health Organization (WHO) has continued to gather data and information on the pharmaceutical situations of Member States, using indicator-based tools to follow up progress or non progress of pharmaceutical activities in countries. Among the tools is the Level I monitoring indicators on structures and processes of the pharmaceutical system in countries, which was used to gather data in this Fact Book. 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 the 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 [ii] . The core indicators can be easily collected using standardized methodologies, small samples of data and simple survey techniques.

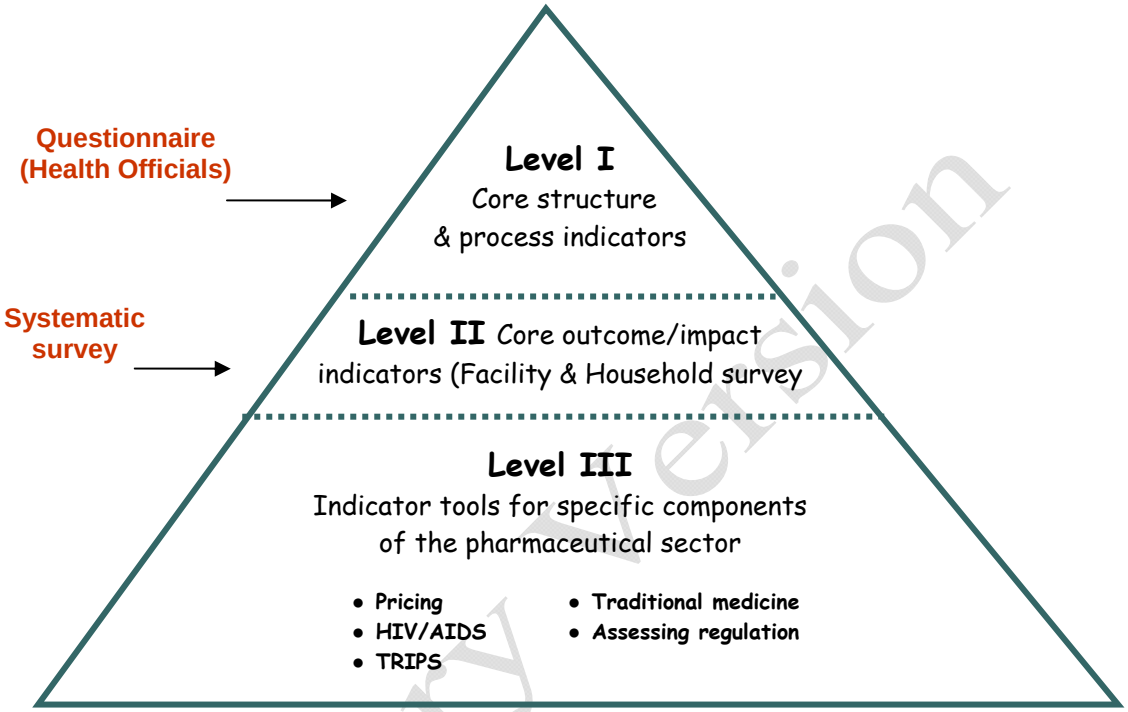

Figure 1. WHO strategy for monitoring country pharmaceutical situations

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 indicators of Level I).

Level II indicators measure the degree of attainment or outcome of the 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"

• 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 to 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 List (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 are: indicators for investigating the use of medicines in health facilities; medicines price surveys; or indicators to monitor the impact of the TRIPS Agreement.

1.3 Countries providing data and structure for the Fact Book

The present Fact Book details the results of the 2007 assessment of Level I indicators by 31 AMRO countries, including high and middle income countries:

Antigua and Barbuda	High Income
Argentina	Middle income
Bahamas	High income
Barbados	High income
Belize	Middle income
Bolivia	Middle income
Brazil	Middle income
Canada	High income
Chile	Middle income
Colombia	Middle income
Costa Rica	Middle income
Cuba	Middle income
Dominican Republic	Middle income
Ecuador	Middle income
El Salvador	Middle income
Grenada	Middle income
Guatemala	Middle income
Guyana	Middle income
Honduras	Middle income
Jamaica	Middle income
Mexico	Middle income
Nicaragua	Middle income
Panama	Middle income
Paraguay	Middle income
Peru	Middle income
Saint Kitts and Nevis	Middle income
Saint Lucia	Middle income
Saint Vincent and the Grenadines	Middle income
Suriname	Middle income
Trinidad and Tobago	High income
Uruguay	Middle income

Data were collected in 2007. Most of the data for Level I indicators were gathered through the country's Ministry of Health. 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 consider that not all countries who answered the questionnaire answered all 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, as far as possible, and to reflect them accurately in the survey report.

The Fact Book summarizes data for the Level I structure and process indicators according to six topics: (1) National medicines policy; (2) Regulatory System; (3) Medicines Supply System ; (4) Medicines Financing ; (5) Production, Trade and Intellectual property; and (6) Rational use of medicines. For each topic there is a brief introduction, followed by tables that summarize the situation in 2007, and the key findings are highlighted after each table and figure. Where possible, the data from 2007 was also compared with data from 2003, when 27 countries answered the Level I questionnaire.

This Fact Book does not attempt to analyse 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 country, sub-regional and regional levels.

2. NATIONAL MEDICINES POLICY

The World Health Organization (WHO) 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"[iii,iv]. 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;
- 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 (NMP) in 2007

	Middle		High		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
NMP official (or draft) document	19	73.1%	3	60.0%	22	71.0%
Official NMP document updated within 5 years*	7	26.9%	1	20%	8	25.8%
NMP implementation plan	11	57.9%	2	50.0%	13	56.5%
*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%

* it was here assumed that those countries not providing dates had not updated their NMP document / NMP implementation plan in the last 5years

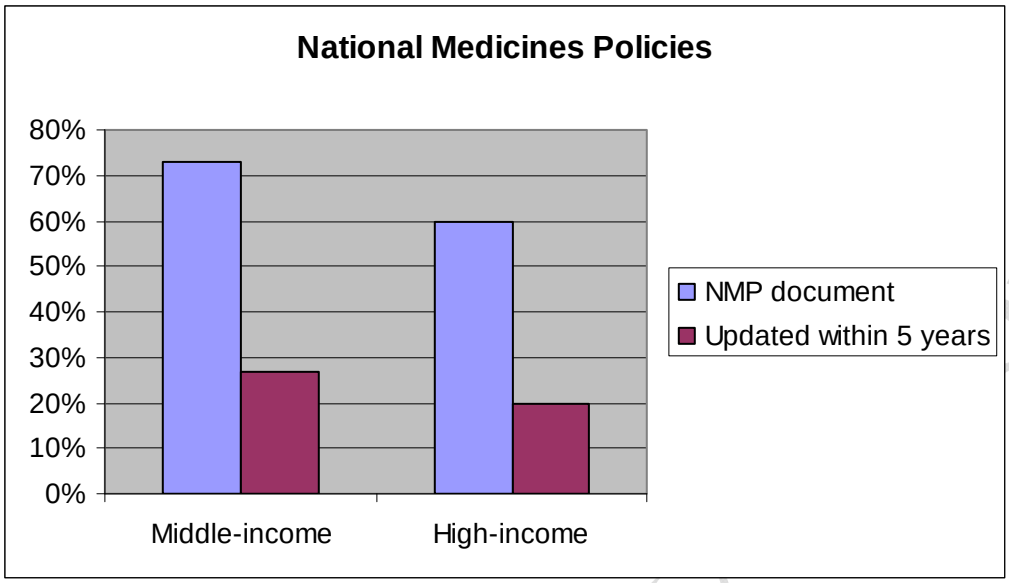

Figure 2. National medicines policies (NMP) in 2007

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

In 2003, sixteen countries had an **Official NMP**, of which ten 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 sixteen of them were integrated into the National Health Policy (NHP). The present data shows a positive change in relation to the situation in 2003.

Table 2. Countries reporting recent indicator assessments

Areas assessed in the last 5 years (2003-2007)	Middle		High	
	Number of countries	%	Number of countries	%
Overall pharmaceutical situation	7	37%	1	50%
Rational use(prescription audit)	6	32%	n.a.	n.a.
Access	8	47%	n.a.	n.a.

- ⇒ ***Not all of the countries reported having assessed their pharmaceutical situation in 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[v].

Table 3. Presence of Medicines Regulatory authority (MRA)

	Middle		High		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%
MRA involved in harmonization initiative	24	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%

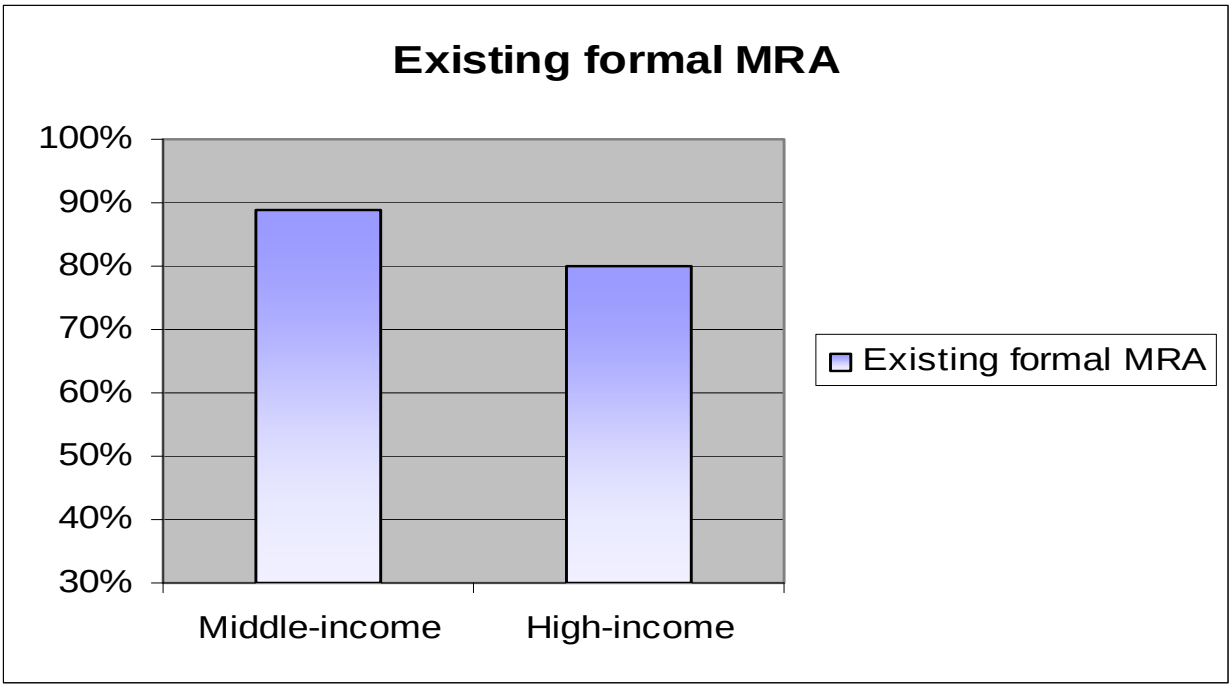

Figure 3. Formal Medicines Regulatory Authority

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

In 2003, there were 21 countries that mentioned having legal provision for a Medicines Regulatory Authority (MRA) and in 2007 the number of countries increased to 28. The number of countries that mentioned having legal provision requiring transparency in 2003 (17) increased to 20 in 2007, and the number of countries with 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, 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 the Secretariat of the network as facilitator of its various working groups.

The PANDRH network 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 [vii].

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

Table 4. Marketing Authorization (MA)

	Middle		High		TOTAL	
	Number of countries	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Provision of marketing authorization	21	80.8%	3	60.0%	24	77.4%
Marketing authorization list publicly available	16	66.7%	2	40.0%	18	58.1%
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 5,997.75 16,448.75 *18*		23,000 23,000 23,000 *1*		**11,571** **6,499 16,849** ***19***	

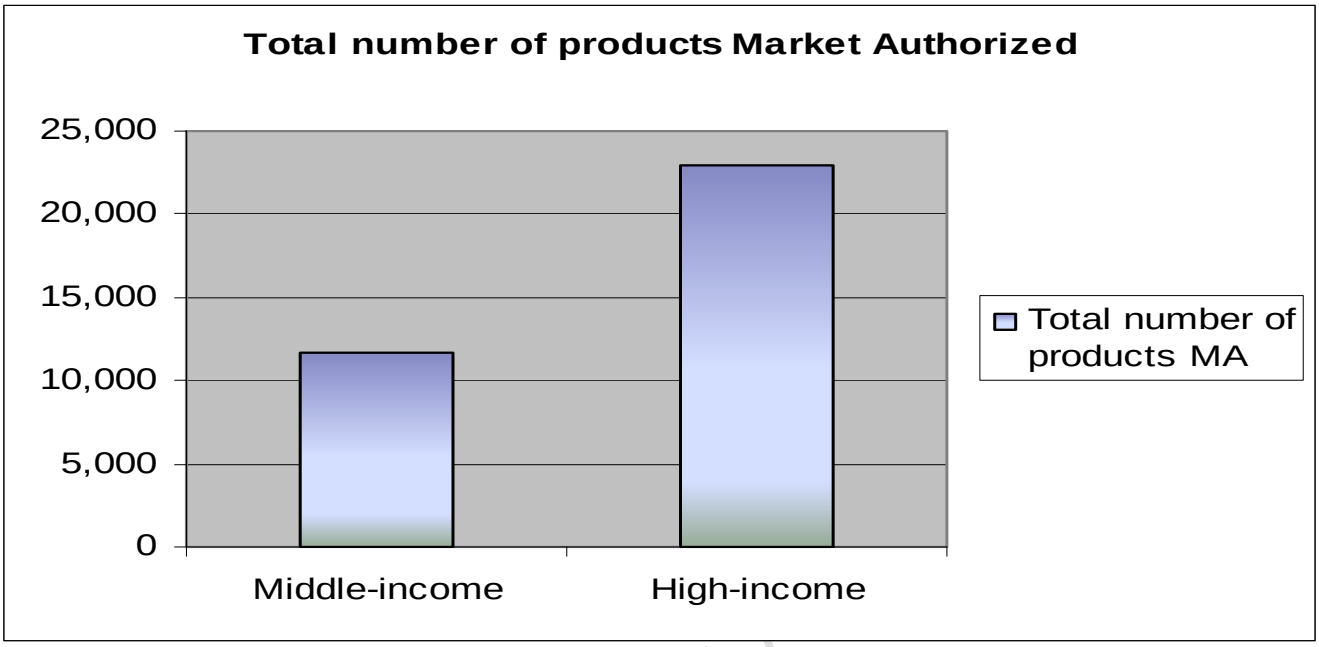

Figure 4. Number of products with MA

- ⇒ ***The majority of countries reported the presence of a comprehensive MA framework.***
- ⇒ ***The MA list was not always publicly available.***
- ⇒ ***The 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 products market authorized, but the rate of non response was very high.***

In 2003, twenty countries mentioned having legal provision for MA. 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 compared with 2003 (11,571 vs 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 related to manufacturing, storing, supplying and dispensing medicines, and of professionals for prescribing and dispensing. Specifications regarding pharmaceutical premises, personnel and procedures must be followed by pharmaceutical manufacturers, distributors and retailers if they want to obtain and retain their licence to operate[vi]. Licensing is extremely crucial to ensure the quality of medicines to be marketed.

Table 5 . Legal provision for licensing

Legal provision for	Middle		High		TOTAL	
	Number of countries	%	Number of Countries	%	Number of countries	%
Manufacturers	24	92.3%	5	100.0%	29	93.5%
Wholesalers/distributors	24	92.3%	5	100.0%	29	93.5%
Importers or exporters of medicines	24	92.3%	3	100%	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 the presence of legal provision for manufacturers, distributors/wholesalers, importers or exporters of medicines and prescribers and pharmacies.***

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

3.4 Regulatory inspection

A regulatory inspection is an applicable tool 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		High		TOTAL	
		Number of countries	%	Number of countries	%	Number of countries	%
Legal provision to inspect premises		25	96.2%	4	80.0%	29	93.5%
Manufacturers	Facilities inspected	20	80.0%	4	80.0%	24	80.0%
	Written national guidelines	18	90.0%	1	50.0%	19	86.4%
Wholesalers/ distributors	Facilities inspected	21	80.8%	3	60.0%	24	77.4%
	Written national guidelines	16	80.0%	1	50.0%	17	77.3%
Importers/ exporters	Facilities inspected	20	80.0%	2	50.0%	22	75.9%
	Written national guidelines	15	83.3%	0	0.0%	15	78.9%
Retail distributors/ pharmacies	Facilities inspected	21	84.0%	3	60.0%	24	82.8%
	Written national guidelines	18	90.0%	0	0.0%	18	85.7%

⇒ ***The majority of countries reported the presence of legal provision to inspect manufacturers, wholesalers/distributors, importers/ exporters and retail distributors/pharmacies***

⇒ ***Most of the middle-income countries also had written national guidelines.***

The number of countries with legal provision for inspection of manufacturers increased from 22 in 2003 to 24 in 2007. Regarding legal provision 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 psychotropics

In order to globally counteract the illicit production of and traffic in narcotics and psychotropic substances, which pose a great danger to public health, the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances was issued in 1988 to provide for legal measures against medicine trafficking. It is of great importance that countries implement legal provision to control and monitor, not only finished products, but also precursors, chemicals and solvents that are used for the production of narcotics and psychotropics[vii,viii]. The Convention further promotes strong international cooperation, as only a joint international approach will allow for a decrease in the use, production and illicit trade of these substances worldwide.

Table 7. Control of narcotics and psychotropics

	Middle		High		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Legal provision for control of narcotics	26	100.0%	5	100.0%	31	100.0%
Signatory to int. convention on control of narcotics	25	100.0%	5	100.0%	30	100.0%

⇒ ***All the countries reported the presence of legal provision for control of narcotics and all countries reported being signatories to the international convention on control of narcotics.***

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 required quality criteria. WHO provides guidelines on establishing testing facilities [ix, x].

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 (for example: a recall, a withdrawal, or other relevant action).

Table 8. Quality Control

Quality Control	Middle		High		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Quality management 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%
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 (district, regional)	3	23.1%	0	0.0%	3	18.8%
Quality control laboratory in another 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/ dispose 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	1,401 448 1874 *15*		166 105 227 *2*		812 183 1,713 *17*	
Number of samples that failed	63.5 18.8 93 *14*		9 6 12 *2*		45 12 91 *16*	

- ⇒ ***The majority of countries reported having a quality management system in place.***
- ⇒ ***The government quality control laboratory was the most commonly used laboratory for testing in middle income countries. High income ones also resorted to private laboratories and laboratories in other countries.***
- ⇒ ***Not all the countries had legal procedures 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 collected samples was 1,287 for 15 countries and the median for the 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) with the participation of 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 performed tests are evaluated by the USP. The evaluation makes it possible:

- to formulate recommendations for participating laboratories to optimize testing capacity and reporting;
- to identify the areas that demand technical cooperation;
- to evaluate the quality of drugs used in priority programs; and
- to develop the concept of reference QC laboratories throughout the region.

Objectives:

- To strengthen the performance in quality control tests of the OMCL of the Americas;
- to increase communication and exchange of information; and
- to harmonize methodologies to facilitate the acceptance/recognition among countries of the validity of the results obtained.

Development of the EQCP

The EQCP is made up of 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 twenty-one 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[xi].

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 [xii, xiii], as part of the essential regulatory functions, with one of its aims being to *"contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use"*[xii].

Since 1968, there has been a WHO Programme for International Drug Monitoring, now co-ordinated by the Uppsala Monitoring Centre (UMC) in Uppsala, Sweden, with oversight by an international board. The principal function of UMC is to manage the international database of ADR reports received from National Centres. The majority of national contributing centres have easy electronic access to these reports. The UMC has established standardized reporting by all National Centres and has facilitated communication between countries to promote rapid identification of signals [xii].

Table 9. Monitoring of Adverse Drug Reactions (ADR)

	Middle		High		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%

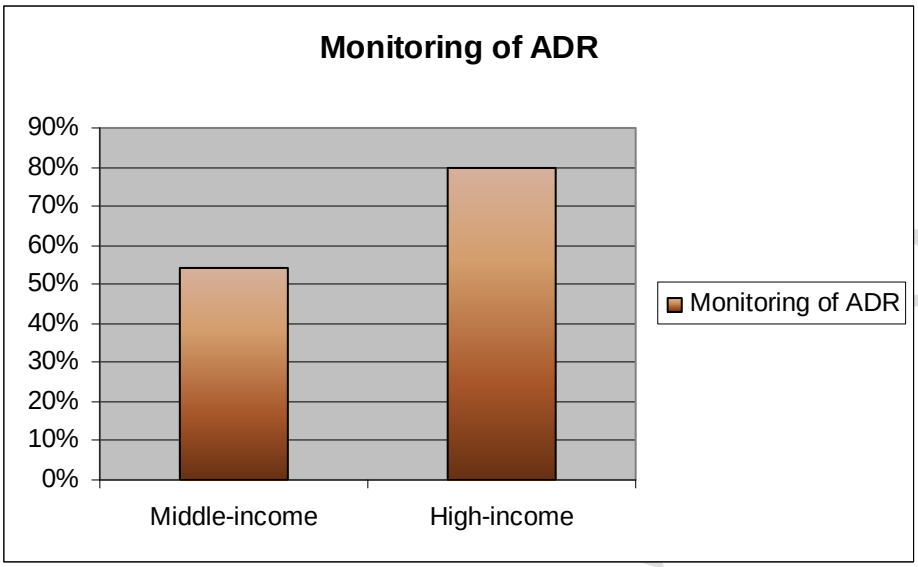

Figure 5. Countries with monitoring of ADRs

- ⇒ ***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, thirteen countries reported monitoring ADRs and this number increased in 2007 to 18, with 14 countries participating in the WHO International Programme for Drug Monitoring.

3.8 Prevention and combat of Counterfeit medicines

A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded 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.[xiv]

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 authorities (health and enforcement alike)[xv].

Table 10. Counterfeit medicines

	Middle		High		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%
from the 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, programmes 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 patients' health 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[xvi]

The prescribers have an additional influence as they determine whether to prescribe a branded medicine or the, mostly, much cheaper 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 be invested in other public health services.

Table 11. Legislation on prescribing and dispensing of generic medicines in the public and private sectors

	Middle		High		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%

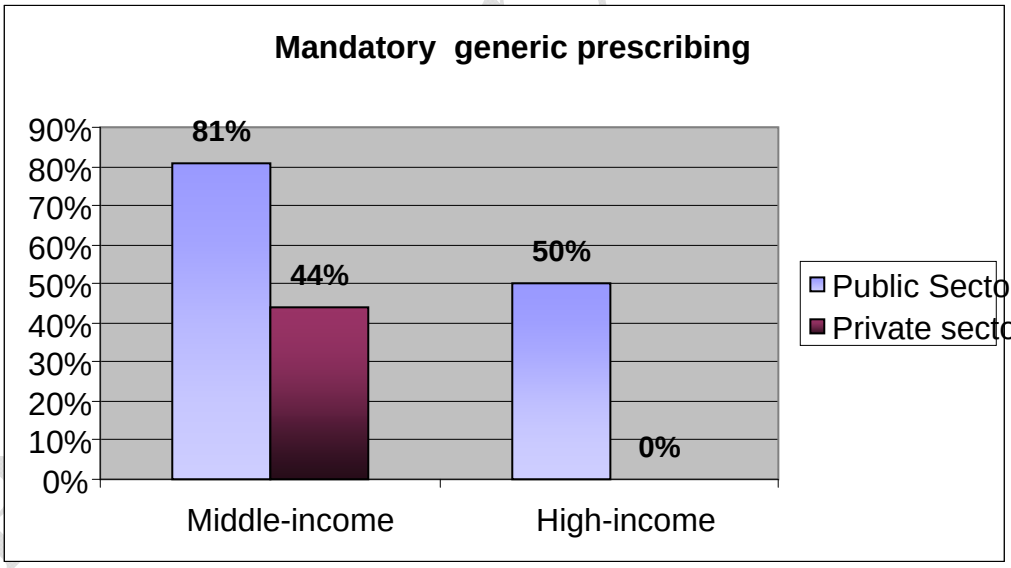

Figure 6. Mandatory generic prescribing

- ⇒ ***The majority of 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 sector 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 this varied from 8 countries to 10. In relation 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 the improvement of access to medicines.

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 the 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 USE

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

- The promotion and marketing of a generic list of medicines from the Essential Medicines List.
- The 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.
- The regulation, evaluation, and authorization of publicity and advertisement of brands.

3.10 Promotion and advertising

Given the known impact of advertising and promotion of medicines on both prescribing behaviour 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.[xvii]

Table 12. Promotion and advertising

	Middle		High		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%	4	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%
Regulations of government including						
Pre-approval for advertisement / promotion	16	80.0%	0	0.0%	16	72.7%
Prohibition of public advertising	17	85.0%	3	100.0%	20	87.0%
Guidelines on advertising of Over the counter (OTC) medicines	14	70.0%	0	0.0%	14	63.6%
Civil society/ Non Governmental Organizations (NGOs) taking active part in monitoring promotional/advertising activities	8	33.3%	2	66.7%	10	37.0%

- ⇒ **The majority of countries reported having legislation on promotion and advertisement of medicines.**
- ⇒ **The government or the national regulatory authority was most often the responsible agency for regulating promotion and advertising in middle income countries.**
- ⇒ **The civil society / NGOs play a minor role in monitoring advertising in middle income countries.**

In 2003, there were 21 countries that reported having legislation on promotion and advertisement; in 2007 four more countries were added.

4. MEDICINES SUPPLY SYSTEM

A well-coordinated medicines supply system helps to ensure that funds available for medicines purchases 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 facility level. The selective approach to priority diseases has resulted in neglect of other important conditions (e.g. chronic diseases, common diseases in children) [iii].

The fragmentation and the segmentation in the health care services, and consequently in the management supply systems; the verticalization of public health programmes (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 Ministries of Health 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 effort, loss of resources and compromise in the quality of the services delivered.

Individual facility-based purchasing may be introduced with the intention to improve 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 (PSP) and distribution

		Middle		High		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							
Ministry of Health	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 of the countries, have pooled procurement in the public sector at the national level.***
- ⇒ ***Ministries of Health (MoH) 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 ones.***
- ⇒ ***MoH were the main distribution agencies in both middle and high income countries.***
- ⇒ ***Non response rates were very high, especially for distribution.***

In 2003, the Ministry of Health performed the procurement function in 19 countries and in 2007 in 26 countries. The distribution function was performed by the Ministry of Health in 12 countries in 2003 and in 18 countries in 2007. Procurement and distribution were performed by a NGO in two countries in 2003. In 2007, procurement was performed by a 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		High		TOTAL	
	Number of countries	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Public sector procurement limited to the EML	11	91.7%	n.a.	n.a.	11	91.7%
provisions for medicines outside EML	13	52%	0	0.0%	13	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, 92.5) *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***	

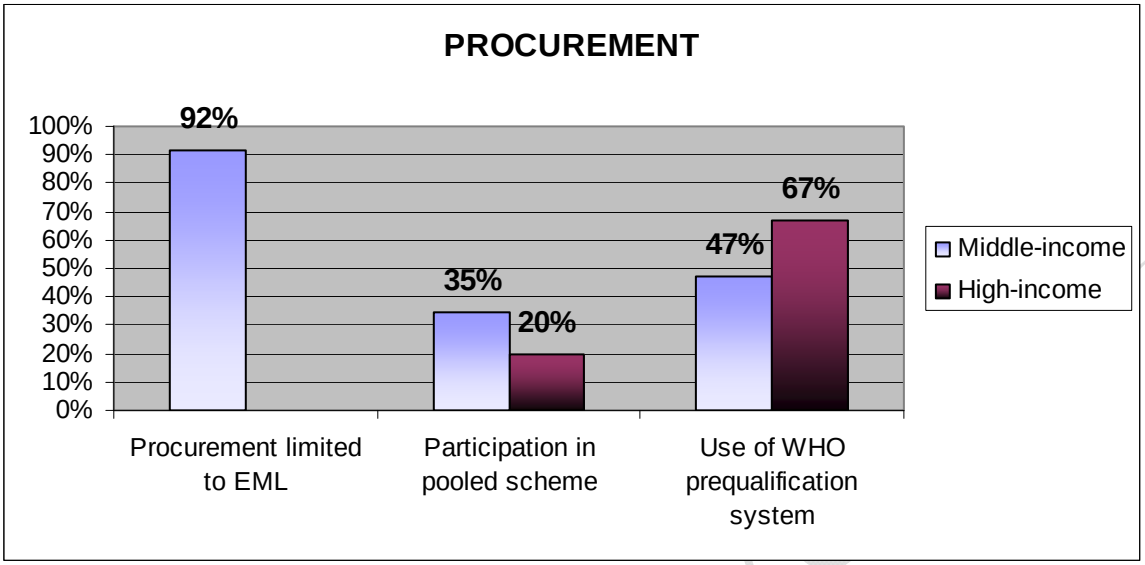

Figure 7. Procurement process for public sector

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

Seventeen countries in 2003 and nineteen countries in 2007 used national competitive tender, while the use of an international competitive tender had a significant increase (varied 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 SF is a programme 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 against HIV, TB, 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 SF 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 SF is open to all PAHO Member States and GFATM principal beneficiaries by signing a participation agreement with the Organization.
There are presently twenty (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;
- To further the continuous availability of public health supplies within PAHO Member States;
- To encourage Member States to improve planning capabilities and use of public health supplies;
- To strengthen Member States public health programs and the application of pertinent PAHO/WHO normative mandates.

The 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 and intellectual property regulation, and supply management.

Webpage: www.paho.org/strategicfund

5. MEDICINES FINANCING

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

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 the community. 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, if 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.[xx]

Table 15. Per capita public expenditure for medicines (TPE) in US $

	Country income level	
	Middle	**High**
	Median [25th, 75th percentile]	
PER CAPITA public expenditure for medicines (TPE) in $US	**$ 6.80**	**$ 30.50**
	$ 3.90 — **$14.40**	**$ 29.90** — **$ 154.70**
	N=21	*N=3*

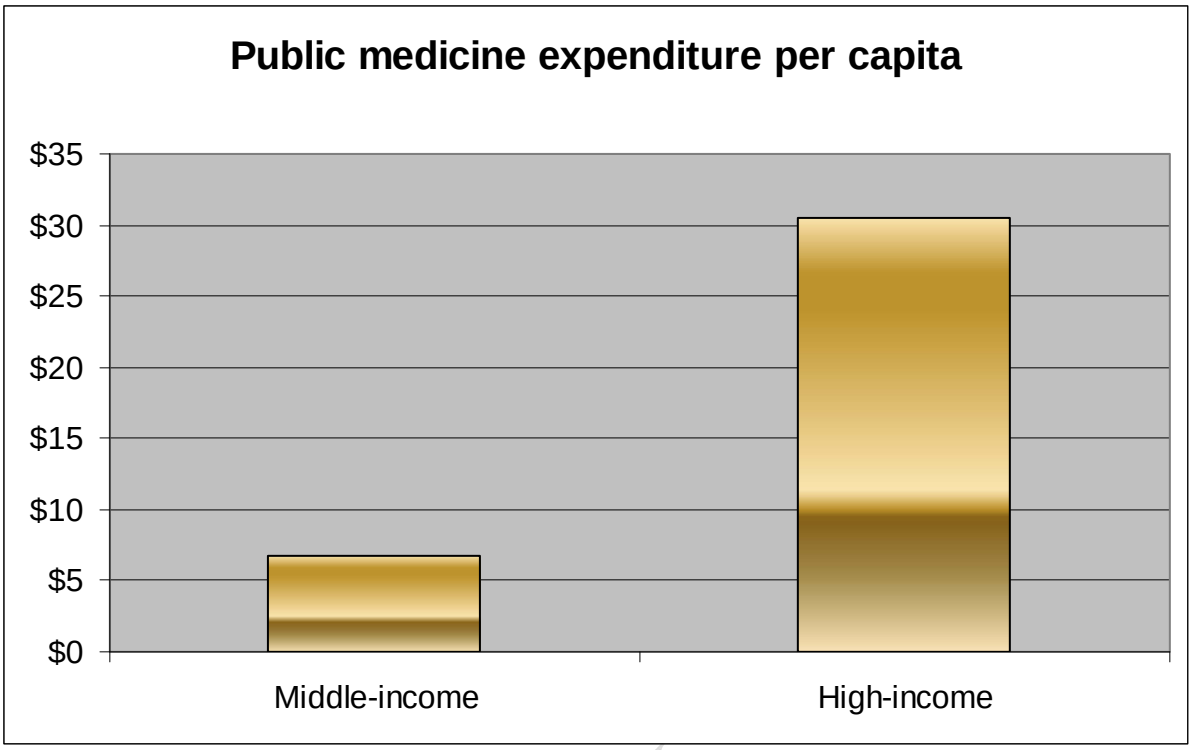

Figure 8. Public medicine expenditure per capita (US$)

⇒ ***The per capita public or government expenditure on medicines was much higher in high income countries than in middle income countries. However, some countries gave very low values.***

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

	Middle		High		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 diseases 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%
Patients, who receive 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 persons	18	81.8%	4	100.0%	22	84.6%

⇒ ***All the countries reported providing some medicines free of charge, these most often being TB 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.***

⇒ ***Free medicines were, in almost all middle income countries, provided to patients who could not afford medicines, 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 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 diseases (STDs), the variation was from 15 to 17. For HIV/AIDS, the variation was significant, from 14 in 2003 to 24 in 2007.

In 2003, fifteen countries reported that medicines were free for those who could not afford them and in 2007 this was reported by twenty-six countries. The reporting of availability of free medicines for children under 5 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 elderly persons, where availability varied from 7 countries in 2003 to 22 in 2007.

Table 17. Fees from medicines

	Middle		High		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	250%	**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 that mentioned 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 in middle income countries.***

⇒ ***In the majority of countries, fees from sale of medicines were not used to pay salaries.***

In 2003, the number of countries who reported that fees were never used for paying salaries was 12, but the rate of response was low. In 2007, the number of countries increased to 23.

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

	Middle		High		TOTAL	
Dispensing of medicines by prescribers	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
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		High		TOTAL	
		Number of countries	%	Number of countries	%	Number of countries	%
Health insured population							
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	*Public sector*	2	8.3%	0	0.0%	2	7.4%
	Private Sector	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	16	84.2%	2	66.7%	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 that covered 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, and the number of countries 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. The number of countries with no coverage

of medicines in the public sector was one in 2003 and four in 2007. There was a significant increase in the number of countries with coverage of some medicines by private insurance, from 11 in 2003 to 18 in 2007. The number of countries with all medicines covered by private insurance showed no change between the two years sampled.

Table 20. Policies on medicines pricing covering different sectors

		Middle		High		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%
Policies covering: medicines prices							
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.a	n.a	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	44.4%
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 done 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 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. However, for NGOs, the countries with a policy on medicines pricing decreased from 6 in 2003 to 4 in 2007.

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

		Middle		High		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%
	NGOs	5	26.3%	1	25.0%	6	26.1%
Regulations on accessibility of medicine price information	Public sector	7	28.0%	2	50.0%	9	31.0%
	Private Sector	3	14.3%	2	40.0%	5	19.2%
	NGOs	2	10.5%	1	25.0%	3	13.0%
Guidelines on medicine donations	Public sector	19	73.1%	5	100.0%	24	77.4%
	Private Sector	10	52.6%	2	66.7%	12	54.5%
	NGOs	11	64.7%	2	50.0%	13	61.9%

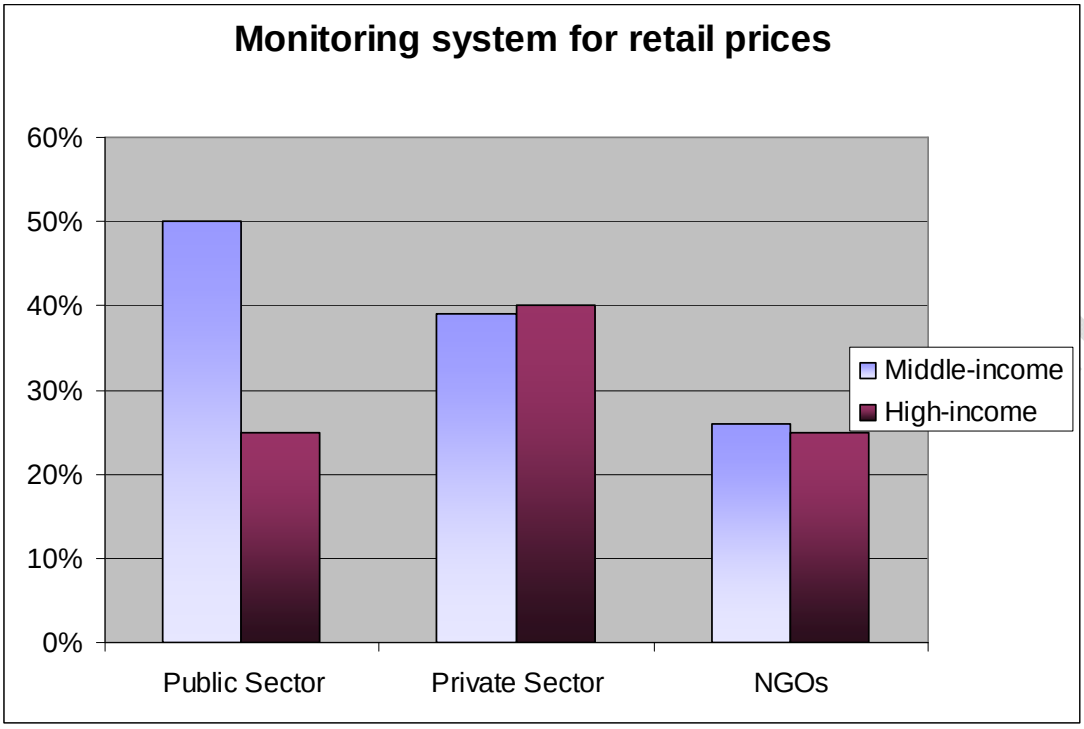

Figure 9. Monitoring system for retail prices

- ⇒ ***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 written guidelines on medicines donation 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) 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 (between 15-20 years), the patent holder has a monopoly on the medicine, which prevents generic competition as a means of reducing prices. Poorer 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.[xxi] 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 affordability and availability of medicines. These safeguards also include setting the criteria for patentability of pharmaceuticals, which adequately reflect public health concerns, legislative provision 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 laws[xxii]; thus, there are limitations on the totality of the information on TRIPS flexibilities presented in the tables below. For example, provision 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 the national law, parallel importation of a product will be permitted into the country from anywhere else, whereas regional exhaustion (as for the whole of the EU) 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 provision for compulsory licensing. Whilst compulsory licensing provision exists within most national laws, the provision 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 Members 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 laws.

For Article 65 of the TRIPS Agreement, there are 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, for developing countries to implement the TRIPS Agreement. The third transition period is for centrally-planned economies, and finally the fourth transition period expired on 1 January 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		High		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 starting materials	5	20.8%	1	20.0%	6	20.7%
Formulation from starting 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% of countries had the capacity to research new substances and produce pharmaceutical starting materials.***

⇒ ***Most countries were capable of producing formulations from starting materials and to repackage finished dosage forms.***

The region has low capacity for research and development (R&D) and for production of pharmaceutical starting 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 starting materials, the variation was from four in 2003 to six in 2007. The number of countries that reported having capacity for formulation from starting 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 TRIPS

		Middle		High		TOTAL	
		Number of countries	%	Number of countries	%	Number of countries	%
Patents granted by national office		20	90.9%	3	60.0%	23	85.2%
National legislation modified to implement TRIPS		16	72.7%	1	25.0%	17	65.4%
TRIPS Article 65		7	41.2%	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							
Compulsory licensing	Yes	11	52.4%	2	40.0%	13	50.0%
Government use	Yes	9	47.4%	2	50.0%	11	47.8%
Parallel importing provisions	Yes	8	38.1%	0	0.0%	8	30.8%
The Bolar exception	Yes	9	47.4%	1	25.0%	10	43.5%

- ⇒ ***Patents were granted by a national office in almost all of the middle income countries and in over half of the high income ones.***
- ⇒ ***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% of middle income countries, except Parallel importing provisions, which fell below.***

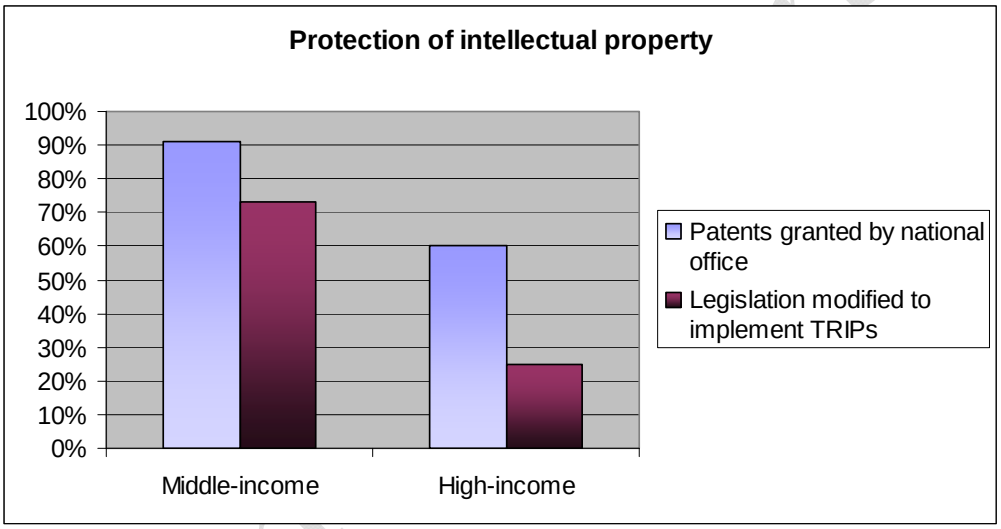

Figure 10. Protection of intellectual property

In 2003, eight countries mentioned having their national legislation modified to implement the TRIPS Agreement, three countries were availing themselves of the provisions of Article 65 of TRIPS, and none of them reported availing themselves of Article 66 of TRIPS. In 2007, there were 17 countries that mentioned having their legislation modified to implement the TRIPS Agreement, 9 of them with provisions for Article 65 of TRIPS, 1 of them with provisions for Article 66 of TRIPS, and 5 of them with provisions for Paragraph 7 (according to the Doha Declaration).

In 2003, five countries had incorporated the provisions for parallel imports but the response was very low. In 2007, eight countries reported the inclusion of this provision in their legislation. Compulsory licensing had been included in 6 countries in 2003, and in 2007 the number of countries with this legal provision had doubled (13 countries). For the Bolar exception, 5 countries reported having included this provision in their legislation in 2003 and inclusion of this provision doubled in 2007 (10 countries).

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".[xxiii] 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;
- 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.[xxiv,xxv] Some policies, strategies and interventions found to be of value include:

- creating a mandated multi-disciplinary 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 availability of medicines and retain well-trained staff.

Table 24. Availability and status of Essential Medicines List (EML)

	Middle		High		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 paediatric EML	19	86.4%	2	66.7%	21	100.0%
* 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 in the last 5years						
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 drugs 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	508 383 600 *21*		580 580 580 *1*		512 386 598 *N=22*	
Pediatric formulations in National EML	58.5 29.25 263.5 *10*		n.a. n.a. n.a. *0*		**58.5** **29.5 263.5** ***10***	

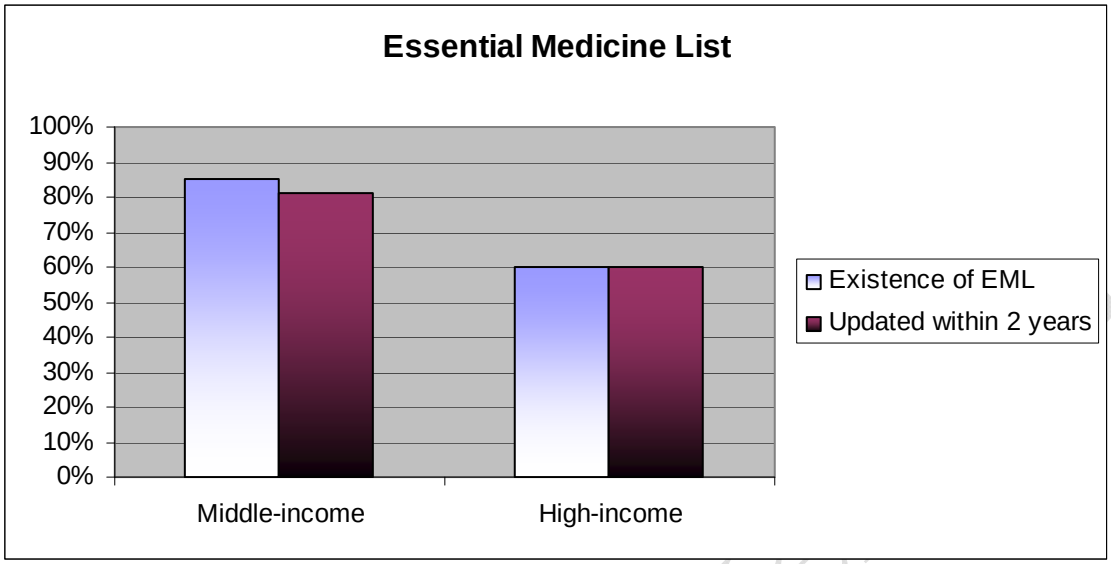

Figure 11. Essential Medicines List

- ⇒ ***Most of the middle income countries had an EML list. Almost all existing EMLs in the Americas Region have been updated in 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 having the last update of the EML done in less than 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 8 countries in 2003 to 9 countries in 2007. The use of the EML for private insurance reimbursement was insignificant in both periods, increasing from 2 countries in 2003 to 3 countries in 2007.

Table 25. Standard Treatment Guidelines (STGs) and Medicines Formulary Manual (MFM)

	Middle		High		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 in the past 5 years*	11	44.0%	1	25%	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%
STGs for key paediatric illnesses	16	80.0%	3	75.0%	19	79.2%
Medicines Formulary Manual	20	76.9%	3	75.0%	23	76.7%
Formulary updated in 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 in 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% of national guidelines had been updated in the past 5 years.***
- ⇒ ***Most of the countries had STGs for key paediatric illnesses.***
- ⇒ ***Medicines Formulary Manuals existed in almost 80% of countries, usually contained only EML medicines.***

Regarding the number of countries that reported having a National STG, there was a significant increase from 13 in 2003 to 25 in 2007. For STGs at the hospital level, there were 10 countries in 2003 and 19 in 2007 and at the primary health care level, there were 12 countries in 2003 and 23 in 2007.

In 2003, there were 19 countries that reported having a national formulary and 23 countries in 2007. In 2003, seventeen countries mentioned 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 in less than five years varied from 13 in 2003 to 16 in 2007.

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

	Middle		High		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
EML concepts						
Doctors	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						
Doctors	12	60.0%	1	50.0%	13	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						
Doctors	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						
Doctors	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%

⇒ ***Doctors, 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 RMU concepts in the training of health workers, great variation was observed between 2003 and 2007. In relation to the EML concepts, variations for doctors, nurses, pharmacists, pharmacy assistants and paramedical staff were from 8 countries to 15, from 8 to 15 countries, from 15 countries to 14, from 4 to 8, and from 4 to 6, respectively.

Regarding the countries that have training available on STG concepts, there was a significant increment in the case of nurses and pharmacists (from 6 to 12 for nurses and from 5 to 8 for pharmacists). In 2007, STG concepts were reported to be present in the training of doctors in 13 countries versus 10 countries in 2003, of pharmacy assistants in 5 countries versus 2 in 2003, and of paramedical staff in 6 countries versus 2 in 2003.

The availability of training in pharmacotherapy showed a significant increase in 2007 for all categories of health workers. Doctors varied from 9 countries in 2003 to 15 in 2007, nurses from only 1 country in 2003 to 10 countries in 2007, pharmacists from 6 countries in 2003 to 10 countries in 2007, and both pharmacy assistants and paramedical staff from 0 in 2003 to 3 countries in 2007.

Rational prescribing concepts were reported to be present in doctors' training in 10 countries in 2003, in nurses' training in 6 countries, and in pharmacists' training in 8 countries. In 2007, these concepts were reported to be present in the doctors' 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		High		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Education Programmes						
Doctors	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 centre						
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 doctors and pharmacists than for nurses. It was very low for pharmacy aides.***
- ⇒ ***Medicines information centres 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 Centre, 12 countries reported having one in 2003 and this number increased to 16 countries in 2007.

In relation to having public education campaigns, 9 countries reported having these on the use of antibiotics and 5 countries on the use of injections in 2003. In 2007, there were 10 countries that reported having campaigns on the use of antibiotics and three countries had campaigns on the use of injections.

Table 28. Prescribing practices

Prescription for medicines by:	Middle		High		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Doctors						
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	40.0%	13	43.3%
Never	7	28.0%	3	60.0%	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	13.0%	0	0.0%	3	11.1%
Never	20	87.0%	4	100.0%	24	88.9%

⇒ ***Most of the 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		High		TOTAL	
	Number of countries	%	Number of countries	%	Number of countries	%
Body designated to promotion of RMU	9	36.0%	3	60.0%	12	40.0%
Requirement for drugs and therapeutic committees	12	46.2%	3	75.0%	15	50.0%
Availability of drugs and therapeutic committees						
Referral hospitals (at least in half of them)	14	56,0%	2	100.0%	16	59.3%
General hospitals (at least in half of them)	14	56.0%	2	66.7%	16	57.1%
Regions/provinces (at least in half of them)	10	43.5%	1	50.0%	11	44.0%

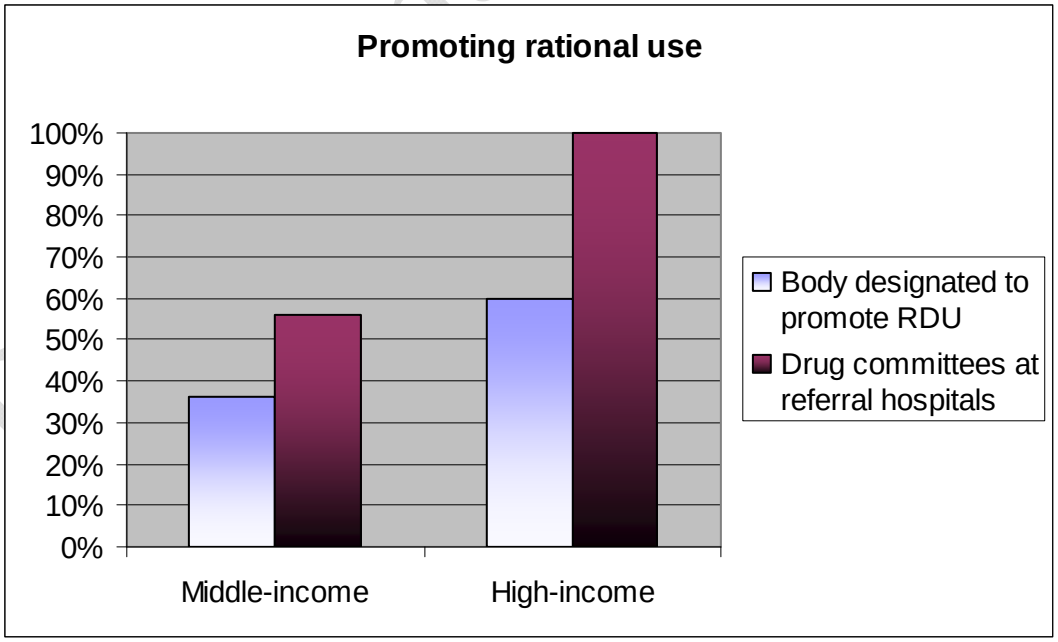

Figure 12. Promoting Rational Use

⇒ ***Bodies 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% of the countries. This proportion was somewhat lower for DTCs in regions and provinces.***

In 2003, there were 11 countries where DTCs were mandated within the NMP: in 2007, DTC implementation was mandatory in 15 countries.

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

	Middle		High		TOTAL	
Antimicrobial resistance	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Strategy for AR containment	10	38.5%	2	40.0%	12	38.7%
Surveillance laboratory for AR	16	61.5%	3	60.0%	19	61.3%
Task force	5	20.0%	1	25.0%	6	20.7%
Frequency of OTC sale						
Antibiotics						
Always	2	7.7%	0	0.0%	2	6.9%
Frequently	13	50.0%	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	0.0%	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%

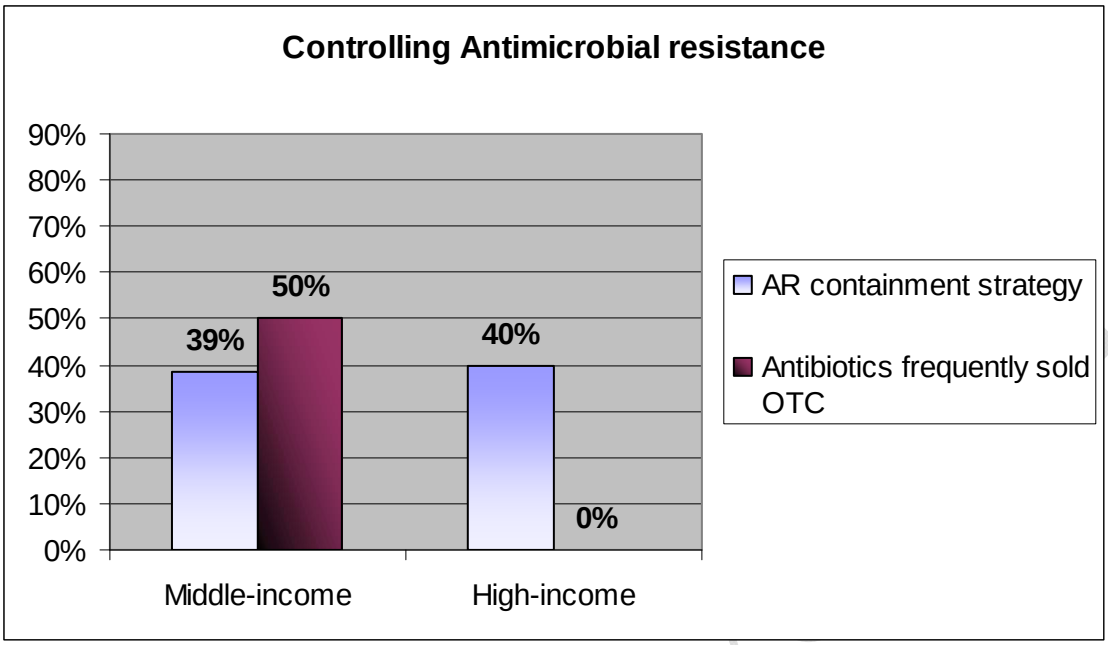

Figure 13. Controlling the antimicrobial resistance

⇒ ***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 of them 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 Strategy on AR control, 13 countries had a reference laboratory for AR surveillance and 7 countries reported having a National Task Force (NTF) for AR Strategy. In 2007, the countries that reported having a National Strategy for AR control increased to 12 and the countries that reported having a laboratory for AR surveillance increased to 19; but the countries with a NTF for AR decreased to 6.

8. FINAL CONSIDERATIONS

The data collected and presented in this Fact Book 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 Fact Book can be useful to guide countries about 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 provision 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 starting materials. The Global Strategy on Innovation, Public Health and Intellectual Property, approved in the 61st World Health Assembly in 2008, provides an opportunity for achieving programmes 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 Centres in only 53.3% of the countries and only 34.5% of the countries developed public information campaigns about 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 antimicrobial resistance (AR) control. A small portion of the countries (38.7%) reported having a National Strategy on AR control and only 20.7% of the countries had a task force for AR control.

Finally, it is important to recall that these results correspond to the 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 Americas Region. Nevertheless, information about the impact of public policies is also required. This information can be obtained using Level II and III indicators.

9. REFERENCES

[i] WHO *Using indicators to measure country pharmaceutical situations Fact Book on WHO Level I and Level II monitoring indicators*. Geneva: WHO, 2006. Available at: http://www.who.int/medicinedocs/index/assoc/s14101e/s14101e.pdf

[ii] WHO *Operational package for monitoring and assessing country pharmaceutical situations.* Geneva, World Health Organization, 2007.

[iii] How to develop and implement a national drug policy. 2nd edition. Geneva, World Health Organization, 2001.

[iv] How to develop and implement a national drug policy. WHO Policy Perspectives on Medicines, No. 06, January 2003. Geneva, World Health Organization, 2003.

[v] WHO Policy Perspectives on Medicines 2004, No. 09, October 2004 - Pharmacovigilance: Ensuring the Safe Use of Medicines.

[vi] Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances, 1997, WHO MD. Available from: http://www.who.int/druginformation/general/innlists.shtml.

[vii] Guidelines for the Control of Narcotic and Psychotropic Substances in the Context of the International Treaties, WHO 1984.

[viii] Narcotic and Psychotropic Drugs - Achieving Balance in National Opioids Control - Guidelines for Assessment, WHO MD 2000.

[ix] National laboratories for drug quality surveillance and control. WHO Expert Committee on Specification for Pharmaceutical Preparations.

[x] Good laboratory practices in government drug control laboratories. WHO Expert Committee on Specification for Pharmaceutical Preparations.

[xi] *WHO The Importance of Pharmacovigilance.* Geneva: WHO, 2002.

[xii] *WHO Policy Perspectives on Medicines, No. 09, October 2004 - Pharmacovigilance: Ensuring the Safe Use of Medicines.*

[xiii] *Safety of medicines - A Guide to Detecting and Reporting Adverse Drug Reactions - Why Health Professionals Need to Take Action, 2002, (WHO).*

[xiv] Counterfeit Drugs - Guidelines for the Development of Measures to Combat Counterfeit Drugs. Geneva, WHO, 1999.

[xv] WHO *Counterfeit Drug Kills!* Geneva: WHO, 2008. Available at: http://www.who.int/impact/FinalBrochureWHA2008a.pdf

[xvi] Guide to Good Prescribing - A Practical Manual, 1994, WHO.

[xvii] Drug Promotion - What We Know, What We Have Yet to Learn - Reviews of Materials in the WHO/HAI Database on Drug Promotion, 2005, HAI/ WHO.

[xviii] World Health Organization. Global comparative pharmaceutical expenditures with related reference information. Geneva: World Health Organization, 2000 (EDM/PAR/2000.2).

[xix] Xu K, Evan DB, Kawabata K, Zeramdini R, Klavus J, Murray CJL. Household catastrophic health expenditure: A multicountry analysis. The Lancet 2003;362:111-117.

[xx] Cameron A, Ewen M, Ross-Degnan D, Laing R. Medicine prices, availability, and affordability in 36 developing and middle-income countries: A secondary analysis. The Lancet, Volume 373, Issue 9659, Pages 240 - 249, 17 January 2009.

[xxi] Globalization, TRIPS and access to pharmaceuticals. *WHO Policy Perspectives on Medicines,* No. 03, March 2001. Geneva, World Health Organization, 2001

[xxii] WHO The use of flexibilities in TRIPS by developing countries: can they promote access to medicines? South Centre and World Health Organization, 2005 (link to the report)

[xxiii] The rational use of drugs. Report of the Conference of Experts, Nairobi, 1985. Geneva, World Health Organization, 1985.

[xxiv] Promoting rational use of medicines: Core components. *WHO Policy Perspectives on Medicines*, No. 05, September 2002. Geneva, World Health Organization, 2002

[xxv] Laing RO, Hogerzeil HV, Ross-Degnan D. Ten recommendations to improve use of medicines in developing countries. *Health Policy and Planning*; 16(1): 13–20; Oxford University Press 2001

ANNEXES

1. *GLOSSARY OF TERMS*
2. *LEVEL I QUESTIONNAIRE 2007 (ENGLISH)*
3. *LIST OF LEVEL I CORE INDICATORS*

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** ____	
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**	

Questions	Responses	Explanations
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		
2.1 Are 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**	
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**	
2.4 Are 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**	
2.8 How many medicinal products have been approved to be marketed? *(count total number of unique dosage forms and strengths)*	**Number** ____	
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**	

Questions	Responses		Explanations
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/distributors:	☐ **Yes** ☐ **No** ☐	☐ **Yes** ☐ **No** ☐	
Importers/exporters:	☐ **Yes** ☐ **No** ☐	☐ **Yes** ☐ **No** ☐	
Retail distributors/pharmacies:	☐ **Yes** ☐ **No** ☐	☐ **Yes** ☐ **No** ☐	
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:			

Questions	Responses	Explanations
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 ____	
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	
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	

Questions	Responses	Explanations
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?	☐ **Industry (self-regulation) only** ☐ **Government or national regulatory authority only** ☐ **Co-regulation** ☐ **Don't Know**	
a) If regulated by government, do regulations include any of the following: 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**	☐ **Yes** ☐ **No** ☐

Questions	Responses		Explanations
	☐No ☐ DK	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	_____%	
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.***			
4.1 What is the total public or government expenditure for medicines in US$ for the most recent year for which data are available?	**US$** _____ **Year** _____		

Questions	Responses	Explanations
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**	
a) If yes, which of the following are free at public primary care		
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:	☐ **Yes** ☐ **No** ☐ **Don't Know**	
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**	
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** ☐ / ***Private sector*** ☐ **Yes** ☐ / ***NGO*** ☐ **Yes** ☐	

Questions	Responses			Explanations
	No ☐ DK	No ☐ DK	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	
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			
5.3 If your country is a member of the World Trade Organization	☐ Yes ☐ No ☐ Don't Know ☐ Country not a member of WTO			

Questions	Responses	Explanations
(WTO), has national legislation been modified to implement the TRIPS Agreement?		
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** ☐ **DK** ☐ **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**	
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**	

Questions		Responses			Explanations
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**			
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**			

		Essential Medicines List (EML)	***Standard Treatment Guidelines (STG)***	***Problem-based pharmaco-therapy***	***Rational prescribing***	
6.5	Are the following prescribing issues part of the basic curricula in most health training institutions for:					
	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**	

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		

Questions	Responses	Explanations
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	
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	
urses/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	
6.13 Is there a national strategy to contain antimicrobial resistance?	☐ Yes ☐ No ☐ Don't Know	

Questions	Responses	Explanations
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
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