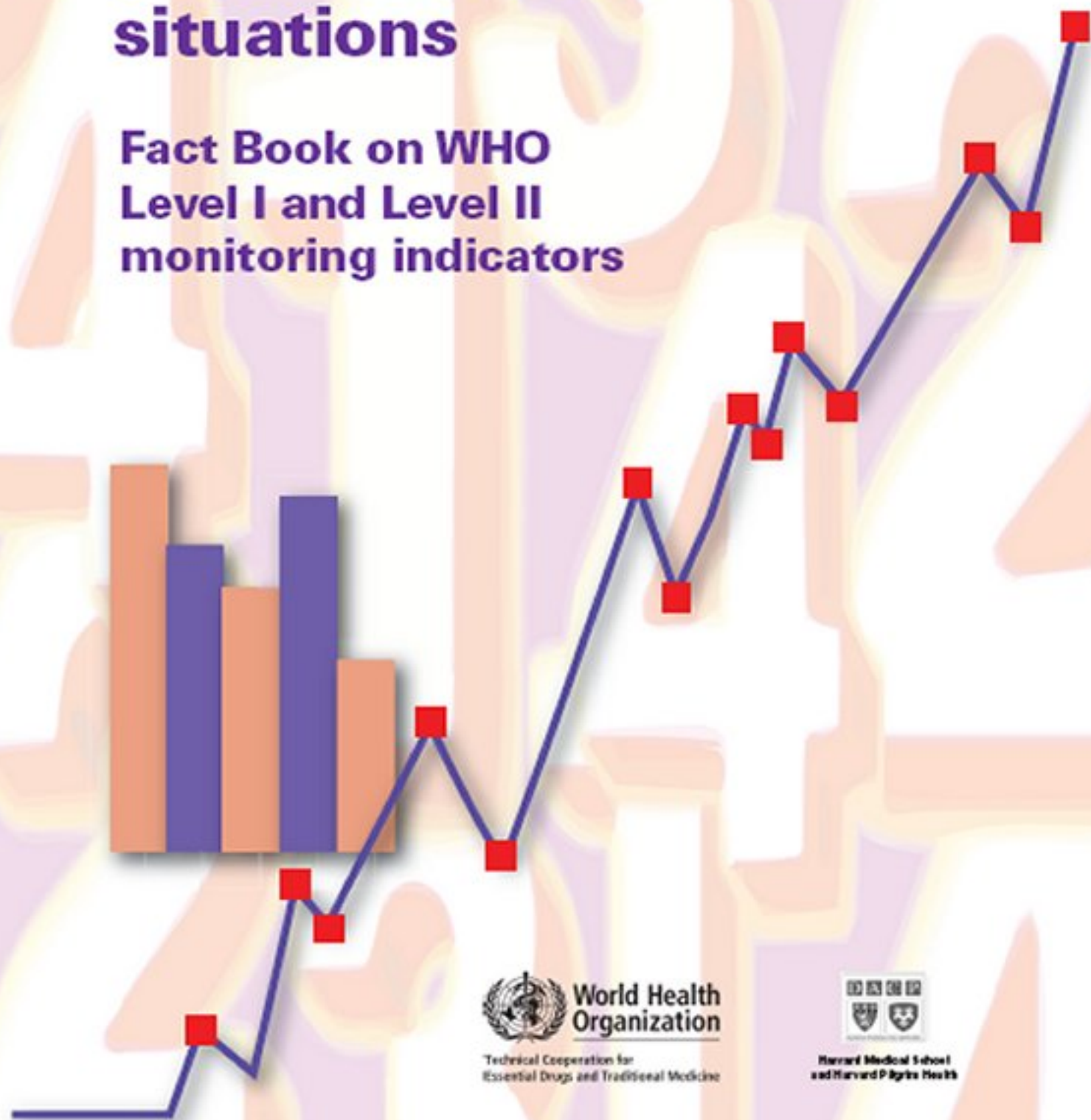# Using indicators to measure country pharmaceutical situations

Fact Book on WHO Level I and Level II monitoring indicators

World Health Organization

Using indicators to measure country pharmaceutical situations

Fact Book on WHO Level I and Level II monitoring indicators

Harvard Medical School
and Harvard Pilgrim Health

World Health Organization

Technical Cooperation for
Essential Drugs and Traditional Medicine

European Community

DFID Department for International Development

PREFACE

In 1975, the Twentieth World Health Assembly, in resolution WHA 28.66, stated the need for the World Health Organization (WHO) to develop means by which it can help Member States to formulate national medicines policies. It should also assist countries to implement strategies such as selection of essential drugs, appropriate procurement of quality drugs based on health needs and should provide education and training in various elements of pharmaceutical programmes.

Currently WHO's work on medicines is guided by the 2004–2007 *WHO medicines strategy*. Against this backdrop, the Fact Book should be read in the context of the vision that people everywhere have access to the essential medicines they need, that the medicines are safe, effective and of good quality; and that the medicines are prescribed and used rationally. Part of the strategy is regular monitoring and evaluation which underpins every aspect of WHO's activities in essential medicines. Monitoring and evaluation aim to answer the following questions: Do people have access to essential medicines? Are people getting medicines that are safe, effective and of good quality? Are these medicines being used properly?

There is a dearth of data and information to answer these questions. The conference of experts held in Nairobi in 1985 requested WHO to provide information on the drug situation at the global and national levels. Efforts have been made to develop tools and establish systems to collect and publish data regularly. In 1988 *The world drug situation* was published. This was updated in 2004 with the publication of *The world medicines situation.* Indicator tools have also been developed and improved during this time.

The data and information in this Fact Book are the product of several years of work on developing and improving data-gathering tools followed by the systematic gathering of information from countries through questionnaires and surveys. This Fact Book is the synthesis of data and information gathered from countries and also updates some of the information in *The world medicines situation.*

This Fact Book aims to summarize and provide a picture of the situations of different pharmaceutical sector components and the current status of national drug policies. In some ways this represents an attempt to measure the impact of the efforts of countries, WHO and other agencies that have been involved in and committed to improving pharmaceutical situations. We would therefore appreciate any comments and corrections on the data and information presented here that we can use to further improve the process of data-gathering and information sharing.

It is hoped that this Fact Book can be a useful tool for researchers, policy-makers, planners and others who need such data and information. We also hope that the data and information presented here can be used to inform priorities and set targets, to assess the strengths and weaknesses of strategies, and paint a picture of national and institutional problems. Countries that have done the survey have used the results to review their pharmaceutical implementation plans and adjust the strategies and activities in areas where problems were identified. This Fact Book could also inform international agencies and donors by supplying information that can be used as baseline data and possibly to infer the potential

impact of activities. Professional groups and nongovernmental organizations (NGOs) can use the results to focus their advocacy and information campaigns.

ACKNOWLEDGEMENTS

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* Available on CD-ROM. Requests should be addressed to the Department of Technical Cooperation for Essential Drugs and Traditional Medicine, World Health Organization, 1211 Geneva 27, Switzerland. Fax: + 41 22 791 4167, e-mail: edmdoccentre@who.int

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ABBREVIATIONS

ADR	Adverse drug reaction
AFRO*	WHO Regional Office for Africa
AMR	Antimicrobial resistance
AMRO*	WHO Regional Office for the Americas
ARI	Acute respiratory infection
DTC	Drug and therapeutics committee
EDM	WHO Essential Drugs and Medicines Policy Department
EML	Essential medicines list
EMRO*	WHO Regional Office for the Eastern Mediterranean
EURO*	WHO Regional Office for Europe
GNI	Gross national income per capita
HIV/AIDS	Human immunodeficiency virus/Acquired immunodeficiency syndrome
INN	International Nonproprietary Name
NGO	Nongovernmental organization
NMP	National medicines policy
ORS	Oral rehydration solution
OTC	Over-the-counter
PAR	Policy, Access and Rational Use (WHO team)
SEARO*	WHO Regional Office for South-East Asia
STG	Standard treatment guidelines
TM/CAM	Traditional medicines and complementary and alternative medicines
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WPRO*	WHO Regional Office for the Western Pacific
WTO	World Trade Organization

* WHO regional offices were used to group countries for purposes of regional data summary and analysis.

SUMMARY OF KEY POINTS

WHO pharmaceutical indicators

The WHA 54.11 WHO medicines strategy acknowledged the four main objectives of WHO's medicines strategy, namely, to frame and implement policy; to ensure access; to ensure quality, safety and efficacy; and to promote rational use of medicines. To monitor the progress of efforts to improve the global medicines situation, WHO has developed a system of indicators that measure important aspects of a country's pharmaceutical situation. Level 1 indicators measure the existence and performance of key national pharmaceutical structures and processes. Level II indicators measure key outcomes of these structures and processes in the areas of access, product quality and rational use. These indicators can be used to assess progress over time; to compare situations between countries; and to reassess and prioritize efforts based on the results.

This Fact Book gives the results of the assessment of Level I indicators conducted in 2003 and of Level II indicator surveys conducted between 2002 and 2004. Indicator data are summarized into eight component topics and within groups of countries classified as low-, middle- and high-income. The importance and key points to note on each component topic are introduced at the beginning of each section. Data and information are given in tables and graphs as current situation – result of 2003 Level I survey – and if progress has been made, by comparing Level I 1999 and 2003 surveys. Impact measures are illustrated by the results from Level I and outcome indicators from Level II.

The key findings are summarized below.

National medicines policy

In 1975, the World Health Assembly in resolution WHA28.66 requested WHO to develop means to assist Member States in formulating national drug policies. Thus, WHO recommends that countries consider formulating, implementing and monitoring a national medicines policy (NMP) as a "commitment to a goal and a guide for action" (*1, 2*) to define a framework for setting and monitoring medium- to long-term objectives in the pharmaceutical sector. The functions and strategies of each component of the policy should be brought together in an implementation plan.

Most countries, especially low-income countries, do have an NMP and implementation plan and most of the NMPs have been updated within the past 10 years. More countries had an official NMP in 2003 than in 1999. Few countries report assessing their pharmaceutical situations with indicators.

Legislation and regulation

A legislative framework is required to implement and enforce pharmaceutical policies both in the public and private sectors. Countries at all income levels report the presence of extensive legal and regulatory frameworks covering all aspects of the pharmaceutical sector. One specific area is policy on the use of generics, with the number of countries reporting that legislation requiring prescribing of generics

or allowing substitution of generics in either the public or private sectors declining substantially since 1999. The results of a systematic survey of prescribing behaviour, did show that the rate of generic prescribing was 80% or more.

Quality control of pharmaceuticals

Quality control is important to ensure that patients receive medicines that are safe and effective. Drug regulatory authorities should have access to a quality control laboratory to test whether samples of medicines meet the required quality criteria. Quality control extends beyond testing to ensuring that medicines are properly stored and not expired (i.e. have not passed their expiry date).

Low-income countries collect fewer samples for quality control purposes and report higher rates of products that fail to meet quality control standards. None of the health facility surveys found expired products at health facilities, pharmacies or warehouses among the key medicines selected. Storage and handling scores are consistently high in warehouses in most countries. Scores for pharmacy stock areas in public health facilities are also satisfactory.

Medicines financing systems and policies

WHO is committed to guiding countries in the development of strategies to promote fair financing mechanisms to improve the affordability and availability of essential medicines in the private and public sectors (*1*). Improving the supply of medicines, particularly in the public sector, and increased public funding and provision of medicines benefits through social health insurance and prepayment schemes, including pricing information and policies, are important strategies (*1*).

Over half of countries have regulations and policies to control the prices of medicines in the public sector, and the percentage is increasing in parallel with increasing country income levels. Middle-income countries are somewhat more likely to regulate medicines prices in the private sector and more likely to subsidize access by providing free medicines for specific diseases in the public sector. Fees are also charged differently: low- and middle-income countries tend to charge flat rate co-payment fees in public health facilities, whereas high-income countries are more likely to charge a percentage co-payment fee.

Less than half as many low-income countries have insurance coverage that includes medicines as higher income countries. Medicines coverage by private insurance increased substantially between 1999 and 2003 in all country income categories.

Public sector medicines supply

A well-coordinated medicines supply system helps to ensure that funds available for purchasing medicines are used effectively and efficiently. An option (*1*) is to develop an efficient mixed system for supplying medicines with public, private and NGO procurement, storage, and distributions services.

Ministries of health are the main public sector procurement agencies, although individual institutions and NGOs play important roles in low-income countries. National competitive tender is the primary purchasing process in the majority of

countries, especially middle- and high-income countries, whereas international tender and negotiation or direct purchasing are widely used in low-income countries.

The proportion of countries that limit procurement to drugs contained in the national EML declines with increasing income.

The survey of health facilities showed that on average, more than 80% of key medicines are available in public and private pharmacies and public warehouses.

Intellectual property rights, patents and local production

Intellectual property rights have an important impact on the affordability and availability of medicines and thereby public health (*1*). The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires WTO member countries to implement and enforce minimum standards of intellectual property rights. However, the 2001 Doha Declaration on the TRIPS Agreement and Public Health had confirmed that TRIPS-compliant mechanisms and flexibilities can be used to enable access to lower priced medicines.

There are problems however in the manner in which the provisions for the TRIPS flexibilities are incorporated into national laws; thus the information on TRIPS flexibilities, such as parallel import, compulsory licensing and the early working exception, has limitations as presented in this Fact Book.

Taking into consideration these limitations and the way questions were asked in a comprehensive survey, it is reported that over 80% of high- and middle-income countries have patent protection for pharmaceutical products, compared to only half of low income countries. Only 1 in 3 low- and middle-income countries have parallel importation provisions in their legislation compared with two thirds of high-income countries. By 2003, 28 of 59 WTO member countries which participated in the survey were taking advantage of provisions allowing a transitional period to comply with TRIPS Article 65.

In this section local production was also described. Local production of medicines is aimed to improve access to high-quality, low-cost medicines. A key challenge is to determine whether the circumstances for successful local production are met, to ensure that investment in local production is not at the expense of cost or quality of medicines.

Production in most countries consists of repackaging finished dosage forms; research and development are mostly confined to high-income countries.

Access to essential medicines

Access can vary between urban and rural areas because of problems with health system development. Pharmacies, medicines distributors, health facilities, and public and private health providers are usually concentrated in cities and regional centres.

Most countries that reported that less than half of their population has adequate access to health facilities are low-income countries and over half are in Africa, whereas 8 out of 10 countries with very high access are in Europe and the Americas. The survey result also showed that the number of low-income countries

reporting high rates of access to essential medicines rose between 1999 and 2003, but the number of high-income countries had fallen.

In many of the countries in which a systematic survey has been done, close to 100% of the medicines prescribed were in stock and dispensed in public health facilities. Medicine prices tended to be much less affordable in the private sector than in the public sector; likewise treatment for adult pneumonia in middle-income countries costs twice as many days' wages as in low-income countries.

Rational use of medicines

Essential medicines lists and standard treatment guidelines

Many factors influence the use of medicines and countries need to implement various strategies to improve rational use. Such strategies can include developing and implementing the use of standard treatment guidelines (STGs) for common conditions, and using essential medicines lists (EMLs) to guide procurement and training.

Almost all low- and middle-income countries have a national EML, and most limit procurement to medicines on that list. The number of medicines included on national EMLs tends to increase with increasing country income. Few countries report that public or private sector insurance reimbursement is linked to the EML.

As an outcome measure, most public health facilities visited during the survey have an EML, although in some cases it is old and functionally obsolete. The rate of prescribing medicines from the EML is very high in public health facilities in most countries, with only two countries reporting rates lower than 60%.

Over 70% of countries reported that they have STGs for primary health care, which are available in most public health facilities surveyed, but some have not been updated recently.

Key policies and regulations to promote rational use

The role of a drug and therapeutics committee (DTC) is to ensure the safe and effective use of medicines. Nearly two thirds of countries report that DTCs are a mandated element in their national medicines policy.

Irrational use of antibiotics contributes to increased antimicrobial resistance (AMR), rendering essential antibiotics ineffective and requiring the use of newer, more expensive antibiotics for the treatment of bacterial illnesses. High-income countries are much more likely to have a national strategy to contain AMR, a national task force to implement the strategy, and a national reference laboratory to conduct surveillance.

Due to lack of regulation and enforcement, over-the-counter (OTC) sales of antibiotics have been a concern worldwide. Most countries surveyed report that OTC sales of antibiotics and injections occur only occasionally or never.

Given the known impact of advertising and promotion of medicines on both prescribing behaviour and patient demand, it is essential to regulate and monitor medicines promotion to ensure that it remains ethical. Most countries report that pharmaceutical promotion is regulated by the government medicines regulatory

agency, although self-regulation of promotion is more common in high-income countries.

Education and information about rational use and accessibility of medicines from the Level I survey of countries revealed that health professionals are widely exposed to concepts of EMLs, STGs, problem-based pharmacotherapy, and rational prescribing during basic training.

Mandatory continuing education for health professionals is more common as country income increases. The requirement for health providers to attend continuing education programmes that include appropriate use of medicines had increased between 1999 and 2003.

Public or independent national drug information services are available for health workers or patients in less than half of the countries surveyed and availability is lowest in low-income countries. The number of countries that support national medicines information services for prescribers and dispensers did not increase between 1999 and 2003.

Public education about antibiotic use and misuse increases with country income level, whereas injection use is more often a focus of public education in low- and middle-income countries.

Improved prescribing behaviour of health workers is one of the expected outcomes shown in the systematic Level II survey of countries. However review of prescriptions revealed that the percentage of patients prescribed antibiotics continues to be high in all countries in which the systematic survey was conducted. First-line antibiotics are usually used to treat paediatric pneumonia, but antibiotics are also commonly given for non-pneumonia acute respiratory conditions (ARIs), most of which will not respond to antibiotics. Prescribing of injections is still very high in low-income countries.

Other outcome indicators are as follows: appropriate drug use is demonstrated with high levels of use of oral rehydration solution (ORS) to treat paediatric diarrhoea and low use of antidiarrhoeals or antispasmodics in children. The number of medicines prescribed per episode of outpatient care is between two and three in most countries. The adequacy of labelling of prescription items varies widely between countries. Four out of five patients in most countries know how to take their medicines when interviewed immediately after the medicines has been dispensed.

Methodological limitations and recommendations

Analyses of the most recent Level I and Level II survey data have also identified several limitations in the current survey instruments and in data collection and management. Recommendations for future improvements include shortening of the Level I questionnaire, automation of data collection and development of composite indicator scores based on Level I data in key domains such as access and rational use.

It is important to note that the current methodology does not measure access to and use of medicines from the perspective of the patient or consumer. Household surveys are needed to assess whether people have access to essential medicines, how they use them, how they pay for them, and how out-of-pocket payments for

medicines impact on household finances. Only household surveys can provide information about the ultimate outcomes of pharmaceutical policies on the functioning and well-being of individuals.

1.   INTRODUCTION

1.1   *Background*

The WHA 54.11 WHO medicines strategy acknowledged the four main objectives of WHO's medicines strategy, namely, to frame and implement policy; to ensure access; to ensure quality, safety and efficacy; and to promote rational use of medicines. The *WHO medicines strategy* 2004–2007 presents the strategies developed to help staff at WHO headquarters and in the regions and countries to work towards realizing this vision.

Monitoring the progress of efforts to improve the global medicines situation is a crucial part of the strategy. 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 (*3*). The core indicators can be easily collected using standardized methodologies, small samples of data and simple survey techniques.
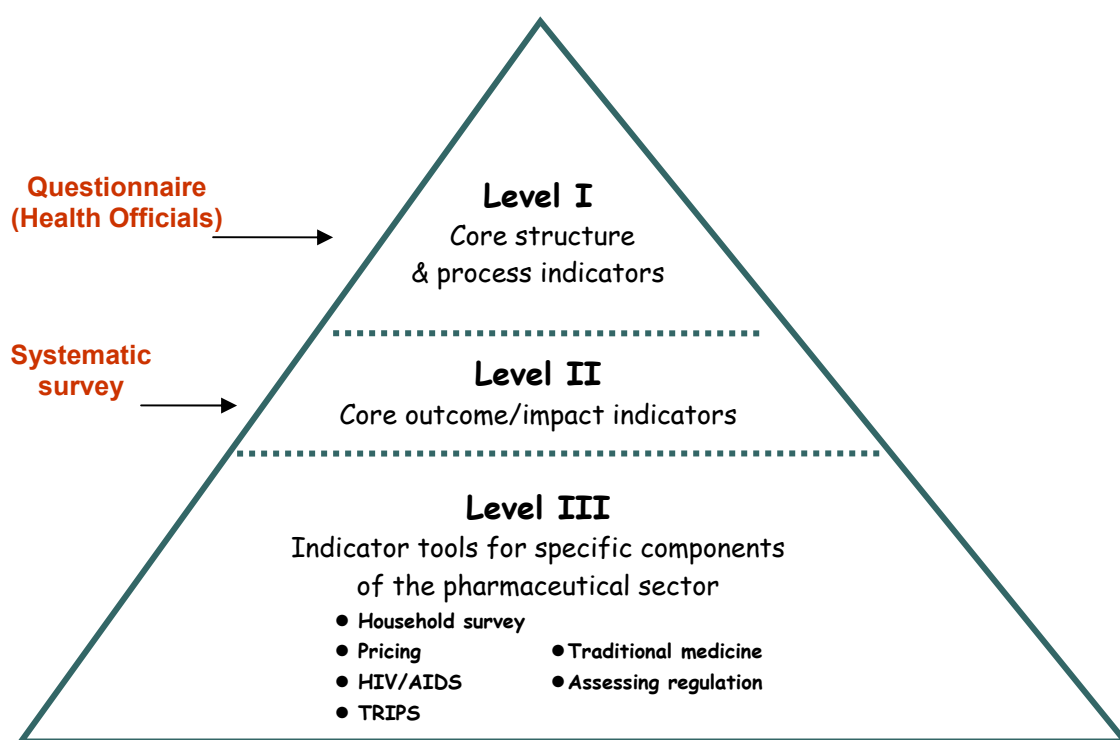
Figure 1. WHO strategy for monitoring country pharmaceutical situations

1.2   *Level I, II and III indicators*

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 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 (3)*.

- Access is measured in terms of the availability and affordability of essential medicines.

- Quality is represented by the absence of expired stock on pharmacy shelves and adequate handling and conservation conditions. Measuring quality by testing samples of pharmaceutical products was deemed too costly to be acceptable 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 STGs and EMLs.

Countries calculate Level II indicators on the basis of data collected with standardized collection instruments at public health facilities, private pharmacies and warehouses (see Annex 2 for the Level II survey). Technical descriptions of some indicators, such as key drugs, measure of affordability, storage and handling scores, adequate labelling and patients' knowledge about the drug dispensed, are given in Annex 3

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.

The present Fact Book details the results of the 2003 assessment of Level I and Level II indicators by 146 and 26 countries, respectively. The current situation is based on the results from the 2003 Level I survey. Where possible, 2003 Level I indicator results were compared with those reported in 1999 to determine whether progress had been made. Sections that describe outcome indicators used information from Level II surveys. For some areas, suitable outcome indicators have not yet been defined.

Some pharmaceutical components/topics presented and described in this Fact Book have more outcome indicator measures (Level II indicators) than others and thus more data are presented. This can be explained by the progress and process in the development of pharmaceutical indicators. There are certain areas in which indicators are more developed and have been used for several years, such as some of the indicators for rational drug use. Obtaining information on these indicators is relatively easy because the method of data collection has long been standardized. Collection of outcome indicators on quality of medicines from a comprehensive pharmaceutical survey is just

being developed, including those for affordability. Other outcome indicators for availability are also being improved. This Fact Book will not attempt to analyse or address pharmaceutical policy issues, or to cover all key pharmaceutical components. The aim of the Fact Book is to provide the latest available information on pharmaceutical situations in various countries, and on the status of national medicines policies, as reflected by WHO Level I and Level II indicators. It is hoped that this information can be used as reference material by those who are interested in working on pharmaceutical sector issues at country, regional and global levels.

1.3 Countries providing data

The present Fact Book details the results of the 2003 assessment of Level I and Level II indicators. Data for Level I indicators were provided by 146 countries, including high-, medium- and low-income countries (see Annex 4 which presents individual Level I data for each country). Data were collected in 2003, thus allowing comparison with the results from 1999.

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

Some problems were noted during data processing owing to the nature of the questionnaires and high volume of information from the 146 countries. Problems included the limitations of the knowledge of respondents and hence the accuracy and validity of some responses. Attempts were made to validate the data as far as possible and to reflect them accurately in the survey report.

Data to measure Level II indicators were collected by 26 countries (see Annex 5 for Level II data on individual countries). Data were collected over a one-month period in each country between 2001 and 2004. The selection of indicators has evolved during this period and thus countries that did the survey later benefited from the experience of earlier surveys, which resulted in the refinement of some indicators. The writers had been careful in using indicators' results and ensuring that the processes of data collection, computation and analysis were standardized for each indicator.

Level II indicators are measured in public health facilities, private drug outlets and in warehouses supplying the public sector.[1] Surveys of 30 public health facilities and their dispensaries gathered information about availability of essential medicines, medicine prices, stockout duration, adequacy of conservation conditions, affordability, prescribing and dispensing habits, and presence of guidelines. A similar survey of five warehouses supplying the public sector also examined availability, stockout duration, and adequacy of conservation conditions. Surveys of 30 private drug outlets assessed availability, affordability and prices of medicines.

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[1] For the purposes of the Level II survey package, a private drug outlet is a permanent retailer selling medicines, whether a pharmacy, drug seller, drug store, or chemical seller. A warehouse is a central, regional or district warehouse supplying the public sector. A public health facility dispensary or public health facility pharmacy refers to the medicines dispensing area of the public health facility whether or not there is a pharmacist present.

1.4   Performance standards for Level II indicators

The target for indicators measuring the extent of adequate labelling, proportion of prescribed medicines dispensed, adherence to treatment guidelines and availability of key medicines is ideally 100%. However, internationally valid standards for other indicators, such as average number of medicines per prescription, and the percentage use of antibiotics and injections, are more complex and have not been empirically established. Targets may require modification over time and between countries, but are currently recommended to be below 2, 30% and 20%, for the average number of medicines per prescription, percentage use of antibiotics and percentage use of injections, respectively. The optimal indicator values in these cases largely depend on disease patterns, policies and treatment guidelines and therefore may vary from country to country and over time.

1.5   Structure of the Fact Book

The Fact Book summarizes data for the Level I structure and process indicators and the Level II outcomes indicators according to eight topics:

- national medicines policy;

- legislation and regulation;

- quality control of pharmaceuticals;

- medicines financing systems and policies;

- supply of medicines in the public sector;

- intellectual property rights and patents, and local production;

- access to essential medicines; and

- rational use of medicines.

We briefly explain why each topic is important and summarize data on the situation in 2003. Where comparable data for 1999 are available, we describe progress made between 1999 and 2003. Level II indicators on access, quality, and rational use of medicines were used to assess whether outcome targets are being achieved.

Indicator data were summarized across countries classified as low-, middle-, or high-income, following the World Bank categorization of countries based on 2004 gross national income per capita (GNI). The criteria were: *low-income*, GNI of US$825 or less; *middle-income*, US$826–US$10 065; and *high-income*, US$10 066 or more (*4*). Annex 7 lists the countries that were included in each income category. Of 140 countries that responded to Level I surveys in 2003, 57 were low-, 65 middle-, and 18 high-income countries. Of 26 countries providing Level II data, 15 were low-, and 11 were middle-income countries.

In each country income category, the numbers and percentages of countries that responded positively to questions about the presence of documents, policies or institutions were reported. When countries were asked to provide numerical data (for example, on the annual budget for medicines and number

of adverse events reported), medians, 25th and 75th percentiles of the responses were used. The median is the middle value of a series of numbers: that is, half of the responding countries reported a value lower than the median, and half reported a value higher than the median. Similarly, the 25th and 75th percentiles are the values reported by 25 and 75 per cent of the countries, respectively. Because medians and percentiles are less sensitive to extreme values than means (averages), they are the best summaries of indicator data which are highly skewed.

This Fact Book presents the information from the Level I database (Annex 4) and information from Level II country reports (Annex 5). However not all data from Level I have been included and analysed. Generally, only aggregate data for questions to which at least 50% of countries responded with a yes/no or numerical response (as requested) were reported. Countries that reported "don't know" and those with missing data were excluded from analyses. For pharmaceutical areas where data for comparisons between 1999 (Annex 6) and 2003 were available, only countries that provided data for both years were included. Annexes 4, 5, and 6 included in this document are contained on a CD-ROM.*

Annexes 1 and 2 contain the Level I questionnaire and Level II survey forms that were the basis for data collection. Readers should consult these to see the content of each question.

It is important to note that assessments of country pharmaceutical situations using the existing Level I and Level II indicators have certain limitations. We discuss these limitations in Chapter 9 and suggest next steps in the process of evaluating and monitoring country pharmaceutical situations.

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* Available on CD-ROM. Requests should be addressed to the Department of Technical Cooperation for Essential Drugs and Traditional Medicine, World Health Organization, 1211 Geneva 27, Switzerland. Fax: + 41 22 791 4167, e-mail: edmdoccentre@who.int

2. NATIONAL MEDICINES POLICY

2.1 Why is this important?

WHO recommends that countries consider formulating, implementing and monitoring a national medicines policy (NMP) as a "commitment to a goal and a guide for action" (*1, 2*). An NMP defines a framework for setting and monitoring medium- to long-term objectives in the public and private pharmaceutical sectors. The NMP should encompass:

- ensuring equitable availability and affordability of essential medicines;

- ensuring that all medicines are safe, efficacious and of high quality; and

- promoting rational use of medicines by health care professionals and consumers.

By attaining these objectives, countries can reduce morbidity and mortality, decrease the incidence of catastrophic illness that can increase impoverishment, and prevent large-scale losses to health and economic systems.

The functions and strategies of each component of the policy should be brought together in an implementation plan. It is recommended that an NMP implementation plan will cover a period of 3–5 years. Incorporation of the NMP into the national health system 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. This should occur in connection with monitoring conducted as part of policy implementation and taking account of changes in health policy and the broader environment that have an impact on the pharmaceutical sector. Standardized indicators of the pharmaceutical situation allow countries to monitor and evaluate the impact of implementing an NMP.

2.2 What is the current situation?

Figure 2 illustrates which countries have either an official or a draft NMP, and whether the policy has been updated within the past 10 years.

Figure 2. Global status of national medicines policies (NMPs)
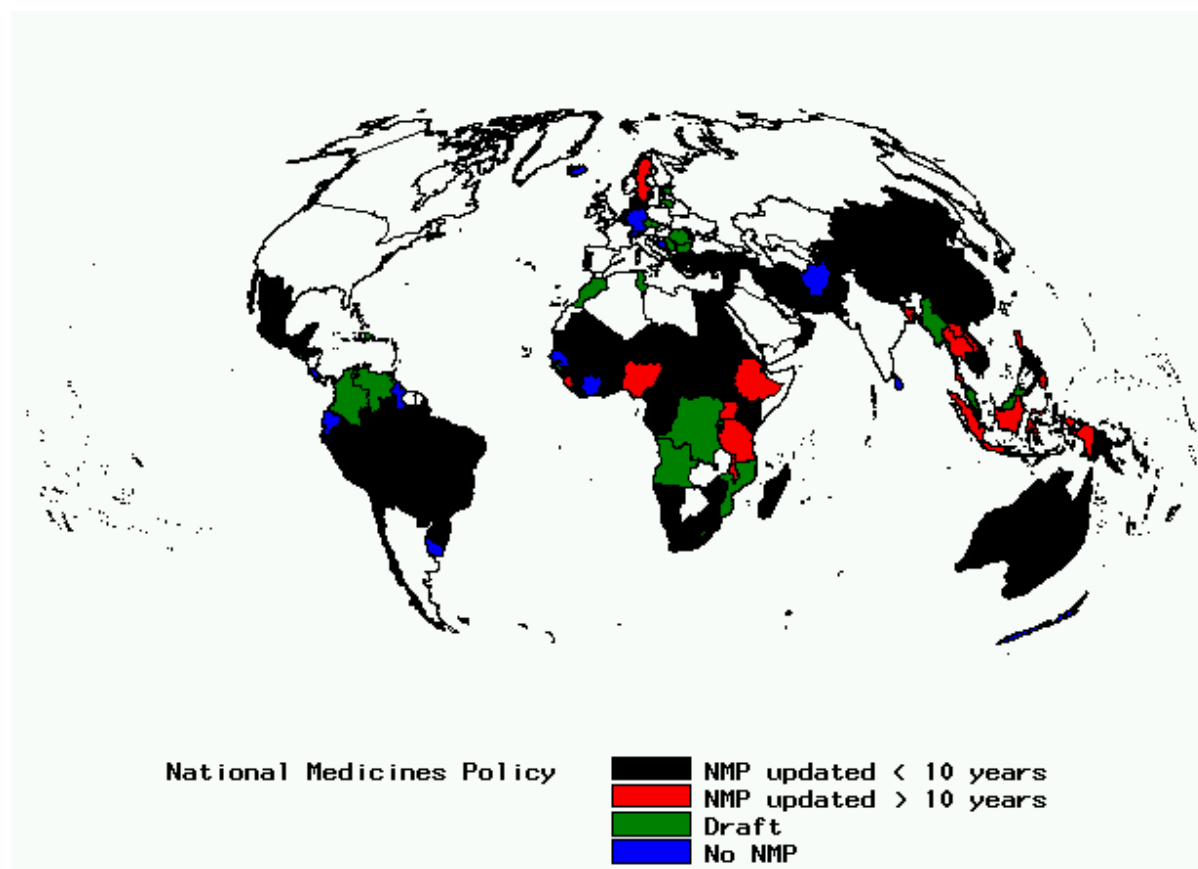
Table 1. Status of national medicines policies (NMPs) in 2003

	Country income level					
	Low		**Middle**		**High**	
NMP status	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
NMP official (or draft)	51	86.0	47	69.1	10	47.6
Official and updated < 10 years [a]	32	75.6	22	84.0	8	83.3
Official and updated > 10 years [a]	8	19.5	4	16.0	1	16.7
NMP implementation plan in place	34	64.2	23	51.1	7	58.3
NMP integrated in health plan	36	66.7	31	64.6	6	54.6

[a] Two low-income countries did not indicate year.

> ➢ *The majority of countries have an NMP and implementation plan integrated with the health plan.*
> ➢ *Low-income countries perform particularly well on these indicators.*
> ➢ *The majority of NMPs have been updated within the past 10 years.*

Table 2.   Countries reporting recent indicator assessments

	Country income level					
	Low		**Middle**		**High**	
Areas assessed[a]	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Overall pharmaceutical situation	20	42.6	20	48.8	5	62.5
Rational use/prescription audit	19	41.3	17	41.5	5	50.0
Access	19	41.3	11	29.7	3	37.5

[a] Assessed within the last 5 years (1999–2003).

> ➢ *Overall, fewer than half of countries report assessing their pharmaceutical situations with indicators.*
> ➢ *Indicator assessments are more common in high-income countries.*

2.3   Have we made progress?

Figure 3. Countries with national medicines policies (NMPs) in 1999–2003[a]
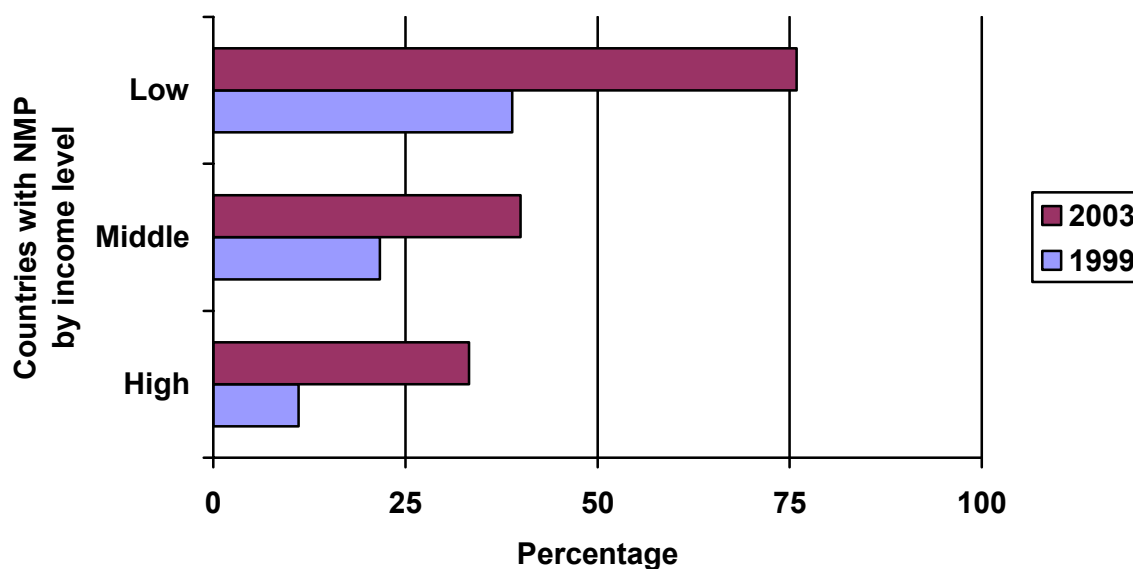
[a] For countries with data on both years.

> ➢ *More countries had an official NMP in 2003 across all income categories.*
> ➢ *The rate of increase of formulation of NMPs was greatest in low-income countries.*

Table 3.   Status of national medicines policies (NMPs) in 1999 and 2003[a]

NMP status	1999 Number of countries	2003 Number of countries
With official NMP	59	76
Updated within last 10 years	54	63
Not updated within last 10 years	5	13
No NMP	31	24

[a] For countries with data in both years.

> ➢ *Between 1999 and 2003, 17 additional countries adopted an NMP.*
> ➢ *The number of countries with an updated NMP (within the last 10 years) increased from 54 in 1999 to 63 in 2003.*

Table 4.   Changes in status of national medicines policy (NMPs) from 1999 to 2003[a]

	Country income level					
	Low		Middle		High	
	Number of countries	%	Number of countries	%	Number of countries	%
NMP status						
1999 none, draft in 2003	4/8	50.0	10/24	41.7	1/13	7.7
1999 draft, still draft in 2003	2/14	14.3	5/14	35.7	0/2	0.0
1999 draft, official in 2003	11/14	78.6	4/14	28.6	1/2	50.0
1999 not updated >10 years, updated by 2003	0/3	0.0	1/3	33.3	0/0	0.0
NMP implementation plan						
1999 none, plan in 2003	6/14	42.9	10/21	47.6	1/4	25.0
Same status in both years	29/37	78.4	21/34	61.8	4/6	66.7
1999 plan, no plan in 2003	2/37	5.4	3/34	8.8	1/6	16.7

[a] For countries with data in both years.

> ➢ *15 countries with no NMP in 1999 had a draft document by 2003.*
> ➢ *16 countries progressed from draft NMP in 1999 to an official document in 2003.*
> ➢ *Only one of the six countries with an NMP that was not updated in 1999 had updated the document by 2003.*
> ➢ *17 countries with no NMP implementation plan in 1999 had developed one by 2003.*

3. LEGISLATION AND REGULATION

3.1 Why is this important?

A legislative framework is required to implement and enforce policies regulating the pharmaceutical sector. Laws and regulations create a legal basis for the control of activities in the public and private pharmaceutical sectors, including administrative measures and sanctions in response to violations. Areas covered include the roles and responsibilities of the drug regulatory authority; market approval and registration of medicines; regulation of premises where medicines can be handled; and the qualifications, rights, and responsibilities of drug manufacturers, importers, exporters, distributors, prescribers and dispensers. Other key regulatory issues include implementation of policies on generic products to ensure the availability and use of lower-priced medicines, and monitoring of adverse drug reactions (ADRs) to products on the market.

Governments need strong national authorities to effectively regulate the manufacture, trade and use of medicines. The regulatory authority must ensure that only safe, effective, high quality medicines are produced, marketed, prescribed and dispensed to protect and promote public health.

3.2 What is the current situation?

Table 5. Presence of key pharmaceutical sector legislation

| | Country income level | | | | | |
| | Low | | Middle | | High | |
Policy area covered	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Establishment of regulatory authority	53	98.2	52	89.7	17	94.4
Marketing authorization	48	90.6	52	88.1	15	83.3
Manufacturing of medicines	48	90.6	50	86.2	16	88.9
Distribution of medicines	54	98.2	50	89.3	17	94.4
Promotion and advertising of medicines	47	88.7	50	87.7	16	88.9
Importation of medicines	53	98.2	53	89.8	17	94.4
Exportation of medicines	38	71.7	40	71.4	13	76.5
Licensing and practice of prescribers	41	82.0	44	81.5	17	100.0
Licensing and practice of pharmacy	51	96.2	47	83.9	17	100.0
Empowerment to enter premises and collect samples and documentation	47	90.4	49	89.1	17	100.0
Requirement for regulatory transparency, accountability and code of conduct	35	71.4	33	70.2	16	88.9

> ➢ *The majority of countries have established a drug regulatory agency.*
> ➢ *Countries at all income levels report the presence of extensive legal and regulatory frameworks covering all aspects of the pharmaceutical sector.*

Table 6. Legislation and regulation on registration of medicines

	Country income level					
	Low		Middle		High	
Components of registration	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Authorization for marketing of medicines required	47	83.9	49	81.7	17	94.4
	Median [25th, 75th percentile]		**Median [25th, 75th percentile]**		**Median [25th, 75th percentile]**	
Number of approved medicines on the market	2413 [1500, 3708]		5000 [2000, 9000]		7296 [3621, 11459]	
Written guidelines for medicines registration	41	73.2	50	80.7	14	82.4
Marketing authorization required for herbal products	34	61.8	40	65.6	16	88.9
Written guidelines for herbal product registration	21	39.6	34	59.7	11	64.7
WHO Certification Scheme required for marketing authorization	41	73.2	39	62.9	7	41.2
INN used in registration of medicines	45	81.8	48	81.4	15	88.2
Publicly accessible list of all registered products	34	61.8	42	68.9	13	72.2
Computerized registration system available	27	49.1	32	51.6	13	72.2
Regulatory authority web site with publicly accessible information	12	21.1	27	43.6	12	66.7

INN, International Nonproprietary Name.

> ➢ *The median number of drugs marketed increases with country income level.*
> ➢ *The requirement for marketing authorization was supported by written guidelines for registration in over three quarters of countries.*
> ➢ *Low-income countries were more likely to require use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.*
> ➢ *The availability of information about drug registration on the Internet increases dramatically with country income level.*

Table 7. Site inspection of establishments as requirement of licensing

	Country income level					
	Low		Middle		High	
Sites inspected	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Manufacturers	43	79.6	51	92.7	17	100.0
Importers/wholesalers	45	83.3	48	92.3	16	100.0
Retail distributors/pharmacies	49	89.1	49	96.1	16	94.1

> ➢ *Most countries inspect importers, manufacturers, distributors and pharmacies.*
> ➢ *Site inspection is somewhat less frequent in low-income countries.*

Table 8.   Monitoring of adverse drug reactions (ADRs)

	Country income level					
	Low		**Middle**		**High**	
ADR activities	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
ADRs monitored	18	32.7	36	62.1	13	86.7

	Median [25th, 75th percentile]	**Median [25th, 75th percentile]**	**Median [25th, 75th percentile]**
Number of validated ADR reports[a]	17 [8, 113]	495 [80, 1200]	1085 [181.0, 2579.5]

[a] Only seven low-income, 26 middle-income and 12 high-income countries provided information on validated ADR reports.

> ➢ *Few low-income countries monitor ADRs, and the median number of ADR reports in these countries is very low.*

Table 9.   Legislation on prescribing and substitution of generic medicines in public and private sectors

	Country income level					
	Low		**Middle**		**High**	
Type of policy on generics	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Generic prescribing						
Obligatory in the public sector	33	58.9	37	60.7	3	17.7
Obligatory in the private sector	10	18.9	12	21.4	2	11.8
Generic substitution						
Permitted in public pharmacies	45	80.4	52	83.9	17	100.0
Permitted in private pharmacies	40	71.4	35	62.5	10	58.8

> ➢ *More than half of low- and middle-income countries have legislation requiring obligatory prescribing of generic products in the public sector.*
> ➢ *Requirements for prescribing generic products in the private sector are unusual in all countries.*
> ➢ *Legislation allowing substitution is more common across all countries than obligatory generic prescribing.*
> ➢ *Generic substitution was common in the public sector of all countries.*

3.3 Have we made progress?

Table 10. Regulation on generic prescribing and substitution in 1999 and 2003

	Country income level[a]					
	Low		**Middle**		**High**	
Type of generics policy	**Number of countries 1999**	**(%) 2003**	**Number of countries 1999**	**(%) 2003**	**Number of countries 1999**	**(%) 2003**
Generic prescribing						
Obligatory in the public sector	40 (100)	26 (65.0)	49 (100)	31 (63.3)	13 (100)	3 (23.1)
Obligatory in the private sector	19 (51.4)	10 (27.0)	29 (64.4)	11 (25.0)	11 (84.6)	2 (15.4)
Generic substitution						
Permitted in public pharmacies	39 (97.5)	27 (67.5)	43 (89.6)	40 (83.3)	13 (100)	11 (84.6)
Permitted in private pharmacies	33 (89.2)	19 (51.4)	35 (72.9)	32 (66.7)	11 (78.6)	9 (64.3)

[a] For countries with data on both years.

> ➢ *The number of countries that have legislation requiring prescription of generics in either the public or private sectors has decreased significantly since 1999.*
> ➢ *The number of countries allowing generic substitution has also decreased in both sectors, although to a lesser extent.*

3.4 Have we achieved the desired outcomes?

Figure 4. Prescribing by generic name in public facilities
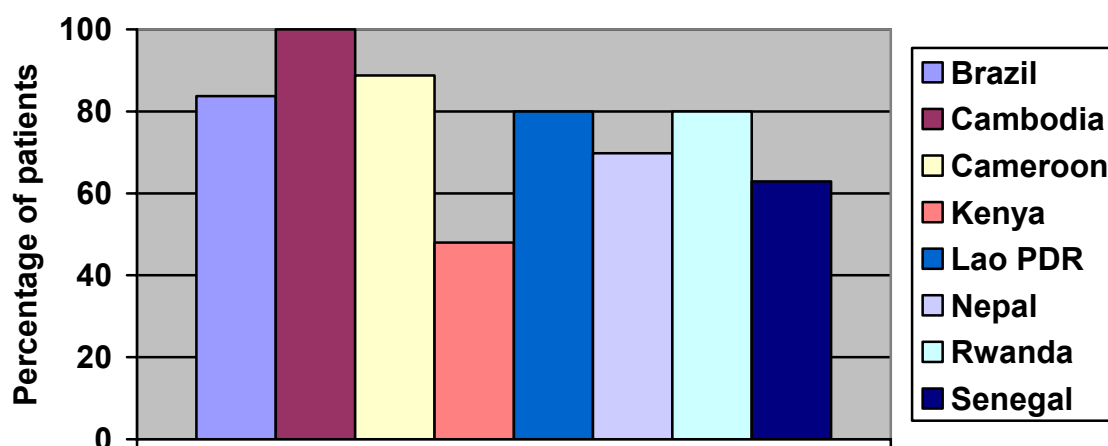
> ➢ *The majority of prescribed drugs in public facilities were written by generic name in the countries where this was surveyed.*
> ➢ *In five of eight countries, the rate of generic prescribing was 80% or more.*

4. QUALITY CONTROL OF PHARMACEUTICALS

4.1 Why is this important?

Quality control is important to ensure that patients receive medicines that are safe and effective. WHO recommends that the drug regulatory authority of each country should have access to a quality control laboratory to test whether medicines samples meet required quality criteria. WHO provides guidelines on establishing testing facilities (*5*, *6*).

Quality control extends beyond testing whether medicinal products contain the right ingredients in the correct amount, to ensuring that they are properly stored and have not passed the expiry date. The latter measure is intended to ensure that, at the final distribution point, patients are getting high quality and efficacious drugs. Countries with tropical climates can experience difficulty in maintaining good drug storage conditions. Prevailing conditions of high temperature and high humidity; common storage problems, such as storage on the floor; lack of systematic arrangement of stock; presence of dust and pests; inadequate protection from direct sunlight; and lack of provision of temperature monitoring charts and facilities to monitor room temperature can lead to degradation of drugs.

4.2 What is the current situation?

Table 11. Product samples collected for regulatory purposes

	Country income level					
	Low		**Middle**		**High**	
Quality control activity	**Median [25th, 75th percentile] Number of samples**		**Median [25th, 75th percentile] Number of samples**		**Median [25th, 75th percentile] Number of samples**	
No. of samples collected[a]	350	[40, 1170]	749	[158, 2500]	409.5	[53, 744]
No. of countries	$n = 37$		$n = 39$		$n = 14$	
No. of samples tested[b]	763	[172, 2202]	923.5	[433, 3382]	427.5	[65, 1073]
No. of countries	$n = 30$		$n = 30$		$n = 12$	
No. (%) of samples failed[a]	36.5 (4.8)	[4, 108]	33.5 (3.6)	[5, 125]	2.5 (<1)	[1, 17]
No. of countries	$n = 30$		$n = 30$		$n = 12$	

[a] Active collection by drug regulatory/quality control agency.
[b] Samples tested can include those submitted by pharmaceutical companies and other groups for testing.

> ➢ *Low-income countries tend to collect fewer samples and of those that were tested, they report higher rates of products failing testing.*

Table 12. Presence of expired medicines in health facilities and warehouses

	Country income level	
	Low	**Middle**
Type of facility		
Public pharmacies	0	0
No. of countries	$n = 12$	$n = 9$
Private pharmacies	0	0
No. of countries	$n = 11$	$n = 10$
Public warehouses	0	0
No. of countries	$n = 9$	$n = 2$

> ➢ *None of the survey teams that conducted Level II surveys of health facilities found expired products present at health facilities or warehouses among the 20 key medicines selected.*

Figure 5. Storage and handling conditions in public health facilities and warehouses
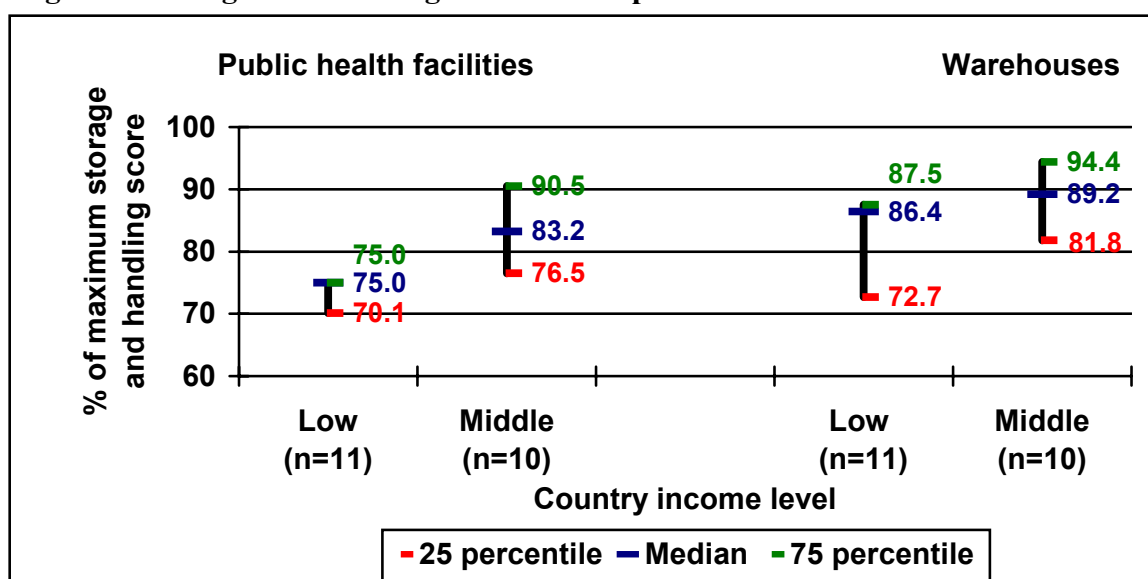
> ➢ *Stock-keeping and handling of medicines in pharmacy stock areas in public health facilities were generally satisfactory.*
> ➢ *Storage conditions in warehouses tended to be better than in pharmacy stock areas in public health facilities.*

Figure 6. Storage and handling conditions in public pharmacies by country
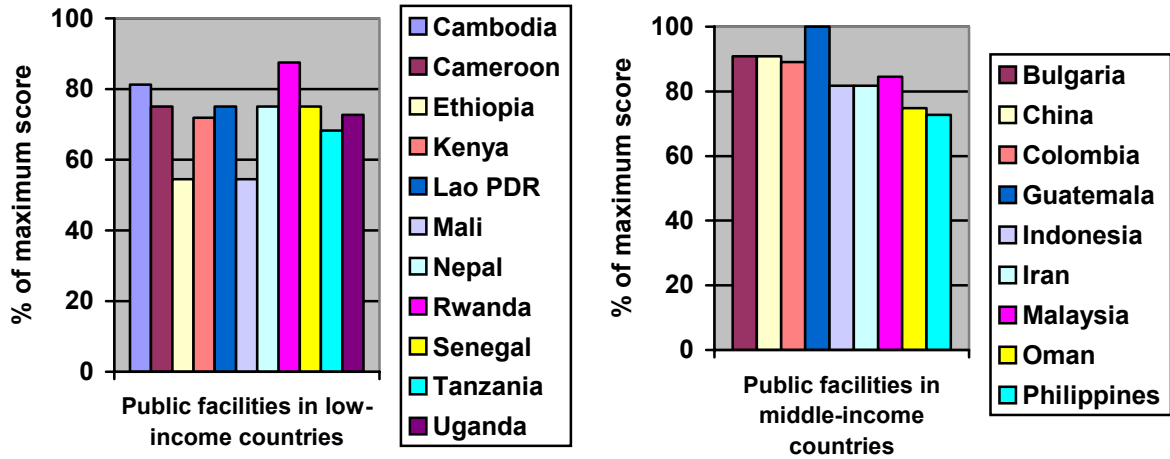
Figure 7. Storage and handling conditions in public warehouses by country
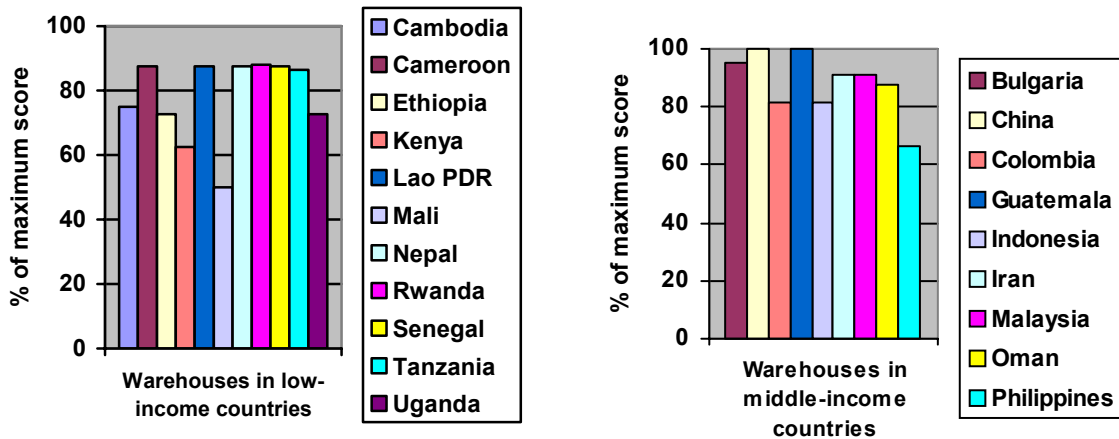
> ➤ *Storage and handling scores were consistently high in most countries.*
> ➤ *Six of eleven low-income countries and eight of nine middle-income countries had warehouse storage and handling scores over 80% of the maximum.*

5. MEDICINES FINANCING SYSTEMS AND POLICIES

5.1 Why is this important?

In developing countries, expenditures on medicines account for 25-65% of total public and private health expenditures, and for 60-90% of out-of-pocket household expenditures on health (*7*). Households are more likely to incur catastrophic expenditures (greater that 40% of income, after subsistence needs are met) when health services, including medicines, require payments, households are poor, and when there is no prepayment or health insurance scheme (*8*).

WHO is committed to guiding countries in the development of strategies to promote fair financing mechanisms to improve medicines supply, especially in the public sector, and to improve affordability of essential medicines in both the private and public sectors (*1*). Increased public funding is important to enable the achievement of 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 (*1*).

Access to specific treatments for high-priority conditions has life-saving implications for individuals and major public health benefits for the community. Although users fees have some advantages if managed properly, they tend also to disproportionately burden the poor. Drug fees from drug sales can create perverse incentives to prescribe inappropriately and should be discouraged unless a strict drug use audit is in place. *(9)* Drug pricing policy is also an important strategy because the cost of medicine is one of the most important obstacles to access. Pricing regulation and policies can provide a good basis for equitable access if they are effectively enabled. Drug prices can be inflated in current market environments.

5.2 What is the current situation?

Table 13. Policies on medicines pricing covering different sectors

	Country income level					
	Low		**Middle**		**High**	
Sector with pricing policy	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Public sector	29	53.7	32	60.4	8	66.7
Private sector	22	46.8	30	65.2	3	33.3
Nongovernmental organization	7	17.5	15	44.1	2	28.6

> ➢ *Over half of all countries had regulations and policies to control drug prices in the public sector, and the percentage increased by country income level.*
>
> ➢ *Middle-income countries were somewhat more likely to regulate prices of medicines in the private sector and in the NGO sector.*

Table 14. Use of fees from drug sales to pay salaries

	Country income level					
	Low		**Middle**		**High**	
How often fees are used to pay salaries	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Always	0	0.0	3	7.1	0	0.0
Often	0	0.0	0	0.0	0	0.0
Occasionally	11	26.2	4	9.5	1	8.3
Never	31	73.8	35	83.3	11	91.7

> ➢ *Most countries never use drug fees to pay salaries, but the use of fees is associated with lower income countries.*
> ➢ *Only three middle-income countries always use fees from drug sales to pay the salaries of health workers.*

Table 15. Free provision of medicines and types of fees in public health facilities

	Country income level					
	Low		**Middle**		**High**	
Types of free medicines	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
All medicines	12	21.8	40	67.8	2	15.4
Malaria medicines	19	37.3	36	81.8	1	9.1
Tuberculosis medicines[a]	50	96.2	45	93.8	9	75.0
Medicines for sexually transmitted diseases	17	34.0	38	79.2	2	18.2
HIV/AIDS-related medicines	16	35.6	37	78.7	7	58.3
All medicines for those who cannot afford them	30	58.8	31	72.1	5	41.7
Medicines for children under 5 years of age	19	38.0	34	77.3	3	23.1
Medicines for pregnant women	19	37.3	34	79.1	1	8.3
Medicines for elderly persons	12	22.2	18	35.3	4	28.6
None[a]	8	14.8	2	3.1	2	11.1
Types of fees charged						
Registration/consultation fees	43	78.2	31	55.4	8	61.5
Dispensing fees	17	33.3	11	21.2	5	38.5
Flat rate co-payments	11	35.5	11	33.3	1	14.3
Percentage co-payments	13	29.6	10	20.4	10	76.9

[a] Inconsistencies in reporting noted.

> ➢ *Medium-income countries are better able to subsidize access by providing free medicines for specific diseases.*
> ➢ *Tuberculosis medicines were the most commonly subsidized medicines at all country income levels, followed by medicines for the indigent population.*
> ➢ *Low-income countries were more likely to report that patients paid consultation fees.*
> ➢ *If there are co-payments in public facilities, low- and middle-income countries tended to charge flat co-payment fees whereas high-income countries were more likely to charge a percentage co-payment fee.*

Table 16. Health insurance and medicines coverage

	Country income level					
	Low		**Middle**		**High**	
Type of insurance coverage	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Public health insurance	22	50.0	33	70.2	11	91.7
Private health insurance	31	73.8	33	80.5	10	76.9
Medicines covered, public insurance	17	38.6	34	73.9	12	85.7
Medicines covered, private insurance	28	77.8	33	80.5	9	100.0
Percentage of cost covered	**Median [25th, 75th percentile]**		**Median [25th, 75th percentile]**		**Median [25th, 75th percentile]**	
Percentage of cost covered, public insurance	50	[10, 80]	95	[20, 100]	75	[60, 100]
No. of countries	*n* = 13		*n* = 22		*n* = 6	
Percentage of cost covered, private insurance	85	[75, 100]	77.5	[40, 90]	62.5	[12.5, 100]
No. of countries	*n* = 15		*n* = 14		*n* = 4	

> ➢ *Fewer low-income countries have public insurance coverage or any insurance that covers medicines.*
> ➢ *Private insurance coverage is more likely to provide medicines benefits across all country income levels.*

5.3   Have we made progress?

Table 17. Countries with medicines covered by health insurance in 1999 and 2003[a]

	Country income level					
	Low-income		**Middle-income**		**High-income**	
Medicines coverage	**Number of countries**	**(%)**	**Number of countries**	**(%)**	**Number of countries**	**(%)**
	1999	**2003**	**1999**	**2003**	**1999**	**2003**
Public health insurance	8/23 (34.8)	8/23 (34.8)	27/35 (77.1)	26/35 (74.3)	8/9 (88.9)	7/9 (77.8)
Private health insurance	8/17 (47.1)	13/17 (76.5)	16/29 (55.2)	24/29 (82.8)	5/6 (83.3)	6/6 (100.0)

[a] For countries with data on both years.

> ➢ *Medicines coverage by private insurance increased substantially between 1999 and 2003 in all country income categories.*
> ➢ *Public medicines coverage has not increased in any income category and the rate in low-income countries is less than half that of medicines coverage in higher income countries.*

Table 18. Public medicines budget and per capita drug expenditures in 1999 and 2003[a]

	Country income level					
	Low **(n = 13)**		**Middle** **(n = 30)**		**High** **(n = 7)**	
	Median	**[25th, 75th percentile]**	**Median**	**[25th, 75th percentile]**	**Median**	**[25th, 75th percentile]**
Annual public medicines budget in 1999 US$ (millions)	4.9	[1.6, 9.0]	17.5	[1.3, 72.7]	38.0	[1.8, 235]
Annual public medicines budget in 2003[b] US$ (millions)	4.0	[1.6, 10]	27.0	[3, 90]	77.0	[16.0, 2,049.0]
Per capita public drug expenditure in 1999 US$	1.0	[0.3, 1.3]	10.1	[5.4, 16.7]	22.4	[1.7, 84.2]
Per capita public drug expenditure in 2003 US$	0.5	[0.3, 0.9]	9.6	[6.9, 31.2]	73.6	[24.6, 204.3]

[a] Only includes countries that reported in both years.
[b] Years range from 2000 to 2003 (85% of countries used 2002).

> ➤ *Public medicines budgets and per capita drug expenditure were lower in 2003 than in 1999.*
>
> ➤ *Differences between low- and high-income countries in annual medicines budgets and expenditures have increased.*
>
> ➤ *Per capita public drug expenditure during 2003 in low-income countries was 5% that of middle-income countries and 0.7% that of high-income countries.*
>
> ➤ *During 1999–2003 per capita public drug expenditure decreased by 50% in low-income countries and by 5% in middle-income countries but increased by 228% in high-income countries.*

6. PUBLIC SECTOR MEDICINES SUPPLY

6.1   Why is this important?

A well-coordinated medicines supply system helps to ensure that funds available for purchasing medicines are used effectively and efficiently. Failures in the supply system can lead to life-threatening shortages of medicines and waste of scarce resources. Problems frequently result when an inefficient public medicines supply system is intended to serve an entire country and/or more efficient private sector supply systems serve only urban populations. An option (*1*) is to develop an efficient mixed medicines supply system of public, private and NGO procurement, storage and distributions services. 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 programmes and as a means to address capacity and infrastructure problems.

Individual facility-based purchasing may be intended to improve the efficiency of medicines management by allowing decisions about drug purchasing to take place closer to the point of use, thus maximizing responsiveness to local needs. However, purchasing of medicines by individual health institutions often lacks transparency, and may not benefit from economies that result from bulk purchasing and centralized tender and procurement. In higher income countries, better infrastructure and a more competitive market among private drug wholesalers can mitigate the possible inefficiencies of individual purchasing.

6.2   *What is the current situation?*

Table 19. Public sector procurement and distribution systems

	Country income level					
	Low		**Middle**		**High**	
Procurement agencies	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Ministry/department of health	46	90.2	45	88.2	9	75.0
Nongovernmental organization	19	50.0	5	15.6	3	37.5
Private organization contracted by government	15	41.7	7	20.6	2	22.2
Individual health institutions	25	58.1	21	55.3	6	66.7
	Median [25th, 75th percentile]		**Median [25th, 75th percentile]**		**Median [25th, 75th percentile]**	
Percentage of procurement done by individual health institutions to total public procurement cost	20% [2%, 20%]		85% [20%, 100%]		55% [20%, 100%)	
	n = 15		*n* = 15		*n* = 2	

Distribution agencies

Ministry/department of health	37	86.1	28	80.0	6	54.6
Nongovernmental organization	12	41.4	4	19.1	2	28.6
Private organization contracted by the government	10	35.7	6	25.0	1	14.3
Individual health institutions	22	59.5	10	40.0	2	28.6

Tender process

National competitive	29	72.5	37	90.2	6	85.7
International competitive	41	82.0	26	68.4	3	37.5
Negotiation/direct purchasing	36	83.7	31	73.8	4	57.1
	Median [25th, 75th percentile]		**Median [25th, 75th percentile]**		**Median [25th, 75th percentile]**	
Percentage of tender done by negotiation/direct purchasing to total cost of tender	10% [5%, 20%]		20% [5%, 65%]		53.5% [5.3%, 99%]	
	n = 25		*n* = 19		*n* = 4	

EML procurement

Procurement limited to EML	43	76.8	27	49.1	1	7.7

EML, Essential medicines list.

> ➢ *Ministries of health are the main public sector procurement agencies, although individual institutions and NGOs play important roles in low-income countries.*
> ➢ *More low-income countries involve NGOs and private organizations in distribution of medicines in the public sector.*
> ➢ *National competitive tender is the primary purchasing process in the majority of countries, especially middle- and upper-income countries.*
> ➢ *International tender and negotiation/direct purchasing are widely used in low-income countries.*
> ➢ *The proportion of countries that limit procurement to drugs in an EML declines with increasing income.*

6.3   Have we achieved the desired outcome?

Figure 8. Stock availability of a basket of essential medicines in different facilities
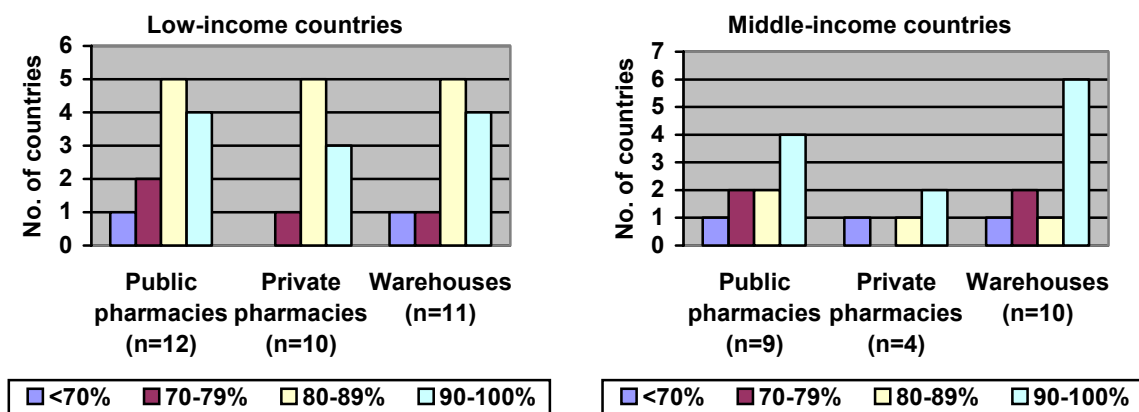
> ➢ *Most countries average > 80% availability of a basket of key essential drugs in public and private pharmacies and public sector warehouses.*
> ➢ *Levels of stocks of key drugs surveyed were satisfactory in low-income countries.*
> ➢ *Key essential drugs were more available in the public sector than in the private sector in middle-income countries.*

Figure 9. Number of days in the last 6 months on which key drugs were out of stock in public pharmacies and warehouses
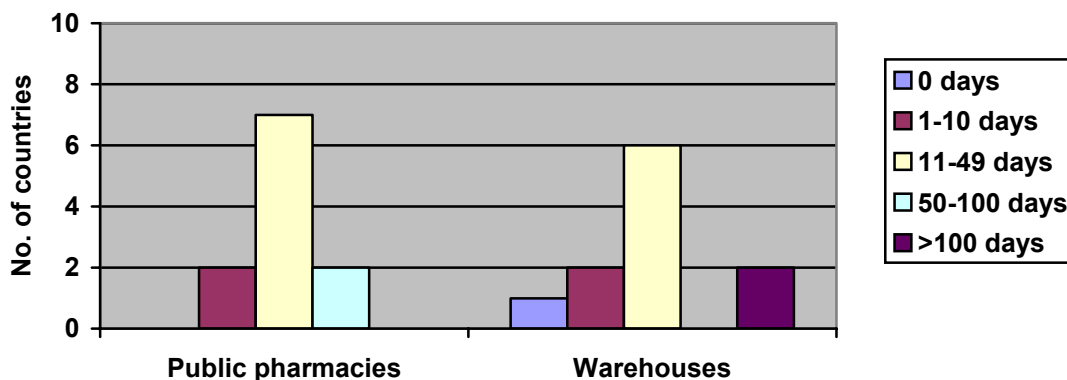
Figure 10. Adequacy of records to evaluate when key drugs were out of stock
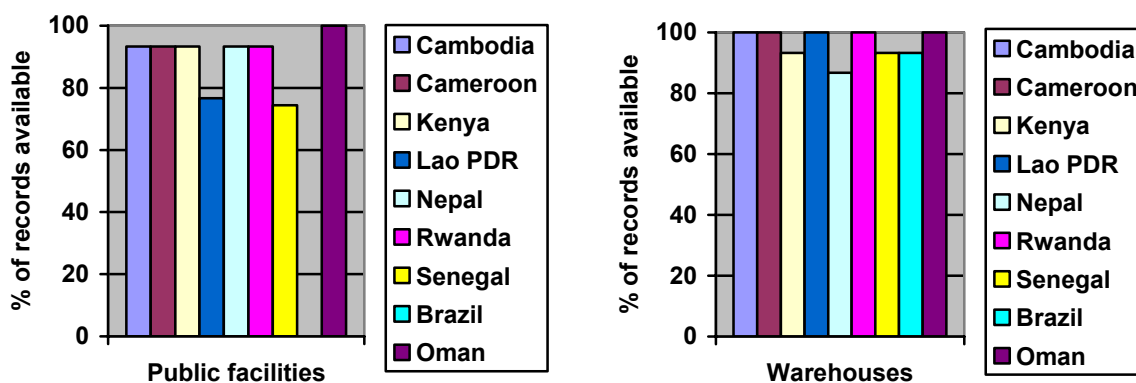
> ➢ *Most countries have adequate records available with which to evaluate stock availability in public pharmacies and warehouses over the preceding six months.*

7. INTELLECTUAL PROPERTY, PATENTS AND PRODUCTION

7.1 Why is this important?

Intellectual property rights have an important impact on affordability and availability of medicines and thereby public health. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires WTO Members to provide minimum standards of intellectual property protection, including patent protection. Patent protection grants exclusive rights to the patent holder for the use, manufacture and sale of a medicine. During the term of the patent, the patent holder has a monopoly on the medicine, which prevents generic competition as a means of reducing prices. Poorer populations in developing countries cannot pay the same prices as those affordable in wealthier countries for newer medicines. TRIPS-compliant mechanisms can be used to access lower-priced drugs. It is important to consider adapting national legislation to incorporate all flexibilities available in the TRIPS Agreement (see below) to safeguard access to essential medicines for all (*1*).

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

There are variations in the manner in which the provisions for such flexibilities have been incorporated into national laws (*10*), thus there are limitations in the completeness of the information on TRIPS flexibilities as presented in the tables below. For example, provisions on parallel import may exist in some countries, but there may be limitations which restrict parallel importation – such as when the explicit consent of the patent holder is required before parallel importation can take place. In such cases, the so-called flexibility is lost. Also, there are essentially two kinds of parallel importation regimes – international exhaustion and regional exhaustion. When the international exhaustion regime is incorporated into the national law, parallel import of a product will be permitted into the country from anywhere else, whereas regional exhaustion (as for the whole of the EU) would allow products to be imported only from within a particular regional grouping. There may therefore be differences in the parallel import provisions that will be important in determining whether or not the flexibilities are maintained.

Such variations also exist in countries in terms of their provisions for compulsory licensing. Whilst compulsory licensing provisions exist within most national laws, the provisions may differ, for example, in terms of the various grounds on which compulsory licence may be granted. It was agreed in the Doha Declaration concerning the TRIPS Agreement and Public Health

that WTO Members were free to determine the grounds on which compulsory licences may be granted. However, this flexibility may not have yet been properly incorporated in all national laws.

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

Some information on local production of medicines aimed to improve 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.

7.2 What is the current situation?

Table 20. Patent protection and marketing authorization provisions for medicines

	Country income level					
	Low		**Middle**		**High**	
	Number of countries	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Countries with patent protection for pharmaceutical products[a]	25	51.0	42	82.4	14	87.5
Provisions in national legislation						
Parallel import provisions	17	35.4	16	37.2	9	64.3
Compulsory licensing provisions	21	44.7	24	55.8	4	33.3
Manufacturers allowed to use patented inventions prior to patent expiration	11	30.6	16	42.1	6	40.0
TRIPS provisions:[b]						
TRIPS Agreement in legislation (n = 70)	11	35.5	23	79.3	9	90.0
Article 65 used (n = 59)	17	70.8	9	36.0	2	20.0
Article 66 used[c] (n = 20)	10	66.7	2	66.7	0	0.0

[a] Currently patent legislation of 49 countries has been reviewed.
[b] World Trade Organization member countries (n = 98).
[c] Least-developed countries.

> ➤ *Over 80% of high- and middle-income countries have patent protection for pharmaceutical products, compared to only half of low-income countries.*
> ➤ *Only one in three low- and middle-income countries has parallel importation provision in legislation compared to two thirds of high-income countries.*
> ➤ *By 2003, 28 of 59 WTO member countries reporting were taking advantage of the provision allowing a transitional period for complying with the TRIPS Agreement (Article 65)*
> ➤ *By 2003, 12 of 20 least-developed WTO member countries reporting were taking advantage of Article 66, see Annex 1.*

Table 21. Number and percentage of countries with capacities for the production of medicines

	Country income level					
	Low		**Middle**		**High**	
Production capacity	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Research and development of new active substances	6	11.8	6	12.2	9	64.3
Production of pharmaceutical active starting materials	11	20.4	15	27.8	10	71.4
Formulation from pharmaceutical starting materials	44	78.6	41	75.9	12	85.7
Repackaging of finished dosage forms	37	69.8	43	76.8	12	85.7

> ➤ *Production in most countries consists of repackaging finished dosage forms.*
> ➤ *Research and development are confined mostly to high-income countries.*

8.   ACCESS TO ESSENTIAL MEDICINES

8.1   *Why is this important?*

Essential medicines save lives, reduce suffering, and improve the functioning and well-being of people who have access to them. On the population level, access to affordable and appropriately used high-quality medicines boosts productivity and economic output (*1*). The Commission on Macroeconomics and Health (*11*) estimated in 2001 that 10.5 million lives per year could be saved by 2015 by scaling up access to existing health interventions to prevent and treat prevalent diseases – many of which depend on essential medicines.

Many factors, including all those reported in this Fact Book, determine access to essential medicines. Access can vary between urban and rural areas because of problems with health system development. Pharmacies, medicines distributors, health facilities, and public and private health providers are usually concentrated in cities and regional centres.

The retail prices of essential drugs can vary widely. Reliance on distribution of medicines in the private sector often means that essential medicines are too expensive for poor patients to afford.

8.2   *What is the current situation?*

Table 22: Estimated percentage of population with access to essential medicines by WHO region and country income level

	Level of access to essential medicines within one hour's walking distance							
	Very low access (< 50%) $n = 18$		**Low to medium (50–80%)** $n = 46$		**Medium to high (81–95%)** $n = 20$		**Very high access (>95%)** $n = 20$	
WHO Region	**No. of countries**	**% **	**No. of countries**	**% **	**No. of countries**	**% **	**No. of countries**	**% **
Africa	10	55.6	19	41.3	4	20.0	0	
Americas	2	11.1	10	21.7	1	5.0	7	35.0
Eastern Mediterranean	1	5.6	2	4.3	4	20.0	1	5.0
Europe	3	16.7	6	13.0	2	10.0	9	45.0
South-East Asia	0	0.0	4	8.7	3	15.0	0	0.0
Western Pacific	2	11.1	5	10.9	6	30.0	3	15.0
Income level								
Low	13	72.2	24	52.2	5	25.0	0	0.0
Medium	5	27.8	19	41.3	15	75.0	10	50.0
High	0	0.0	3	6.5	0	0.0	10	50.0

> ➢ *72% of countries with < 50% access are in the low-income category, and over half are in Africa.*
> ➢ *Eight out of 10 countries with very high access are in Europe and the Americas.*

8.3 Have we made progress?

Figure 11. Estimated access to essential medicines within 1 hour's walking distance in 1999 and 2003*

* Includes only countries with data for both years.
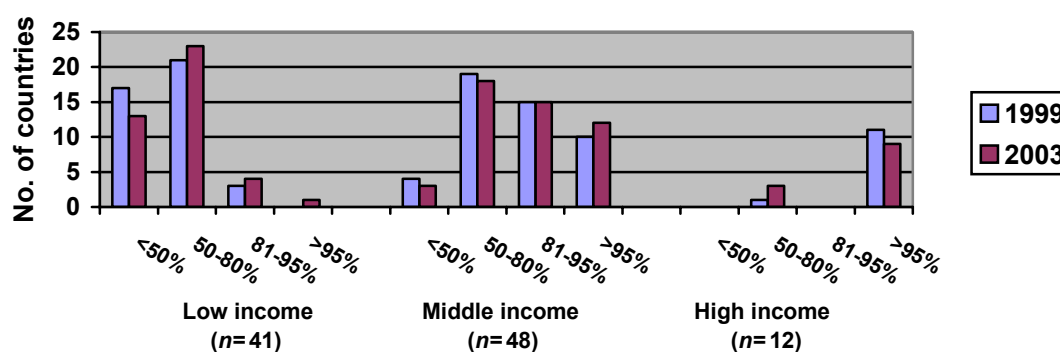
Table 23. Access to essential medicines by country income level, 1999 and 2003

Estimated percentage of population with access to essential medicines	Low-income *n* = 41		Middle-income *n* = 48		High-income *n* = 12	
	Number of countries[a]	(%)	Number of countries[a]	(%)	Number of countries[a]	(%)
	1999	2003	1999	2003	1999	2003
<50%	17 (41.5)	13 (31.7)	4 (8.3)	3 (6.3)	0	0
50–80%	21 (51.2)	23 (56.1)	19 (39.6)	18 (37.5)	1 (8.3)	3 (25.0)
81–95%	3 (7.3)	4 (9.8)	15 (31.3)	15 (31.3)	0	0
>95%	0	1 (2.4)	10 (20.8)	12 (25.0)	1 (91.7)	9 (75.0)

> ➢ *The number of low-income countries reporting high rates of access to essential medicines (> 80% of people having access within one hour) had risen between 1999 and 2003, but the number of high-income countries had fallen.*

8.4   Have we achieved the desired outcomes?

Figure 12. Proportion of prescribed medicines dispensed in public facilities by country
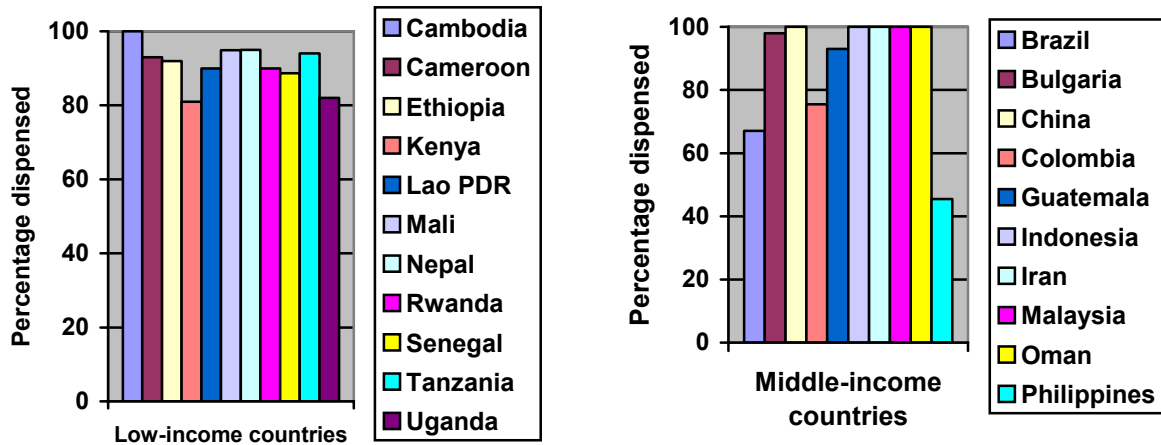
> ➢ *In many countries, close to 100% of the medicines prescribed were in stock and dispensed in public health facilities.*

Figure 13. Affordability of pneumonia treatment for children and adults
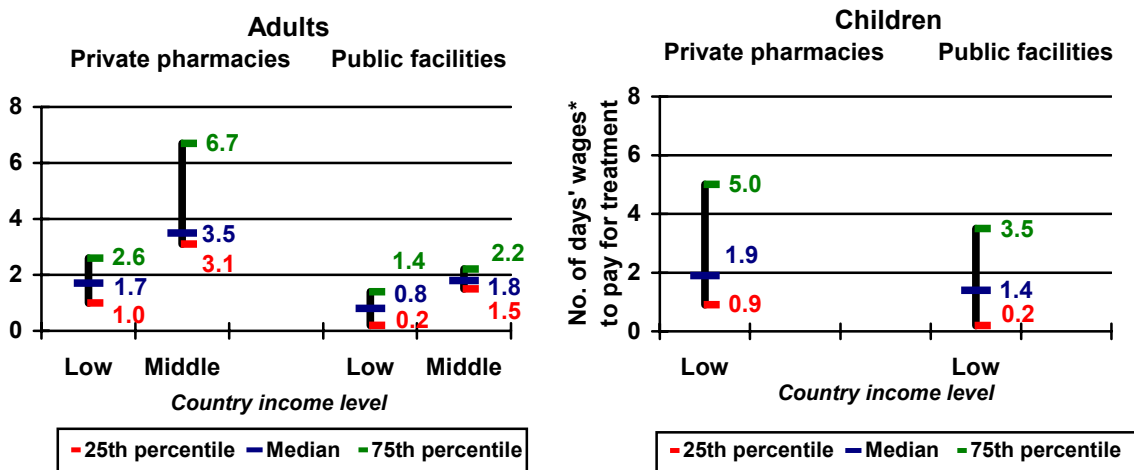
[a] Based on day's wage of the lowest paid government worker.

[b] Only one middle-income country reported on pneumonia treatment for children, so results are not included.

> ➢ *The prices of medicines tended to be much less affordable in the private sector than in the public sector.*
> ➢ *Treatment for adult pneumonia in middle-income countries cost twice as many days' wages as in low-income countries.*

9. RATIONAL USE OF MEDICINES

9.1 Why is this important?

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" (*12*). Overuse, underuse and misuse of medicines may lead to unnecessary suffering and death, and waste 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; and

Many factors influence use of medicines, and countries need to implement various strategies to improve rational use. Some policies, strategies and interventions found to be of value include: creating a mandated multi-disciplinary national body to coordinate policies on medicine use; standard treatment guidelines (STGs) for common conditions; using essential medicines lists (EMLs) to guide procurement and training; establishing drug and therapeutics committees to coordinate medicines 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.

Essential medicines lists, treatment guidelines, formularies

9.2 Why is this important?

The essential medicines concept is the basis for rational use of medicines (*1*). Ideally, countries develop and routinely update EMLs and drug formularies that meet the needs of their population according to a number of criteria, including disease patterns, patient characteristics, treatment recommendations formulated in STGs, and level of care provided. Using an EML makes management of medicines easier in all respects: procurement, storage and distribution are easier with fewer items, and prescribing and dispensing are

more straightforward for health professionals if they have to know about fewer medicines. A national EML should be based upon national STGs.

Together an EML and STGs help to ensure rational drug use. STGs should be developed for each level of care, based on prevalent clinical conditions and the skills of prescribers practicing at that level. The STGs consist of systematically developed statements to help prescribers make decisions about appropriate treatments for specific clinical conditions, providing a benchmark for satisfactory diagnosis and treatment. Adherence to the recommendations in STGs should be reinforced by prescription audit and feedback.

A formulary can be an important source of evidence-based information about medicines but it is important that it is consistent with STGs and the EML if all three strategies are to achieve the maximum overall effect.

9.3   What is the current situation?

Figure 14. Countries with essential medicines lists (EMLs) updated within last five years
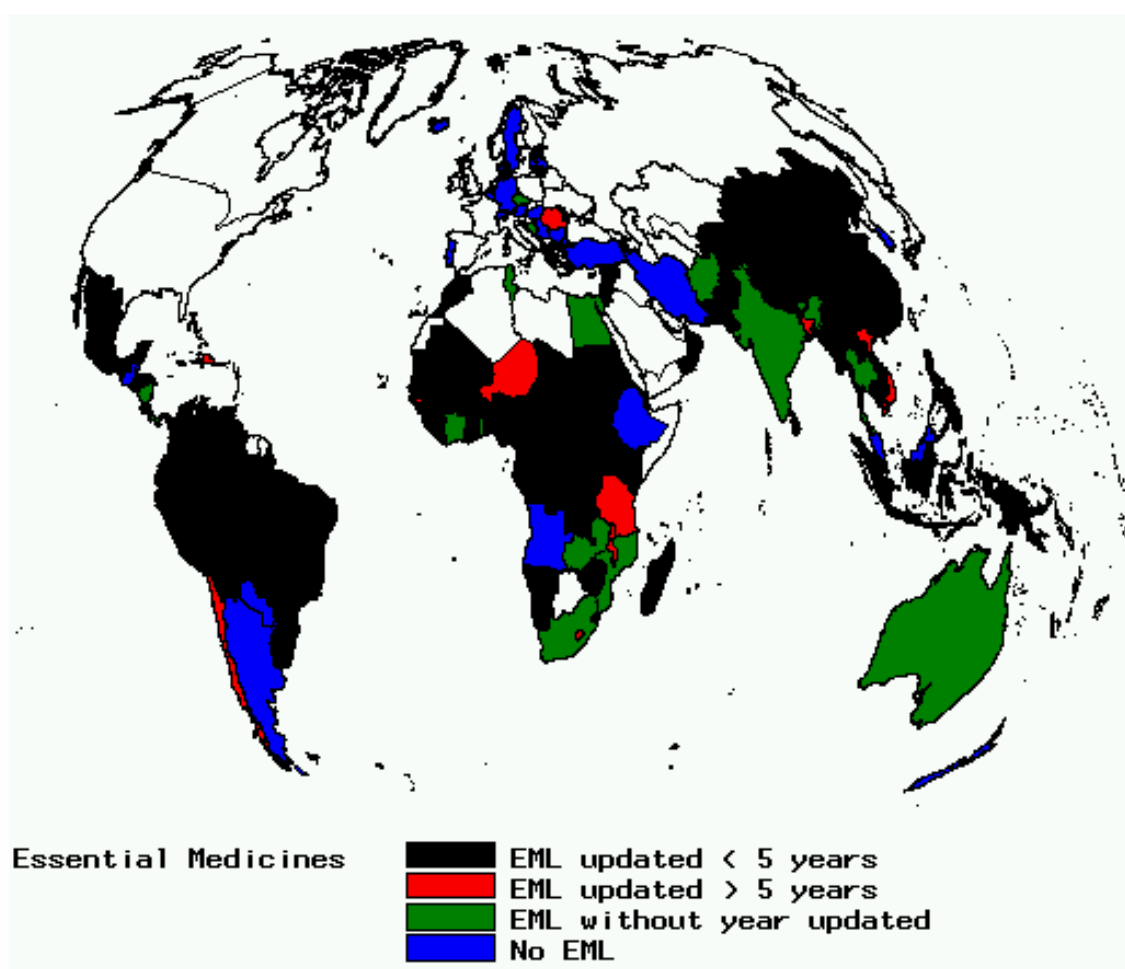
Table 24. Status of essential medicines lists (EMLs), standard treatment guidelines (STGs) and national medicines formularies

	Country income level					
	Low		**Middle**		**High**	
	Number of countries	**%**	**Number of countries**	**%**	**Number of countries**	**%**
EML existence and use						
National EML exists	55	98.2	52	86.7	6	33.3
	Median [25th, 75th percentile]		**Median [25th, 75th percentile]**		**Median [25th,75th percentile]**	
Number of medicines in EML	286	[249, 339] (*n* = 39)	397	[300, 594] (*n* = 41)	660	[608, 1200] (*n* = 5)
EML updated within last 5 years[a]	35		5		4	
EML not updated within last 5 years[a]	10		38		1	
Public sector procurement using EML	54	96.4	51	85.0	5	38.5
Public insurance reimbursement using EML	12	27.3	24	52.2	1	9.1
Private insurance reimbursement using EML	3	7.3	5	12.2	2	18.2
Types of STGs						
National STG	35	67.3	31	58.5	7	53.9
STG for hospital level	21	48.8	21	46.7	6	60.0
STG for primary health care level	33	75.0	32	65.3	7	70.0
Status of formulary						
National medicines formulary (NMF) exists	35	66.0	43	70.5	11	73.3
NMF covers only medicine on EML	22	56.4	27	57.5	2	20.0

[a] Only those that reported the year of update.

> ➢ *Almost all low- and middle-income countries have an EML, and most limit procurement to medicines on the list.*
>
> ➢ *The number of medicines included on EMLs tends to increase with increasing country income.*
>
> ➢ *Only a few countries reported that public or private sector insurance reimbursement was linked to the EML.*
>
> ➢ *Standard treatment guidelines are available for primary health care in over 70% of countries.*
>
> ➢ *National formularies exist in over two thirds of countries, and over half of low- and middle-income countries limit the formulary to medicines on the EML.*

9.4   *Have we made progress?*

Table 25. Status of essential medicines lists (EMLs) in 1999 and 2003[a]

	Country income level					
	Low		**Middle**		**High**	
EML status	**Number of countries**		**Number of countries**		**Number of countries**	
	1999	**2003**	**1999**	**2003**	**1999**	**2003**
EML < 5 years (updated)[a]	38	34	42	39	7	5
EML > 5 years (not updated)[a]	14	9	16	5	7	none listed
1999 EML not updated in previous 5 years, but updated by 2003[b]	7/14 (50.0)		9/16 (56.3)		0 (0.0)	

[a] Includes only countries responding and indicating date of update in both years.
[b] Includes countries responding in both years (with EML >5 years in 1999 and has updated in 2003.

Table 26. National standard treatment guideline (STG) status in 1999 and 2003

	1999	2003
	Number of countries	**Number of countries**
STGs updated within previous 3 years	37	14
STGs not updated within previous 3 years	87	78

> ➢ *Most countries have updated their EML.*
> ➢ *Most countries have STGs, but some have not been updated recently.*

9.5   *Have we achieved desired outcomes?*

Table 27. Presence/availability of essential medicines list (EML) and standard treatment guidelines (STGs) and adherence to EML in prescribing

	Country income level			
In public facilities	**Low**		**Middle**	
Number (%) of countries with current EML present in public facilities	10	83.3	8	88.9
Number (%) of countries with at least 2 STGs present (1 national and 1 disease-specific)	10	83.3	8	88.9
		Median [25th, 75th percentile]		**Median [25th, 75th percentile]**
% patients prescribed medicines on EML	91.5	[85.4, 93.8] (*n* = 11)	97.0	[86.6,100] (*n* = 9)

Figure 15: Rates of prescribing medicines from the essential medicines list (EML) by country
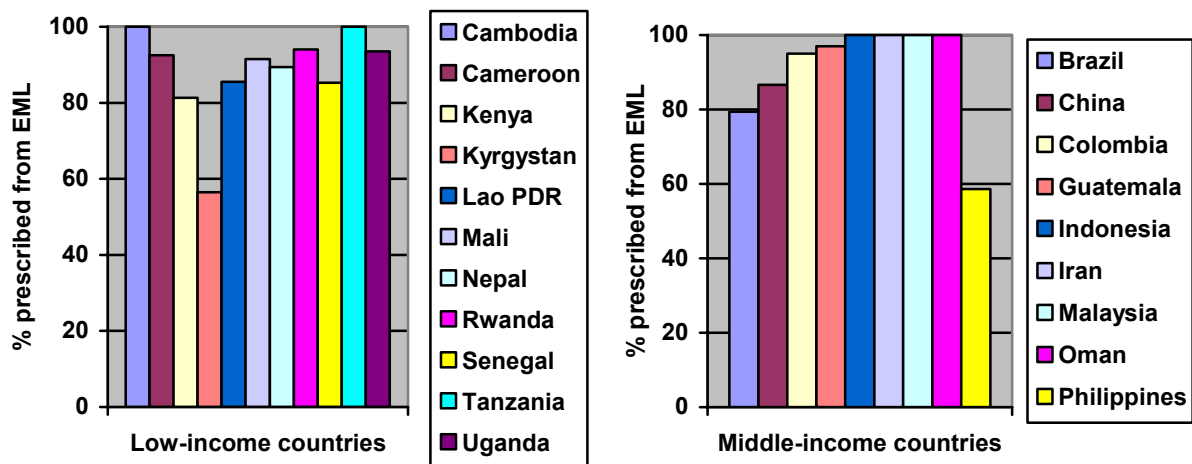
> ➢ *The rate of prescribing medicines from the EML is very high in public health facilities in most countries.*
> ➢ *Only two countries report rates of prescribing from the EML lower than 60%.*

Key policies and regulations to promote rational use

9.6   Why is this important?

The role of a drug and therapeutics committee (DTC) is to ensure the safe and effective use of medicines in a health facility or the area under its jurisdiction. The DTC must have clear objectives, a firm mandate, the support of senior hospital staff, transparency, wide representation, technical competence, a multidisciplinary approach and sufficient resources to implement its decisions.

Over-the-counter (OTC) sale of antibiotics is a concern worldwide. This can be due to lack of enforcement of regulations or lack of information on the part of consumers about the potential negative impacts of antibiotic misuse. Irrational use of antibiotics contributes to increased antimicrobial resistance, rendering essential antibiotics ineffective and requiring the use of newer, more expensive antibiotics for treating bacterial illnesses. The result of unnecessary and ineffective use of antibiotics is an increase in avoidable morbidity and mortality.

Given the known impact of advertising and promotion of medicines on both prescribing behaviour and patient demand, it is essential to regulate and monitor medicines promotion to ensure that it remains ethical. All promotional claims should be reliable, accurate, truthful, informative, balanced, up-to-date, and capable of substantiation and in good taste. WHO has proposed a set of ethical criteria for the promotion of medicines that countries can use as a basis for developing their own national measures (*13*).

9.7 What is the current situation?

Table 28. Regulation of pharmaceutical promotion and advertising

	Country income level					
	Low		**Middle**		**High**	
Type of regulation	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Company self-regulation	8	15.7	16	33.3	9	56.3
Government agency or medicines regulatory authority	48	84.2	49	87.5	14	87.5
Co-regulation (countries responding yes to both)	6/51	11.8	14/47	29.8	8/16	50.0

> ➢ *Most countries report that pharmaceutical promotion is regulated by the government medicines regulatory agency.*
> ➢ *Self-regulation of promotion is more prevalent in high-income countries.*

Table 29. National policies concerning drug and therapeutics committees (DTCs) and antimicrobial resistance (AMR)

	Country income level					
	Low		**Middle**		**High**	
Policies/regulations	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
DTC mandate in NMP	37	69.8	32	62.8	7	70.0
National AMR strategy	13	23.6	18	38.3	11	78.6
Reference laboratory for AMR surveillance	22	41.5	29	60.4	8	61.5
National task force for AMR strategy	6	13.6	16	34.0	6	54.6

NMP, National medicines policy.

> ➢ *Nearly two thirds of countries report that DTCs are a mandated element in their national medicines policy.*
> ➢ *High-income countries were much more likely to have a national AMR strategy, a national task force to implement the strategy and a national reference laboratory to conduct surveillance.*

9.8 Have we achieved desired outcomes?

Table 30.   Establishment of drug and therapeutics committees in hospitals[a]

	Country Income Level					
	Low		**Middle**		**High**	
Level of hospital	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Referral hospitals	25	52.1	27	61.4	6	85.7
General hospitals	19	38.8	25	55.6	10	90.9
Regional/provincial hospitals	17	36.2	13	31.7	6	75.0

[a] Countries responding that all or most hospitals have drug and therapeutics committees.

> ➢ *The number of DTCs remains low in medium- and low-income countries.*

Table 31.   Over-the-counter (OTC) sales of antibiotics and injections[a]

	Country income level					
	Low		**Middle**		**High**	
Type of medication	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
Antibiotics never available OTC	5/26	19.2	17/34	50.0	8/17	47.0
Antibiotics occasionally available OTC	18/26	69.2	15/34	44.1	6/17	35.2
Injections never available OTC	6/29	20.6	22/43	51.1	11/16	68.7
Injections occasionally available OTC	19/29	65.5	19/43	44.1	3/16	18.7

[a] Only countries that responded to the questions of whether antibiotics and injections are " always", "only on occasion" or "never sold OTC".

> ➢ *Very few low-income countries reported that antibiotics and injections are never sold OTC and the majority reported that they were occasionally sold OTC; few responding countries reported that antibiotics and injections are always sold OTC.*

Education and information about rational use

9.9   *Why is this important?*

Rational use of medicines depends on the knowledge, attitudes and behaviours of prescribers and patients. Training in rational pharmacotherapy, linked to STGs and EMLs, can help establish good prescribing habits and should be part of the basic curricula of medical, nursing and pharmacy students. In-service education allows health workers to keep up to date with changes in pharmacotherapy, to become familiar with policies, to share experiences and learn from discussion with their peers. In some countries, continuing education is a licensure requirement for health professionals. Continuing education is more likely to be effective if it is problem-based, face-to-face, targeted, and involves professional societies, universities and the ministry of health.

Patient demand and popular media are important drivers of medicines use. Without sufficient and accurate knowledge about the risks and benefits of using medicines, consumers can have unrealistic expectations. Countries should consider a range of strategies to better inform consumers about appropriate use of medicines.

Frequently, advertising by pharmaceutical companies is the only source of easily available information on medicines. Unbiased consumer information on use of medicines is much needed in the form of public education campaigns or through independent information centres. Targeted public education should take into account the cultural beliefs and social factors that influence use of medicines.

Health facilities where medicines are dispensed should also provide adequate information through verbal information and adequate labelling. Both prescription and non-prescription medicines should have labels that are accurate, legible and easily understood.

9.10 What is the current situation?

Table 32. Types of basic medicines training available to health workers

Country income level

	Low		Middle		High	
	Number of countries	%	Number of countries	%	Number of countries	%
EML concepts						
Doctors	33	67.4	25	67.6	5	62.5
Nurses	39	76.5	25	65.8	3	42.9
Pharmacists	38	77.6	32	78.1	3	42.9
Pharmacy assistants	30	65.2	22	56.4	2	25.0
Paramedical staff	24	57.1	12	46.2	0	0.0
STG concepts						
Doctors	28	62.2	23	67.7	6	85.7
Nurses	30	62.5	20	62.5	4	66.7
Pharmacists	28	63.6	17	46.0	4	66.7
Pharmacy assistants	22	50.0	10	33.3	1	14.3
Paramedical staff	18	42.9	12	46.2	0	0.0
Pharmacotherapy training						
Doctors	27	62.8	25	83.3	7	77.8
Nurses	20	47.6	14	51.9	3	42.9
Pharmacists	27	62.8	19	55.9	2	28.6
Pharmacy assistants	14	33.3	10	35.7	0	0.0
Paramedical staff	10	27.0	7	30.4	0	0.0
Rational prescribing concepts						
Doctors	31	70.5	25	78.1	7	87.5
Nurses	28	62.2	19	63.3	4	57.1
Pharmacists	26	61.9	23	65.7	4	57.1
Pharmacy assistants	17	41.5	13	43.3	1	12.5
Paramedical staff	14	35.9	8	33.3	0	0.0

EML, Essential medicines list; STG, standard treatment guideline.

> ➤ *Health professionals are widely exposed to concepts of EMLs, STGs, problem-based pharmacotherapy and rational prescribing during basic training.*

Table 33. Obligatory continuing education on medicines for health care providers

Country income level

	Low		Middle		High	
Provider type	Number of countries	%	Number of countries	%	Number of countries	%
Doctors	20	37.7	28	53.8	7	77.8
Nurses/midwives/paramedical staff	22	40.7	18	40.0	5	55.6
Pharmacists	17	32.1	26	49.1	6	60.0
Pharmacy aides/assistants	14	26.4	17	34.7	4	44.4

> ➢ *The likelihood of requiring mandatory continuing education for health professionals increases with country income.*

Accessibility of medicines information

9.11   What is the current situation?

Table 34. Public or independent medicines information for providers and consumers

<div align="center">Country income level</div>

Recipient	Low		Middle		High	
	Number of countries	%	Number of countries	%	Number of countries	%
Prescribers	18	32.1	28	45.2	6	46.2
Dispensers	17	30.9	29	48.3	6	46.2
Consumers	14	25.5	24	40.7	7	53.9

> ➢ *Public or independently funded national drug information services were available for health workers or patients in less than half the countries, irrespective of income level.*
> ➢ *Low-income countries have the lowest rates of provision of drug information.*

Table 35. Public education campaigns on rational medicines use topics

<div align="center">Country income level</div>

Topic of campaign	Low		Middle		High	
	Number of countries	%	Number of countries	%	Number of countries	%
Use of antibiotics[a]	20	37.0	26	49.1	9	64.3
Use of injections[a]	20	36.4	17	34.7	2	18.2
Other topics/issues[a]	27	51.9	30	61.2	7	58.3

[a] Campaign must have been conducted in the previous 2 years (2001–2003).

> ➢ *The likelihood of public education about antibiotic use and misuse increases with country income level.*
> ➢ *Injection use is more often the focus of public education in low- and middle-income countries.*

9.12 *Have we made progress?*

Table 36. Medicines information for prescribers and dispensers in 1999 and 2003[a]

	Country income level					
	Low		**Middle**		**High**	
Information recipients	**Number of countries**	**%**	**Number of countries**	**%**	**Number of countries**	**%**
1999 prescribers/dispensers	12	38.7	26	51.0	8	66.7
2003 prescribers	18	32.1	28	45.2	6	46.2
2003 dispensers	17	30.9	29	48.3	6	46.2

[a] Asked about prescribers and dispensers in combination in 1999, but asked about them separately in 2003.

> ➢ *The percentage of countries that support national medicines information services for prescribers and dispensers does not appear to have increased between 1999 and 2003 at any income level.*

9.13 *Have we achieved desired outcomes?*

Figure 16. Prescribing of antibiotics and injections
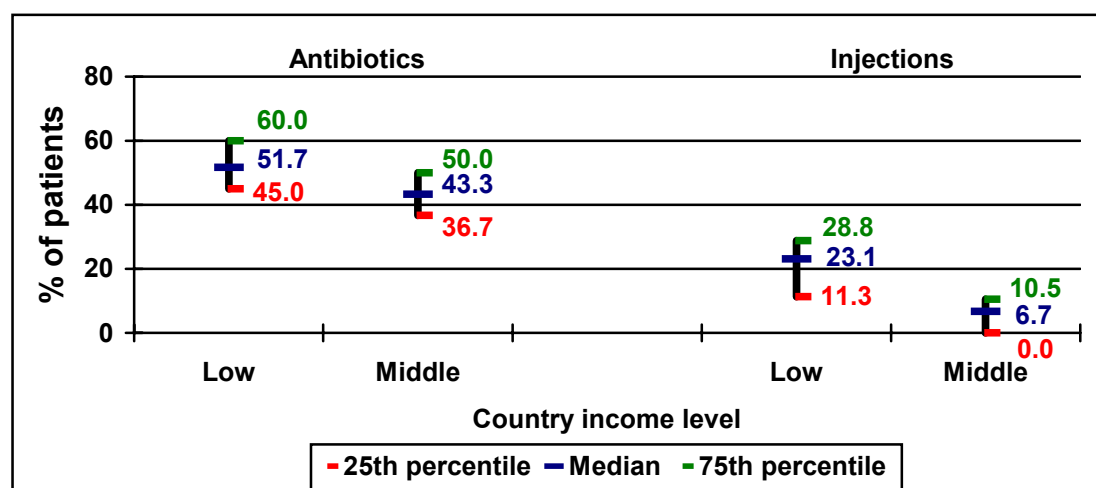
> ➢ *The percentage of patients prescribed antibiotics is high in all countries.*
> ➢ *Prescribing of injections is still very high in low-income countries.*

Figure 17. Medicines labelling and patient knowledge about use
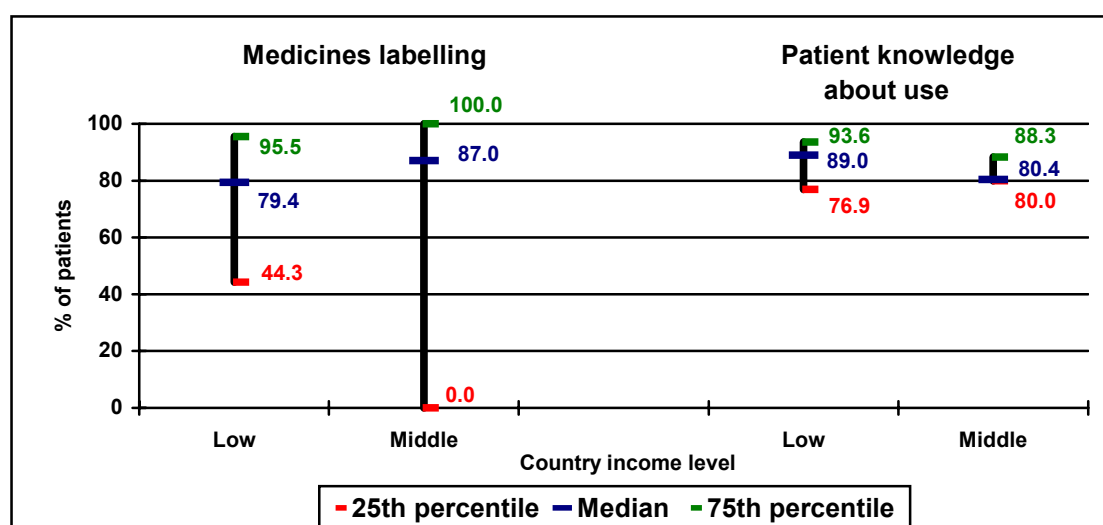
> ➤ *The adequacy of labelling of prescription items varied widely between countries.*
> ➤ *Four out of five patients knew how to take their medicines when interviewed immediately after the medicines were dispensed.*

Table 37. Quality of treatment of diarrhoea and acute respiratory infections (ARIs)

	Country income level			
	Low		**Middle**	
	Median	**[25th, 75th percentile]**	**Median**	**[25th, 75th percentile]**
Paediatric diarrhoea with ORS[a]	80.0	[71.9, 87.5]	95.0	[90, 100]
	(*n* = 10)		(*n* = 3)	
Paediatric diarrhoea with antidiarrhoeal/antispasmodic[b]	0	[0, 40]	5	[0, 5]
	(n = 10)		(n = 3)	
Paediatric pneumonia with first-line antibiotic[b]	90.0	[80, 100]	85	[70, 100]
	(*n* = 9)		(*n* = 2)	
Paediatric pneumonia with >1 antibiotic[b]	0	[0, 25]	0	[0, 0]
	(*n* = 10)		(*n* = 3)	
All ARI patients with antibiotic treatment[b]	90.0	[70.0, 98.8]	50	[20, 100]
	(*n* = 10)		(*n* = 3)	

ORS, Oral rehydration solution.
[a] Recommended treatment.
[b] Undesirable treatment.

> ➤ *Oral rehydration solution (ORS) is commonly used to treat paediatric diarrhoea and first-line antibiotics are usually given to treat paediatric pneumonia in low- and middle-income countries.*
> ➤ *The use of antidiarrhoeals or antispasmodics for treating diarrhoea in children is low.*
> ➤ *There was a high rate of prescribing antibiotics for acute respiratory infections, most of which will not respond to antibiotics.*

Figure 18. Average number of medicines per prescription in public health facilities
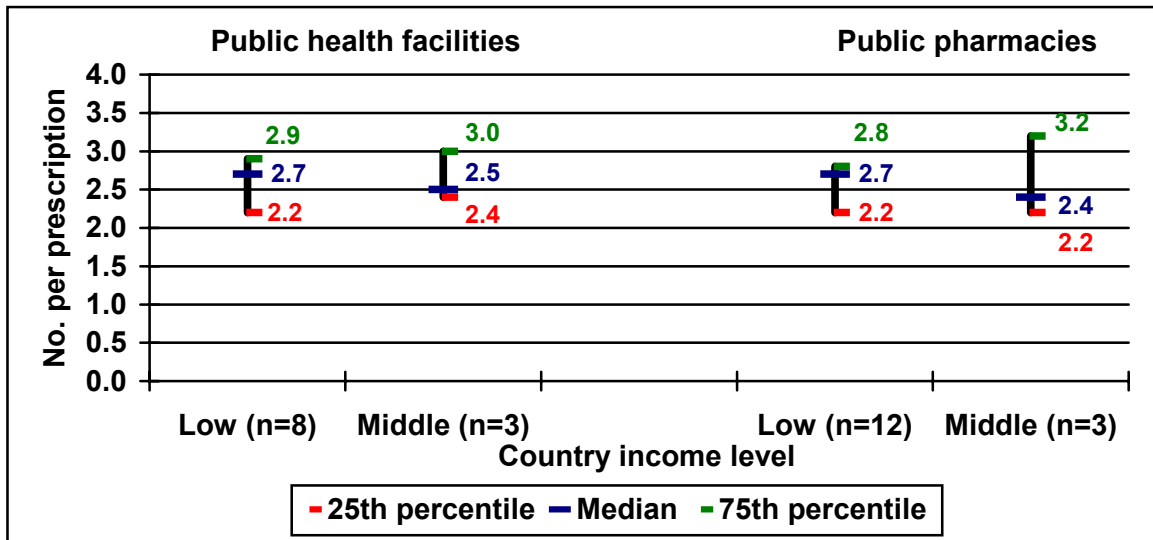
> ➢ *The number of medicines prescribed per episode of outpatient care was 2–3 for most countries.*

10. METHODOLOGICAL LIMITATIONS AND RECOMMENDATIONS

10.1 Accomplishments

Much progress has been made since WHO began developing indicators for monitoring country pharmaceutical situations more than 10 years ago (*14*, *15*). This Fact Book summarizes what is known about country pharmaceutical situations, using the most recently collected data on Level I and Level II indicators. With 140 of 192 WHO Member States responding to Level I surveys in 2003, many data on the structure and process of pharmaceutical sectors are available. Some comparisons with 1999 data are now possible as the start of longitudinal monitoring. Data on access to, and quality and rational use of medicines have been collected in Level II surveys of samples of facilities in 31 countries. The methodology for data collection has been refined, and trained individuals are now available in countries to conduct future Level II surveys.

Using the current indicators and methods, countries are able to perform comprehensive assessments of their pharmaceutical sector, to evaluate their data in the light of existing policies and in comparison to other countries, and to develop strategies for change and improvement.

Analyses of the Level I and Level II survey data contained in this Fact Book also highlight some of the limitations of the surveys and point to recommendations for future improvements. Limitations fall into two broad categories: limitations of the current questionnaires and data collection instruments, and limitations related to survey administration and data management.

10.2 Limitations of the questionnaire and recommendations for improvement

The current Level I questionnaire is long; some skip patterns are difficult to follow, and, based on responses received, the wording of several items was unclear. These characteristics tended to increase the amount of missing data. Changes in the wording of some items between the 1999 and the 2003 surveys limited the possibilities for comparing results over time.

In future surveys, the Level I questionnaire could be shortened by focusing on key items with face validity and high response rates which also are important for longitudinal monitoring. Administering the survey electronically using a web-based technology where skip patterns can be automatically controlled would eliminate confusion in the flow of items and force completion of required items.

It is important to note that informed country officials are asked to provide Level I data, and the accuracy of the data depends largely on the knowledge of individual respondents. Some data asked for in the survey may be difficult to obtain, particularly when numerical estimates are required (e.g. percentage of the population with access to medicines within 1 hour's walking distance and percentage of cost of medicines covered by insurance).

It is unclear to what extent responses to Level I questionnaires would coincide if two respondents were to be asked. Some items may be more liable to subjective errors, and completion of the survey by more than one individual could be used to test the reliability of data on individual items. Responses to some items could also be validated against data from other sources. Only items with high reliability and validity should be retained in future surveys.

The current Level II surveys assess the overall situation related to availability and use of medicines in small convenience samples of health centres and pharmacies. The aim of these surveys is to provide reasonable indicators of policy issues to be targeted in future interventions. Because the samples are small, the results cannot capture all aspects of the situation in the country as a whole. When countries desire more precise estimates, the numbers, types and geographical distribution of facilities can be expanded.

10.3 Limitations of data management and recommendations for improvement

Level I and II surveys are currently completed in the form of electronic questionnaires sent to respondents in the countries being surveyed. As mentioned above, one way to increase the reliability of data and decrease the numbers of missing responses would be to develop an automated web-based data collection method for both surveys, with built-in controls for admissible answers, an online glossary of terms, and answers to frequently asked questions. For greater consistency over time, respondents could be shown their previous answers to individual survey items. Collection of Level II survey data requires fieldwork. Additional training for collectors of data in Level II surveys may be needed to increase data quality. Standard computerized data entry and reporting templates would facilitate data analysis.

10.4 Further development of a household survey

Level I and Level II surveys do not measure access to and use of medicines from the perspective of patients and consumers. Only household surveys can provide population-based information about how pharmaceutical policies affect the well-being of individuals. Household surveys were tested on a pilot basis in some Level II surveys. The methods and content of these household surveys will need further work to develop standardized approaches to assess whether and how people access medicines, how they use them, how much they pay for them, and how out-of-pocket payments for medicines affect household finances.

10.5 Development of composite scores

Monitoring involves looking at many different aspects of the structure, process and outcomes of a pharmaceutical system. It would be advantageous to be able to summarize key dimensions of performance such as access or rational use with a single composite score. For example, the current Level I questionnaire contains 19 questions on various aspects of access to medicines. A composite access score might be able to summarize these items into one measure that gives an indication of the overall performance of the system in this area.

Responses to the individual Level I items that contribute to such a score would guide the development of strategies for improvement.

Composite measures of Level I structure and process indicators would be particularly advantageous if they could reliably predict performance on Level II outcome indicators. If Level I composite scores correlated well with Level II indicators of access and rational use, then it may be possible to use Level I data, which are easier and less expensive to collect, to monitor progress in these domains. Level II surveys could then be targeted to countries for which Level I access composite scores indicate a problem. Psychometric methods exist for the systematic development of composite and index scores from individual items and scales. These methods use statistical tests to evaluate the correlations between items and their optimal contribution to an overall score (for example, access to medicines). Only items that are sufficiently correlated would be included in a composite score. Correlation coefficients rather than expert opinion would form the basis for weighting the items that contribute to a composite score.

To proceed with the development of composite scores would require a multi-step approach. The first step would be to define the aspect that each composite score is intended to measure (e.g. access to medicines, rational use and product quality assurance), as well as specific components of that domain (e.g. availability, affordability and acceptability might all be components of the domain of access to medicines). The second step would be to formulate specific questions with face validity that address each of the identified components. These questions would include many of the current Level I items. Next, several respondents would be asked to complete the individual items and the reliability of their responses would be checked. Finally, for items that prove to be reliable, statistical methods would be used to develop an overall composite measure for each domain.

Validating each composite score would also include assessing its relationship with related domains. For example, composite scores of access to medicines should be higher in countries with higher incomes and/or cheaper medicines, as well as in countries with universal health insurance covering medicines. Similarly, if Level I composite scores are correlated with Level II indicators that measure outcomes of pharmaceutical objectives in a given domain, this would further validate the use of the composite score as a monitoring tool.

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ANNEXES

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1. Level I indicator survey form

2. Level II indicator survey and summary forms

3. Description of some Level II indicators reported in this Fact Book

4. Level I data from 2003, by country (alphabetically by country name and income-level indicators); organized by sections in Level I survey and this final report.*

5. Level II data by country (alphabetically by country name and income-level indicators); organized by Access (6 indicators), Quality (2 indicators), Rational use of medicines indicators (10 indicators).*

6. Level I data from 1999, by country on variables used for comparisons between 1999 and 2003.*

7. Country income level by region

* Available on CD-ROM. Requests should be addressed to the Department of Technical Cooperation for Essential Drugs and Traditional Medicine, World Health Organization, 1211 Geneva 27, Switzerland. Fax: + 41 22 791 4167, e-mail: edmdoccentre@who.int

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Annex 1   Level I indicator survey form

QUESTIONNAIRE ON STRUCTURES AND PROCESSES
OF COUNTRY PHARMACEUTICAL SITUATION

DK = Don't Know

Country	**Date (dd/mm/yyyy)** ....
Name of respondent(s)	**Position(s)** ....
....	....

1.   NATIONAL MEDICINES (DRUG) POLICY (NMP)

1.1 Is there a National Medicines Policy (NMP) document? *(See glossary for a definition of NMP.) If no, skip to 1.4.*	**Yes/No/Don't Know __**
Is it an official or draft document?	**Official/Draft/Don't Know __**
What year was it last updated?	**Year ____**
1.2 Is there an NMP implementation plan that sets activities, responsibilities, budgets, and timeline?	**Yes/No/Don't Know __**
If yes, when was it last updated?	**Year ____**
1.3 Is the NMP integrated into a published/official national health policy/plan? If yes, when was it last updated?	**Yes/No/Don't Know __ Year ____**
1.4 Is there a national policy on traditional and complementary/ alternative medicine (TM/CAM) either as part of the medicines policy or health policy or as a separate document? *(TM/CAM is defined in the glossary).*	**Yes/No/Don't Know __**
If yes, when was it last updated?	**Year ____**
1.5 Has a national assessment/indicator study been conducted? If yes, what areas have been studied and when was the most recent study covering each area conducted?	**Yes/No/Don't Know __**
Overall pharmaceutical situation:	**Yes/No/Don't Know __ Year ____**
Rational use/prescription audit:	**Yes/No/Don't Know __ Year ____**
Access:	**Yes/No/Don't Know __ Year ____**

2.   LEGISLATION/REGULATION

2.1 Is there a medicines law? If yes, when was it last updated? Which of the following areas are covered by medicines legislation and when was each last updated?	**Yes/No/Don't Know __ Year ____**
Establishment of regulatory authority:	**Yes/No/Don't Know __ Year ____**
Marketing authorisation of pharmaceuticals:	**Yes/No/Don't Know __ Year ____**
Manufacturing of medicines:	**Yes/No/Don't Know __ Year ____**
Distribution of medicines:	**Yes/No/Don't Know __ Year ____**
Promotion & advertising of medicines:	**Yes/No/Don't Know __ Year ____**
Importation of medicines:	**Yes/No/Don't Know __ Year ____**
Exportation of medicines:	**Yes/No/Don't Know __ Year ____**
Licensing & practice of prescribers:	**Yes/No/Don't Know __ Year ____**
Licensing & practice of pharmacy:	**Yes/No/Don't Know __ Year ____**
Herbal medicines *(See glossary for definition)*:	**Yes/No/Don't Know __ Year ____**
Empowers inspectors to enter premises and collect samples and documentation:	**Yes/No/Don't Know __ Year ____**
Requires transparency, accountability and code of conduct in regulatory work:	**Yes/No/Don't Know __ Year ____**

2.2	System and operation of medicines registration:	
a)	Is marketing authorisation required for medicines to be sold? If yes, how many medicinal products have been approved to be marketed? *(express as number of dosage forms & strengths)*	**Yes/No/Don't Know __** **Total_____**
	Is marketing authorisation required for herbal medicines to be sold? If yes, how many herbal medicinal products have been approved to be marketed? *(express as number of dosage forms & strengths)* *(See glossary for a definition of herbal medicines)*	**Yes/No/Don't Know __** **Total_____**
b)	Are there detailed written guidelines, including reference guidelines and criteria, for submitting applications for the registration of medicinal products? Are there guidelines covering the registration of herbal medicines?	**Yes/No/Don't Know __** **Yes/No/Don't Know __**
c)	Is the WHO Certification Scheme certificate required as part of the marketing authorisation process?	**Yes/No/Don't Know __**
d)	Is INN used in the registration of medicines?	**Yes/No/Don't Know __**
e)	Is a list of all registered products publicly accessible? *(Registered product is defined in the glossary.)*	**Yes/No/Don't Know __**
2.3	Is there a computerised registration system that facilitates retrieval of information on registered products? *(Registration system is defined in the glossary.)*	**Yes/No/Don't Know __**
	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 __**
2.4	Is licensing a requirement? *(Licensing is defined in the glossary.)* If yes, is it based on site inspection of: Manufacturers: Importers/wholesalers: Retail distributors/pharmacies:	**Yes/No/Don't Know __** **Yes/No/Don't Know __** **Yes/No/Don't Know __** **Yes/No/Don't Know __**
2.5	Are there written national guidelines/codes/checklists for the inspection of: Manufacturers: Importers/wholesalers: Retail distributors/pharmacies:	 **Yes/No/Don't Know __** **Yes/No/Don't Know __** **Yes/No/Don't Know __**
2.6	Is prescribing by generic name obligatory in the: Public sector: Private sector:	 **Yes/No/Don't Know __** **Yes/No/Don't Know __**
	Is generic substitution permitted at: *(Generic substitution is defined in the glossary.)* Public pharmacies: Private pharmacies:	 **Yes/No/Don't Know __** **Yes/No/Don't Know __**
2.7	Is promotion/advertisement of medicines regulated by: Company self-regulation: Government agency or medicines regulatory authority:	 **Yes/No/Don't Know __** **Yes/No/Don't Know __**
	Are civil society/non-governmental organisations involved in review, assessment, or surveillance of promotion/ advertisement of medicines?	**Yes/No/Don't Know __**
	Do regulations on promotion/advertisement of medicines include: *(See glossary for the distinction between promotion and advertisement.)* Published ethical criteria for medicines promotion: Pre-approval for promotional materials: Pre-approval for advertisement materials: Explicit prohibition on advertising prescription medicines: Detailed restrictions on advertising non-prescription medicines:	 **Yes/No/Don't Know __** **Yes/No/Don't Know __** **Yes/No/Don't Know __** **Yes/No/Don't Know __** **Yes/No/Don't Know __**

2.8	Are adverse drug reactions (ADR) monitored? If yes, what is the total number of each of the following for the most recent year for which data is available?	**Yes/No/Don't Know** __	
	Total number of validated ADR reports received:	___ ____ **(Year** ___**) DK**☐	
	Total number of reporting physicians:	___ ____ **(Year** ___**) DK**☐	
	Total number of physicians in country:	___ ____ **(Year** ___**) DK**☐	
	Are ADR of herbal medicines monitored?	**Yes/No/Don't Know** __	

3. QUALITY CONTROL OF PHARMACEUTICALS

3.1	Testing of medicines samples collected last year for regulatory purposes (i.e. including drug registration and post-marketing surveillance, but excluding testing done in conjunction with procurement activities):	Total number of samples	
	Total number of samples collected:	___ ____	**Don't Know** ☐
	Total number of samples tested:	___ ____	**Don't Know** ☐
	Total number of samples that failed identity or assay:	___ ____	**Don't Know** ☐
3.2	Where have the above samples *(see 3.1)* been tested:	Percentage of total samples tested	
	Government quality control laboratory:	___ %	**Don't Know** ☐
	Local academic institutions:	___ %	**Don't Know** ☐
	Quality control laboratory in another country:	___ %	**Don't Know** ☐
	Private quality control laboratory:	___ %	**Don't Know** ☐

4. ESSENTIAL MEDICINES LIST (EML)

4.1	Are there Essential Medicines Lists (EML)? *(An Essential Medicines List is a government-approved selective list of medicines or national reimbursement list)*		*Total number of medicines*	*Year of last update*
	National EML:	**Yes/No/DK**__	___ ____	___
	State or provincial list:	**Yes/No/DK**__	___ ____	___
	List for primary health care:	**Yes/No/DK**__	___ ____	___
4.2	Are EMLs being used in:			
	Public sector procurement:	**Yes/No/Don't Know** __		
	Public insurance reimbursement:	**Yes/No/Don't Know** __		
	Private insurance reimbursement:	**Yes/No/Don't Know** __		
4.3	Are local herbal medicines included on the national EML?	**Yes/No/Don't Know** __		

5. MEDICINES SUPPLY SYSTEM

5.1	Who is responsible for public sector drug procurement and distribution? What percentage of the total cost is each responsible for?	*Procurement*	*Distribution*
	Ministry/Department of Health:	**Yes/No/DK**__ ___ %	**Yes/No/DK**__ ___ %
	Non-governmental organisation (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**__ ___ %
5.2	Is government procurement limited to medicines on the EML?	**Yes/No/Don't Know** __	
	If no, is a percentage of the budget set aside for non-EML items?	**Yes/No/Don't Know** __	
	What is the percentage?	___ %	
5.3	Type of tender and percentage of the total cost for each: *(Tender is the process by which competing bids are entered for a particular contract.)*		*Percentage of total cost*
	National competitive tender:	**Yes/No/DK**__	___ %
	International competitive tender:	**Yes/No/DK**__	___ %
	Negotiation/direct purchasing:	**Yes/No/DK**__	___ %
5.4	Is drug registration a prerequisite for government purchases?	**Yes/No/Don't Know** __	

6. MEDICINES FINANCING

6.1	What is the total public or government budget for medicines in US$ for the most recent year for which data is available?	**$**_____ ____**, Year** ___		
6.2	Are there guidelines on medicines donations that cover the public sector, the private sector, or non-governmental organisations (NGO)?	*Public Sector*	*Private Sector*	*NGO*
		Yes/No/DK__	**Yes/No/DK**__	**Yes/No/DK**__

6.3	Which medicines are free at primary public health facilities:	**Yes/No/Don't Know** __
	All medicines are free of charge:	
	Malaria medicines are free:	**Yes/No/Don't Know** __
	Tuberculosis medicines are free:	**Yes/No/Don't Know** __
	Sexually transmitted diseases medicines are free:	**Yes/No/Don't Know** __
	HIV/AIDS-related medicines are free:	**Yes/No/Don't Know** __
	Medicines are free to those who cannot afford them:	**Yes/No/Don't Know** __
	Medicines are free for children under 5 years of age:	**Yes/No/Don't Know** __
	Medicines are free for pregnant women:	**Yes/No/Don't Know** __
	Medicines are free for elderly persons:	**Yes/No/Don't Know** __
	No medicines are free of charge:	☐ **(Don't Know** ☐**)**

6.4	Which fees are charged in public health 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 copayments:	**Yes/No/Don't Know** __
	Percentage copayments:	**Yes/No/Don't Know** __
	(Co-payments cover part of the cost of medicines, the other part being paid by an insurer or government.)	

6.5	Is revenue from fees or drug sales used to pay the salaries of public health personnel in the same facility?	**Always/Frequently/Occasionally/Never/DK**__

6.6	Health insurance: *(Health insurance is any prepayment scheme for health care costs additional to but excluding subsidies funded through the Ministry of Health budget.)*	*Public*	*Private*
	What percentage of the population has health insurance?	**All/Some/None/DK**__	**All/Some/None/DK**__
	Are medicines covered by health insurance?	**All/Some/None/DK**__	**All/Some/None/DK**__
	Of the covered medicines, what percentage of the cost is covered:	____**%**	____**%**

		Public sector	*Private sector*	*NGO*
6.7	Is there a pricing policy on medicines that covers the public sector, the private sector, or non-governmental organisations?	**Yes/No/DK**__	**Yes/No/DK**__	**Yes/No/DK**__
	If yes, does it apply to:			
	All medicines, some or none:	**All/Some/None/DK** __	**All/Some/None/DK** __	**All/Some/None/DK** __
	Is maximum wholesale mark up established in laws/regulations:	**Yes/No/DK**__	**Yes/No/DK**__	**Yes/No/DK**__
	If yes, amount:	____**%**	____**%**	____**%**
	Maximum retail mark up established in laws/regulations:	**Yes/No/DK**__	**Yes/No/DK**__	**Yes/No/DK**__
	If yes, amount:	____**%**	____**%**	____**%**
	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**__

7. ACCESS TO ESSENTIAL MEDICINES

7.1	In your opinion, what percentage of the population has regular access to essential medicines (i.e. minimum of 20 most essential medicines available and affordable at public and private facilities within a one-hour walking distance)?	____**%**

		Public health facility	*Private health facility*	*Public or private retail drug outlet*
7.2	What percentage of:			
	The population is within one-hour walking distance to:	____**%**	____**%**	____**%**
	Facilities have essential medicines available:	____**%**	____%	____**%**
	The population can afford essential medicines at:	____**%**	____%	____**%**

8. PRODUCTION

8.1	What is the medicines production capability in the country?	**Yes/No/Don't Know** __
	Research and development of new active substances:	
	Production of pharmaceutical active 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** __

8.2	For each of the following types of local production, indicate number of factories and total annual sales in US$ for the most recent year for which data is available:	*Number of factories*	*Sales in US$*	*Year*	*Don't know*
	Starting materials:	_____	$_____	_____	DK☐
	Finished products:	_____	$_____	_____	DK☐
	Products containing active substances developed/marketed for the first time during the last 5 years:	_____	$_____	_____	DK☐

8.3	What is the total volume and US$ value of the medicines market? Generic medicines compose what percentage of market volume and value?	**Volume _____, Value $_____** **Volume ____ %, Value ____ %**

9. RATIONAL USE OF MEDICINES

9.1	Are there standard treatment guidelines (STGs) produced by the health ministry/department for major conditions? *(STGs are recommendations about how to treat a clinical condition.)*		*Number of conditions/ diseases*	*Year of publication or review*
	National STG:	**Yes/No/DK__**	_____	_____
	STG for hospital level:	**Yes/No/DK__**	_____	_____
	STG for primary health care level:	**Yes/No/DK__**	_____	_____

9.2	Is there a National Medicines Formulary manual? *(A formulary manual contains summary drug information.)*	**Yes/No/Don't Know __**
	If yes, does it cover only medicines on the Essential Medicines List?	**Yes/No/Don't Know __**
	What year was it last published/reviewed:	**Year ____**

9.3	Are any of the following aspects of the essential medicines concept generally part of the basic curricula in most health training institutions/universities for: *(Essential medicines are those that satisfy the priority health care needs of the population. See glossary for a definition of problem-based pharmacotherapy).*	*Essential Medicines List*	*Standard Treatment Guidelines*	*Problem-based pharmaco-therapy*	*Rational prescribing*
	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__**

9.4	Are there independent publicly or non-commercially funded obligatory continuing education programs which 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 __**

9.5	Is there a public or independently funded nationally accessible (e.g. by phone) medicines information centre or service co-ordinated by the Ministry of Health, academia, and/or a non-commercial non-governmental organisation that provides information on demand to:	
	Prescribers:	**Yes/No/Don't Know __**
	Dispensers:	**Yes/No/Don't Know __**
	Consumers:	**Yes/No/Don't Know __**

9.6	Has there been any public education campaign concerning rational medicines use in the previous two years conducted by Ministry of Health/non-governmental organisation/academia on the following topics:	
	Use of antibiotics:	**Yes/No/Don't Know __**
	Use of injections:	**Yes/No/Don't Know __**
	Other topics/issues:	**Yes/No/Don't Know __**

9.7	How often do the following personnel prescribe at the primary health care level in the public sector?	
	Doctors:	**Always/Frequently/Occasionally/Never/DK__**
	Nurses/midwives/paramedical staff:	**Always/Frequently/Occasionally/Never/DK__**
	Pharmacists:	**Always/Frequently/Occasionally/Never/DK__**
	Pharmacy aides/assistants:	**Always/Frequently/Occasionally/Never/DK__**
	Personnel with less than one month formal health training:	**Always/Frequently/Occasionally/Never/DK__**

9.8	Is there a government department with a specific mandate to promote the rational use of medicines and co-ordinate medicines use policies?	**Yes/No/Don't Know __**
9.9	What proportion of facilities have a 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)	
	Referral hospitals:	**All/Most/Half/Few/None/Don't Know __**
	General hospitals:	**All/Most/Half/Few/None/Don't Know __**
	Regions/provinces:	**All/Most/Half/Few/None/Don't Know __**
	Is there a mandate for drugs and therapeutics committees in the national medicines policy?	**Yes/No/Don't Know __**
9.10	Is there a national strategy to contain antimicrobial resistance?	**Yes/No/Don't Know __**
	Is there a national reference laboratory to coordinate epidemiological surveillance of antimicrobial resistance?	**Yes/No/Don't Know __**
	Is there a funded national intersectoral task force to coordinate the implementation of interventions to promote appropriate use of antimicrobials and prevent the spread of infection?	**Yes/No/Don't Know __**
9.11	Are the following medicines sold over the counter without any prescription?	
	Antibiotics:	**Always/Frequently/Occasionally/Never/DK__**
	Injections:	**Always/Frequently/Occasionally/Never/DK__**

10. INTELLECTUAL PROPERTY RIGHTS PROTECTION AND MARKETING AUTHORIZATION
(See glossary for definitions of terms used in this section.)

10.1	Is patent protection legally provided for pharmaceutical products? If yes, indicate:	**Yes/No/Don't Know __**		
	Year introduced:	**__**		
	Type:	**Process/Product/Both/Don't Know __**		
	Duration of patent validity:	**__**		
10.2	Which intellectual property right protection regime/activities are provided for traditional medical knowledge?		*Year introduced*	*Duration of data protection n*
	TRIPS:	**Yes/No/DK__**	**____**	**____**
	Sui generis regimes:	**Yes/No/DK__**	**____**	**____**
	Digital library:	**Yes/No/DK__**	**____**	**____**
	National inventory of medicinal plants:	**Yes/No/DK__**	**____**	**____**
	Others:	**Yes/No/DK__**	**____**	**____**
	None:	☐ **(DK☐)**		
10.3	TRIPS-Agreement (Agreement on Trade Related Aspects of Intellectual Property Rights):			
a)	Is your country a World Trade Organization Member? *If no, skip to 10.4*	**Yes/No/Don't Know __**		
b)	Has national legislation been modified to implement the TRIPS Agreement? If yes, what year did it go into effect?	**Yes/No/Don't Know __ Year ____**		
c)	Is your country availing itself of the transitional period provided by Article 65 of the TRIPS Agreement?	**Yes/No/Don't Know __**		
d)	If your country is a least-developing country (LDC), has it availed itself of the transitional period accorded to LDCs in Article 66 of the TRIPS Agreement?	**Yes/No/DK/Country not an LDC __**		
10.4	Have parallel importing provisions on pharmaceuticals been incorporated into national legislation? If yes, have these provisions been applied?	**Yes/No/DK/Currently being discussed __** **Yes/No/DK/Currently being discussed __**		

10.5 Have compulsory licensing provisions for pharmaceuticals been incorporated into national legislation? If yes, under what conditions?	**Yes/No/DK/Currently being discussed __**
National emergency:	**Yes/No/Don't Know __**
Public non-commercial use:	**Yes/No/Don't Know __**
Remedying anti-competitive practices:	**Yes/No/Don't Know __**
Other:	**Yes/No/Don't Know __**
10.6 Are generic pharmaceutical manufacturers allowed to use patented inventions for the purpose of obtaining marketing approval prior to patent expiration?	**Yes/No/DK/Currently being discussed __**

COMMENTS ABOUT INDICATORS AND VALUES

Item Number	Comment

QUESTIONNAIRE ON STRUCTURES AND PROCESSES
OF COUNTRY PHARMACEUTICAL SITUATION

Glossary of Terms:

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.

Compulsory licensing: This term is used when the judicial or administrative authority is allowed by law to grant a licence, 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.

Co-payments: Co-payments cover part of the cost of medicines, the other part being paid by an insurer or government.

Drug 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 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 6.6 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 6.5 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.

Herbal medicines: Herbal medicines are plant-derived material or preparations with therapeutic or other human health benefits, which contain either raw or processed ingredients from one or more plants. Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products, which are classified in the medicines category according to a national regulatory framework. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients, however, finished products or mixture products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal. In some countries, herbal medicines may also contain, by tradition, natural organic or inorganic active ingredients which are not of plant origin.

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.

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

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.

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.

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.

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

Tender: Tender is the process by which competing bids are entered for a particular contract.

Traditional medical knowledge: Knowledge related to traditional medicine (see definition of *Traditional medicine and complementary/alternative medicine*).

Traditional medicine and complementary/alternative medicine (TM/CAM): Traditional medicine is the sum total of the knowledge, skills, and practices based on theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illnesses. The terms "complementary medicine" and "alternative medicine" can be used interchangeably with "traditional medicine" in some countries. The term "complementary and alternative medicine" can also be used to refer to a broad set of health care practices that are not part of the country's own tradition and are not integrated into the dominant health care system.

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.

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 and 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 than 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.

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* [WIPO note] January 1, 1995

Annex 2   Level II indicator survey and summary forms

Survey Forms 1–15

Survey Forms	Number of copies needed for:			Total number of copies needed
	Training*	**Field Test***	**Survey****	
Public health facility pharmacies/dispensaries				
SF 1 Availability of key medicines (% medicines expired)	10	10	30	50
SF 2 Price of key medicines	10	10	30	50
SF 3 Average stockout duration Adequate record keeping	10	10	30	50
SF 4 Adequate conservation conditions and handling of medicines	10	10	30	50
SF 5 Affordability of treatment for adults and children under 5 years of age	10	10	30	50
SF 6 Average number of medicines per prescription % medicines dispensed or administered % medicines adequately labelled % patients know how to take medicines Average cost of medicines and related fees	10	10	30	50
Public health facilities				
SF 7 Average number of medicines per prescription % patients prescribed antibiotics/injections % prescribed medicines on Essential Medicines List % medicines prescribed by generic name (INN)	10	10	30	50
SF 8 Availability of Standard Treatment Guidelines Availability of Essential Medicines List	10	10	30	50
SF 9 % tracer cases treated according to recommended treatment protocol/guide	10	10	30	50
Private pharmacies/drug outlets				
SF 10 Affordability of treatment for adults and children under 5 years of age	10	10	30	50
SF 11 Availability of key medicines (% medicines expired)	10	10	30	50
SF 12 Price of key medicines	10	10	30	50
Central/regional/district warehouses supplying the public sector				
SF 13 Availability of key medicines (% medicines expired)	10	10	5	25
SF 14 Average stockout duration Adequate record keeping	10	10	5	25
SF 15 Adequate conservation conditions and handling of medicines	10	10	5	25

*   *Note each data collector should be provided with one copy of each survey form for use during training and another copy of each form for use during the field test*

**   *Copies of survey forms for the actual survey should not be completed until after the country-specific items have been introduced*

Survey form 1: **Public health facility pharmacy/dispensary**
Indicator: **Availability of key medicines**
% medicines expired

Facility _____ **Date** _____
Region _____ **Investigator** _____

Key medicines to treat common conditions [A]	In stock Yes=1, No=0 [B]	Expired medicines on shelves Yes=1, No=0 [C]
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
	[B^1] = Sum of B =	**[C^1] = Sum of C =**
	[B^2] = % in stock = **B^1 ÷ 15 x 100 =**	**[C^2] = % expired =** **C^1 ÷ B^1 x 100 =**

Optional additional medicines	In stock Yes=1, No=0	Expired medicines on shelves Yes=1, No=0
1.		
2.		
3.		

Notes:
[A] A list of 15 key medicines should be identified at the national level and preprinted on the survey forms. The process is described in *The Manual,* pages 29–30. If medicines for specific health programmes are identified for investigation, the "optional additional medicines" table may be used and analysed separately.
[B] Mark "1" if stock is available in the facility on the day of the visit if any quantity of any dosage form is available. Mark "0" if the medicine is not physically available. Add the total at the bottom [B^1]. Calculate the percentage in stock [B^2] by dividing the total in stock [B^1] by 15 and multiplying by 100.
[C] For all medicines in stock, check if expired or not. If any of the medicine has an expiry problem, mark "1" for yes. Do not count expired medicines stored in a separate area for destruction. Add the total at the bottom [C^1]. Calculate the percentage expired [C^2] by dividing the total expired [C^1] by the total number of medicines in stock [B^1] and multiplying by 100.

***Survey form 2*:** **Public health facility pharmacy/dispensary**
Indicator: **Price of key medicines**

UNDER DEVELOPMENT

Facility _____ **Date** _____
Region _____ **Investigator** _____

Key medicines to treat common conditions [A]	Preparation and unit (strength and dosage form, e.g. for amoxicillin: 25 mg/ml suspension in100 ml bottle) [B]	Lowest price paid by **facility** [C]	Lowest price paid by **patient** [D]
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			

Optional additional medicines	Preparation and unit	Lowest price paid by facility	Lowest price paid by patient
1.			
2.			
3.			

Notes:
[A] The list of 15 key medicines and optional additional medicines identified for *Survey Form 1* should also be preprinted on this form.
[B] At the national level, identify a commonly dispensed preparation and unit for each key medicine and preprint these on the survey form, include syringe, needle and water for injection and other essential components of administering the medicine if applicable. If a flat rate is charged for a treatment course, then identify treatment course rather than unit.
[C] For each available medicine, determine the lowest price in the local currency paid by the facility for the identified preparation and unit. The lowest priced branded or generic equivalent medicine should be used. If facilities generally receive the medicine for free from the Ministry of Health, record the price paid when the medicine is purchased elsewhere if facilities are permitted to occasionally procure medicines from other sources. If data is not available, mark N/A.
[D] For each available medicine, determine the lowest price in the local currency paid out-of-pocket by a patient for the identified preparation and unit. The lowest priced branded or generic equivalent medicine should be used. If patients pay flat charges for each medicine, this amount should be recorded as the price of the medicine. Indicate a "0" if medicines are given free.

Survey form 3: **Public health facility pharmacy/dispensary**

Indicator: Average stockout duration
Adequate record keeping

Public Health Facility Pharmacy

Facility #_____
(1-30)

Facility _____ **Date** _____

Region _____ **Investigator** _____

Key medicines to treat common conditions [A]	Records cover at least 6 months within the past 12 months Yes=1, No=0 [B]	Only collect data for medicines with records covering at least 6 months within the past 12 months		
		Number of days out of stock [C]	Number of days covered by the review (at least 6 months) [D]	Equivalent number of days per year $[E] = C \times 365 \div D$ [E]
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
	$[B^1]$ = Sum of B =			$[E^1]$ = Sum of E =
	$[B^2]$ = % adequate records = $B^1 \div 15 \times 100$ =			
$[F]$ = Average number of stockout days = $E^1 \div B^1$ =				

Optional additional medicines	Records cover at least 6 months within the past 12 months Yes=1, No=0	Only collect data for medicines with records covering at least 6 months in the past 12 months		
		Number of days out of stock	Number of days covered by the review	Equivalent number of days per year $[E] = C \times 365 \div D$
1.				
2.				
3.				

Notes:

[A] The list of 15 key medicines and optional additional medicines identified for *Survey Form 1* should also be preprinted on this form.

[B] Go through the stock cards and indicate which medicines have records covering at least 6 months within the previous 12 months. Add the total at the bottom $[B^1]$. Calculate the percentage of medicines with adequate records $[B^2]$ by dividing the number of medicines with records covering at least 6 months $[B^1]$ by 15 and multiplying by 100.

[C] The review should cover 6-12 months. Go through the stock cards covering the review period. Indicate the number of days each medicine was not available or marked "0" on the card. A medicine is considered in stock if any quantity of it is available in generic or branded form.

[D] Indicate the number of days actually reviewed for each medicine.

[E] Compute the equivalent number of stockout days per year for each medicine by multiplying the number of days out of stock [C] by 365 and dividing by the number of days covered by the review [D]. Add the total number of stockout days $[E^1]$.

[F] Calculate the average number of stockout days by dividing the total number of stockout days $[E^1]$ by the total number of medicines reviewed $[B^1]$.

Example:

Key medicines to treat common conditions [A]	Records cover at least 6 months within the past 12 months Yes=1, No=0 [B]	Only collect data for medicines with records covering at least 6 months in the past 12 months		
		Number of days out of stock [C]	Number of days covered by the review [D]	Equivalent number of days per year $[E] = C \times 365 \div D$ [E]
Cotrimoxazole	1	90	180	182.5
Paracetamol	1	30	365	30
amoxicillin	0			
	$[B^1]$ = Sum of B = 2			$[E^1]$ = Sum of E =212.5
	$[B^2]$ = % adequate records = $B^1 \div 3 \times 100$ = 66.7			
$[F]$ = Average number of stockout days = $E^1 \div B^1$ = 106.25				

Survey form 4: **Public health facility pharmacy/dispensary**
Indicator: **Adequate conservation conditions and handling of medicines**

Facility _____   **Date** _____

Region _____   **Investigator** _____

Checklist	Storeroom True=1, False=0 [A]	Dispensing Area/Room True=1, False=0 [B]
1. There is a method in place to control temperature (e.g. roof and ceiling with space between them in hot climates).		
2. There are windows that can be opened or there are air vents.		
3. No direct sunlight can enter the area (e.g. windowpanes are painted or there are curtains/blinds to protect against the sun).		
4. Area is free from moisture (e.g. leaking ceiling, roof, drains, taps, etc.).		
5. Medicines are not stored directly on the floor.		
6. In the facility there is a cold storage with temperature chart.*		
7. Medicines are stored in a systematic way (e.g. alphabetical, pharmacological or first expiry-first out).		
8. There is no evidence of pests in the area.		
9. Tablets/capsules are not manipulated by naked hand.		
	$[A^1]$ = Sum of A =	$[B^1]$ = Sum of B =
	$[A^2]$ = Score = $A^1 \div 8$ x 100 =	$[B^2]$ = Score = $B^1 \div 8$ x 100 =

Notes:
[A] Indicate "1" if all parts of the statement are true for the storeroom and "0" if any part of it is false. Sum the total number of true statements $[A^1]$. Calculate the score for the storeroom $[A^2]$ by dividing the sum of true statements $[A^1]$ by 8 and multiplying by 100.

[B] Indicate "1" if all parts of the statement are true for the dispensing area/room and "0" if any part of it is false. Sum the total number of true statements $[B^1]$. Calculate the score for the dispensing area $[B^2]$ by dividing the sum of true statements $[B^1]$ by 8 (number of applicable statements for each storage area recorded on form) and multiplying by 100.

* It may be necessary to look elsewhere in the facility for some of the criteria (e.g. refrigerator)

					Public Health Facility Pharmacy
Survey form 5:	**Public health facility pharmacy/dispensary**				Facility #____ (1-30)
Indicator:	**Affordability of treatment for adults and children under 5 years of age**				

Facility _____   **Date** _____

Region _____   **Investigator** _____

Medicine/INN and Preparation [A]	Number of units needed to complete treatment [B]	Unit price (one vial, tablet, or capsule) [C]	Total cost of treatment [D] = B x C [D]	Equivalent number of days wages [G] = D ÷ E [G]	Ratio of cost of treatment and optional measure [H] = D ÷ F [H]
Moderate pneumonia (without hospitalization):					
Adult treatment of choice:				$[G^1] =$	$[H^1] =$
Child <5 treatment of choice:				$[G^2] =$	$[H^2] =$
Other condition: _____ (without hospitalization):					
Adult treatment of choice:				$[G^3] =$	$[H^3] =$
Child <5 treatment of choice:				$[G^4] =$	$[H^4] =$
[E] = Lowest daily government salary (divide weekly salary by 7 or monthly salary by 30) =					
[F] = Optional standard of measure: _____ =					

Notes:

[A] Using standard treatment guidelines, identify at the national level and preprint on the form the treatment of choice and the recommended preparation for moderate pneumonia and another important disease (e.g. malaria in African countries) in adults and children. Do not include symptomatic medicines, e.g. for fever or cough.

[B] The number of units of each medicine needed for the duration of treatment (based on standard treatment guidelines) should be identified at the national level and preprinted on the survey forms.

[C] Indicate in local currency the unit price or the price the facility charges patients for each medicine. The lowest priced branded or generic equivalent medicine should be used. If there are flat charges paid for each medicine given to patients, this amount should be recorded as the price of the medicine. Indicate "0" if medicines are given free. Add cost of syringe to unit price, if applicable.

[D] Calculate total cost of treatment [D] by multiplying the number of units needed [B] by unit price [C]. Only one medicine (antibiotic) should be used to calculate cost of treatment and not a combination of medicines. If patients are charged a flat fee for treatment course, record this as total cost of treatment.

[E] At the national level identify and preprint on the form the lowest daily government salary. If the weekly salary is known, divide this by 7 to obtain the daily salary. If the monthly salary is known, divide this by 30 to obtain the daily salary.

[F] At the national level, a second standard, such as poverty line, food basket, or other relevant figure may be identified and preprinted on the form.

[G] Calculate the number of days wages needed to pay for treatment by dividing the cost of treatment [D] by the lowest daily government salary [E].

[H] Calculate the ratio of cost of treatment and the optional standard of measure by dividing the cost of treatment [D] by the optional standard.

Example:

Medicine/INN and Preparation [A]	Number of units needed to complete treatment [B]	Unit price (one vial, tablet, or capsule) [C]	Total cost of treatment [D] = B x C [D]	Equivalent number of days wages [G] = D ÷ E [G]	Ratio of cost of treatment and optional measure [H] = D ÷ F [H]
Moderate pneumonia (without hospitalization):					
Adult treatment of choice: Procaine penicillin: 1g 1 mill IU	3 injections	280 (injection plus syringe)	840	11.2	17
Child <5 treatment of choice: Amoxicillin: 25 mg/ml suspension in 100 ml bottle	1 bottle	220 per bottle	220	2.93	4.5
[E] = Lowest daily government salary (divide weekly salary by 7 or monthly salary by 30) = 75					
[F] = Optional standard of measure: Poverty line (annual income of 18000) ÷ 365 = 18000 ÷ 365 = 49.3					

Survey form 6: **Public health facility pharmacy/dispensary:Patient care form**

Indicators: Average number of medicines per prescription   % patients know how to take medicines
% medicines dispensed or administered   Average cost of medicines and related fees
% medicines adequately labelled

Facility _____   **Date** _____

Region _____   **Investigator** _____

Patient sex M/F [A]	Number of medicines prescribed [B]	Number of medicines dispensed or administered [C]	Number of medicines adequately labelled [D]	Patient knows how to take medicines Yes=1, No=0 [E]	Amount patient paid for purchased medicines [F]	Amount patient paid in other fees [G]
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						
21.						
22.						
23.						
24.						
$[A^1]$ = Sum cases =	$[B^1]$ = Sum of B =	$[C^1]$ = Sum of C =	$[D^1]$ = Sum of D =	$[E^1]$ = Sum of E =	$[F^1]$ = Sum of F =	$[G^1]$ = Sum of G =
$[A^2]$ = Sum females =	$[B^2]$ = Average number of medicines = $B^1 \div A^1$ =	$[C^2]$ = % dispensed = $C^1 \div B^1$ x 100 =	$[D^2]$ = % adequately labelled = $D^1 \div C^1$ x 100 =	$[E^2]$ = % know how to take medicines = $E^1 \div A^1$ x 100 =	$[H]$ = Average cost = $(F^1 + G^1) \div A^1$ =	
$[A^3]$ = % females = $A^2 \div A^1$ x 100 =						

Notes:

[A] Interview 30 patients leaving the dispensing area/pharmacy. Record the number of cases $[A^1]$ and the number of females $[A^2]$. Calculate the percentage of females by dividing the total number of females $[A^2]$ by the total number of cases $[A^1]$ and multiplying by 100.

[B] Record the number of medicines (chemical entity, INN, generic) prescribed for each patient. Combination medicines in one dosage form count as one medicine. Sum the number of medicines prescribed for all patients $[B^1]$. Calculate average number of medicines prescribed $[B^2]$ by dividing number of medicines prescribed $[B^1]$ by number of cases $[A^1]$.

[C] Record the number of medicines dispensed or administered to each patient. Sum the total number $[C^1]$. Calculate the percentage of medicines dispensed $[C^2]$ by dividing the number of medicines given to all patients $[C^1]$ by the total number of medicines prescribed $[B^1]$ and multiplying by 100.

[D] Record the number of medicines labelled with at least the name of the medicine and how to take it. Count only medicines meeting at least both criteria. Total the number $[D^1]$. Calculate the percentage of medicines adequately labelled $[D^2]$ by dividing the total number of adequately labelled medicines $[D^1]$ by the total number of medicines dispensed $[C^1]$ and multiplying by 100.

[E] Determine if patient knows how to take all medicines dispensed. Mark "1" only if patient can correctly state how ALL medicines should be taken and "0" otherwise. Sum the total $[E^1]$. Calculate the percentage of patients who know how to take all medicines $[E^2]$ by dividing the total number who know how to take all medicines $[E^1]$ by the total number interviewed $[A^1]$ and multiplying by 100.

[F] Record the amount each patient paid out-of-pocket for the medicines received at the facility. Check with a receipt if possible. Sum the total amount $[F^1]$.

[G] Record the amount of other non-diagnostic fees paid by the patient, such as visit or injection fees but not lab or x-ray fees. Sum the total amount $[G^1]$.

[H] Calculate the average amount cost by adding the amounts paid for medicines $[F^1]$ and fees $[G^1]$ and dividing by the total number interviewed $[A^1]$.

Public Health Facility Pharmacy

Facility #_____
(1-30)

Survey form 7:   Public health facility: Rational medicine use
                      Prescribing indicator form

Indicators: Average number of medicines per prescription   % prescribed medicines on EML
                  % patients prescribed antibiotics/injections   % medicines prescribed by generic name

Facility _____   **Date** _____
Region _____   **Investigator** _____

Type R/P	Patient sex M/F	Number of medicines prescribed	Antibiotic prescribed Yes=1, No=0	Injection prescribed Yes=1, No=0	Number of prescribed medicines on Essential Medicines List (EML)	Number of medicines prescribed by generic name (INN)
[A]	[B]	[C]	[D]	[E]	[F]	[G]
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						
21.						
22.						
23.						
24.						
25.						
	$[B^1]$ = Sum cases =	$[C^1]$ = Sum of C =	$[D^1]$ = Sum of D =	$[E^1]$ = Sum of E =	$[F^1]$ = Sum of F =	$[G^1]$ = Sum of G =
	$[B^2]$ = Sum females =	$[C^2]$ = Average number of medicines = $C^1 \div B^1$ =	$[D^2]$ = % receiving antibiotics = $D^1 \div B^1$ x 100 =	$[E^2]$ = % receiving injections = $E^1 \div B^1$ x 100 =	$[F^2]$ = % EML = $F^1 \div C^1$ x 100 =	$[G^2]$ = % INN = $G^1 \div C^1$ x 100 =
	$[B^3]$ = % females = $B^2 \div B^1$ x 100 =					

Notes:

[A] From outpatient treatment records, select 30 patients seen within the last 12 months (R = retrospective sampling). If records are not available, select 30 patients currently being treated (P = prospective sampling). Sample can combine R and P. The process is described on page 27–28 of *The Manual*. Mark "R" if patient was selected retrospectively and "P" if patient was selected prospectively.

[B] Record the number of cases $[B^1]$ and the number of females $[B^2]$. Calculate the percentage of females by dividing the total number of females $[B^2]$ by the total number of cases $[B^1]$ and multiplying by 100.

[C] Record number of medicines (chemical entity, INN, generic) prescribed. Combination medicines in one dosage form count as one medicine. Total the number of medicines prescribed $[C^1]$. Calculate average number of medicines prescribed $[C^2]$ by dividing number of medicines prescribed $[C^1]$ by number of cases $[B^1]$.

[D] Record "1" if patient was prescribed any antibiotics and "0" otherwise. Total the cases receiving antibiotics $[D^1]$. Calculate percentage of cases with antibiotics $[D^2]$ by dividing number of cases with antibiotics $[D^1]$ by number of cases $[B^1]$ and multiplying by 100.

[E] Record "1" if patient was prescribed any injections and "0" otherwise. Total the cases receiving injections $[E^1]$. Calculate percentage of cases receiving injections $[E^2]$ by dividing number of cases with injections $[E^1]$ by number of cases $[B^1]$ and multiplying by 100.

[F] Record number of prescribed medicines on the national Essential Medicines List (EML). Total the number of prescribed medicines on the EML $[F^1]$. Calculate the percentage of prescribed medicines on the EML $[F^2]$ by dividing the number of medicines on the EML $[F^1]$ by the number of medicines prescribed $[C^1]$ and multiplying by 100.

[G] Record number of medicines prescribed by INN. Total the number of medicines prescribed by INN $[G^1]$. Calculate percentage of medicines prescribed by INN $[G^2]$ by dividing number of medicines prescribed by INN $[G^1]$ by number of medicines prescribed $[C^1]$ and multiplying by 100.

Survey form 8: **Public health facility: Essential medicine information**
Indicators: **Availability of Standard Treatment Guidelines (STG)**
Availability of Essential Medicines List (EML)

Facility _____ **Date** _____
Region _____ **Investigator** _____

Standard Treatment Guidelines (STG) available	**Yes=1, No=0** [A]
STG for pneumonia (as part of combined STG publication or disease specific STG document)	
STG for _____(as part of combined STG publication or disease specific STG document)	
[A^1] =Both STGs are present =	

Essential Medicines List (EML) updated within last 5 years available	**Yes=1, No=0** [B]
National EML	
Provincial/District EML	
Facility-specific EML	
Other EML (describe):	
[B^1] =At least one current EML is present =	

Notes:
[A] Identify at the national level and preprint on the form the second required STG. This should be for an important disease in the region, e.g. malaria in Africa. Check to see if there is a copy of each of the STGs either as part of combined STG publication or disease specific STG document. Record "1" if the facility is able to present a copy of the document and "0" if the facility is unable to present the document. If both STGs are present record "1" in [A^1] otherwise record "0".
[B] Record "1" next to each type of EML that is both physically present in the facility and updated within the past five years. If the facility is unable to present the document or it has been more than 5 years since it was last updated, record "0". If any current EML is available, mark "1" in [B^1], otherwise record "0".

Survey form 9: Public health facility
Indicator: % of tracer cases treated according to recommended treatment protocol/guide

Public Health Facility
Facility #____ (1-30)

Facility _____ **Date** _____

Region _____ **Investigator** _____

Tracer conditions and medicines prescribed [A]	Use of medicines by case Yes=1, No=0 [B]										Total number of cases [C]	Number of cases prescribed medicine [D]	% of cases prescribed medicine [E] = D ÷ C x 100 [E]
	1	2	3	4	5	6	7	8	9	10			
Non-bacterial diarrhoea in children under age 5													
ORS													
Antibiotic													
Antidiarrhoeal and/or antispasmodic													
Mild/moderate (outpatient) pneumonia in children under age 5													
[A¹] 1ˢᵗ line antibiotic(s) in national STG:													
Any 1ˢᵗ line antibiotic													
Prescribed >1 antibiotic													
Non-pneumonia acute respiratory tract infection (ARI) in patients of any age													
Any antibiotic													
[A²] Optional tracer condition 1:													
[A²] Optional tracer condition 2:													

Notes:

[A] At the national level, identify and preprint on the form the first-line antibiotic(s) mentioned in the national STG for pneumonia [A¹]. If data on treatment of other conditions is desired, preprint on the form the optional tracer conditions [A²] and the medicines that will be used to measure recommended or non-recommended practices.

[B] From general adult or pediatric outpatient records, select 10 patient encounters with each target condition. If possible, choose only single diagnosis encounters. Write "1" or "0" for each case selected to indicate whether or not each target medicine was prescribed.

[C] Sum the total number of cases in each row.

[D] Sum the total number of cases in each row that were prescribed the target medicine.

[E] For each row, calculate the percentage of patients receiving each medicine [E] by dividing the total number of cases that were prescribed each medicine [D] by the total number of cases [C] and multiplying by 100.

Survey form 10:   Private pharmacy/drug outlet
Indicator: Affordability of treatment for adults and children under 5 years of age

Facility _____   **Date** _____
Region _____   **Investigator** _____

Medicine/INN and Preparation [A]	Number of units needed to complete treatment [B]	Unit price (one vial, tablet, or capsule) [C]	Total cost of treatment [D] = B x C [D]	Equivalent number of days wages [G] = D ÷ E [G]	Ratio of cost of treatment and optional measure [H] = D ÷ F [H]
Moderate pneumonia (without hospitalization):					
Adult treatment of choice:				$[G^1] =$	$[H^1] =$
Child <5 treatment of choice:				$[G^2] =$	$[H^2] =$
Other condition: _____ (without hospitalization):					
Adult treatment of choice:				$[G^3] =$	$[H^3] =$
Child <5 treatment of choice:				$[G^4] =$	$[H^4] =$
[E] = Lowest daily government salary (divide weekly salary by 7 or monthly salary by 30) =					
[F] = Optional standard of measure: _____ =					

Notes:
[A]   The treatment of choice for pneumonia and the other selected condition identified for *Survey Form 5* should also be preprinted on this form.
[B]   The number of units of each medicine needed for the duration of treatment identified for *Survey Form 5* should also be preprinted on this form.
[C]   Indicate in local currency the unit price or the price the pharmacy charges patients for each medicine. The lowest priced branded or generic equivalent medicine should be used. Add cost of syringe to unit price, if applicable.
[D]   Calculate total cost of treatment [D] by multiplying the number of units needed [B] by unit price [C]. Only one medicine (antibiotic) should be used to calculate cost of treatment and not a combination of medicines.
[E]   The lowest daily government salary identified for *Survey Form 5* should also be preprinted on this form.
[F]   The second standard of measure identified for *Survey Form 5* should also be preprinted on this form.
[G]   Calculate the number of days wages needed to pay for treatment by dividing the cost of treatment [D] by the lowest daily government salary [E].
[H]   Calculate the ratio of cost of treatment and the optional standard of measure by dividing the cost of treatment [D] by the optional standard [F].

Example:

Medicine/INN and Preparation [A]	Number of units needed to complete treatment [B]	Unit price (one vial, tablet, or capsule) [C]	Total cost of treatment [D] = B x C [D]	Equivalent number of days wages [G] = D ÷ E [G]	Ratio of cost of treatment and optional measure [H] = D ÷ F [H]
Moderate pneumonia (without hospitalization):					
Adult treatment of choice: Procaine penicillin: 1g 1 mill IU	3 injections	280 (injection plus syringe)	840	11.2	17
Child <5 treatment of choice: Amoxicillin: 25 mg/ml suspension in 100 ml bottle	1 bottle	220 per bottle	220	2.93	4.5
[E] = Lowest daily government salary (divide weekly salary by 7 or monthly salary by 30) = 75					
[F] = Optional standard of measure: Poverty line (annual income of 18000) ÷ 365 = 18000 ÷ 365 = 49.3					

<table>
<tr><td></td><td>Private Pharmacy

Facility #_____
(1-30)</td></tr>
</table>

***Survey form 11*:** **Private pharmacy/drug outlet**
Indicator: **Availability of key medicines**
% medicines expired

Facility _____ **Date** _____
Region _____ **Investigator** _____

Key medicines to treat common conditions [A]	In stock Yes=1, No=0 [B]	Expired medicines on shelves Yes=1, No=0 [C]
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
	$[B^1]$ = Sum of B =	$[C^1]$ = Sum of C =
	$[B^2]$ = % in stock = $B^1 \div 15 \times 100$ =	$[C^2]$ = % expired = $C^1 \div B^1 \times 100$ =

Optional additional medicines	In stock Yes=1, No=0	Expired medicines on shelves Yes=1, No=0
1.		
2.		
3.		

Notes:
[A]   The list of 15 key medicines and optional additional medicines identified for *Survey Form 1* should also be preprinted on this form.
[B]   Mark "1" if stock is available in the pharmacy on the day of the visit if any quantity of any dosage form is available. Mark "0" if the medicine is not physically available. Add the total at the bottom $[B^1]$. Calculate the percentage in stock $[B^2]$ by dividing the total in stock $[B^1]$ by 15 and multiplying by 100.
[C]   For all medicines in stock, check if expired or not. If any of the medicine has an expiry problem, mark "1" for yes. Do not count expired medicines stored in separate area for destruction. Add the total at the bottom $[C^1]$. Calculate the percentage expired $[C^2]$ by dividing the total expired $[C^1]$ by the total number of medicines in stock $[B^1]$ and multiplying by 100.

Survey form 12: **Private pharmacy/drug outlet**
Indicator: **Price of key medicines**

UNDER DEVELOPMENT

Facility _____   **Date** _____

Region _____   **Investigator** _____

Key medicines to treat common conditions [A]	Preparation and unit (strength and dosage form, e.g. for amoxicillin: 25 mg/ml suspension in100 ml bottle) [B]	Lowest price paid by **pharmacy** [C]	Lowest price paid by **patient** [D]
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			

Optional additional medicines	Preparation and unit	Lowest price paid by pharmacy	Lowest price paid by patient
1.			
2.			
3.			

Notes:
[A] The list of 15 key medicines and optional additional medicines identified for *Survey Form 1* should also be preprinted on this form.
[B] The preparation and unit for each key medicine identified for *Survey Form 2* should also be preprinted on this form, including syringe, needle and water for injection and other essential components of administering the medicine, if applicable.
[C] For each available medicine, determine the lowest price in the local currency paid by the pharmacy for the identified preparation and unit. The lowest priced branded or generic equivalent medicine should be used. If data is not available, mark N/A.
[D] For each available medicine, determine the lowest price in the local currency paid out-of-pocket by a patient for the identified preparation and unit. The lowest priced branded or generic equivalent medicine should be used.

		Central/district warehouse
		Facility #_____ (1-5)

Survey form 13: **Central/regional/ district warehouse supplying the public sector**

Indicator: **Availability of key medicines % medicines expired**

Facility _____ **Date** _____

Region _____ **Investigator** _____

Key medicines to treat common conditions [A]	In stock Yes=1, No=0 [B]	Expired medicines on shelves Yes=1, No=0 [C]
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
	$[B^1]$ = Sum of B =	$[C^1]$ = Sum of C =
	$[B^2]$ = % in stock = $B^1 \div 15 \times 100$ =	$[C^2]$ = % expired = $C^1 \div B^1 \times 100$ =

Optional additional medicines	In stock Yes=1, No=0	Expired medicines on shelves Yes=1, No=0
1.		
2.		
3.		

Notes:
[A] The list of 15 key medicines and optional additional medicines identified for *Survey Form 1* should also be preprinted on this form.
[B] Mark "1" if stock is available in the warehouse on the day of the visit if any quantity of any dosage form is available. Mark "0" if the medicine is not physically available. Add the total at the bottom $[B^1]$. Calculate the percentage in stock $[B^2]$ by dividing the total in stock $[B^1]$ by 15 and multiplying by 100.
[C] For all medicines in stock, check if expired or not. If any of the medicine has an expiry problem, mark "1" for yes. Do not count expired medicines stored in separate area for destruction. Add the total at the bottom $[C^1]$. Calculate the percentage expired $[C^2]$ by dividing the total expired $[C^1]$ by the total number of medicines in stock $[B^1]$ and multiplying by 100.

Survey form 14: **Central/regional/**
district warehouse supplying the public sector

Indicator: **Average stockout duration**
Adequate record keeping

Central/district warehouse
Facility #_____ (1-5)

Facility _____ **Date** _____
Region _____ **Investigator** _____

Key medicines to treat common conditions	Records cover at least 6 months within the past 12 months Yes=1, No=0	Only collect data for medicines with records covering at least 6 months within the past 12 months		
		Number of days out of stock	Number of days covered by the review (at least 6 months)	Equivalent number of days per year $[E] = C \times 365 \div D$
[A]	[B]	[C]	[D]	[E]
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
	$[B^1]$ = Sum of B =			$[E^1]$ = Sum of E =
	$[B^2]$ = % adequate records = $B^1 \div 15 \times 100$ =			
[F] = Average number of stockout days = $E^1 \div B^1$ =				

Optional additional medicines	Records cover at least 6 months within the past 12 months Yes=1, No=0	Only collect data for medicines with records covering at least 6 months in the past 12 months		
		Number of days out of stock	Number of days covered by the review	Equivalent number of days per year $[E] = C \times 365 \div D$
1.				
2.				
3.				

Notes:
[A] The list of 15 key medicines and optional additional medicines identified for *Survey Form 1* should also be preprinted on this form.
[B] Go through the stock cards and indicate which medicines have records covering at least 6 months within the previous 12 months. Add the total at the bottom $[B^1]$. Calculate the percentage of medicines with adequate records $[B^2]$ by dividing the number of medicines with records covering at least 6 months $[B^1]$ by 15 and multiplying by 100.
[C] The review should cover 6-12 months. Go through the stock cards covering the review period. Indicate the number of days each medicine was not available or marked "0" on the card. A medicine is considered in stock if it is available in generic or branded form.
[D] Indicate the number of days actually reviewed for each medicine.
[E] Compute the equivalent number of stockout days per year for each medicine by multiplying the number of days out of stock [C] by 365 and dividing by the number of days covered by the review [D]. Add the total number of stockout days $[E^1]$.
[F] Calculate the average number of stockout days by dividing the total number of stockout days $[E^1]$ by the total number of key medicines reviewed $[B^1]$.

Example:

Key medicines to treat common conditions	Records cover at least 6 months within the past 12 months Yes=1, No=0	Only collect data for medicines with records covering at least 6 months in the past 12 months		
		Number of days out of stock	Number of days covered by the review	Equivalent number of days per year $[E] = C \times 365 \div D$
[A]	[B]	[C]	[D]	[E]
Cotrimoxazole	1	90	180	182.5
Paracetamol	1	30	365	30
Amoxicillin	0			
	$[B^1]$ = Sum of B = 2			$[E^1]$ = Sum of E =212.5
	$[B^2]$ = % adequate records = $B^1 \div 3 \times 100$ = 66.7			
[F] = Average number of stockout days = $E^1 \div B^1$ = 106.25				

	Central/district warehouse
	Facility #____ (1-5)

Survey form 15: **Central/regional/ district warehouse supplying the public sector**

Indicator: **Adequate conservation conditions and handling of medicines**

Facility _____   **Date** _____

Region _____   **Investigator** _____

Checklist	Storeroom True=1, False=0 [A]
1. There is a method in place to control temperature (e.g. roof and ceiling with space between them in hot climates).	
2. There are windows that can be opened or there are air vents.	
3. No direct sunlight can enter the area (e.g. window panes are painted or there are curtains/blinds to protect against the sun).	
4. Area is free from moisture (e.g. no leaking ceiling, roof, drains, taps, etc.).	
5. Medicines are not stored directly on the floor.	
6. In the facility there is a cold storage with temperature chart.	
7. Medicines are stored in a systematic way (e.g. alphabetical, pharmacological or first expiry-first out).	
8. There is no evidence of pests in the area.	
	$[A^1]$ = Sum of A =
	$[A^2]$ = Score = $A^1 \div 8 \times 100$ =

Notes:
[A]   Indicate "1" if all parts of the statement are true for the storeroom and "0" if any part of it is false. Sum the total number of true statements $[A^1]$. Calculate the score for the storeroom $[A^2]$ by dividing the sum of true statements $[A^1]$ by 8 and multiplying by 100.

ANNEX 3   Description of Level II indicators reported in this Fact Book

Selecting the basket of key medicines
A list of 15 key medicines used to treat common health problems must be selected to measure availability, presence of expired medicines, medicine price and stock-out duration. These are basic requirements of key medicines in all levels of health care:

- They are included on the national essential medicines list.
- They are the most important therapeutically and based on national treatment guidelines or at least on the consensus of experts.
- They are the most widely used of the medicines meeting the above criteria.
- They are expected to be available at all primary health care facilities at all times.

Drugs known to be problematic are not be included in the basket of drugs as this would reduce the value of this indicator. Instead, such drugs can be monitored separately as "optional additional drugs". Likewise, other drugs that may be of interest, but do not meet all the above requirements could be included on the optional list.

Storage and handling
The storage conditions and handling of medicines affect their quality. A checklist was used to rate the conservation conditions and handling of medicines. Scores were determined from the total number of "true" responses to items on the checklist.

Affordability of treatment for adults and children
Affordability is expressed as the ratio of the cost of treating moderate pneumonia (standard treatment and no hospitalization) in adults and in children to the lowest daily government wage.

Adequacy of labelling of medicines at public health facility dispensaries
An adequate label includes the name of the medicine, the amount to be taken and the frequency of administration. In some situations, countries may adjust these minimum requirements.

Patients' knowledge of how to take medicines
The patient should have adequate knowledge of the appropriate dosage and duration of the course of treatment with each medicine (i.e. how much, how often and for how long he or she should take each medicine). Countries may adjust these criteria.

Availability of standard treatment guidelines and essential medicines list
The surveyor will ask to see a copy of the relevant STGs. A facility is only recorded as having a particular STG if the facility is able to produce the document upon request.

Annex 4 **Level I data from 2003, by country (alphabetically by country name and income-level indicators); organized by sections in Level I survey and this final report.***

Annex 5 **Level II data by country (alphabetically by country name and income-level indicators); organized by Access (6 indicators), Quality (2 indicators), and Rational Use of Medicines indicators (10 indicators).***

Annex 6 **Level I data from 1999, by country on variables used for comparisons between 1999 and 2003.***

* Available on CD-ROM.
Requests should be addressed to
the Department of Technical Cooperation
for Essential Drugs and Traditional Medicine,
World Health Organization, 1211 Geneva 27, Switzerland.
Fax: + 41 22 791 4167, e-mail: edmdoccentre@who.int

Annex 7   Country income level (CIL)

Country income levels (CIL) are based on the World Bank's country economies classifications for 2004.[1] We compared the classifications listed in *The World medicines situation*[2] from the year 2000 to the 2004 World Bank classifications. We also used 2004 World Bank classifications for countries for which no income level was given in the WMS report and for those for which CIL changed between 2000 and 2004 (Bahrain, China, Equatorial Guinea, Honduras, Indonesia, Papua New Guinea and the Republic of Korea). Two territories of New Zealand, Cook Islands and Niue, were missing CIL in 2000 and were not listed in 2004. Based on their 2004 GDP per capita listed in the *World fact book*[3] both were categorized as middle-income countries. The Democratic Republic of the Congo was also not listed in 2004, but was categorized as low-income in 2000, and that categorization was used.

Table: Country income level by WHO Region

	Africa	America	Eastern Mediterranean	Europe	South-East Asia	Western Pacific	Total (percentage)
Low-Income	37	1	3	4	6	6	57 40.7%
Middle-Income	7	25	7	11	4	11	65 46.4%
High-Income	0	1	2	11	0	4	18 12.9%
Total	44	27	12	26	10	21	140 100.0%

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[1] *Country classification. Classification of economies.* The World Bank Group, 2004.
Available at: http://www.worldbank.org/data/countryclass/countryclass.html
[2] *The world medicines situation*. Geneva, World Health Organization, 2004.
[3] *World fact book 2004.* Central Intelligence Agency, 2003 edition.
Available at: http://www.cia.gov/cia/publications/factbook/index.html

Do people have access to essential medicines? Are people getting medicines that are safe, effective and of good quality? Are these medicines being used properly? To help answer such critical questions WHO has developed a monitoring strategy based on a set of indicators which assess progress in country pharmaceutical situations, make comparisons between countries, and reassess and prioritize efforts based on the results. The WHO Level 1 indicators measure the existence and performance of key national pharmaceutical structures and processes. Level II indicators measure key outcomes of these structures and processes in the areas of access to medicines, product quality and rational use. Monitoring the progress of efforts to improve the global pharmaceutical situation in this way underpins every aspect of WHO's Medicines Strategy.

The data and information in this Fact Book are the product of several years' work on developing and improving data-gathering tools, followed by the systematic collection of information from countries through questionnaires and surveys. The publication provides an overview of different pharmaceutical sector components and the current status of national drug policies. To some degree it also attempts to measure the impact of the efforts of countries, WHO and other agencies that are committed to improving the pharmaceutical situation worldwide. Results of the assessment of Level I indicator surveys conducted globally in 2003 and of Level II indicator surveys conducted between 2002 and 2004 are given. Countries are grouped according to whether they are low-, middle- or high-income. Level II outcome indicators are classified according to eight components: national medicines policy; legislation and regulation; quality control of pharmaceuticals; medicines financing systems and policies; supply of medicines in the public sector; intellectual property rights and patents and local production; access to essential medicines; and rational use of medicines.

With the development of its operational package for monitoring and assessing country pharmaceutical situations, WHO 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. The data and information presented here can be used to inform priorities and set targets, to assess the strengths and weaknesses of strategies, and provide a picture of national and institutional problems.

The Fact Book is a useful tool for researchers, policy-makers, planners and others involved in the pharmaceutical sector. It can supply international agencies and donors with baseline data, and with information which may help them to assess the potential impact of activities. Professional groups and nongovernmental organizations will also find the results presented in the book valuable for focusing their advocacy and information campaigns.