



WORLD HEALTH ORGANIZATION

WHO

MEDICINES STRATEGY

COUNTRIES AT THE CORE

2004-2007



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REVIEW PROCESS AND ACKNOWLEDGEMENTS

The WHO Medicines Strategy 2004-2007 was developed by WHO country, regional, and headquarters staff working in essential drugs and medicines policy, in consultation with other WHO Programmes and with key development partners. The Strategy is mainly an update of the WHO Medicines Strategy 2000-2003 and was developed in three phases:

PHASE I

Internal update of the WHO Medicines Strategy 2000-2003 by five working groups composed of country, regional, and headquarters WHO staff. Consultations were held through regular telephone conferences and email exchanges on five different areas: Policy, Traditional Medicine, Access, Quality and Safety, and Rational Use.

PHASE II

External review on the first draft which resulted from Phase I, with our full range of partners, including representatives from Member States from all regions and all levels of development, WHO Expert Committees, WHO Collaborating Centres, the wider UN family, non-governmental organizations and other international organizations.

PHASE III

Finalization through a series of video conferences between headquarters and regional offices, as well as conference calls with Member States.

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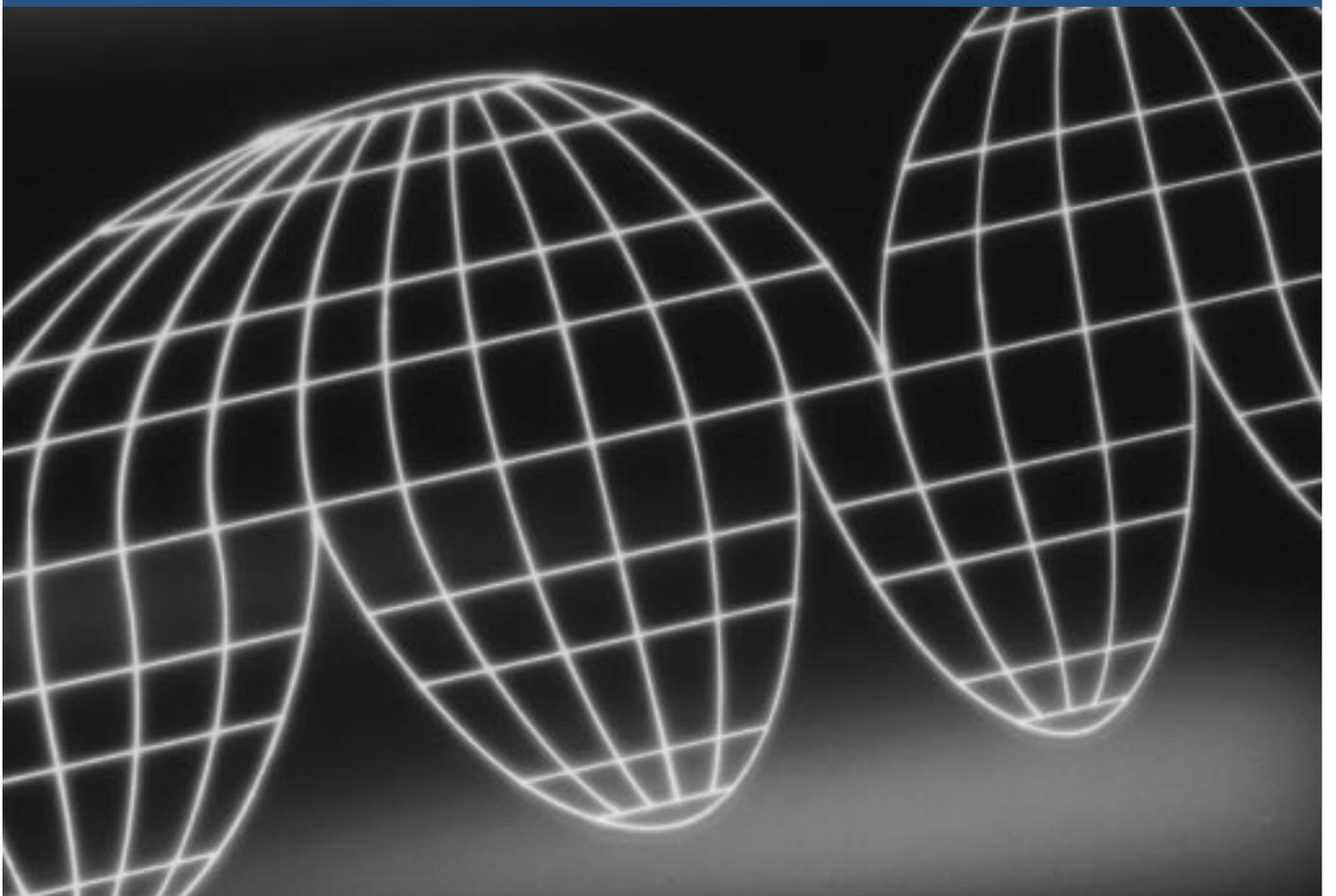
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ACRONYMS

ACT	Artemisinin combination therapy
ADR	Adverse Drug Reaction
API	Active Pharmaceutical Ingredient
ARV	Antiretroviral
AFRO	WHO African Regional Office
AMRO	WHO Americas Regional Office
ASEAN	Association of Southeast Asian Nations
ATC	Anatomic Therapeutic Chemical
CADREAC	Agreement of Drug Regulatory Authorities in European Union Associated Countries
CAM	Complementary and Alternative Medicine
CMS	Central Medical Stores
CPA	Confederation of Pharmaceutical Associations
CSO	Civil Society Organization
DDD	Defined Daily Dose
DOTS	Directly Observed Treatment Short-Course
DTC	Drug and Therapeutics Committee
EC	European Commission
EDM	Essential Drugs and Medicines Policy
EMA	European Medicines Evaluation Agency
EMRO	WHO Eastern Mediterranean Regional Office
EU	European Union
GACP	Good Agricultural and Collection Practices
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GMP	Good Manufacturing Practices
GTDP	Good Trade and Distribution Practices
HAI	Health Action International
ICH	International Conference on Harmonization of technical Requirements for registration of Pharmaceuticals for Human Use
INN	International Nonproprietary Name
INRUD	International Network for Rational Use of Drugs
IPC	International Pharmaceutical Coordination
MDG	Millennium Development Goal
MSF	Médecins Sans Frontières

MSH	Management Sciences for Health
NGO	Non-governmental Organization
NIS	Newly Independent States
NMP	National Medicines Policy
NPO	National Professional Officer
OAPI	Organisation Africaine de la Propriété Intellectuelle
PAHO	Pan American Health Organization
QC	Quality Control
SADC	Southern African Development Community
SMACS	Pharmaceutical Starting Materials Certification Scheme
SEARO	WHO South-East Asian Regional Office
TDR	UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases
TB	Tuberculosis
TM	Traditional Medicine
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDCP	United Nations Drug Control Programme
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
WHA	World Health Assembly
WIPO	World Intellectual Property Organization
WPRO	WHO Western Pacific Regional Office
WTO	World Trade Organization

HIGHLIGHTS



OUR VISION

Our vision is 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.

EXPANDING ACCESS TO ESSENTIAL MEDICINES

Scaling up access to essential medicines — especially for HIV/AIDS, tuberculosis (TB), and malaria — is critical to global efforts by WHO to prevent millions of deaths a year, reduce suffering, and help reduce the economic burden of illness on the poorest families.

WHO estimates that over 10.5 million lives a year could be saved by 2015 — also boosting economic growth and social development — by expanding access to existing interventions for infectious diseases, maternal and child health, and noncommunicable diseases.

Most of these interventions depend on essential medicines. Yet today, almost 2 billion people — one-third of the global population — do not have regular access to essential medicines. In some of the lowest-income countries in Africa and Asia, more than half of the population have no regular access to essential medicines.

In developing countries, where an estimated 40 million people are infected with HIV/AIDS, life-saving antiretroviral medicines (ARVs) are available to only 300 000 of the 5-6 million people currently in need of treatment — a crisis

that WHO has declared to be a global health emergency.

Average per capita spending on pharmaceuticals in high-income countries is 100 times higher than in low-income countries — about US\$ 400 compared with US\$ 4. WHO estimates that 15% of the world's population consumes over 90% of the world's production of pharmaceuticals (by value).

Access to health care is a fundamental human right, enshrined in international treaties and recognized by governments throughout the world. However, without equitable access to essential medicines for priority diseases the fundamental right to health cannot be fulfilled. Access to essential medicines is also one of the UN's Millennium Development Goals (MDGs).

Note:

Numbered references (sources) are listed at the end (pages 147-149). References indicated by a letter in the text are explained in Endnotes (page 150).

OUR GOAL

WHO's goal in medicines is to help save lives and improve health by ensuring the quality, efficacy, safety and rational use of medicines, including traditional medicines, and by promoting equitable and sustainable access to essential medicines, particularly for the poor and disadvantaged.

THE CHALLENGE OF MEETING ESSENTIAL MEDICINE NEEDS

Essential medicines save lives, reduce suffering, and improve health, but only if they are of good quality and safe, available, affordable, and properly used. However, in many countries today not all these conditions are being met.

- **Unaffordable medicine prices** — especially for newer products such as ARVs and artemisinin-based antimalarial drugs — limit access to medicines in resource-poor settings. In developing countries today, because of high prices, medicines account for 25%-70% of overall health care expenditure, compared to less than 15% in most high-income countries.
- **Irrational use of medicines** is a major problem worldwide. It is estimated that half of all medicines are inappropriately prescribed, dispensed or sold and that half of all patients fail to take their medicine properly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards.
- Elsewhere, **unfair health financing mechanisms** which leave households responsible for the cost of the essential medicines they need, place the heaviest burden on the poor and sick who are least able to pay. In some countries, one-third of people living in poor households receive none of the essential medicines they need for acute illness.

→ The persistence of **unreliable medicines supply** systems is one of the main reasons why many countries are unable to ensure a regular, sustainable supply of essential medicines. Failures at any point in the supply system can lead to shortages of medicines and avoidable suffering and deaths. In addition, inefficient procurement systems have been found to pay up to twice the global market price for essential medicines and lead to unnecessary waste of resources

→ **The quality of medicines** varies greatly — especially in low- and middle-income countries. While most countries have a medicines regulatory authority and formal requirements for registering medicines, one-third of WHO Member States have either no regulatory authority or only limited capacity to regulate the medicines market. In recent assessments carried out by WHO, 50%-90% of samples of antimalarial drugs failed quality control tests and more than half of ARVs assessed did not meet international standards. In addition, the sale of counterfeit and substandard medicines remains a global concern.

→ **New medicines are needed** for diseases that disproportionately affect the poor, especially 'neglected' diseases. Most medicines R&D (over 90%) is focused on the medical conditions of the richest 20% of the global population. Only 1% of the medicines developed over the past 25 years were for tropical diseases and TB, which together account for over 11% of global disease burden.

ACHIEVEMENTS 2000-2003

In response to these challenges, WHO provides policy guidance and country support to help improve access to essential medicines and assure their safety, quality, and rational use. Over the past four years, over 120 countries worldwide have been supported in this way. Recent achievements include:

- Support to efforts to expand access to medicines — including for HIV/AIDS, TB, and malaria, and other priority diseases — through progress on critical issues such as selection, regulation, quality assurance, prices, and monitoring of trade agreements.
- Establishment of a new prequalification programme for priority medicines which has been extended from HIV/AIDS medicines to cover medicines for TB and malaria.
- Launch of the WHO Traditional Medicines Strategy to support the safe and informed use of traditional and complementary medicine and protect traditional medicines knowledge.
- Implementation of a global system for monitoring country progress in medicines, including the use of household surveys, to assess the affordability, availability, source, and appropriate use of medicines.
- Expansion of information on comparative medicine prices worldwide to ensure that countries and consumers do not have to pay more than necessary for essential medicines.
- Revision of essential medicines selection process to ensure a more evidence-based, independent, and transparent selection process. Reasons for selection are published on the WHO Medicines Library website, together with comparative information on prices and the WHO Model Formulary.
- Launch of intensified training programmes on: Good Manufacturing Practices (GMP); quality assurance and registration of generic drugs, especially ARVs; and rational use of medicines.
- Launch of a campaign to raise awareness about the dangers of counterfeit and substandard medicines.

RESPONDING TO COUNTRY NEEDS

With the launch of the *WHO Medicines Strategy 2004-2007: Countries at the Core*, WHO is continuing to respond to the medicines challenges of the 21st century through a wide range of initiatives. The new strategy is based on four key objectives: strengthening [national medicines policy](#); improving [access](#) to essential medicines; improving the [quality and safety](#) of medicines; and promoting their [rational use](#).

Over the next four years, top priority is being given to expanding access to quality essential medicines – with a particular focus on scaling up access to ARVs to meet the WHO target of ensuring that 3 million people in developing countries have access to treatment for HIV/AIDS by 2005. Emphasis is also being placed on efforts to improve medicines financing, supply systems, and quality assurance. The detailed planning of this strategy is outlined in the summary table on p.22-23 in chapter 1. WHO's strategic priorities for medicines over the next four years include:

RESPONDING TO COUNTRY NEEDS

Medicines policy: ensuring the implementation and monitoring of national medicines policies, with a focus on

- Continued support to ensure that all countries develop a national medicines policy and that these are implemented, monitored, and regularly updated in line with broader health and development objectives.
- Supporting countries in their efforts to use public health safeguards in international, regional, and bilateral trade agreements to improve access to priority medicines.
- Promoting and monitoring: access to essential medicines as a fundamental human right; public investment in medicines R&D, especially for neglected diseases; and ethical practices in the pharmaceutical sector.
- Implementation of WHO's strategy for traditional medicine to ensure affordable access, protection of intellectual property rights, and guidance on safety, efficacy, and quality assurance.

Access: ensuring equitable financing, affordability, and delivery of essential medicines, with a focus on

- Expanding access to quality essential medicines for priority diseases, especially HIV/AIDS, through development and use of standard treatment guidelines, prequalification of new medicines, market intelligence on prices, and guidance on issues such as patents.
- Strengthening medicines supply systems through country assessments, promotion of 'best practices', and medicines supply management training.
- Promoting establishment of sustainable ways of financing medicines expenditure through health insurance schemes.

Quality and safety: assuring the quality and safety of medicines by strengthening and implementation of regulatory and quality assurance standards, with a focus on

- Assuring the quality, safety, and efficacy of priority medicines, especially for HIV/AIDS, TB, and malaria, by establishing standards and training tools.
- Support to national drug regulatory authorities through assessment, information exchange, and capacity building.
- Support to ensure that countries are able to carry out post-marketing safety monitoring of new medicines such as ARVs and antimalarials which are scheduled for use among populations on a wide scale.

Rational use: promoting therapeutically sound and cost-effective use of medicines by health workers and consumers, with a focus on

- Efforts to increase rational use of medicines among prescribers and consumers through working with health insurance systems to promote the use of essential medicines.
- Training, networking, and information exchange to promote the rational use of medicines in an effort to prevent deaths and illness and reduce medicines expenditure.

TRACKING PROGRESS

Regular monitoring and evaluation underpins every aspect of WHO's work in essential medicines. A package of core indicators has been developed to assess the pharmaceutical situation at country level. Every four years, WHO conducts a global survey, using Level I core indicators, to assess structures and processes in the pharmaceutical system at the national level. Data from this are used to identify priority areas of work, plan the WHO Medicines Strategy, and set targets. WHO's medicines strategy for 2004-2007 includes 47 country progress indicators which will be used to monitor progress and determine whether the strategic targets have been met.

Surveys involving central warehouses, public health facilities, private pharmacies, and households are also carried out, using Level II core indicators, to assess access to quality essential medicines and investigate whether medicines are used rationally. Results from these assessments can be used by all stakeholders to identify strengths and weaknesses, establish priorities, and set targets. In addition, WHO and its partners have developed a series of detailed survey packages which can be used to investigate a specific function such as the medicines supply system.

OPERATIONAL CAPACITY

WHO is well placed to fulfil its mission in essential medicines – working in partnership with Member States and through effective coordination between WHO headquarters, regional offices, and country offices. At the regional level, essential medicines teams coordinate the work of WHO throughout the region. In over 30 countries, Medicines Advisers play a key support role — liaising with Ministries of Health and helping coordinate the work of a wide range of public and private sector partners.

WHO has established operational, scientific, and strategic partnerships in medicines including public and private sector businesses and research institutes, bilateral aid agencies, non-governmental organizations (NGOs), UN agencies, and international organizations. Scientific partners include 40 WHO Collaborating Centres and a network of over 70 national 'pharmacovigilance' centres which monitor medicines safety worldwide.

MEDICINES AND PUBLIC HEALTH



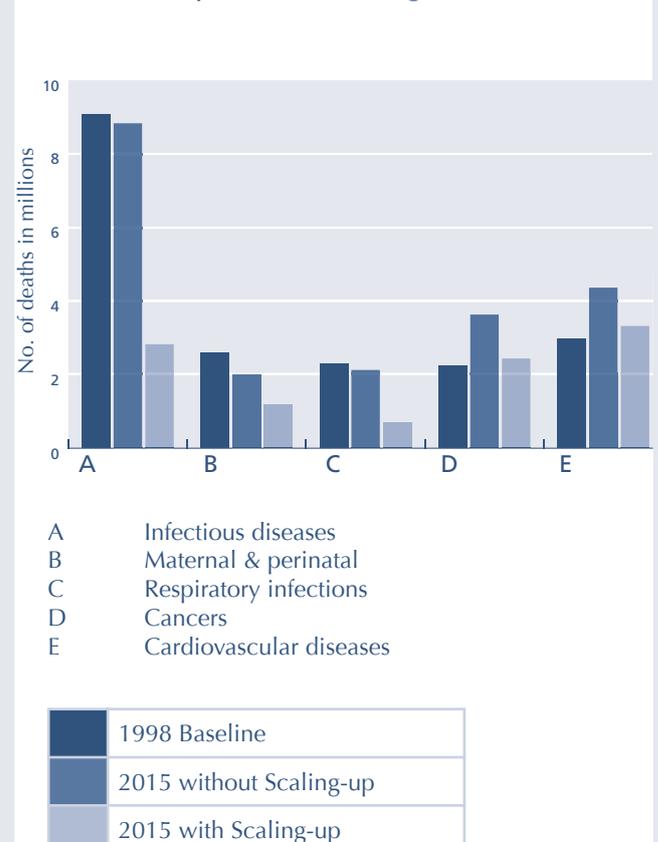
Essential medicines save lives, reduce suffering, and improve health. But only if they are of good quality and safe, available, affordable, and rationally used. The concept of essential medicines encourages health systems to focus on access to those medicines that represent the best balance of quality, safety, efficacy and cost to meet priority health needs within any given health care setting. Over the last 25 years the concept has proven to be a global necessity for countries from the poorest to the wealthiest.

CURRENT CHALLENGES IN A CHANGING WORLD

In 2002, there were almost 6 million deaths from HIV/AIDS, TB, and malaria. Of the over 1 million who died from malaria, most were children in Africa. In addition, WHO estimates that in 2002 over 2 million children in developing countries died from perinatal conditions and 4 million died from just three diseases — pneumonia, measles, and diarrhoea. Meanwhile heart disease, stroke, cancer, and other chronic diseases are a major cause of death in high- and middle-income countries, and an increasing problem in low-income countries. Yet for nearly all of these major health problems, medicines exist that can extend life and reduce disability.

In 2001, the Commission on Macroeconomics and Health estimated that 10.5 million lives per year could be saved by the year 2015 — also boosting economic growth and development — by scaling up access to existing health interventions to prevent or treat infectious diseases, maternal and perinatal conditions, childhood diseases, and noncommunicable diseases. Most of these interventions depend on essential medicines.

Figure 1: 10.5 million lives per year could be saved by ensuring access to existing medicines, vaccines, and prevention strategies



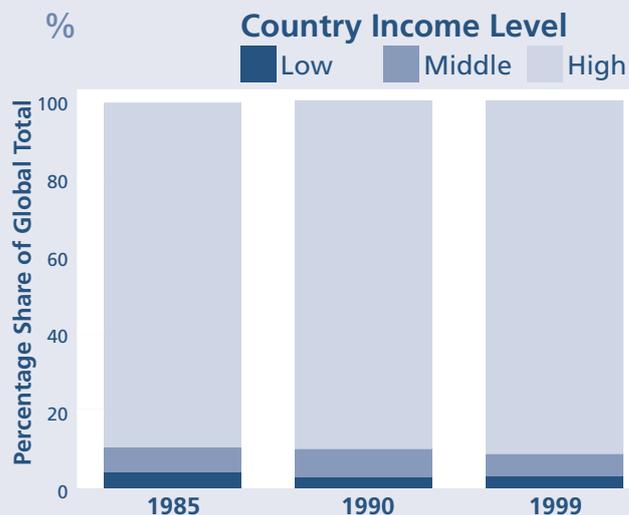
Source: Commission on Macroeconomics and Health, WHO, 2001

Essential medicines also have a huge economic impact on countries and on households. In developing countries today, because of high prices, medicines account for 25%-70% of total health care expenditures, compared to less than 15% in most high-income countries. For governments and NGOs providing primary health care, medicines are the largest expense after personnel costs. For households in low-income countries, medicines represent 50%-90% of out-of-pocket spending on health. Yet in some countries, less than half of people living in poor households receive all the medicines they need for acute illness – and one-third receive none of the medicines they need.

Despite considerable progress in access to essential medicines over the last 25 years, an estimated 1.7 billion people today still have no regular access to quality essential medicines. While this is a smaller percentage of the global population than in 1977, when the first WHO Model List of essential medicines was published, gross inequity in access to medicines remains the overriding feature of the world pharmaceutical situation.

From 1985 to 1999, the global share of pharmaceuticals production and consumption

Figure 2: Estimated global share of pharmaceutical consumption (by value) in low-, middle-, and high-income countries



Source: World Medicines Situation, WHO (forthcoming).

(by value) increased in high-income countries, but fell in low-income countries — despite an increase in population. As a result, WHO estimates that 15% of the world's population consumes 91% of the world's production of pharmaceuticals (by value).

Compared to 1985, many more countries today have national medicines policies. However, in low-income countries, all too often these policies lack implementation plans and supporting strategies such as price control, generic promotion or the effective regulation of quality. These realities are a continuing challenge for WHO in promoting the concept of essential medicines.

Over the past 15 years, there have also been changes in the global context in which national medicines policies are being implemented. The global burden of disease has undergone a major shift as both the scale and impact of HIV/AIDS have become fully apparent. In 1988, there were an estimated 6.3 million HIV/AIDS cases worldwide. By the end of 2003 an estimated 40 million people were living with HIV/AIDS. Of those, about 30% live in southern Africa — home to just 2% of the world's population — and an estimated 2.5 million are children under the age of 15. During 2003, WHO estimates that about 5

million people were newly infected with HIV and there were about 3 million AIDS deaths.

The global response to the HIV/AIDS pandemic has brought into focus a number of key issues in medicines policy. One of these is the critical importance of innovation. The research and development of new, safe, and effective medicines is critical to saving lives and reducing suffering from a new disease on an epidemic scale.

However, many of these new medicines have been at the centre of continuing controversies about prices and the legal limits to competition through intellectual property rights in the form of patents. In a global trading situation, intellectual property rights occupy an important place and medicines have held centre stage in discussions in and around the World Trade Organization (WTO) about whether, and at what speed, implementation of a single set of international trade rules should occur.

25 YEARS OF EXPERIENCE WITH THE ESSENTIAL MEDICINES CONCEPT

The essential medicines concept arose from the growing recognition that medicines bring dangers as well as great promise, and the realization that developing countries were spending up to 40% of their health expenditure on medicines. Originally known as “essential drugs”, the concept emerged in the 1970s with a definition of essential drugs in 1975 and the publication of the first WHO Model List of Essential Drugs in 1977 followed by the 1978 Declaration of Alma Ata that identified “provision of essential drugs” as one of the eight elements of primary health care.

The 1980s saw the operationalization of the essential drugs concept with the establishment of the Action Programme for Essential Drugs in Geneva and national essential drugs programmes in five countries. A number of non-governmental organizations (NGOs) such as Health Action International (HAI) and the International Network for Rational Use of Drugs (INRUD) were formed to support the implementation of the concept.

Consolidation and expansion during the 1990s was carried out in an environment that was changing politically, pharmaceutically, and epidemiologically.

Revalidation of the concept is taking place in the 21st century with inclusion of access to essential medicines in the UN’s Millennium Development Goals (MDGs), and with WHO modernizing the methods for selection and publishing the first WHO Model Formulary.

This has led to a complete overhaul and renewal of the whole essential medicines concept.

HOPE AND PROMISE FOR THE FUTURE

Significant progress has been made in: strengthening national pharmaceutical programmes, with notable achievements in countries in each of the six WHO regions; developing effective medicines regulation; maximizing the impact of WHO clinical guidelines; helping countries respond to the impact of trade on their pharmaceutical sector; promoting safe and effective use of traditional medicine; and monitoring WHO's work in essential drugs and medicines policy.

WHO's current priority in medicines is to expand access to essential medicines, particularly for low-income and disadvantaged populations and for the priority diseases of HIV/AIDS, TB, and malaria. Considerable progress is being made on drug selection and drug pricing. Greater focus is being put on financing, supply systems, and quality assurance, areas in which effective work with countries and partnerships with other international organizations, aid agencies, and NGOs are crucial for achieving sound, sustainable results.

OUR GOAL

Our vision is 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.

WHO's goal in medicines is to help save lives and improve health by ensuring the quality, efficacy, safety and rational use of medicines, including traditional medicines, particularly for the poor and disadvantaged.

The challenge for WHO in 2004-2007 is to continue to interpret the concept of essential medicines via a strategy and activities that reflect both the ongoing issues and the current high profile issues around access to, financing, and quality of medicines.

This document sets out the WHO Medicines Strategy for the years 2004-2007. The title of the document acknowledges the fact that all the activities should benefit countries, which remain at the core of our work. *Countries at the core* expresses the current wider vision of WHO as well as acknowledging the fact that over the past 25 years the activities of the Essential Drugs and Medicine Policy (EDM) department have been focused on countries.

The *WHO Medicines Strategy 2000-2003* (WMS 2000-2003) was anchored in WHO's constitution and the numerous resolutions adopted by the World Health Assembly (WHA) which have guided WHO's work in the medicines area for

many years. In May 2001 the WHA endorsed the WMS 2000-2003 (Resolution WHA54.11). Progress in the implementation of WMS 2000-2003 has been measured by a set of 26 indicators. For most of these, indicator status as of 1999 was included, against which targets for 2003 were set. Table 5 in chapter 4 sets out the new indicators for the latest Strategy, together with the status as of 1999 and 2003, where available, and the new targets for 2007.

The *WHO Medicines Strategy 2004-2007* (WMS 2004-2007) is an update of WMS 2000-2003. It is the result of a global WHO consultation exercise involving WHO headquarters, regional offices, and country offices. It takes into account more recent WHA resolutions (WHA 55.14, May 2002, WHA 56.27, WHA 56.31, both May 2003) which consider the evolving international context. WHA 56.27 *“Intellectual property rights, innovation and public health”* requests WHO’s Director-General to support Member States in efforts to improve access to medicines “in the exchange and transfer of technology and research findings... in the context of paragraph 7 of the Doha Declaration” and to “monitor and analyse the pharmaceutical and public health implications of relevant international agreements...” WHA 56.31 *Traditional Medicine*, requests WHO to facilitate

the work of Member States “in formulating national policies and regulations on traditional medicine and complementary and alternative medicine.”

PROGRESS IN 2000-2003

The WHO Medicines Strategy 2000-2003 was based on four core objectives: (1) promoting the formulation, implementation, and monitoring of [national drug policies](#) as guides to coordination of action by all stakeholders, (2) expanding [access to essential medicines](#) through improvements in financing and supply systems, (3) improving the [quality and safety](#) of medicines through strengthening of norms and standards and through support for effective regulation and information exchange, and (4) promoting [rational use of medicines](#) by health professionals and consumers in the public and private sectors.

Progress in 2002-2003 has been tracked through a set of country progress indicators, which are detailed below in [Table 3](#). Specific country, regional, and global achievements are described in the annual reports for Essential Drugs and Medicines Policy¹, Essential Drugs in Brief,² and the reports to the World Health Assembly³. Some examples of these achievements include:

- [Country support](#) in essential medicines, tailored to the priorities of each country, provided to over 120 countries, with intensive support to over 20 countries, and documented improvements in access, quality, and rational use of medicines.
- [Implementation of a global system for monitoring country progress](#) and launch of a targeted assessment package for monitoring access to medicines, used in over 20 countries, which includes household surveys on access to and use of medicines.
- [Launch of the WHO Traditional Medicines Strategy](#) to support safe and informed use of traditional and complementary medicine and protect traditional knowledge.
- [Provision of systematic guidance on the impact of trade liberalization and globalization on access to medicines](#), focusing on bilateral, regional, and international trade agreements, in particular the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

- Intensive work on access to medicines for HIV/AIDS, TB, malaria, and other priority diseases, with a focus on selection, regulation, quality assessment, prices, and monitoring of trade agreements.
- Expansion of information on comparative medicine prices worldwide and development of a new price survey methodology to help health systems and consumers become more informed buyers of quality medicines.
- Launch of the first global training programme on GMP to improve the quality of medicines production worldwide.
- Creation of a programme for quality assessment for priority products (prequalification) which now covers HIV/AIDS, TB, and malaria.
- Expansion of the WHO International Programme for Monitoring Drug Safety, which also marked its 25th year and now extends to 72 countries.
- Revision of the essential medicines selection process to ensure a more evidence-based, independent, and transparent process. Reasons for selection are published on the WHO Medicines Library website, together with comparative information on prices and the WHO Model Formulary.
- Development of comprehensive training programmes on rational use of medicines, including programmes on problem-based therapy, rational use in community prescribing, pharmacoconomics, and drugs and therapeutics committees.
- Launch of a campaign to raise awareness about the dangers of counterfeit and substandard medicines.

OBJECTIVES AND EXPECTED OUTCOMES FOR 2004-2007

The WMS 2004-2007 retains the same **four objectives** as the previous strategy, but divides expected outcomes into **seven components**. These objectives and components reflect what is needed in countries to achieve the essential medicines vision. WHO's work for the next four years is then defined in terms of support for countries to achieve these aims.

WHO MEDICINES STRATEGY 2004-2007

SUMMARY TABLE OF PLANNING ELEMENTS

OBJECTIVES	COMPONENTS	EXPECTED OUTCOMES IN COUNTRIES		
POLICY Commitment among all stakeholders to medicines policies based on the essential medicines concept, and to coordinated implementation, monitoring and evaluation of policies.	1 Implementation and monitoring of medicines policies Advocate and support the implementation and monitoring of medicines policies based on the concept of essential medicines. Monitor the impact of trade agreements on access to quality essential medicines. Build capacity in the pharmaceutical sector.	1.1	Medicines policies developed, updated and implemented taking into consideration health, development, and intersectoral policies	
	1.2	Implementation of medicines policy regularly monitored and evaluated		
	1.3	Public health aspects protected in the negotiation and implementation of international, regional, and bilateral trade agreements		
	1.4	Human resources capacity increased in the pharmaceutical sector		
	1.5	Promotion of innovation based on public health needs, especially for neglected diseases		
	1.6	Gender perspectives introduced in the implementation of medicines policies		
	1.7	Access to essential medicines recognized as a human right		
	1.8	Ethical practices promoted and anti-corruption measures identified and implemented in the pharmaceutical sector		
	2 Traditional medicine and complementary and alternative medicine Adequate support provided to countries to promote the safety, efficacy, quality, and sound use of traditional medicine and complementary and alternative medicine.	2.1	TM/CAM integrated into national health care systems where appropriate	
		2.2	Safety, efficacy, and quality of TM/CAM enhanced	
		2.3	Availability and affordability of TM/CAM enhanced	
		2.4	Rational use of TM/CAM by providers and consumers promoted	
	ACCESS Equitable financing, affordability and delivery of essential medicines in line with Millennium Development Goals, Target 17.	3 Fair financing mechanisms and affordability of essential medicines Guidance provided on financing the supply and increasing the affordability of essential medicines in both the public and private sectors.	3.1	Access to essential medicines improved, including medicines for HIV/AIDS, malaria, TB, childhood illnesses and noncommunicable diseases
			3.2	Increased public funding of medicines promoted along with cost containment mechanisms
3.3			Increased access to medicines through development assistance, including the Global Fund	
3.4			Medicines benefits promoted within social health insurance and pre-payment schemes	
3.5			Medicine pricing policies and exchange of price information promoted	
3.6			Competition and generic policies implemented	
4 Medicines supply systems Efficient and secure systems for medicines supply promoted for both the public and private sectors, in order to ensure continuous availability of essential medicines.		4.1	Supply systems assessed and successful strategies promoted	
		4.2	Medicines supply management improved	
		4.3	Local production assessed and strengthened, as appropriate and feasible	
		4.4	Good procurement practices and purchasing efficiency improved	
		4.5	Public-interest NGOs included in national medicine supply strategies, where appropriate	

OBJECTIVES	COMPONENTS	EXPECTED OUTCOMES IN COUNTRIES	
<p>QUALITY AND SAFETY</p> <p>The quality, safety and efficacy of all medicines assured by strengthening and putting into practice regulatory and quality assurance standards</p>	<p>5</p> <p>Norms and standards for pharmaceuticals</p> <p>Global norms, standard, and guidelines for the quality, safety, and efficacy of medicines strengthened and promoted.</p>	5.1	Pharmaceutical norms, standards, and guidelines developed or updated
	<p>6</p> <p>Medicines regulation and quality assurance systems</p> <p>Instruments for effective drug regulation and quality assurance systems promoted in order to strengthen national drug regulatory authorities.</p>	5.2	Medicines nomenclatures and classification efforts continued
		5.3	Pharmaceutical specifications and reference materials developed and maintained
		5.4	Balance between abuse prevention and appropriate access to psychoactive substances achieved
		6.1	Medicines regulation effectively implemented and monitored
		6.2	Information management and exchange systems promoted
		6.3	Good practices in medicine regulation and quality assurance systems promoted
		6.4	Post-marketing surveillance of medicine safety maintained and strengthened
		6.5	Use of substandard and counterfeit medicines reduced
	6.6	Prequalification of products and manufacturers of medicines for priority diseases and quality control laboratories, as appropriate, through procedures and guidelines appropriate for this activity	
6.7	Safety of new priority and neglected medicines enhanced		
6.8	Regulatory harmonization monitored and promoted, as appropriate, and networking initiatives developed		
<p>RATIONAL USE</p> <p>Therapeutically sound and cost-effective use of medicines by health professionals and consumers</p>	<p>7</p> <p>Rational use by health professionals and consumers</p> <p>Awareness raising and guidance on cost-effective and rational use of medicines promoted, with a view to improving medicines use by health professionals and consumers.</p>	7.1	Rational use of medicines by health professionals and consumers advocated
		7.2	Essential medicines list, clinical guidelines, and formulary process developed and promoted
		7.3	Independent and reliable medicines information identified disseminated and promoted
		7.4	Responsible ethical medicines promotion for health professionals and consumers encouraged
		7.5	Consumer education enhanced
		7.6	Drug and therapeutics committees promoted at institutional and district/national levels
		7.7	Training in good prescribing and dispensing practices promoted
		7.8	Practical approaches to contain antimicrobial resistance developed based on the WHO Global Strategy to contain Antimicrobial Resistance
		7.9	Identification and promotion of cost-effective strategies to promote rational use of medicines

Figure 3:
Ensuring access to essential medicines requires a coordinated set of actions



PRIORITIES FOR 2004-2007

The central priority for 2004-2007 remains that of expanding access to essential medicines, one of the health-related MDGs to which the international community is committed. To achieve this goal, WHO will emphasize access to all essential medicines, including those for HIV/AIDS, TB, malaria, and childhood illness.

Ensuring access to essential medicines depends on success in putting in place the four key pieces of the access puzzle: rational selection, affordable prices, sustainable financing, and reliable health supply systems (Figure 3). Work in this area will include analysis of effective drug supply strategies, including supply services operated by faith-based organizations.

Within the overall objective of access, WHO will give the greatest attention to scaling up access to ARVs to meet the WHO target of ensuring that 3 million people in developing countries have access to treatment for HIV/AIDS by 2005.

New and continued priorities in the area of national medicines policies include:

- implementation of the WHO Traditional Medicine Strategy
- promotion and monitoring of access to essential medicines as a human right
- greater attention to innovation to ensure the development of new medicines for neglected diseases and other priority needs
- ensuring a public health-oriented approach to national implementation of trade agreements
- promoting a stronger ethical dimension in the pharmaceutical sector, including the use of anti-corruption measures.

Finally, during 2004-2007 increased attention will be given to medicines safety through expanded safety monitoring and continued strengthening of quality assurance.

COMPONENTS OF THE STRATEGY



COMPONENT 1

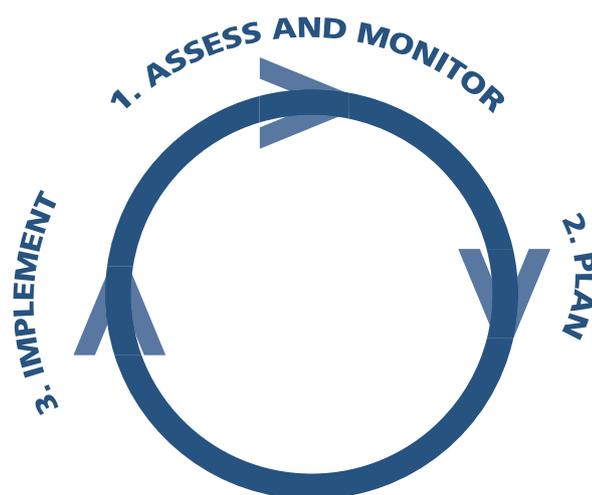
NATIONAL POLICIES ON MEDICINES

National medicines policies (NMPs) are commitments to goals and guides for action. They provide frameworks within which priorities are set, the activities of the pharmaceutical sector can be coordinated, and legislation developed to support public health needs. They cover both the public and the private sectors and involve all the main actors in the pharmaceutical field. While recognizing that each country's situation is unique, WHO proposes⁴ that the general objectives of medicines policies should be to ensure:

- Access: equitable availability and affordability of essential medicines
- Quality: quality, safety, and efficacy of all medicines
- Rational use: therapeutically sound and cost-effective use of medicines by health professionals and consumers.

A NATIONAL MEDICINES POLICY:

- presents a formal record of values, aspirations, aims, decisions, and medium- to long-term government commitments
- defines the national goals and objectives for the pharmaceutical sector, and sets priorities
- identifies the strategies needed to meet those objectives, and the various actors responsible for implementing the main components of the policy
- creates a forum for national discussions on these issues.



The policy *process* is just as important as the policy *document*. A systematic approach to the policy process includes assessment of the pharmaceutical situation, planning a strategy based on the results of this assessment, implementation of the strategy, and ongoing monitoring. Assessment and monitoring of the pharmaceutical situation are vital in order to identify strengths and weaknesses, determine priority health needs, track progress, coordinate donor support, and raise funds. Data gathered during assessments should be used to inform policy plans. The planning process should involve all key stakeholders. Working together to define objectives, set priorities, and develop strategies helps ensure joint ownership of plans and the commitment of key stakeholders — a critical need in view of the national effort necessary for implementation.

Although many countries have adopted and revised NMPs, not all of them have succeeded in systematically implementing these policies and monitoring them effectively or ensuring that they are tailored to national health priorities. New challenges are also arising. For instance, the impact of international, regional, and bilateral trade agreements on access to medicines needs to be carefully monitored to safeguard public

health. Other challenges include increasing the human resource capacity in the pharmaceutical sector, promoting innovation of medically needed new medicines for neglected diseases and other public health priorities, addressing gender differences in access and rational use of medicines, promoting the recognition of access to medicines as a human right, and promoting ethical practices and anti-corruption measures in the pharmaceutical sector.

In defining the expected outcomes for WHO Medicines Strategy 2004-2007, WHO will advocate for and support the implementation and monitoring of medicines policies based on the concept of essential medicines; will monitor the impact of trade agreements on access to quality essential medicines; and will build capacity in the pharmaceutical sector.

EO 1.1

Medicines policies developed, updated, and implemented, taking into consideration health, development, and intersectoral policies to achieve maximum impact

Rationale

Experience in many countries has shown that issues relating to medicines are best addressed within a common policy framework. Effective NMPs improve access and rational use of quality essential medicines. WHO recommends that all countries formulate and implement comprehensive NMPs, within the framework of a particular health care system, a national health policy and, where appropriate, a programme of health sector reform. The goals of NMPs should be consistent with broader health objectives and their implementation should help attain those objectives.

Progress

In 2001, WHO revised and updated its publication on *How to develop a national drug policy*. Over the past two years, over 120 countries have been supported in the development, updating, and implementation of NMPs. In response to WHO's Questionnaire on Structures and Processes of Country Pharmaceutical Situations, 98 out of 131 countries reported having a NMP⁵.

The Essential Drugs Monitor, which has reported on the findings of numerous country case studies on different aspects of the development and implementation of NMPs, continues to provide an invaluable resource for Member States.

Whilst the number of countries with NMPs is impressive, many of these were developed, of necessity, as 'stand alone' policies. There is now a need to update these NMPs, in consultation with key stakeholders, to take account of changing health, development and intersectoral policies. Meanwhile, in some countries, NMPs exist on paper but have not been disseminated, implemented or monitored in a systematic manner.

Meeting the challenges in 2004-2007

Over the next four years WHO will:

- advocate for and support the development of NMPs and associated implementation plans, including plans for ongoing monitoring.
- support countries in their efforts to review their NMPs and to integrate them into wider health and intersectoral policies and programmes.
- encourage strengthened collaboration between ministries of health and other key stakeholders in the development and review of NMPs, through ensuring ownership and commitment to NMPs and implementation strategies.
- Commission articles for the Essential Drugs Monitor outlining country experiences in the development and implementation of NMPs as a means of sharing global knowledge.

OUTCOME INDICATORS	1999		2003		2007	
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with an official national medicines policy document – new or updated within the last 10 years	67/152	44%	55%	62/123	50%	59%
No. of countries with a national medicines policy implementation plan – new or updated within the last 5 years	41/106	39%	43%	49/103	48%	61%

EO 1.2

Implementation of medicines policy regularly monitored and evaluated, providing data that can be used in adjusting policy and interventions to improve access to medicines

Rationale

As an integral part of a NMP, a system for monitoring and evaluation is a constructive management tool that enables ongoing assessment of progress, and contributes to the necessary management decisions, policy development or reform. Standards can be set and comparison made between countries, areas, and facilities, as well as over time — providing evidence-based information on progress.

There is also a need to measure household access to medicines. While indicators measured at facility/provider level have proved to be useful, the household survey is an important tool to obtain accurate information on how a population group is accessing and using the medicines it needs.

Progress

A WHO survey package has been developed for monitoring and assessing pharmaceutical situations through the use of measurable indicators. Until recently, efforts by countries to monitor their pharmaceutical situation were hampered by the lack of time and resources needed to carry out training, gather data in the field, and analyse the results. The new tool, together with a detailed guide on how to carry out technical preparation, training and field surveys, has been used in 22 countries — resulting in savings in both time and cost. The system and process has evolved into a practical tool that can be used in countries. The surveys have provided a wealth of information on issues such as access, rational use, and medicines supply systems.

Results from Bulgaria and the Philippines have shown the value of repeating monitoring and assessment at different points in time. In the Africa Region, active involvement of health ministry personnel in the data collection teams has been an impetus to review country pharmaceutical action plans and to direct activities to priority areas identified in the survey. In Nepal, the survey package, including the household survey,

is to be adapted as a regular monitoring tool. In addition, several countries in the Americas Region included in the European Commission (EC)-WHO joint programme will undertake baseline country surveys.

WHO is also developing a quantitative household survey package that covers health-seeking behaviour and the affordability, availability, source, and appropriate use of medicines. Household surveys have been carried out in several African countries and in Nepal.

Challenges

One of the key challenges is to persuade countries and donors to recognize that investment of time and finances in monitoring and evaluation is worthwhile. It is important that all countries carrying out monitoring and assessment do so by using or adapting the current survey tool. The use of a fixed set of key indicators is vital to ensure that repeated and comparable monitoring can be carried out. While qualitative and descriptive assessment can be useful, it should not replace the need to qualitatively measure actual impact.

Another challenge is to find ways of moving beyond data analysis to discussion, presentation of results to different groups in the country as evidence for use in planning, and identification and prioritization of strategies. Clear presentation of data and information has proved to be valuable in generating debate and in-depth discussion to identify what action is needed.

A third challenge is the need to balance available resources and local capacity to undertake the survey, including adequate training in gathering survey data. Conducting surveys at the household level is a complex task. Quantitative and qualitative questionnaires need to be carefully structured in order to obtain reliable information from respondents. There is also a need to ensure appropriate and manageable sampling.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- further refine and promote the monitoring and data collection tools to develop an evidence-based approach to policy development.
- provide support, where requested, to promote the process of monitoring and evaluation and assist governments in developing a regular monitoring process appropriate to country needs and available human and financial resources.
- promote innovative methods for training country staff or other concerned groups who can assist the government in efforts to gather data from health facilities and households.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries having conducted a national assessment of their pharmaceutical situation in the last 4 years	na	na	na	47/90	52%	58%

EO 1.3**Public health aspects protected in the negotiation and implementation of international, regional, and bilateral trade agreements through inter-country collaboration and legislative steps to safeguard access to essential medicines****Rationale**

WHO supports the use of measures to protect public health and promote access to medicines, consistent with the provisions of the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health. The Doha Declaration (paragraph 4) affirmed that the TRIPS Agreement “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health, and in particular, to promote access to medicines for all”. The Doha Declaration was agreed after intense debate about the implications of intellectual property rights on public health and access to medicines.

Mindful of such concerns about the current patent system, especially as regards access to medicines in developing countries, the 56th World Health Assembly (WHA) urged Member States to consider adapting national legislation in order to use to the full the flexibilities contained in the TRIPS Agreement. The WHA further noted that in order to tackle new public health problems with international impact — such as the emergence of severe acute respiratory syndrome (SARS) — access to new medicines with potentially therapeutic effect, and to health innovations and discoveries should be universally available without discrimination.

Progress

The Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines is coordinated by four WHO Collaborating Centres, with additional input from appropriate experts. The Network has developed indicators and an assessment tool published in 2004 on the basis of field tests. To date, assessments have been completed in 11 countries in East Asia, Eastern Europe, and Latin America^{7 8}.

WHO PERSPECTIVES ON ACCESS TO MEDICINES⁶

Access to quality essential medicines is a human right

Affordability of essential medicines is a public health priority

Essential medicines are not simply another commodity; TRIPS safeguards are crucial

Patent protection has been an effective incentive for research and development of new medicines

Patents should be managed in an impartial way, protecting the interests of the patent holder, as well as safeguarding public health principles

Countries should assess the public health impacts of the TRIPS Agreement before introducing requirements more stringent than the TRIPS requirements (“TRIPS-plus”) in national legislation or as a part of regional or bilateral trade agreements or extending TRIPS requirements to non-WTO members

Figure 4:
WHO policy and technical support on TRIPS to over 70 countries



Challenges remaining

In many countries, especially low-income countries, there is insufficient awareness, implementation, and assessment of the provisions in international, regional, and bilateral trade agreements that can be used to safeguard access to essential medicines.

Meeting the challenges in 2004-2007

Over the next four years WHO will:

→ Support countries in their efforts to improve access to medicines, including through direct country support and technical assistance on the use of flexibilities and safeguards in their national legislation in accordance with the Doha Declaration.

→ Cooperate with countries to ensure effective implementation of the August 30 Decision, of the WTO General Council^a and to promote a permanent solution that is simple and workable, to help WTO members with insufficient or no manufacturing capacity in the pharmaceutical sector to make effective use of compulsory licensing under the TRIPS Agreement.

→ Monitor and provide independent data and analysis on the pharmaceutical and public health implications of relevant international agreements, including WTO and other trade agreements, in order to assist countries in the effective assessment and development of pharmaceutical and health policies and regulatory measures that maximize the positive and mitigate the negative impact of such agreements.

OUTCOME INDICATORS	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries integrating TRIPS Agreement flexibilities into national legislation to protect public health	na	na	na	32/105	30%	45%

EO 1.4

Human resources capacity increased in the pharmaceutical sector through education and training programmes to develop capacity and to motivate and retain personnel in sufficient numbers within a clearly defined and organized structure

Rationale

Effective medicines policy implementation can only be achieved when appropriate numbers of well-trained and motivated pharmaceutical staff are employed and functioning in an efficient way. Motivation arises as a result of an effective policy, a clear understanding of the rationale and objectives of the policy, adequate remuneration for work, well-defined roles and responsibilities, and clear standards for performance.

Progress

In 2002 alone, WHO support to countries included the training of nearly 900 health professionals in: medicines regulation, quality assurance, and anti-counterfeit activities; rational use of medicines by health professionals; public sector medicines supply; national medicines policy development and monitoring; the impact of trade agreements on access to medicines; medicines financing and pricing; improving medicines use by consumers; and establishment of pharmaceutical norms and standards⁹. These training programmes were held in all six WHO regions, in English, French, and Spanish.

Challenges remaining

In many countries, policy implementation is constrained by the lack of sufficient numbers of adequately trained and motivated pharmaceutical staff and difficulties in retaining trained staff. In some sub-Saharan countries there are less than 10 pharmacists in the public service. In addition, other health professionals are not adequately educated about the essential medicines concept, which is central to understanding and implementing a national medicines policy. Although WHO offers a number of training courses, the challenge is to ensure that courses are integrated into larger strategies to build human capacity in pharmaceuticals, that appropriate participants are identified and selected, and that they receive follow-up support.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- provide technical assistance to governments with severe staff shortages to help them address key policy issues (including support in the development of strategies to train and retain pharmaceutical staff and to improve the knowledge of all health professionals in the concept of essential medicines).
- work with universities to ensure the integration of the essential medicines concept in curricula for health professionals.
- maximize the impact of WHO training courses through: ensuring that courses fit into broader strategies to increase human resource capacity in pharmaceuticals; courses are focused on relevant topics, regularly updated, and available in the appropriate languages; participants are carefully selected and receive follow-up support.

Figure 5: Medicines training for health professionals in 2001



- 1 Access to essential medicines** – medicines policy issues, pharmacoconomics, drug management
- 2 Medicines quality** – good manufacturing practices, TB drug quality, combating counterfeit drugs, good laboratory practices, managing the analytic laboratory, thin layer chromatography
- 3 Medicines regulation** – basic training, computer-assisted registration, good clinical practice
- 4 Monitoring medicines safety and use** – pharmacovigilance, the study of adverse reactions, anatomical therapeutic chemical classification system/defined daily doses
- 5 Rational use of medicines** – promoting rational drug use, teaching rational pharmacotherapy, promoting rational drug use in the community, drugs and therapeutics committees, data analysis for rational use research

OUTCOME INDICATORS	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries that provide both basic and continuing education programmes for pharmacists	54/85	64%	na	34/110	31%	35%

EO 1.5**Promotion of innovation based on public health needs, especially for neglected diseases through policies and actions creating a favourable environment for innovation of medically needed new medicines****Rationale**

Most medicines development is carried out by the R&D-based pharmaceutical industry and the selection of products is driven largely by market demand. As a result, medicines for some diseases and health conditions are neglected because no viable market currently exists for these products.

WHO estimates that over 95% of global investments in drug development today are targeted to the medical needs of the richest 20% of the world's population. By contrast, only 1% of the drugs developed over the last 25 years were for tropical diseases, and TB, diseases that together account for over 11% of global disease burden.

The lack of investment in medicines R&D for diseases of public health importance has a major impact on health, especially in low-income countries. For example, there is a shortage of effective, safe, and affordable health technologies that can be used to reduce the burden of parasitic and infectious diseases in low- and middle-income countries. New medicines are also needed to replace toxic treatments for trypanosomiasis (sleeping sickness) and leishmaniasis, to combat drug-resistant malaria and TB, and to treat some diseases that are as yet untreatable.¹⁰ These neglected diseases cause high mortality and morbidity, mainly among the poor, who have little purchasing power. Moreover, the few medicines, diagnostics, and vaccines that do exist for neglected diseases are often too complicated to use in rural environments.

Other 'pharmacological gaps' with considerable public health impact include: the lack of safe and effective medicines for some high-burden diseases (Alzheimer's disease and some forms of cancer) for which scientific approaches are lacking; lack of investment in R&D for low-prevalence diseases (e.g. cystic fibrosis) or for mainly low-income markets (e.g. TB and malaria); lack of safety and efficacy R&D on the use of medicines among specific groups (e.g. pregnant women); and lack of user-friendly and appropriate formulations of drugs for specific groups (e.g. children and the elderly), which cause difficulties in dosing and administration.

There is a need for public funding for R&D to address these pharmacological gaps which have a considerable public health impact. This calls for careful and transparent prioritization of treatment needs, on the basis of sound epidemiological information, clear public health criteria, and wide consultation.

Progress

WHO has initiated work on developing a methodology to prioritize research based on disease burden and an assessment of the pharmaceutical gap. This builds on the work of the Global Forum for Health Research and the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR).

Meeting the challenges in 2004-2007

Over the next four years WHO will:

- work with other partners to establish a medicines development agenda based on priority public health needs and develop a systematic methodology for this together with an initial list of recommendations for public investment in medicines R&D. Wherever possible, the public health justification will be supported by pharmacoeconomic analysis of the potential benefits. Work on the agenda will include efforts in Europe to identify potential research needs which are relevant for both countries in economic transition (including several new EU members) and for developing countries.
- seek to identify better delivery mechanisms and improved formulations for existing preventive and therapeutic medicines.

Many developing countries and countries in transition lack the capacity to undertake research to determine priority public health needs. Public-private partnerships such as the Medicines for Malaria Venture, Global Alliance for TB Research, and the Drugs for Neglected Diseases Initiative offer models for collaboration between public institutions in the North and South to address neglected diseases.

The lack of regulatory capacity in developing countries for scientific assessment of new drug applications for public health priority diseases remains a challenge. In parallel with capacity building in developing countries, alternative regulatory pathways and mechanisms for scientific assessment should be elaborated and implemented in partnership with national regulatory authorities from both developing and developed countries.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries promoting research and development of new active substances	na	na	na	21/114	18%	22%

EO 1.6

Gender perspectives introduced in the implementation of medicines policies by identifying gender differences in access to and rational use of medicines, and by supporting women in their central role in health care

Rationale

While access to essential medicines is a problem for both women and men in many parts of the world, in some countries gender-related barriers in access to health services and medicines are greater for women than men due to social and cultural factors. For example, although women have a central role as health care providers for the family, they do not always control the family income and may not be able to decide for themselves when they need to seek health care or purchase medicines. In addition, their disproportionate share of work within the household, including growing the food, collecting water and fuel, and caring for the family, limits the time available to seek health care services. As a result, they often fail to see help until their illness is at a critical stage.

To address these inequalities between women and men, WHO recommends that countries should introduce a gender perspective in their medicines policy.¹¹ NMPs should: ensure that the needs of both women and men are addressed in an equitable way; facilitate women's access to health; support women and women's organizations in their central role in providing health care in their home and communities; and provide adequate education and means to ensure that women purchase the appropriate medicines and use them rationally.

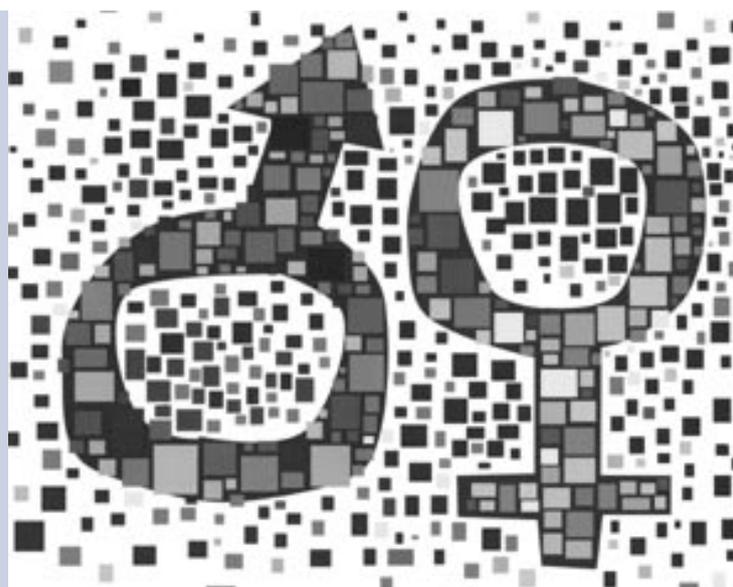
Progress

Over the past few years, WHO has been active in promoting a focus on gender in the MDGs, particularly those relating to the education of boys and girls and to other health-related goals where gender may have an impact. WHO has also been reporting gender disparities for various health topics through a series of publications entitled *Gender and Health*¹². These information sheets describe and analyse the information available, the areas where more research is needed, and the policy implications. The existing information sheets cover a wide range of health problems from road traffic injuries to blindness and TB.

Challenges remaining

Despite the availability of much data on access to and use of medicines, there is a lack of data disaggregated by sex and of gender-sensitive studies on these issues. Several indicators included in the WHO survey package for assessing the pharmaceutical situation at country level now differentiate the sex of the population surveyed. However the sample size of the various surveys is still too small to draw any significant conclusions about gender-related issues.

Inequalities between women and men remain a major obstacle to the social and economic development of many countries. Three-fifths of the 115 million children currently out of school are girls, and two-thirds of the 876 million illiterate adults are women.¹³



Meeting the challenges 2004-2007

Over the next four years WHO will:

- work with countries, academic institutions, and NGOs to adapt existing pharmaceutical monitoring tools for collecting sex-disaggregated data and promote gender-sensitive studies on access to and use of medicines.
- develop policy guidance to support the introduction of a gender perspective in medicines policies, aimed at reducing gender inequalities and improving women's access to and use of medicines.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries providing free medicines for pregnant women at primary public health facilities	na	na	na	54/106	51%	60%

Figure 6:
National recognition of the right to health



Source: Kinney ED, "The International Human Right to Health: What Does This Mean for our Nation and World?" in *Indiana Law Review*, Vol 34, 2001, page 1465.

EO 1.7

Access to essential medicines recognized as a human right via advocacy and policy guidance to recognize and monitor access to essential medicines as part of the right to health

Rationale

The right to health is referred to in the opening paragraph of the WHO Constitution. It has also been recognized in many global and regional human rights treaties, such as the International Covenant on Economic, Social and Cultural Rights (ICESCR) which has been signed by over 140 countries. In the authoritative General Comment No.14 (2000) by the Committee on Economic, Social and Cultural Rights, the right to health facilities, goods, and services in article 12.2.(d) of the Covenant is understood to include, *inter alia*, the appropriate treatment of prevalent diseases, preferably at community level, and the provision of essential drugs *as defined by WHO*. While the Covenant provides for progressive realization and acknowledges the limits of available resources, State parties have an immediate obligation to

guarantee that the right to health will be exercised without discrimination of any kind, and to take deliberate and concrete steps towards its full realization.

Progress

All countries in the world have signed at least one of the international treaties that confirm the right to health as a human right (Figure 6); and 109 countries have included the right to health in their constitution. In an increasing number of countries, especially in Latin America but also in Thailand and South Africa, individuals or NGOs have initiated and won constitutional court cases, demanding from their government the equitable realization of the right to health — for example, winning universal access to certain types of essential medicines.

Within the UN system, a Special Rapporteur on the Right to Health was appointed in 2001. The Special Rapporteur is working in close collaboration with WHO, with the aim of including regular reporting on equitable access to essential medicines as part of the obligatory five-year reporting by State parties to the International Covenant.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- advocate a rights-based approach as one additional means to promote access to essential medicines, by collecting and disseminating information on successful activities in developing countries and by formulating and providing practical advice to individuals and NGOs active in this field.
- continue to collaborate with the UN Special Rapporteur on the Right to Health to promote regular reporting on access to essential medicines within standardized reporting systems on the progressive realization of the Right to Health.

Challenges remaining

Not all countries have recognized the right to health in their national constitution, and many countries lack the means to ensure that the right of access to essential medicines is fulfilled. But even where resources are limited, not all countries recognize that they have an obligation to distribute equitably and without discrimination, and with special consideration for the poor and disadvantaged, whatever health services are possible within their means. An additional challenge is that many countries do not gather any data on gender- or income-related access to essential medicines.

OUTCOME INDICATORS	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries that provide HIV/AIDS-related medicines free at primary public health facilities	na	na	na	60/104	58%	65%

EO 1.8

Ethical practices promoted and anti-corruption measures identified and implemented in the pharmaceutical sector using the experience of successful programmes addressing aspects of corruption encountered in the pharmaceutical sector

Rationale

The 'medicines chain' includes many different steps starting from R&D and ending with the consumption of the medicine by the patient. Each step needs to be protected from unethical or corrupt practices to ensure that patients not only have the medicine they need, but also that the medicine is safe, of good quality, has a fair price, and has not been purchased as a result of undue commercial influence.

The commercial reality of the pharmaceuticals market continues to tempt the many different actors involved, both in the public and private sector, to test its ethical limits. This may be the result of intentional mismanagement by an individual, but also of the inability of individuals

Figure 7: Different measures of success



to identify and manage in an ethical manner a conflict of interest that may arise while interacting with other institutions.

The gap between public health and commercial objectives in the pharmaceutical sector is well illustrated by the way success is measured within the public health arena and the pharmaceutical industry (Figure 7).

Progress

WHO has addressed some ethical practices in the pharmaceutical sector. These include the development of ethical criteria for medicines promotion and advocating that patents should be managed in an impartial way, protecting the interests of the patent-holder as well as safeguarding public health principles¹⁴. WHO has also advocated responsible practices in the donation of medicines (see also EO 6.7, 7.4).

In addition, WHO has initiated a dialogue between international experts, NGOs, and the international pharmaceutical industry in an effort to work together to fight corruption that hinders access to medicine in Latin America and the Caribbean. In 2000, the WHO Regional Office for the Americas and the World Bank organized a workshop on ethical business practices, which addressed the issue of corruption in the pharmaceutical sector.

Challenges remaining

Many examples of corruption and lack of ethical practices in the pharmaceutical arena are reported in the press and in scientific journals¹⁵. They are also highlighted by organizations such as Transparency International, a non-profit NGO which aims to curb corruption^{16 17}.

Figure 8 summarizes some of the ethical issues encountered throughout the medicines chain.

The results of these unethical practices include reduced quality of health care, shortages of medically needed medicines and medical supplies, unsafe and poor quality products on the market, financial losses for health care systems due to irrational use of medicines through unethical promotion, and the undermining of public trust in science.

Meeting the challenges 2004-2007

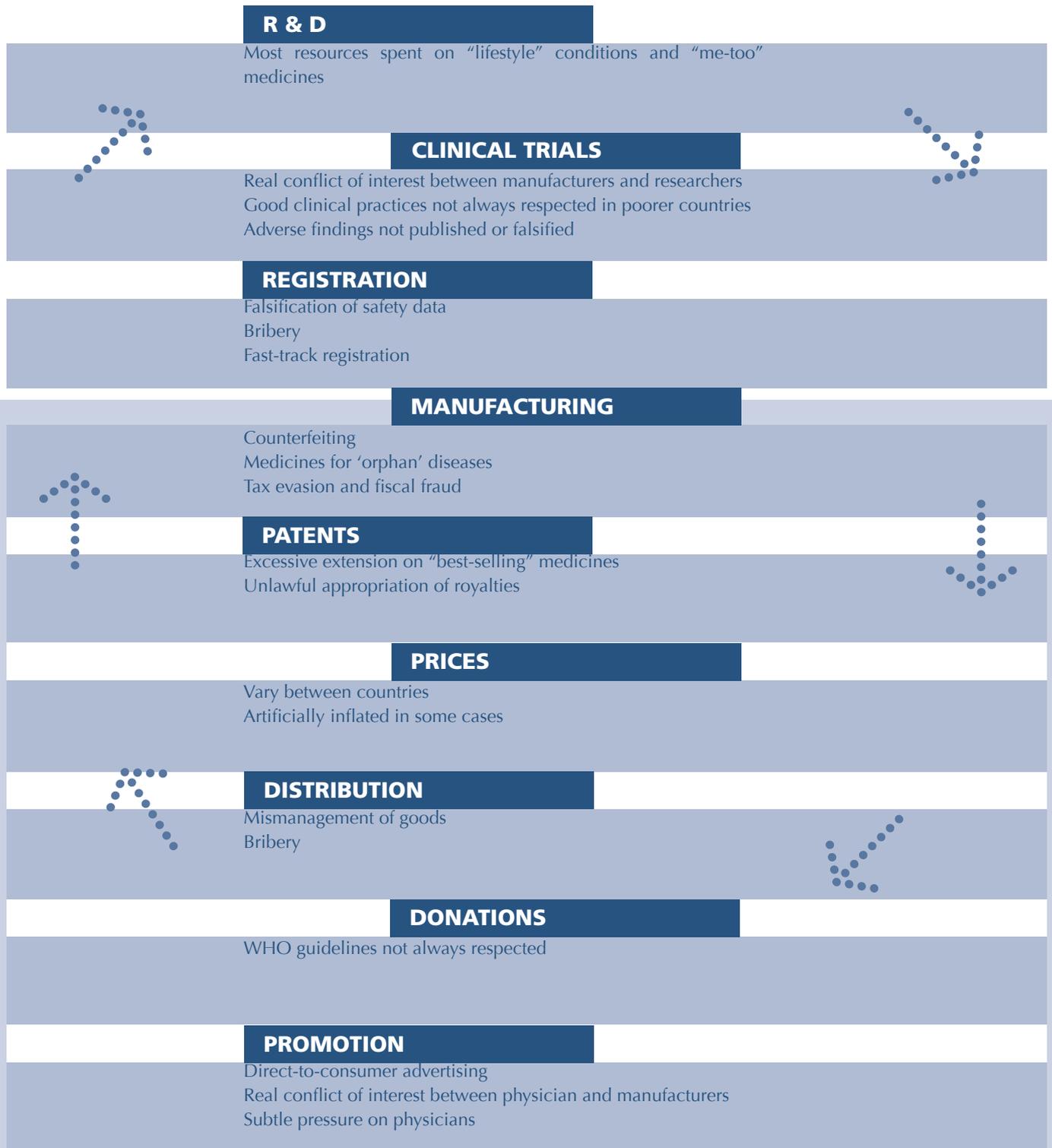
Over the next four years WHO will:

- work with countries and partners to identify successful programmes which have tackled corruption and conflict of interest in the pharmaceutical sector.
- based on the results obtained, develop a programme for public health officials to enable them to identify and manage conflict of interest in their interactions with commercial enterprises and civil society organizations (CSOs).
- continue to promote the implementation of ethical practices in specific pharmaceutical sector areas where relevant, relying also on guidelines issued by other impartial organizations.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with medicines legislation requiring transparency, accountability and code of conduct for regulatory work	na	na	na	84/114	74%	80%

Figure 8:
Challenges are present at every stage in the medicines chain



COMPONENT 2

NATIONAL POLICIES ON TRADITIONAL MEDICINE AND COMPLEMENTARY AND ALTERNATIVE MEDICINE

Populations throughout the world use traditional medicine to help meet their primary health care needs. Traditional medicine^b (TM), which has many positive features, is a comprehensive term that covers a wide variety of therapies and practices — traditional, complementary or alternative medicine (TM/CAM) — which vary greatly from country to country and from region to region. It plays an important role in treating illnesses as well as improving the quality of life of those suffering from minor illness or from certain incurable diseases. In addition, global expenditure on TM/CAM is not only significant but growing rapidly.¹⁸

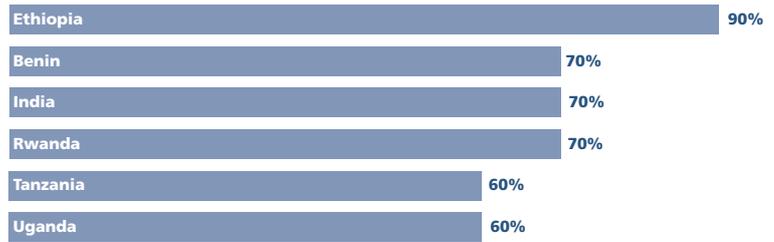
Member States have difficulty assuring the safety, efficacy, and quality of TM/CAM products and therapies due to the lack of national policy frameworks, appropriate legislative and regulatory measures, and education/training and qualification schemes for practitioners.

In 2002, in an effort to meet the growing challenges in the area of traditional medicine, WHO developed a comprehensive working strategy for TM for 2002-2005. The Strategy has four main objectives:

- To integrate relevant TM and/or CAM with national health care systems, as appropriate, by developing and implementing national policies and programmes.
- To promote the safety, efficacy, and quality of TM/CAM by expanding the knowledge base on the safety, efficacy, and quality of TM/CAM, and by providing guidance on regulatory and quality assurance standards.
- To increase the availability and affordability of TM/CAM, with an emphasis on access for poor populations.
- To promote the therapeutically sound use of appropriate TM/CAM by both providers and consumers.

In May 2003, the 56th World Health Assembly adopted a resolution on TM, which urges Member States, in accordance with established national legislation and mechanisms, to adapt, adopt, and implement the WHO Traditional Medicines Strategy as a basis for national traditional medicine programmes or work plans. It requests WHO to support Member States by providing internationally acceptable guidelines and technical standards, seeking evidence-based

Populations using traditional medicine for primary health care



Populations in developed countries who have used complementary and alternative medicine at least once

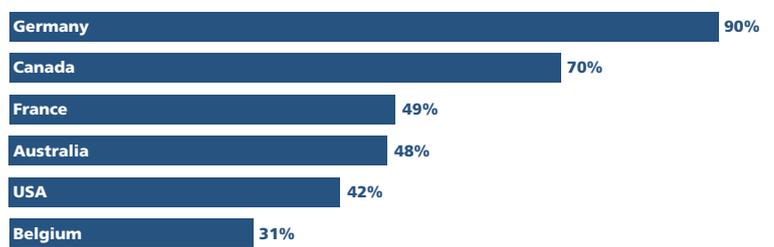


Figure 9: Use of traditional and complementary and alternative medicine

Sources: Eisenberg DM et al, 1998; Fisher P and Ward A, 1994; Health Canada, 2001; *BMJ*, 2002, 325.990; WHO, 1998; and government reports submitted to WHO.

information, and facilitating information sharing.¹⁹ WHO Regional Committees in AFRO, EMRO, SEARO, and WPRO have each discussed TM at recent sessions. The WHO Regional Committees for Africa, Eastern Mediterranean, South-East Asia, and Western Pacific adopted resolutions on TM in 2000, 2001, 2002 and 2003 respectively.

WHO's mandate is to provide adequate support to countries to promote the safety, efficacy, quality, and sound use of traditional medicine and complementary and alternative medicine.

EO 2.1

TM/CAM integrated in national health care systems where appropriate by developing and implementing national TM/CAM policies and programmes

Rationale

National medicines policies are the basis for: defining the role of TM/CAM in national health care systems; ensuring that the necessary regulatory and legal mechanisms are created for promoting and maintaining good practice; assuring the authenticity, quality, safety and efficacy of TM/CAM products and therapies; and providing equitable access to TM/CAM health care resources as well as information about them. In recognition of this, the WHA Resolution on TM urges Member States, where appropriate, to formulate and implement national policies and regulations on TM/CAM in support of proper use of traditional medicine, and its integration into national health care systems, depending on the circumstances in their countries.

Progress

Over the past four years, WHO has supported countries in their efforts to establish national policies on TM/CAM tailored to individual country needs. As a result, 39 countries now have a national policy on TM/CAM, compared with 25 countries in 1999, and 46 countries are either establishing or intend to establish a policy. In addition, WHO provided technical support in response to requests from Member States.

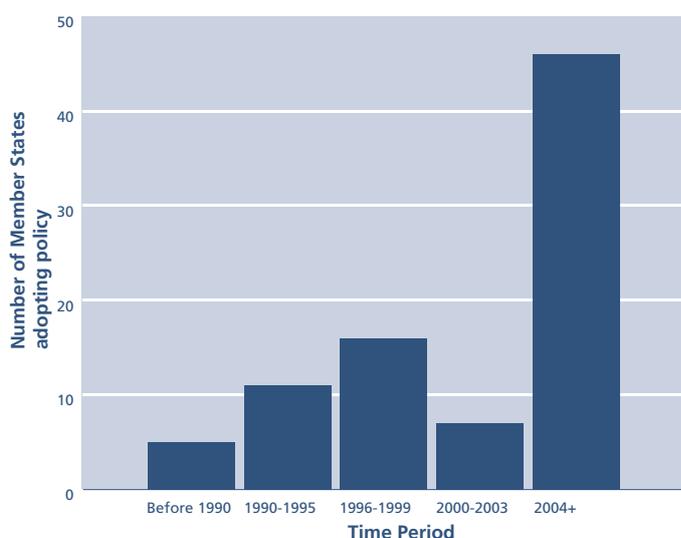
In the Western Pacific Region, for example, the WHO Regional Office organized a series of workshops to support countries in developing and formulating their national policy on TM, issued a document on the development of national policy on TM in 2000, and developed an action plan on TM in the Pacific Island States in 2001. In order to facilitate policy development, WHO

published a global review document on the *Legal status of traditional medicine and complementary/alternative medicine*.²⁰ This review includes information and data from 123 countries and is intended to help share their various experiences among Member States. In addition, in 2002-2003 WHO conducted a global survey on national policy on TM/CAM, in order to assess the current situation and identify individual country needs for technical assistance from WHO.

Challenges remaining

In many countries, efforts to establish a national policy and to ensure the regulation of TM/CAM medicine are hampered by the lack of: research and evidence-based information on TM/CAM; knowledge and understanding of TM/CAM, which differs greatly from Western medicine in its philosophy and approaches; and education/training and qualification schemes for practitioners. There is an urgent need for better information sharing and for evidence-based information to support Member States in efforts to develop national policies and regulation to assure the safety, efficacy, and quality of TM/CAM.

Figure 10:
Development of National Policy on TM/CAM



Source: Interim summary analysis of WHO global survey on national policy on traditional medicine and complementary/alternative medicine, 2002-2003

Meeting the challenges 2004-2007

Over the next four years WHO will:

- based on the findings of the global survey on national policy on TM/CAM in 2002-2003, analyse and review the current situation and identify the main difficulties faced by individual Member States in formulating the national policy and regulation; provide guidance on the development of national policies on TM; and facilitate information sharing among countries.
- provide intensive medium-term technical support to a selected number of interested countries to help formulate a comprehensive national policy/programme on TM/CAM and support its implementation.
- expand evidence-based information on quality, safety, and cost-effectiveness of TM/CAM in order to support Member States, where appropriate, in their efforts to integrate TM/CAM into national health care systems.

OUTCOME INDICATORS	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with national TM Policy ^c	25	na	na	39/127 ^c	31% ^c	37%

EO 2.2

Safety, efficacy, and quality of TM/CAM enhanced through expanding the knowledge base on the safety, efficacy, and quality of TM/CAM, and providing guidance on regulation and quality assurance standards

Rationale

TM/CAM practices have evolved within different cultures in different regions. As a result, there has been no parallel development of standards and methods, either national or international, for evaluating them. This is especially true of herbal medicines, the efficacy and quality of which can be influenced by numerous factors. The regulation and registration of herbal medicines are the key measures to ensure their safety, quality, and efficacy.

Progress

Over the past four years, WHO has developed a series of technical guidelines to support countries in establishing the regulations for ensuring the safety, efficacy, and quality of TM therapies and products. In addition, seven regional training workshops have been held in five WHO regions (covering 52 countries) to help strengthen national capacity in the regulation of herbal medicines. Four WHO Regions (AFRO, AMRO, EMRO, and SEARO) developed regional minimum requirements for registration of herbal medicines based on WHO technical guidelines.

According to the WHO global survey on national policy on TM/CAM in 2002-2003, 82 countries currently regulate herbal medicines, compared with 60 countries in 1995-99, and 78 countries have a registration system for herbal medicines.

In 1999, a WHO report on malaria in Africa revealed that over 60 % of sick children with fevers were treated with herbs at home and by

traditional health practitioners – often the only form of treatment they received. However, the safety and efficacy of these antimalarial herbs have not been fully understood. In response, in 2000 WHO initiated a pilot project on the contribution of traditional medicine in combating malaria and has been supporting national clinical studies on antimalarial herbal medicines in three African countries. A mid-term review of the studies was completed in 2002.

WHO has collected evidence-based information on TM/CAM such as analysis and review of acupuncture based on controlled clinical trials, published in 2002 in cooperation with its collaborating centres and other research institutes. In 2003, WHO also supported China in the evaluation of research in integrated treatment for SARS cases.

In addition, in 2003 WHO developed guidelines on Good Agricultural and Collection Practices (GACP) for medicinal plants and initiated the development of guidelines on assessing the safety of herbal medicines, with particular reference to residues and contaminants.

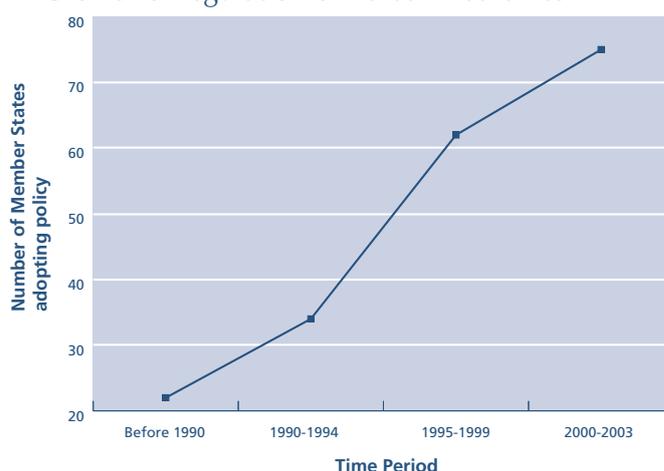
Challenges

The quantity and quality of the safety and efficacy data on traditional medicine are far from sufficient to meet the criteria needed to support its use worldwide. One of the reasons for the shortage of research data is the lack of financial incentives as most of these products are not covered by patents. Scientifically justified and accepted global research methodology for evaluating the efficacy and safety of traditional medicine is a major challenge.

Although there has been a recent increase in the number of governments that regulate herbal medicines, national regulation and registration of herbal medicines vary from country to country. Where herbal medicines are regulated, they are categorized in different ways (e.g. prescription medicines, dietary supplements, health food).

However, a group of herbal products categorized other than as medicines, may also exist within the same country. Moreover, the regulatory status of a particular herbal product varies in different countries. Regulatory status also determines the access or distribution route of these products. An additional challenge is the increasing popularity of herbal products categorized other than as medicines or foods. There is an increased risk of medicine-related adverse events, due to lack of regulation, weaker quality control systems, and loose distribution channels (including mail order and Internet sales).

Figure 11:
Growth of regulation of herbal medicines



Source: Interim summary analysis of WHO global survey on national policy on traditional medicine and complementary/alternative medicine, 2002-2003

Meeting the challenges 2004-2007

Over the next four years WHO will:

- publish global guidelines on the regulation of herbal medicines (2004).
- continue to support Member States in their efforts to establish effective regulatory systems for registration and quality assurance of herbal medicines by: organizing training workshops to strengthen national capacity on these issues; and supporting efforts to develop national lists of medicinal plants together with information on their safety.
- increase efforts to improve access to TM/CAM and expand the information available on the safety, efficacy, and quality of TM/CAM by: conducting technical reviews of research on use of TM/CAM therapies for prevention, treatment, and management of common diseases and conditions; expanding selective support for clinical research into use of TM/CAM for priority public health problems such as malaria, HIV/AIDS, and common diseases; and collating and exchanging accurate information.
- establish criteria for evidence-based data on the efficacy, safety, and quality of TM/CAM therapies, in order to facilitate research.

OUTCOME INDICATORS	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries regulating herbal medicines ^d	48	na	na	82/127 ^d	65 ^d	75%

EO 2.3

Availability and affordability of TM/ CAM enhanced through measures designed to protect and preserve TM knowledge and national resources for their sustainable use

Rationale

WHO recognizes that TM knowledge is the property of the communities and nations where that knowledge originated and should be fully respected. However, in many parts of the world, knowledge of TM is often passed on orally from one generation to the next, and can easily be lost or incorrectly transferred. The appropriate use of TM requires the transfer of correct knowledge and practice, in order to ensure its safety and efficacy. Preservation of knowledge of medicinal plants and medicinal plant resources — the most common form of medication in TM/CAM worldwide — is vital to ensure the safety and effective application of herbal medicines in health care as well as their sustainable use.

Progress

In 2002, in response to increased awareness of intellectual property rights issues relating to TM, WHO held an inter-regional workshop on this in Bangkok, Thailand. The African Region has also organized a meeting of regional experts to discuss guidelines for the protection of TM knowledge.

In 2003, WHO developed guidelines on GACP for cultivated and wild medicinal plants (see also EO 2.2), which are designed, *inter alia*, to encourage and support the sustainable cultivation and collection of medicinal plants of good quality.

Many countries have started to take action on protection of traditional medicine through recording the use of their traditionally used medicinal plants. For instance, in Côte d'Ivoire, the TM programme at the Ministry of Health carried out a survey involving traditional health practitioners in 7 of its 19 regions. As a result of this, a list has been drawn up of more than 1000 plants used by traditional health practitioners in these regions and the TM programme has developed national monographs on 300 of these medicinal plants. National lists of medicinal plants have also been developed in Bhutan and Myanmar. Elsewhere, the Iranian Government

Meeting the challenges in 2004-2007

Over the next four years WHO will:

- support Member States in developing their national inventory/catalogue of medicinal plants, which can be used to: facilitate the identification of medicinal plants used by communities; record their distribution; support efforts to establish intellectual property rights.
- establish criteria and indicators to measure cost-effectiveness and equitable access to TM/CAM.

has also taken steps to protect its TM knowledge – in 1991 establishing the National Academy of Traditional Medicine in Iran and Islam and in 2002 recording 2500 flora among 8000 traditionally used medicinal plants in Iran.

Challenges

One of the major challenges in the use of TM is the lack of measures to protect and preserve the TM knowledge and national resources necessary for its sustainable use. Another is the potential discovery of active ingredients in TM that could be used in R&D and patented for use in Western medicine – leaving the country and community of origin without fair compensation and with no access to the outcome of the research.

OUTCOME INDICATORS	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with a national inventory of medicinal plants as a means to provide intellectual property rights protection for traditional medical knowledge	na	na	na	9/39	23%	33%

EO 2.4

Rational use of TM/CAM by providers and consumers by promoting therapeutically sound use of appropriate TM/CAM

Rationale

Rational use of TM/CAM depends on a range of factors, including the need for adequate training, registration, and licensing of providers, proper use of products of assured quality, and provision of scientific information and guidance for the public.

The efficacy and safe practice of TM/CAM therapies are closely linked to the qualification of practitioners. Good practice in TM is dependant on proper training, the registration of practitioners, and the licensing of TM/CAM practice.

Progress

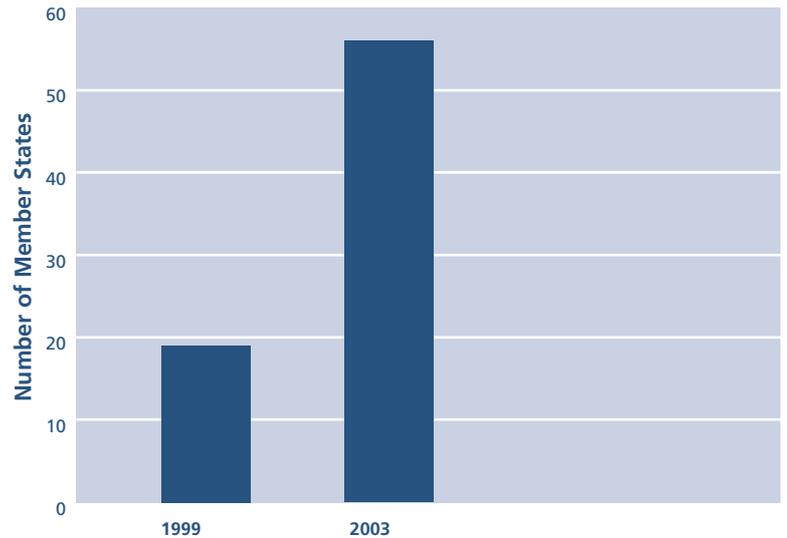
In 2002, WHO published Volume 2 of the WHO monographs on selected medicinal plants, containing 30 monographs. Volume 3, providing an additional 31 monographs is in the final stage of production. The European Commission

recommends WHO monographs to its members as an authoritative reference on the quality, safety, and efficacy of medicinal plants. Today, over 12 other countries use WHO monographs for their regulation and registration of herbal medicines. In addition, several countries, including Armenia, Benin, Mexico, Malaysia, South Africa and Viet Nam, have developed their own national monographs based on the WHO format. In 2003, WHO developed guidelines for consumer information on the appropriate use of TM/CAM.

Challenges

A range of health care professionals serve as qualified providers of TM/CAM, operating within each country's national health care delivery system and legislative framework. However, many countries do not have a national scheme for training, education, qualification, licensing, and registration of providers of TM/CAM. As a result, providers of TM/CAM medicines, such as physicians, nurses and pharmacists, may have little training and understanding of how herbal medicines, for example, impact on the health of patients who are often taking other prescription medicines as well. This information is also relevant when diagnostic and treatment decisions are made.

Figure 12:
Growth of National Institutes



Source: Interim summary analysis of WHO global survey on national policy on TM/CAM, 2002- 2003.

Traditional medicines are increasingly used outside the confines of traditional culture and far beyond traditional geographical areas, without proper knowledge of their context and use. Moreover, they are also used in different doses, extracted in different ways, and used for indications which are different from their traditional intended use. To compound the problem, contrary to their use in the traditional context, traditional medicines are now often used in combination with other medicines – a practice which has become a safety concern.

There is a widespread misconception that ‘natural’ means ‘safe’ and many believe that remedies of natural origin carry no risk. Although a great deal of information on TM/CAM is available through a variety of channels, many consumers are unable to evaluate and select reliable information in order to make a decision on the use of TM/CAM products for self-medication.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- continue to develop basic training guidelines on major forms of TM/CAM, including chiropractic, herbal medicines, and manual therapies.
- continue to develop authoritative references for Member States, such as the WHO monographs on selected medicinal plants.
- organize an inter-regional workshop to implement WHO guidelines on proper use of TM/CAM by consumers, to strengthen national capacity in providing reliable consumer information on TM/CAM.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with national research institute in the field of TM/CAM ^e	19	na	na	56/127 ^e	44% ^e	51%

In high-income countries, average per capita spending on pharmaceuticals is 100 times more than in low-income countries – about US\$ 400 compared with about US\$ 4. At the opposite ends of the spectrum, there is a 1000-fold difference between what the highest spending and lowest spending countries spend on pharmaceuticals.

Source: WHO National Health Accounts

COMPONENT 3

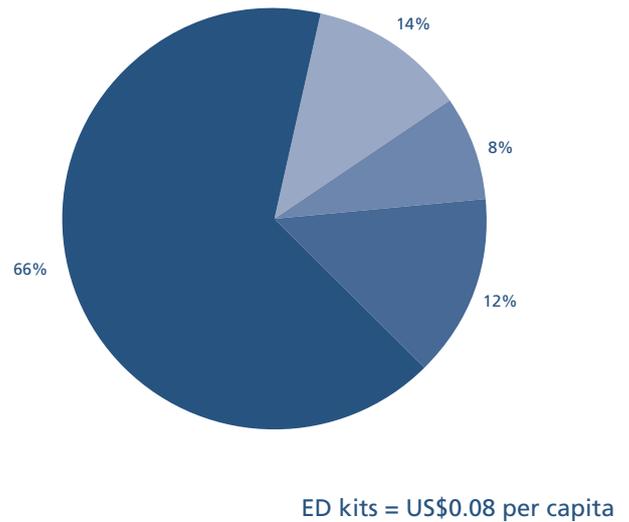
SUSTAINABLE FINANCING MECHANISMS FOR MEDICINES

Figure 13:

Financing medicines: the Uganda experience

US\$2.30 gap translates into – US\$4.00 - US\$5.00 in out-of-pocket household expenditures on drugs

GAP
PROJECT
CENTRAL
DECENTRALIZED



Adequate and sustainable financing of medicines remains a remote prospect for almost half of the world’s population.

Since 1995, private sources of finance for pharmaceuticals have become more important in all countries, with attendant risks to public health objectives. Governments’ share in pharmaceutical spending has fallen faster than their share in total health spending. While external assistance has boosted pharmaceutical spending in a small number of countries, most countries with high HIV/AIDS mortality are still spending less than US\$ 5 per capita on medicines.

Both published studies and WHO National Health Accounts confirm that pharmaceuticals expenditure in developing countries accounts for 25%-65% of total public and private health expenditure, and for 60%-90% of out-of-pocket household spending on health.²¹

In Uganda, it was estimated that annual per capita medicine needs in 2002-2003 were US \$3.50. Figure 13 shows that the available funds from local, central, and externally funded project sources totalled only US\$1.20 per capita, leaving US\$2.30 per capita — or two-thirds of the

financial resources for medicines — to be met from household sources. From these figures it was estimated that a typical household’s out-of-pocket spending on medicines would have to be between US\$4 and US\$5 for needs to be met. Such a heavy financial burden will obviously hit poorer households hardest.

A much greater role for public finance is needed, involving both developing country governments and international donors. In addition, increased efficiency in public finance is needed in order to expand access to essential medicines.

In view of the heavy burden of medicines expenditure, especially in developing countries, and the unique aspects of managing this critical health resource, WHO provides guidance on financing the supply of medicines, in an effort to increase the affordability of essential medicines in both the public and private sectors.

EO 3.1

Access to essential medicines improved, including medicines for HIV/AIDS, malaria, TB, childhood illnesses, and noncommunicable diseases

Rationale

In 2001, the Commission on Macroeconomics and Health²² demonstrated the close links between health and poverty reduction. The lack of access to essential medicines and other health interventions to prevent or treat diseases such as HIV/AIDS, TB, and malaria results in high mortality and morbidity and holds back social and economic development. In addition, in some countries, the lack of medicines in health facilities has lowered people's confidence in the health care delivery system. As a result, other services offered by the health system, including vital immunization programmes, have been adversely affected.

Progress

The Stop TB Partnership and the Global Drug Facility have demonstrated that: new resources can be mobilized; innovative partnerships, even at grass-roots level, can be forged for effective country level action; and pooled resources can create an effective negotiating tool for price setting in non-structured markets. In addition, through joint product development agreements, WHO has been able to achieve differential prices for a number of key antimalarial drug products.

Standard treatment guidelines for HIV/AIDS and malaria have been reviewed and updated and reflected in the WHO Model List of Essential Medicines and Formulary. These guidelines help countries to select drug products that are optimal for their setting, taking into account both the epidemiological situation and drug resistance

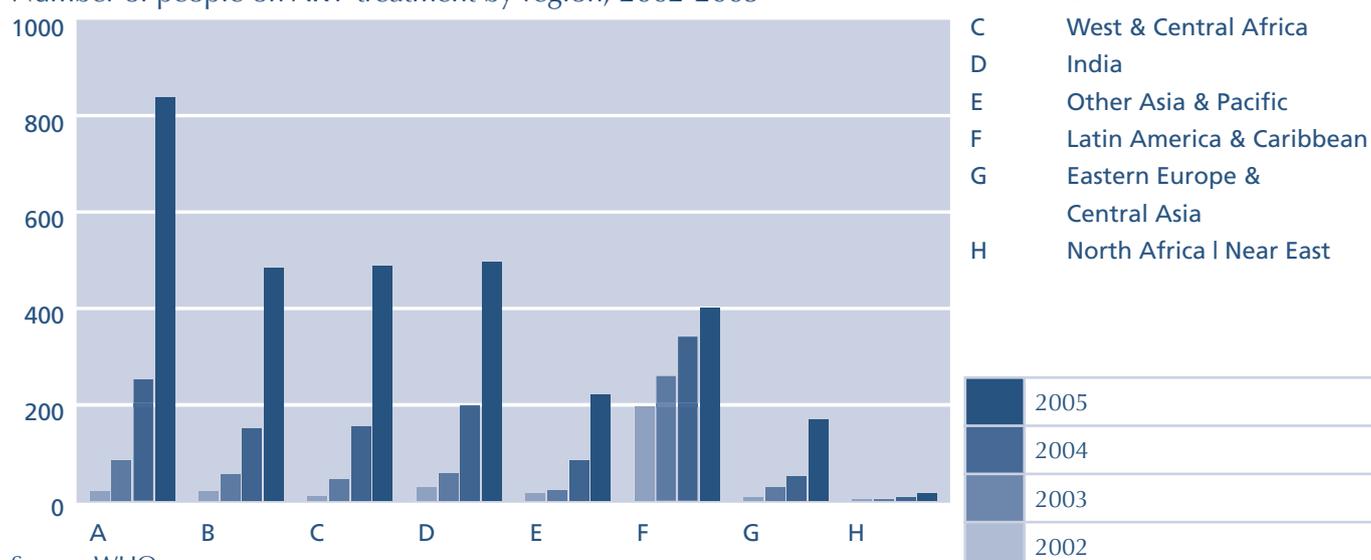
patterns. WHO is also contributing to ensuring the quality of new medicines for HIV/AIDS, TB, and malaria through the prequalification process. In this way, national medicine supply systems and regulatory authorities are able to make evidence-based decisions about medicines.

Price information on selected essential medicines is provided through a collaborative effort involving WHO and partners — allowing national programmes to compare medicine prices offered by various sources. This is a valuable tool for ensuring competitive pricing in the international medicines market.

Challenges

The high disease burden due to HIV/AIDS, TB, and malaria in many countries is a major challenge for governments. Efforts to improve access to essential medicines for these three diseases require a substantial increase in both human and financial resources, as well as strengthened medicines supply systems. The high cost of individual treatment, especially for lifelong treatment for HIV/AIDS, is a major hurdle for many governments and individuals. Effective delivery of many of the medicines for these diseases requires accurate diagnosis and close monitoring of the patient's response to treatment. To achieve this, it is vital that health systems develop and implement the necessary supporting infrastructure, train health staff, and provide the information needed by patients to ensure optimal therapy. The development of resistance to currently available therapies is a significant threat to treatment. Innovative measures to contain the rate and extent of drug resistance need to be identified.

Figure 14:
Number of people on ARV treatment by region, 2002-2005



Source: WHO

Meeting the challenges 2004-2007

Over the next four years WHO will:

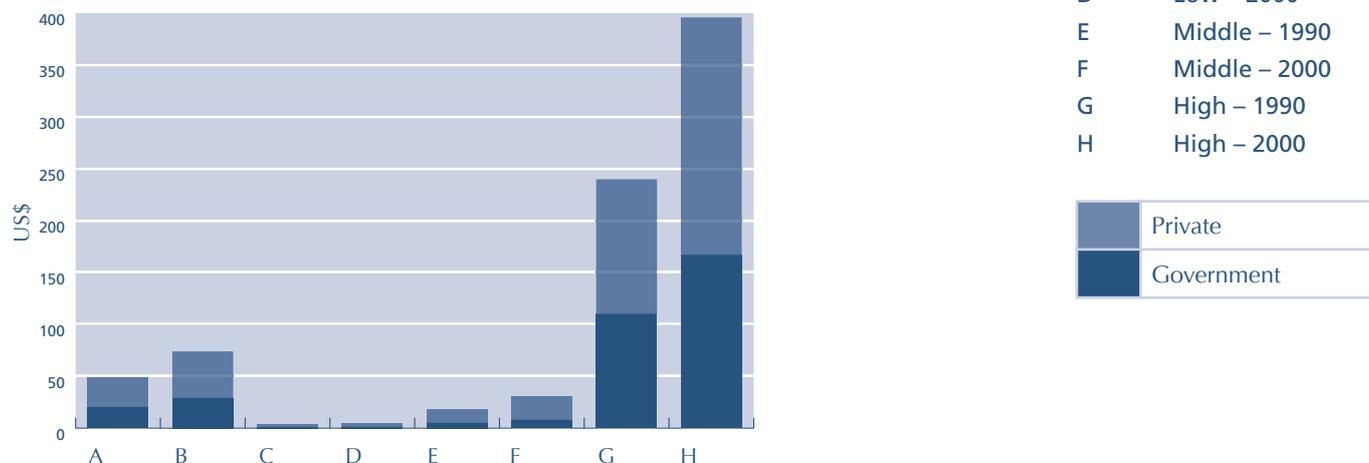
- support global and sub-regional initiatives to expand access to essential medicines by adopting a more focused approach through a reorientation of the efforts of all WHO departments, including EDM, around the challenges of the three diseases.

- provide: the relevant standards (normative work); guidance (e.g. through the pre-qualification of suppliers); information (e.g. on prices, patents, and regulatory status); essential medicines programme management experience and staffing; and country support.

- develop and put into operation the WHO AIDS Drugs and Diagnostics Facility and the Malaria Facility. The effective functioning of these facilities will depend on the ability of EDM to build on internal and external partnerships and to provide intensified technical guidance and operational support.

OUTCOME INDICATORS	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries where less than 50% of the population has access to essential medicines	29/184	16%	14%	15/103	15%	14%

Figure 15:
Per capita spending on pharmaceuticals by main source, 1990 and 2000, by country income groups



Source: WHO National Health Accounts Database

EO 3.2

Public funding of medicines increased through increased organizational capacity to implement sustainable drug financing strategies and systems

Rationale

In many countries today, private out-of-pocket spending on medicines is the largest component of household spending on health. In many low-income countries in particular, private out-of-pocket spending accounts for 50%-90% of pharmaceutical sales. (Figure 15) During the 1990s, the private share of global expenditure on medicines increased²³. Yet governments have the responsibility to ensure that medicine financing mechanisms are established and managed in such a way as to achieve equitable access to essential medicines.

While health financing reform should improve the use of public resources, it should not be aimed at reducing public spending on health and medicines²⁴. Market-oriented reform policies are not geared to protecting the needs of the poorest people and, without public financial support, the

poor may be denied access to medicines. There is a critical need to assess the effect of user charges for medicines in the public sector, in particular their impact on public health objectives.

Progress

Recent progress in increasing public funding of medicines has been inadequate due to the widespread emphasis on health sector reform. However, all WHO regions have identified medicines financing among their priorities and WHO has provided technical support in several countries. In SEARO, for example, WHO supported the appraisal of new financing options such as revolving funds or social insurance coverage. Much of the recent focus in medicines financing has been on the mobilization of additional funding resources internationally, through the Global Fund and the Commission on Macroeconomics and Health. In addition, WHO input to the Millennium Project has stressed the importance of rethinking domestic medicine financing strategies, in particular the role of user charges, and of ensuring that national Essential Medicines Lists are recognized as a statement of resource needs for public medicines financing. In recent years, WHO has developed technical material on health financing generally and on medicines financing in particular.²⁵

Meeting the challenges 2004-2007

Over the next four years WHO will:

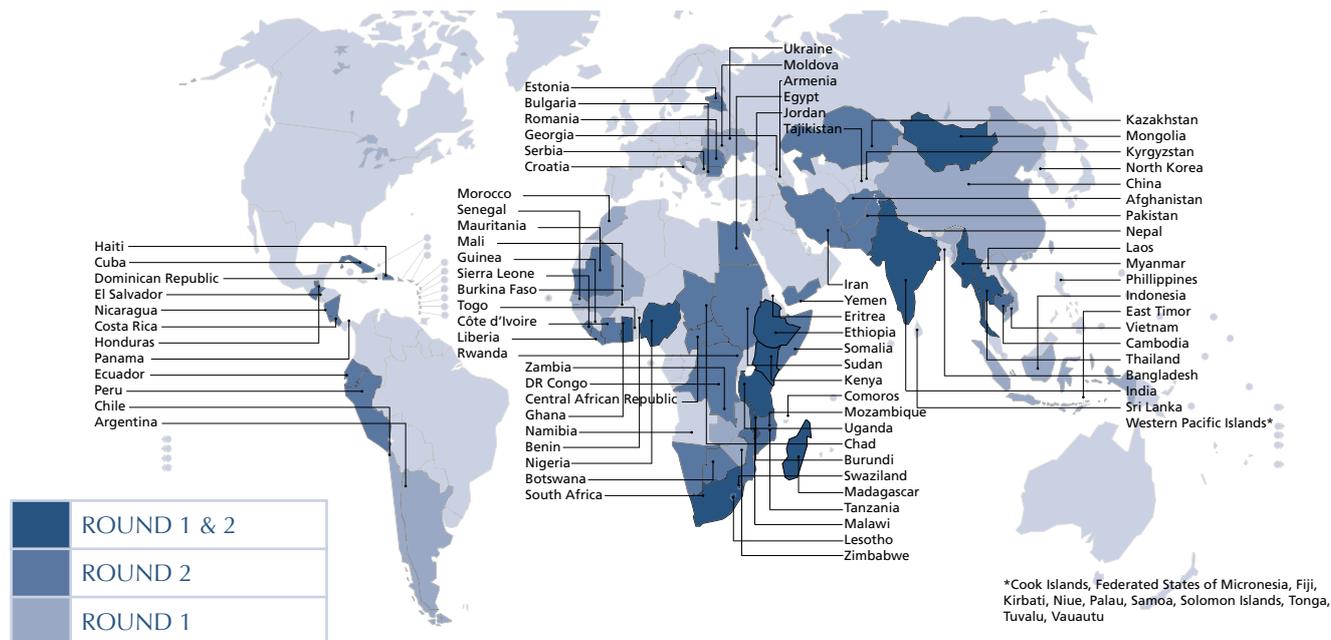
- launch an evidence-based consultative approach to national medicines financing, involving different stakeholders.
- develop medicine financing assessments to provide guidance for adaptation and use in different country settings.
- identify short- and medium-term financing strategies to achieve measurable improvements in access, on the basis of approaches that have been shown to work.
- publish and disseminate case studies and guidelines.

Challenges remaining

Medicines financing is in crisis in many countries. Policy advice from international agencies in the last two decades has stressed the need for a reduced role for the public sector and a greater reliance on private financing and provision, and trends in pharmaceutical spending confirm that this has occurred. WHO estimates that almost 2 billion people are currently without access to essential medicines — a number that does not appear to have declined since 1987. Many countries need to re-affirm that finance for the purchase of essential medicines for the poor and disadvantaged and for diseases with a major public health impact is a public responsibility, and to find effective ways of integrating private medicine providers into public health policy.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with public spending on medicines below US\$2 per person per year	38/103	37%	35%	24/80	30%	20%



EO 3.3

Development assistance increased for access to medicines, including the Global Fund

Rationale

There is increased global political will and commitment towards investment in health. In particular, there is a growing realization among high-income countries that investing in health is also an investment in development and in global security. In 2001, the Commission on Macroeconomics and Health called for a major increase in donor funding for health. A year later, the Global Fund²⁶ was launched to mobilize additional resources to combat HIV/AIDS, TB, and malaria, which together account for about 6 million deaths a year. Out of a total of US\$ 1.5 billion approved by the Global Fund by January 2003, 46% has been earmarked for procurement of medicines and commodities for use over the next two years in over 150 programmes in 93 countries.

Other major funding sources for these priority diseases include the World Bank's multi-country HIV/AIDS programme (MAP)²⁷ and more recently

the initiative by the President of the United States, involving US\$ 15 billion for HIV/AIDS over five years. The disbursement of such large amounts of money needs to be accompanied by the development of quality, sustainable health services, including national essential medicines programmes, for which WHO is in a position to provide the necessary technical assistance.

WHO has developed an extensive portfolio of norms, standards, practical guidelines, and other management tools required for effective utilization of the above-mentioned funds at national and global levels. Examples are the WHO prequalification scheme, price and patent information, interagency guidelines* on donations and on review of and support to medicines supplies agencies. In addition, WHO increasingly supports Member States in their preparations for applications to the Global Fund.

Challenges remaining

Improving access to essential medicines through the use of a range of external sources involves a variety of challenges. Of these, the need to ensure sustainability is arguably the most important and difficult to address. Other challenges include: the gap between current funding levels and health

Figure 16:
Global Fund Progress Report 2003

In its first year, in two rounds of programme proposals and approvals, the Global Fund awarded US\$1.5 billion to 153 programmes in 92 countries and put systems in place to support efficient disbursement of funds and ensure accountability.

Source: Global Fund

needs; the need for recipients to monitor funding and report to a range of donors using a variety of different reporting formats and cycles; and the lack of absorptive capacity to use funds and commodities effectively. For WHO, the challenge is to expand and further strengthen its normative and operational guidance, not only for the funding agencies involved but also for WHO's own work at global, regional, and country level, which is expected to increase substantially over the next year as part of WHO's renewed focus on HIV/AIDS, TB, and malaria.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- continue to actively engage with partners both within and outside WHO to develop strategies towards scaling up access to medicines for HIV/AIDS, TB, and malaria which are in line with the essential medicines concept and which build on and/or strengthen national health and medicines systems.
- update existing tools on a regular basis and add new ones, including databases for forecasting global demand for ARVs and guidance on fixed-dose combinations, for example.
- develop a proposal for a global facility for HIV/AIDS and a similar structure for malaria, in collaboration with the Global Fund, the World Bank, UNAIDS, and UNICEF.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
Percentage of key medicines available in public health facilities	na	na	na	22	77%	na

EO 3.4

Medicines benefits promoted within social health insurance and prepayment schemes

Rationale

Different forms of prepayment schemes involving the use of pooled resources are used by health policy-makers to develop an organized health system²⁸. Direct public funding, expansion of health insurance coverage and pharmaceutical benefits, extension of employer roles in health and drug financing, support from NGOs, and community financing sources have the potential both to increase the level of resources available for health and to promote equitable access. Prepayment schemes allow the healthy to subsidize the sick and, through income-based premiums, the rich to subsidize the poor. Both shifts imply that health care becomes more affordable for the poor and the sick.

Progress

Social and private health insurance coverage has led to expanded medicine benefits in countries as diverse as Argentina, the People's Republic of China, Egypt, Georgia, India, the Islamic Republic of Iran, Kyrgyzstan, South Africa, Thailand and Viet Nam. Some of these have special arrangements for rural and low-income populations, and medicines represent 25%-70% of total costs for these schemes. Each country's social and economic context defines the most suitable routes toward broader and deeper insurance protection. In Western and Central Europe, countries are increasingly collaborating in the exchange of information and experiences on cost-containment measures, and in the use of cost-effectiveness analysis as an aid to medicines reimbursement decisions (including a WHO review of the technology appraisal programme of the National Institute For Clinical Excellence in the UK). WHO is working with such programmes to address the issue of medicines management within health insurance.

Challenges remaining

The development of widespread health insurance mechanisms is a capacity-intensive process which typically takes many years to reach full implementation and even then requires active management. A country's overall economic performance in this period is a major enabling or constraining factor. Most low- and middle-income countries start with a diverse set of health and medicine financing mechanisms, with prepayment sometimes accounting for only a minority share of total health or medicine spending. Equitable sharing of financial risks and protection among the population is thus often very limited, particularly in relation to the cost of medicines.

Meeting the challenges 2004-2007

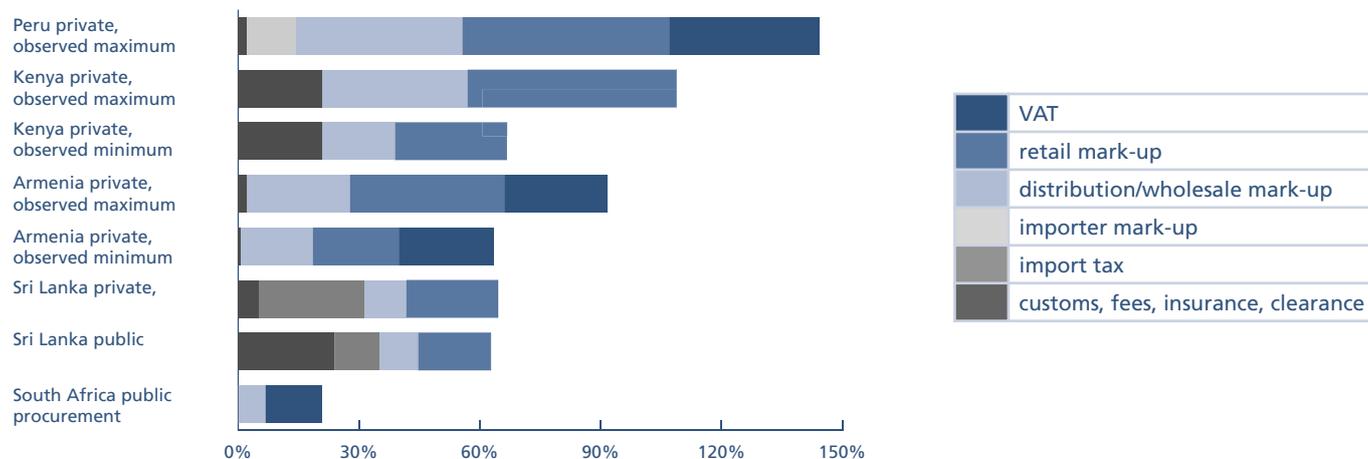
Over the next four years WHO will:

- support countries in all regions in reviewing the state of national and sub-national prepayment and insurance arrangements, and assessing their impact and potential in terms of access to medicines.
- compile and disseminate lessons from individual countries.
- advocate for the adoption of health insurance and prepayment schemes and provide experience-based policy guidance to countries.
(These activities will be carried out in synchronization with those under EO 3.2)

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with public health insurance covering the cost of medicines	71/111	64%	70%	79/117	68%	73%

Figure 17:
Medicine prices: local components of private sector prices as percentage of landed import price



EO 3.5 Medicine pricing policies and price information promoted to improve affordability of essential medicines

Rationale

In the complex national and global markets for medicines, access to price information for comparable medicines is often difficult and expensive. Yet such market intelligence is essential for informed purchasing decisions. In 2001, the World Health Assembly, recognizing the importance of timely and reliable information on medicine prices, called on WHO to: “..explore the feasibility and effectiveness of implementing, in collaboration with non-governmental organizations and other concerned partners, systems for voluntary monitoring drug prices and reporting global drug prices...and to provide support to Member States in that regard” [WHA54.11 operative para 2.(2)]

Progress

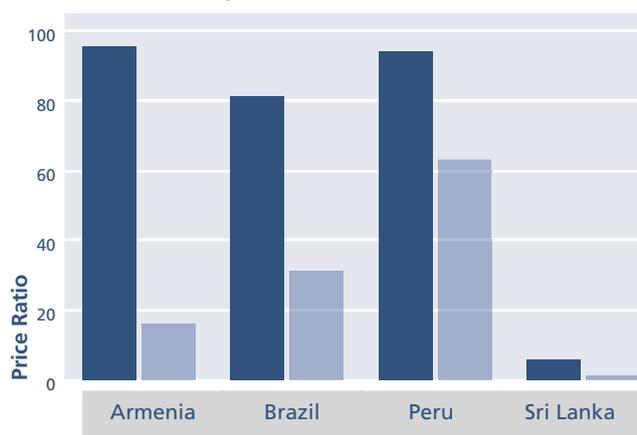
WHO is working with others in the UN family and development partners to maintain three international price information services:

- Management Sciences for Health (MSH) in collaboration with WHO: *International Drug Price Indicator Guide*. Boston, MA, Management Sciences for Health. Published annually.
- UNICEF, UNAIDS, WHO, Médecins Sans Frontières : *Sources and Prices of Selected Medicines and Diagnostics for People Living With HIV/AIDS*. Geneva, World Health Organization. Published annually.
- International Trade Centre: *Pharmaceutical Starting Materials/Essential Drugs Report*. Geneva, International Trade Centre/UNCTAD/WTO. Published monthly.

The Global TB Drug Facility (as part of the Stop TB Partnership) provides web-based price information on anti-TB medicines for use in implementing the Directly Observed Treatment Short Course (DOTS) strategy. In addition, European countries are increasingly putting their national price information on the web.

WHO also maintains regional price information services, including the *AFRO Essential Drugs Price Indicator*, which compares national tender prices for essential medicines; and the Pan American

Figure 18: Variations in the price of ciprofloxacin: originator brand and generics



Source: www.haiweb.org/medicineprices

Health Organization (PAHO) website on ARVs in Latin America and the Caribbean, which provides information on prices, uses, and access policies for ARVs. The WHO website now provides links to electronic sources of public information on medicine prices in several languages²⁹.

In 2003, a new manual on the compilation and analysis of medicine prices, *Medicine Prices: a new approach to measurement*³⁰, was jointly developed and published by HAI and WHO. It is intended to be of use to a range of different organizations involved in efforts to achieve more affordable medicine prices in low- and middle-income countries. It provides guidance on collecting retail price information for selected key medicines through surveys of health facilities in different sectors, and on comparing local prices with international reference prices. Analysis is also encouraged of the different components of retail price (Figures 17 and 18), and of the affordability of treatment for selected common conditions. The HAI (Europe) website has a public database of results from the nine pilot surveys carried out in the development of these materials, and this will grow as more studies are undertaken.

The manual and accompanying workbook resulted from discussions in the regular WHO-Public Interest NGO Round Table. A revised edition, following extensive field testing and review, is scheduled for 2005.

Big variations in medicine prices for the same or similar products, especially the newer essential medicines, remain the norm, both within and between countries. Informed purchasing is therefore difficult for many individual or institutional purchasers, and price transparency remains a distant goal.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- continue and, where possible, expand price information in collaboration with other UN agencies and development partners.
- issue an annual publication on the sources and prices of antimalarial medicines in 2004, following the success of the annual publication on HIV/AIDS-related medicines.
- in collaboration with HAI, continue to support workshops in several regions for government, academic, and NGO personnel on how to undertake a survey on medicine prices.
- carry out in-depth studies of HIV/AIDS and malaria medicine prices to monitor price changes over time and to explore policy options in different national settings.
- further develop information materials on prices and pricing policy guidelines to enable countries to consider different options and strategies for pricing mechanisms to ensure affordable prices for essential medicines.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with a pricing policy for maximum retail mark-up in the private sector	na	na	na	36/75	48%	55%

EO 3.6

Competition and generic policies implemented along with guidelines for maximizing competition in procurement practices

Rationale

WHO has long advocated the use of generic medicines of known quality as a cost-effective means of ensuring access to and the availability of essential medicines³¹. Several industrialized countries make extensive use of generic medicines, and competitive bulk procurement by generic name is a central feature of most essential drugs programmes. Yet recent evidence from Member States, particularly low- and middle-income countries, suggests that the potential of generic medicines is seldom fully attained in the formulation and implementation of national medicines policy. The use of generic drugs can be promoted at various levels, from procurement to the point of purchase. In the private market, price competition can be encouraged through generic prescribing and generic substitution. There are four main factors that influence the use of generic drugs and the success of generic drug programmes: supportive legislation, quality assurance capacity, acceptance by prescribers and the public, and economic incentives.

Progress

While over half of low-income countries have formulated NMPs, two-thirds of these have not yet been implemented. In 1999, less than 20% of WHO Member States confirmed that they required or allowed generic prescribing in the public sector, though over 40% confirmed that generic substitution was allowed at private medicine retail outlets³². Clearly, much more can be achieved by countries to integrate generic medicines into the daily decision-making of purchasers, prescribers, dispensers, and patients.

Challenges remaining

Major challenges remain in the four areas identified above. Supportive legislation is often lacking. Too few countries have effective quality assurance capability, and many prescribers and patients remain sceptical about generic medicines. The potential of generic products to increase access to essential medicines is far from fully utilized.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- continue to advocate for the use of generics and seek ways to motivate countries to adopt generic policies.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
Countries in which generic substitution is allowed in private pharmacies	83/135	61%	75%	99/132	75%	81%

COMPONENT 4

SUPPLYING MEDICINES

Efforts by WHO and other partners to scale up access to essential medicines for priority diseases have refocused attention on the need to ensure the effectiveness of medicine supply systems. Reliable supply systems are vital³³ in order to ensure that health commodities and medical and pharmaceutical services are delivered to patients in accordance with acceptable quality standards, and to guarantee uninterrupted services and supply. A well-coordinated supply system will ensure that public funds available for drug purchases are used effectively to maximize access, obtain good value for money, and avoid waste. This in turn will increase confidence in health services and promote attendance by patients. However, good coordination between these central elements of the supply system is critical. Failures at any point in the medicines supply system can lead to life-threatening shortages and to waste of limited resources. Therefore monitoring and evaluation of medical and pharmaceutical services are essential to ensure that any major weaknesses are identified and addressed.

Many developing countries continue to struggle with inefficient public supply systems unable to meet the demands of their health care delivery objectives or the expectations of health

workers and the general public. In response, governments have tried to introduce market forces into public medicine supply systems/central medical stores (CMS). The aim was to improve both the efficiency and quality of services by introducing private sector management features in the public medicines supply structure. In many countries, public sector management performance is characterized by low wages unrelated to performance, limited motivation, inflexible personnel policies and inefficient administrative and financial procedures. By contrast, private sector management is more likely to be characterized by performance-based wages, more flexible personnel policies, and streamlined administrative procedures. The role of governments is to ensure that both public and private pharmaceutical sectors are able to supply sufficient quantities of safe, effective drugs, which are of good quality and affordable. The challenge is to find a balance between public health objectives and economic realities.

The supply of medicines in emergency situations poses an additional challenge. The world community is usually quick to send large and often unsolicited donations of drugs and medical supplies — some of which can be of great help and save lives, but others which can

Figure 19:
Reliable health and supply systems – successful examples exist in all regions



do more harm than good. In response, in 1998 WHO worked together with a large group of international humanitarian aid agencies to develop a standard kit of essential medicines, supplies, and basic equipment, ready for dispatch within 24 hours, for use in the first phase of an acute emergency involving large population movements or a sudden influx of refugees. In addition, interagency guidelines for drug donations have been developed (1999) to help guide donors and recipients³⁴. In 2003, WHO also published interagency guidelines for price discounts of single-source pharmaceuticals³⁵.

Progress

Governments have developed strategies to increase private sector involvement in the CMS system to improve their efficiency and performance, such as divestiture, introduction of private management features, and contracting out of services. In doing so, governments had

to take into account the country's capacities and economic realities as well as the possible involvement of the private sector. Strong government commitment and appropriate actions appears to be essential for successful reform implementation³⁶. Examples of country progress can be found in EO 4.1.

WHO will support countries to run efficient and secure systems for medicines supply management in both the public and private sectors to ensure continuous availability and delivery of medicines at all levels of the distribution chain.

EO 4.1

Supply systems assessed and successful strategies promoted to identify strengths and weaknesses in the supply systems and improve the performance and functioning of national medicines supply systems

Rationale

Many countries have to contend with a twin-track medicines supply system — comprising an often inefficient public medicine supply system intended to serve the entire country and a variety of private supply systems serving mostly urban areas. Recent experience indicates that medicine supply systems are most effective when they are based on an appropriate mix of public, private, and NGO procurement, storage, and distribution services.

Public medicines supply systems are not meeting either the demands or the needs of countries

Problems include:

- organizational structure and financial mechanism are rigid and inadequate
- capital and budget allocations are insufficient for a well-functioning system
- number and/or capacity of supply staff are not sufficient to fulfil the tasks
- no career development or incentive structure

→ procurement procedures are not transparent and efficient

→ government interference.

The CMS strategy has been successful only where public funding is substantial and sustainable, and where the economy has been stable. This is not the case in most developing countries. As a result of health sector reforms, a number of different types of supply strategies have evolved out of the highly centralized public sector supply system. These vary considerably in relation to the role of the government, the role of the private sector, and the use of incentives to boost efficiency.

Progress

Innovative approaches to public and private supply systems have been adopted in countries such as Benin and other West African countries, Colombia, Guatemala, the Newly Independent States (NIS) of East and Central Europe, South Africa, and Thailand.³⁷ These reflect different combinations of public and private, centralized, and decentralized approaches. The potential to improve access through private sector channels has also been demonstrated in countries as diverse as Indonesia, Kenya, and Nepal. WHO has supported developments in supply systems in the NIS countries and the Balkan Region and provided training to improve the effectiveness of supply systems in Peru and Colombia.

Elsewhere, alternative supply mechanisms such as regional and sub-regional bulk purchasing schemes have been successfully adopted by the Gulf Cooperation Council and by the Organization of Eastern Caribbean States Pharmaceutical Procurement Service which operate pooled procurement systems for six and eight countries respectively.

MEDICINE SUPPLY STRATEGIES

Central medical stores

Centralized, fully public management, warehousing, and delivery system

(Semi-)autonomous supply agency

Centralized, (semi-)private management and warehousing system

Direct delivery system

Centralized decision-making but decentralized, private direct delivery system

Prime distributor

Centralized decision-making but decentralized, private warehousing and delivery system

Fully private supply

Decentralized decision-making, fully private wholesalers and pharmacies system.

Challenges remaining

To date there has been no systematic evaluation of the advantages and limitations of the different supply strategies in different (particularly low-income) settings. Thus, empirical evidence on which to base policy-making is limited. The challenge for governments is to establish the most appropriate medicines supply strategy, and to identify the extent to which the private sector, including NGOs, can be a partner in supply and distribution systems.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- support countries in their efforts to integrate innovative public-private approaches through an efficient mix of public, private, and NGO sectors in order to ensure the continuous availability and delivery of medicines of assured quality to all levels of the health care system.
- carry out a multi-country study in Africa to evaluate existing public sector supply systems, including development of a comprehensive assessment tool to enable Member States to assess their own systems.
- explore with stakeholders the options for drawing on the experiences of the NGO sector, including faith-based organizations (see also EO 4.5) to help countries formulate a feasible national medicines supply system based on an efficient public-private mix.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with public sector procurement limited to national essential medicines list	71/133	53%	60%	84/127	66%	74%

EO 4.2

Medicines supply management improved through training programmes and career development plans to increase capacity and reduce staff turnover

Rationale

Running a national medicines supply system requires a wide range of knowledge and skills, to be applied in a professional manner at appropriate points in the supply system. In developing countries, where medicines account for 25%-65% of total health spending, improvements in medicines management skills can result in significant savings for the public sector.

Governments have the responsibility for planning and overseeing the training and career development of staff in the national medicines supply system, and for allocating adequate funding for staff development. Managing human resources well is a complex task, requiring efforts to ensure that the appropriate staff are trained and available, that staff are motivated and kept up to date, and that staff turnover is not too high. Those involved in the medicines supply system should receive training in medicines management, supervision, and key administrative skills.

Efficient medicines management is based on four key functions, which form the basis of existing training courses on medicines management: selection, procurement, distribution, and use.

Progress

WHO and partners have organized international, regional, and national training courses in medicines management, including:

- Heidelberg University and Swiss Tropical Institute module course on “Rational Drug Management” as part of the TropEd European

Masters programme in International Health, since 2002.

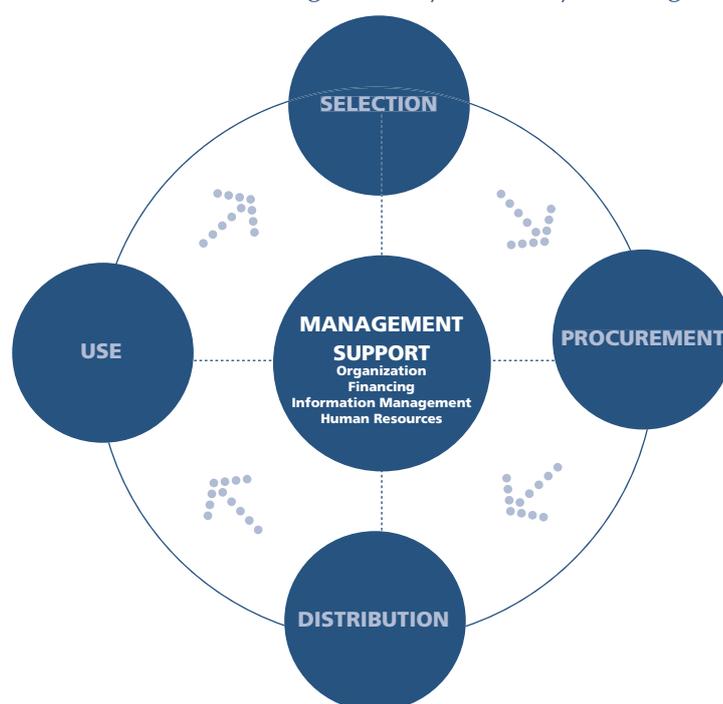
- MSH/IDA course on “Managing Drug Supply for Primary Health Care”, annually, since 1995.
- MSH/IDA course on “La Gestion Optimale des Médicaments pour les Soins de Santé Primaires”, annually, since 2003.
- World Bank course on “Integrated Approach to the Procurement of Health Sector Goods”, since 2002.
- MSH/Stop TB regional courses on “Drug Procurement for Tuberculosis”, since 2001.
- CPA distance learning programme for health care workers involved in medicines management, on “Managing Drug Supplies”, since 1995.
- Pharmaceutical Assistants Training, for health care workers in faith-based health facilities in Kenya, Tanzania, and Uganda.

Challenges remaining

One of the consequences of the free movement of goods and services is the exodus of trained professionals from developing countries in search of better paid jobs in industrialized countries which have a shortage of trained health and pharmaceutical professionals. In addition to this brain drain, many developing countries are also experiencing the loss of well trained health and pharmaceutical personnel due to HIV/AIDS.

The procedures involved at country level in applying for grants from the Global Fund, the World Bank, and the US President’s HIV/AIDS Fund, and for supplies from the Global TB Drug Facility distract already over-stretched medicines management staff from their routine tasks and duties. All these challenges result in an increased need for trained personnel and for incentives to keep them in public service.

Figure 20:
Medicines Management Cycle: Policy and Legal



Meeting the challenges 2004-2007

Over the next four years WHO will:

- continue to encourage the development of management capacity at all levels through specific training programmes and courses and the inclusion of appropriate reference materials in basic training programmes.
- support countries in their preparation for grant applications to the Global Fund and other grant providers, including capacity building activities in drug management and distribution at national and district level (see also EO 3.3).
- support the development of different forms of regional and national training courses such as e-learning and other distance learning, to increase the number of people trained.
- introduce the new curriculum of the Pharmaceutical Assistants Training in 2004 to meet national requirements for pharmacy assistants' competencies and skills; and work in collaboration with the Confederation of Pharmaceutical Associations (CPA) to update the existing distance learning modules and develop a set of modules tailored to the needs of pharmacists in various health care settings (2004).

OUTCOME INDICATORS	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries providing continuing education to pharmacists and pharmacy aides/assistants	39/103	38%	na	31/111	28%	32%

EO 4.3

Local production assessed and strengthened, on the basis of policy guidance to create a favourable environment for government or international support to domestic production of selected essential medicines

Rationale

In some countries, the development of local production facilities for medicines may be appropriate. For example, there may be benefits for the general economy from increased employment, for the health service in more self-sufficiency, and additional benefits in the form of skills development and improved access to medicines. However, local production of medicines has proved to be unsuccessful in some settings, in particular in countries with: limited markets; weak infrastructure; a shortage of mid-level and higher qualified staff; inability to maintain product quality and offer competitive prices; lack of skilled workers; and dependence on imported raw materials and technology and on foreign currency. Efforts to ensure that GMP is implemented and to assure the quality of products may be difficult for countries with limited human resource capacity. WHO encourages governments to undertake a thorough situation analysis to determine the feasibility of any proposal to encourage or support local manufacture of pharmaceutical products.

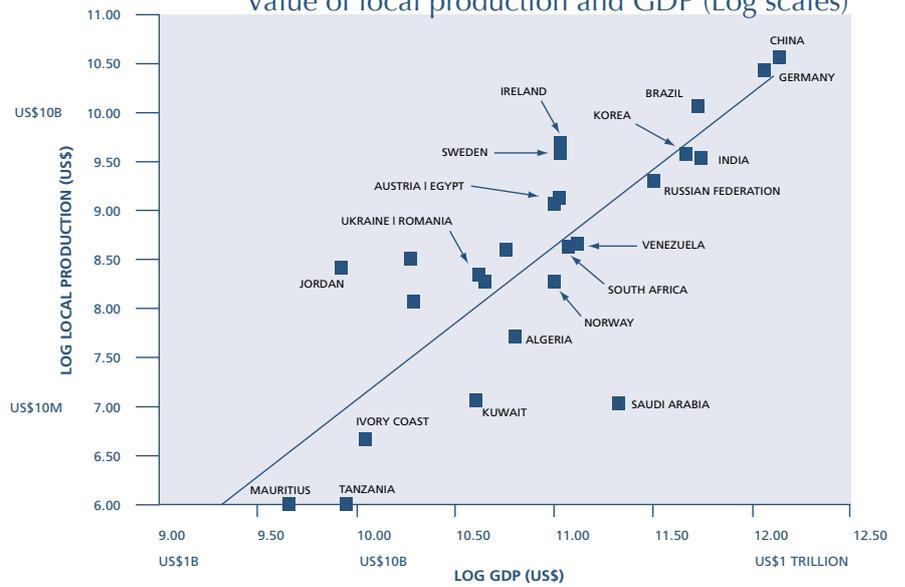
Progress

There are a number of examples of successful local production of medicines, including successful public sector involvement in countries such as Argentina, Bangladesh, Brazil, Cuba, and Egypt. In addition, there are examples of successful production of generic medicines by both private and public sector manufacturers in Eastern Europe (e.g. Hungary, Slovenia, and Ukraine). In most cases, local production has been successful either where the domestic market is large (India, Pakistan, China, Brazil) or where export markets have been established. A recent paper has provided useful information on the issues.³⁸ One of the key findings of this study was the strong correlation between gross domestic product (GDP) and the value of local production.

Challenges

A key challenge is understanding when to invest in building local production capacity. While there may be strong local support for such enterprises, this could be at the expense of access to quality assured products. At present there are no indicators that can be used to predict which industries are likely to be successful.

Figure 21:
Value of local production and GDP (Log scales)



Meeting the challenges 2004-2007

Over the next four years WHO will:

- evaluate successful local production projects to provide tools and guidance on best practices in order to help countries carry out feasibility studies to assess the viability of local medicines production. The aim is to ensure that any investment is maximized to achieve the objective of accessibility without compromising quality or price.
- continue to support manufacturers participating in the prequalification scheme in preparing product dossiers to a global standard.
- continue to carry out site inspections to assist manufacturers in ensuring that GMP is followed throughout the production process.
- continue to help strengthen national regulatory authorities.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with local production capability	na	na	na	36/122	30%	na

EO 4.4

Procurement practices and purchasing efficiency improved through guidance on good procurement practices, medicines management information support, and work with countries to strengthen procurement procedures.

Rationale

Good procurement practices are essential to ensure access to essential medicines. Procurement involves efforts to quantify drug requirements, select procurement methods, prequalify products and suppliers, manage tenders, establish contract terms, assure drug quality, obtain best prices, and ensure adherence to contract terms.

The aim is to:

- procure the most cost-effective drugs in the quantities needed
- select reliable suppliers of quality products
- ensure timely delivery
- achieve the lowest possible total cost.

Transparent procurement procedures influence quality and affordability and are essential to ensure a reliable supply of medicines³⁹. Inefficient procurement systems have been found to pay up to twice the world market price for essential medicines.⁴⁰ Poor quality medicines or delayed deliveries from unreliable suppliers contribute to unnecessary waste of budgets, life-threatening shortages, antimicrobial resistance, and avoidable fatalities.

Progress

Over recent years, WHO has supported countries, directly or through regional efforts, in their efforts to help strengthen procurement. Savings of 25%-50% in purchase prices and procurement of quality medicines have been documented in some of these programmes. Assistance has also been provided for the establishment of sub-regional procurement systems in West Africa and the Pacific Islands.

Recent policy guidance and operational research has included:

- *Operational Principles for Good Pharmaceutical Procurement*, published by WHO with five UN agencies, 1999.
- *Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies*. WHO Western Pacific Regional Office (WPRO), 2002.
- *Interim Guidelines for the Assessment of a Procurement Agency*. WHO, 2003,
- Updated lists of qualified suppliers of selected medicines for HIV/AIDS, TB, and malaria. This is one of the outcomes of the Pilot Procurement Quality and Sourcing Project, supported by UN agencies and the World Bank.
- *Operational Package for Assessing Country Pharmaceutical Situation*. WHO, 2003.

Challenges remaining

Existing government policies, rules, and regulations for procurement, as well as institutional structures, are frequently inadequate and sometimes hinder overall purchasing efficiency. Other continuing challenges include erratic funding, lack of accurate objective information, poor decision-making processes, and poor supplier performance. More recent challenges include: increasing pressure on procurement agencies to obtain the lowest possible price; greater difficulty in assuring the source and quality of medicines in an increasingly global pharmaceutical market; and the need for procurement agencies to better understand patents and the available safeguards in the TRIPS Agreement. Government procurement agencies are also affected by emerging trends such as increasing interest in regional and sub-regional procurement, large-scale procurement with Global Fund financing, and the integration of the procurement of products for reproductive health into the regular government procurement systems.



Meeting the challenges 2004-2007

Over the next four years WHO will:

- expand its work on good procurement practice to support regional and national efforts to improve procurement systems and practices.
- complete work on the Guidelines for Assessment of a Procurement Agency.
- expand the listing of qualified suppliers of selected essential medicines and technical guidance on patents.
- provide support to at least 20 countries in the use of the Operational Package for Assessing Country Pharmaceutical Situation.
- facilitate WHO's '3 by 5' initiative by supporting about 30 countries with high HIV/AIDS incidence in efforts to strengthen their national procurement systems.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with at least 75% of public sector procurement carried out by competitive tender	81/88	92%	95%	58/70	83%	87%

EO 4.5

Public-interest NGOs included in medicine supply strategies, in support of national medicine supply strategies to reach remote areas

Rationale

Public-interest NGOs and faith-based organizations often work in areas where the private for-profit health sector does not have incentives to exist. These organizations play an important role in meeting the overall health needs and medicine requirements of these rural and often disadvantaged populations. WHO, in collaboration with the Ecumenical Pharmaceutical Network based in Nairobi, Kenya, has undertaken a study in 10 sub-Saharan African countries on medicines supply and distribution activities by faith-based organizations. Preliminary findings indicate that these organizations support the overall public health sector by covering 40% of the population and support around 80% of health facilities, in mainly rural areas.

As a result, faith-based organizations such as those in the African Region have substantial experience in the successful management of medicine supplies, mostly through a pooled purchase mechanism (e.g. Ghana, Nigeria, Malawi, Zambia, Kenya, and Uganda). In most cases, they operate efficiently, have well-motivated staff, and have adopted sound management principles, including accountability. Although their skills, experience, and achievements are not always recognized or used by national governments, some governments do acknowledge the contribution of these organizations and collaborate with them to jointly supply and distribute medicines supplies in the public health sector. The Joint Medical Stores in Uganda and Mission of Essential Medicines and Supplies in Kenya are good examples of this kind of collaboration.

WHO already works in collaboration with many public-interest NGOs, is involved in training courses for NGO personnel, and has published papers on NGO contributions. Another example is the close collaboration with Médecins Sans Frontières (MSF) in the production of a joint report about MSF's experiences in procuring and supplying ARVs in 10 countries where it operates HIV/AIDS treatment programmes⁴¹. WHO also works with international non-profit suppliers of low-cost essential medicines, in particular on the composition and distribution of the WHO New Emergency Health Kit, and through the Green Light Committee for the supply of medicines for multidrug-resistant TB.

Challenges remaining

Many governments do not fully recognize or acknowledge the important contribution that NGOs and faith-based organizations could make and are already making in the equitable delivery of basic health care. Many good examples of cost-effective drug supply management by NGOs and faith-based organizations are ignored and not used to their full potential as examples for public services.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- work with public-interest NGOs, faith-based organizations, and countries to support the assessment of best practices within NGOs and faith-based organizations for incorporation into national medicines supply policies and strategies.
- support the NGOs and faith-based organizations by offering them a full share of available technical information, policy guidance, and training opportunities.
- continue to promote the use of all available channels, including NGOs and faith-based organizations, in the delivery of health care to rural and disadvantaged populations (including the prevention, care, and treatment of HIV/AIDS).

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with NGOs involved in medicines supply	na	na	na	29/64	45%	na

COMPONENT 5

NORMS AND STANDARDS FOR PHARMACEUTICALS

From the outset, WHO has worked to establish and promote international standards for the quality of pharmaceuticals. Under Article 2 of the WHO Constitution, WHO is required to “develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products”.

Without assurance that medicines are relevant to priority health needs and that they meet acceptable standards of quality, safety, and efficacy, any health service is evidently compromised. In developed countries, considerable administrative and technical effort is directed to ensuring that patients receive effective medicines of good quality. It is crucial to the objective of health for all that a reliable system of medicines control is brought within the reach of every country.

The existence of international harmonization initiatives in different parts of the world demonstrates the importance that governments attach to drug regulation; at the same time, it offers opportunities for countries to review and improve their regulatory systems.⁴²

Member States continue to look to WHO for guidelines on the development of pharmaceutical

regulation, legislation, and quality assurance. In response, the WHO Expert Committee on Specifications for Pharmaceutical Preparations has adopted a large number of guidelines in the area of quality assurance⁴³. Guidelines have been adapted by Member States or regional harmonization groups to meet their own needs and circumstances.

Another critical pharmaceutical service provided by WHO is the system of International Nonproprietary Names (INN), which is used to identify each pharmaceutical substance or active ingredient by a unique and universally accessible name. This function is fundamental to ensure that dispensing and prescribing is governed by a common nomenclature allowing communication among health professionals and consumers. This is of increasing importance in view of the globalization of trade in pharmaceuticals and the need for better communication among health professionals. The existence of several names for the same product can be a source of confusion and a potential risk to health.

The WHO Expert Committee on Specifications for Pharmaceutical Preparations meets regularly and publishes statements, guidelines, and recommendations that provide the tools for

quality assurance systems worldwide⁴⁴. Important key elements are quality assurance guidance texts in the areas of production, testing, and distribution of medicines. These include guidance on: good manufacturing practices; quality assurance for regulatory approval; prequalification of medicines, laboratories, and supply agencies; model certificates for quality assurance-related activities; quality control testing; new specifications for inclusion in the Basic Tests series and the International Pharmacopoeia; and International Chemical Reference Standards. All these elements are intended for use by national regulatory authorities, manufacturers, and other interested parties. *The International Pharmacopoeia* is in widespread use throughout the world and plays a major role in defining the specifications of pharmaceutical products. It also provides a valuable tool in the quality control of imported products⁴⁵.

The need to scale up access to affordable quality medicines for HIV/AIDS, TB, and malaria in developing countries has raised many challenges within the pharmaceutical world. These challenges come on top of the reality that among national regulatory authorities there is a variable capacity to interpret and apply existing norms and standards and guidelines on regulation, quality

control, nomenclature, and classification of pharmaceuticals.

WHO will work to strengthen and promote global norms, standards, and guidelines for the quality, safety, and efficacy of medicine.

EO 5.1

Pharmaceutical norms, standards and guidelines developed or updated to promote good practice in quality assurance and regulatory matters

Rationale

Existing WHO pharmaceutical norms, standards, and guidelines have to be continually updated to keep pace with advances in pharmaceutical science and technology. Today, as efforts get under way to scale up access to quality essential medicines in developing countries, there is an urgent need for WHO to further strengthen the development of international standards and guidelines on the assessment of multi-source generic products.

In addition, the continuing sale of substandard and counterfeit medicines in some countries has highlighted the need for international agreements in order to strengthen existing preventive measures. Elsewhere, increasing trade and commerce, and the supply of life-saving medicines by both private and public parties, require new approaches to quality assurance at the international, regional, and national level.

The statutory instruments, advice, and recommendations provided by the WHO Expert Committee on Specifications for Pharmaceutical Preparations can help national authorities, especially national drug regulatory authorities and procurement agencies, to combat problems such as the production, distribution, and sale of substandard and counterfeit medicines, financial waste, and the emergence of resistance to medicines for priority infectious diseases.

Progress

WHO has helped raise awareness of the need for regulatory measures covering the safety of and trade in starting materials, including active pharmaceutical ingredients and excipients, and the implementation of GMP. In response to a Resolution of the World Health Assembly (WHA52.19) and recommendations made in various fora, including the 10th International Conference of Drug Regulatory Authorities, the Expert Committee has adopted new mechanisms for the control and safe trade of starting materials for pharmaceuticals, for action by governments, manufacturers, traders and brokers: (1) Good Trade and Distribution Practices (GTDP); and (2) Pharmaceutical Starting Materials Certification Scheme (SMACS). Member States are being encouraged to participate in a pilot phase.

The Expert Committee has updated widely used existing WHO guidelines on GMP and added specific texts such as Guidelines on Good Manufacturing Practices for Radiopharmaceutical Products and the Model Certificate of Good Manufacturing Practices.

A series of guidance texts have been adopted by the Expert Committee in relation to the prequalification of suppliers of medicines for HIV/AIDS, TB, and malaria, including:

- Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by UN agencies
- Procedure for assessing the acceptability, in principle, of quality control laboratories for use by UN agencies.

- Guidelines for drafting a laboratory information file.
- Procedure for assessing the acceptability, in principle, of procurement agencies for use by UN agencies.
- Guidelines for drafting a procurement agency information file.
- Interim guidelines for the assessment of a procurement agency.
- Model Quality Assurance System for the prequalification, procurement, storage, and distribution of pharmaceutical products.

Challenges

Countries' priorities, needs, resources, and requirements in pharmaceuticals differ substantially. This has enormous implications for WHO's work, both in developing global guidelines and advising Member States on their adaptation and adoption. Current developments in the international harmonization of drug regulation provide an opportunity for WHO to review and update existing standards and guidelines.

Today, WHO is at the forefront of continuing international efforts to define and harmonize clear and practical standards and guidelines for pharmaceuticals, particularly in response to the increasing globalization of trade in pharmaceuticals and the supply of medicines by intermediaries. Additional regulatory guidance is also urgently needed for the assessment of the quality, safety, and efficacy of fixed-dose combination medicines for public health priority diseases.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- continue to review, update, and develop norms, standards, and guidelines for quality assurance and quality assessment in medicines registration .
- improve the dissemination and promotion of WHO guidelines (e.g. quality assurance guidance, GMP guidelines) and strengthen communication strategies in order to ensure effective implementation of the guidelines.
- establish a Global Alliance for the Quality of Pharmaceuticals, in collaboration with other partners, with a particular focus on capacity building in quality assurance at the national level.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries using the WHO Certification Scheme as part of the marketing authorization process	na	na	na	87/135	64%	75%

EO 5.2

Medicines nomenclature and classification efforts continued through assignment, promotion, and protection of international nonproprietary names, and the promotion and development of ATC/DDD system

Rationale

International Nonproprietary Names (INN) identify pharmaceutical substances or active pharmaceutical ingredients. Each INN (often referred to as a “generic” name) is a unique name that is globally recognized and is public property. The existence of an international nomenclature for pharmaceutical substances, in the form of INN, is important for the clear identification and safe prescription and dispensing of medicines to patients, as well as for communication and exchange of information among health professionals and scientists, businesses, and governments worldwide. Providing INN is one of the oldest services that WHO provides to Member States. INN are made available in all six WHO languages (Arabic, Chinese, English, French, Russian, and Spanish) as well as in Latin. The work of the INN Programme and the assignment of INN are both guided by International INN Expert Group.

An additional classification system has been developed to serve primarily as a tool for drug utilization research. The Anatomical Therapeutic Chemical (ATC) classification system together with the Daily Defined Dose (DDD) continues to be developed and maintained by the WHO Collaborating Centre for Drug Statistics Methodology in Oslo, Norway, under the supervision of the WHO International Working Group for Drug Statistics and Methodology. The Working Group, comprised of experts in clinical pharmacology and medicines utilization representing the six WHO Regions, meets twice

a year and oversees the work of the Collaborating Centre for Drug Statistics Methodology. The ATC classification system with its hierarchical codes divides drugs into different groups according to the organ system on which they act and their chemical, pharmacological, and therapeutic properties. In the ATC system, one drug can have several ATC codes due to different therapeutic use and local application formulations. The DDD is a unit of measurement in drug utilization studies reflecting average daily maintenance dose of the drug when used for its main indication. Although ATC codes are increasingly used for classification purposes (i.e. in drug formularies), the main utility of ATC codes is in conjunction with DDD for drug utilization research worldwide.

Progress

The use of the INN system is expanding with the increase in the number of names. Its wide application and global recognition are also due to close collaboration with numerous national medicines nomenclature bodies in the process of INN selection. As a result, most of the pharmaceutical substances used today in medical practice are designated by an INN. The use of INN is common in scientific literature, regulatory affairs, research, and clinical documentation. They are also used for administrative purposes. Their importance is increasing due to expanding use of generic names for pharmaceutical products.

Nonproprietary names are widely used in

pharmacopoeias, product labelling and information, advertising and other promotional materials, medicines regulation, and scientific literature, and as a basis for product names in the case of generic medicines. The INN Programme is collaborating closely with the WHO Collaborating Centre for Drug Statistics Methodology in Oslo, Norway, and the INN and ATC databases have been cross-linked — providing a unique source of information for medicines regulatory authorities, scientists, and others in the pharmaceutical field. Information technology tools to facilitate access to the information are being developed (e.g. web-based access through MedNet, Cumulative List of INN with additional information on CD). Active collaboration with medicine regulatory authorities (e.g. the European Medicines Evaluation Agency (EMA)), pharmacopoeias (e.g. Japanese Pharmacopoeia), nomenclature bodies (e.g. United States Adopted Names Council), and other interested parties is becoming part of the main INN Programme activities.

The use of the ATC/DDD system is widening globally. Many regulatory authorities today use ATC codes for drug registration and other administrative purposes. ATC codes are also increasingly referred to in drug formularies and other information sources. Recent publications by the Centre include: *Guidelines for ATC classification and DDD assignment* and an *Index* with all the assigned ATC/DDDs (both issued annually, the latest 2003). A recent publication, *An Introduction to Drug Utilization Research* (WHO, 2003), has broken new ground in promoting drug utilization research by giving simple and robust advice on how best to carry out and benefit from drug utilization research with the aim of promoting rational use of drugs.

Challenges remaining

There is a continuing need to promote the importance and use of unified classification systems for medicines so as to avoid confusion and facilitate the exchange of information and research into the therapeutic use of medicines. The health and financial benefits from methodologically sound drug utilization research remain underestimated, whereas the costs are overestimated. There is a growing need for problem-oriented training activities that are integrated with public health programmes.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- continue to support and promote the collaborative programmes in nomenclature and classification of medicines.
- increase capacity to deliver training in drug utilization research in collaboration with other interested parties

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries using INNs in medicines registration	na	na	na	108/131	82%	90%

EO 5.3

Pharmaceutical specifications and reference materials developed and maintained for use in quality control laboratories and publication in the International Pharmacopoeia

Rationale

Evidence of increasing counterfeiting activity in pharmaceuticals in both developed and developing countries has prompted widespread concern about the quality of pharmaceutical products. Without detailed specifications that are internationally applicable it is impossible to assess quality and make a judgement as to the integrity of a substance or a product. WHO has played a central role in developing and publishing specifications to assist Member States in their efforts to perform quality control testing for products in their markets.

Progress

The WHO Expert Committee on Specifications for Pharmaceutical Preparations has endorsed a range of statements, guidelines, and recommendations which provide the tools for quality control testing, new specifications for inclusion in the series of Basic Tests series and the International Pharmacopoeia, as well as International Chemical Reference Standards for national regulatory authorities, manufacturers, and other interested parties. The International Pharmacopoeia is used in a large number of countries throughout the world and plays a major role in defining the specifications of pharmaceutical products. It also provides a valuable tool in the quality assurance of imported products.

WHO has worked in collaboration with UN agencies and other international partners to establish quality specifications for starting materials and finished products. A project was initiated involving the development of new international pharmacopoeial requirements, especially for priority drugs used in the treatment of HIV/AIDS, TB, and malaria, for many of which no public standards exist. In 2003, a set of specifications was published in the International Pharmacopoeia to enable testing to be carried out on all artemisinin derivatives (active substances as well as finished dosage forms) used in the treatment of malaria — the only pharmacopoeia to include this set of standards so far.

Challenges remaining

There is an urgent need to establish international quality specifications for new medicines for HIV/AIDS, TB, and malaria in order to assist procurement by UN and other agencies for use on a wide scale in developing countries. This is a major undertaking involving many partners, including manufacturers, national and regional pharmacopoeia commissions, and collaborating laboratories. At the same time, there is a need to assess whether the more stringent product specifications resulting from the introduction by the International Conference on Harmonization of Requirements for Pharmaceuticals for Human Use (ICH) of certain quality guidelines will produce additional public health benefits. In addition, there is a continuing need to complement and update existing quality specifications.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- produce quality control specifications and reference materials and appropriate advice to national quality control laboratories, especially for new medicines for public health priority diseases such as ARVs for HIV/AIDS.
- work closely with the WHO Collaborating Centre for Chemical Reference Substances in Sweden, and with other centres which validate the methods and challenge the specifications developed with products on their national market.
- support closer collaboration between pharmacopoeias and national regulatory authorities to meet the challenge of assuring the quality of medicines traded internationally.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. and types of pharmaceutical specifications and reference materials developed by WHO HQ	na	na	105	96	na	50

EO 5.4

Achieving balance between abuse prevention and appropriate access to psychoactive substances through enhancing the implementation of relevant guidelines to promote rational use of controlled medicines

Rationale

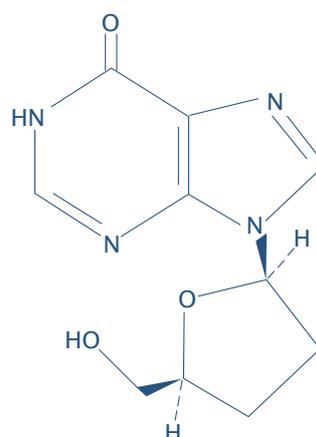
WHO is mandated by the 1961 UN Single Convention on Narcotic Drugs and the 1971 UN Convention on Psychotropic Substances to undertake medical and scientific review of psychoactive substances for international control with a view to preventing abuse of these substances. International drug control is a joint undertaking involving WHO, the United Nations Commission on Narcotic Drugs, International Narcotic Control Board, and Member States. In parallel with fighting the illicit use of narcotic and psychotropic drugs, the goals of drug conventions also include ensuring the availability of and access to psychoactive substances for medical use. To achieve these two objectives, WHO promotes the balanced drug control policy among its Member States.

Progress

Since 1949, through its Expert Committee on Drug Dependence, WHO has reviewed more than 410 substances. Between 1948 (when WHO was established) and 2003, the number of narcotic drugs under international control increased from 18 to 118, and the number of psychotropic substances from 32 to 116. In order to facilitate the review process, in 2000 WHO amended the Guidelines for the WHO Review of Dependence-Producing Psychoactive Substances for International Control.⁴⁶ The anticipated adoption of these guidelines in 2004 will further clarify the review principle for psychotropic substances.

Figure 22:

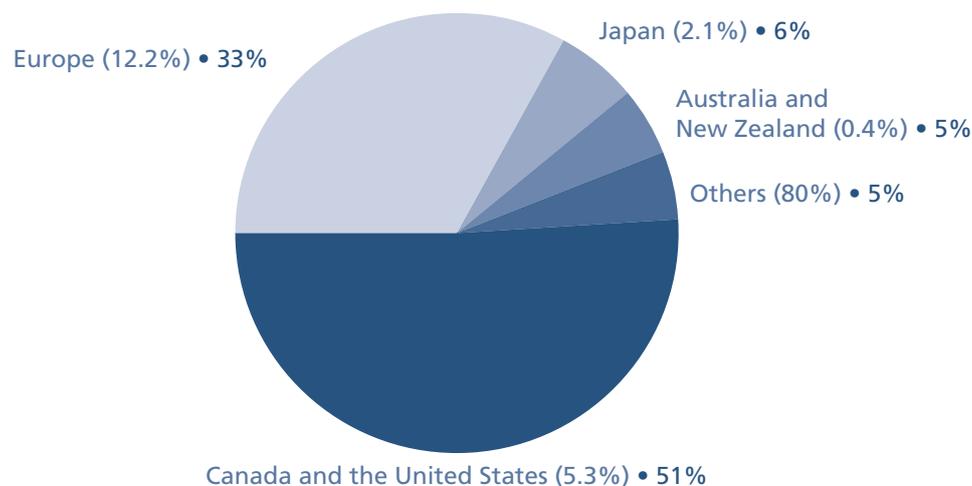
Formula for new HIV/AIDS medicines: didanosine



didanosine

In 2000, WHO issued a document on *Achieving Balance in National Opioids Control Policy: Guidelines for Assessment*⁴⁷ for use by Member States. WHO also assisted the United Nations International Drug Control Programme (UNDCP) in drafting guidelines for national regulations concerning travellers under treatment with internationally controlled drugs. The guidelines, adopted by the 45th session of the Commission on Narcotic Drugs in 2002, are intended to facilitate and enhance the security of patients who wish to continue their treatment while travelling. In 2002, WHO organized a workshop with the Central European countries in Hungary on improving access to opioids for pain and palliative care in the countries of Central and Eastern Europe.

Figure 23:
Global distribution of consumption of morphine in 2001
Source: *Report of the International Narcotics Control Board for 2002*⁴⁸



Note:
Percentages in brackets refer to shares of the world's population.

Challenges remaining

Many new chemical substances with psychoactive properties continue to be synthesized, distributed, and abused. These substances should be rapidly detected, reviewed, and put under international control, as necessary. However, overly restrictive regulations in many countries on the distribution of psychoactive drugs, including narcotic pain killers, continue to limit their availability, resulting in the suffering of cancer patients and others due to inadequately treated severe pain or untreated mental disorders. As the International Narcotics Control Board has highlighted, significant differences exist between countries in the extent to which narcotic drugs are used for the treatment of pain — with their use in most developing countries, in particular, at an extremely low level.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- continue to support the Expert Committee on Drug Dependence by providing clear guidance for the review process.
- enhance cooperation with the UNDCP and the International Narcotics Control Board and other relevant organizations in collecting information on new psychoactive substances that could be abused.
- continue to advocate and promote the rational use of controlled medicines, particularly in developing countries, by facilitating the implementation of relevant guidelines in Member States.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of substances reviewed and recommended for classification for international control	2/3.	66%	na	5/5.	100%	80%

COMPONENT 6

REGULATION AND QUALITY ASSURANCE OF MEDICINES

Work carried out by WHO in 2001 showed that counterfeit and substandard medicines continue to be a major concern globally. Specific problems included the wrong level or absence of the active ingredient. In Cambodia, for example, 50% (115/230) of samples of 24 different pharmaceutical products collected from the market were unregistered. Laboratory tests based on registration status showed that of 98 imported registered products, 6 (6%) failed the laboratory test. Results of tests on 112 imported but unregistered products showed that in 22% of the samples the active ingredients were lower than the amount indicated by the label. The overall failure rate for the total of 230 samples was 13%. Studies such as these serve as a starting point for formulating national strategies for fighting counterfeit drugs.

(Annual Report 2001 – Essential Drugs and Medicines Policy: Extending the Evidence Base, Geneva, WHO, 2002).

The production and distribution of medicines requires public oversight and stewardship. Unlike ordinary goods and services, an unregulated medicines market place will fail: it will be not only inequitable, but also inefficient and probably dangerous to public health.⁴⁹

The three main components of stewardship in the medicines market are:

- Product registration: assessing and authorizing products for market entry, based on quality, safety, and efficacy; and monitoring their quality and safety after entry.
- Regulation of manufacturing, importation, and distribution.
- Regulation of medicine information and promotion.

Most countries have a medicines regulatory authority and formal requirements for registering medicines. However, medicines regulatory authorities differ substantially in their human and financial resources and capacity. One-third of WHO Member States have no medicines regulatory authority, or at best very limited capacity for regulation of the pharmaceutical

market. Regulatory gaps are common, with the informal sector for medicines supply often neglected.

The quality of medicines varies greatly, particularly in low- and middle-income countries

WHO has been active in supporting countries in their efforts to assure the quality of products, particularly in response to the increasing availability of affordable HIV/AIDS medicines. In March 2001, WHO launched a project to develop a system for the prequalification of manufacturers of ARVs, including both innovator and generic producers. Working closely with the International Pharmaceutical Coordination group (IPC), comprising WHO, UNICEF, UNAIDS, UNFPA, and the World Bank, WHO established consensus on the product standards to be met by suppliers in order to gain prequalification status, and on the need to establish a list of prequalified HIV/AIDS medicines and their suppliers.⁵⁰ The system has now been expanded to include a prequalification process for TB and malaria medicines and their suppliers.

Other elements in a comprehensive programme to promote access to quality medicines for HIV/AIDS and other priority health problems have included:

the creation of a WHO Model Quality Assurance System for procurement; feedback to regulators on information collected during assessments of ARVs, to increase their capacity to ensure the quality of ARVs on their national market; and regional workshops for drug regulators on registration of generic ARVs.⁵¹

In the light of the proposed expansion of ICH into pharmacovigilance, it is a challenge for WHO to:

- strengthen links with ICH to avoid unnecessary duplication
- become more active in developing guidelines on pharmacovigilance
- disseminate its reports and data more widely
- raise awareness of its work by encouraging all Member States to participate in the WHO Programme for International Drug Monitoring.

Currently, WHO attends meetings of the ICH Steering Committee and the Global Cooperation Group with observer status; these roles are important and should be maintained. However, appropriate strategies for consultation and communication with Member States need to be developed to ensure that WHO is not seen as de facto automatically endorsing ICH products, but as providing advice on the potential impact of those products on non-ICH Member States.

WHO will contribute to the quality, safety and efficacy of all medicines assured by strengthening and putting into practice regulatory and quality assurance standards

EO 6.1

Medicines regulation effectively implemented and monitored as the capacity of staff is increased through training activities resulting in better knowledge, organization, financing, and management

Rationale

Problems related to the safety and quality of medicines exist in many countries throughout the world, developing and developed countries alike. However, the magnitude of the problem is much greater in developing countries, where poor quality medicines may be the only ones to reach the poor. Some incidents have resulted in deaths, with children often the victims. They involve the use of medicine containing toxic substances or impurities, medicines whose claims have not been verified, medicines with unknown and severe adverse reactions, substandard preparations, or outright fake and counterfeit medicines. Effective medicine regulation is required to ensure the safety, efficacy, and quality of medicines available in both the public and private sectors, as well as the accuracy and appropriateness of medicine information available to health professionals and the public.

Progress

WHO has provided technical and administrative support to countries, including the development, publication, and dissemination of various tools (standards, norms, guidelines, training, and software packages) and guidance to assist in the establishment or strengthening of national regulatory authorities as well as the implementation of regulatory activities.

In 2002, WHO published the results of a multi-country study which identified some of the problems encountered by countries in promoting effective drug regulation. The report also provided simple conceptual frameworks for medicine regulation, for use by policy-makers as a basis for designing medicine regulatory systems, as well as suggested strategies for improving drug regulation performance. In addition, the report outlined key features of medicine regulatory systems in different countries, highlighting best practices and the lessons to be learned.⁵²

Challenges remaining

Despite the support provided by WHO and other international organizations and donor countries to strengthen medicine regulation, in many developing countries there remains a huge capacity gap among national regulatory authorities that needs to be addressed.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- in collaboration with other partners, carry out an assessment of national medicine regulatory authorities to monitor progress, identify weaknesses, and develop strategies in consultation with national authorities to improve medicine regulation.
- facilitate training courses in the different areas of medicine regulation and provide tools and technical advice as needed.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries implementing basic medicines regulatory functions	70/138	51%	56%	90/130	69%	74%

EO 6.2

Information management and exchange systems promoted and made accessible through shared databases. Basic regulatory information shared among national regulatory authorities and made available to the general public

Rationale

While the world is undergoing a revolution in access to information, almost to the point of overload, access to independent information on the safety and efficacy of medicines remains limited. Although the information exists and is available from many sources, access is constrained either by lack of technology or by lack of understanding about how to access it. WHO recognizes the need to establish a system for regular exchange of information on pharmaceutical products between regulatory authorities in less-developed countries which often lack the capacity and tools to obtain information that is up to date. WHO also recognizes the need for regulatory authorities to provide unbiased information to prescribers.



Progress

Efforts by WHO to strengthen the Information Exchange system have included: the formal designation of National Information Officers within the national regulatory authorities in Member States; active support of drug surveillance activities by the WHO Collaborating Centre for International Drug Monitoring in Sweden; continued sponsorship of the biennial International Conferences of Drug Regulatory Authorities; regular publications of regulatory and drug safety information in the WHO Pharmaceuticals Newsletter, WHO Drug Information, and WHO Restricted Pharmaceuticals List updates; and ad hoc publications of Drug Alerts for the rapid dissemination of urgent safety information to Member States.

In order to address the need for unbiased information, a multi-country study was set up to document the variability of prescribing information from different sources concerning indications, side effects, and warnings about the possible adverse effects of selected drugs. The results show substantial differences between the materials available to prescribers and patients in different countries. Differences were even found within a single country when written materials from different brands of the same drug were compared.⁵³

Challenges remaining

While the WHO Information Exchange System continues to build on regular and active input from the more developed Member States, many of the less developed countries do not have the capacity, resources, training, infrastructure or even a mandate to contribute equally. Developing countries should be encouraged to become more fully and actively involved in order to make this exchange more useful, relevant, and multi-dimensional.

In addition, the network of National Information Officers and the expansion of electronic exchange of information needs to be considerably strengthened and put into action to ensure close liaison between Member States and WHO for all drug safety and regulatory information.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- ➔ continue to facilitate the development and exchange of information on the safety and efficacy of medicines by: raising national awareness and creating political commitment for good regulatory practices; fostering collaborations and partnerships between governments and the pharmaceutical industry, health professionals, curricula and professional associations; supporting training programmes for capacity building; and providing technical assistance to regulatory authorities.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with a computerized medicines registration system	na	na	na	72/135	53%	60%

EO 6.3

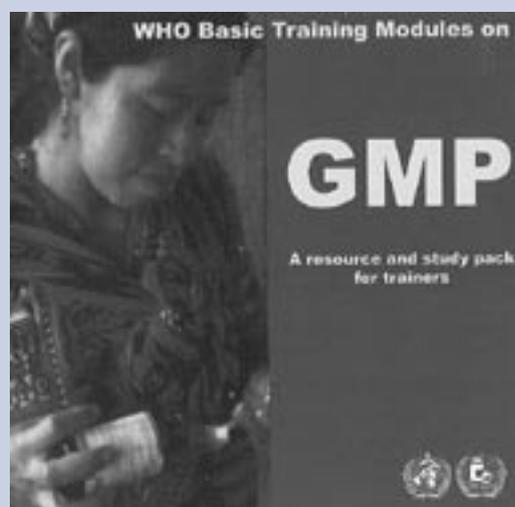
Good practices in medicine regulation and quality assurance systems to ensure that quality is maintained in clinical trials, production, supply and distribution, and post-marketing surveillance

Rationale

Essential tools (standards, norms, guidelines) and guidance for good regulatory and quality assurance practices are widely available, but need to be constantly updated. Some good practice guidelines, such as GMP and Good Clinical Practice (GCP) guidelines, are normative documents. Others, like Good Regulatory Practices, may be of more general nature and oriented to improving the overall performance of medicines regulatory agencies. Proper implementation of these regulatory and quality assurance tools according to locally established standard operating procedures is essential as a quality management step for proper implementation of regulation, and to ensure that the medicines used are safe, effective, and of good quality. The success of regulation is dependent not only on the regulators but also on the full compliance of those being regulated (manufacturers and distributors).

Progress

Additional guidelines and tools have been developed, such as new GMP training modules for validation, water, heating, ventilation, and air conditioning systems. An external quality assurance assessment scheme for national and regional quality control laboratories has been continued in all six WHO regions, involving 36 laboratories. In addition, WHO has developed a tool for reviewing national medicine regulatory capacity, including implementation of GMP guidelines. The review is designed to help both WHO and the concerned national authorities to identify priority areas for capacity building, technical advice, and support. This collaborative work has enabled assessments to be carried out in a number of countries in order to identify weaknesses in national regulatory authorities and action needed to strengthen capacity. The experience accumulated through this collaborative work has helped further refine the data collection tools and the methodology of the reviews.



Challenges

Three types of common imbalance have been identified in regulatory practice:

- much more time is assigned to pre-marketing assessment than to post-marketing surveillance
- while product registration is considered a major responsibility by all the drug regulatory authorities, the regulation of drug distribution channels and information does not enjoy the same level of attention
- in many countries, GMP inspection receives more attention and resources than inspection of distribution channels.⁵⁴

The quality of products in the market is at risk if regulators and those being regulated fail to apply and monitor principles of good practice in production, supply and distribution of medicines, and post-marketing surveillance.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- promote implementation of good practice by providing necessary guidelines, tools, and technical assistance
- continue to help Member States to assess regulatory capacity and improve regulatory performance by capacity building
- continue to pursue the external quality assessment scheme for medicines control laboratories in all six WHO regions.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with basic quality assurance procedures	95/122	78%	80%	111/137	81%	85%

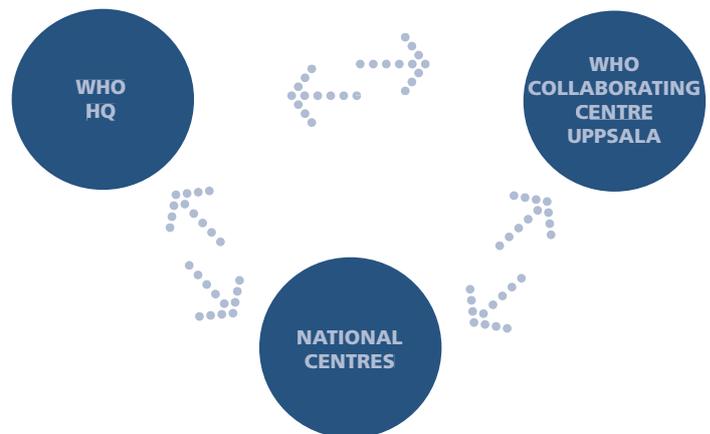
EO 6.4

Post-marketing surveillance of medicines safety maintained and strengthened through the ongoing development of pharmacovigilance centres and their involvement in international adverse drug reaction monitoring systems

Rationale

The aims of pharmacovigilance are to promote patient care and patient safety in relation to the use of medicines, especially with regard to the prevention of unintended harm from the use of medicines; to improve public health and safety in relation to the use of medicines through the provision of reliable, balanced information resulting in more rational use of medicines; and to contribute to the assessment of the risk-benefit profile of medicines, thus encouraging safer and more effective use of medicines. Through efforts to promote pharmacovigilance WHO seeks to ensure that all medicines in all Member States are subject to monitoring for adverse reactions.

Figure 24: WHO Programme for International Drug Monitoring

**Progress**

The WHO Programme for International Drug Monitoring is comprised of three parts, each of which is integrally linked and has a role in adverse drug reaction monitoring.

The Programme has issued several guidelines on adverse drug reaction monitoring in the Safety of Medicines series. These include: *Guidelines for setting up and running a Pharmacovigilance Centre*; *The Importance of Pharmacovigilance*; and *A guide to detecting and reporting adverse drug reactions*. The Programme has also run training courses on pharmacovigilance, including a course in 2003 held jointly with Roll Back Malaria to monitor the introduction of new antimalarials in five African countries. The Programme network has expanded to include 72 countries and the global database has increased to over 3 million reports of adverse events from the participating countries.

Challenges remaining

The biggest challenge in adverse drug reaction monitoring is under-reporting by health professionals. There is an urgent need to raise awareness among all interested parties of the importance of monitoring medicines. More countries need to establish the process elements of an Adverse Drug Reaction Centre (ADR) and consequent involvement in international monitoring. The established ADR centres need to improve reporting, both qualitatively and quantitatively. The scope of pharmacovigilance continues to broaden as the array of medicinal products grows. It includes the use of herbal and traditional medicines, blood products, biologicals, and vaccines. A more recent and urgent challenge has arisen with the launch by WHO of the '3 by 5' initiative aimed at providing ARVs for 3 million people by 2005. These new drugs are being introduced into populations where there is little infrastructure to monitor their use.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- promote pharmacovigilance through activities and Annual Meetings of the National Centres participating in the International Drug Monitoring Programme.
- collaborate with existing pharmacovigilance centres for capacity building in countries currently not included in the Programme.
- maintain normative activities, including the annual meetings of the Advisory Committee on the Safety of Medicinal Products and the production of guidelines in the Safety of Medicines series. Forthcoming publications include: *Pharmacovigilance and Public Health* and the *Safety Monitoring of Herbal medicines*.
- increase efforts to provide training in pharmacovigilance.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries monitoring adverse drug reactions	56/191	29%	35%	72/192	38%	45%

EO 6.5

Use of substandard and counterfeit medicines reduced as a result of the development and application of effective strategies to detect the existence and combat the production and circulation of such products

Rationale

Governments have to regulate the manufacture, import, export, distribution, and supply of medicines in order to ensure that the products used are safe, effective, of good quality, and rationally used. To achieve this, governments have to establish strong national regulatory authorities with adequate human, financial and other resources, and an adequate legal basis. The regulatory authorities effectively control the market through measures such as the establishment of a mandatory licensing system for companies and products; inspection of premises; and post-marketing surveillance activities. It is estimated that about 30% of WHO Member States, most of them low-income countries, have either no national regulatory system or one that is not functioning well. As result, in many of these countries 20%-30% of samples collected from markets fail quality tests. The use of substandard or counterfeit medicines may cause damage to health, treatment failure or death, and in the long term lead to the waste of scarce resources. Moreover, treatment with ineffective medicines such as antibiotics leads to the emergence of antimicrobial resistance, which may effect a wide section of the population. Efforts to strengthen medicine regulation will help improve implementation of regulatory requirements and standards by manufacturers and distributors and thereby contribute to the reduction of substandard and counterfeit medicines.

Progress

WHO develops and distributes standards, norms, and guidelines to Member States to help them regulate the manufacture, importation, and distribution of medicines. WHO has also provided guidance, technical assistance, and training to medicine regulatory authorities to help build national regulatory and quality assurance capacity. More specifically, in the area of counterfeit medicines, WHO has developed guidelines for combating counterfeit medicines, organized intercountry, regional, and international workshops and training courses, and has undertaken advocacy activities to make government decision-makers and the public aware of the problem of counterfeit medicines. In the Greater Mekong Subregion (GMS) countries (Cambodia, China, Lao PDR, Myanmar, Thailand, and Viet Nam) WHO recently launched a special programme to combat counterfeit medicines. WHO has also supported post-marketing quality assessment activities in a number of countries to gather information on the quality of products.

EO 6.6

Prequalification (initial assessment, ongoing monitoring and prequalification) of products and manufacturers of medicines for priority diseases and of quality control laboratories, as appropriate, through procedures and guidelines appropriate for this activity

This expected outcome comprises three activities:

- finalization of the Model Quality Assurance System.
- prequalification of products and manufacturers for products used in the treatment of HIV/AIDS, TB, and malaria.
- prequalification of quality control laboratories.

1 Finalization of the Model Quality Assurance System

Rationale

The objective is to finalize a model, based on norms and standards for procurement agencies, that will ensure that all UN partners follow the same process and procedure in procurement activities, meeting international standards. This includes good practices for prequalification, purchasing, storage, and distribution.

Progress

The third draft of the Model Quality Assurance System is in the final stages and was discussed at a meeting of the IPC in New York in November 2003, involving UN procurement organizations and NGOs.

Challenges

Many organizations do not have the infrastructure

or resources needed to implement quality systems for prequalification of products and manufacturers, purchasing, storage, and distribution that meet international recommendations. The challenge will be to harmonize the process and procedure in procurement activities amongst these organizations as well as to target the level at which the minimum standards should be set for the Model Quality Assurance System.

2 Prequalification of products and manufacturers for products used in the treatment of HIV/AIDS, TB, and malaria

Rationale

The prequalification of products and manufacturers aims to assess product data and information as well as manufacturing sites, to establish whether these meet internationally recommended norms and standards established by WHO. The objective is to ensure that only products meeting acceptable quality standards will be procured. Purchasing or sourcing of products that have not been prequalified from manufacturers that are not prequalified may result in the supply of substandard or counterfeit products, or of products that do not meet specifications, norms, and standards in relation to safety, efficacy or quality — with obvious risks for the patient.

Progress

Following the launch by WHO of the prequalification project, over 400 product dossiers have been assessed and several manufacturing sites have been inspected. To date, more than 50 products (including both innovator and generic products) have been found to meet the WHO norms and standards. These are included in a list of prequalified products and manufacturers.

Challenges remaining

Several substances and products are not included in pharmacopoeia monographs. Some substances have specific properties which make assessment more difficult (e.g. chirality). Not all products can be considered either innovator or generic products. The number of manufacturers of Active Pharmaceutical Ingredients (APIs) and finished products such as those used in the treatment of multidrug-resistant TB are limited. The number of manufacturers of APIs and finished products such as artemisinin and its derivatives, as well as the artemisinin combination therapy (ACT) products, are limited. In addition, some manufacturers do not have the resources to improve compliance with GMP. Not all manufacturers have generated all the required data to prove safety, efficacy, and quality of their products. More time is needed to meet the target of prequalifying a certain number of products and manufacturers.

3 Prequalification of quality control laboratories

Rationale

Interested quality control laboratories will be assessed as part of a prequalification procedure. The assessment should indicate whether these laboratories meet international standards as defined by WHO in GMP and Good Practice for Pharmaceutical Control Laboratories. The results of analysis of products obtained from laboratories not meeting international standards may be inaccurate.

Progress

WHO has established norms and standards for quality control laboratories. A procedure for the prequalification of laboratories has already been developed.

Challenges remaining

There is a need to encourage laboratories to participate in the prequalification process and establish whether these laboratories have the capability to perform analysis of complex products.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- establish the Model Quality Assurance System through negotiation and discussion, targeting it at a level that meets minimum requirements for norms and standards, to allow procurement organizations to establish and implement a quality control system.
- improve awareness of the requirements, norms, and standards through the assessment and appropriate training of regulators and industry, resulting in improved regulatory control of products.
- assess quality control laboratories for compliance with international standards as part of the prequalification project.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of products assessed and approved	na	na	na	93	na	na

EO 6.7

Safety of new priority and neglected medicines enhanced through training workshops and increased capacity to assess safety issues

Rationale

With all newly registered products there is limited experience of large-scale operational use or of the safety of these medicines when used among special population groups, such as infants, pregnant women, and people suffering from malnutrition or HIV/AIDS. This is a particular problem for new medicines for priority and neglected diseases since these are normally introduced with some urgency and there is a need to ensure that this is done within acceptable standards of safety assessment. The urgency of this problem is exemplified by current efforts to provide ARVs to 3 million people by 2005 — for use in settings which differ from those where most of the safety studies have been carried out.

Progress

A training course on pharmacovigilance was held in Zambia in 2002, involving five African countries which are introducing ACT for malaria in response to increasing levels of resistance to antimalarials (Burundi, Democratic Republic of Congo, Mozambique, Zambia, and Zanzibar). The course focused on basic methods and skills for drug safety monitoring, with the aim of introducing a common system of pharmacovigilance of new antimalarial treatments in each country, with access to the WHO database and to international expertise. Similar

courses are planned for other diseases including HIV/AIDS.

Challenges remaining

A major challenge is the need to ensure the integration of this work throughout WHO programmes. The Programme to Eliminate Lymphatic Filariasis, for example, has introduced a system for monitoring adverse effects of the drugs used in mass populations. Other disease programmes need to be aware of the need for high-level coordination of these efforts. Meanwhile, as efforts get under way to scale up access to ARVs in developing countries, there is a need to develop plans for pilot programmes to monitor the safety of these medicines among groups suffering from malnutrition or affected by more than one disease. Partnerships with other organizations are needed to strengthen WHO's work in this critical area.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- ➔ increase efforts to provide training courses for pharmacovigilance in the area of neglected diseases and continue to raise awareness of this problem.
- ➔ support national initiatives to conduct post-marketing surveillance of medicines such as ARVs and antimalarials.
- ➔ train regulators and health care professionals in safety monitoring, with a special focus on new combination medicines for HIV/AIDS, TB, and malaria, and other priority public health diseases.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries participating in training programmes for introducing new therapies for priority and neglected diseases, e.g. malaria and AIDS	0	na	na	7	na	20

EO 6.8

Regulatory harmonization monitored and promoted as appropriate, and networking initiatives developed, to facilitate and improve regulatory processes in countries

Rationale

Harmonization of technical requirements for registration of medicines can contribute to public health by improving access to safe, effective, and good-quality pharmaceutical products. It can also facilitate the development of fair and transparent regulatory processes, improve international collaboration, reduce duplication of work by different regulatory agencies, and facilitate trade and competition. The harmonization initiatives, whether regional or sub-regional, are ongoing in all WHO regions. The major focus of many of those initiatives is to first harmonize basic regulatory requirements for generic medicines. The ICH, an initiative started by Europe, Japan, and the United States in 1990, has been focusing on establishing harmonized requirements to evaluate the quality, safety, and efficacy of new innovative drugs, thereby avoiding the necessity to duplicate many time-consuming and expensive test procedures. As a result, the time spent on regulatory approval of new drugs has been shortening, and marketing of these products takes place internationally with minimal delay for the patients. By 2003, the ICH regions have largely harmonized regulatory requirements for the quality, safety, and efficacy of new drugs.

Progress

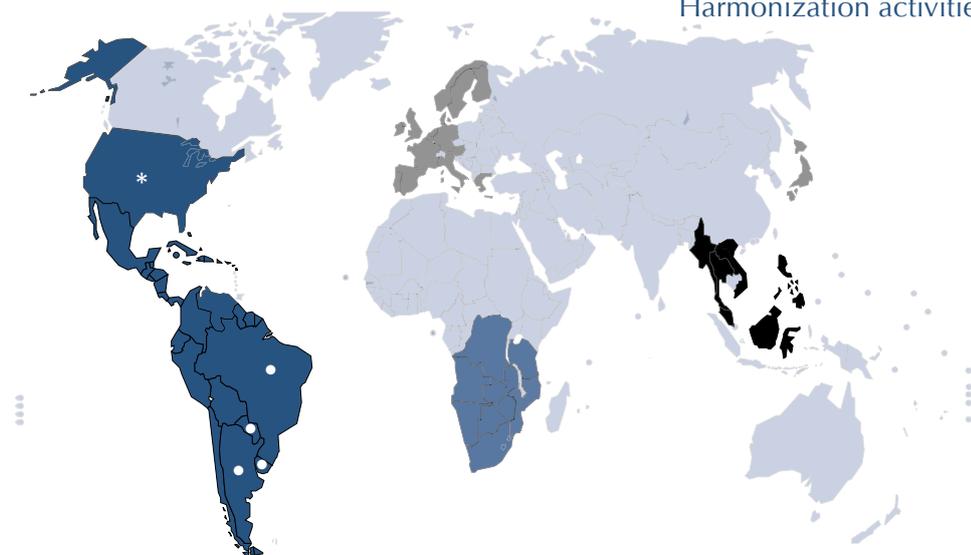
WHO/EURO actively supported the establishment of the Collaboration Agreement of Drug Regulatory Authorities in European Union Associated Countries (CADREAC), which has made rapid progress since its first Annual Meeting in Sofia in 1997. Ten CADREAC countries

have finalized their regulatory harmonization and are expected to join the European Union in 2004. In the Americas, the Pan-American Network for Drug Regulatory Harmonization has made considerable progress since its first Steering Committee meeting in 2000 in Puerto Rico. Other WHO-supported initiatives include the ASEAN Pharmaceutical Harmonization and harmonization amongst Southern African Development Community (SADC) countries. The non-ICH harmonization initiatives are emphasizing the importance of training of regulators as an important vehicle to drive harmonization forward.

Challenges remaining

The huge gaps in existing regulatory capacities are hindering harmonization. Progress has been slowed by limited resources and lack of political will. The regulatory approval of generic drugs which are more affordable for patients remains largely unharmonized, paradoxically more so in countries where health care systems rely heavily on the use of generic drugs. Regulatory assessment of products by national authorities, especially in the case of new medicines, often gives limited added value to the work already done by other regulatory authorities. The potential for financial savings through mutual recognition of regulatory assessments remains underestimated. There is also a tendency to adopt sophisticated technical requirements before basic measures have been put in place to protect public health and ensure the quality (e.g. basic registration requirements, GMP, and supply chain inspection) of medicines.

Figure 25:
Harmonization activities supported by WHO



- ASEAN (Association of South East Asian Nations):**
Brunei, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Thailand, Singapore, Vietnam
- * **ICH (International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals Human Use):** European Union, Japan, USA
- MERCOSUR** (created in 1991 with the signing of the Treaty of Asuncion):
Argentina, Brazil, Paraguay, Uruguay
- PANDRA (Pan American Network for Drug Regulatory Harmonization)**
All the countries of the Americas
- SADC (Southern African Development Community):** Angola, Botswana, Congo Demoractic Republic, Lesotho, Malawi, Mauritius, Namibia, Mozambique, South Africa, Swaziland, Seychelles, Tanzania, Zambia, Zimbabwe
- UEMOA (Monitory and Economic Union of West Africa)**
Benin, Burkina Faso, Côte d'Ivoire, Guinea Bissau, Maili, Niger, Senegal, Togo

Meeting the challenges 2004-2007

Over the next four years WHO will:

- continue to promote and monitor networking and harmonization efforts both regionally and internationally.
- continue to provide technical assistance to promising harmonization initiatives.

- increase its capacity to deliver technical assistance through increased collaboration, partnerships, and alliances with other technical organizations such as the Pharmaceutical Inspection Co-operation Scheme.
- continue its observer and/or facilitator role in international groups on harmonization, including ICH, to ensure that the views and needs of all countries are properly represented.

OUTCOME INDICATORS	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries participating in harmonization initiatives supported financially and technically by WHO	na	na	na	15/191	8%	18%

Definition of rational use of medicines

“Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.” (WHO, 1985).

COMPONENT 7

USING MEDICINES RATIONALLY

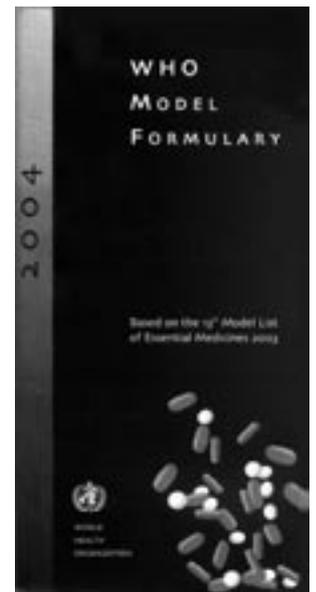
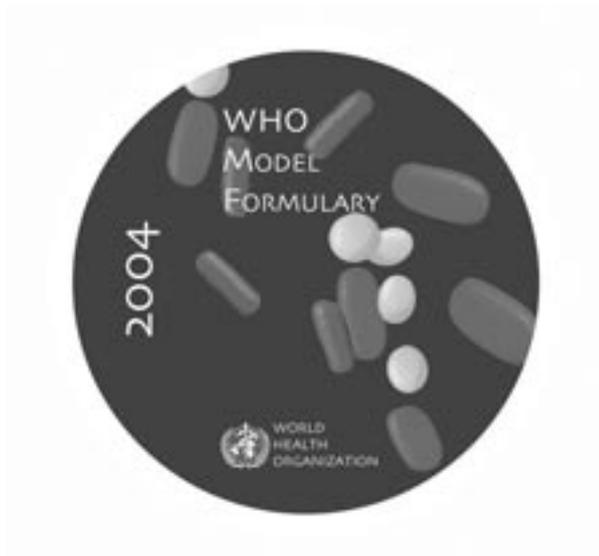
Irrational use of medicines is a major problem worldwide. WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards.

Examples of irrational use of medicines include:

- use of too many medicines per patient ('poly-pharmacy')
- inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections
- over-use of injections when oral formulations would be more appropriate
- failure to prescribe in accordance with clinical guidelines
- inappropriate self-medication, often of prescription-only medicines
- non-adherence to dosing regimes.

WHO advocates 12 key interventions to promote more rational use:

- 1 Establishment of a multidisciplinary national body to coordinate policies on medicine use
- 2 Use of clinical guidelines
- 3 Development and use of national essential medicines list
- 4 Establishment of drug and therapeutics committees in districts and hospitals
- 5 Inclusion of problem-based pharmacotherapy training in undergraduate curricula
- 6 Continuing in-service medical education as a licensure requirement
- 7 Supervision, audit and feedback
- 8 Use of independent information on medicines
- 9 Public education about medicines
- 10 Avoidance of perverse financial incentives
- 11 Use of appropriate and enforced regulation
- 12 Sufficient government expenditure to ensure availability of medicines and staff.



WHO Model Formulary

Countries at all levels of development – nearly 160 countries in total – have used criteria including safety, efficacy, quality and public health value to produce selective national, provincial and state lists of essential medicines and vaccines. These have become the basis for training, reimbursement, public education, and other public health priorities.⁵⁵

WHO has itself applied evidence-based techniques to develop the most recent Model List of Essential Medicines⁵⁶ and the WHO Model Formulary, which reflects the contents of WHO-recommended treatment guidelines.

WHO will work to ensure that medicines are used in a therapeutically sound and cost-effective way by health professionals and consumers in order to maximize the potential of medicines in the provision of health care

EO 7.1

Rational use of medicines by health professionals and consumers advocated

Rationale

Decisions about the use of medicines are strongly influenced by health professionals and consumers. However, it is these two groups which can be the most reluctant to implement policies about rational use. For health professionals and prescribers, rational use will often conflict with peer pressure and/or commercial interests. For consumers, especially where the treatment is free of charge or in the event of serious illness, there is a natural demand to have the 'latest' treatment (on the assumption that this equates to 'best') regardless of cost. Both of these groups are influenced by the marketing and promotional activities of product patent holders. Despite the scientific logic of rational use training and guidance material, such as treatment protocols, there is strong resistance to their application.

Progress

There has been a major increase in the volume of information in support of rational use, together with increasing use of objective scientific evidence to formulate protocols and policies at international and country levels. The rapid expansion of movements such as the Cochrane Foundation has made vital information readily available. WHO has contributed to this process over the past 20 years through demonstrating the value of evidence-based action. The *Essential Drug Monitor*, a twice-yearly publication with a 40 000 print-run issued in five languages, is a major channel for advocacy among health professionals and policy-makers. Some of the themes covered have included prescribing skills, improving drug use, drug donations, networking for action, managing drug supply, access,

antimicrobial resistance, medicines promotion, and 25 years of the essential medicines concept. Other networks concerned with promoting rational use of medicines have also been supported, including INRUD, INDIA-DRUG (an email discussion group) and the International Society for Drug Bulletins. In 2003, in response to the increasing problem of patient failure to adhere to therapy for chronic diseases, WHO published a review of the evidence for action.⁵⁷

Challenges remaining

There is a need to engage some of the major players — manufacturers, prescribers, and providers and consumers of medicines — on the importance of ensuring the rational use of medicines. The challenge is to find ways and means to translate the logic of the existing rational use messages and practice into convinced action by the majority of practitioners and consumers. Although intervention research during the past decade has helped identify strategies and interventions that are effective in promoting rational use of medicines, many of these strategies have not been taken on board by governments. In many countries today, more than half of all patients are not treated in accordance with clinical guidelines (WHO/EDM rational drug use database, 2003).

Meeting the challenges 2004-2007

Over the next four years WHO will:

- adapt and distribute materials to countries and promote the use of training and networking with consumer groups and professional societies. While some activities will strengthen the existing training courses, others will involve the more effective use of the Internet to disseminate information.
- launch a coordinated plan of activity at country, regional, and headquarter levels, to ensure that participants in all training courses are followed up more closely at country level.
- conduct a readership survey and evaluation of the Essential Drugs Monitor and make changes where necessary to increase circulation.
- broaden the scope of rational use activities to include chronic diseases such as HIV/AIDS, particularly on the issue of treatment adherence.

OUTCOME INDICATORS	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries where the promotion of the rational use of medicines is coordinated at the national government level	na	na	na	93/127	73%	75%

EO 7.2

Essential medicines list, clinical guidelines, and formulary process developed and promoted

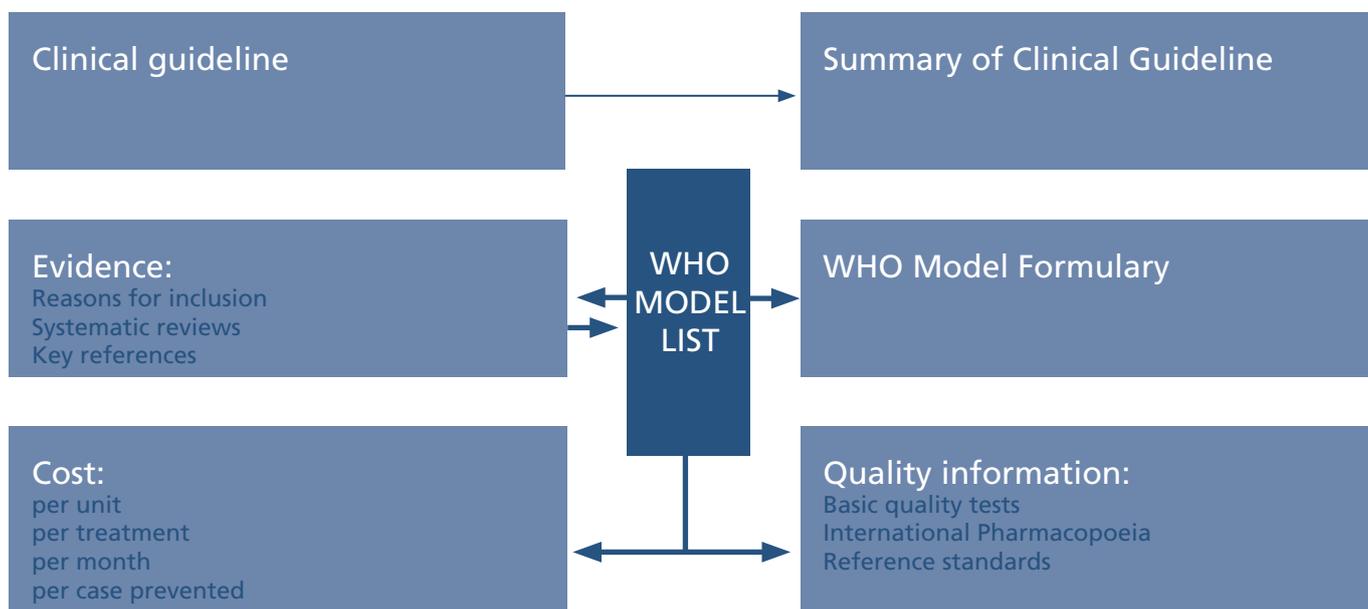
Rationale

The selection of a list of medicines, based on a number of criteria including disease pattern and recommended treatments, is the foundation of the essential medicines concept⁵⁸. Clinical guidelines indicate the most cost-effective therapeutic approach, on the basis of valid clinical evidence. Their impact is greatest if the end-users, prescribers and, to a certain extent, patients are closely involved in developing the guidelines. Formularies are commonly publications that combine the list of medicines with concise guidance on their safe and rational use. Evidence from practice and research has demonstrated that the most cost-effective use of medicines may vary — depending on factors such as local market prices, availability, and distribution costs — and there is a need to support countries in developing or updating their rational use publications.

Progress

The WHO Model List of Essential Medicines has been regularly revised and proved to be a valuable tool over the past 25 years, complemented and enhanced by the publication in 2002 of the WHO Model Formulary⁵⁹. Collaboration within WHO has resulted in a formulary that incorporates updates in treatment protocols from the disease-specific departments in WHO. Access is available via the WHO Essential Medicines Library on the WHO website⁶⁰. The Library links essential medicines to WHO treatment guidelines, the Model Formulary, price information, pharmacopoeal monographs, and other WHO sites including information on adverse drug reactions and the ATC/DDD classification (Figure 24). There are now 135 countries with national standard treatment guidelines and 156 countries with national essential medicines lists, of which about 75% have been updated within the last five years.

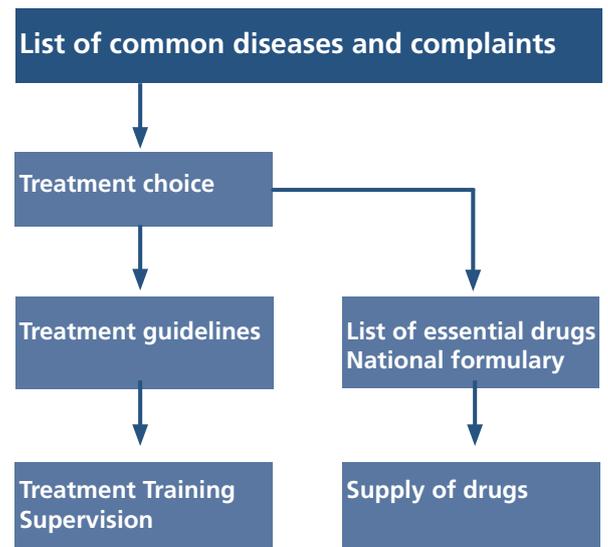
Figure 26: The WHO Essential Medicines Library (<http://mednet3.who.int/eml/>)



Challenges remaining

There is a continuing need within WHO for systematic evidence-based approaches to the production of authoritative treatment guidelines to assist countries and to form the basis of the Model List (Figure: 27). National formularies, lists of medicines that are reimbursable (“positive lists”), and treatment guidelines exist but are only occasionally evidence-based, rarely updated, and often ignored. The challenge is to provide technical assistance to countries to improve their techniques of selection and to develop or update their rational use materials.

Figure 27: Relation between treatment guidelines and a list of essential medicines



Meeting the challenges 2004-2007

Over the next four years WHO will:

- provide technical support to countries to revise their national formulary and positive list development, using an evidence-based approach.
- strengthen the process of developing evidence-based clinical guidelines within WHO for use by WHO and other UN agencies (UNICEF, UNFPA, UNHCR).

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with national list of essential medicines updated within the last 5 years	129/175	74%	75%	82/114	72%	75%
No. of countries with treatment guidelines updated within the last 5 years	60/90	67%	70%	47/76	62%	65%

EO 7.3

Independent and reliable medicines information identified, disseminated, and promoted

Rationale

Reliable, objective, and evidence-based information is the foundation of rational medicines use. With the development of specialized networks and websites, access to such information is readily available in most parts of the world where there is access to the Internet. However, this still leaves many countries without access to independent and reliable medicines information. In a global survey carried out in 1999, only 50% of 138 reporting countries had Drug Information Centres. The regional range was 40%-89%. The lack of independent and reliable medicines information in many countries is compounded by the pharmaceutical industry's investment in marketing activities, including direct-to-consumer advertising. In the USA, for example, the pharmaceutical industry spent about US\$ 15 billion on promotional activities in 2000.⁶¹

Progress

The major advance in this area has been the production of the WHO Model Formulary and the WHO Medicines Library (see also EO 7.2). In addition, a manual on the production of National or Institutional Formularies based on the WHO Model Formulary will be released in 2004. This manual will be issued as a CD-ROM, also containing the WHO Model Formulary.

Challenges remaining

Information available to professionals and consumers is frequently provided by the manufacturers or suppliers of medicines, both of which have a commercial interest, rather than from independent sources with a consumer interest. The imbalance in funding for such activities means that it is difficult for prescribers to obtain comparative unbiased information.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- provide technical support to strengthen national capacity to develop and disseminate medicines information.
- support national efforts to produce national or institutional formularies and national drug information bulletins.
- work with the International Society of Drug Bulletins to produce a manual for use at national level in the production of Drug Information Bulletins.

OUTCOME INDICATORS	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with a national medicines information centre able to provide independent information on medicines to prescribers and/or dispensers	62/123	50%	59%	53/129	41%	50%
No. of countries with a medicines information centre / service accessible to consumers	na	na	na	45/127	35%	40%

EO 7.4

Responsible ethical medicines promotion for health professionals and consumers encouraged

Rationale

The rational use of medicines has often been undermined by the unethical marketing of medicinal products through advertising or the activities of medical representatives. The Report by WHO's Director-General to the 49th World Health Assembly highlights the continued "imbalance between commercially produced drug information and independent, comparative, scientifically validated and up-to-date information on drugs for prescribers, dispensers, and consumers."

Drug companies spend large amounts of money on promoting their products to doctors around the world. In the United States, the industry spent over US\$13.2 billion in 2000, while US\$1.1 billion was spent in Italy in 1998. In the developing world, promotion accounts for 20%-30% of sales revenue. There are currently over 80 000 sales representatives in the United States, where the industry sponsored some 314 000 physician events in 2005. Meanwhile, growth in spending on direct-to-consumer advertising of prescription drugs, which is allowed in the United States, has been dramatic, with nearly US\$ 2.4 billion being spent in 2001.⁶²

Progress

WHO and HAI/Europe have coordinated a project to establish a database on promotional activities (<http://www.drugpromo.info>). It is hosted and administered by the WHO Collaborating Centre for Drug Information at the Science University of Malaysia. The objectives of the project are to:

- document inappropriate medicines promotion both in developing and developed countries.
- document the impact of inappropriate medicines promotion on health.
- provide information about tools that can be used to teach health professionals about medicines promotion.
- promote networking among groups and individuals concerned about medicines promotion by providing links through the website.

As part of the project, four reviews have been written to provide an overview of key promotion-related issues including:

- What attitudes do people (professional and lay) have towards promotion?
- What impact does pharmaceutical promotion have on attitudes and knowledge?
- What impact does pharmaceutical promotion have on behaviour?
- What interventions have been tried to counter promotional activities, and with what results?

Challenges remaining

While these reviews clearly document the large amounts spent on promotion, there is little evidence on effective ways of addressing this problem in different country settings. The challenge for WHO is to determine what can and should be done to ensure responsible ethical medicines promotion.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- continue to promote criteria for medicines promotion⁶³ and provide technical support to countries in monitoring and regulating the promotion of medicinal products.
- undertake further research to evaluate the impact of interventions aimed at: improving the preparation of doctors and pharmacists to deal with promotional challenges; how guidelines affect gifts being used as promotional inducements; and how the enforcement of Conflict of Interest guidelines affect promotional activities.
- review and update where necessary WHO's 1988 guidelines on ethical criteria for medicines promotion to take account of developments in communication such as the Internet and direct-to-consumer advertising.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with basic system for regulating pharmaceutical promotion	92/132	70%	80%	83/113	73%	76%

EO 7.5

Consumer education enhanced in recognition of the growing significance of self-medication and of consumer access to knowledge and advice of variable quality

Rationale

Consumers of medicines are the final decision-makers on the use of medicines, whether prescribed or purchased over the counter without prescription. However, insufficient attention is paid to consumer education on the importance of rational use of medicines. Self-medication is increasing in importance, either by default or as a result of deliberate public policy. In developing countries today, out-of-pocket spending by consumers is the main source of spending on medicines. In many countries, the distinction between prescription-only and over-the-counter medicines is meaningless as almost all medicines are available for sale.

Progress

The need for skills development for community education in rational medicine use has been clearly identified in WHO research. In response, a new interactive and skills-oriented training programme on community education in the rational use of medicines has been developed by WHO, in partnership with the University of Amsterdam and an experienced group of developed and developing country experts, and made available in Asia and Africa. In addition, two manuals, one on investigating drug use in communities and the other on interventions to change medicines use in communities, are being prepared by partners at the University of Amsterdam.

Challenges remaining

Despite the risks to personal health from misguided self-medication or the inappropriate use of prescribed treatment by consumers, the full impact of these practices cannot be quantified. The challenge is to promote rational use of medicines amongst consumers with the same level of success as the pharmaceutical industry achieves in marketing their products. As yet there is limited information available as to which are the most effective interventions for use in developing and transitional countries. Further research is needed in different environments and sectors.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- support efforts to provide information and education designed to improve rational use of medicines by consumers. The long-term aim of the training programme on community education is to develop a network of trained people committed to implementing community education in rational use of medicines, evaluating the impact of their work, reporting on experience, and sharing expertise.
- promote and support systematic research activities aimed at identifying the most effective interventions for improving rational use.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries that have implemented a national consumer education campaign in the last two years	na	na	na	72/120	60%	60%

EO 7.6

Drug and therapeutics committees promoted at institutional and district/national levels.

Rationale

An effective drug and therapeutic committee (DTC) will establish and monitor policies and systems for medicines management in hospitals, health programmes or geographical areas. Hospital DTCs are vital structures for implementing comprehensive and coordinated rational medicines use strategies in hospitals. They should be considered as a cornerstone of the hospital pharmaceutical programme, with responsibility for developing and coordinating all hospital policies related to pharmaceuticals, such as the selection of standard treatments and hospital formularies. These committees should also be responsible for adapting the national clinical guidelines and essential medicines list to the needs of the hospital and for carrying out medicines utilization studies and prescription reviews, as well as developing educational strategies to improve medicines use and management.

Progress

A WHO manual on the establishment and functions of DTCs was published in 2003. In collaboration with MSH, an international course with accompanying materials was developed and four international and four national courses were conducted in 2000-2003. A web-based discussion group and a follow-up workshop for past DTC course participants were provided by MSH in collaboration with WHO. Several intervention research projects involving DTCs, aimed at promoting better use of medicines, have been

or are currently being supported (in Cambodia, Ghana, Indonesia, Kenya, Laos, and Zimbabwe).

Challenges remaining

Although DTCs have been established in many different settings, many of them fail to ensure the correct management of medicines within the institution or area they represent. In many developing countries, DTCs are hampered by a shortage of qualified staff and lack of capacity in many hospitals and by the lack of incentives from governments or hospital authorities to encourage staff to attend meetings. While some DTCs are responsible for the selection of medicines for the hospital formulary, very few are involved in monitoring medicines use or implementing strategies to improve rational use.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- provide training, support, and advice to countries seeking to establish and sustain functioning DTCs. This will involve regional and international training courses as well as targeted support in response to requests from countries.
- continue to support intervention research projects on promoting the rational use of medicines through DTCs and present some past results at the next international conference for improving the use of medicines.
- ensure that future participants at international DTC courses are followed up more closely at country level. Past experience has shown that participants do not use the information they have learnt unless they have developed definite plans of action during the training courses and have follow-up visits at country level.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with DTCs in the majority of regions/provinces	na	na	na	32/96	33%	40%

EO 7.7**Training in good prescribing and dispensing practices promoted****Rationale**

Rational use depends on the knowledge, attitudes, and practices of health care practitioners and consumers. Educational strategies for both groups are essential but these are often inappropriate or neglected. In basic (undergraduate) training of health care practitioners, for example, there is often a focus on the transfer of narrow, time-limited pharmacological knowledge, rather than on the development of lifetime prescribing skills and the ability to assess medicines information critically.

Progress

WHO has had an impact on the training of prescribers worldwide through the publication of the Guide to Good Prescribing and training in the use of this. The Teachers Guide to Good Prescribing was published in 2001. Work is in progress to develop material for a Guide to Good Pharmacy Practice. Three international training courses per year in English, French, and Spanish on problem-based pharmacotherapy have been supported. An evaluation of their impact is under way.

Over the past three years, in partnership with other concerned groups, WHO has conducted a wide range of training courses on different aspects of rational use of medicines, together with the production and promotion of training materials.

Training courses related to the rational use of medicines

- Promoting the rational use of medicines, in collaboration with INRUD and coordinated by Management Sciences for Health (MSH), USA. This course teaches the investigation of medicine use in primary health care and how to promote rational use of medicines by providers.
- Promoting rational medicine use in the community, in collaboration with the University of Amsterdam, the Netherlands. This course teaches the investigation of medicine use in the community, and how to promote rational use of medicines by consumers.
- Drugs and therapeutics committees, in collaboration with the Rational Pharmaceutical Program coordinated by Management Sciences for Health, USA. This course teaches methods for evaluating medicine utilization and how to promote rational use of medicines in hospitals and districts.
- Problem-based pharmacotherapy teaching, in collaboration with Groningen University, The Netherlands, the University of Cape Town, South Africa, the University of La Plata, Argentina (in Spanish) and the National Centre for Pharmacovigilance, Ministry of Health, Algiers, Algeria (in French). This course teaches a

problem-based approach to rational prescribing based on WHO's Guide to Good Prescribing.

- Pharmacoeconomics, in collaboration with the University of Newcastle, Australia. This course teaches how to do economic evaluation in medicine selection.
- Medicine policy issues for developing countries, in collaboration with Boston University, USA. This course teaches about general medicines policy including aspects relating to promoting more rational use of medicines.
- ATC/DDD methodology for medicine consumption, in collaboration with the WHO Collaborating Centre for Drug Statistics Methodology. This course provides an introduction to the application of ATC/DDD methodology in measuring medicine consumption.

Challenges remaining

In many undergraduate medical curricula there is insufficient focus on clinical pharmacotherapy and problem-based teaching methods are not used. As a result, traditional training programmes for health professionals do not prepare them adequately for the rational use of medicines in health care.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- advocate for and support the inclusion of problem-based and skills-based pharmacotherapy teaching in undergraduate and postgraduate training programmes for health professionals.
- support an evaluation of the prescribing habits of doctors and prescribers who received problem-based pharmacotherapy training compared with those who did not. Such evaluation can be used to advocate for more appropriate training on clinical pharmacotherapy teaching at both undergraduate and postgraduate levels.

OUTCOME INDICATORS

No. of countries that include the concept of essential medicines in basic curricula for medicine and / or pharmacy

1999		2003			2007
# REPORTING	%	TARGET	# REPORTING	%	TARGET
na	na	na	72/88	82%	85%

EO 7.8

Practical approaches to contain antimicrobial resistance developed based on the WHO Global Strategy to Contain Antimicrobial Resistance.

Rationale

Irrational use of antimicrobials, including their use in agriculture, is one of the major drivers of increasing antimicrobial resistance. As a result, some infections are now untreatable with first-line antimicrobials in some parts of the world. Surveys have revealed that 25%-75% of antibiotic prescriptions in teaching hospitals in both developed and developing countries are inappropriate.⁶⁴ In addition, as many as 30%-60% of patients in primary health care centres receive antibiotics (perhaps twice what is clinically needed).⁶⁵ Surveys have also revealed that most episodes of illness are self-medicated and that most people purchase incomplete courses of medication, including antibiotics, and/or do not adhere to the correct dosing regimes.

Progress

WHO has recognized antimicrobial resistance to be a problem of increasing public health concern and passed a number of resolutions encouraging Member States to take measures to contain antimicrobial resistance⁶⁶. The *WHO Global Strategy to Contain Antimicrobial Resistance* and other supporting documents were published in 2001⁶⁷ and a follow-up meeting on how to implement the Global Strategy held in 2002. EDM has provided technical assistance in developing national plans to contain antimicrobial resistance in six countries and three regions. A number of pilot projects have been started in India and South Africa involving the development of a methodology for the linked surveillance of antimicrobial use and resistance.

Challenges remaining

The continuing overuse, underuse, and misuse of antibiotics leads to antimicrobial resistance patterns that are neither measured nor contained, with consequent health and financial implications for countries — a problem that is on the increase worldwide. At the national level there is often a lack of data on antimicrobial use and data on resistance are inappropriate for use at the local level as resistance patterns and antimicrobial use can vary widely within countries. In addition, there is a lack of methods applicable at the local level for measuring antimicrobial resistance and use.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- work with other agencies to develop tools and promote programmes to measure and contain the threat of antimicrobial resistance.
- pursue the pilot projects aimed at developing a methodology for linked surveillance of antimicrobial use and resistance at country level and use the results to guide practical advice to countries.
- continue to provide targeted technical support, where requested, to countries and regions.
- develop a policy perspective paper to advise policy-makers on how to contain antimicrobial resistance.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries with national strategy to contain antimicrobial resistance	na	na	na	37/113	33%	40%

EO 7.9

Identification and promotion of cost-effective strategies to promote rational use of medicines

Rationale

Since irrational use of medicines is not limited to one area of the health sector, strategies should be designed to cover the public and private sectors and to target self-medication and prescribing habits. What is needed is a major shift in the knowledge and behavioural patterns of both individuals and social groups, including households, communities, health professionals, educational institutions, and industry. In view of the financial constraints, there is a need to identify and target priority areas. From a health economics perspective, these areas should be those which are expected to yield the largest improvement in social benefit (or reduction of unnecessary social costs) for the money invested.⁶⁸

Progress

WHO, in collaboration with partners including MSH and the Universities of Harvard and Boston in the United States, has supported more than 20 intervention research projects in developing countries, aimed at providers and consumers, hospitals, primary health care and the community, and private and public sectors. Technical support for these has included supervisory visits as well as workshops for proposal development and data analysis. A policy perspective paper outlining core components of a national strategy to promote rational use of medicines was published in 2002.⁶⁹ WHO is also developing a quantitative database of all medicine use studies from 1993 onwards in order to assess global progress in promoting rational use of medicines. In addition, WHO has supported INRUD and associated training programmes. A major advance was the first francophone course on promoting rational use of medicine, conducted in Rwanda in 2003. This will be replicated in 2004 and followed up with field activities.

Challenges remaining

Irrational prescribing, dispensing, and consumption of medicines exist even in the presence of agreed strategies and policies for rational use, especially in developing countries. Although past research has identified the effectiveness of many interventions, particularly when used in combination, many countries have not implemented or scaled up such strategies, possibly because of the expense involved. The challenge for WHO is to evaluate the cost-effectiveness of various strategies and to advocate a package of priority cost-effective interventions to be adopted by countries. An additional challenge is the need to identify effective interventions to improve medicines use in hospitals and in the treatment of chronic diseases such as HIV/AIDS in developing countries.

Meeting the challenges 2004-2007

Over the next four years WHO will:

- continue to support intervention research projects to evaluate the cost-effectiveness of interventions to improve the rational use of medicines. The results of projects supported in the last four years and the WHO rational medicine use database will be presented at the 2nd International Conference for Improving the Use of Medicines in April 2004 in Thailand. The global agenda for the next five years, to be decided at this conference, will include evaluation of the impact of national policies on medicines use and the cost-effectiveness of interventions.
- continue to work with INRUD to support training programmes on promoting rational use of medicines, running fewer courses but with greater follow-up of participants' activities at country level.
- increase efforts to improve the rational use of medicines for chronic diseases.

OUTCOME INDICATORS

	1999		2003			2007
	# REPORTING	%	TARGET	# REPORTING	%	TARGET
No. of countries that have undertaken a national assessment / study of the rational use of medicines	na	na	na	57/97	59%	60%

IMPLEMENTING
THE STRATEGY
COUNTRIES AT THE CORE



REQUEST FOR SUPPORT FROM COUNTRY

If WHO has not been active in pharmaceuticals in a country before or for a long period of time

TYPE A SITUATION ANALYSIS

- Determine priority needs and what further support would be most appropriate
- Financed primarily from unspecified funds

TYPE B SPECIFIC TECHNICAL SUPPORT

- Timely interventions usually focused on a subset of the following areas: policy, access, quality safety and efficacy, rational use
- Financed primarily from unspecified funds

*i.e. funds for which the donor has not specified a particular purpose or use.

**i.e. funds for which the donor has specified a particular purpose or use.

TYPE C COMPREHENSIVE PROGRAMME SUPPORT

- Ministry of Health/WHO implementation plan covering most or all of the following areas: policy, access, quality, safety and efficacy, rational use
- Financed primarily from specified funds**
- Time frames may cover two or more biennia
- Usually necessitates full-time pharmaceutical adviser in country
- May involve drug supply

REQUEST FOR SUPPORT FROM COUNTRIES OR REGIONS

TYPE IC INTERCOUNTRY PROGRAMMES

- Involves two or more countries, frequently from the same region
- Financed primarily from unspecified funds*
- Usually focused on a subset of the following areas: policy, access, quality, safety and efficacy, rational use

Working with countries – supporting and enabling national resources/capacity

Working with countries on policy and technical issues has always been and continues to be the highest priority for WHO in the field of medicines. It is essential that countries' needs and experiences are at the core of all WHO's work in pharmaceuticals.

WHO support in medicines is demand driven. It can be classified into four main types, sometimes used in combination: situation analysis, specific technical support, comprehensive programme support, and intercountry programmes. In 2002, WHO provided direct support in the pharmaceutical sector to 113 countries. Twenty-two countries received comprehensive programme support, 85 received specific technical support, and WHO supported six countries in situational analyses⁷⁰.

Country work is also a fundamental resource for WHO. Only by undertaking such work can the Organization develop its evidence and knowledge base and continue to maintain its position as the leading UN technical agency on public health issues.

WHO working together – coordination, communication and collaboration

WHO country support in medicines benefits from effective coordination, collaboration, and communication between EDM teams and WHO headquarters, regional offices, and country offices and between WHO and its partners. Working together enables a unified vision for the future and a common strategy to reach it. WHO's guiding principles for country support are given in Figure 28.

Strengthening WHO regional and country capacity

To improve its effectiveness at country level, WHO is implementing a strategy to strengthen its regional and country offices. An important part of decentralization and strengthening WHO capacity has been the appointment of regional and issue focal points at headquarters, an increase in the number of staff in regional offices, the recruitment of Medicines Advisers in selected country offices, and efforts to strengthen partnerships with health care providers, CSOs, consumers, donors, and other international agencies.

Each regional office has an essential medicines

Figure 28: Model of EDM Country Support



Figure 29: Medicines Advisers recruited in 11 African countries



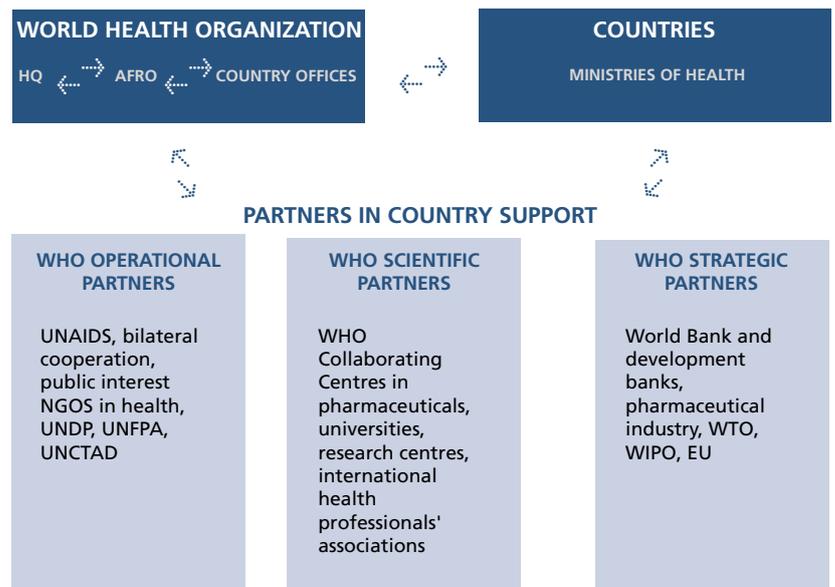
A total of 32 Medicines Advisers provide support in five WHO regions

team which coordinates WHO work in the region and facilitates sub-regional cooperation where appropriate. There are now a total of 13 people in the WHO essential medicines teams in the regional offices.

Country office capacity has strengthened by the recruitment of Medicine Advisers, national professional officers (NPOs) with specialized expertise in pharmaceuticals and medicines. Medicine Advisers are a key long-term support mechanism for sustainable pharmaceutical development. They work with Ministries of Health to identify needs and priorities; plan, implement, and monitor action; and coordinate with other partners.

Countries are prioritized for recruitment of Medicine Advisers based on the following selection criteria:

- Geographical, cultural, language distribution
- Priority/severity of need
- WHO country capacity
- Level of development
- Likelihood of sustainable impact
- Potential cost-effectiveness
- Involvement of other partners.



Working in partnership – supporters and co-workers

All available resources must be called upon and well coordinated to promote appropriate and effective national medicines policies, access, quality and safety, and appropriate use of essential medicines. EDM expertise and resources are maximized through close collaboration and co-ordination within EDM and between EDM and its partners. EDM partners in country support include public and private sector businesses and research institutes, CSOs, and global entities.

Efforts to strengthen partnerships within EDM teams and departments and between EDM headquarters and regional and country offices, and to build operational, scientific, and strategic partnerships with others are key to fulfilling WHO's goals in pharmaceuticals.

It is in coordination with operational partners that WHO supports countries to develop and sustain effective pharmaceutical sectors, including access to and appropriate use of quality medicines.

It is with strategic partners that WHO can promote improvements in global public health.

It is with the expertise of scientific partners that WHO can provide the level of specialist technical advice requested by countries. More than 40 WHO Collaborating Centres now work with WHO on medicine priorities.

Examples of such partnerships in the past three years include:

- The development in 2002 of the *Handbook on Access to HIV/AIDS Treatment* in partnership with the HIV/AIDS Alliance and UNAIDS.
- The project to prequalify manufacturers of ARVs, including generic producers, based in WHO and operating in collaboration with the IPC.
- In 1995-2002, the development of a computerized system for registration, involving original work in Tunisia Pharmacy and Medicines Directorate and subsequent developmental work in the EMEA.
- A collaborative project with HAI Africa to improve the involvement of civil society in policy development and implementation in countries in the region.
- Collaboration with four WHO Collaborating Centres to develop materials in relation to TRIPS and to monitor the impact of TRIPS and other trade agreements on public health and access to essential medicines.

Working in line with WHO Strategy – links in the knowledge chain building strength

In turning to WHO for expert advice on medicines, countries may request data and statistics concerning health information and advice on a wide range of health issues or advice on new and innovative approaches to long-standing or newly emerging health problems. WHO's response will be in line with the corporate strategy of fulfilling its mandate and drawing on the core function to create, synthesize, and disseminate knowledge through a series of related approaches (Figure 30)

Figure 30: Creation, synthesis, and dissemination of knowledge**Stimulating strategic and operational research**

Create new knowledge, through networking and collaboration, to meet present and future challenges relating to pharmaceuticals; and identify innovative and viable approaches to ensure access to, and the quality and appropriate use of medicines.

Articulating and advocating policy options

Develop and disseminate needs-driven, ethical, evidence-based and action-oriented policy options to help countries — confronted with many difficult decisions in a changing global context — manage their pharmaceutical sector and increase its contribution to public health.

Developing norms and standards

Develop norms and standards as a foundation for the effective regulation, control, manufacture, and sale of medicines, and to guide international harmonization of the pharmaceutical trade.

Producing guidelines and practical tools

Provide policy-makers and essential medicines managers with practical guidelines and tools for implementing the components of a national medicine policy and for promoting capacity-building, particularly when there is a lack of national pharmaceutical experts.

Developing human resources

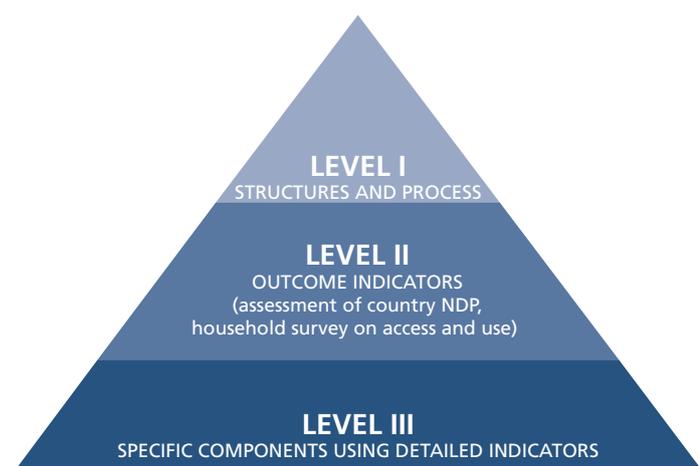
Build country capacity to effectively implement the various components of a national medicine policy by developing clear guidelines on the human resources required, ensuring that undergraduate and postgraduate curricula for all health professions incorporate the essential medicines concept, and developing and promoting in-service training and supervision for health staff at all levels.

Managing information

Synthesize and disseminate information on pharmaceutical issues, including assessing trends, comparing performance, and monitoring the potential impacts on health of global economic, social or political developments.

MONITORING PROGRESS



Figure 31: Monitoring Progress

Monitoring progress with the strategy – measuring against indicators at country level

It is important to have a regular source of information on the pharmaceutical situation at the country, regional, and global level that can be used as a guide for governments and stakeholders. This information should link to strategies and priority activities implemented in countries.

In recent years, WHO has developed a number of tools to track progress on key indicators and essential components of country pharmaceutical situations. One of these tools is the questionnaire on the structures and processes of the country pharmaceutical situation (*the Level I questionnaire*), which includes indicators that are collected from all Member States every four years.

Level I indicators provide a method to rapidly assess the implementation of national medicines policies and their components. These indicators are evaluated through a questionnaire completed at the national level. These core indicators are used to assess existing structures and processes in a national pharmaceutical system such as legislation/regulations, quality control of pharmaceuticals, essential medicines list, medicines supply system,

medicines financing, access to essential medicines, production, rational use of medicines, intellectual property rights protection, and marketing authorization.

Information from Level I indicators are now being used by WHO to monitor its priority areas of work and to analyse country, regional, and global performance in the pharmaceutical sector. Country progress indicators corresponding to target outcomes in the WHO Medicines Strategy were selected mostly from Level I indicators.

Country progress indicators were identified based on expected activity outcome and challenging issues relevant to WHO work on pharmaceuticals. However, the indicators are intended to measure the collective efforts of the government and other groups, agencies, and stakeholders involved in pharmaceuticals.

The results of the 2003 survey have been compared against targets for the WHO Medicines Strategy 2000-2003 and used as baseline data for the 2004-2007 Strategy. New targets for each indicator were then established for the conclusion of the new Strategy by 2007 (see summary table of Country Progress Indicators below).

Country Progress Indicators for Expected Outcomes of WHO Medicines Strategy 2004-2007

	# Reporting	%	Target	# Reporting	%	Target
EO 1.1 Medicines policies developed, updated and implemented taking into consideration health, development, and intersectoral policies to achieve maximum impact						
Countries with an official national medicines policy document—new or updated within the last 10 years	67/152	44%	55%	62/123	50%	59%
Countries with a national medicines policy implementation plan—new or updated within the last 5 years	41/106	39%	43%	49/103	48%	61%
EO 1.2 Implementation of medicines policy regularly monitored and evaluated, providing data that can be used in adjusting policy and interventions to improve access to medicines						
Countries having conducted a national assessment of their pharmaceutical situation in the last 4 years	na	na	na	47/90	52%	58%
EO 1.3 Public health aspects protected in the negotiation and implementation of international, regional and bilateral trade agreements through inter-country collaboration and legislative steps to safeguard access to essential medicines						
Countries integrating TRIPS Agreement flexibilities into national legislation to protect public health	na	na	na	32/105	30%	45%
EO 1.4 Human resources capacity increased in the pharmaceutical sector through education and training programmes to develop capacity and to motivate and retain personnel in sufficient numbers within a clearly defined and organized structure						
Countries that provide both basic and continuing education programmes for pharmacists	54/85	64%	na	34/110	31%	35%
EO 1.5 Promotion of innovation based on public health needs, especially for neglected diseases, through policies and actions creating a favourable environment for innovation of medically needed new medicines						
Countries promoting research and development of new active substances	na	na	na	21/114	18%	22%
EO 1.6 Gender perspectives introduced in the implementation of medicines policies by identifying gender differences in access to and rational use of medicines and supporting women in their central role in health care						
Countries providing free medicines for pregnant women at primary public health facilities	na	na	na	54/106	51%	60%
EO 1.7 Access to essential medicines recognized as a human right via advocacy and policy guidance to recognize and monitor access to essential medicines as part of the right to health						
Countries that provide HIV/AIDS-related medicines free at primary public health facilities	na	na	na	60/104	58%	65%
EO 1.8 Ethical practices promoted and anti-corruption measures identified and implemented in the pharmaceutical sector, using the experience of successful programmes addressing aspects of corruption encountered in the pharmaceutical sector						
Countries with medicines legislation requiring transparency, accountability and code of conduct for regulatory work	na	na	na	84/114	74%	80%
EO 2.1 TM/CAM integrated in national health care systems where appropriate by developing and implementing national TM/CAM policies and programmes						
Countries with national TM policy	25	na	na	39/127*	31%*	37%
EO 2.2 Safety, efficacy and quality of TM/CAM enhanced through expanding the knowledge base on safety, efficacy and quality of TM/CAM and providing guidance on regulation and quality assurance standards						
Countries regulating herbal medicines	48	na	na	82/127*	65%*	75%
EO 2.3 Availability and affordability of TM/CAM enhanced through measures aiming to protect and preserve TM knowledge and national resources for their sustainable use						
Countries with a national inventory of medicinal plants as a means to provide intellectual property rights protection for traditional medical knowledge	na	na	na	9/39	23%	33%
EO 2.4 Rational use of TM/CAM by providers and consumers by promoting therapeutically sound use of appropriate TM/CAM						
Countries with national research institute in the field of TM/CAM	19	na	na	56/127*	44%*	51%
EO 3.1 Access to essential medicines improved, including medicines for HIV/AIDS, malaria, TB, childhood illnesses, and noncommunicable diseases						
Countries where less than 50% of the population has access to essential medicines	29/184	16%	14%	15/103	15%	14%
EO 3.2 Public funding of medicines increased through increased organizational capacity to implement sustainable drug financing strategies and systems						
Countries with public spending on medicines below US\$2 per person per year	38/103	37%	35%	24/80	30%	20%

Expected Outcomes and Indicators WMS 2004 - 2007	1999		2003		2007	
	# Reporting	%	Target	# Reporting	%	Target
EO 3.3 Development assistance increased for access to medicines, including the Global Fund						
Percentage of key medicines available in public health facilities	na	na	na	22 ¹	77 ²	na
EO 3.4 Medicines benefits promoted within social health insurance and prepayment schemes						
Countries with public health insurance covering the cost of medicines	71/111	64%	70%	79/117	68%	73%
EO 3.5 Medicine pricing policies and price information promoted to improve affordability of essential medicines						
Countries with a pricing policy for maximum retail mark-up in the private sector	na	na	na	36/75	48%	55%
EO 3.6 Competition and generic policies implemented along with guidelines for maximizing competition in procurement practices						
Countries in which generic substitution is allowed in private pharmacies	83/135	61%	75%	99/132	75%	81%
EO 4.1 Supply systems assessed and successful strategies promoted to identify weaknesses in the supply systems and improve the performance and functioning of national medicines supply systems						
Countries with public sector procurement limited to national essential medicines list	71/133	53%	60%	84/127	66%	74%
EO 4.2 Medicines supply management improved through training programmes and career development plans to increase capacity and reduce staff turnover						
Countries providing continuing education to pharmacists and pharmacy aides/assistants	39/103	38%	na	31/111	28%	32%
EO 4.3 Local production assessed and strengthened, on the basis of policy guidance to create a favourable environment for government or international support to domestic production of selected essential medicines						
Countries with local production capability	na	na	na	36/122	30%	na
EO 4.4 Procurement practices and purchasing efficiency improved through guidance on good procurement practices, medicines management information support, and work with countries to strengthen efficient procurement procedures						
Countries with at least 75% of public sector procurement carried out by competitive tender	81/88	92%	95%	58/70	83%	87%
EO 4.5 Public-interest NGOs included in medicine supply strategies, in support of national medicine supply strategies to reach remote areas						
Countries with NGOs involved in medicines supply	na	na	na	29/64	45%	na
EO 5.1 Pharmaceutical norms, standards and guidelines developed or updated to promote good practice in regulatory matters						
Countries using the WHO Certification Scheme as part of the marketing authorization process	na	na	na	87/135	64%	75%
EO 5.2 Medicines nomenclature and classification efforts continued through assignment, promotion and protection of international nonproprietary names, and the promotion and development of ATC/DDD system.						
Countries using INNs in medicines registration.	na	na	na	108/131	82%	90%
EO 5.3 Pharmaceutical specifications and reference materials developed and maintained for use in quality control laboratories and publications in the International Pharmacopoeia						
Number and types of pharmaceutical specifications and reference materials developed by WHO HQ	na	na	105	96	na	50
EO 5.4 Achieving balance between abuse prevention and appropriate access to psychoactive substances through enhancing the implementation of relevant guidelines to promote rational use of controlled medicines						
Number of substances reviewed and recommended for classification for international control	2/3.	66%	na	5/5.	100%	80%
EO 6.1 Medicines regulation effectively implemented and monitored as the capacity of staff is increased through training activities resulting in better knowledge, organization, financing, and management						
Countries implementing basic medicines regulatory functions	70/138	51%	56%	90/130	69%	74%
EO 6.2 Information management and exchange systems promoted and made accessible through shared databases. Basic regulatory information made available to the general public						
Countries with a computerized medicines registration system	na	na	na	72/135	53%	60%
EO 6.3 Good practices in medicine regulation and quality assurance systems to ensure that product quality is maintained in production, clinical trials, supply and distribution						
Countries with basic quality assurance procedures	95/122	78%	80%	111/137	81%	85%

Expected Outcomes and Indicators WMS 2004 - 2007	1999		2003		2007	
	# Reporting	%	Target	# Reporting	%	Target
EO 6.4 Post-marketing surveillance of medicine safety maintained and strengthened through the ongoing development of pharmacovigilance centres and their involvement in international adverse drug reaction monitoring systems						
Countries monitoring adverse drug reactions	56/191	29%	35%	72/192	38%	45%
EO 6.5 Use of substandard and counterfeit medicines reduced as a result of the development and application of effective strategies to detect the existence and combat the production and circulation of such products						
Countries with >10% of tested medicines failing quality tests	na	na	na	20/71	28%	25%
EO 6.6 Prequalification (initial assessment, ongoing monitoring and prequalification) of products and manufacturers of medicines for priority diseases; and of quality control laboratories, as appropriate, through procedures and guidelines appropriate for this activity						
Number of products assessed and approved	na	na	na	93	na	na
EO 6.7 Safety of new priority and neglected medicines enhanced through training workshops and increased capacity to assess safety issues						
Countries participating in training programmes for introducing new therapies for priority and neglected diseases, e.g. malaria and AIDS	0	na	na	7	na	20
EO 6.8 Regulatory harmonization monitored and promoted as appropriate, and networking initiatives developed, to facilitate and improve regulatory processes in countries						
Number of countries participating in harmonization initiatives supported financially and technically by WHO	na	na	na	15/191	8%	18%
EO 7.1 Rational use of medicines by health professionals and consumers advocated						
Countries where the promotion of the rational use of medicines is coordinated at the national government level	na	na	na	93/127	73%	75%
EO 7.2 Essential medicines list, clinical guidelines and formulary process developed and promoted						
Countries with national list of essential medicines updated within the last 5 years	129/175	74%	75%	82/114	72%	75%
Countries with treatment guidelines updated within the last 5 years	60/90	67%	70%	47/76	62%	65%
EO 7.3 Independent and reliable medicines information identified, disseminated and promoted						
Countries with a national medicines information centre able to provide independent information on medicines to prescribers and/or dispensers	62/123	50%	59%	53/129	41%	50%
Countries with a medicines information centre/service accessible to consumers	na	na	na	45/127	35%	40%
EO 7.4 Responsible ethical medicines promotion for health professionals and consumers encouraged						
Countries with basic system for regulating pharmaceutical promotion	92/132	70%	80%	83/113	73%	76%
EO 7.5 Consumer education enhanced in recognition of the growing significance of self-medication and of consumer access to knowledge and advice of variable quality						
Countries that have implemented a national consumer education campaign in the last two years	na	na	na	72/120	60%	60%
EO 7.6 Drug and therapeutics committees promoted at institutional and district/national levels						
Countries with DTCs in the majority of regions/provinces	na	na	na	32/96	33%	40%
EO 7.7 Training in good prescribing and dispensing practices promoted						
Countries that include the concept of essential medicines in basic curricula for medicine and/or pharmacy	na	na	na	72/88	82%	85%
EO 7.8 Practical approaches to contain antimicrobial resistance developed based on the WHO Global Strategy to Contain Antimicrobial Resistance						
Countries with national strategy to contain antimicrobial resistance	na	na	na	37/113	33%	40%
EO 7.9 Identification and promotion of cost-effective strategies to promote rational use of medicines						
Countries that have undertaken a national assessment/study of the rational use of medicines	na	na	na	57/97	59%	60%

* Data collected from Traditional Medicine Survey

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ENDNOTES

- ^a The decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health by the WTO General Council was agreed by WTO Members on August 30, 2003. It is sometimes referred to as the August 30 Decision or the Paragraph 6 Decision.
- ^b The term “traditional medicine” (TM) is used in this document, the term “complementary and alternative medicine” (CAM) is used where the dominant health care system is based on allopathic medicine, or where TM has not been incorporated into the national health care system.
- ^c Data collected from Traditional Medicine Survey
- ^d Data collected from Traditional Medicine Survey
- ^e Data collected from Traditional Medicine Survey
- ^f A number of relevant guidelines have been developed under the umbrella of the Interagency Pharmaceutical Coordination (IPC) group which, in addition to WHO/EDM, includes UNAIDS, UNICEF, UNFPA, and the World Bank.
- ^g Based on 22 countries that have completed the Level II survey
- ^h Average
- ⁱ Based on 22 countries that have completed the Level II survey
- ^j Average

