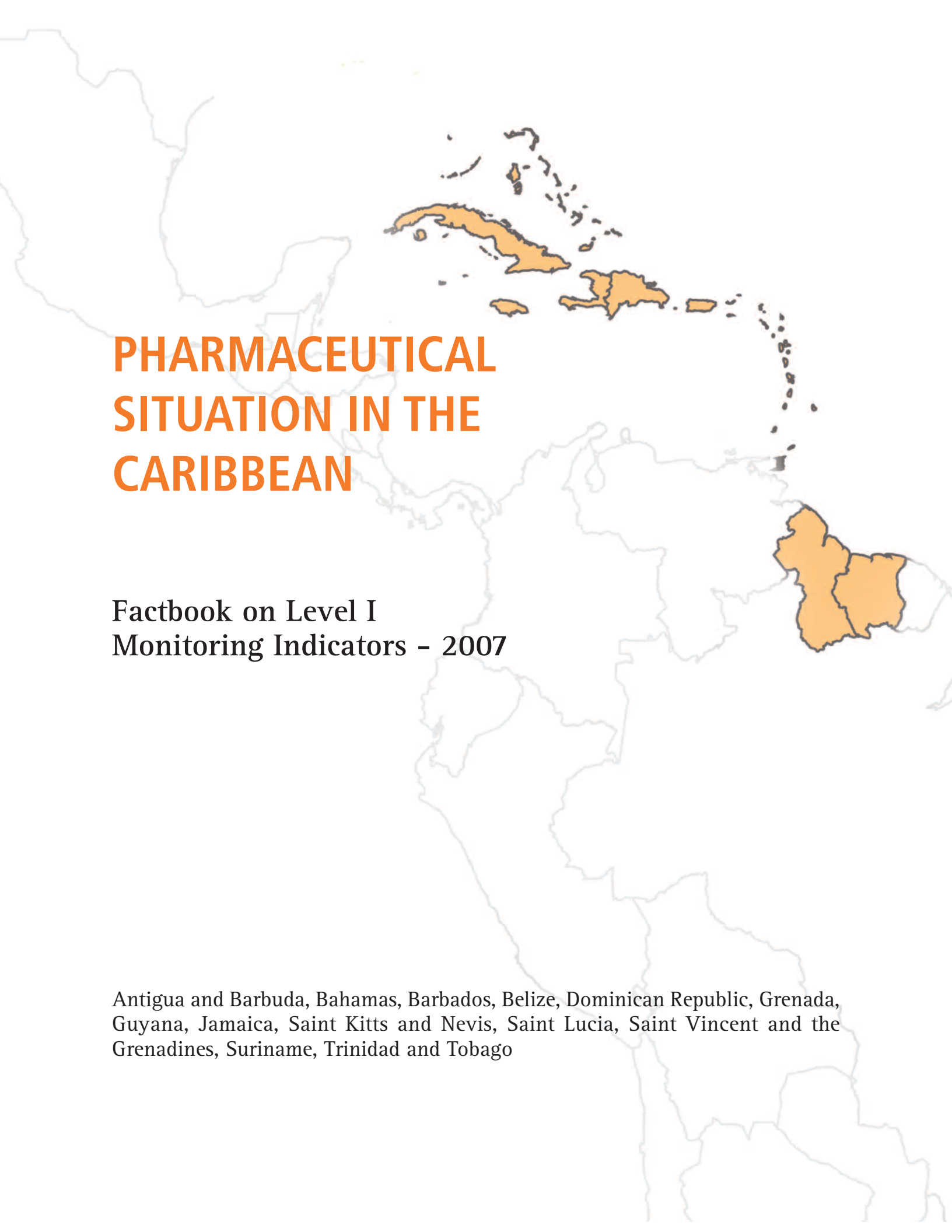
PHARMACEUTICAL SITUATION IN THE CARIBBEAN

Factbook on Level I Monitoring Indicators – 2007

Pan American Health Organization
Regional Office of the World Health Organization

Technical Series: Essential Medicines, Pharmaceutical Policies



PHARMACEUTICAL SITUATION IN THE CARIBBEAN

Factbook on Level I Monitoring Indicators – 2007

Antigua and Barbuda, Bahamas, Barbados, Belize, Dominican Republic, Grenada, Guyana, Jamaica, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname, Trinidad and Tobago

Acknowledgements/Disclaimer

European Union

This document has been produced with the financial assistance of the European Community and the technical support of the Pan American Health Organization/World Health Organization. The views expressed herein are those of the authors and can therefore in no way be taken to reflect the official opinion of the European Community or the Pan American Health Organization/World Health Organization.

PAHO HQ Library Catalog-in-Publication

Pan American Health Organization
"Pharmaceutical Situation in the Caribbean: Fact book on Level I Monitoring Indicators - 2007"
Washington, D.C.: PAHO, © 2010

ISBN: 978-92-75-13131-2

I. Title
1. NATIONAL DRUG POLICY
2. DRUG AND NACOTIC CONTROL – legislation & jurisprudence
3. PHARMACEUTICAL TRADE
4. LEGISLATION, PHARMACY
5. DRUG, ESSENTIAL – standards
6. DRUG INDUSTRY – economics
7. DRUG AND NARCOTIC CONTROL – organization & administration
8. CARIBBEAN REGION

NLM QV 733.DC3

CONTENTS

LIST OF TABLES

ACKNOWLEDGEMENTS

Publication of this *Factbook on the Pharmaceutical Situation of the Caribbean* was made possible thanks to the collaboration of national authorities, who contributed data in response to the WHO Level I Questionnaire on the Pharmaceutical Situation.

This initiative was fully supported by the Medicine Programme Coordination (MPC) of the Essential Medicines and Pharmaceutical Policies Department of the World Health Organization (WHO), the Medicines and Technology (MT) Project of the Area of Health System based on Primary Health Care of PAHO/WHO and the Caribbean Programme Coordination (CPC) Office of PAHO/WHO.

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 took place in 2007 and 2008 and was coordinated by the PAHO/WHO Regional Adviser on Pharmaceutical Policies, Nelly Marin Jaramillo, and in the Caribbean by the former Subregional Adviser on Medicines, Vaccines and Health Technologies, Christophe Rerat, and relied on the collaboration of the advisers of Medicines and Health Systems and Services of the PAHO subregion and country offices of the region.

Edelisa D. Carandang, Gilles Bernard Forte, and Enrico Cinnella (WHO) were responsible for the systematization, designing the framework, and preparing the draft of the document. Adriana Ivama, Subregional Adviser on Medicines and Biologicals, PAHO/WHO - CPC Office, and Nelly Marin, Regional Adviser on Pharmaceutical Policies of PAHO/WHO, were responsible for organizing and editing the publication.

The document was revised by Adriana Ivama, Nelly Marin, James Fitzgerald, Vera Lucia Luiza, Valerie Kerr, and Paul Pivey.

We would like to acknowledge the efforts of all our colleagues who made this publication possible. This initiative is part of the development of the EC/ACP/WHO Partnership on Pharmaceutical Policies.

LIST OF ACRONYMS

ADRs:	Adverse drug reactions
AIDS:	Acquired Immune Deficiency Syndrome
AMRO:	WHO Regional Office for the Americas (PAHO)
AR:	Antimicrobial resistance
OCPC:	Office of Caribbean Programme Coordination
CARIPROSUM:	Caribbean Regional Network of Pharmaceutical Procurement and Supply Management Authorities
CRDTL:	Caribbean Regional Drug Testing Laboratory
DTC:	Drug and therapeutic committee
EML:	Essential medicines list
HIV:	Human Immunodeficiency Virus
INN:	International Nonproprietary Name
LDC:	Least-developed countries
MRA:	Medicines regulatory authority
NMP:	National medicine policy
NGO:	Non-governmental organization
OECS:	Organization of Eastern Caribbean States
OTC:	Over the counter
PANDRH:	Pan American Network for Drug Regulatory Harmonization
PAHO:	Pan American Health Organization
PPS:	Pooled Procurement Service
QC:	Quality control
R&D:	Research and Development
RMU:	Rational Medicines Use
STGs:	Standard treatment guidelines
TPE:	Total public expenditure for medicines
TRIPS:	Agreement on Trade-Related Aspects of Intellectual Property Rights
UMC:	Uppsala Monitoring Centre
WHA:	World Health Assembly
WHO:	World Health Organization
WMS:	WHO medicines strategies
WTO:	World Trade Organization
UN:	United Nations
VIGICARIB:	Caribbean Network for Pharmacovigilance

PREFACE

This Factbook is part of an effort to collect, systematize and make available information about the pharmaceutical situation in the countries of the Caribbean. The data is compared with the entire Region of the Americas, in the context of the development of the European Union and World Health Organization Project for Africa, Caribbean and Pacific Island Countries, "Partnership on Pharmaceutical Policies".

A previous publication on the Level I survey at the global level was conducted in 2003, but this is the first publication of its kind on the pharmaceutical situation in the Caribbean. The 2007 survey results presented in this document are part of the commitment to perform regular monitoring to determine whether there are enabling situations and environments in countries to realize the vision of people having access to the essential medicines they need; that the medicines are safe, effective and of good quality; and that medicines are prescribed and used rationally.

As in the previous Factbook, this document aims to summarize and provide an overview of the pharmaceutical situation in countries of the Caribbean which have contributed data through their health ministries. Data are presented as facts, with key findings following each table and figure.

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

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

EXECUTIVE SUMMARY

WHO Pharmaceutical Indicators

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

The Pan American Health Organization/World Health Organization (PAHO/WHO) have continued to gather data and information on the pharmaceutical situations of the Member States using indicator-based tools to follow up progress (or lack thereof) of pharmaceutical activities in countries. Among the tools utilized is the Level I monitoring indicators on structures and processes of national pharmaceutical systems.

This instrument was used to gather the data presented in this Factbook, which details the results of the 2007 assessment in 13 Caribbean countries: Antigua and Barbuda, Bahamas, Barbados, Belize, Dominican Republic, Grenada, Guyana, Jamaica, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname, and Trinidad and Tobago.[i] The Caribbean data are compared with the entire Region of the Americas, comprising 31 participating countries, and where possible, with data from 2003, when nine Caribbean countries responded to the questionnaire.

[i] The percentages are presented in relation to the total number of answers for each question. The total number of participant countries varies from 9 (2003) to 13 (2007), but not all countries answered all questions and it has to be to be taken into account when analyzing the percentages.

National Medicines Policy (NMP)

The primary objectives of a NMP are to ensure access, quality and rational 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 NMP goals and objectives are articulated in the national health plans, and to facilitate the efficient use of resources.

The number of countries with a NMP increased from three (27.27%) in 2003—of which two were officially adopted—to seven (53.8%) in 2007, with four officially adopted (57.1%). In 2003, two countries had an implementation plan, and one had the NMP integrated into its NHP. In 2007, slightly more than half (five or 55.6%) of the countries had an implementation plan, and 44.4% of NMPs were integrated into the 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 all types of measures available to governments, whether legal, administrative, or technical, to ensure the safety, efficacy, and quality of medicines, as well as the relevance and accuracy of product information. Medicines regulatory authorities (MRAs) are essential for ensuring stringent regulation of the manufacture, trade, and use of medicines in order to protect public health. A legal framework must be in place for the MRA to guarantee independent testing and assessment of the quality, efficacy, and safety of medicines.

In 2003, only four countries reported having a legal framework in place for a **Medicines regulatory authority (MRA)** and four (66.6%) had established a MRA. In 2007, eleven (84.6%) countries had the requisite legal framework in place, and nine (69.2%) had established MRAs. In 2003, none of the MRAs had a website, while by 2007 three (25%) countries had MRA websites. Regarding legal provisions to promote transparency, in 2003 three countries (60%) had these and in 2007 five out of eleven countries (45.5%) had such provisions.

In 2003, only three countries (50%) reported having legal provisions governing **marketing authorization** (MA), but only two of them (28.57%) had an operating MA system. In 2007, the number of countries with legal provisions governing MA increased to six (46.2%). In 2003, no Caribbean country had information on MA publicly available, but by 2007 four (30.8%) countries made such information available. Regarding the use of INN and the use of a computerized system, the number of countries doubled in 2007 to six and two, respectively, and the use of the WHO Certification Scheme varied from three countries (42.9%) in 2003 to four (30.8%) in 2007.

In 2003, four countries in the Caribbean had legal provisions in place governing the licensing of medicine manufacturers and wholesalers/importers (66.67%), and three for medicines importation (60%). In 2007, the number of countries with legal provisions covering these areas increased considerably to more than 90%. With respect to the licensing of prescribers, five (71.42%) countries had these legal provisions in place in 2003, which had increased to 12 (92.3%) countries by 2007. With

respect to the licensing of pharmacies, four (66.67%) countries had these legal provisions in 2003, as compared to 13 (100%) by 2007.

The total number of respondents with legal provisions governing the **inspection** of manufacturers did not vary from 2003 to 2007 in the Caribbean. With respect to legal provisions for inspecting importers and wholesalers, the number of countries varied from five (71.4%) in 2003 to eight (61.5%) in 2007. With regard to legal provisions for inspecting distributors and pharmacies, there was a small variation between 2003 and 2007, with six (85.71%) and eight countries (66.7%), respectively.

In 2007, all Caribbean countries reported having legal provisions in place for the **control of narcotics** and psychotropic substances, and were also signatories to international conventions in this regard.

Quality control is less common in the Caribbean when compared to the Region of the Americas as a whole. Slightly more than 50% of the Caribbean countries had a quality control system in place in 2007. In 2003, it was reported that a total of 172 samples was collected in four countries and that all of them were tested (an average of 43 per country). However, the countries did not provide information regarding the number of samples that failed such tests. In 2006, a total of 1,236 samples were tested in five countries (a median of 206 per country). The total number of samples that failed to meet standards was 36 (2.9%), an average of seven per country.

Regarding **pharmacovigilance**, in 2003 only two (25%) countries reported monitoring adverse drug reactions (ADRs), and this number more than doubled in 2007, when five (38.5%) countries reported ADR monitoring; two of them were participating in the WHO International Program for Drug Monitoring. In March 2008, the Caribbean Network of Pharmacovigilance (VIGICARIB) was established, supported by PAHO/WHO.

Counterfeit medicines represent an enormous public health challenge. In some countries, this is a rare occurrence, while in others it is an everyday reality. Only seven (53.8%) of the participating Caribbean countries reported having laws or regulations pertaining to counterfeit medicines.

There was no significant change in the number of countries with policies for prescribing **generics** in the public sector (five or 62.5% in 2003, and seven or 53.8% in 2007). However, with regard to mandatory prescribing of generics in the private sector, the number of countries doubled (one or 12.5% in 2003, to two or 16.7% in 2007) but still remained minimal. In all participating countries there were legal provisions for generic substitution in place in public sector pharmacies; that is, eight in 2003 and thirteen in 2007. For generic substitution in private pharmacies, six (75%) countries had such provisions in 2003 and nine (75%) in 2007.

Given the known impact of **advertising and promotion of medicines** on prescribing behavior and patient demand, it is essential to regulate and monitor medicines promotion. In 2003, only one (33.1%) country reported having self-regulation of promotion/advertisement, which increased to four (36.4) in 2007. Three (60%) countries reported governmental regulation of medicines advertising and promotion in 2003, and six (54.5%) countries in 2007. In 2003, none of the countries reported civil society or NGO participation in the monitoring of advertising activities, while two (20%) countries reported having this type of monitoring in 2007.

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 to waste of scarce resources. The existence of a large number of different partners with their own medicines supply strategy has led to a lack of coordination, resulting in duplication, inefficiency, and increased workload, especially at the level of facilities. The selective priority diseases approach has resulted in neglect of other important conditions, such as chronic diseases and common childhood diseases.

All the participating Caribbean countries reported having pooled public sector **procurement** at the national level. In 2003, the health ministry performed the procurement function in all seven countries and in 2007 in twelve (92.3%) countries. The distribution function was performed by the health ministry in five (100%) countries in 2003 and in seven (87.5%) countries in 2007. The procurement activity was performed by a private institution in one (50%) country in 2003 and in two (28.6%) countries in 2007. Procurement was performed by individual health institutions in three (75%) countries in 2003 and there was no such report in 2007. Three countries used more than one type of procurement mechanism in both 2003 and 2007.

In both 2003 and 2007, four countries reported that procurement was limited to the essential medicines list (66.67% in 2003, and (100% in 2007). The same number of countries (four) used a national competitive tender in 2003 (80%) and in 2007 (50%). It is observed that the countries used more than one procurement method. Regarding the use of international competitive tendering, the variation observed was from six (85.7%) countries in 2003 to nine (81.8%) in 2007. The use of negotiation or direct purchasing increased from two (66.67%) countries in 2003 to six (75%) in 2007. Five (41.7%) of the countries responding to the questionnaire in 2007 participated in a pooled procurement scheme.

Medicines Financing

Access to specific treatments for high priority conditions has life-saving implications for individuals and major public health benefits for communities. Pricing regulation and policies can provide a good basis for equitable access if effectively implemented. The number of countries that reported having a public sector **policy on medicines** pricing varied from two (33.33%) in 2003 to six (50%) in 2007; for the private sector it varied from two (33.3%) in 2003 to four (33.3%) in 2007.

The median **total expenditure on medicines** in the public sector for the Region of the Americas (US$34,087,493) was considerably higher than in participating Caribbean countries (US$4,000,000), but the median public expenditure per capita was much higher in the participating Caribbean countries (US$20.90) when compared to the Region of the Americas as a whole (US$11.50).

In 2003, the number of countries with coverage of all **essential medicines free of charge** at public facilities was five (83.33%) and in 2007 it was six (60%). In 2003, five (83.33%) Caribbean countries reported providing free medicines for those unable to afford them, increasing to 13 (100%) in 2007. A greater variation, in percentage terms, was observed in the reporting for elderly persons, where the availability of free medicines varied from three (42.85%) countries in 2003 to ten (76.9%) in 2007.

In 2003, five (83.33%) countries reported providing **all medicines free of charge** at the primary care level, and in 2007 this policy was reported by eight (66.7%) countries. Free medicines for HIV/AIDS varied from four (66.67%) to eight (88.9%) countries in 2003 and 2007, respectively.

In 2003, not one country reported having all medicines covered by private insurance, but by 2007 there were two (18.2%) such countries. In 2003, the number of countries reporting **coverage** by the public sector for some medicines was four (57.14%) and in 2007 there were seven (62.6%) such countries. The number of countries with no coverage of medicines in the public sector remained at two (28.6% in 2003, and 18.2% in 2007).

Production and Trade

Intellectual property rights have an important impact on the affordability and availability of medicines, and thereby on public health. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) requires that WTO Members provide minimum standards of intellectual property protection, including patent protection. It is important to consider amending national legislation to incorporate all TRIPS Agreement flexibilities to safeguard access to essential medicines for all.

In 2003, three (33.3%) countries reported having provisions for patent protection of pharmaceutical products. In 2007, five (55.6%) countries reported having patents granted by a national office, and four (44.4%) reported having amended their legislation to implement the TRIPS Agreement. Four countries had provisions for TRIPS Article 65; one (33.3%) had provisions for TRIPS Article 66; and two (40%) had provisions for Paragraph 7 (in accordance with the Doha Declaration).

In 2003, the implementation of **TRIPS flexibilities** was under discussion. In 2007, only one country had already included this flexibility provision in its legislation. With respect to compulsory licensing, it had been discussed in four (57.14%) countries in 2003, and in 2007 only two (22%) countries had such legal provisions. With regard to the "Bolar exception," three countries (50%) reported that it had been discussed in 2003; however, none of the countries reported having such legal provision in 2007.
The lack of capacity for research and development (R&D) and for production of pharmaceutical raw materials remained unchanged between 2003 and 2007 in the Caribbean. This capacity was also limited in the entire Region of the Americas, as only six countries (20.7%) mentioned having R&D activities in 2007. The number of countries that reported capacity for formulation from raw materials doubled from 2003 (four, 50%) to 2007 (eight, 61.5%), and repackaging of finished dosage forms varied from four (50%) countries in 2003 to seven (58.3%) in 2007.

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."*[2] Overuse, under use, and misuse of medicines may lead to unnecessary suffering and death and waste scarce resources.

There was a small variation in the number of Caribbean countries with an **essential medicines list** (EML) between 2003 (seven, 100%) and 2007 (ten, 76.9%). The average number of medicines in national lists varied from 614 in 2003 to 464 in 2007. All countries with an EML used it in public sector procurement (eight in 2003, and ten in 2007). With respect to the public insurance reimbursement scheme, use of the EML varied from two (40%) countries in 2003 to five (50%) in 2007. The EML was also used for private insurance reimbursement by two countries in both 2003 (25%) and 2007 (22.2%).

The number of countries that reported having **national standard treatment guidelines** (STGs) varied from four (50%) in 2003 to nine (75%) in 2007. For STGs at the hospital level, there were two (28.57%) countries in 2003 and seven (58.3%) in 2007, and at the primary health care level there were STGs in four (66.67%) countries in 2003 and eight (66.7%) in 2007.

In 2003, eight (88.9%) countries reported having a **medicines national formulary (MNF)** and nine (75%) in 2007. In 2003, all countries stated that their national formularies covered only the EML and in 2007 there were only four (50%) such countries. The number of countries that reported having conducted the last update of the MNF within less than five years varied from eight (100%) in 2003 to five (41.7%) in 2007.

Although great variation was observed between 2003 and 2007 regarding the presence of the concepts related to **rational medicines use (RMU) in the education of health workers**, there was still minimal presence of these concepts in curricula. The number of countries with an independent medicines information center remained the same from 2003 (three, 37.5%) to 2007 (three, 23.1%), with access for prescribers, dispensers, and consumers. Most of the prescribing of medicines was done by physicians, but nurses and pharmacists also played a minimal role in this activity.

The number of countries with an antimicrobial resistance (AR) strategy remained the same (two) in 2003 as in 2007. The number of countries with an AR surveillance laboratory increased from five (55.6%) in 2003 to seven (53.8%) in 2007. Regarding the existence of an AR task force, in 2003 two countries (22.2%) reported having one, but by 2007 no country had an existing task force.

Final Considerations

The summarized information provided by the Level I indicators for the Caribbean countries is very valuable for analyzing progress in the six areas of the pharmaceutical system. It is important to take into consideration the limitations of the questionnaire, as it is evident that in some areas more specific information was needed. Regarding the presence of a national medicines policy, the 2007 data shows a positive change compared with the situation in 2003, but special attention has to be paid to the implementation of the policy.

The regulation of medicines is one of the inconclusive issues. Progress can be observed in the availability of legal provisions for the medicines regulatory authority (MRA) or for some individual components. Nevertheless, more information is needed regarding the process and the results of essential functions of medicines regulation.

Regarding the high *per capita* public medicines expenditure in the Caribbean, country size, and consequently, the scope of pharmaceutical marketing; the complexity of the health systems; and the effectiveness of the procurement mechanisms, including the use of brand or generic medicines, are some of the factors to be considered when conducting a comparative analysis. Detailed information and additional strategies are required in this area to strengthen the medicines supply system, thereby ensuring its sustainability.

In 2007, the number of countries that changed their national legislation to implement the TRIPS Agreement and its flexibilities was still minimal. Special attention should be paid to this area, with consideration being given to the implementation of the global strategy on intellectual property rights. The availability and utilization of essential medicines lists and standard treatment guidelines increased in the Caribbean. It would be useful to obtain additional information regarding the use of these tools and their impact on rational medicine use. In this regard, the application of Level II indicators and household surveys would be very opportune. On the other hand, the introduction of concepts related to the rational medicine use in the curricula of health professionals is an inconclusive issue in the Caribbean.

Some progress was observed in 2007 with respect to 2003 baseline data, but there is still a significant amount of work required to improve the pharmaceutical sector in the Caribbean. These data are an important tool for subregional stakeholders to identify gaps and establish priorities through an inter-sectoral approach.

1. INTRODUCTION

1.1. Background

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

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

In the previous biennia, WHO's work on medicines has been guided by the (WMS) WHO medicines strategies 2000-2003 and 2004-2007. Both strategies have emphasized the use of indicators to measure the situation in countries, and to ascertain the impact of the WMS in achieving pharmaceutical objectives in countries. The WMS 2004-2007, approved as a resolution in WHA 54.11, has highlighted the challenges in medicines access and use in the twenty-first century. Resolution WHA 54.11 acknowledged the four main objectives of WHO's medicines strategy, namely, to frame and implement policy; to ensure access; to ensure quality, safety, and efficacy; and to promote rational use of medicines. The *WHO medicines strategy* 2004–2007[3] presented the strategies developed to help staff at WHO headquarters, and in the regions and countries, to work towards realizing this vision. Monitoring the progress of efforts to improve the global medicines situation is a crucial part of the strategy.

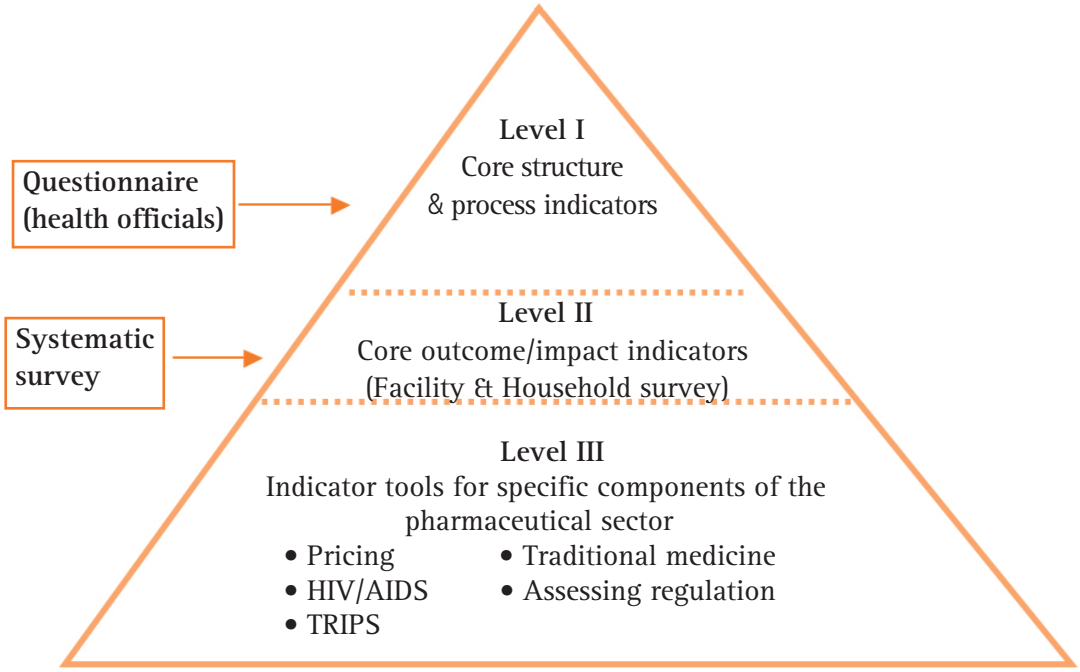
WHO has continued to gather data and information on the pharmaceutical situations of the Member States, using indicator-based tools to follow up on the progress—or lack thereof—of pharmaceutical activities in the countries. Among the tools is the Level I monitoring indicators on structures and processes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

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. 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 protection of intellectual property rights (see Annex 1 for the Level I questionnaire).

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 and essential medicines lists.

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 Contributing, Data and Structure for the Factbook

This Factbook details the results of the 2007 assessment of Level I indicators by 13 high- and middle-income countries in the Caribbean:[ii]

1. Antigua and Barbuda	High-income
2. Bahamas	High-income
3. Barbados	High-income
4. Belize	Middle-income
5. Dominican Republic	Middle-income
6. Grenada	Middle-income
7. Guyana	Middle-income
8. Jamaica	Middle-income
9. Saint Kitts and Nevis	Middle-income
10. Saint Lucia	Middle-income
11. Saint Vincent and the Grenadines	Middle-income
12. Suriname	Middle-income
13. Trinidad and Tobago	High-income

The data presented were provided by the countries' health ministry in response to the Level I questionnaire. Some problems were noted during data processing, owing to the nature of the questionnaire and the high volume of information from the 13 countries. Problems included limited

[ii] It is important to note that not all the countries answered all the questions. As can be seen, the number of respondents for each question is variable. and the percentages are related to the number who answered each question.

knowledge of respondents; hence, the questionable accuracy and validity of some responses. Attempts were made to validate the data, insofar as possible, and to reflect them accurately in the survey report. Given the small number of respondents, no great significance should be attached to the percentages given in the survey report. The Caribbean data are compared with that of the Region of the Americas.[iii]

Insofar as possible, the data for 2007 were also compared with data from 2003, when nine Caribbean countries provided responses to the Level I questionnaire: Bahamas; Barbados; Belize; Dominica; Dominican Republic; Grenada; Guyana; Saint Kitts and Nevis; and Saint Lucia.

This Factbook summarizes data for the Level I structure and process indicators according to six categories: (1) national medicines policy; (2) regulatory system; (3) medicines supply system; (4) medicines financing; (5) production and trade; and (6) essential medicines and rational use. Each category includes a brief introduction, followed by tables that summarize the situation in 2007, and where possible, it was compared with the results from 2003 when data was available.

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

[iii] Thirty-one countries of the Americas provided responses to the Level I questionnaire: Antigua and Barbuda; Argentina; Bahamas; Barbados; Belize; Bolivia; Brazil; Canada; Chile; Colombia; Costa Rica; Cuba; Dominican Republic; Ecuador; El Salvador; Grenada; Guatemala; Guyana; Honduras; Jamaica; Mexico; Nicaragua; Panama; Paraguay; Peru; Saint Kitts and Nevis; Saint Lucia; Saint Vincent and the Grenadines; Suriname; Trinidad and Tobago; and Uruguay. For more details of the Region of the Americas, please see the publication *Pharmaceutical Situation in the Americas: Factbook of Level I Monitoring Indicators - 2007*.

2. NATIONAL MEDICINES POLICY

The World Health Organization has noted that it takes a comprehensive and common framework to develop suitable policies that can tackle all the interdependent problems and involve all stakeholders at the same time. Therefore, WHO highly recommends that countries formulate and implement a national medicines policy (NMP) as a *"commitment to a goal and a guide for action."*[5, 6] A NMP defines a framework for setting and monitoring medium- to long-term objectives in the public and private pharmaceutical sectors. The primary objectives of a NMP are to ensure:

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

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

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

Table 1. Status of national medicines policies in 2007

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
National medicines policy (NMP) status				
NMP document	7	53.8	22	71.0
NMP Official	4*	57.1	16	72.7
Official NMP document updated within last 5 years	2	15.4	8	25.8
NMP implementation plan	5	55.6	13	56.5
NMP implementation plan updated within 5 years	4	40	10	41.7
NMP integrated in NHP	4	44.4	16	66.7

**One of the countries reported having its NMP officially adopted and updated in 2007; however, it was still a draft document.*

- More than half of the countries (53.8%) in the Caribbean have a NMP document, but only two were officially adopted and updated within the last 5 years, while 71% of countries in the Americas have a NMP, 8 of which had been updated within the same 5-year period;
- Five of the Caribbean countries with NMPs have an implementation plan and less than half are integrated into the National Health Policy (NHP).

The number of countries with a NMP increased from three (27.27%) in 2003, of which two had been officially adopted, to seven (53.8%) in 2007, with four officially adopted (57.1%). In 2003, two countries had an implementation plan and one had the NMP integrated into the national health policy (NHP). In 2007, slightly more than half (five or 55.6%) of the countries had an implementation plan and 44.4% of the NMPs were integrated into the NHP. The data here show a positive change in relation to the situation in 2003.

Table 2. Countries reporting indicator assessments

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Areas assessed				
Overall pharmaceutical situation	8	100	16	76.2
Rational use/prescription audit	5	62.5	13	65.0
Access	4	66.7	12	66.7

- All Caribbean countries that answered this question reported having assessed the pharmaceutical situation;
- Most reported having assessed rational use, conducted prescription audits (five, 62.5%), or assessed access (four, 66.7 %).

In 2003, four countries (57.14%) reported having assessed the pharmaceutical situation, two (40%) reported having assessed the rational use of medicines and access in the Caribbean. We can see an increase in the number of countries that conducted any type of assessment. Nevertheless, no information about the relevant study and its results was provided.

3. REGULATORY SYSTEM

Regulation of medicines is a public policy that restricts private sector activities in order to attain certain social goals set by the State. Such a policy includes all types of measures available to governments, whether legal, administrative, or technical, to ensure the safety, efficacy and quality of medicines, as well as the relevance and accuracy of product information. The objective of this regulation is to ensure health safety, defined as the *"safety of individuals against the therapeutic risks of any nature, risks linked to choice of therapy, with acts of prevention, diagnosis or treatment and with the use of health goods and products, as well as health interventions and decisions from health authorities."*[7]

Key regulatory functions include licensing of premises, persons, and practices; inspection of manufacturing facilities and distribution channels; product assessment and registration (marketing authorization); adverse drug reaction (ADR) monitoring; quality control (QC); and monitoring and control of medicines promotion and advertising. Each of these functions targets a different aspect of pharmaceutical activities, but all of them must be undertaken simultaneously to ensure effective consumer protection.[8]

A legislative framework is part of the regulatory structure. It is required to implement and enforce pharmaceutical sector policies. Laws and regulations create a legal basis for the 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 are handled; and the qualifications, rights, and responsibilities of medicines manufacturers, importers, exporters, distributors, prescribers, and dispensers.

3.1. Medicines Regulatory Authority

Three components are key to ensuring health safety:

- Management should be entrusted to an authority with verifiable decision-making autonomy to ensure that only health concerns are taken into account and purely economic interests are excluded;
- Control should be carried out by a body of experts, with policing power; and
- These experts should be independent, transparent, and free of conflicts of interest. [7]

A medicines regulatory authority (MRA) is essential for ensuring stringent regulation of the manufacture, trade, and use of medicines in order to protect public health. Consequently, the MRA must have a legal framework in place to guarantee independent testing and assessment of the quality, efficacy, and safety of medicines.

The MRA should also ensure the integrity of the interaction between patients and dispensers once a prescription has been issued. To ensure this, the MRA should be following several mutually-reinforcing activities such as registration, licensing, controlling, and monitoring.[9]

Table 3. Presence of medicines regulatory authority

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Policy area covered:				
Legal provision for establishment of MRA	11	84.6	28	90.3
Existing formal MRA	9	62.9	27	87.1
Legal provisions requiring transparency	5	45.4	20	71.4
MRA involved in harmonization initiative	10	83.3	28	93.3
Publicly accessible MRA website	3	25.0	19	63.3
Sources of funding for MRA:				
Government budget	11	91.7	29	96.7
Medicines registration fees	1	14.3	14	66.7
Other	1	20	7	53.8

- Most participating Caribbean countries (84.6%) report having legal provisions for the establishment of a MRA. In the Caribbean, 9 countries reported having an established MRA (69.2%), while in the Americas 87.1% reported having one;
- Provisions requiring transparency and publicly accessible websites are less common in the participating Caribbean countries, as compared to the Region of the Americas as a whole;
- Government is the main source of funding for the MRA in the Caribbean, while in the Region of the Americas as a whole, medicine registration fees are also widely used.

In 2003, only four countries reported having legal provisions in place for a **medicines regulatory authority (MRA)** and four (66.6%) had a MRA established. In 2007, eleven (84.6%) countries had the requisite legal provisions, and nine (69.2%) had established MRAs. In 2003, none of the MRAs had a website, while in 2007 three (25%) had MRA websites. With regard to legal provisions for transparency, in 2003 three (60%) countries had such provisions and in 2007 five countries (45.5%) had them.

3.2 Marketing Authorization or Registration

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.[10]

It is recommended that the International Nonproprietary Name (INN) be used, as it can contribute to the harmonization and standardization of product names and simplifies the procurement, the prescribing, the distribution, and the dispensing of medicines across country borders, thereby decreasing the risk of mistakes due to confusing the names of medicines.[11]

Table 4. Legislation and regulation for registration of medicines

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Policy areas covered				
Provisions for marketing authorization	6	46.2	24	90.3
Marketing authorization list publicly available	4	30.8	18	87.1
Computerized system for registered products	2	18.2	20	71.4
WHO Certification Scheme part of MA	4	30.8	16	93.3
INN used in registration of medicines*	6	46.2	24	63.3
Official registration committee	4	30.8	16	55.2
	Median (25th, 75th percentile)		Median (25th, 75th percentile)	
Total no. of products with MA	7,175		14	66.7
	4,763	9,588	6,499	16,849
	N=12		N=19	

** In this case, one of the Caribbean countries that mentioned not having marketing authorization declared using INN for registration.*

- Less than half of the participating Caribbean countries have provisions for marketing authorization, while in the Region of the Americas as a whole, most countries grant marketing authorization;
- The average total number of products in the market in the participating Caribbean countries is lower than that of the Region of the Americas as a whole, although this result is based on a very small sample.

Among countries in the Caribbean with legal provisions in place for marketing authorization, only in four (30.8%) was the information publicly available, and in only two (18.2%) had this activity been computerized. This result was significantly different from the Region of the Americas as a whole, where most countries (twenty-four;.77.4%) had the requisite legal provisions and publicly available information, and the activity was computerized.

In 2003, only three countries (50%) reported having legal provisions for marketing authorization (MA), but only two (28.57%) had an operating MA system. In 2007, the number of countries with legal provisions for MA increased to six (46.2%). In 2003, the average number of approved products in the two countries with MA was 10,073.5 (range: 2,000 to 18,147). As the size of the countries is variable, arriving at a meaningful comparison is difficult. Additionally, in 2007 only two countries answered this question, with an average of 7,175 (range: 2350 to 12,000) approved products.

There was an increase in all other parameters for 2007, as compared with 2003. In 2003, no Caribbean country had publicly available MA information, while in 2007 there were four (30.8%). Regarding the use of INN and a computerized system, the number of countries doubled, while use of the WHO Certification Scheme varied from three (42.9%) countries in 2003 to four (30.8%) in 2007.

3.3 Licensing

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

Table 5. Legal provisions governing licensing

	CARIBBEAN		AMERICAS	
	No. of Countires	%	No. of Countries	%
Legal provisions governing licensing:				
Manufacturers	12	92.3	29	93.5
Distributors/wholesalers	12	92.3	29	93.5
Medicine importers or exporters	11	91.7	27	93.1
Prescribers	12	92.3	30	96.8
Pharmacy	13	100.0	31	100.0

In 2003, there were four countries with legal provisions governing the licensing of medicine manufacturers, distributors, and importers (66.67%), and three for importation (60%). In 2007, the number of countries with legal provisions in these areas increased considerably to more than 90%. Regarding the licensing of prescribers, the number of countries with such legal provisions varied between 2003 and 2007 from five (71.42%) to twelve (92.3%). With respect to the licensing of pharmacies, the variation was from four (66.67%) to thirteen (100%) countries.

- Almost all of the participating Caribbean countries have legal provisions in place for the licensing of manufacturers, importers, exporters, prescribers, and pharmacies.

In 2007, the percentages presented from the Caribbean respondents were similar to those of the Region of the Americas as a whole.

3.4 Regulatory Inspection

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

Table 6. Legal provisions governing the inspection of premises

		CARIBBEAN		AMERICAS	
		No. of Countries	%	No. of Countries	%
Legal provisions governing the inspection of premises					
Manufacturers	Facilities inspected	6	50.0	24	80.0
	Published national guidelines	4	57.1	19	86.4
Wholesalers/ distributors	Facilities inspected	8	61.5	24	77.4
	Published national guidelines	4	57.1	17	77.3
Importers/exporters	Facilities inspected	8	61.5	22	75.9
	Published national guidelines	4	66.7	15	78.9
Retail distributors/ pharmacies	Facilities inspected	8	66.7	24	82.8
	Published national guidelines	5	71.4	18	85.7

- More than half of the participating Caribbean countries have legal provisions to inspect premises. However, it is less common when compared to the Region of the Americas as a whole;
- Not all of the countries that have legal provisions governing inspections have published inspection guidelines.

The total number of respondents with legal provisions for inspecting manufacturers did not vary from 2003 to 2007 in the Caribbean. With regard to legal provisions governing inspection of importers and wholesalers, the number of countries varied from five (71.4%) in 2003 to eight (61.5%) in 2007. With regard to legal provisions for inspecting distributors and pharmacies, there was a slight variation: from six (85.71%) to eight (66.7%) countries.

Considering the data from 2007 for the entire Region of the Americas, the percentages of countries with legal provisions and written guidelines governing inspection were higher than in the Caribbean for all areas of inspection.

3.5 Control of Narcotics and Psychotropic Substances

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 United Nations (UN) Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances was issued in 1988 to provide legal measures against drug trafficking. It is very important that countries implement legal provisions to control and monitor not only finished products, but also the precursors, chemicals, and solvents that are used for the production of narcotics and psychotropic substances.[12, 13] 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 psychotropic substances

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Policy areas covered:				
Legal provisions governing the control of narcotics	13	100.0	31	100.0
Signatory to an international convention on narcotics control	13	100.0	30	100.0

- All the countries have legal provisions governing the control of narcotics and they are signatories to international conventions in this regard.

There was no data available in 2003 on the control of narcotics and psychotropic substances. In 2007, the Caribbean situation was very similar to that of the Region of the Americas as a whole.

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 has access to a quality control laboratory to test whether medicines samples meet the required quality criteria. WHO provides guidelines on establishing testing facilities.[14, 15]

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

Table 8. Quality Control

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Quality management system in place				
Samples tested for:	6	46.2	24	90.3
Medicines registration	4	30.8	18	87.1
Post-marketing surveillance	2	18.2	20	71.4
Samples tested in:	4	30.8	16	93.3
Government quality control laboratory	6	46.2	24	63.3
Local academic institutions	4	30.8	16	55.2
Private laboratory	4	30.8	18	87.1
Mini laboratories (e.g., district, regional)	2	18.2	20	71.4
Quality control laboratory in a third country	4	30.8	16	93.3
Quality control procedures for imported medicines	6	46.2	24	63.3
Legal procedures to recall or dispose of defective products	4	30.8	16	55.2
Quality testing in 2006	**Average (25th, 75th percentile)**		**Average (25th, 75th percentile)**	
Number of samples tested	113.5		812	
	17	261.8	183	1,713
	N=6		N=17	
Number of samples that failed	3		45	
	2	15	12	91
	N=5		N=16	

- Quality control is less common in the Caribbean when compared to the Region of the Americas as a whole, as only half of the countries have a quality management system in place;
- Most participating Caribbean countries use third-country laboratories, while those from the Region of the Americas as a whole use mainly government labs;
- The average number of samples tested in the Caribbean is considerably lower when compared to the number tested in the entire Region of the Americas.

In 2003, it was reported that a total of 172 samples was collected in four countries and that all were tested (an average of 43 per country). However, the countries did not provide information on how many samples failed the tests. In 2006, a total of 1,236 samples were tested in five countries (an average of 206 per country). The total number of samples that failed to meet the standards was 36 (2.9%), an average of 7 per country.

Three countries in the Caribbean operate national laboratories: the Dominican Republic; Guyana; and Trinidad and Tobago. Moreover, there is one subregional quality control laboratory (the Caribbean Regional Drug Testing Laboratory – CRDTL), located in Jamaica.[16] All of these laboratories are operated by the public sector. Countries that do not have a national laboratory send their samples to be tested at the CRDTL or to laboratories outside the region. Three countries have tests conducted by private laboratories.

The Caribbean Drug Testing Laboratory (CRDTL) was established in 1974 through an agreement among the CARICOM Member States. The laboratory shall:

(a) Perform microbiological and pharmacological tests on samples of drugs submitted by any participating government and report the results thereof to that government;
(b) Perform biological availability tests on selected types of drugs;
(c) Investigate the stability of drugs under the conditions of storage prevailing in the region; and
(d) Establish points of contact with all appropriate agencies interested in drug testing and provide information and advisory services to support the activities of drug control officials in the region.

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.[17]

Adverse drug reactions (ADRs) are a common, though often 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 [18, 19] as part of the essential regulatory functions. One of its aims is to *"contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use."*[17]

Since 1968, there has been a WHO Program for International Drug Monitoring, now coordinated by the Uppsala Monitoring Centre (UMC) in Uppsala, Sweden, with oversight by an international board. The principal function of UMC is to manage the international database of ADR reports received from national centers. Most contributing national centers have easy electronic access to the database. The UMC has established standardized reporting by all national centers and has facilitated communication between countries to promote rapid identification of signals.[17]

Table 9. Monitoring of adverse drug reactions

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Monitoring of adverse drug reactions (ADRs)	5	38.5	18	58.1
Local level	2	40.0	11	64.7
Regional level	1	20.0	8	50.0
Central level	4	66.7	16	88.9
International reporting of ADRs	3	23.1	14	48.3

- Less than half of the participating Caribbean countries monitor ADRs, usually at the central level;
- International reporting of ADRs is not widespread.

In 2003, only two (25%) countries reported monitoring ADRs and this number more than doubled in 2007, when five (38.5%) countries reported having ADR monitoring; two of them were participating in the WHO International Program for Drug Monitoring.

In March 2008, the Caribbean Network of Pharmacovigilance (VIGICARIB) was established, supported by PAHO/WHO.

The mission of VIGICARIB is: *"To support the development and the strengthening of pharmacovigilance through activities and proposals of harmonized regulatory actions that promote the safe and rational use of drugs as a necessary component of public health policies in the Caribbean."*

The objectives are to:

1. Design a network to foster communication among national pharmacovigilance centers, services, or units and strengthen decision making in the area of pharmacovigilance;
2. Promote dialogue, disseminate information on drug safety, and share knowledge, criteria, and methodologies used in pharmacovigilance;
3. Collaborate in pharmacovigilance implementation, analysis, and evaluation of the impact on public health and patient safety by linking with PANDRH, regional public health programs, and other institutions or partners;
4. Stress the importance of pharmacovigilance, as a priority component of drug policy and public health programs, and to maintain a high level of visibility in this area;
5. Identify gaps and resources, and to strengthen technical assistance among member countries of the network;
6. Harmonize norms, standard procedures, and tools (forms) used by the members of the network, including joint research on pharmacovigilance.

3.8 Prevention and Combat of Counterfeit Medicines

Counterfeit medicines, whether branded or generic, are deliberately or fraudulently mislabeled with respect to identity or source and may have fake packaging. As these medicines might contain wrong ingredients, an inappropriate dosage, or lack active substances they can be a major threat to health and thus need to be combated.[20]

Counterfeit medicines represent an enormous public health challenge. In some countries this is a rare occurrence, while in others it is an everyday reality. Even one single case of counterfeit medicine is unacceptable because, in addition to putting patients at risk and undermining the public's confidence in their medicines, it also betrays the vulnerability of the pharmaceutical supply system and jeopardizes the credibility of national health and enforcement authorities.[21]

Table 10. Counterfeit medicines

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Laws or regulations on counterfeit medicines	7	53.8	20	64.5
Sources used to detect counterfeit medicines				
national authorities	10	83.3	22	84.6
specific/ad hoc studies	9	81.8	21	87.5
pharmaceutical sector	12	100.0	27	96.4
Civil society/NGOs	9	100.0	19	86.4

- Only half of the participating Caribbean countries have laws or regulations on counterfeit medicines;
- All sources are almost equally used to detect counterfeit medicines.

There is no available 2003 data on counterfeit medicines. Only seven (53.8%) participating Caribbean countries reported having laws or regulations on counterfeit medicines. Besides this survey, in 2007 a survey on the "Situation of Prevention and Combat of Counterfeit Medicines in the Caribbean" was also conducted[iv], developed by the Working Group of Prevention and Combat of Counterfeit Medicines of the Pan American Network of Drug Regulatory Harmonization (PANDRH).[22] Among the findings, were the following:

[iv] Seven countries participated in the survey: Antigua and Barbuda; Barbados; Dominica; Dominican Republic; Guyana; Saint Lucia; and Suriname, representing a population of 10,810,628 inhabitants.

It was considered necessary to improve the cooperation and information exchange mechanisms among the countries for improving the effectiveness of prevention and combat of counterfeit medicines. The strengthening of regulation, control, and inspection throughout the pharmaceutical chain is necessary and must be backed by inter-sectoral cooperation. Special attention could be paid to the lack of formally established regulatory authorities and/or the weaknesses of the mechanisms to regulate medicines and facilities involved in the pharmaceutical chain in most countries in the Caribbean, which are real limitations to tackling counterfeiting issues.

3.9. Prescribing and Dispensing of Generic Medicines

Selecting the best and safest medicine for an individual, out of a broad range of choices, requires a high level of expertise and considerable skill on the part of the prescriber or dispenser. Prescribing contra-indicated medications or the wrong dosage can have a major deleterious impact on the health of patients and even threaten their lives. Evaluating the eligibility of and providing education for prescribing and dispensing staff is therefore crucial in order to ensure appropriate and competent prescribing practices.[23]

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

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

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Policies on generic medicines				
Prescribing generics mandatory in:				
Public sector	7	53.8	23	76.7
Private sector	2	16.7	10	37.0
Permitting generic substitution in:				
Public pharmacies	13	100.0	27	90.0
Private pharmacies	9	75.0	21	77.8
Incentives to promote generics dispensing:				
Public pharmacies	5	38.5	8	26.7
Private pharmacies	2	18.2	6	22.2

- Mandatory prescribing of generics is slightly less common in participating Caribbean countries, when compared to the entire Region of the Americas;
- All participating Caribbean countries allow generic substitution in public pharmacies and 75% also allow it in private pharmacies.

There was no significant change in the number of countries with policies for prescribing generics in the public sector. The variation was from five or 62.5% in 2003 to seven or 53.8% in 2007. However, with regard to the mandatory prescribing of generics in the private sector, the number of countries doubled (one or 12.5% in 2003 to two or 16.7% in 2007), although this was still minimal. In all participating countries there were legal provisions in place for generic substitution in public sector pharmacies; that is, eight in 2003 and thirteen in 2007. For generic substitution in private pharmacies, about 80% of countries had such legal provisions: six countries in 2003 and nine countries (75%) in 2007.

3.10. Promotion and Advertising

Given the known impact of advertising and promotion of medicines on both prescribing behavior and patient demand, it is essential to regulate and monitor medicines promotion to ensure that it remains ethical. All promotional claims should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation, and in good taste.[24]

Table 12. Legislation and regulation on medicines promotion and advertising

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Legislation on promotion/advertising	8	61.5	25	83.3
Responsible agency for regulating promotion/advertising:				
Industry	4	36.4	4	14.3
Government or national regulatory authority	6	54.5	22	78.6
Co-regulation	1	9.1	2	7.1
Government regulation including:				
Pre-approval for advertisement/ promotion	3	42.9	16	72.7
Ban on public advertising	6	75.0	20	87.0
Guidelines on the advertising of over-the-counter (OTC) medicines	3	42.9	14	63.6
Civil society/NGOs taking part in monitoring advertising activities	2	20.0	10	37.0

- More than half of participating Caribbean countries have legislation on promotion/advertising;
- In six countries (54.5%) the government is responsible for the regulation of drug promotion/advertisement.

In 2003, one (33.1%) country reported self-regulation of promotion/advertisement, and in 2007 there were four (36.4%) such countries. Three (60%) countries reported having governmental regulations in 2003 and six (54.5%) in 2007.

Regarding the participation of civil society and/or NGOs, none of the countries reported such participation in 2003, while two countries (20.0%) reported this type of participation in 2007.

4. MEDICINES SUPPLY SYSTEM

A well-coordinated medicines supply system helps to ensure that funds available for the procurement of medicines are used effectively and efficiently. Failures in the supply system can lead to life-threatening medicines shortages and waste of scarce resources.

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 medicines supply strategy, has led to a lack of coordination of supply systems, resulting in duplication, inefficiency, and increased workload, especially at the level of facilities. The selective approach to priority diseases has resulted in neglect of other important conditions, such as chronic illness and common childhood diseases. [3]

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

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

The Prequalification of Medicines Program (PQP), initiated in 2001, is a service provided by the World Health Organization to facilitate access to medicines that meet unified international standards of quality, safety, and efficacy for HIV/AIDS, malaria, tuberculosis and reproductive health.

The work is done via stringent assessment of pharmaceutical product dossiers; inspection of pharmaceutical manufacturing sites (both for finished dosage forms and active pharmaceutical ingredients); contract research organizations (CROs); prequalification of pharmaceutical quality control laboratories (QCLs); and advocacy for medicines of assured quality. The Bill and Melinda Gates Foundation, as well as UNITAID, are the main financial supporters of the WHO Prequalification of Medicines Program.

In 2008, there were a total of 40 medicinal products prequalified, an increase from the 21 products in 2007, for a total of nearly 200 products.[25]

Table 13. Public sector procurement (PSP) and distribution

		CARIBBEAN		AMERICAS	
		No. of Countries	%	No. of Countries	%
	Entire public sector procurement pooled at national level	13	100.0	25	80.6
Responsible agency for PSP and distribution:					
Health ministry	Procurement	12	92.3	26	89.7
	Distribution	17	87.5	18	85.7
NGOs	Procurement	2	28.6	4	25.0
	Distribution	0	0.0	2	20.0
Private institution	Procurement	2	28.6	2	12.5
	Distribution	2	100	3	27.3
Individual health institution	Procurement	0	00	11	52.4
	Distribution	0	0.0	9	64.3

- All the participating Caribbean countries have pooled procurement in the public sector at the national level;
- The health ministry is ordinarily responsible for PSP and distribution.

The health ministry performed the procurement function in all seven countries (100%) in 2003, and in 12 (92.3%) countries in 2007. The distribution function was also performed by the health ministry in five countries (100%) in 2003, and in seven (87.5%) countries in 2007. Procurement and distribution by an NGO was not performed in the region in 2003. In 2007, procurement was performed by an NGO in two (28.6%) countries. Procurement was performed by a private institution in one (50%) country in 2003, doubling to two (28.6%) countries by 2007. Procurement was performed by individual health institutions in three (75%) countries in 2003, while no country reported the involvement of such institutions in 2007. Three countries used more than one procurement mechanism in both 2003 and 2007.

In November 2004, a network comprising the national health authorities responsible for procurement and supply management, the Caribbean Regional Network of Pharmaceutical Procurement and Supply Management Authorities (CARIPROSUM)[v], was established, supported by PAHO/WHO:

The mission of CARIPROSUM is: *"To promote the continuous availability of affordable pharmaceutical products meeting standards in safety, quality, and efficacy, for Caribbean public health programs and services, through inter-country and regional cooperation."*

The objectives are to:
1. Promote dialogue and share experiences in pharmaceutical procurement;
2. Harmonize norms, standards, and administrative procedures in pharmaceutical procurement;
3. Strengthen the capacity for purchasing and distribution of essential drugs;
4. Foster technical cooperation among countries.

[v] For additional information, see: http://www.paho.org/english/ad/ths/ev/acceso-cariprosum.htm

Table 14. Essential medicines list procurement and tender process

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Public sector procurement limited to EML	4	100.0	11	91.7
If yes, is there provision for purchasing medicines outside EML?	5	41.7	13	46.4
Country participation in pooled procurement scheme	5	41.7	10	34.5
Tender board overseeing public sector procurement	11	91.7	23	82.1
If yes, are the key functions of the procurement office and tender committee clearly separated?	8	88.9	19	90/5
Use of WHO Prequalification system	6	66.7	11	50.0
Type of tender:				
National competitive tender	4	50.0	19	82.6
International competitive tender	9	81.8	19	73.1
Negotiation/direct purchasing	6	75.0	19	82.6

- Public sector procurement is limited to the EML in all countries that responded to this question in the Caribbean and in most countries of the Region of the Americas;
- Participation in pooled procurement schemes is not uncommon among the participating countries of the Caribbean, and most countries have a tender board overseeing public sector procurement.

The number of countries where procurement is limited to the EML remained the same in 2003 (four, 66.67%) as in 2007 (four, 100%). Regarding procurement mechanisms, the number of countries that used national competitive tendering remained the same in 2003 (four, 80%) as in 2007 (four, 50%). The use of international competitive tendering increased from six (85.7%) countries in 2003 to nine (81.8%) countries in 2007, and the use of negotiation or direct purchasing increased from two (66.67%) in 2003 to six countries (75%) in 2007.

Five (41.7%) countries responding to the questionnaire in 2007 participated in a pooled procurement scheme. The Eastern Caribbean Countries participate in the Organization of Eastern Caribbean States Pooled Procurement Service (OECS/PPS).

Successful Pooled Procurement Scheme in the Caribbean

The Eastern Caribbean Drug Service, established under the Eastern Caribbean Drug Service Agreement in 1986, and subsequently renamed the OECS/Pharmaceutical Procurement Service (OECS/PPS) in 2000, is designated as the pooled procurement agency through which all nine OECS Member States purchase tendered pharmaceuticals and other medical products. OECS/PPS has provided its Member States with a reliable supply of high quality pharmaceuticals, which are safe and effective. It has a comprehensive quality assurance program that encompasses a restricted international tendering system, under contractual terms that ensure quality and post-marketing surveillance.

The OECS/PPS has an advantage over an individual country's procurement capacity because the aggregate OECS tender executed on behalf of the nine OECS Member States has successfully attracted and maintained competitive prices for the past 20 years. The estimated 37% reduction on the unit cost of pharmaceuticals and other medical products has resulted in annual savings of US$1.2 million by OECS Member States. The annual cost-savings, after 20 years of joint purchasing arrangements, has reinforced OECS/PPS as an excellent model of economic and functional cooperation among the OECS Member States, with a combined population of about 570,000 citizens.

In addition to pooled procurement, OECS/PPS provides OECS countries with a wide range of related services, which include training and technical assistance, a common medicines formulary manual, drug utilization studies, and quality assurance. The policy changes crucial to OECS/PPS' success were political will, financial commitment, centralized tendering, and institutional alliances among the health ministries and finance ministries, and a common currency regulated by the Eastern Caribbean Central Bank.

Source: OECS/PPS, 2009.

5. MEDICINES FINANCING

In the developing countries, expenditure on medicine accounts for between 25 and 65% of total public and private health expenditure, and for between 60 and 90% of out-of-pocket household expenditure on health. Poor households are more likely to incur catastrophic expenditure (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.[27]

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

Access to specific treatments for high priority conditions has life-saving implications for individuals and major public health benefits for communities. A medicines pricing policy is also an important strategy, since the price of medicine is one of the most important obstacles to access. Pricing regulation and policies can provide a good basis for equitable access if effectively enabled. The prices of medicines can be inflated in current market environments. In recent years, WHO has made efforts to develop a standardized methodology for surveying medicines prices and has conducted numerous pricing surveys in WHO regions. [28]

Table 15. Total and per capita public expenditure for medicines (TPE) in US$, 2007

	CARIBBEAN	AMERICAS
	Median (25th, 75th percentile)	Median (25th, 75th percentile)
Median TPE for medicines in US$	$4,000,000	$34,087,493
	$815,000 | $3,000,000	$3,750,000 | $53,081,172
	N=9	N=24
Median Public medicines expenditure per capita in US$	$20.90	$11.50
	N=9	N=24

- The median of the total expenditure on medicines in the public sector in the Americas is considerably higher than in participating Caribbean countries;
- However, the median of public expenditure per capita is much higher in the participating Caribbean countries, when compared to the Region of the Americas as a whole.

Country size, and consequently the scope of pharmaceutical marketing, the complexity of health systems, the effectiveness of the procurement mechanisms, and the use of brand or generic medicines are some of the factors to be considered when analyzing these differences. There is no medicines expenditure data available for 2003.

Table 16. Medicines provided free of charge

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
National policy including some free medicines*	7	53.8	23	76.7
Types of free medicines at primary care level:**				
All medicines	8	66.7	17	70.8
Malaria medicines	7	77.8	18	85.7
Tuberculosis medicines	7	77.8	24	92.3
Sexually transmitted infections medicines	5	62.5	17	77.3
HIV/AIDS-related medicines	8	88.9	24	96.0
At least one vaccine	10	100.0	25	100.0
Patients who receive free medicines:				
Patients who cannot afford medicines	13	100.0	26	92.9
Children under 5 years of age	12	92.3	26	96.3
Older children	10	83.3	20	83.3
Pregnant women	9	75.0	24	88.9
Elderly	10	76.9	22	84.6

*Some countries have legal provisions in place for universal access to medicines.
**Some countries provide more than one type of medicines.

- All participant countries, both in the Caribbean and in the entire Region of the Americas, have national provisions for supplying medicines free of charge for some specific diseases or vulnerable groups;
- All participating Caribbean countries provide free medicines to those who cannot afford them, and most countries also provide free medicines to other vulnerable categories.

In 2003, all medicines were free of charge in five (83.33%) countries, and in eight (66.7%) countries in 2007. Free malarial drugs were provided by three (75%) countries in 2003, and more than doubled to seven countries in 2007, although the proportion remained almost the same at 77.8%. For free tuberculosis drugs, the variation was small, from five (100%) in 2003 to seven (77.8%) countries in 2007. For countries that provided free medicines used in the treatment of sexually transmitted infections (STIs), there was no variation: five countries in both 2003 (100%) and in 2007 (62.5%). For HIV/AIDS, the variation was from four (66.67%) countries in 2003 to eight (88.9%) in 2007.

In 2003, five countries reported that medicines were free of charge for those who were unable to afford them (83.33%), as compared with 100% of the participant countries (13) in 2007. Six countries (100%) reported making free medicines available for children under 5 years of age in 2003, as compared with twelve countries (92.3%) in 2007. The provision of free medicines for pregnant women, varied from five countries (100%) in 2003 to nine (75.0%) in 2007. The greatest variation was observed in the availability of free medicines for the elderly population, with availability ranging from three (42.85%) to ten countries (76.9%).

Table 17. Fees for medicines and dispensing in public primary care facilities

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Types of fees charged:				
Registration/ consultation fees*	12	100.0	27	100.0
Dispensing fees	1	8.3	3	10.7
Flat fees for medicines	3	77.8	5	18.5
Flat rate co-payments for medicines	3	25.0	5	17.9
% Co-payments for medicines	3	27.3	6	25.0

Continued

Table 17. Continued

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
How often fees are used to pay salaries?				
Always	0	0.0	0	0.0
Frequently	0	0.0	0	0.0
Occasionally	0	23.1	9	30.0
Never	12	76.9	21	70.0
Dispensing of medicines by prescribers (public sector)				
Always	0	0.0	0	0.0
Frequently	0	0.0	0	0.0
Occasionally	3	23.1	0	30.0
Never	10	76.9	21	70.0
Dispensing of medicines by prescribers (private sector)				
Always	0	0.0	0	0.0
Frequently	4	30.8	5	17.2
Occasionally	8	61.5	13	44.8
Never	1	7.7	11	37.9

*It is possible that the way the question was stated may cause misunderstanding, as registration is a regulatory action (normally charged) not related to the consultation (medical visit) that is free of charge in some countries that answered the questionnaire. At least one country reported that the entire population is covered by public health insurance.

- All participating countries charge registration/consultation fees, but fees in the Caribbean are never used to pay salaries;
- Dispensing of medicines in the public sector is only occasionally done by the prescriber, but this practice is not uncommon in the private sector.

In 2003, the number of countries reporting that fees are never used to pay salaries was five (83.33%) and in 2007 it was 12 (100%). In 2007, physicians dispensed medicines occasionally in the public sector in three countries (23%). In the private sector, prescriber dispensing occurred frequently in four countries (30.8%) and occasionally in eight countries (61.5%). These proportions are lower in the public sector and higher in the private sector in the Caribbean countries as compared to countries in the region of the Americas as a whole.

Table 18. Health insurance and medicines coverage

		CARIBBEAN		AMERICAS	
		No. of Countries	%	No. of Countries	%
Population covered with health insurance					
All	Public sector	2	20.0	5	18.5
	Private sector	1	9.1	2	7.7
Some	Public sector	8	80.0	20	74.1
	Private sector	10	81.9	24	92.3
None	Public sector	0	0.0	2	7.4
	Private sector	0	0.0	0	0.0
Medicines covered by health insurance					
All	Public sector	2	18.2	6	22.2
	Private sector	2	25.0	4	18.2
Some	Public sector	7	62.6	17	63.0
	Private sector	6	75.0	18	81.8
None	Public sector	2	18.2	4	14.8
	Private sector	0	0.0	0	0.0

- Most countries provide public health insurance to at least part of the population.
- In most of the countries, some medicines are covered by either public and/or private health insurance schemes.

In 2003, no country reported having its entire population covered by public health insurance, but in 2007 there were two countries (20%) that provided such coverage. Countries reporting some public health insurance coverage of the population varied from four (50%) in 2003 to eight (80%) in 2007, while countries reporting some private health insurance coverage of the population varied from five (71.43%) in 2003 to ten (81.9%) in 2007.

With regard to medicines coverage, in 2003 no country reported having all medicines covered by private insurance but in 2007 two countries (18.2%) reported providing this coverage. Countries that reported coverage by the public sector for some medicines was four (57.14%) in 2003 and seven (62.6%) in 2007. Countries reporting no medicines coverage in the public sector remained at two, representing 28.6% of responding countries in 2003 and 18.2% of responding countries in 2007.

There was a small increase in the number of countries with coverage of some medicines by private insurance, from four (57.14%) in 2003 to six (75%) in 2007. In 2003, two countries reported coverage of all medicines by private insurance, and this remained unchanged in 2007 (28.57%).

Table 19. Policies on medicines pricing covering different sectors

		CARIBBEAN		AMERICAS	
		No. of Countries	%	No. of Countries	%
Policy covering medicine prices	Facilities inspected	6	50.0	16	53.3
	Private Sector	4	33.3	12	42.9
	NGO	1	11.1	4	18.2
If yes, which areas are covered?					
Maximum wholesale mark-up	Facilities inspected	2	28.6	8	53.3
	Private Sector	5	83.3	8	66.7
	NGO	2	100.0	4	50.0
Maximum retail mark-up	Facilities inspected	2	28.6	9	60.0
	Private Sector	6	75.0	11	70.6
	NGO	2	66.7	5	50.0
Duty on raw pharmaceutical materials	Facilities inspected	2	28.6	5	33.3
	Private Sector	7	77.8	10	62.5
	NGO	3	75.5	4	44.4
Duty on finished pharmaceutical materials	Facilities inspected	2	28.6	6	37.5
	Private Sector	8	88.9	12	70.6
	NGO	3	75.0	5	45.4

- Only half of the participating countries in the Caribbean have a policy covering medicines pricing in the public sector. Policies covering medicines pricing in the private and NGO sectors is even less common;
- Most of the countries that responded to this question have policies related to maximum retail mark-up, duties on raw materials and finished pharmaceutical materials for the private sector, both in the Caribbean and the Region of the Americas as a whole.

The number of countries with a public sector policy on medicines pricing varied from two (33.33%) in 2003 to six (50%) in 2007. For the private sector, this varied from two (33.3%) in 2003 to four (33.3%) countries in 2007. There was no variation for NGOs (only one country in 2007). The proportions from the Caribbean countries are very similar to those of the Region of the Americas as a whole.

Table 20. Monitoring, information, and guidelines on medicine prices and donations

		CARIBBEAN		AMERICAS	
		No. of Countries	%	No. of Countries	%
Monitoring system for retail prices	Public sector	2	16.7	14	46.7
	Private Sector	3	25.0	11	39.3
	NGO	2	118.2	6	26.1
Regulations on accessibility of retail medicine price information	Public sector	4	33.3	9	31.0
	Private Secto	4	33.3	5	19.2
	NGO	3	27.3	3	13.0
Guidelines on medicine donations	Public sector	10	76.9	24	77.4
	Private Sector	4	50.0	12	54.5
	NGO	3	37.5	13	61.9

- Only a few Caribbean countries reported having a monitoring system for retail prices, and regulations on accessibility of retail medicine price information is also uncommon;
- Most Caribbean countries (76.9%) mentioned having guidelines on medicine donations.

6. PRODUCTION AND TRADE

Intellectual property rights (IPRs) have an important impact on the affordability and availability of medicines, and thereby public health. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) requires that WTO Members provide minimum standards of intellectual property protection, including patent protection for pharmaceutical products. Patent protection grants exclusive rights to the patent holder for the production and sale of a given medicine. During the term of the patent, the patent holder has a monopoly on that medicine, which prevents generic versions from entering the market, therefore preventing a reduction of prices through competition. Disadvantaged populations in the developing countries cannot afford to pay the same prices as wealthier countries for newer medicines. TRIPS-compliant mechanisms can be used to grant access to lower-priced medicines. It is important to consider adapting national legislation to incorporate all flexibilities available in the TRIPS Agreement (see below) to safeguard and promote access to essential medicines for all.

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

There are variations in the manner with which the provisions for such flexibilities have been incorporated into national legislation[30]; thus, there are limitations on the exhaustiveness of the information on TRIPS flexibilities, as presented in the tables below. For example, provisions on parallel imports may exist in some countries, while at the same time other constraints are also to be found, 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 or nullified de facto. Also, there are essentially two kinds of parallel importation regimes: international exhaustion and regional exhaustion. When the international exhaustion regime is incorporated into national law, parallel imports of a product will be permitted into the country from anywhere else where the patent has already expired, whereas regional exhaustion (as for the whole of the European Union) would allow products to be imported only from within a particular regional grouping. There may, therefore, be differences in the parallel imports provisions, which will be important in determining whether or not the flexibilities can be upheld.

Similar variations also exist in countries in terms of their provisions for compulsory licensing. While compulsory licensing provisions exist within most national legislation, such provisions may differ, for example, in terms of the various grounds on which compulsory licenses may be granted. It was agreed in the 2001 Doha Declaration concerning the TRIPS Agreement and Public Health that WTO Members have sovereign autonomy to determine the grounds on which compulsory licenses may be granted within the broader public health framework. However, this flexibility may not have yet been properly incorporated in all national laws.

Article 65 of the TRIPS Agreement provides for four separate and different transition periods. The first transition period lasted until 1995, when developed country WTO Members had to implement the TRIPS Agreement, but developing country Members had to implement the basic international trade provisions of most-favored-nation and national treatment. The second transition period expired on 1 January 2000, at which time the developing countries were to implement the TRIPS Agreement. The third transition period was for centrally-planned economies. The fourth and final 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 for the first time.

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 21. Country capacity for research and production of medicines

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Medicines production capability				
R&D of new active substances	0	0.0	6	20.7
Production of pharmaceutical raw materials	0	0.0	6	20.7
Formulation from raw materials	8	61.5	26	83.9
Repackaging of finished dosage forms	7	58.3	25	83.3

- Participant Caribbean countries are not equipped for research and development (R&D) of new active substances or to produce pharmaceutical raw materials. Regarding formulation from raw materials and repackaging, they are less likely to perform, when compared to countries comprising the Region of the Americas as a whole.

The lack of R&D capacity and for the production of pharmaceutical raw materials in the Caribbean did not improve between 2003 and 2007. It was also limited in the Region of the Americas as a whole, as only six countries (20.7%) reported conducting R&D activities in 2007.

The number of countries that reported capacity for formulation from raw materials doubled from four (50%) in 2003 to eight (61.5%) in 2007. For repackaging of finished dosage forms, the number of countries varied from four (50%) in 2003 to seven (58.3%) in 2007.

Table 22. Patent protection and TRIPS flexibilities

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Patents granted by national office	5	55.6	23	85.2
National legislation modified to implement TRIPS	4	44.4	17	65.4
TRIPS Article 65	4	57.1	9	42.9
LDCs: TRIPS Article 66	1	33.3	1	9.1
Doha Declaration (Paragraph 7)	2	40.0	5	26.3
Introduction of TRIPS in the national legistation				
Compulsory licensing provision	2	22.2	13	50.0
Government use	2	25.2	11	47.8
Parallel importing provision	1	11.1	8	30.8
Bolar exception	0	0.0	10	43.5

- Only half of the participating Caribbean countries have patents granted by a national office as compared with the whole Region of the Americas, where most of the countries have a national patent office.
- Half of the participating Caribbean countries have modified their legislation to implement TRIPS and half have included Article 65.

In 2003, seven Caribbean countries reported membership in WTO, one did not know its status, and one country was not a member. In 2007, of the countries that responded to the questionnaire, one country remained a non-member of WTO. In 2003, three countries reported having provisions in place for patent protection of pharmaceutical products (33.3%). In 2007, five countries reported having patents granted by a national office (55.6%).

In 2003, none of the countries reported modifying their national legislation to implement the TRIPS Agreement; two countries were availing themselves of the provision of TRIPS Article 65 (28.57%); and none indicated availing themselves of TRIPS Article 66. In 2007, four countries (50%) reported having modified their legislation to implement the TRIPS Agreement, all of them with provisions for TRIPS Article 65; one (33.3%) with provision for TRIPS Article 66; and two (40%) with provisions for Paragraph 7 (according to the Doha Declaration).

In 2003, the implementation of the flexibilities of TRIPS was under discussion. Four countries were discussing the implementation of a provision for parallel importation. In 2007, only one country had already included this provision in its legislation. Regarding compulsory licensing, it had been discussed in four countries (57.14%) in 2003 and in 2007 only two countries (22.2%) had such legal provisions. With regard to the Bolar exception, three countries (50%) reported that it had been discussed in 2003, but none of the countries reported having such legal provision in 2007.

7. ESSENTIAL MEDICINES AND RATIONAL USE

Overuse, 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.

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." [2]

Many factors influence the use of medicines, and countries need to implement various strategies to improve rational use.[31,32] Some policies, strategies, and interventions found to be of value include:

- Creating a mandated multidisciplinary national body to coordinate policies on medicine use;
- Standard treatment guidelines (STGs) for common conditions; using essential medicines lists (EMLs) to guide procurement and training;
- Establishing drug and therapeutics committees to coordinate medicines selection and management in hospitals;
- Implementing problem-based pharmacotherapy training in undergraduate curricula; mandating continuing in-service medical education as a licensure requirement;
- Establishing effective supervision in health systems;
- Using audit and feedback to inform clinicians and facilities about their practice;
- Developing independent sources of information about medicines for providers and consumers;
- Avoiding perverse financial incentives to overuse medicines;
- Establishing and enforcing a sound regulatory framework; and
- Guaranteeing sufficient government expenditure to ensure availability of medicines and retain well-trained staff.

Table 23. Availability and status of essential medicines list

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Existence of EML*	5	55.6	23	85.2
EML updated within the last 5 years	4	44.4	17	65.4
No separate pediatric EML	4	57.1	9	42.9
Use of EML in different sectors				
Public sector procurement	2	40.0	5	26.3
Public insurance reimbursement	1	33.3	1	9.1
Private insurance reimbursement	2	22.2	13	50.0
Committee for EML medicines selection	2	25.2	11	47.8
	Median (25th, 75th percentile)		Median (25th, 75th percentile)	
Number of medicines in EML	464		512	
	350	526	386	598
	N=8		N=22	
Pediatric formulations in national EML	40		58.5	
	30	50	29.5	263.5
	N=2		N=10	

*Includes all countries with EML (irrespective if year of update was indicated or not)

- Most of the participant countries have an EML, but none of them have a separate pediatric EML. The situation is very similar in the Caribbean and in the Region of the Americas as a whole;
- The EML is always used for public sector procurement and less often for public insurance reimbursement;
- The participating Caribbean countries have a slightly lower median number of medicines in their EML as compared to the Region of the Americas as a whole.

In the Caribbean, there was a variation in the number of countries with an EML, from seven (100%) in 2003 to ten (76.9%) in 2007. The average number of medicines included in the EML varied from 614 in 2003 to 464 in 2007. The number of countries that had updated their EML within the last five years varied from seven (87.5%) to nine (100%) in 2007.

Almost all countries with an EML used it in public procurement (eight in 2003 and ten in 2007). In public insurance reimbursement, the usage of the EML varied from two countries (40%) in 2003 to five countries (50%) in 2007. The EML was also used for private insurance reimbursement by two countries in both 2003 (25%) and 2007 (22.2%).

Table 24. Standard treatment guidelines and medicines formulary manual

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
National STGs	9	75.0	25	86.2
National STGs updated within the last 5 years	5	41.7	12	41.4
Hospital STGs	7	58.3	19	67.9
Primary care STGs	8	66.7	23	82.1
STGs for key pediatric illnesses	3	37.5	19	79.2
Medicines Formulary Manual*	9	75.0	23	76.7
Formulary updated within the past 5 years	5	41.7	16	53.3
Covering only EML medicines	4	50.0	11	61.9

* Besides these nine countries, there are two countries that are members of the OECS who have a common medicines formulary, but they did not mention it in the questionnaire.

- Availability of STGs are slightly less common in the participating Caribbean countries, when compared to the Region of the Americas as a whole;
- STGs for key pediatric illness are uncommon;
- Most countries have a medicine formulary manual.

The number of countries that reported having a National STG varied from four (50%) in 2003 to nine (75%) in 2007. Two countries (28.57%) in 2003 and seven (58.3%) in 2007 reported having STGs for the hospital level, while four (66.67%) countries had them for the primary care level in 2003 and eight (66.7%) in 2007.

In 2003, eight (88.9%) countries reported having a national formulary and nine (75%) countries in 2007. In 2003, all countries stated that their national formularies covered only the EML and in 2007 there were only four countries (50%). The number of countries that reported having conducted the last update of the MNF within less than five years varied from eight (100%) in 2003 to five (41.7%) in 2007, which indicates the need for updating the formulary.

Table 25. Medicines concepts present in health workers education

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
EML concepts:				
Physicians	5	55.6	15	60.0
Nurses	6	60.0	15	60.0
Pharmacists	5	50.0	14	58.3
Pharmacy assistants	3	27.3	8	29.6
Paramedical staff	2	33.3	6	33.3
STG concepts:				
Physicians	2	33.3	13	59.1
Nurses	3	50.0	12	57.1
Pharmacists	3	42.9	8	40.0
Pharmacy assistants	1	12.5	5	21.7
Paramedical staff	2	40.0	6	37.5
Pharmacotherapy training:				
Physicians	4	57.1	15	71.4
Nurses	2	40.0	10	52.6
Pharmacists	3	50.0	10	52.6
Pharmacy assistants	1	12.5	3	13.0
Paramedical staff	1	25.0	3	18.8

Continued

Table 25. Continued

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Rational prescribing concepts:				
Physicians	3	50.0	15	68.2
Nurses	2	40.0	11	52.4
Pharmacists	3	60.0	11	52.4
Pharmacy assistants	1	12.5	3	12.0
Paramedical staff	1	25.0	4	23.5

- Few countries provide training related to rational medicines use;
- Among health workers, physicians and nurses are most exposed to EML concepts;
- Pharmacotherapy training is more common for physicians, nurses, and pharmacists than for pharmacy assistants and paramedical staff among the countries that responded to this question.

In relation to EML concepts, the reporting of their presence in the education of physicians varied from two countries (20%) in 2003 to five (55.6%) in 2007; for nurses the variation was from three (37.5%) in 2003 to six countries (60%) in 2007; for pharmacists it varied from six countries (75%) in 2003 to five (50%) in 2007; for pharmacy assistants the variation was from one (12.5%) in 2003 to three (27.3%) in 2007; and for paramedical staff the number of countries doubled, from one (12.5%) in 2003 to two (33.3%) in 2007.

Regarding STG concepts, these were reported to be present in only one country in pharmacy curricula in 2003. In 2007, it was reported to be present in the curricula for physicians in two countries (33.3%); for nurses and pharmacists in three countries (50% and 43%, respectively); for pharmacy assistants in one country (12.5%); and for paramedical staff in two countries (40%).

In 2003, pharmacotherapy training was reported to be present in pharmacy curricula in only one country. In 2007, it was reported to be present in the curricula for physicians in four countries (57.1%); for nurses in two countries (40%); for pharmacists in three countries (50%); and for paramedical staff in one country (25%).

In 2003, rational prescribing concepts were reported to be present in the curricula of physicians and nurses in one country (14.3%) and in the curricula of pharmacists in three countries (33.3%). In 2007, these concepts were reported to be present in the curricula for physicians in three countries (50%); for nurses in two countries (40%); for pharmacists in three countries (60%); and for paramedical staff in one country (25%).

The above facts illustrate a wide variation regarding the inclusion of RMU concepts in health worker education programs.

Table 26. Mandatory continuing education and information on medicines for health workers

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Physicians	6	46.2	10	37.0
Paramedical staff	5	41.7	8	28.6
Pharmacists	6	46.2	10	34.5
Pharmacy aides/assistants	1	9.1	2	7.7
Medicines information center:				
Prescribers	3	23.1	16	53.3
Dispensers	3	23.1	16	53.3
Consumers	3	23.1	14	46.7
Education campaigns:				
Use of antibiotics	2	15.4	10	34.5
use of injections	1	7.7	3	11.1

- Almost half of the participating Caribbean countries have mandatory education programs for physicians, nurses, and pharmacists;
- Only one quarter of the participating Caribbean countries had medicines information centers (MICs);
- MICs are less common in the Caribbean countries than in the Region of the Americas as a whole, and the same is true with respect to education campaigns.

Regarding the existence of independent MICs, three countries reported having one in 2003 (37.5%) for prescribers, dispensers, and consumers, and the number of countries remained the same in 2007 (three, 23.1%

With regard to public education campaigns, five countries (55.55%) reported having these on the use of antibiotics in 2003, two (22.2%) on the use of injections; and five countries reported carrying out such campaigns on other topics. In 2007, only two countries reported conducting campaigns on the use of antibiotics (15.4%), and one on the use of injections (7.7%).

Table 27. Prescribing practice

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Prescription of medicines by:				
Physicians				
Always	8	61.5	19	61.3
Frequently	5	38.5	12	38.7
Occasionally	0	0.0	0.0	0.0
Never	0	0.0	0.0	0.0
Nurses/midwives/paramedical staff				
Always	0	0.0	1	3.3
Frequently	3	23.0	6	20.0
Occasionally	5	41.7	13	43.3
Never	4	33.3	10	33.3
Pharmacists/pharmacy aides/assistants				
Always	0	0.0	1	3.4
Frequently	1	9.1	3	10.3
Occasionally	0	0.0	2	6.9
Never	10	90.9	23	79.3
Personnel with <1 month of training				
Always	0	0.0	0.0	0.0
Frequently	0	0.0	0.0	0.0
Occasionally	0	0.0	13	11.1
Never	10	100.0	24	88.9

- Most prescribing is done by physicians, but nurses also play a role;
- Prescribing by pharmacists is very uncommon, and prescribing by personnel with little training never occurs in the participating Caribbean countries.

Table 28. Monitoring and promotion of rational medicines use

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Body designated to monitor and promotion of RMU	5	38.5	12	40.0
Requirement for drugs and therapeutic committees (DTCs)				
Availability of DTCs in all/most of the below-mentioned facilities	6	46.2	15	50.0
Referral hospitals*	4	36.4	16	59.3
General hospitals*	4	33.0	16	57.1
Regions/provinces*	2	20.0	11	44.0

* Includes the number of countries with DTC in at least half of hospitals.

- In the participating Caribbean countries, bodies designated to monitor and promote RMU are not very common, and DTCs are not usually present at health facilities.

Table 29. National policies on antimicrobial resistance and over-the-counter sales of antibiotics and injections

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
AR containment strategy	2	15.4	12	38.7
AR surveillance laboratory peutic committees (DTCs)	7	53.8	19	61.3
AR Task force	0	0.0	6	20.7

Continued

Table 29. Continued

	CARIBBEAN		AMERICAS	
	No. of Countries	%	No. of Countries	%
Frequency of OTC sale of antibiotics				
Always	0	0.0	2	6.9
Frequently	4	36.4	13	44.8
Occasionally	6	54.5	8	27.6
Never	1	9.1	6	20.7
Frequency of OTC sale of injections				
Always	0	0.0	2	7.7
Frequently	2	22.2	8	30.8
Occasionally	5	55.6	11	42.3
Never	2	22.2	5	19.2

- Only a minority of countries have an AR containment strategy;
- OTC sales of antibiotics are not uncommon, while OTC sales of injections seem to be less widespread.

The number of countries with an antimicrobial resistance (AR) containment strategy remained the same in 2003 (two, 22.2%) as in 2007 (two, 15.4%). The number of countries with an AR surveillance laboratory changed from five (55.55%) in 2003 to seven (53.8%) in 2007. Regarding the existence of an AR task force, in 2003, two countries (22.2%) reported having one, but no country reported having such a task force in 2007.

In 2007, four countries (36.%) reported OTC sales of antibiotics were frequent, and six (54.5%) stated that such sales were occasional. Two countries (22.2%) stated that OTC sales of injections occurred frequently, while in five countries (55.6%) this was an occasional occurrence.

FINAL CONSIDERATIONS

The summarized information provided by the Level I indicators for the Caribbean countries is very valuable for analyzing progress in the six areas of the pharmaceutical system. It is important to take into consideration the limitations of the questionnaire, as it is evident that in some areas, more specific information was needed. Regarding the presence of a national medicines policy, the 2007 data shows a positive change in relation to the situation in 2003, but special attention has to be paid to the implementation of the policy.

The regulation of medicines is one of the inconclusive agenda issues. Progress can be observed in the availability of legal provisions for the medicines regulatory authority (MRA) or for some individual components. Nevertheless, more information is needed regarding the process and the results of essential functions of medicines regulation.

Regarding the high per capita public medicines expenditure in the Caribbean, country size, and consequently the scope of pharmaceutical marketing, the complexity of the health systems, and the effectiveness of the procurement mechanisms, including the use of brand or generic medicines, are some of the factors to be considered when conducting a comparative analysis. Detailed information and additional strategies are required in this area to strengthen the medicines supply system, thereby ensuring its sustainability.

In 2007, the number of countries that changed their national legislation to implement the TRIPS Agreement and its flexibilities was still minimal. Special attention should be paid to this area, with consideration being given to the implementation of the global strategy on intellectual property rights. The availability and utilization of essential medicines lists (EMLs) and standard treatment guidelines (STGs) increased in the Caribbean. It would be useful to obtain additional information regarding the use of these tools and their impact on rational medicines use (RMU). In this regard, the application of Level II indicators and household surveys would be very opportune. On the other hand, the introduction of RMU concepts in the curricula of health professionals is also an inconclusive issue in the Caribbean. Some progress was observed in 2007 in relation to the baseline data in 2003, but there is still a significant amount of work required to improve the pharmaceutical sector in the Caribbean. These data are an important tool for the subregional stakeholders to identify gaps and establish priorities through an inter-sectoral approach.

REFERENCES

[1] *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

[2] Conference of Experts on the Rational Use of Drugs, Nairobi, 1985. *Report*. Geneva, World Health Organization, 1987.

[3] *WHO Medicines strategy 2004-2007:* Countries at the Core. Geneva: World Health Organization, 2004.

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

[5] WHO. *How to develop and implement a national drug policy.* 2nd ed. Geneva: World Health Organization, 2001.

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

[7] DURAND, Christelle. Le Systeme de Securité Sanitáire en France. In: *SEMINÁRIO INTERNACIONAL DE DIREITO SANITÁRIO,* V. São Paulo, 3-7 October 1999. Segurança sanitária no mundo globalizado:
aspectos legais. Washington, DC: OPAS/OMS, 1999. (Serie de informes técnicos, 74) p. 1-16. Available at: http://www.paho.org/Portuguese/HDP/HDD/it74.pdf

[8] *WHO Effective Drug Regulation:* A multicountry study. Geneva: WHO, 2002.

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

[10] *Marketing authorization of pharmaceutical products with special reference to multi-source(generic) products:* a manual for drug regulatory authorities. Geneva, World Health Organization, 1998.

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

[12] *WHO Guidelines for the Control of Narcotic and Psychotropic Substances in the Context of the International Treaties,* Geneva: WHO 1984.

[13] *WHO Narcotic and Psychotropic Drugs - Achieving Balance in National Opioids Control:* Guidelines for Assessment. Geneva: WHO MD 2000.

[14] *WHO National laboratories for drug quality surveillance and control.* WHO Expert Committee on Specification for Pharmaceutical Preparations. Twenty-ninth Report. Geneva, World Health Organization, 1984 (WHO Technical Report Series, No. 704).

[15] *WHO Good laboratory practices in government drug control laboratories*. WHO Expert Committee on Specification for Pharmaceutical Preparations. Thirtieth Report. Geneva, World Health Organization, 1987 (WHO Technical Report Series, No. 748).

[16] CARICOM. *Agreement Establishing the Caribbean Regional Drug Testing Laboratory (1974).* Available at: http://www.caricom.org/jsp/secretariat/legal_instruments/agreement_crdtl.jsp?menu=secretariat
[17] *WHO The Importance of Pharmacovigilance.* Geneva: WHO, 2002.
[18] Pharmacovigilance: Ensuring the Safe Use of Medicines. WHO Policy Perspectives on Medicines, No. 09, October 2004.
[19] *WHO Safety of medicines:* A Guide to Detecting and Reporting Adverse Drug Reactions - Why Health Professionals Need to Take Action. Geneva: WHO, 2002.
[20] *WHO Counterfeit Drugs:* Guidelines for the Development of Measures to Combat Counterfeit Drugs. Geneva: WHO, 1999.
[21] *WHO Counterfeit Drugs Kill!* Geneva: WHO, 2008. Available at: http://www.who.int/impact/FinalBrochureWHA2008a.pdf
[22] PAHO/WHO. *Situation on Prevention and Combat of Counterfeit Medicines in the Caribbean Countries.* Barbados: PAHO/WHO - OCPC, 2008.
[23] *WHO Guide to Good Prescribing:* A Practical Manual. Geneva: WHO, 1994.
[24] *WHO/HAI 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).
[25] WHO. *Prequalification of Medicines Programme:* A United Nations Programme managed by WHO - Quality medicines for everyone. 2008 Annual Report. Geneva: WHO, 2009. Available at: http://healthtech.who.int/pq/info_general/documents/2008_AnnualReport.doc
[26] World Health Organization. *Global comparative pharmaceutical expenditures with related reference information.* Geneva: World Health Organization, 2000 (EDM/PAR/2000.2).
[27] Xu K, Evan DB, Kawabata K, Zeramdini R, Klavus J, and Murray CJL. Household catastrophic health expenditure: A multicountry analysis. *The Lancet* 2003; 362:111-117.
[28] Cameron A, Ewen M, Ross-Degnan D, and 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
[29] Globalization, TRIPS and access to pharmaceuticals. *WHO Policy Perspectives on Medicines,* No. 03, March 2001. Geneva, World Health Organization, 2001.
[30] *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?* South Centre and World Health Organization, 2005 (http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf).
[31] *Promoting rational use of medicines:* Core components. WHO Policy Perspectives on Medicines, No. 05, September 2002. Geneva, World Health Organization, 2002
[32] 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

ANNEX 1

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

Access to essential medicines: The availability and affordability of essential medicines. To be accessible, medicines must be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, appropriately used and at a price the individual and the community can afford.

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

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

Appropriate use of medicines: Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

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

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

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

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

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

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

Dispensing fee: Normally a fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up. The fee more accurately reflects the work involved in handling a prescription; a percentage mark-up makes profit dependent on the sale of expensive medicines.

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

Drug: (see medicine)

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

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

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

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

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

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

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

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

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

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

Marketing authorization: An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality.

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

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

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

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

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

National medicines (drug) policy (NMP): A national medicines policies is an expression of the government's goals and priorities for the medium to long term for the pharmaceutical sector. It also identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and private sectors, and involves all the main actors in the pharmaceutical field.

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

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

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

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

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

Rational medicines use: Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

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

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

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

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

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

Transitional period: TRIPS provides transitional periods during which countries are required to bring their national legislation and practices into conformity with its provisions. The latest dates for WTO Members were/are: 1996 for developed countries; 2000 for developing countries (as a general rule); 2005 for developing countries who had not introduced patents before joining the WTO; and 2006 for least-developed countries (extended to 2016 by the Doha Declaration). The TRIPS Agreement specifically recognizes the economic, financial, administrative and technological constraints of the least-developed countries. It therefore provides the possibility for further extension of the transitional period.

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

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

Article 65: Transitional Arrangements

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

Article 66: Least-Developed Country Members

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

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

WHO Certification Scheme: The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce guarantees, through the issue of a WHO certificate, the quality of pharmaceutical products entering international commerce. It is a simple administrative procedure that enables importing countries to obtain information on whether a product has been authorised to be placed on the market in the exporting country, and assurance that the manufacturer has been found to comply with WHO standards of good manufacturing practice. This system is particularly useful for countries with limited capacity for quality control of drugs.

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

ANNEX 2

Level I questionnaire 2007

Questionnaire on structures and processes of country pharmaceutical situations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Questions	Responses	Explanations
6.13 Is there a national strategy to contain antimicrobial resistance?	☐Yes ☐No ☐Don't Know	
6.14 Is there a national reference laboratory to coordinate epidemiological surveillance of antimicrobial resistance?	☐Yes ☐No ☐Don't Know	
6.15 Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection?	☐Yes ☐No ☐Don't Know	
6.16 How frequently are the following types of medicines sold over the counter without any prescription:		
Antibiotics:	☐Always ☐Frequently ☐Occasionally	
Injections:	☐Always ☐Frequently ☐Occasionally	

List of respondents

Name	Position	Address	E mail	Section(s) completed

Comments about indicators and values

Item number	Comment

ANNEX 3

List of level I core indicators

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

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

Pan American Health Organization
Regional Office of the World Health Organization

9 789275 131213