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WHO Medicines Strategy:

Framework for Action in
Essential Drugs and Medicines Policy

2000-2003



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WHO Medicines Strategy: 2000–2003

Framework for Action in Essential Drugs and Medicines Policy

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Abbreviations, acronyms & WHO Regions

AFRO	WHO Regional Office for Africa (see below for Member States covered)
AMRO/PAHO	WHO Regional Office for the Americas/Pan American Health Organization (see below for Member States covered)
ASEAN	Association of South-East Asian Nations
CDS/CPE	Communicable Diseases Cluster/Department of Communicable Diseases Control, Prevention and Eradication
CDS/STB	Communicable Diseases Cluster/Stop TB Initiative
DGO	Director General's Office
EDM	Department of Essential Drugs and Medicines Policy (within Health Technology and Pharmaceuticals Cluster)
EIP/OSD	Evidence and Information for Policy Cluster/Department of Organization of Health Services Delivery
EMRO	WHO Regional Office for the Eastern Mediterranean (see below for Member States covered)
EU	European Union
EURO	WHO Regional Office for Europe (see below for Member States covered)
FCH/CAH	Family and Community Health Cluster/Department of Child and Adolescent Health and Development
FCH/HIS	Family and Community Health Cluster/HIV/AIDS/STI Initiative
FCH/RHR	Family and Community Health Cluster/Department of Reproductive Health and Research
GMG/IIS	General Management Cluster/Department of Informatics and Infrastructure Services
GMP	good manufacturing practices
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
HTP/VAB	Health Technology and Pharmaceuticals Cluster/Department of Vaccines and Biologicals
ICH	International Conference on Harmonisation
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
INN	International Nonproprietary Name
n.a.	not applicable
NGO	nongovernmental organization
NMH/MNH	(former) Noncommunicable Diseases Cluster/Department of Mental Health
NMH/NCP	Noncommunicable Diseases and Mental Health Cluster/Department of Noncommunicable Disease Prevention
SDE/EHA	Sustainable Development and Healthy Environments Cluster/Department of Emergency and Humanitarian Action
SDE/HSD	Sustainable Development and Healthy Environments Cluster/Department of Health in Sustainable Development
SEARO	WHO Regional Office for South-East Asia (see below for countries covered)
SIAMED	WHO model system for computer-assisted drug registration
STI	sexually transmitted infections
TB	tuberculosis
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 International Drug Control Programme
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WPRO	WHO Regional Office for the Western Pacific (see below for Member States covered)
WSMI	World Self-Medication Industry
WTO	World Trade Organization

WHO African Region Member States are: Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome & Principe, Senegal, Seychelles, Sierra Leone, South Africa, Swaziland, Togo, Uganda, United Republic of Tanzania, Zambia, Zimbabwe.

WHO Americas Member States are: Antigua & Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Puerto Rico, Saint Kitts & Nevis, Saint Lucia, Saint Vincent & Grenadines, Suriname, Trinidad & Tobago, United States of America, Uruguay, Venezuela.

WHO Eastern Mediterranean Member States are: Afghanistan, Bahrain, Cyprus, Djibouti, Egypt, Islamic Republic of Iran, Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Morocco, Oman, Pakistan, Qatar, Saudi Arabia, Somalia, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates, Yemen.

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WHO South-East Asian Member States are: Bangladesh, Bhutan, Democratic Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand.

WHO Western Pacific Member States are: Australia, Brunei Darussalam, Cambodia, China, Cook Islands, Fiji, Japan, Kiribati, Lao People's Democratic Republic, Malaysia, Marshall Islands, Micronesia, Mongolia, Nauru, New Zealand, Niue, Palau, Papua New Guinea, Philippines, Republic of Korea, Samoa, Singapore, Solomon Islands, Tokelau, Tonga, Tuvalu, Vanuatu, Viet Nam.

Highlights —

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Serious illness is a major reason why poor populations remain trapped in poverty. Either they cannot afford health care or else its cost is so high that they are pushed into debt and dependency. The knock-on effects are many and long lasting. Parents cannot afford to send their children to school, working days are lost and economic productivity declines. In countries hit hardest by diseases such as malaria and HIV/AIDS, development has ceased altogether.

Yet cost-effective tools for fighting ill health do exist. Essential drugs are one of those tools. By increasing access to essential drugs, their safety and their rational use, we could make the most of pharmaceutical potential to improve health status and secure development gains.

The impacts of essential drugs

As their name implies, essential drugs:

... have a profound health impact —

Effective drug treatment now exists for most leading infectious diseases, including acute respiratory infections, HIV/AIDS, malaria, diarrhoeal diseases, tuberculosis and the complications of measles. Essential life-saving drugs have also been developed for leading noncommunicable diseases such as ischaemic heart disease and cerebrovascular disease. Every one of these diseases impinges on poor populations disproportionately, detracting from health gains and delaying progress in other areas such as education and economic development.

... increase health system effectiveness —

Essential drugs are high-value commodities. Their availability draws patients to health facilities, where they can also benefit from preventive services. Moreover, if drug procurement is efficient and transparent, the confidence of governments, ministries of finance and donors in a country's health system is increased, and provision of financial and other resources for health system development encouraged. Conversely, lack of essential drugs means that attendance at health facilities drops and that health workers cannot perform effectively. Health status then stagnates or declines.

... increase the cost-effectiveness of pharmaceutical expenditure —

In many developing countries, medicines represent the largest household health expenditure. And in terms of total health expenditure, for both developing and transitional economies, public pharmaceutical expenditure is second only to spending on staff costs. So by focusing pharmaceutical expenditure on essential drugs, the cost-effectiveness of government and out-of-pocket drug expenditure can be enhanced and pharmaceutical health impact heightened.

Progress and challenges

Much has been achieved in pharmaceuticals in the 50 years since WHO began establishing international pharmaceutical standards and guidelines, and since the introduction 25 years ago of the essential drugs and national drug policy concepts. Nearly 160 countries now have national essential drugs lists, while

over 100 countries have national drug policies in place or under development. Similarly, rational drug use concepts and teaching are spreading in all regions. Most importantly of all, though, access to essential drugs grew from 2.1 billion people in 1977 to 3.8 billion people in 1997.

Yet at the beginning of the 21st century essential drugs remain unavailable, unaffordable, unsafe, or improperly used in many parts of the world. An estimated one-third of the world population lacks regular access to essential drugs, with this figure rising to over 50% in the poorest parts of Africa and Asia. And even if drugs are available, weak drug regulation may mean that they are substandard or counterfeit, rather than safe and effective. Irrational use — for example, high rates of antibiotic prescription, overuse of injections, very short dispensing times and incorrect drug use by patients — is of great public health concern too. Inappropriate spending on medicines is often a major source of impoverishment for already disadvantaged populations.

Policy guidance, management tools and training materials, derived from successful essential drugs initiatives, do exist. But they remain insufficiently known and inadequately applied.

WHO Medicines Strategy: 2000–2003

This strategy is WHO's response to these problems. Moreover, it directly supports WHO's corporate strategy and, within this, the overall strategic plan for health technology and pharmaceuticals. The *Medicines Strategy 2000–2003* seeks to:

- create a One-WHO approach to essential drugs and medicines policy
- provide a common policy and technical framework for WHO's pharmaceuticals work with countries
- strengthen and expand operational linkages among WHO activi-

ties involving medicines, health systems, communicable diseases and noncommunicable diseases

- provide a clear framework for pharmaceuticals work with development partners, be they UN agencies, governments, non-governmental organizations (NGOs) or professional associations.

Strategic directions

The *Medicines Strategy* takes WHO's mission in essential drugs and medicines policy as its starting point: **To help save lives and improve health by closing the huge gap between the potential that essential drugs have to offer and the reality that for millions of people — particularly the poor and disadvantaged — medicines are unavailable, unaffordable, unsafe or improperly used.**

WHO is already working with a wide range of partners to achieve this aim by providing global guidance on essential drugs and medicines, and by working with countries to implement national drug policies to ensure equity of access to essential drugs, drug quality and safety, and rational use of drugs. Traditional medicine activities are an integral part of this work.

These activities are in turn contributing to all four WHO strategic directions to:

- reduce the excess mortality of poor and marginalized populations
- reduce the leading risk factors to human health
- develop sustainable health systems
- develop an enabling policy and institutional environment for securing health gains.

The greatest impact, however, of WHO medicines activities is and will continue to be on reducing excess mortality and morbidity from diseases of poverty, and on developing sustainable health systems. This strategy aims to extend and increase that impact. Understandably, in view of the many

demands on health systems, its emphasis is on integrated solutions, which are both equitable and sustainable.

Core functions: improving health through knowledge, advocacy and partnerships

As the world's leading international public health agency, WHO's fundamental role is to create, synthesize and disseminate practical knowledge by: articulating policy and advocacy positions; working in partnership; producing guidelines and practical tools; developing norms and standards; stimulating strategic and operational research; developing human resources; and managing information.

The *Medicines Strategy* pays considerable attention to each of these core functions since they provide a solid basis for ethical, needs-driven, evidence-based action in pharmaceuticals. Tensions often exist, however, between public health, national development and economic interests, and sometimes constrain progress in the pharmaceutical sector. The experience, expertise, authority and financial resources of a number of partners will therefore be vital to successfully carrying out the activities described in this strategy. So even greater efforts will be made to enhance partnerships within WHO, with UNICEF and other UN agencies, with the World Bank, with NGOs, with universities, with industry, and with all other members of the WHO "extended medicines family".

Country work: why and how?

WHO has always had a strong country presence in medicines. Technical support has been provided in response to countries' determination to develop their pharmaceutical sector to help improve the health of their populations. At the

same time, many donors have been keen to use WHO's health and pharmaceutical expertise when providing their own country support. This wealth of experience will help greatly in effectively implementing this strategy where it is most needed — in countries.

The need is great. Combined factors such as globalization, shifting demographics and patterns of disease, and a rapidly changing economic environment are vastly increasing the complexity of decisions concerning how best to improve and maintain health.

The need is also reciprocal. Country work is a fundamental resource for WHO. Only by undertaking such work can WHO expand its evidence and knowledge base. This is crucial if the Organization is to maintain its position as the world's leading authority on public health issues and its capacity to serve Member States.

Over the next four years, WHO will increase the impact of its country work by:

- strengthening pharmaceutical programmes in priority countries, according to identified criteria
- integrating medicines work into overall WHO country cooperation strategies
- expanding its network of country programme advisors and establishing essential drugs access advisors in priority countries, especially in Africa and Asia
- increasing support to regional and subregional networks and to working groups focusing on pharmaceutical issues
- further integration of planning, implementation, and information-sharing among WHO country, regional and headquarters staff working in pharmaceuticals
- expanding direct country support relationships with key development partners such as the World Bank and bilateral donors.

Framework for action

The *WHO Medicines Strategy 2000–2003* addresses policy, access, quality and safety, and rational use. Among these four objectives, the greatest emphasis for the next four years will be on securing access to essential drugs for priority health problems. Priority health problems include malaria, tuberculosis, HIV/AIDS and childhood illnesses, the burden of which falls most heavily on impoverished populations.

Objective 1. Policy — Ensure commitment of all stakeholders to national drug policies, to coordinated implementation, and to monitoring policy impact

The national drug policy process brings all interested parties together to focus political commitment, financing and human resources on pharmaceutical sector improvements. A national drug policy therefore provides a framework for action relating to pharmaceuticals within an overall national health policy. Its goals should therefore be consistent with broader health system objectives, and its implementation should support those objectives. Additionally, every national drug policy should be accompanied by an implementation plan.

WHO will help countries to actively implement national drug policies and monitor their impact. The policy objective has two main components:

- **Implementation and monitoring of national drug policies** — help countries to formulate and implement their national drug policy, and to monitor key components of national drug policy implementation.
- **Health system development supported by essential drugs policies and programmes** — work with countries to integrate their work in essential drugs and medicines policy into their national health system, in support of health system development.

Objective 2. Access — Ensure equitable availability and affordability of essential drugs, with an emphasis on diseases of poverty

Access to essential drugs is a key priority for WHO. From the patient's or consumer's point of view, access to essential drugs means that such drugs can be obtained within reasonable travelling distance (i.e. are geographically accessible), they are readily available in health facilities (i.e. are physically available), and affordable (i.e. are financially available). But meeting these three conditions remains a difficult challenge and will require an integrated, sustainable approach. Such an approach is incorporated in this objective's three main components:

- **Access strategy and monitoring for essential drugs** — help countries to ensure and monitor access to essential drugs, focusing on diseases of poverty, such as malaria, HIV/AIDS, tuberculosis and childhood illnesses.
- **Financing mechanisms and affordability of essential drugs** — ensure the implementation of national strategies to finance the supply and increase the affordability of essential drugs, in both the public and the private sectors.
- **National and local public sector drug supply systems and supply capacity** — support countries to run efficient public sector drug supply systems, ensuring the availability of essential drugs at all levels of the distribution chain.

Objective 3. Quality and safety — Ensure the quality, safety and efficacy of all medicines by strengthening and putting into practice regulatory and quality assurance standards

Global standards for drug quality are becoming increasingly rigorous. Yet the quality of drugs on the market in many countries remains a major public health concern. Similarly, major efforts to improve drug regulation at national and international levels have been

instigated, such as the development of norms and standards, but enforcement of regulatory standards remains a challenge for every country. The quality and safety objective includes four components:

- **Norms, standards and guidance for pharmaceuticals** — strengthen global norms, standards and guidelines for the quality, safety and efficacy of drugs, including traditional medicine, and provide guidance for global harmonization efforts.
- **Drug regulation and quality assurance systems** — support countries to establish and maintain effective drug regulation and quality assurance systems.
- **Information support for pharmaceutical regulation** — improve the access of national regulatory and pharmaceutical control authorities to reliable information management systems, and to mechanisms for exchange of independent information on drug quality, safety and efficacy.
- **Guidance for control and use of psychotropics and narcotics** — provide advice and guidance on psychotropic and narcotic substances in accordance with WHO's mandate under international treaties.

Objective 4. Rational Use — Ensure therapeutically sound and cost-effective use of drugs by health professionals and consumers

Improving drug use by prescribers, dispensers and the general public helps to reduce morbidity and mortality, and to contain drug expenditure. The challenge is how best to ensure therapeutically sound and cost-effective use of drugs, at all levels of the health system, in both the public and private sectors, by both health professionals and consumers. WHO will work to support three components:

- **Rational drug use strategy and monitoring** — support countries in implementing and monitoring a national strategy to promote rational use of drugs by health professionals and consumers.
- **Rational drug use by health professionals** — develop national standard treatment guidelines, essential drugs lists, educational programmes and other effective mechanisms to promote rational drug use by all health professionals.
- **Rational drug use by consumers** — establish effective systems to provide independent and unbiased drug information to the general public — including on traditional medicine — and to improve drug use by consumers.

Monitoring and evaluation

Monitoring and evaluation are crucial to achieving the pharmaceutical objectives of access and rational use of quality drugs. The *WHO Medicines Strategy: 2000–2003* incorporates 26 country progress indicators corresponding to the strategy's target outcomes, and representing pharmaceutical components and strategies that are key to the delivery of effective health services. The indicators will be used to monitor and evaluate country, regional and global pharmaceutical situations and progress. Results of this monitoring and evaluation will contribute to ongoing modification and refinement of WHO work in essential drugs and medicines policy. They will also be reported to policy-makers and other players responsible for decisions relating to health systems planning, national drug policy implementation and allocation of technical, human and financial resources. □

The impact of essential drugs

The 20th Century witnessed revolutionary progress in improving human health, leading to dramatic declines in mortality and equally dramatic increases in life expectancy. Income growth, higher educational levels, improved sanitation conditions and better food intake all contributed to this progress. Development of drugs, particularly essential drugs, also played a significant role.^{1,2}

The essential drugs concept (Box 1) was introduced to accelerate the positive impacts of drugs on health status, particularly for developing countries. The impacts of essential drugs fall into three categories, outlined below.

Box 1 The essential drugs concept

First introduced in 1975, the essential drugs concept is now widely accepted as a highly pragmatic approach to providing the best of modern, evidenced-based and cost-effective health care. It is as valid today as it was 25 years ago when first introduced. The essential drugs concept does not exclude all other drugs, but rather focuses therapeutic decisions, professional training, public information, and financial resources on those drugs that represent the best balance of quality, safety, efficacy and cost for a given health setting.

The essential drugs concept is also a global concept. Health systems of all types, from basic health systems in the poorest countries to highly developed national health insurance schemes in the wealthiest have recognized its therapeutic and economic benefits. Moreover, the concept is forward-looking. It promotes the need to regularly update drug selections in light of new therapeutic options and changing therapeutic needs, the need to ensure drug quality, and the need for continued development of better drugs, drugs for emerging diseases and drugs for coping with changing resistance patterns.

Health impact

Essential drugs save lives and reduce suffering, especially for impoverished populations:

Potentially, every individual can live a long and substantially healthy life. Effective drug treatment exists for most of the leading infectious diseases, including acute respiratory infections, HIV/AIDS, malaria, diarrhoeal diseases, tuberculosis and the complications of measles. Life-saving drugs have also been developed for the leading non-communicable diseases, including ischaemic heart disease and cerebrovascular disease. Increasing access to essential drugs would therefore contribute significantly to reducing poverty which does so much to delay development.

Conversely, substandard and counterfeit drugs can kill:

Although high drug regulation and quality standards exist, less than one in three developing countries benefit from effective drug regulation. Government cutbacks have undermined the ability of existing authorities to safeguard public health, while increasing global trade in drugs has brought global quality assurance challenges.

Health system impact

Essential drugs increase the credibility of a health system and promote patient participation:

Confidence in health care facilities depends on their having the resources to provide health care when needed. The availability of essential drugs encourages patients to attend health care facilities where they can also benefit from preventive services and public health messages. Conversely, if essential drugs are

“Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times, in adequate amounts and in the appropriate dosage forms.”

The Use of Essential Drugs.

6th Report of the Expert

Committee. WHO Technical

Report Series 850.³

known to be out of stock, attendance levels fall.

Effective and transparent drug procurement increases the confidence of governments, ministries of finance and donors in a country's health system: If drugs are procured efficiently and cost-effectively, governments and others are more likely to make financial and other resources available for health system development.

Economic impact

Medicines represent the second largest government public health expenditure: For most ministries of health in developing and transitional economies, public spending on pharmaceuticals represents the largest health expenditure after staff salaries. Indeed, in some countries, drug expenditure — as a percentage of public health care spending — can be as high as 40%.⁴ By focusing on essential drugs, rational drug selection, good procurement practices, reliable quality assurance and efficient distribution systems, best health care value for public pharmaceutical expenditure can be assured.

In low- and middle-income countries, medicines represent the largest out-of-pocket household health expenditure: Focusing on essential drugs can also increase the impact of “out-of-pocket” pharmaceutical expenditure. In high-income countries, two-thirds of medicines are pre-paid through government revenues and social health insurance programmes. In other words the cost of medicines is not borne by the patient. But in developing countries, 50 to 90% of medicines are paid for out-of-pocket at the time of illness. Indeed, in poorer countries, payments for medicines represent the largest out-of-pocket household health expenditure.⁵ But at least if this money is spent on effective medicines that represent best value for money, its health impact is maximized.

1.1 Substantial progress has been made

The good news is that much has been achieved in pharmaceuticals in the 25 years since the essential drugs concept was introduced. In 1975 only a dozen or so countries had what would now be considered an essential drugs list or an essential drugs programme. Today, three out of four countries in the world — nearly 160 countries in all — have adopted national essential drugs lists as the basis for public procurement systems, reimbursement schemes, training, public education and other national health activities. And over 100 countries have national drug policies in place or under development.⁶ Even more importantly, a growing number of countries are moving from policy to action through coordinated national drug policy implementation plans.

Twenty-five years ago, objective information on the rational use of drugs was extremely limited, especially in developing countries. Medical training about drugs was often based on brand names and little attention given to systematic teaching about rational drug use. Today, nearly 100 governments and numerous national nongovernmental organizations (NGOs) have developed therapeutic manuals and formularies, providing health professionals with up-to-date, accurate advice on diagnosis and treatment. The use of generic names is the accepted standard for medical training, and the WHO curriculum for good prescribing is being adopted by leading medical universities in countries at all levels of development.^{6,7}

Perhaps most importantly, 25 years ago, less than half the world's population had regular access to essential drugs. Today, through a combination of public and private health systems, nearly two-thirds of the world's people are estimated to have access to full and effective treatment with the medicines they need. In absolute terms, the

number of people with access to essential drugs grew from roughly 2.1 billion in 1977 to 3.8 billion in 1997.⁸

These accomplishments illustrate just what can be done when governments, public interest groups, the private sector and international organizations such as WHO combine efforts to improve health.

1.2 Unfinished agenda and new challenges

The bad news is that not all people have benefited equally from improvements in health care. Worldwide, about 50 million people die every year. Of these, 10 million deaths (20%) are due to a few common communicable diseases — acute respiratory infections, diarrhoeal diseases, tuberculosis and malaria. Another 10 million deaths every year are due to two leading types of noncommunicable disease: ischaemic heart disease and cerebrovascular disease.⁹ These diseases affect poor

populations disproportionately: for them, 60% of deaths are due to the common communicable diseases, and a further 30% to noncommunicable diseases.¹⁰ So although in absolute numbers access to essential drugs has increased greatly, over one-third of the world's population still lacks such access and pays a heavy price in terms of poor health and elevated mortality.

In the poorest parts of Africa and Asia, the picture is even worse, with over 50% of the population lacking access to even the most basic essential drugs. Poverty, newly emerging diseases, and the high prices of newly developed essential drugs are just some of the factors hampering efforts to improve the situation.¹¹

Poor drug quality is another major concern.¹² For although global standards for drug quality are becoming increasingly rigorous, the actual quality of drugs on the market is inadequate in many countries. Surveys from a number of developing countries show that between 10 and 20% of sampled drugs fail quality control tests.¹³ Part of the reason for this is insufficient drug regulatory capacity. Fewer than one in three developing countries are estimated to have fully functioning drug regulatory authorities. Failure to apply good manufacturing practices is another contributory factor and often results in toxic, sometimes lethal, products. Meanwhile, global trade in pharmaceuticals is bringing global quality assurance challenges.

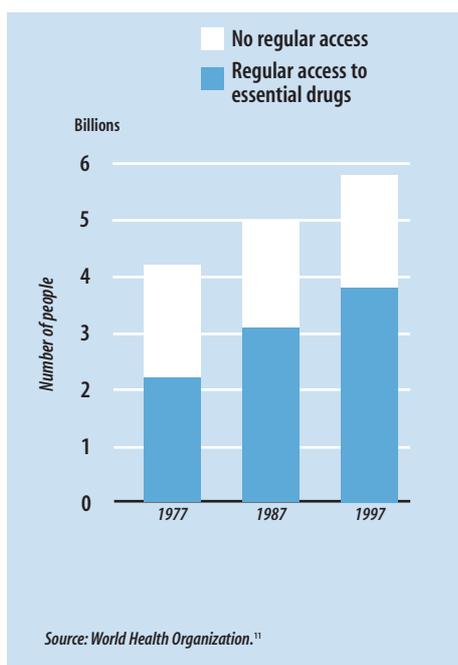
Quality issues also concern traditional medicine. In developing countries up to 80% of the population relies on traditional medicine to meet its health care needs. Such medicine is not only affordable, but also widely available and trusted. In developed countries, traditional and complementary medicine has always been secondary to the practice of modern Western medicine, but a rapid upsurge is now being observed in its popularity. However, the efficacy of much traditional medicine — no matter where it is practised — is as yet scientifically unproven, and

“Despite the long list of successes in health achieved globally during the 20th century, the balance sheet is indelibly stained by the avoidable burden of disease and malnutrition that the world’s disadvantaged populations continue to bear.”

The World Health Report

1999.²

Figure 1: The number of people with access to essential drugs has doubled in 20 years but one-third of the world’s population still lacks such access



provision of traditional medicine is often unregulated.

Irrational use of drugs also remains widespread, despite progress made in drug selection, therapeutic information and training. For example, up to 75% of antibiotics are prescribed inappropriately, even in teaching hospitals.¹⁴ This is contributing to growing antimicrobial resistance, particularly in relation to major infectious diseases, including bacterial diarrhoea, gonorrhoea, malaria, pneumonia and tuberculosis. The more potent, new, second-line drugs needed to conquer such resistance are usually 3–10 times more expensive than first-line drugs. Sometimes they are 50–90 times more expensive, as in the case of multidrug-resistant tuberculosis. In poorer countries, even first-line antibiotic treatments may be out of the financial

reach of patients. In fact, 90% of customers in these countries buy only three days' supply of antibiotics or less.^{15,16} Other irrational use problems relate to dispensing time — on average a mere 15 to 80 seconds per patient in some settings, with virtually no time for counselling.¹⁷ Worldwide, only 50% of patients take their medicines correctly.¹⁸

In brief, this *Medicines Strategy* must be effectively and rapidly implemented if the unfinished agenda and new challenges of the pharmaceutical sector are to be tackled successfully in the early 21st Century. But by providing an overview of what remains to be done, a framework for action for all partners, and indicators for measuring progress, this strategy aims to make these tasks less daunting. □

Strategic directions

2.1 WHO strategic directions

WHO's work covers numerous health-related technical areas, but its overall objective is the attainment by all peoples of the highest level of health. In order to help WHO staff — wherever they work — to meet this objective, the Organization recently set out four strategic directions. These are helping to ensure clear priorities and a shared agenda (Figure 2).⁴⁹ Implementation of the *Medicines Strategy* will contribute to all four WHO strategic directions.

working with countries — at their request — to implement national drug policies to ensure equity of access to essential drugs, drug quality and safety, and rational use of drugs. Development and implementation of national drug policies are carried out within the overall national health policy context, with care taken to ensure that their goals are consistent with broader health objectives. Work in traditional medicine forms an integral part of this work.

2.2 WHO Medicines Strategy: 2000–2003

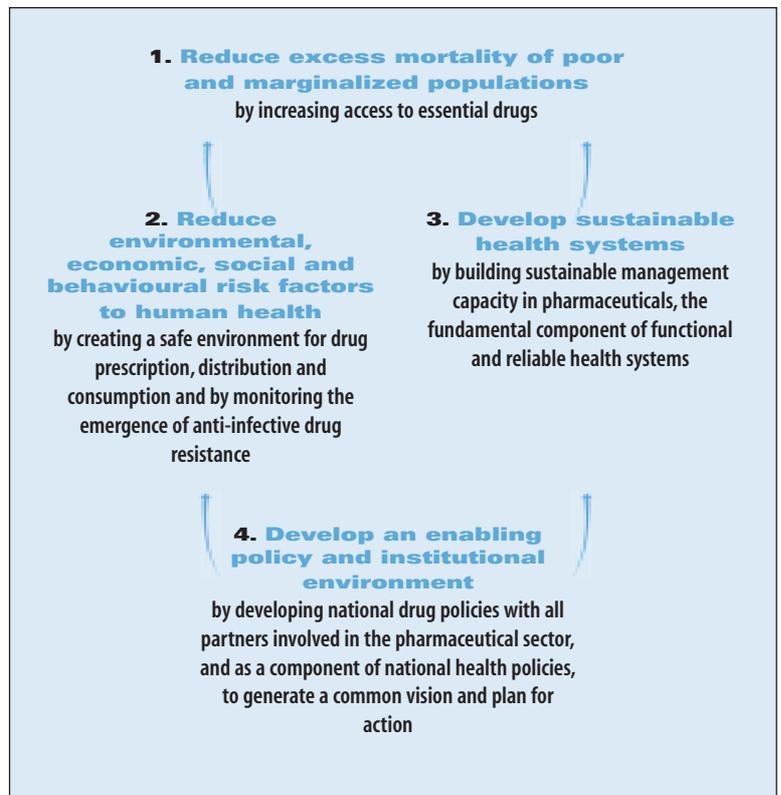
WHO's mission in essential drugs and medicines policy, country work that flows from that mission, the pharmaceutical needs of WHO's diverse Member States, and World Health Assembly Resolutions concerning implementation of the Revised Drug Strategy, all served as key reference points during development of this strategy.

WHO's mission in essential drugs and medicines policy

WHO's mission in essential drugs and medicines policy is to help save lives and improve help by closing the huge gap between the potential that essential drugs have to offer and the reality that for millions of people — particularly the poor and disadvantaged — medicines are unavailable, unaffordable, unsafe or improperly used.

The Organization works to fulfil this mission by providing global guidance on essential drugs and medicines, and

Figure 2: Essential drugs and medicines policy activities contribute to all four WHO strategic directions



Revised Drug Strategy

The World Health Assembly and the WHO Executive Board have been guiding WHO's work in the pharmaceutical sector since the Organization's inception in 1948. Resolutions adopted by the World Health Assembly cover many areas of responsibility, such as publication of the *International Pharmacopoeia*, selection and approval of international nonproprietary names (INNs), promotion of the essential drugs concept and ensuring rational drug use.

Currently, most of WHO's work in pharmaceuticals is guided by the Revised Drug Strategy. This consists of a series of resolutions that have expanded and updated this work in the light of new and continued challenges. In May 1999 the World Health Assembly adopted resolution WHA52.19 on the Revised Drug Strategy²⁰ requesting WHO to intensify its activities in six areas (see Box 2).

WHO's objectives in medicines for 2000–2003

WHO's strategy in medicines for 2000–2003, presented in its entirety in Chapter 5, covers four main objectives, to guide pharmaceutical work at country, regional and global levels.

Policy: ensure commitment of all stakeholders to national drug policies, to coordinated implementation, and to monitoring policy impact.

Access: ensure equitable availability and affordability of essential drugs, with an emphasis on diseases of poverty.

Quality and safety: ensure the quality, safety and efficacy of all medicines by strengthening and putting into practice regulatory and quality assurance standards.

Box 2 The 1999 World Health Assembly Resolution on the Revised Drug Strategy requested WHO to intensify work in six areas

National drug policies

- ◆ strengthen support to Member States in developing, implementing and monitoring national drug policies

Pharmaceuticals and trade agreements

- ◆ monitor and analyse the pharmaceutical and public health implications of international trade agreements, such as the WTO TRIPS Agreement
- ◆ advise Member States on international trade issues, within the framework of national drug policies and regulatory measures

Drug information and drug promotion

- ◆ help Member States strengthen their own independent drug information capacity
- ◆ provide information on counterfeit drugs and medicines
- ◆ develop tools to help stakeholders actively apply the WHO Ethical Criteria for Medicinal Drug Promotion
- ◆ monitor new forms of promotional activity

Drug quality

- ◆ support mechanisms to extend the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce to cover control of starting materials
- ◆ establish guidelines on drug quality issues relating to export, import and transit of pharmaceutical products
- ◆ promote implementation of good manufacturing practices

Drug donations

- ◆ promote improved implementation of good drug donation practices

Partnerships

- ◆ encourage continuing dialogue and collaborative partnerships between Member States, other UN agencies, nongovernmental organizations and the private sector on issues relating to access to essential drugs.

Rational use: ensure therapeutically sound and cost-effective use of drugs by health professionals and consumers.

Box 3 Access: priority area for 2000–2003

Among this strategy's four objectives, access to essential drugs is a key priority area for 2000–2003. WHO is working with all partners to ensure that access continues to increase, and will continue to ensure that this issue remains high on the world's health agenda during the next four years. The focus will be on increasing access to essential drugs for treating the major diseases of poverty, including malaria, HIV/AIDS, tuberculosis and childhood illnesses.

Four factors are critical for securing and increasing access:

- ◆ rational selection of essential drugs and drug development
- ◆ affordable prices for governments and consumers
- ◆ sustainable financing, through general government revenues and social health insurance
- ◆ reliable supply systems, with a mix of public and private services.

Ethical values

Activities for pursuing the attainment of each strategy objective were planned with careful attention to broad ethical considerations. This was essential. WHO sets normative standards for medical products, provides guidance on regulatory standards, defines and classifies diseases, provides therapeutic advice (such as treatment guidelines), produces a model list of essential drugs (which is widely used by countries and development agencies), and actively advises countries on such areas as the development of national drug policy. The actual and potential economic impact of these activities is considerable.

So WHO must act and must be perceived to act independently, according to the best scientific evidence, and free of any possible commercial or political influence. This is especially important in light of the wealth of experience demonstrating that scientific and economic

achievements alone cannot guarantee that health goals are met. Rather, health development must be guided by basic key values to ensure that health improvements benefit everyone, but particularly those most in need.

Accordingly, The Health For All vision²¹ recognized that:

- access to health care is a fundamental **human right**
- **ethical approaches** must be applied to health policy, research and service provision
- **equity**-oriented policies and strategies that emphasise solidarity should be implemented
- a **gender** perspective should be incorporated into health policies and strategies.

Each of the activities that form part of this *Medicines Strategy* can be justified on the grounds of contributing to the upholding and furthering of each of the above values.

Integration and sustainability

The *WHO Medicines Strategy* was also developed primarily with a long-term view. That is, activities have been planned that will contribute to the integration and sustainability of health systems.

Currently, the health care systems of many developing and transitional countries are overstretched, underfunded and faced with multiple problems such as the HIV/AIDS epidemic, resistant malaria and multidrug-resistant tuberculosis. At the same time, poor communities continue to witness the death of hundreds upon hundreds of children from diarrhoea and respiratory infections, even though effective treatments have long existed for these illnesses.

Given the urgency of these health problems and the suffering they inflict, development of vertical drug management and supply systems may achieve some rapid gains, especially for poor and disadvantaged populations. But

“Health is in itself opportunity – for each individual and the community we live in. In a world torn by economic, ethnic, religious and cultural divisions, health remains as one of the few truly universal values.”

Director-General

Dr Gro Harlem Brundtland,

Statement to the Executive

Board at its 105th Session,

January 2000.²²

“Combating disease epidemics, striving to reduce infant mortality, and fighting for safer pregnancy are all WHO priorities. But the Organization will have very little impact on these and other battlegrounds unless it is equally concerned to strengthen the health systems through which the ammunition of life-saving and life-enhancing interventions are delivered to the front line.”

The World Health Report 2000.²³

they can only ever be short-term solutions. Long-term solutions to long-standing problems demand a more comprehensive approach. This means that ministries of health, development agencies, and the private and voluntary sectors must work together to ensure that medicines and medicines policies help build health systems that are not only equitable, but also integrated. An integrated health system promotes health, seeks to prevent ill health and provides health care without overlap, duplication or gaps. Additionally, the human, technical and financial resources to ensure its continuity are available.

By prioritizing access, quality and safety, and rational use of medicines for diseases of poverty, this strategy will help reduce the world's disease burden, improve health and accelerate development where it is needed most (Figure 3). And by focusing on drug financing, affordability, regulatory control and overall pharmaceutical sector development, the strategy will help strengthen the performance of health system functions. These consist primarily of: stewardship (or oversight); creating resources (through investment and training); delivering services (that is, provision); and financing (including collecting funds, pooling those funds and purchasing medical supplies and services).²³

2.3 Health technology and pharmaceuticals

The *WHO Medicines Strategy* is part of a broader strategy, covering projected work to be undertaken by the Health Technology and Pharmaceuticals Cluster during 2000–2003. The cluster strategy²⁴ covers not only the work of the Department of Essential Drugs and Medicines Policy, but also that of the Department of Blood Safety and Clinical Technology, and the Department of Vaccines and Biologicals. One of the aims of the cluster strategy is to create synergy between the cluster departments in areas such as financing, supply systems, strengthening of regulatory capacity, quality assurance and monitoring of impacts.

Five core competencies and **three priority areas** have been identified for the cluster, as presented in Figure 4.

Research and development for new essential drugs is handled by separate research departments in the Communicable Diseases, and Family and Community Health Clusters. □

Figure 3: The *WHO 2000–2003 Medicines Strategy* provides the pharmaceutical foundation for improved health outcomes and stronger health systems

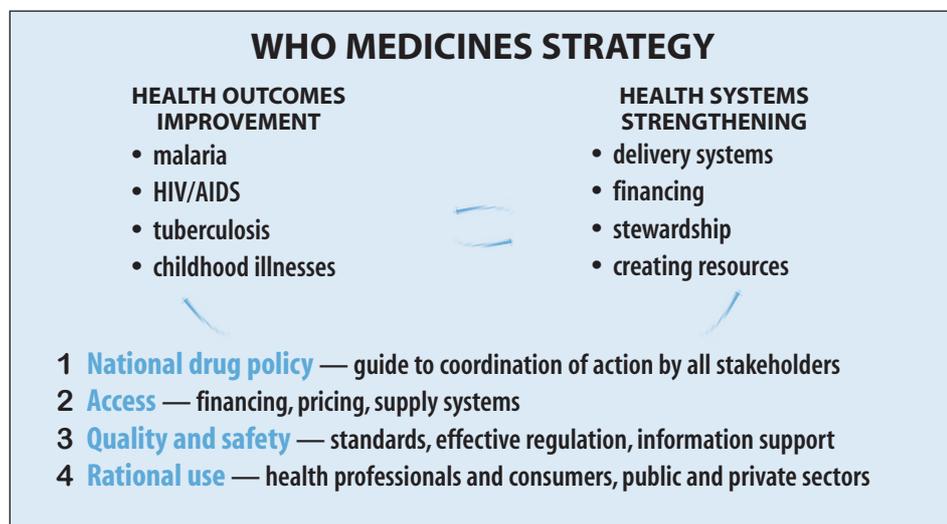


Figure 4: Health technology and pharmaceutical core competencies and priority areas

		Blood safety, products and devices	Vaccines and biologicals	Essential drugs and medicines policy
		Priority		
Competency	RESEARCH AND DEVELOPMENT	Blood safety, including injection safety	Immunization with an emphasis on polio eradication	Access to essential drugs, with an emphasis on drugs for diseases of poverty* * See Section 5.2.
	ACCESS			
	QUALITY AND ASSURANCE			
	USE			
	MONITORING IMPACT			

Core functions — improving health through knowledge, advocacy and partnership

Core functions for essential drugs and medicines policy are summarized in Table 1. They largely parallel those set out for WHO as a whole in the new corporate strategy for the WHO Secretariat.¹⁹ An additional

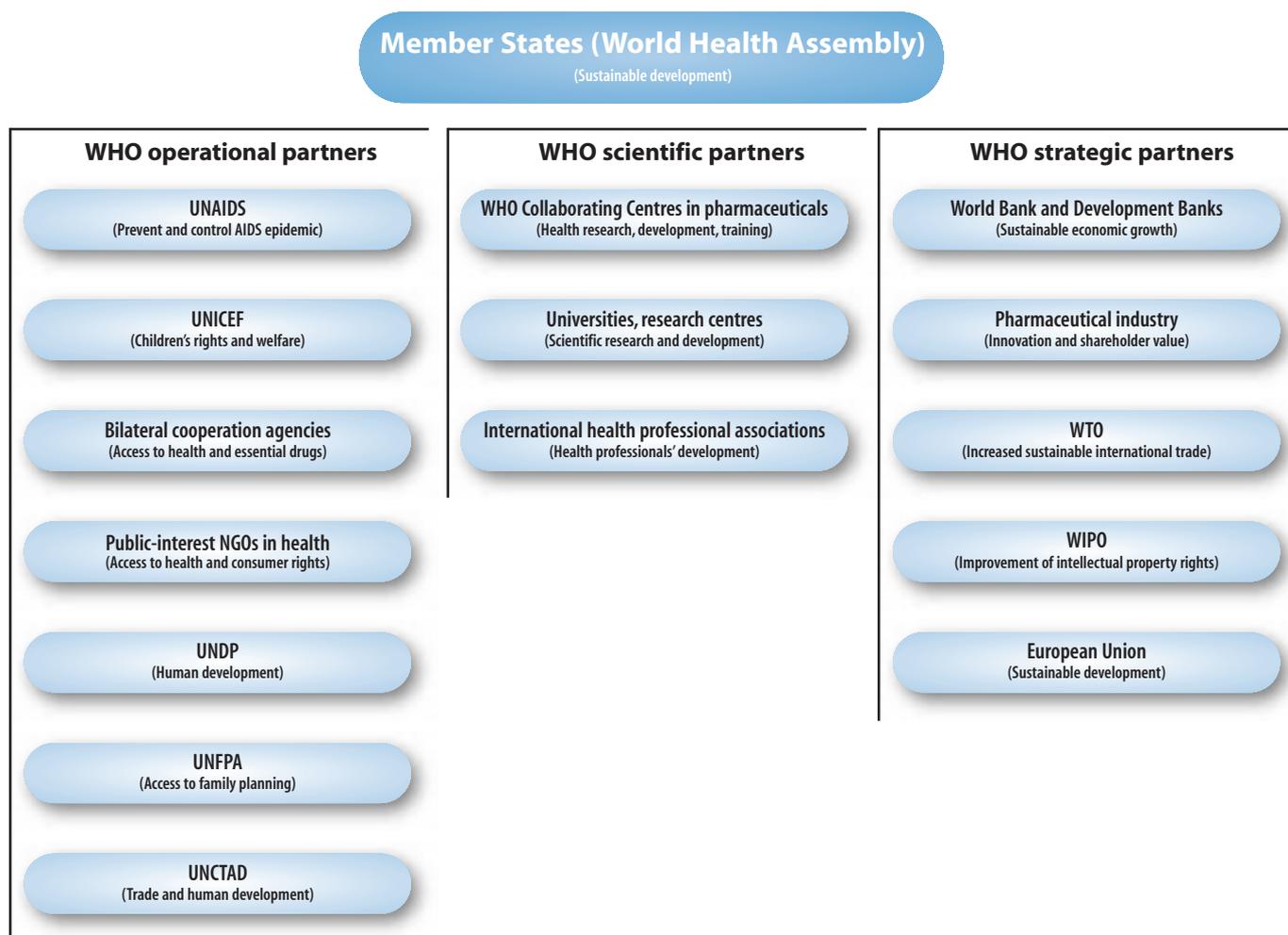
core function — support to countries — is described separately in Chapter 4, and is carried out in parallel with the other core functions.

The core functions outlined in Table 1 have always been perceived as part

Table 1 Core functions — how WHO operates in pharmaceuticals

Creation, synthesis and dissemination of knowledge	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.
	Working in partnership	Ensure productive, mutually beneficial relationships within WHO, with UNICEF and other UN agencies, the World Bank, nongovernmental organizations, universities, industry, and all other international actors in pharmaceuticals through mechanisms such as the Interagency Pharmaceutical Coordination group and the Director-General's roundtable process.
	Producing guidelines and practical tools	Provide policy-makers and essential drugs managers with practical guidelines and tools for implementing the components of a national drug policy and to promote capacity-building, particularly when national pharmaceutical experts are lacking.
	Developing norms and standards	Develop norms and standards as a foundation for effective regulation, control, manufacture and sale of drugs, and to guide international harmonization of the pharmaceutical trade.
	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 quality and appropriate use of drugs.
	Developing human resources	Build country capacity to effectively implement the various components of a national drug policy by developing clear guidelines on the human resources required, ensuring that undergraduate and postgraduate curricula for all health professions incorporate the essential drugs 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 developments, be these economic, social or political.

Figure 5: Increasing the health impact of pharmaceuticals — WHO international partners in pharmaceuticals and their principal areas of operation



of WHO's mandate. Countries, development agencies, NGOs, health professionals and the public all look to WHO for data and statistics concerning health, expert advice on the widest range of health issues imaginable, and new and innovative approaches to solving long-standing and newly emerging health problems. This is especially true in relation to medicines. No other agency or institution has the equivalent depth, range and length of experience in this field, irrespective of the precise issue in question. Pharmaceutical production, quality and efficacy, recommended treatment or use, drug financing and procurement, and research tools and methods for investigating problems relating to pharmaceuticals, are all areas in which WHO's knowledge

is unsurpassed. Advice on developing human resources in pharmaceuticals is equally dependent on such depth of knowledge.

Creation, synthesis and dissemination of knowledge are also key to WHO's role in articulating and advocating policy options. This was well illustrated by WHO's activities in the area of drug donations. Whether a rapid response in an acute emergency or an element of development aid, supply must match demand — otherwise drug donations risk becoming their own disaster. In 1996 WHO issued the *Guidelines for Drug Donations*. A 1998 survey showed that they had had a very positive impact. Yet examples of bad drug donations continued, including expired drugs, unidentifiable drugs and

inappropriate drugs. WHO adopted three approaches to meet the continuing challenge of improving unsatisfactory donation practices. It revised the 1996 guidelines, reissuing them in 1999, in collaboration with 15 international agencies. It asked private and voluntary organizations and pharmaceutical companies to underwrite those guidelines. And it updated the *New Emergency Health Kit 98* to take account of changes in the *WHO Model List of Essential Drugs*, and to bring the kit into line with a new UN list of drugs recommended for use in acute emergencies.

But as the above example clearly shows, the complexity of today's world means that WHO cannot succeed alone. So although it is the UN organization with primary responsibility for health, it can be fully effective only by developing partnerships with other organizations and agencies, based on real needs and existing capacities at country, regional and global levels. WHO's principal partners in pharmaceutical activities are shown in Figure 5. Working with these partners helps WHO not only maintain but also further develop its

knowledge base and expertise in all areas of pharmaceuticals.

Various innovative mechanisms have already been established to strengthen such partnerships. They include the Interagency Pharmaceutical Coordination (IPC) group and the Director-General's roundtable process. WHO, UNFPA, UNICEF and the World Bank are all IPC members and the group addresses issues such as global and country-level coordination, improving drug donations and pharmaceutical procurement practices. It has met twice-yearly since 1996 and has a rotating secretariat. Roundtables are also ongoing and working to bring about sustained improvements in public health. So far, roundtables have been held with public-interest NGOs, the research-based pharmaceutical industry, the generic drug industry and the self-medication industry. The roundtables have led to new projects and approaches for tackling problems such as increasing access to antimalarials, improving drug quality and fighting unethical drug promotion. □

Country work — why and how?

4.1 Country work in context

Policy and technical support to countries continues to be WHO's largest area of activity in pharmaceuticals. Direct support is provided in response to countries' expressed wish to develop their pharmaceutical services. In addition, many donors have been keen to use WHO's health and pharmaceutical expertise when providing their own country support.

Normative work is equally demand-driven, and evidence-based. For example, the *First Model List of Essential Drugs* was developed in response to numerous country requests for pharmaceutical sector assistance.

At the same time, though, country work is a fundamental resource for WHO. Only by undertaking such work can the Organization develop its evidence and knowledge base, and maintain its level of health expertise.

Placing countries — with their needs and the experience they provide — at the core of *all* WHO's pharmaceutical work is essential.

4.2 How WHO works with countries on medicines

WHO is working to increase the impact of its country work by making it more strategic and more focused.²⁶ Country offices are being strengthened (through capacity-building and staff development) and "country cooperation strategies" (to provide a framework for the entire range of WHO support to a country) are

being drawn up jointly by Regional Offices and Headquarters. Concurrently, WHO is working with other development partners on specific issues, such as poverty, and to develop specific approaches to development problems, such as sector-wide approaches (known as SWAPs).

Regarding pharmaceuticals, WHO works with countries through the coordinated efforts of: its *WHO Representative offices* in countries (WRs); its *pharmaceutical advisers* designated in each regional office; and its *regional focal points* located within the Department of Essential Drugs and Medicines Policy (EDM) at Headquarters.

Each pharmaceutical adviser and the corresponding EDM regional focal point are responsible for developing and implementing an integrated Regional Office-EDM Plan of Action for their region, based on the expressed needs of national authorities and pharmaceutical plans prepared by WHO country offices. Given the process of globalization, and the continuing development of regional and subregional pharmaceutical markets, WHO's structure gives it a tremendous comparative advantage when carrying out regional and intercountry activities.

Within countries, the ministry of health (MOH) is WHO's primary focal point. The MOH has primary responsibility for driving and coordinating national drug policy implementation, within the overall context of its country's national health policy. In supporting this process, WHO encourages the MOH to integrate essential drugs programmes with health services and to coordinate all programmes with a drug component. It also encourages the MOH to work

"We are structuring our work to ensure that WHO speaks with one voice in the area of pharmaceuticals and essential drugs...WHO remains committed to working with countries to develop and implement effective national policies and programmes."

Director-General

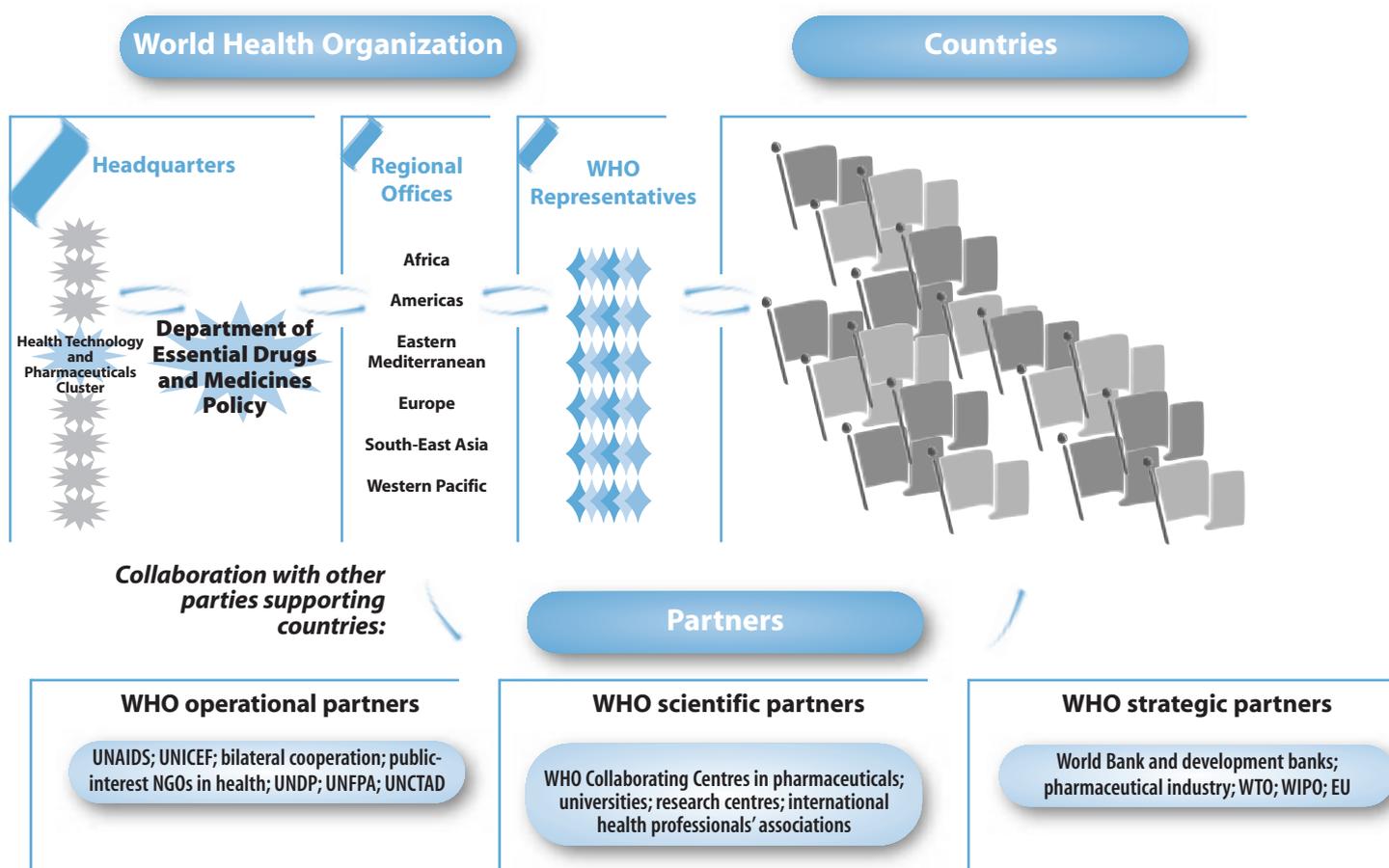
Dr Gro Harlem Brundtland,
address to Ad Hoc Working
Group on the Revised Drugs
Strategy, Geneva,
13 October 1998.²⁵

closely with other parties whose activities may influence or relate to the pharmaceutical sector, including other ministries such as industry, trade, finance, health professionals at grass-roots level, and WHO's partners as highlighted in Figure 6.

WHO coordination at country level is also crucial for the success of any

essential drugs programme. The daily activities of the WHO Representative's office and other partners' country offices, joint missions with other UN agencies, development banks and donors, and joint planned and funded projects, all contribute to such coordination. (Global coordination mechanisms are described in Chapter 3.)

Figure 6: WHO's interactions with countries are central to its activities



4.3 Types of WHO support

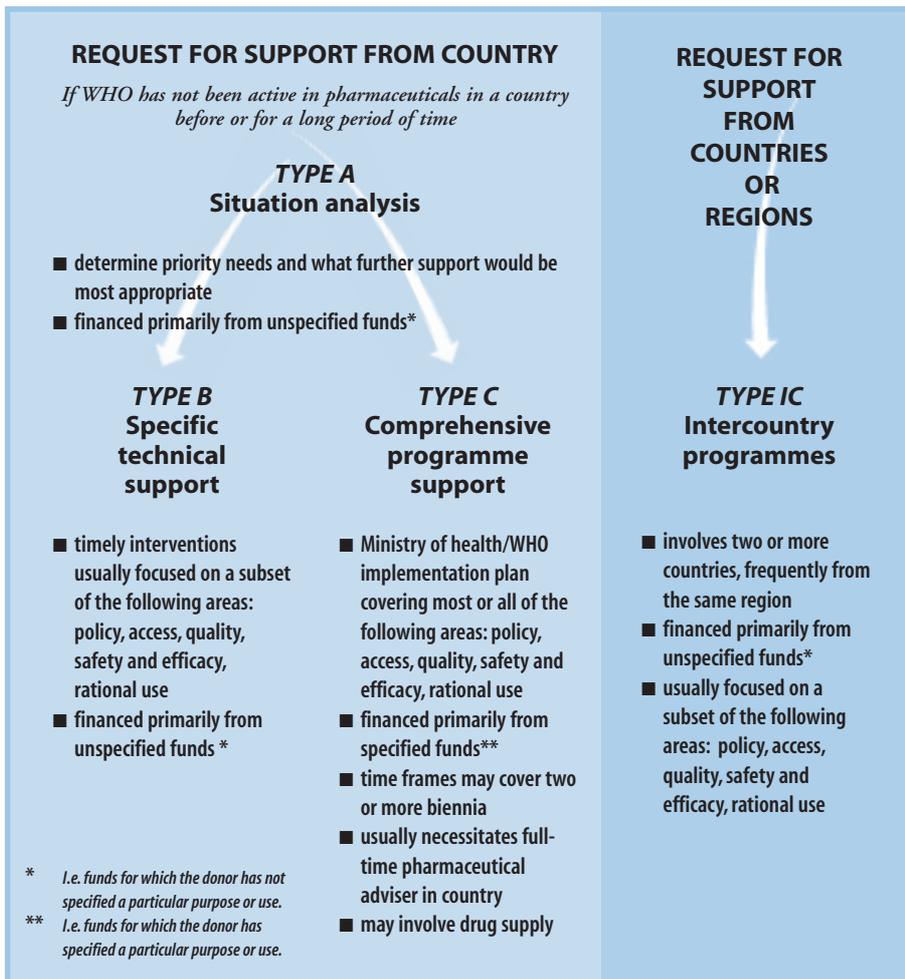
Of the specific types of support that WHO provides to countries, three involve projects and activities at country level, while a fourth focuses on inter-country, subregional, regional, and inter-regional programmes and activities (Figure 7).

Evidently, over time, support to countries may shift. For example, specific technical support to a country (type B) may evolve into a comprehensive programme (type C), or vice-versa. In view of WHO's increasing focus on regional and subregional activities, some pharmaceutical technical support to countries (type B) is being shifted to intercountry programmes (type IC), in the form of regional funds. These are managed jointly by the regional adviser and EDM's regional focal point.

WHO's human and financial resources are limited, however. Criteria for country presence are therefore extensive and cover:

- severity of country need
- country's level of development
- potential for success of proposed activities
- potential for sustainable impact of proposed activities
- demonstration or development value of proposed activities
- opportune timing (for example, resources are available or political commitment is strong)
- cost-effectiveness
- funding opportunities
- support to the pharmaceutical sector provided by other agencies or organizations. □

Figure 7: WHO pharmaceutical support to countries and regions is adapted according to national and regional need



Framework for action: objectives and expected outcomes for 2000–2003

The four strategic objectives outlined in Chapter 2 provide the framework for WHO medicines work for 2000–2003: (1) implementation and monitoring of national drug policies; (2) equitable availability and affordability of essential drugs, especially for diseases of poverty; (3) quality, safety and efficacy of all drugs; and (4) rational use of drugs. Each of these four objectives contains between two and four specific components. Within each component, expected outcomes for 2000–2003 have been defined.²⁷

The country progress indicators included in each component description provide a quantitative measure for the 1999 status of the component, and a target to be achieved for that component by 2003. The selected indicators and targets strike a realistic balance between data needed for a meaningful assessment of progress in an area of activity, and what is actually measurable in most settings. Most of the progress indicators used are based on routinely reported information and information gathered for the four-yearly *World Drug Situation* survey. A small number of progress indicators requiring field surveys have also been included. Understandably, these latter indicators will be used only in those countries which benefit from comprehensive WHO programme support in essential drugs and medicines policy (see Chapter 4).

Chapter 6 outlines how the progress indicators will be used to measure the impact of WHO medicines work during 2000–2003.

5.1 Policy: Ensure commitment of all stakeholders to national drug policies, to coordinated implementation, and to monitoring policy impact

The national drug policy process brings together all interested partners in the pharmaceutical sector, encouraging them to focus political commitment, financing and human resources on improving access to drugs, improving drug quality and promoting rational drug use. The essential drugs concept is key to this process. In practical terms it means focusing on a number of carefully selected drugs and an agreed standard treatment guideline. A better supply of drugs, assured drug quality, more rational prescribing, lower costs and better health outcomes can then be assured.

The national drug policy itself provides a framework for action relating to pharmaceuticals within the overall national health policy. The goals of a national drug policy should therefore be consistent with broader health objectives, and its implementation should help attain those objectives.

Component 1: Implementation and monitoring of national drug policies:

Help countries to formulate and implement their national drug policy, and to monitor key components of national drug policy implementation

"We remain committed to national drug policies as part of national health policies. The national drug policy process can and should engage the public sector, professional bodies, the private sector, consumers, academics, and other concerned partners. Together they can develop a common vision and plan of action."

Director-General

Dr Gro Harlem Brundtland,
address to Executive Board Ad Hoc Working Group on the Revised Drug Strategy,
October 1998.²⁵

Table 2 WHO Medicines Strategy 2000–2003 — objectives, components and expected outcomes

Objectives	Components	Expected outcomes
Policy: Ensure commitment of all stakeholders to national drug policies, to coordinated implementation, and to monitoring policy impact	1. Implementation and monitoring of national drug policies Help countries to formulate and implement their national drug policy, and to monitor key components of national drug policy implementation	1.1 National drug policies developed and updated 1.2 National drug policies implemented 1.3 Global national drug policy progress monitored and impact evaluated 1.4 Poverty perspective introduced into national drug policies 1.5 Gender perspective introduced into national drug policies
	2. Health system development supported by essential drugs policies and programmes Work with countries to integrate their work in essential drugs and medicines policy into their national health system, in support of health system development	2.1 Essential drugs concept integrated into national health programmes 2.2 Development of sustainable management capacity in pharmaceuticals 2.3 Traditional medicine integrated into national health care systems
Access: Ensure equitable availability and affordability of essential drugs, with an emphasis on diseases of poverty	3. Access strategy and monitoring for essential drugs Help countries to ensure and monitor access to essential drugs, focusing on diseases of poverty, such as malaria, HIV/AIDS, tuberculosis and childhood illnesses	3.1 Increased access to essential drugs for priority health problems 3.2 Increased access to newly developed and abandoned essential drugs 3.3 Standard indicators to measure equitable access to essential drugs 3.4 Access to drugs promoted within international trade agreements
	4. Financing mechanisms and affordability of essential drugs Ensure the implementation of national strategies to finance the supply and increase the affordability of essential drugs, in both the public and the private sectors	4.1 Planning and advocacy for public sector drug financing 4.2 New drug-financing strategies 4.3 Increased affordability of essential drugs in public and private sectors 4.4 Expanded coverage and improved drug benefits within health insurance 4.5 Increased drug price information and guidance on drug price policies
	5. National and local public sector drug supply systems and supply capacity Support countries to run efficient public sector drug supply systems, ensuring the availability of essential drugs at all levels of the distribution chain	5.1 Enhanced drug supply management capacity 5.2 Improved drug supply management as part of health sector reform 5.3 Adherence to good pharmaceutical procurement practices 5.4 Cost-effective and reliable local drug production promoted 5.5 Adherence to good drug donation practices among donors and recipients
Quality and Safety: Ensure the quality, safety and efficacy of all medicines by strengthening and putting into practice regulatory and quality assurance standards	6. Norms, standards and guidance for pharmaceuticals Strengthen global norms, standards and guidelines for the quality, safety and efficacy of drugs, including traditional medicine, and provide guidance for global harmonization efforts	6.1 Norms, standards, and guidelines developed or updated 6.2 Quality control specifications, basic tests, screening tests and international chemical reference materials for pharmaceuticals developed 6.3 Drug nomenclature and classification efforts continued 6.4 Promotion of WHO norms, standards, guidelines, nomenclature and WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce 6.5 Coordination of regional and international harmonization of norms
	7. Drug regulation and quality assurance systems Support countries to establish and maintain effective drug regulation and quality assurance systems	7.1 Drug regulation effectively implemented and monitored 7.2 Drug manufacturing, distribution and inspection practices improved 7.3 Substandard and counterfeit drugs combated 7.4 <i>Regulatory Situation of Herbal Medicines: Worldwide Review</i> updated
	8. Information support for pharmaceutical regulation Improve the access of national regulatory and pharmaceutical control authorities to reliable information management systems, and to mechanisms for exchange of independent information on drug quality, safety and efficacy	8.1 Increased exchange of information on quality, safety and efficacy of medicines 8.2 Reliable information management systems created 8.3 Access to international adverse drug reaction monitoring system extended
	9. Guidance for control and use of psychotropics and narcotics Provide advice and guidance on psychotropic and narcotic substances in accordance with WHO's mandate under international treaties	9.1 Psychoactive substances assessed for international control 9.2 Rational use of controlled medicines promoted
Rational use: Ensure therapeutically sound and cost-effective use of drugs by health professionals and consumers	10. Rational drug use strategy and monitoring Support countries in implementing and monitoring a national strategy to promote rational use of drugs by health professionals and consumers	10.1 Advocacy of rational drug use 10.2 Identification and promotion of successful rational drug use strategies 10.3 Responsible drug promotion encouraged 10.4 Information support on use of traditional medicine 10.5 Antimicrobial resistance contained
	11. Rational drug use by health professionals Develop national standard treatment guidelines, essential drugs lists, educational programmes and other effective mechanisms to promote rational drug use by all health professionals	11.1 Development of national standard treatment guidelines and essential drugs lists supported 11.2 Support for problem-based and skill-based in-service training programmes 11.3 Drugs and therapeutics committees established and operating effectively 11.4 International technical guidelines and standards on traditional medicine expanded
	12. Rational drug use by consumers Establish effective systems to provide independent and unbiased drug information — including on traditional medicine — to the general public and to improve drug use by consumers	12.1 Effective systems of drug information 12.2 Public education in rational drug use and consumer empowerment

Progress

Progress in developing and implementing national drug policies since publication in 1988 of *Guidelines for Developing National Drug Policies*²⁸ has been impressive:

- At the end of 1999, 66 countries had introduced official national drug policies within the last 10 years. A further 41 countries were developing national drug policies or had developed such a policy more than 10 years ago. In 1998–1999 alone, 23 countries adopted or substantially revised their national drug policies, most of them with WHO assistance, and including countries as diverse as Australia, India, Jordan, the Maldives and Yemen.
- More and more countries are now moving directly from policy to action by creating a master plan for policy implementation; recent

examples include Brazil, Chad and India.

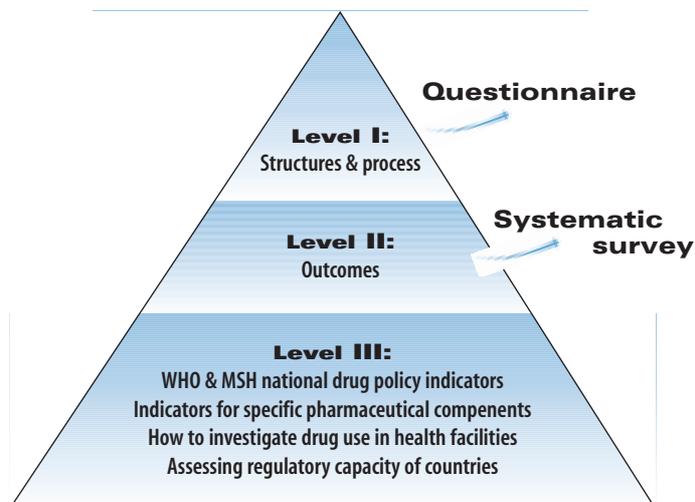
- For countries with an active national drug policy process such as Australia, Bolivia and South Africa, significant pharmaceutical sector improvements have been observed.
- A small but growing number of countries routinely monitor their progress, including Cambodia, Indonesia and Zimbabwe.

Monitoring is very important. It helps to ensure that development and implementation of drug policies is effective, and, if not, that the necessary adjustments are made. Two different levels of routine indicator-based monitoring for use at country level have been developed and are being put in place. Level 1 monitoring uses core structural and process indicators that can be easily collected without a survey. Level 2

Figure 8: By the end of 1999 over 100 countries had national drug policies in place or under development



Figure 9: Core indicators are used to monitor and refine national drug policies to ensure maximum health impact



monitoring uses outcome indicators that can be easily collected using data samples during simple surveys. WHO is working with an increasing number of countries to monitor the implementation and evaluate the impact of their national drug policies. (Chapter 6 explains in more detail how these indicators will be used to monitor implementation of the *WHO Medicines Strategy 2000–2003*.)

Challenges

Scores of countries have developed national drug policies.²⁹ All too often, though, a policy exists on paper while in practice drugs are unavailable at health facilities, large quantities of dangerously substandard drugs circulate on the market, and prescribing practices are unsafe and wasteful.

The challenges are to encourage countries without national drug policies to develop and officially adopt them and to ensure that countries with such policies implement them effectively. At the same time, a “culture of monitoring” which uses the results of monitoring to inform policy action, is needed.

In terms of policy content WHO is committed to ensuring that national drug policies tackle not just pharmaceutical but also broader development issues such as poverty and gender.^{2, 11} Poverty is often a result of ill health and, conversely, poor populations are most vulnerable to ill health and have less access to health care. This is reflected in morbidity and mortality statistics. Communicable diseases remain the leading cause of death and disability among impoverished populations worldwide even though cost-effective treatments exist for most of them. So by prioritizing treatment for communicable diseases, policy-makers can do much to improve the health of poor populations, to improve their life expectancy and to reduce the differences in health status between rich and poor.³⁰

Gender is an equally important development issue given that 70% of the 1.3 billion people living in poverty are women, twice as many women as men are illiterate (600 versus 300 million), and women’s access to health care often considerably more limited than that of men.³¹ Even finding data on women’s access to and use of drugs can be difficult. Thus while studies on the world population’s access to drugs abound, sex-disaggregated data on this topic are very scarce.

Expected outcomes for 2000–2003

1.1: National drug policies developed and updated following needs assessment and wide consultation at national level with policy-makers, health professionals and key partners.

- ✓ WHO will provide technical assistance on national drug policy development to countries, facilitate national drug policy meetings involving all partners, organize training courses on drug policy issues and publish a revised edition of *Guidelines for Developing National Drug Policies*.

Figure 10: 36% of countries with a national drug policy have no implementation plan

1.2: National drug policies implemented through national pharmaceutical master plans and routinely monitored at national level.

✓ Through provision of technical assistance to countries and facilitation of national and regional workshops, WHO will support the elaboration of national pharmaceutical master plans and strategies, and implementation of national drug policy components.

1.3: Global national drug policy progress monitored and impact evaluated through yearly updating of global and country information and data in WHO's global computerized database.

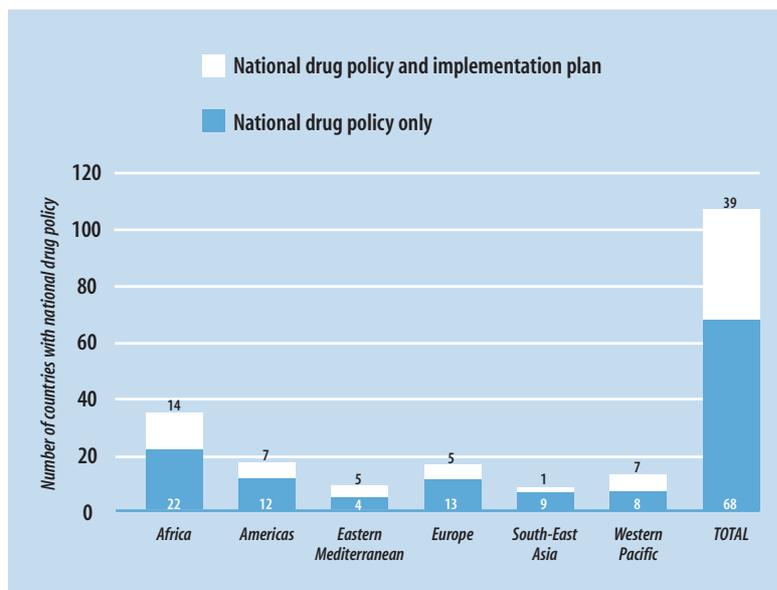
✓ WHO will monitor global national drug policy progress, help countries to monitor their own progress in implementing their national drug policies and collect additional data on pharmaceutical sector development from other sources, such as international organizations and industry.

1.4: Poverty perspective introduced into national drug policies during elaboration and implementation of national drug policies.

✓ WHO will raise awareness among national policy-makers and international organizations of the positive impacts of strategies that aim to improve the health of impoverished populations. Specifically, WHO will encourage development of national drug policies that prioritize treatment for the major communicable diseases.

1.5: Gender perspective introduced into national drug policies during the elaboration and implementation of national drug policies.

✓ Following operational research in several countries, and in consultation with gender experts, WHO will develop a standard protocol on introducing a gender perspective into national drug



Country progress indicators	1999 Status		2003 Target
	No./No. reporting	%	
Countries with an official national drug policy document — new or updated within the last 10 years	(66/151)	44%	55%
Countries with a national drug policy implementation plan — new or updated within the last 5 years	(39/107)	36%	43%

policies. It will also promote the collection of sex-disaggregated data on access to drugs and drug use for use during the development and modification of national drug policies.

Component 2: Health system development supported by essential drugs policies and programmes

Work with countries to integrate their work in essential drugs and medicines policy into their national health system, in support of health system development

Progress

After much debate and research both within and outside the Organization, WHO recently established²³ that the fundamental goals of any country's health system are:

- improving the health of the population it serves

- ensuring fairness in financial contribution to health care
- responding to people's non-health expectations.^a

These goals are fully supported by those of national drug policies (see Table 3). Available, affordable, good quality, and rationally used medicines improve population health, while public drug financing, health insurance schemes and generic policies help make drugs affordable, thereby contributing to fair health financing. Last but definitely not least, efforts to ensure, for example, adequate dispensing and prescribing time, and equal access to treatment for men and women, help ensure that a health system respects the individual, and pays due heed to client needs.

As well as clarifying the goals of health systems WHO has strived continually to show that contributing to health system effectiveness has positive impacts on educational levels, economic growth and political participation.

Two-thirds of all WHO resources for essential drugs and medicines policy are now invested directly in country work aimed at implementing national drug policies and essential drugs programmes. As a result, considerable progress has been achieved in increasing the contribution of the pharmaceutical sector to health system development, particularly in the Newly Independent States, Latin America and, albeit to a lesser extent, in Africa.

"If we do not design health programmes and policies with a gender perspective, we may reach only half of the population."

Director-General

Dr Gro Harlem Brundtland, address to UN Commission on the Status of Women, New York, 3 March 1999.³¹

^a This includes respecting people's dignity, autonomy and confidentiality of information. "Responsiveness" is not a measure of how a health system responds to health needs, which is reflected in health outcomes, but of how the system performs relative to non-health aspects, meeting or not meeting a population's expectations of how it should be treated by providers of prevention, care or non-personal services.²³

Table 3 National drug policies help health systems achieve their goals

Health system goals	National drug policy features
Improved population health	<ul style="list-style-type: none"> ◆ Efficient and sustainable drug supply systems ◆ New essential drugs for priority health problems ◆ Quality assurance through good manufacturing, distribution and inspection practices ◆ Reliable drug information ◆ Evidenced-based standard treatment guidelines, essential drugs lists and national formularies ◆ Public education and consumer empowerment
Fair financing	<ul style="list-style-type: none"> ◆ Equitable public sector drug financing strategies, with focus on impoverished populations ◆ Social health insurance schemes covering essential drugs ◆ Affordable drugs through generic competition, bulk purchasing, and reduced import duties, taxes and distribution costs ◆ Use of lowest cost equivalent drug in therapeutic category through therapeutic competition ◆ Free drugs from public and private providers for priority health problems
Reponsiveness to non-health expectations	<ul style="list-style-type: none"> ◆ Policy and legal framework for defining roles and responsibilities of prescribers and dispensers ◆ Human resource development and management strategies ◆ Ethical criteria for medicinal drug promotion

Box 4 The increasing interest in and application of traditional, and complementary and alternative medicine

Traditional medicine

Traditional medicine existed long before the development and spread of modern Western medicine. Knowledge of traditional medicine — frequently intertwined with and reflecting a country's culture, history and beliefs — is often passed on orally from generation to generation and often incorporates sophisticated theory and system.²³

Traditional medicine practices include medication and non-medication therapies. Medication therapies use raw materials or extracts from medicinal plants, animals and mineral materials. Non-medication therapies may include acupuncture, manual therapy, spiritual healing, diets and traditional exercises. Traditional medicine practices have been used by local communities for a considerable time and are therefore trusted and accepted.

Complementary or alternative Medicine (CAM)

The term “complementary or alternative medicine” is used in some countries to refer to a broad set of health care practices that — even though they may be of a country's own traditions — are not integrated into its dominant health care system. Thus in countries where national health care is based on modern Western medicine, traditional medicine and other therapies are usually considered to be complementary or alternative systems of medicine.

Complementary or alternative medicine practices include systems of traditional and folk medicine and other natural therapies such as herbal medicines, chiropractic and homeopathy.

WHO has also moved ahead to help ensure that traditional medicine systems reach their full potential for improving health care. Experience is showing that although the specific focus may vary, many of the basic questions regarding traditional medicine in relation to health systems are similar from region to region and from country to country. For example, the Chinese and Indian Governments are each concerned with how best to use traditional medicine to strengthen health care in remote areas. Similarly, in Africa, the emphasis is on use of local resources and making traditional medicine an integrated component of minimal health care packages. Meanwhile, in developed countries, the growing interest in and application of traditional medicine have created a common need for governments to both regulate its use and ensure that demand for treatment involving traditional medicine is met safely.

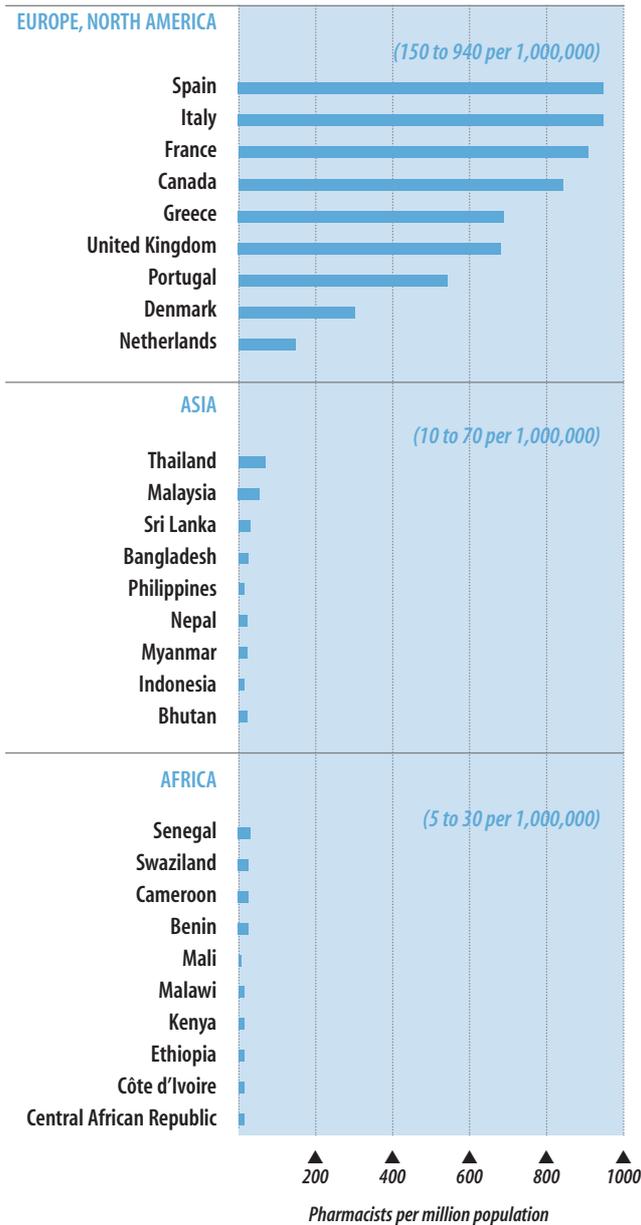
Challenges

A national drug policy cannot be successfully developed in a vacuum. Rather, it must be developed within the framework of a national health policy and health care system. Only then are

the two types of policy likely to be mutually supportive. All too often, however, a national drug policy is developed without reference to the national health policy, and in isolation from ongoing health sector development. It may even be developed before the national health policy is in place. If so, essential drugs programmes are likely to be run in parallel to rather than in collaboration with other health programmes. Precious human and technical resources will then be wasted. At the same time, many health professionals will be unaware of the essential drugs concept, and procurement, prescribing and use of drugs less than optimal.

Traditional medicine policy is another area of concern. More and more countries have a traditional medicine policy and are integrating traditional medicine into their national health care systems. In many others, though, traditional medicine and its practitioners are not officially recognized. Opportunities for improving and providing health care are therefore lost, particularly in those developing countries where up to 80% of the population uses plant-based traditional medicines to help meet health care needs.

Figure 11: The pharmacy service gap — nearly a 100-fold variation in pharmacists per million population



Source: World Health Organization 1994.³³

Many of the problems described here can be fully resolved only if a country's pharmaceutical sector is strengthened. This will in turn call for a greater number of well-trained pharmacists and greater understanding of the potential role of the pharmacist in population health care. Unfortunately, many developing countries continue to suffer severe shortages of pharmaceutical staff. Indeed, there is a huge gap between lower- and higher-income countries in terms of pharmacy training and pharmacy service provision (Figure 11). A weak pharmaceutical sector has many unwanted repercussions. For example, at local level, dispensing of pharmaceutical products, including prescription-only drugs may well be by untrained drug sellers.³² At national planning level, health policy-makers may fail to develop sustainable management capacity in pharmaceuticals or ensure that national drug policy, national health policy and health system development complement and fully support each other. (See also Component 11).

Expected outcomes for 2000-2003

2.1: Essential drugs concept integrated into national health programmes following advocacy activities aimed at health policy-makers and health professionals working in health systems development at national level.

✓ WHO will continue to advocate for application of the essential drugs concept during national drugs policy and health system development, and to ensure that national drug policy objectives fit in with the broader objectives of national health policies. This will include advocacy via all types of country support activities, including expert consultant and national drug policy meetings.

Country progress indicators	1999 Status		2003 Target
	No./No. reporting	%	
Countries with a national drug policy included in the national health plan	n.a.*	n.a.	n.a.
Countries with a national policy on traditional medicine	(31/46)	n.a.	n.a.

* Data will be collected in 2000.

2.2: Development of sustainable management capacity in pharmaceuticals *by strengthening country capacity to manage and implement sustainable national essential drugs programmes.*

✓ WHO will focus primarily on strengthening national pharmaceutical resources through training of ministry of health officials and WHO national staff, and whenever possible increasing human resources in WHO country offices for carrying out activities relating to the pharmaceutical sector.

2.3: Traditional medicine integrated into national health care systems *through development and implementation of national policies on traditional medicine.*

✓ Work will include providing information on traditional medicine policies and regulation of traditional medicine activities and products to national health policy-makers and national drug regulatory authorities. Additionally, workshops will be organized on how to develop a national traditional medicine policy. A worldwide review of the legal status of traditional and complementary/alternative medicine will also be carried out.

5.2 Access: Ensure equitable availability and affordability of essential drugs, with an emphasis on diseases of poverty

Secure and sustainable access to essential drugs depends on:

- **Rational selection and use**³⁴ based on development of a national essential drugs list, so that health facilities focus drug-purchasing and prescribing on drugs that represent the best balance of quality, safety, efficacy and cost.

Figure 12: Increasing access to essential drugs — a framework for collective action



- **Affordable prices** to ensure that the drug expenditure of governments, other health care providers and consumers is cost-effective and represents best value for money.
- **Sustainable financing** through equitable funding mechanisms such as government revenues and social health insurance (involving prepayment and pooling of financial risk) and through transitional measures such as development assistance and drug donations.
- **Reliable supply systems** incorporating a mix of public and private supply services, to ensure regular supply of essential drugs of assured quality in health care facilities, and sufficient research and development for new drugs.

Each of the above four critical elements must be firmly in place if access to essential drugs is to be increased (see Figure 12). Too often, manufacturers who could reduce drug prices blame poor access on the unreliability of supply systems. Policy-makers who could influence drug financing blame the high drug prices imposed by drug manufacturers. Meanwhile, health care managers who could improve supply systems put the blame on inadequate financing. But the reality is that all of these stakeholders must combine their efforts and expertise, and work towards common solutions.

“Let us be frank about it: essential and life-saving drugs exist while millions and millions of people cannot afford them. That amounts to a moral problem, a political problem and a problem of credibility for the global market system...”

Director-General

Dr Gro Harlem Brundtland,
Statement to the Executive Board at its 105th Session, January 2000.²²

Regarding rational selection, it should be noted that evidence-based treatment guidelines and essential drugs lists are not static but need to be constantly updated. Updating is dependent on research and development (R&D) efforts, which ensure that new drugs are brought to the market. For instance, new drugs are needed for new diseases such as HIV/AIDS, and for “old” or “neglected” diseases for which existing drugs are no longer effective, not produced in sufficient quantity or not adapted to field conditions in developing countries.³⁵

Tuberculosis, malaria and a number of other tropical illness represent “neglected diseases” for which R&D has been insufficient. WHO is involved in several new public–private initiatives to stimulate R&D for new medicines and vaccines, including the Medicines for Malaria Venture and the Global Alliance on Vaccines and Immunization. Within WHO, stimulating development of new medicines, vaccines, diagnostic tools and other technology is handled by one of several departments, depending on the target condition and type of technology demanded. Currently, departments in the Health Technology

and Pharmaceuticals Cluster, Communicable Diseases Cluster, and Family and Community Health Cluster are the most active in medicines and vaccines development.

Within the *WHO Medicines Strategy*, rational selection and use are considered under the rational drug use objective. The remaining three elements are dealt with below.

Component 3: Access strategy and monitoring for essential drugs

Help countries to ensure and monitor access to essential drugs, focusing on diseases of poverty, such as malaria, HIV/AIDS, tuberculosis and childhood illnesses

Progress

Access to essential drugs has increased considerably in the past 20 years. Nearly two-thirds of the world’s population can now obtain full and effective medical treatment with the drugs they need. In absolute terms, the number of people estimated to have access to essential drugs grew from roughly 2 billion in 1977, to 4 billion in 1997. And whereas in 1975, only a dozen countries had what would now

Table 4 Examples of policy options to increases access to essential drugs for priority health problems

Objective	Public and NGO sectors	Private sector
Rational selection	<ul style="list-style-type: none"> > Evidenced-based and cost-effective selection (national essential drugs list) > Independent drug information 	<ul style="list-style-type: none"> > Reimbursement lists > Treatment guidelines > Drug information bulletins
Affordable prices	<ul style="list-style-type: none"> > Competitive bulk purchasing > Drug tendering > Pooled procurement > Equity pricing of newer drugs 	<ul style="list-style-type: none"> > Price information > Price competition through generics > Price control > Containment of distribution costs
Sustainable financing	<ul style="list-style-type: none"> > Drug benefits in social health insurance > Targeted public/NGO financing > External financing 	<ul style="list-style-type: none"> > Better use of household spending > Drug benefits in private insurance > Community and employer financing
Reliable supply systems	<ul style="list-style-type: none"> > Integration of supply systems > Efficient public–private mix > Task-specific decentralization 	<ul style="list-style-type: none"> > Good pharmacy practice > Better rural–urban location of pharmacies > Management of informal sector

Table 5 Collaborating to increase access to drugs for priority health problems

Medicines Issues confronting UN programmes	WHO medicines response
Malaria — Roll Back Malaria	
<ul style="list-style-type: none"> ➤ Insufficient access to effective treatment ➤ Most antimalarials purchased in private sector but choice and use do not always follow national guidelines ➤ Problems in guaranteeing drug quality and safety ➤ Increasing drug resistance to current antimalarials ➤ High cost of effective new drugs 	<ul style="list-style-type: none"> ➤ Pilot public–private partnership projects in Africa to improve access to effective treatment ➤ Investigating use of traditional herbal medicine ➤ Improving linkage between disease control and public–private drug supply ➤ Country-based network on quality and use of minilabs or test kits ➤ Taskforce on research and development of new antimalarials ➤ Negotiations with pharmaceutical companies to lower price of new antimalarials
HIV/AIDS — Global UN strategy on access to HIV/AIDS drugs (UNAIDS with its co-sponsors)	
<ul style="list-style-type: none"> ➤ 70% of global HIV/AIDS cases are in Africa where access problems greatest ➤ Prohibitive cost of HIV/AIDS drugs, which patients must pay for out-of-pocket ➤ Public financing and risk-pooling are insufficient ➤ Health services and families cannot cope with caring for HIV/AIDS patients 	<ul style="list-style-type: none"> ➤ Coordination of global UN strategy on access to HIV/AIDS drugs ➤ Intensified country support to integrate access to HIV/AIDS drugs in national essential drugs programmes (including pooled procurement) ➤ Advocacy of “equity pricing”^{**} and generic competition ➤ Negotiations with pharmaceutical companies to lower price of new HIV/AIDS drugs ➤ Targeted country support on use of TRIPS safeguards to increase access to HIV/AIDS drugs ➤ Encouraging governments to increase public funding for health care and to develop health financing mechanisms ➤ Collaboration with NGOs to expand social support
Tuberculosis — Stop TB initiative	
<ul style="list-style-type: none"> ➤ Adherence to DOTS strategy (1st-line treatment) ➤ Increasing multidrugresistant “hot-spots” ➤ High treatment cost for multidrugresistant-TB ➤ Substandard and counterfeit drugs ➤ Insufficient effective drugs 	<ul style="list-style-type: none"> ➤ Development of fixed-dose combinations ➤ “Green light” committee for pooled procurement of 2nd-line anti-TB drugs ➤ Creation of Stop TB Facility, with focus on research and development of new anti-TB drugs ➤ Guidance on pooled procurement and pre-selection of suppliers ➤ Introduction of improved quality control methods and mapping of poor-quality suppliers
Childhood Illnesses — Integrated Management of Childhood Illness (IMCI) initiative	
<ul style="list-style-type: none"> ➤ Insufficient access to essential drugs, including paediatric formulations at 1st-level health centres ➤ Medicines issues for malaria are also valid for IMCI – 3 out of 4 people who die from malaria are children 	<ul style="list-style-type: none"> ➤ Headquarters collaboration expanded to regional levels through participation and contribution to IMCI country reviews ➤ IMCI supporting efforts to improve drug supply and drug management for priority diseases

^{**}“Equity pricing” (also known as differential pricing or market segmentation) is the concept that poor populations should pay less than wealthier populations for life-saving drugs.

be considered a national essential drugs list, today nearly 160 countries have adopted such a list. Of these, more than 80% are new or have been updated within the last five years. WHO's *Model List of Essential Drugs* has proven to be of great value in this respect.³⁶

WHO has elaborated and tested a number of policy options to boost access to essential drugs with high public health impact (Table 4). It has also extended collaboration on this issue with other UN programmes, such as Roll Back Malaria, the Stop TB Initiative and UNAIDS, and launched a multitude of activities to get medicines to where they are most needed (Table 5).

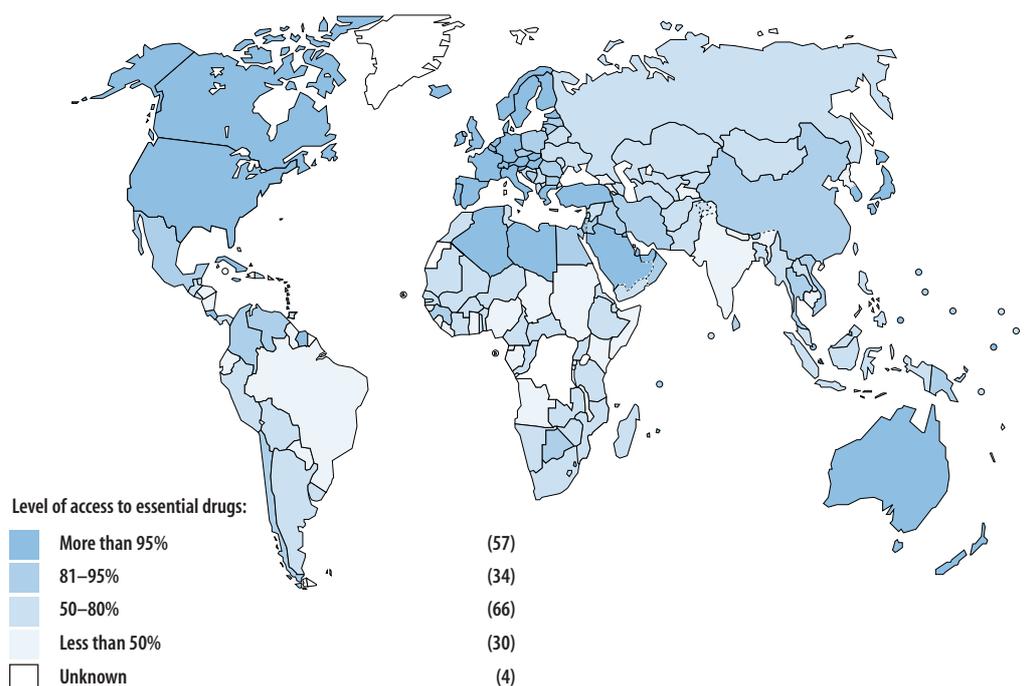
WHO has also been responding to Member States' increasing concern about the potential impact of new global trade-related agreements, including the WTO TRIPS Agreement, on access to pharmaceuticals. As the leading agency in health, WHO has provided policy guidance and produced a number of technical publications to raise awareness of the issues involved, and the actions countries can take to at least maintain current levels of access to essential drugs.³⁷ WHO's position

regarding pharmaceuticals and trade agreements is that essential drugs are part of the broader right to health care and not simply just another commodity. Patents for pharmaceuticals should therefore be managed so as not simply to protect the interest of the patent holder, but also to protect public health. WHO is also helping countries to apply the safeguards incorporated in the TRIPS Agreement.

Challenges

However, despite these promising trends, securing access to essential drugs remains an enormous challenge. One-third of the world's population — almost exclusively in low- and middle-income countries — continues to lack regular access to essential drugs. In the poorest parts of Africa and Asia, this figure rises to over 50% (Figure 13). The reasons are well known and include inadequate financing and poor health care delivery. For countries mired in foreign debt or struggling with an ailing economy, the prospects for improving access to essential drugs are bleak. This is especially so given that total pharmaceutical expenditure, as well as other health expenditure, is linked to the

Figure 13: Access to essential drugs has grown but inadequate financing and poor health care delivery are still constraining factors



economic development level of a country, and tends to increase only when gross domestic product increases.⁵

The statistics are equally alarming for communicable diseases. For the 20% of the global population that lives in poverty, 60% of deaths are due to diseases such as malaria and HIV/AIDS.¹⁰ The disease burden associated with these two diseases is particularly overwhelming. More than 33 million people live with HIV and 90% of them live in developing countries, without access to the drugs that could reduce their suffering and prolong their lives. Similarly, every year, more than one million people in developing countries die from malaria — simply because they do not have access to effective treatment.³⁸ (The main challenges relating to access to drugs are summarized in Table 5.)

Confronted with this unacceptable burden of ill health, the international community has become increasingly committed to reducing health gaps between rich and poor. WHO will likewise maintain its focus on the identified priority health problems of the worst off, and help countries act quickly and effectively to make essential drugs available and affordable.³⁰ That said, the attainment of health also requires that other sectors such as education and agriculture also receive their due share of public resources. Too often, though, scarce resources are used instead to build up military capacity or yet further increase the well-being of a minority.

Trade is another sector that impacts heavily on health. New global trade agreements — not only the WTO TRIPS Agreement — are likely to affect drug prices, technology transfer, and levels of resources available for research and development into tropical diseases. WHO will continue to help countries understand the potential impacts of such agreements, and to protect health interests during the globalization process.⁴⁰ Careful monitoring of all these issues is also called for.

Country progress indicators	1999 Status		2003 Target
	No./No. reporting	%	
Countries where less than 50% of the population has access to essential drugs	(30/187)	16%	14%
% of key drugs available in health facilities (Type C countries*)	n.a.**	n.a.	80%

* Measured in countries with comprehensive programmes.
** Data will be collected in 2000.

Expected outcomes for 2000-2003

3.1: Increased access to essential drugs for priority health problems, particularly for poor populations through close collaboration between a wide range of partners.

✓ Work with international and national programmes concerned with malaria, tuberculosis, HIV/AIDS and childhood illness to ensure a comprehensive and coordinated approach to securing access to essential drugs, based on the four-point framework of selection, affordability, finance and supply systems.

3.2: Increased access to newly developed and abandoned essential drugs through expanded collaboration with development partners.

✓ WHO will work with global partners, such as UNICEF, the World Bank, WTO, generic drug manufacturers and the pharmaceutical research industry to develop new strategies and agreements to increase access to “new” essential drugs for priority health problems in low- and middle-income countries, and to continue production of “old” essential drugs.

3.3: Standard indicators to measure equitable access to essential drugs developed and tested through operational research for use by governments and NGOs in developing countries to monitor access at various health care levels.

✓ After developing a set of simple, easily applied, standard indicators, based

“It is an indication of the topsy-turvy world in which we live that the doctor, the school-teacher or the nurse feels more threatened by financial conservatism than does the general and the air marshal”.

1998 Nobel laureate in economics Amartya Sen, World Health Assembly 1999, keynote address.³⁹

on the outcome of operational research, and in consultation with governments and NGOs, WHO will promote their use by monitoring systems worldwide. This will help identify obstacles and constraints to improving the availability and affordability of essential drugs.

3.4: Access to drugs promoted within international trade agreements by advising countries on their options under, for example, the WTO TRIPS Agreement, and helping them to monitor the impacts of such agreements on access to essential drugs.

✓ WHO will develop standardized methods and sentinel systems, which can be adapted for use at national level, for monitoring the impacts on pharmaceuticals of the WTO TRIPS Agreement. WHO will also advise countries on how to implement TRIPS safeguards, amend and review national legislation to take account of these safeguards, and continue to collaborate with other organizations concerned about the impact of globalization.

Component 4: Financing mechanisms and affordability of essential drugs

Ensure the implementation of national strategies to finance the supply and increase the affordability of essential drugs, in both the public and private sectors

Progress

WHO continues to be heavily involved in efforts to increase drug financing, both publishing guidance on drug financing mechanisms and putting it into practice. Efforts have included assessment of public financing for drug benefits within social health insurance schemes, a review of experience with user fees for drugs, and greater input into the planning of development bank loans for pharmaceutical projects. Box 5 distils WHO experience in this important area.

One particularly promising trend supported by WHO is the growth in

health insurance coverage and expanded drug benefits in countries as diverse as Argentina, Egypt, Georgia, India, the Islamic Republic of Iran, the People's Republic of China, South Africa, Thailand and Viet Nam. Some insurance programmes have special arrangements for rural and low-income populations.⁴² Increasingly, WHO is working with such programmes to apply the essential drugs concept and to address the particularities of drug management within health insurance. The aim is to reduce drug costs.

Indeed, concerns about drug costs remind us that although sustainable financing is critical, drug costs must be affordable for governments and consumers if access is to be maintained. A number of measures have been successfully developed to contain the drug prices paid by governments and the drug costs of health insurance programmes. Many of them can also be used to contain direct consumer expenditure. They include pooled procurement arrangements, generic^b substitution and improved price information.

Generic substitution, in particular, has considerable potential for contributing to increased financial access. In fact, it is a proven cost-effective strategy for containing drug expenditure.⁴⁴ The average price of generic drugs can fall by as much as 30% of the innovator drug price when the number of generic versions of the drug on the market increases.⁴⁵ WHO is therefore actively encouraging development of drug policies based on the promotion of generic medicines of assured quality. Competition among chemically different but therapeutically similar patented drugs can also reduce the prices of patented products. The results of a study illustrated in Figure 14 show that the price of antiretroviral products fell by 73% in five years once a number of antiretroviral products had become available.⁴⁶

^b A generic medicine is a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights.⁴³

Box 5 Guidance on drug financing

Public financing for drugs and for drug benefits within social health insurance

- ◆ have achieved the greatest equity and solidarity where actively pursued and are therefore the preferred approach to drug financing
- ◆ require mechanisms to ensure that financing from general revenues is targeted at priority health problems and poor populations
- ◆ depend on specialized knowledge and experience of drug benefits within health insurance

Out-of-pocket payment by households

- ◆ is the most common source of drug financing in low-income countries
- ◆ creates significant barriers to access for impoverished populations
- ◆ associated with wasteful and often dangerous use of drugs
- ◆ benefits from policies aimed at promoting availability, best prices and rational use

User fees at government facilities

- ◆ can be used as a transitional measure to other more equitable, sustainable approaches
- ◆ often create barriers to access with little or no improvement in care unless lessons from experience are applied to minimize problems

Voluntary and other local financing through nongovernmental organizations, community groups, employers

- ◆ varies widely among countries, but accounts for up to 50% of rural curative services in some
- ◆ can provide greater benefit with supportive government policies

Development assistance and loans:

- ◆ are an interim mechanism which should be directed at sustainable long-term drug services and priority public health problems
- ◆ should not undermine national policy

Sources: World Health Organization, 1998, 2000.^{5,41}

Challenges

High-income countries spend substantially more per capita on drugs than low- and middle-income countries. As shown in Figure 15, public spending on drugs in over three dozen countries is less than US\$ 2 per capita per year. In such countries, inadequate and misdirected financing is arguably the greatest barrier to access to life-saving essential drugs. The need is to persuade their governments that they have a vital role to play in financing health services and drug provision, and to help them carry out that role.

Thus although user fee schemes for drugs in public health services are becoming increasingly common, they should be seen only as transitional measures towards the long-term aims of more equitable prepaid public financing and social health insurance. This is because user fee schemes can exacerbate existing inequity —

especially for impoverished populations. They may also create financial incentives for health care providers. User fees should therefore complement rather than replace government allocations for drugs. In the meantime, perceived service quality improvement will also be essential to encourage users to take advantage of services offered.⁵

Social or universal health insurance is of course vastly preferable to user fees since it promotes equity, solidarity and affordability. Almost all the health systems of developed market economies feature social health insurance. But in low-income countries overall coverage continues to be low: a mere 10.3% in sub-Saharan Africa, and 27.3% in Asia (excluding China and India).⁵ And when health insurance schemes do exist, drug expenditure can easily amount to 25 to 70% of their total costs, making them very difficult to

Figure 14: Competition reduces drug prices — the example of antiretrovirals in one major market

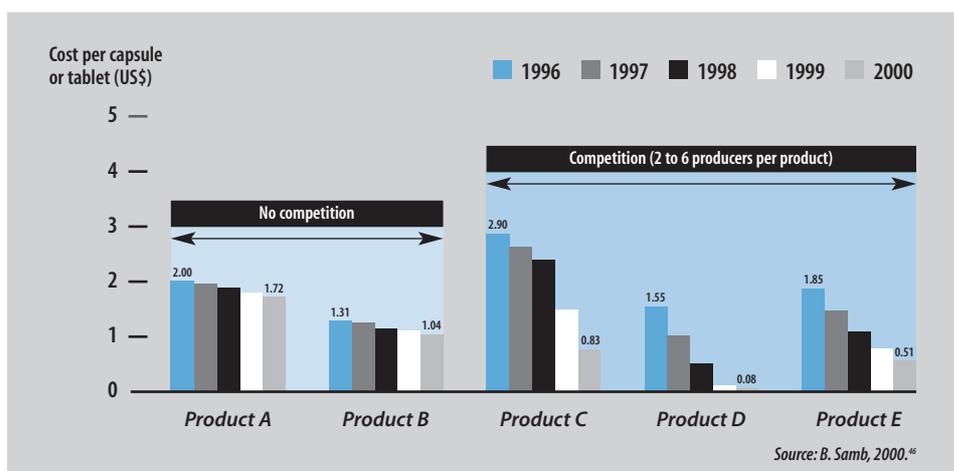


Figure 15: In over 3 dozen countries public drug expenditure is less than US\$ 2 per capita — inadequate by most estimates

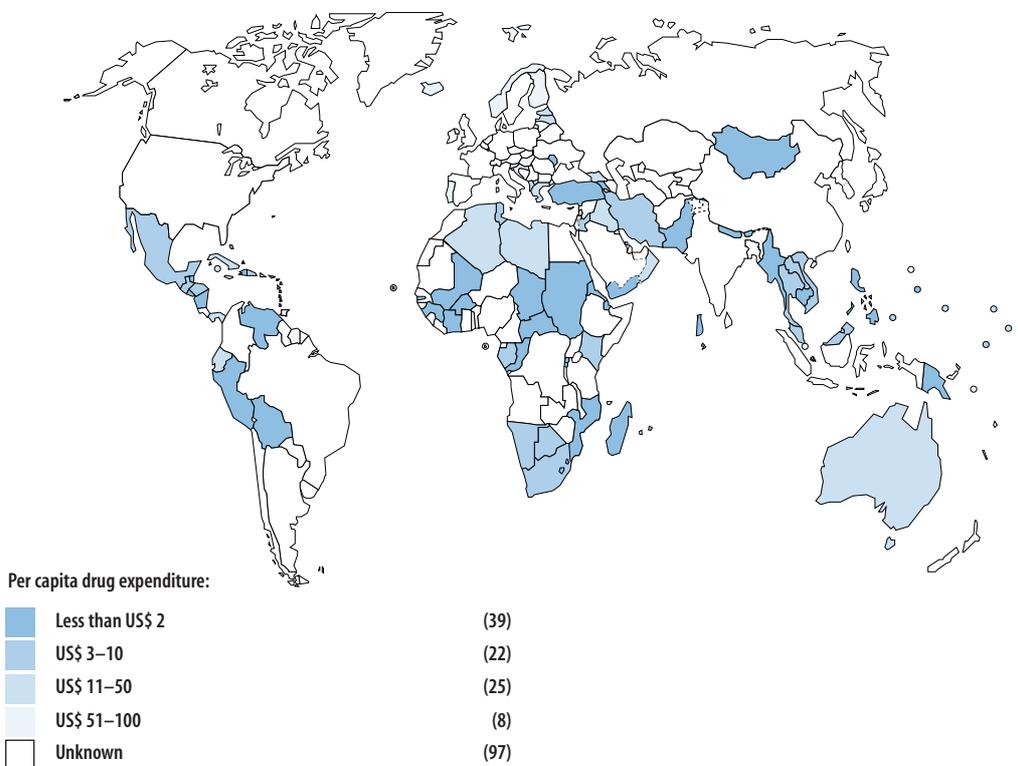
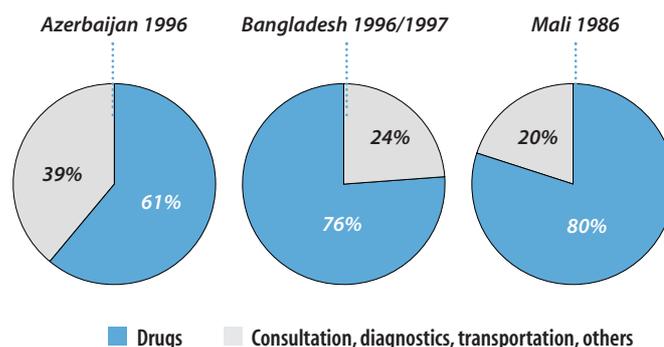


Figure 16: In transitional and developing economies, drugs are the largest out-of-pocket household health expenditure



Sources: K. Diarra, S. Coulibaly, 1990;⁴⁷ UNICEF, 1997.⁴⁸

sustain.¹⁰ But by introducing the essential drugs concept to these schemes, WHO could help improve their sustainability and their attractiveness to governments.

Low health insurance coverage indicates that out-of-pocket spending on drugs is likely to be high.⁵ In fact, in lower-income countries, household (out-of-pocket) expenditure on drugs accounts for between 61 and 80% of total health expenditures (Figure 16), and can be a major source of impoverishment.^{47, 48}

Affordability of drugs could be increased substantially, however, by eliminating or reducing import duties, distribution costs and dispensing fees. These can account for up to 80% of the total price paid for drugs. In particular, import duty can be as high as 30%, while value-added and other national and local taxes can amount to 20% of a drug cost.⁴¹ At the same time, generic markets could be encouraged. This would require not only appropriate legislation and regulations, but also reliable quality assurance capacity, professional and public acceptance of generic drugs and economic incentives and information (for both prescribers and consumers).³²

Information is also crucial if maximum value for drug expenditure is to be assured, and governments and consumers enabled to lobby for fair drug prices. Various international organizations do regularly produce price lists, and some countries include drug prices in therapeutic manuals or print the maximum retail prices on packages. But dissemination of price information for finished products and raw materials, in particular, is minimal in most low-income countries.

Not surprisingly, in view of the difficulties involved in drug financing, drug donations have become a popular means of tackling specific diseases, including river blindness, elephantiasis, leprosy and other diseases targeted for eradication. Drug donations do indeed contribute to health progress in the

short term. But on a long-term basis, self-sufficiency is the only viable means of tackling increasing disease burdens.⁴² In the mid-term, therefore, drug donations should be planned as a sustainable component of the drug supply system.

Country progress indicators	1999 Status		2003 Target
	No./No. reporting	%	
Countries with public drug expenditure per capita of less than US\$ 2.00	(39/94)	41%	35%
Countries with generic substitution allowed in private pharmacies	(83/134)	61%	75%
Countries with public health insurance covering drug costs	(71/111)	64%	70%

Expected outcomes for 2000–2003

4.1: Planning and advocacy for public sector drug financing and implementation of national drug financing strategies.

✓ Work will include technical assistance to countries and capacity-building in forecasting drug requirements at national level, advocacy for appropriate levels of sustainable public drug financing, facilitating national and regional meetings on national drug financing, and encouraging countries to develop prepaid drug-financing mechanisms that

are appropriate to their socioeconomic context.

4.2: New drug-financing strategies *developed through operational research and promoted.*

✓ WHO will actively support development of alternative drug-financing mechanisms to improve use of public resources, the quality of services and access to primary care with drug provision, with a special focus on poor populations. Development of endowment funds for eradication and control of specific communicable diseases in least-developed countries will be investigated.

4.3: Increased affordability of essential drugs in public and private sectors *through generic policies, pricing policies, local production (where appropriate) and other mechanisms.*

✓ WHO will work with countries and other partners to develop public-private partnerships to make low-cost and good-quality pharmaceutical products available in both the public and private sectors, and to all groups of society. Cost-effective procurement at subregional level, where feasible, will also be promoted.

4.4: Expanded coverage and improved drug benefits within health insurance *through operational research, development of policy guidance, and production and dissemination of training materials on introducing and implementing health insurance schemes.*

✓ WHO will help countries: undertake operational research into implementation of drug benefit mechanisms; consider national and local health insurance schemes based on the essential drugs concept; and facilitate national and regional workshops on health insurance based on a core set of training materials.

4.5: Increased drug price information and guidance on drug price policies *through market intelligence, dissemination of price information on raw materials and finished products, and operational research and policy guidance in the field of price information and pricing policies.*

✓ Activities will include the building of capacity in market intelligence services and drug price monitoring systems at national level, and technical assistance to implement and monitor national drug price policies. Distribution of price information on raw materials and finished products will also be increased.

Component 5: National and local public sector drug supply systems and supply capacity

Support countries to run efficient public sector drug supply systems, ensuring the availability of essential drugs at all levels of the distribution chain

Progress

The fourth critical element for securing access to essential drugs is a reliable mix of public and private drug supply. In the last decade, four types of drug supply system, in addition to traditional Central Medical Stores, and with increasing levels of private sector features, have been developed (see Box 6).

These systems vary considerably with respect to the role of the government, the role of the private sector, and the incentives, if any, for efficiency.³² But whatever system is developed, it aims to ensure continued availability of essential drugs with low rates of drug stock-outs, and low total drug costs for a given level of service. Controlling costs by introducing private sector features to public systems (such as outsourcing, or by decentralizing storage and distribution) helps achieve these goals. For an increasing number of countries, including Benin, Colombia,

Box 6 Public-private drug supply systems for governments and institutional health services

Central medical stores

- ◆ centralized, public sector system
- ◆ conventional supply system
- ◆ drugs procured and distributed by centralized government unit

Autonomous or semi-autonomous supply agency

- ◆ centralized, private or semi-private system
- ◆ bulk procurement, storage and distribution by autonomous or semi-autonomous agency (government drug supply agency)

Direct delivery system

- ◆ decentralized, largely private approach
- ◆ tenders establish the supplier and price for each item
- ◆ drugs delivered directly by supplier to districts, major facilities

Primary distributor ("prime vendor")

- ◆ centralized, largely private approach
- ◆ drug procurement office establishes contracts with drug suppliers and separate contract with a single prime vendor
- ◆ prime vendor warehouses and distributes drugs to districts, major facilities

Fully private supply

- ◆ decentralized, fully private approach
- ◆ private wholesalers and pharmacies manage all aspects of drugs supply with government facilities

Source: *Management Sciences for Health/World Health Organization, 1997.*⁵⁰

Guatemala, the Newly Independent States, South Africa and Thailand, a public-private mix is working well.⁴⁹

Recent WHO activities to improve drug supply have included publication of guidelines and manuals, and support to international training courses (*Managing Drug Supply for Primary Health Care*) and a distance learning programme (in collaboration with several organizations) to upgrade the drug supply management skills of government officials.

With emergency relief activities increasing during the last decade, WHO has also been active in drug supply programmes — for example in former Yugoslavia, Haiti and Iraq — that seek to ensure that pharmaceutical needs are met. It has also promoted the standardization of emergency health kits (e.g. *The New Emergency Health Kit* and the essential drugs kits used in former Yugoslavia).

Challenges

Despite many promising developments in drug supply, many countries continue to struggle with a mix of inefficient

public supply systems (intended to serve the entire country) and private supply systems (which mostly serve urban areas). Decentralization of public services has sometimes compounded the problem. And although more efficient drug supply systems have been introduced, it remains to be documented whether they have succeeded in increasing access throughout the public health care system to affordable good-quality essential drugs.

Nevertheless, following good procurement practices would help improve national drug supply significantly. *The Operational Principles for Good Pharmaceutical Procurement*⁵¹ produced by the International Pharmaceutical Coordination group in 1999 indicate the critical steps in the procurement process and elaborate twelve operational principles. The document now needs to be widely disseminated and acted upon. Principal target groups include national and local procurement agencies. The drug supply operations of international organizations, and international and

"Substantive improvements in the supply and use of pharmaceuticals are possible. In most health systems, the potential for improving the supply process is tremendous, reflecting in part the magnitude of current inefficiencies and waste."

Management Sciences for Health/World Health Organization, 1997.⁵⁰

national NGOs, could also be improved if they followed these principles.

Drug production facilities are also of concern. In many developing countries they are still found in the public sector — a relic of past strategies to improve drug supply and availability. But if they are to function optimally, countries must critically evaluate their operation, particularly in terms of compliance with good manufacturing practices, production capacity and their range of products.

Drug donations are another form of drug supply and can do much to alleviate suffering and save lives. Moreover, the growing number of natural disasters and new and continuing armed conflicts suggest that the need for drug donations will not diminish. However, whether a rapid response to an acute emergency or as an element of development aid, supply must match demand. In 1996 WHO produced *Guidelines for Drug Donations* to improve the quality of drug donations. A survey of the impact of the guidelines showed a very positive impact. The second edition of the guidelines, produced in 1999 in collaboration with 15 international agencies, must now be fully endorsed and adhered to by all drug donors, be they governments, organizations or large corporations.⁵²

Country progress indicators	1999 Status		2003 Target
	No./No. reporting	%	
Countries with public sector procurement based on a national list of essential drugs	(70/132)	53%	60%
Countries with at least 75% of public sector procurement carried out by competitive tender	(79/88)	90%	95%
Countries implementing the 1999 interagency guidelines on drug donations	n.a.*	n.a.	80%

*Data will be collected in 2000.

Expected outcomes for 2000–2003

5.1: Enhanced drug supply management capacity through development of training materials, and provision of international, regional and national training programmes in drug supply and distribution management for national governments and not-for-profit health care organizations.

✓ WHO will continue to actively support existing drug management training courses, as well as development of regional, national and local initiatives on drug management capacity-building, in collaboration with national institutions, NGOs and other WHO partners.

5.2: Improved drug supply management as part of health sector reform through global guidance, and international, regional and national training programmes, with emphasis on drug supply issues within decentralized health care systems.

✓ WHO will provide technical assistance to countries, facilitate meetings and workshops on public–private drug supply options in decentralized health care systems, and support operational research activities to improve drug supply systems.

5.3: Adherence to good pharmaceutical procurement practices through promotion of use of a list of essential drugs and informed decision-making through increased availability of reliable price information.

✓ Activities will include technical assistance to countries and training in good procurement practices, facilitation of regional, national and local meetings and workshops on good procurement practices, and collection and distribution of reliable price information on raw materials and finished pharmaceutical products.

5.4: Cost-effective and reliable local drug production promoted where and when appropriate.

✓ WHO will support feasibility studies to guide countries as to their role in drug production, and to provide recommendations on the relevance of starting or maintaining local drug production.

5.5: Adherence to good drug donation practices among donors and recipients through advocacy, international networking, monitoring, and assistance to countries to develop national drug donation guidelines.

✓ WHO will continue to distribute and advocate adherence to the interagency revised *Guidelines for Drug Donations*⁵² and the interagency *Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies*.⁵³ It will also monitor donation practices worldwide.

5.3 Quality and safety: Ensure the quality, safety and efficacy of all medicines by strengthening and putting into practice regulatory and quality assurance standards

Effective drug regulation promotes and protects public health by ensuring the quality, safety and efficacy of medicines before they reach consumers. WHO's major contribution in this area relates to development of internationally recognized norms, standards and guidelines. These are then adapted by countries to meet their specific drug regulatory needs and, provided they are adequately enforced, help maintain public confidence in pharmaceuticals.

Component 6: Norms, standards and guidance for pharmaceuticals

Strengthen global norms, standards and guidelines for the quality, safety and efficacy of drugs, including traditional medicine, and provide guidance for global harmonization efforts

Progress

The development of norms, standards and guidelines to promote quality assurance and quality control is an integral part of WHO's Constitution and a unique responsibility. It has been endorsed and supported through numerous World Health Assembly resolutions, and more recently in those on the Revised Drug Strategy.

Much of the work is ongoing since it involves providing advice as information becomes available. For example, development of quality control specifications for essential drugs — for inclusion in *The International Pharmacopoeia* — started in the 1950s. The fifth volume will soon be published. Similarly, WHO's contribution to quality control in laboratories was initiated in 1970, and has included drafting of guidelines for national quality control laboratories, and provision of further guidance on samples and validation. Thereafter, in 1975, the first edition of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce was issued. Since then the scheme has been revised twice, and now boasts a total of 142 Member State participants.

Development of the WHO system of International Nonproprietary Names (INN) is another ongoing activity. Introduced by WHO in 1950, this system is a means of identifying each pharmaceutical substance or active pharmaceutical ingredient by a unique name that is universally recognized and universally accessible as public property. Given the growth in global pharmaceutical markets and international pharmaceutical trade, use of INNs by all countries has become increasingly important. Conversely, the existence of several names for the

"WHO continues to establish and develop authoritative norms and standards to assist countries in the assurance of the quality, safety and efficacy of medicines. This is a goal supported and pursued by all parts of WHO."

WHO Director-General
Dr Gro Harlem Brundtland,
keynote address,
9th International Conference of
Drug Regulatory Authorities,
April 1999.⁵⁴

Figure 17: International nonproprietary name — one name worldwide



same pharmaceutical substance can be a source of considerable confusion (Figure 17). To date more than 7000 INNs for generic and newly developed products have been selected, published and translated into five languages. WHO is also working in close collaboration with WIPO to protect INNs against use as trademarks.

Good manufacturing practices (GMP) have also been actively promoted by WHO. All WHO GMP texts are now available in a single publication for easy reference, a revision of the text on sterile products is being finalized, and additional GMP guidance is being developed for inspectorates, as well as draft pre-approval inspection and quality system requirements for national GMP inspectorates.

In terms of actual pharmaceutical products, activities to ensure the quality of starting materials are well under way, including the development of a model certificate of analysis and mechanisms to improve quality assurance and relevant commercial trading practices.

WHO has also provided guidance on the selection of comparator pharmaceutical products for equivalence assessment of generic products^c and their potential to increase access to essential drugs.

Regarding use of pharmaceutical products, WHO has developed the ATC/DDD system (Anatomical Therapeutic Chemical Classification system/defined daily dose) to collect drug use data. This data is essential for assessing trends in drug use and cost, assessing use in light of existing guidelines, measuring the impact of interventions against misuse, and ultimately measuring access, quality and cost-effectiveness of care.

Challenges

The increasing globalization of commerce and trade, and the merging of pharmaceutical companies, are internationalizing pharmaceutical production. Pharmaceutical norms and standards are thus more important than ever before since they serve as a common reference point for ensuring minimum safety and quality. One of WHO's roles is to continue to define such norms and standards, and to help countries apply them.

Safety and quality of pharmaceuticals are also being promoted through regional and international efforts to harmonize drug regulation, such as those led by the International Conference on Harmonisation (ICH), the European Union, ASEAN (Association of South-East Asian Nations), CAN (Andean Community), CADREAC (The Collaboration Agreement of Drug Regulatory Authorities in European Union Associated Countries), and MERCOSUR (Southern Common Market). These efforts are to be welcomed since international consensus on quality, safety and efficacy standards can speed up access to new medicines. It also favours price competition among generic pharmaceutical products.

That said, quality assurance levels differ from country to country — not all countries have the same capacity and resources for implementing agreements on drug regulation harmonization. Drug

^c More generally termed "multisource" products by drug regulators.

regulation experts accordingly recommend a step-wise approach for achieving the highest level of drug regulation and quality control in each country. WHO's role is to identify areas in which further guidance needs to be developed for preliminary and intermediate steps. Simple screening tests for detecting substandard and counterfeit drugs are just one example.

More generally, WHO's task is to help countries consider the implications of the relevant harmonization agreements. This is particularly true with regard to ICH, which currently does not include representatives from all developing countries. WHO needs to evaluate the impact of ICH guidelines, and advise non-ICH Member States on how to adapt existing guidelines to their own needs and conditions.

At the same time WHO must ensure that its own normative guidelines, such as its guidelines on good clinical practice (GCP), are maintained and updated. The GCP guidelines aim to provide globally accepted and applicable standards for biomedical research involving human subjects, and must therefore take recent developments in science and technology fully into account.

Rapidly evolving science and technology are likewise creating problems for regulatory authorities everywhere. Training and specialization requirements for dealing with the ever-increasing complexity of assessing technologically advanced products can be especially burdensome. But by developing norms and standards for use in new areas of health technology and product development, WHO can reduce this problem, while at the same time helping to minimize unnecessary

duplication of scientific expertise and effort.

Globalization of the pharmaceutical industry is also bringing other safety issues to the fore. For example, non-prescription medicines are becoming increasingly available to the general public in all countries, including through such channels as the Internet. Yet resources for monitoring their safety are often lacking.

Expected outcomes for 2000-2003

6.1: Norms, standards and guidelines developed or updated including: norms and standards for pharmaceutical legislation and regulation, for assessment of quality, safety and efficacy, and for quality assurance; standards for safe trade in starting materials and finished drug products; and guidelines concerning sale of medical products on the Internet.

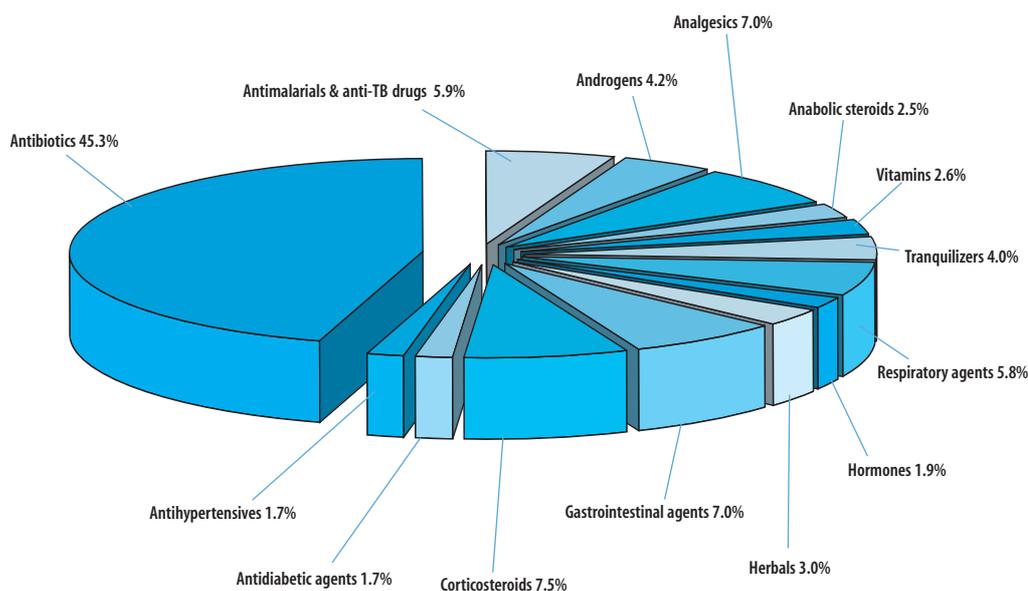
✓ Specific work will include developing guidelines on safe trading in the context of globalization, and on the purchase and sale of medical products on the Internet. The WHO guidelines on good clinical practice will be revised, and guidelines produced by other institutions or regional collaborative groups evaluated.

6.2: Quality control specifications, basic tests, screening tests and international chemical reference materials for pharmaceuticals developed. The quality control specifications will be included in The International Pharmacopoeia.

✓ Work will include development of pharmacopoeial monographs, publication of the sixth volume of *The International Pharmacopoeia*, and creation and maintenance of international reference materials, screening tests and basic tests.

Country progress indicator	1999 Status		2003 Target
	No./No. reporting	%	
Countries participating in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce	(142/191)	74%	80%

Figure 18: Antibiotics and other essential drugs are commonly counterfeited leading to treatment failure and sometimes even death



Note: By April 1997, WHO had received reports of 771 cases of counterfeit drugs, as broken down above.
Source: World Health Organization, 1999.⁵⁸

6.3: Drug nomenclature and classification efforts continued through assigning, promoting and protection of international nonproprietary names (INNs) and promotion and development of ATC/DDD system (Anatomical Therapeutic Chemical Classification system/defined daily dose).

✓ INNs will be assigned to new pharmaceutical substances, their use promoted and measures for protecting against their misuse strengthened. ATC/DDD classification will continue to be developed and promoted, particularly for drug use studies, by the International Working Group on Drug Statistics Methodology.

6.4: Promotion of WHO norms, standards, guidelines, nomenclature and WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International

Commerce at national and international levels.

✓ WHO will provide support for workshops, conferences, publications and other promotional measures to ensure adoption and implementation by countries and international organizations of WHO norms, standards, guidelines and nomenclature, and also the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

6.5: Coordination of regional and international harmonization of norms through networking with interested parties, and regular review of WHO's position on global harmonization.

✓ WHO will continue to collaborate with the International Conference on Harmonisation, and support regional drug regulatory networks.

Component 7: Drug regulation and quality assurance systems

Support countries to establish and maintain effective drug regulation and quality assurance systems

Progress

WHO's experience in drug regulation has shown that countries generally develop drug regulatory capacity in phases and over a long period of time. For countries with limited resources it is therefore particularly important to set priorities. Drug regulatory activities can later be expanded gradually, in line with development of the pharmaceutical sector, and as resources become available.⁵⁵

In an attempt to find means of accelerating the development of drug regulation capacity, WHO has created a multicountry working group. Consisting of ten WHO Member States, the group is assessing the drug regulation performance — both strengths and weaknesses — of a variety of drug regulatory authorities. The ultimate aim is to develop alternative strategies for decision-makers for improving drug regulation, and for promoting a culture of mutual problem-solving.

WHO is also establishing collaborative projects with the European Agency for the Evaluation of Medicinal Products (EMA), to develop methodologies for strengthening pharmaceutical inspectorates, and computerized systems to support the work of drug regulatory authorities.

Meanwhile, provision of training for national regulatory officials in GMP inspection, good distribution practices inspection, drug registration and quality control, is doing much to enhance existing drug regulation capacity. WHO's basic training modules for GMP are nearing completion and will be used to train trainers to enable more rapid spread of GMP implementation.

At the same time WHO has been helping countries to combat the

growing problem of counterfeit and substandard drugs. Activities have included establishing a network of anti-counterfeit pharmaceutical liaison officers, expanding the WHO database on counterfeits, organizing workshops and international meetings on the issue, and helping countries to implement the Organization's *Guidelines for the Development of Measures to Combat Counterfeit Drugs*.⁵⁶

The quality and safety aspects of traditional medicine — particularly herbal medicines — is another emerging issue for many drug regulation authorities, and reflects the increased use of and interest in this type of health care. WHO has responded by producing a number of authoritative reference materials, such as the *Regulatory Situation of Herbal Medicines: Worldwide Review*.⁵⁷ Containing information from 50 countries on the regulation of herbal medicines, it is proving to be an invaluable reference for other countries seeking to develop their own systems for regulation and registration of herbal medicines.

Challenges

But despite all the efforts made to improve drug regulation at national and international levels, fewer than one in six WHO Member States have well-developed drug regulation. Those that do are usually wealthy, industrialized countries. About three in six Member States undertake drug regulation of varying levels of development and operational capacity, while two in six have either no drug regulatory authority or very limited drug regulation capacity.

Given this picture it is not surprising that in many developing countries the quality, safety and efficacy of both imported and locally manufactured medicines cannot be guaranteed. This is because pharmaceutical manufacturers, importers and distributors do not comply with the regulatory requirements, and smuggling and illegal importation of drugs are often rife.

"Today, the quality of drugs and, therefore, their effectiveness and safety are less and less certain, especially for the poorest populations, who are attracted by lower-priced drugs sold outside pharmacies."

Bernard Pécoul et al., 1999.

Access to Essential Drugs in

Poor Countries. A Lost Battle?⁵⁵

Substandard^d and counterfeit drugs^e are then not only sold in these countries but also exported or re-exported. By April 1999, reports of 771 cases of substandard drugs had been entered into the WHO database on counterfeit drugs, 77% of which were from developing countries (Figure 18). (Data analysis showed that in 60% of the 325 cases for which detailed data were available, an active ingredient was lacking.)⁵⁸

The situation is worsened by the fact that medicines exported from industrialized countries are not regulated to the same level as those domestically consumed, while export of drugs to developing countries via free trade zones is increasing. Relabelling of products to mask details of their origin is also known to occur. Tackling these issues will require effective partnerships between WHO, national authorities and the pharmaceutical industry.

Strengthened drug regulation efforts at international level are also required following the concentration of

pharmaceutical manufacturers within a limited number of large corporations, and increased pharmaceutical trading following international and regional trade agreements. Some policy-makers now believe that drug regulation represents an unnecessary barrier to trade and should be reduced to a minimum. Pharmaceuticals, however, cannot be considered a standard commodity since consumers and prescribers are unable to assess their quality, safety and efficacy.

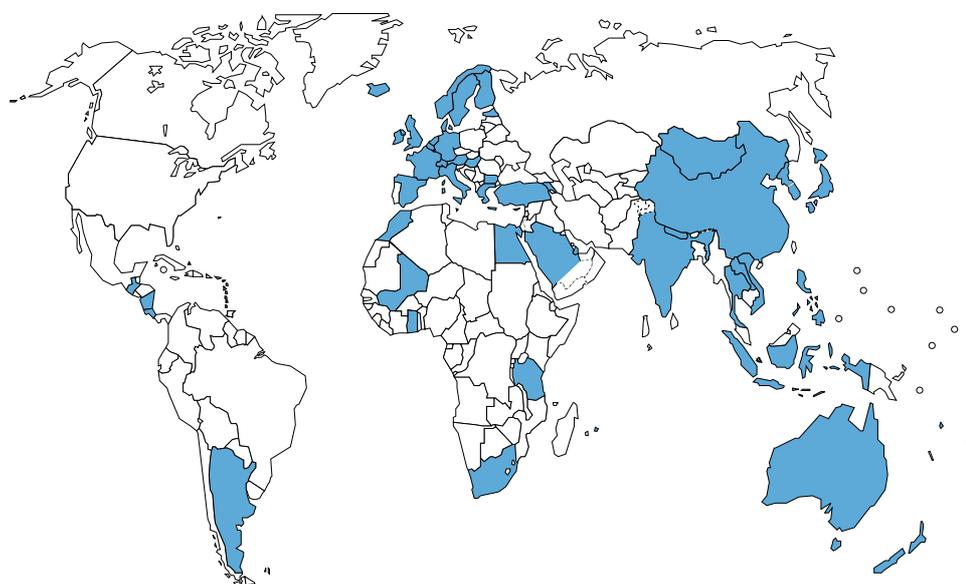
This is well illustrated by the problem of how to protect consumers from substandard and dangerous drugs moving on international markets, and increasingly distributed via the Internet, over which there is little jurisdiction. Even if a product can be sold legally over the Internet within the country in question, the quality, safety and efficacy of pharmaceuticals sold in this way cannot be assured by the consumer.⁵⁹

Growing international and national trade in alternative medicines, including herbal products, is also becoming more complex, following rapid increases in demand. Significant quantities of herbal products are now imported by countries in Europe, North America and Asia. For example, between 1992 and 1996,

^d A substandard drug is a pharmaceutical product that does not comply with established standards.

^e A counterfeit pharmaceutical product is a product that is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients or with the wrong ingredients, with no or incorrect quantities of active ingredient, or with fake packaging.

Figure 19: A growing number of countries report having laws and regulations covering herbal medicines, but many more are needed



Country reporting laws and regulations covering herbal medicines

Australia's importation of Chinese herbal medicines increased fourfold, while Korea now imports about 30,000 tons of medicinal plants every year.^{60, 61} As in the case of any other pharmaceutical material or product, their safety and therapeutic value must be assured if their full health benefits are to be attained. A growing number of countries are developing national policies on traditional medicine that cover quality and safety, but much remains to be done.

Country progress indicators	1999 Status		2003 Target
	No./No. reporting	%	
Countries operating basic drug regulatory system (key legislation and drug regulatory authority functions)	(92/135)	68%	75%
Countries with basic quality assurance procedures (good manufacturing practices and sampling to test drugs)	(87/139)	62%	75%
Countries with laws and regulations covering herbal medicines	(48/60)	n.a.	n.a.

Expected outcomes for 2000–2003

7.1: Drug regulation effectively implemented and monitored through better organization, financing, staffing and management of regulatory functions.

✓ Activities will include the development and promotion of drug regulation tools and training courses, facilitation of workshops and seminars, participation in regional and international conferences, such as the International Conference of Drug Regulatory Authorities and the Eastern Mediterranean Drug Regulatory Authorities Conference, and support to drug regulatory networks.

7.2: Drug manufacturing, distribution and inspection practices improved through

provision of training modules and other tools for promoting good manufacturing practices, good distribution practices, inspection practices and other related enforcement mechanisms.

✓ WHO will finalize the good manufacturing practices (GMP) training modules, and continue to help countries implement GMP.

7.3: Substandard and counterfeit drugs combated by raising decision-makers' awareness of the issue, increasing the capacity of enforcement authorities to take necessary action, and encouraging the different stakeholders, including the pharmaceutical industry, to work together on common solutions.

✓ WHO will continue to promote the WHO guidelines on counterfeit drugs⁵⁶ at national, regional and global levels. It will also maintain and extend its database on counterfeit drugs, and support the network of anti-counterfeit pharmaceutical liaison officers.

7.4: Regulatory Situation of Herbal Medicines: Worldwide Review updated following completion of data collection on regulatory situation of herbal medicines from Member States.

✓ As well as updating and extending its review of the regulatory situation of herbal medicines, WHO will encourage all countries to ensure the quality and safety of herbal medicines through development and implementation of suitable regulations.

Component 8: Information support for pharmaceutical regulation

Improve the access of national regulatory and pharmaceutical control authorities to reliable information management systems, and to mechanisms for exchange of independent information on drug quality, safety and efficacy

Progress

Reliable and rapid information exchange, as well as efficient data management, are essential to the effective operation of drug regulatory authorities. WHO is successfully using several means to promote such exchange.

The International Conference of Drug Regulatory Authorities (ICDRA) is a good example of WHO's networking activities. Supported by WHO, ICDRA is the only international forum where representatives of national and regional drug regulatory authorities can exchange information and debate drug regulatory matters. Held biennially since 1980 — the most recent in April 1999, in Berlin, attracted over 250 participants — the conferences have often been the starting point for development of World Health Assembly resolutions on drug regulation.

WHO also supports regional technical cooperation and networking. Examples include ASEAN technical cooperation among countries (TCAC) and the African Drug Regulatory Authorities Network (AFDRAN). Both ASEAN and AFDRAN have been active in human resource development, harmonization issues, and development of regulatory and quality assurance tools in their regions.

The WHO Programme on International Drug Monitoring is another good example of information support for pharmaceutical regulation — but on a very specific issue. The Global Database on Adverse Drug Reactions is situated within the programme, in Uppsala, Sweden. The data collected is used to generate early warning signals of potential adverse drug reactions. More generally, the programme offers WHO Member States a tool for developing and reporting on activities concerned with adverse drug reaction monitoring. Additionally, the programme provides guidance and training courses on pharmacovigilance.⁶² These are carried out jointly with the Uppsala Monitoring Centre, and supported by the network of national centres in 56 countries.

WHO also provides information on regulatory matters to Member States through regular publications such as *WHO Drug Information* (quarterly journal), the *WHO Pharmaceuticals Newsletter* (monthly) and *WHO Drug Alerts*.

With so many drugs circulating on national and international markets, and in view of the growing quantity of pharmaceutical information, electronic information support has become a necessity. WHO has developed SIAMED, a model system for computer-assisted drug registration, to help countries harmonize regulatory systems and improve the drug registration efficiency of their drug regulatory authority. The system can record information and decisions, and helps create a global overview of drugs that have been authorized to date. When this system is in operation, drug regulatory decisions are much more likely to be made consistently and transparently. In Africa, SIAMED is being used to help harmonize registration procedures for generic essential drugs.

Challenges

The main challenge in terms of information support to drug regulatory authorities in developing authorities is how best to help them access the safety and efficacy information they most need. Currently, the best means would be for WHO to liaise with selected Collaborating Centres to establish a network of sources of readily accessible, summarized unbiased information, in at least three widely used languages. This would be an invaluable resource and reference to support the work of national drug regulatory authorities.

Many drug regulatory authorities also experience problems in maintaining a clear picture of the drugs circulating on their markets. Yet without a complete and comprehensive inventory of these drugs countries cannot hope to define, let alone operate, a rational drug policy. WHO's task, therefore, is to continue to introduce SIAMED where needed and to

keep up to date with information technology developments that could be of use and relevance to drug regulatory authorities.

Not only the proliferation of pharmaceutical information, but also the ever-growing number of new medicines calls for a WHO response. Various regulatory guidelines relating to safety are needed. Guidelines currently planned include *Safety Monitoring of New Drugs in the Immediate Postmarketing Phase*, *Guidelines on the Safe Use of Drugs in Pregnancy* and *Guidelines on the Safe Use of Drug Combinations*. However, many others will be needed.

With spontaneous postmarketing surveillance extending to most countries, there is an urgent need to react positively to early warning signals about adverse drug reactions. A standing committee needs to be set up with the necessary expertise to analyse reports made by the WHO Programme on International Drug Monitoring. This will require networking within WHO, with the WHO Regions, as well as with individual Member States.

Country progress indicators	1999 Status		2003 Target
	No./No. reporting	%	
Countries with computerized drug registration	n.a.*	n.a.	n.a.
Countries with adverse drug monitoring/registration system	(56/191)	29%	35%

*Data will be collected in 2000.

Expected outcomes for 2000-2003

8.1: Increased exchange of information on quality, safety and efficacy of medicines through provision of access to a multilingual database system containing information on quality, safety and efficacy of medicines, supported by WHO and WHO Collaborating Centres.

✓ WHO will continue to gather and disseminate information through its *WHO*

Drug Information periodical, *WHO Drug Alerts* and the *WHO Pharmaceuticals Newsletter* and expand activities relating to electronic distribution of drug quality and drug safety information.

8.2: Reliable information management systems created for national drug regulatory and control authorities through provision of computerized database systems and assistance to establish computer-assisted drug registration and licensing.

✓ Activities will include support to countries, as well as collaboration with the European Union, to develop standard drug registration systems for the European Agency for the Evaluation of Medicinal Products, and for European countries.

8.3: Access to international adverse drug reaction monitoring system extended to drug regulatory authorities of additional countries.

✓ WHO will guide national authorities in monitoring adverse drug reactions, and further develop its international programme on adverse drug reaction monitoring.

Component 9: Guidance for control and use of psychotropics and narcotics

Provide advice and guidance on psychotropic and narcotic substances in accordance with WHO's mandate under international treaties

Progress

Three international drug control treaties now provide the legal basis for the international prevention of drug abuse.

WHO undertakes medical and scientific review of psychotropic and narcotic substances before the United Nations Commission on Narcotic Drugs makes decisions on their control status. Since 1949, through its Expert Committee on Drug Dependence, WHO

has reviewed more than 400 substances. Between 1948 (when WHO was established) and 1999 the number of narcotic drugs under international control increased from 18 to 118, and the number of psychotropic substances from 32 to 111.

Concurrently, WHO is developing guidelines to improve the prescribing of controlled drugs, with the aim of preventing dependence and abuse.

Challenges

However, overly restrictive drug control regulations can hamper access to controlled medicines for therapeutic use. A balance must therefore be struck between medical and regulatory requirements. For example, overly strict control of psychotropics and narcotics can render them unobtainable during emergency situations. Emergency victims may then be deprived of adequate pain relief and sedation, particularly during or following emergency surgery. WHO's role is to balance the conflicting concerns and interests of the various stakeholders, be they regulators, manufacturers, prescribers, patients or law-enforcement authorities, when control regulations are being developed.

Country progress indicator	1999 Status		2003 Target
	No./No. reporting	%	
Number of substances reviewed and recommended for classification for international control	(2/3)*	66%	83%

*I.e. UNDCP accepted two out three of WHO's recommendations concerning substances for international control.

Expected outcomes for 2000-2003

9.1: Psychoactive substances assessed for international control through joint updating with United Nations of lists of controlled narcotic drugs and psychotropic substances.

✓ WHO will support the Expert Committee on Drug Dependence, and produce guidelines for WHO review of

dependence-producing psychoactive substances for international control, as well as for early warning systems for abuse. It will also collect information on new psychoactive substances.

9.2: Rational use of controlled medicines promoted to optimize the risk-benefit ratio.

✓ WHO will promote rational use of controlled medicines by finalizing and disseminating its document on *Achieving Balance in National Drug Control Policy: Guidelines for Self-assessment* and the *Model Guidelines for the International Provision of Controlled Medicines for Emergency Care*.

5.4 Rational use: Ensure therapeutically sound and cost-effective use of drugs by health professionals and consumers

Improving the use of drugs by health workers and the general public is crucial both to reducing morbidity and mortality from communicable and non-communicable diseases, and to containing drug expenditure.

Ideally, therapeutically sound and cost-effective use of drugs by health professionals and consumers is achieved at all levels of the health system, and in both the public and the private sectors. A sound rational drug use programme in any country has three elements:

- **Rational drug use strategy and monitoring** — advocating rational drug use, identifying and promoting successful strategies, and securing responsible drug promotion.
- **Rational drug use by health professionals** — working with countries to develop and update their treatment guidelines, national essential drugs lists and formularies, and supporting training programmes on rational drug use.

- **Rational drug use by consumers** — supporting the creation of effective systems of drug information, and empowering consumers to take responsible decisions regarding health care.

WHO supports governments and organizations in carrying out each of these elements.

Component 10: Rational drug use strategy and monitoring

Support countries in implementing and monitoring a national strategy to promote rational use of drugs by health professionals and consumers

This component contains all the elements necessary to design and monitor a successful, comprehensive programme to promote rational drug use: advocacy of the concept of rational drug use, measurement tools to monitor the situation, and identification of successful intervention strategies. It also includes activities that concern health workers and the public alike: responsible drug promotion; provision of information on the use of traditional medicine; and efforts to contain antimicrobial resistance. Efforts specifically targeted at health workers and consumers are detailed in Components 11 and 12.

Progress

Since the 1985 Nairobi Conference on the Rational Use of Drugs, the concept of rational drug use has been widely disseminated by WHO, and is now incorporated in all drug policies and essential drugs programmes. Standardized indicators for investigating drug use in health facilities, have been developed by WHO and these are now the global standard. Qualitative and quantitative methods to measure drug use in communities have also been developed and are used extensively.

In terms of rational drug use training, more than 500 health

professionals, mainly from developing countries, have been trained through an international course on promoting rational drug use, held once a year in Asia and once a year in Africa. The course materials were recently updated and are now available on the Internet and on CD-ROM.

Significant work has also been undertaken on actual rational drug use interventions. The first global International Conference on Improving the Use of Medicines, held in Thailand in 1997, reviewed all available evidence on the impact of rational drug use interventions in developing countries. This resulted in a global research agenda and an interagency research programme to research additional potential interventions in Asia, Africa and the Americas.

Challenges

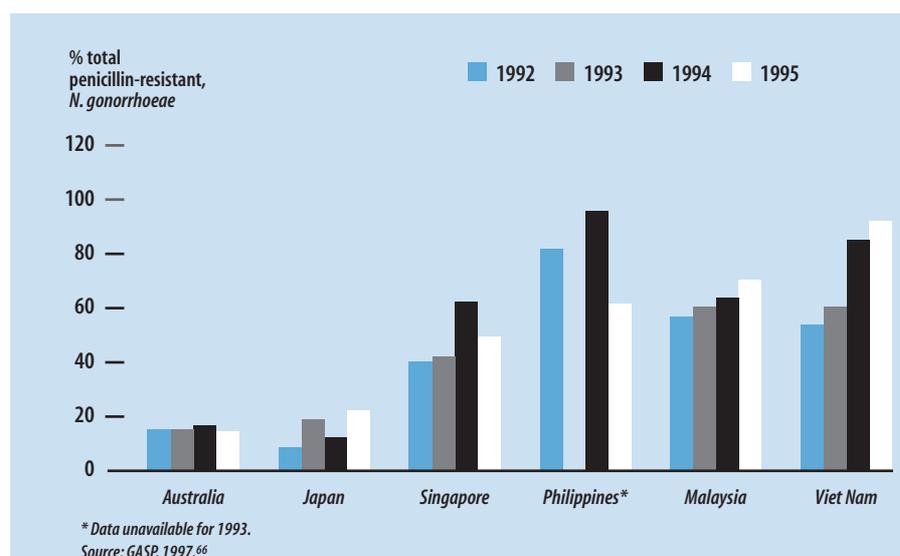
Despite all the efforts made, however, irrational prescribing, dispensing and consumption of medicines remains widespread, especially in the private sector. A hazard to health, such irrational use can also be a major source of impoverishment for poor populations. It is a particularly serious problem in developing countries where between 50 and 90% of drug purchases are made in the private sector.⁵

Drug promotion — effectively monitored in only 52 of 102 countries for which relevant data are available — is also of intense concern. Too often, medical representatives of pharmaceutical companies are the primary source of drug information for prescribers.⁶⁴ In many countries, continuing education in good prescribing is unavailable, and if it is available it is often dominated by promotional messages from pharmaceutical companies rather than independent sources. Most prescribers are not trained to evaluate such information critically.⁵⁰ This situation is not helped by the increasing blurring of the boundary between commercial and independent information.

"...the rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community."

Conference of Experts on the Rational Use of Drugs, Nairobi, 1985.⁶³

Figure 20: Antibiotic resistance varies greatly: within countries, between countries, over time and in rate of change



Traditional medicine is another area where much progress remains to be made in rational use. This is partly because the clinical efficacy of traditional remedies is as yet unproven. Consumers of traditional medicine products therefore risk wasting their money and even endangering their health.

Irrational use has particularly serious consequences if it involves antibiotics. Misuse of antibiotics is contributing to the worldwide increase in antimicrobial resistance that is now being observed for most common pathogens. Chloroquine resistance, for example, has been reported from 81 countries, and up to 98% of *Neisseria gonorrhoea* is resistant to penicillin.⁶⁵ The costs of antimicrobial resistance are very high. Second-line treatment for resistant meningitis or malaria may be 50–90 times as expensive as the original drugs, while one year's treatment of multidrug-resistant tuberculosis costs US\$ 8,000–12,000, compared with about US\$ 40 for first-line treatment. Containing antimicrobial resistance is crucial if drug costs are to be affordable and common diseases to remain treatable.

Country progress indicators	1999 Status		2003 Target
	No./No. reporting	%	
Countries with basic system (including legislation) for regulating pharmaceutical promotion	(58/142)	41%	50%
Countries with national drug information centre able to provide independent drug information to prescribers and/or dispensers	(57/136)	42%	50%

Expected outcomes for 2000–2003

10.1: Advocacy of rational drug use directed at national experts, government officials and international organizations, with a focus on the therapeutic and economic need for rational use of medicines.

- ✓ Work will include development of guidelines on how to develop a national programme to promote rational drug use, continuation of the annual WHO/International Network for Rational Use of Drugs training courses (in English) in Africa and Asia, and provision of these courses in French and Spanish in Africa and Latin America.

10.2: Identification and promotion of successful rational drug use strategies following operational research to identify cost-effective interventions to promote therapeutically sound and cost-effective drug use by health professionals and consumers, leading to production of global guidelines and training manuals to promote their application.

✓ WHO will support the global research agenda identified at the 1997 International Conference on Improving the Use of Medicines, but focus especially on expansion of activities into Latin America. Priority research topics will include rational use of malaria drugs and antibiotics, and drug use in hospital settings and in the private sector.

10.3: Responsible drug promotion encouraged through advocacy, promotion of adherence to the WHO Ethical Criteria for Medicinal Drug Promotion, and support for development of national guidelines for drug promotion and national measures to prevent and monitor perverse incentives for prescribers and dispensers.

✓ Work will include development of standardized tools to measure levels of drug promotion activities, continued expansion of a global database on the impact of promotional practices, and development of training materials for students, health workers and consumers on how to read and interpret promotional materials. Special efforts will be made to empower NGOs to monitor the impact of drug promotion.

10.4: Information support on use of traditional medicine with WHO acting as a "clearing house".

✓ WHO will develop its own database on traditional medicine and a WHO web-site on traditional medicine. It will also make a collective analysis of national surveys on use of traditional medicine.

10.5: Antimicrobial resistance contained through better use of resistance surveillance information, and by ensuring timely and appropriate measures on the part of governments, professional bodies, industry, consumers and other stakeholders.

✓ WHO will develop a global strategy to contain antimicrobial resistance. Standardized measuring tools and practical guidelines to contain antimicrobial resistance will be developed for hospitals and for national governments, as will training materials for medical and pharmacy students on combating antimicrobial resistance.

Component 11: Rational drug use by health professionals

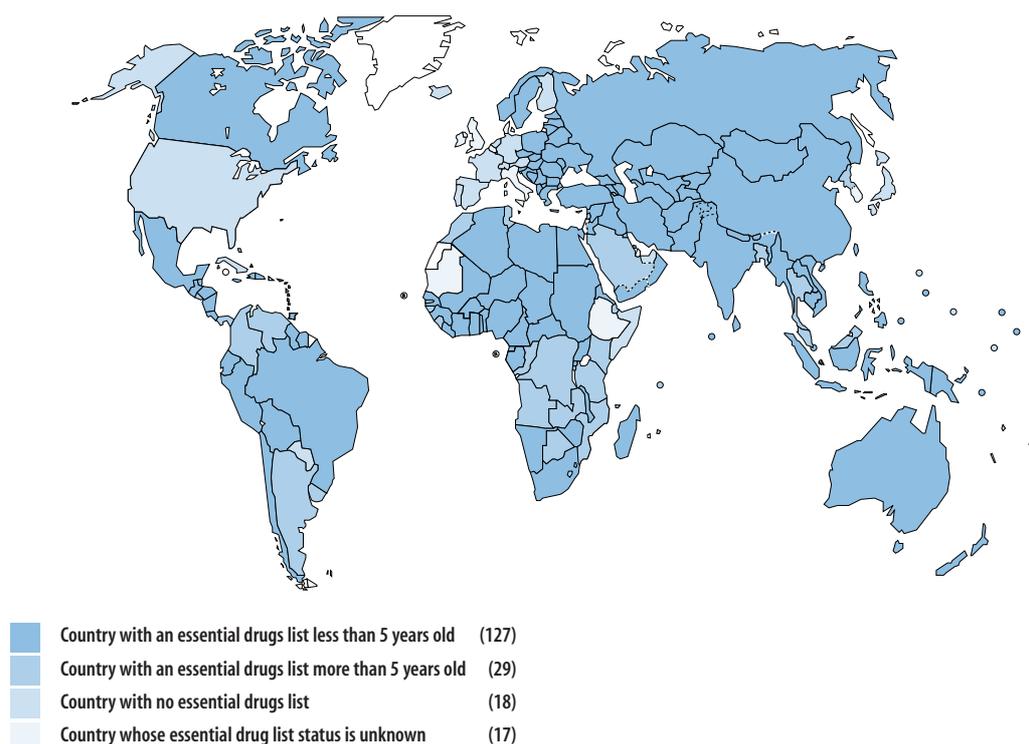
Develop national standard treatment guidelines, essential drugs lists, educational programmes and other effective mechanisms to promote rational drug use by health professionals

Progress

Extensive research has shown that standard treatment guidelines, essential drugs lists and formularies promote rational prescribing of drugs by prescribers.^{67, 68} Progress in developing each of these tools has been considerable. By the end of 1999, 156 countries had an essential drugs list, of which 127 were new or updated within the previous five years, with 94 divided according to level of care. In addition, 135 countries have developed national treatment guidelines, of which 112 have been updated in the last five years. There are now more than 100 national formularies, and by the end of 1999, 88 countries in all six WHO regions had introduced the essential drugs concept into curricula for medicine and pharmacy students.

The *WHO Model List of Essential Drugs*, and regional and international rational drug use courses, form a large part of ongoing WHO efforts to improve drug use by health professionals. The *WHO*

Figure 21: The essential drugs concept is becoming global — 156 countries have a national list of essential drugs



Model List of Essential Drugs is generally updated every two years by the WHO Expert Committee on the Use of Essential Drugs. The 11th *Model List* — describing just over 300 drugs — was revised in November 1999 and published in December 1999.⁶⁹ Training helps put the principles upon which the list is founded into practice. International training courses for university teachers in problem-based pharmacotherapy teaching are held every year in Europe, Africa and Latin America. Two randomized controlled trials with over ten centres in developed and developing countries have shown that the teaching methods transfer lasting skills in rational prescribing.⁷⁰

The WHO *Guide to Good Prescribing* has proved to be another invaluable tool. Translated into 18 languages and now available on at least six different web-sites, it continues to be one of the Organization's most successful publications. Primarily intended for undergraduate medical students who

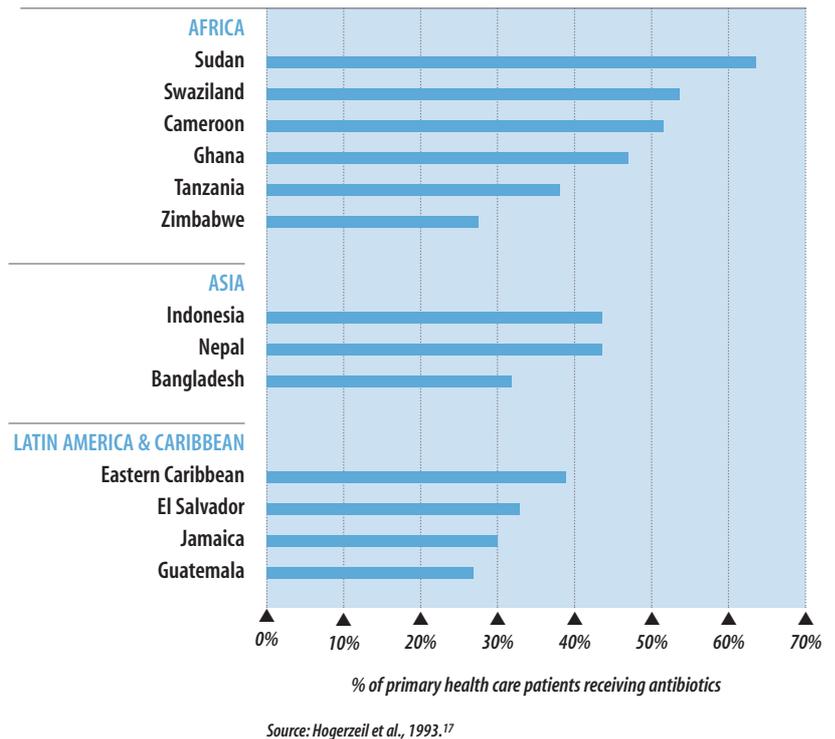
are about to enter the clinical phase of their studies, it provides step-by-step guidance on the process of rational prescribing.⁷⁰

The *WHO Monographs on Selected Medicinal Plants* are also doing much to promote rational drug use, but in the area of traditional medicine. Volume 1 was published in 1999 to guide Member States in the proper use of medicinal plants, to provide them with a model for the development of their own monographs, and to facilitate information exchange. A second volume was finalized in the same year. The *Monographs* were recently recommended by the European Commission to Member States as an authoritative reference.

Challenges

Despite the growing body of knowledge on rational use interventions, numerous studies have documented the continuing widespread irrational prescribing of drugs, including the

Figure 22: 27 to 63% of patients in primary health care centres receive antibiotics — perhaps twice what is clinically justified



overuse of antibiotics in primary health care. One review, for instance, found that 25 to 75% of antibiotic prescriptions in teaching hospitals in a large number of developed and developing countries were inappropriate in terms of either indication, selection, dosage or duration, or a combination of these.¹⁴

Popular and widespread in developing countries, injection therapy can also be an example of irrational drug use. One study showed that in some countries children have received 20 injections on average by the age of two.⁷¹ Of all injections given, 5% or less were for immunization and 95% for curative purposes; most of the latter were unnecessary. Furthermore, over 50% of all injections given were unsafe, with increased risk of transmission of bloodborne pathogens such as hepatitis B and C, and HIV.⁷²

The main challenge regarding rational drug use by prescribers is that knowledge alone is not enough to change behaviour, and that complex and multifaceted solutions are needed. Training programmes must therefore be complemented with other means, such as supervision, medical audit, regulatory measures, financial incentives and public education. For example, a conflict of interest occurs when prescribers also sell (and are therefore likely to overprescribe) drugs. A training course alone will not solve this problem since financial incentives may be a large part of the problem.

Many new drugs and second-line drugs are very expensive and accordingly unaffordable for many governments and consumers. This adds an economic dimension to the process of developing treatment guidelines and selecting essential drugs. Difficult decisions have to be made by health care managers concerning the recommended treatment for multidrug-resistant tuberculosis and malaria, for HIV/AIDS and for other infectious diseases, so that treatment is available to all who need it.

In developed countries drugs and therapeutics committees have been successful in promoting rational prescribing.⁷³ However, ongoing studies suggest that such committees are more difficult to run in developing countries. Medical and pharmacy training in most developing countries is still very traditional, with much emphasis on drug knowledge and very little on public health, prescribing skills, drug management or patient care.

For traditional medicine, the major problem concerning rational use relates to the fact that few plant species that provide medicinal herbs have been scientifically evaluated for their possible medical application. Safety and efficacy data are available for even fewer plants.

Country progress indicators	1999 Status		2003 Target
	No./No. reporting	%	
Countries with treatment guidelines updated within the last 5 years	(55/86)	64%	70%
Countries with national list of essential drugs updated within the last 5 years	(127/175)	73%	75%
Countries that include the essential drugs concept in basic curricula for medicine and/or pharmacy	(88/100)	88%	90%

Expected outcomes for 2000–2003

11.1: Development of national standard treatment guidelines and essential drugs lists *will be supported, as will development of model prescribing information, a model formulary and model list of essential drugs. Additionally, global guidance on how to develop such materials at country or institutional level will be provided.*

✓ WHO will develop a database containing all WHO standard treatment guidelines, review the development process of the *WHO Model List of Essential Drugs*, develop a *WHO Model Formulary*, and organize an annual training course on pharmaco-economic analysis to support the process of drug selection.

11.2: Support for problem-based and skill-based in-service training programmes *incorporating the essential drugs concept, learning objectives and problem-based learning methods.*

✓ Work will include: continuation of the annual international training courses on problem-based pharmacotherapy, but with expansion into French-speaking Africa; finalizing of the *Teacher's Guide to Good Prescribing*; and development of a *Guide to Good Pharmaceutical Care* to stimulate reform of pharmacy curricula in developing countries and countries in transition.

11.3: Drugs and therapeutics committees established and operating effectively *at the hospital and primary care levels, and efforts to strengthen the role of the pharmacist in the treatment team.*

✓ WHO will conduct operational research and pilot projects on the best means of promoting drugs and therapeutics committees, in order to develop and test practical guidelines for running such committees in developing countries.

11.4: International technical guidelines and standards on traditional medicine expanded, *particularly for medicinal plants and acupuncture.*

✓ WHO will publish the third volume of the *WHO Monographs on Selected Medicinal Plants*, WHO guidelines on methodology for research into and evaluation of traditional medicines, and a review of the clinical practice of acupuncture.

Component 12: Rational drug use by consumers

Establishing effective drug information systems to provide independent and unbiased drug information — including on traditional medicine — to the general public and to improve drug use by consumers

Progress

An extensive review by WHO of public education on drugs provided valuable insight into strategies used, and their strengths and weaknesses.⁷⁴ Its findings — widely disseminated in English, French, Spanish and Russian — identified how different players could contribute to more effective approaches to such education.

Additionally, the WHO guide to investigating drug use in the community has contributed to a growing body of knowledge on consumer understanding, attitudes and practices regarding drug use that is being used to strengthen future public education programmes.⁷⁵ An updated edition, based on users' experience, provided the core research methodology for a new WHO course on promoting rational drug use in the community.

In parallel, efforts have continued to support independent sources of drug information. These are essential to enable consumers and others to become fully informed about the drugs available in their countries. Experiences with independent drug bulletins are being shared with developing countries through networks such as the

International Society of Drug Bulletins, in which WHO participates.

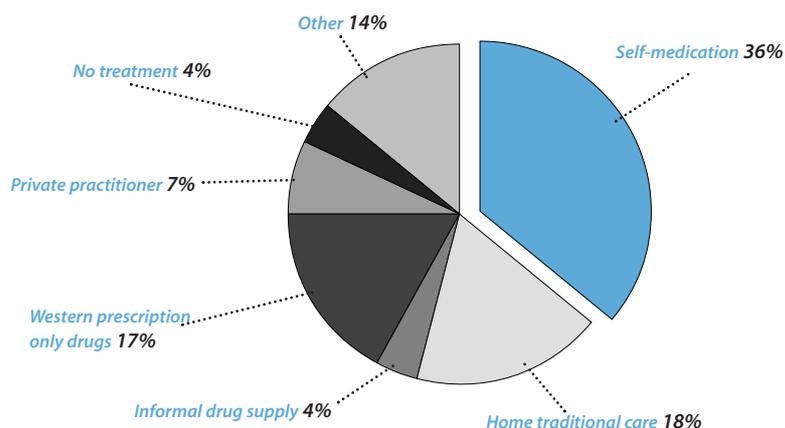
Drug information centres — increasingly well established in developed countries — are another important source of independent drug information. Their number in developing countries is now beginning to grow, often with WHO support. Some also function as WHO Collaborating Centres. A global network of centres, linked electronically, is contributing to shared information and experience.

Challenges

Improving consumers' drug use is equally or more important than improving the practice of health providers. Health professionals have a major influence on the overall use of medicines in a country. But it is the consumer, throughout the world, who takes the final decision about whether and where to seek health care, what medicine is actually taken, how much and when, and from what source. These decisions are influenced by knowledge, culture, drug promotion and personal finances. These factors operate even more strongly among communities whose primary source of modern medicines is not a trained health worker, but the local (often informal) drug seller. For example, in Sri Lanka, self-medication has been observed to be the primary source of care even in cases of acute illness (see Figure 23).

At the same time, independent drug information and public education about drug use have always been underserved and underfunded. The financial resources available for producing commercial, promotional information on drugs vastly outweigh those available for provision of comparative independent information, and for undertaking the assessments to make the necessary comparisons between therapies. Moreover, substantive community education interventions are complicated and costly. They are also problematic

Figure 23: In Sri Lanka, self-medication is a major source of care for acute illness, with high risk of treatment failure



Source: World Health Organization, 1997.³²

because their results are often incremental and difficult to measure. Funding and sustaining them can therefore be difficult. They also tend to be organized by NGOs. Since NGOs often work through informal networks, objective evaluation of interventions and publication of the results are not easily arranged.

In view of the lack of independent drug information and advice, rates of adherence to treatment are understandably low in both rich and poor countries. Worldwide, some 50% of people fail to take their medicines correctly. Part of the problem is that self-medication of “prescription” drugs is widespread. In observational studies of pharmacies in Asia, for example, about half of consumers bought only one or two tablets at a time, and 90% bought less than 10 tablets.^{15, 16} This was doubtless partly linked to what the consumers could afford, but lack of awareness about appropriate treatment regimens was probably another important factor.

Furthermore, since most drug purchases in developing countries take place in the private sector, where prescribing and selling functions are often combined, consumers are often sold medicines with a higher profit margin, even though these may be no more or less effective than cheaper medicines. Concurrently, profit motives and pressure to please the patient can lead to over-treatment of mild illnesses,

overuse of injections and misuse of anti-infective drugs. Money is wasted and risk of treatment failure is increased.

In short, the consumer is too often unaware of the potential problems surrounding prescribing and the price, quality and effectiveness of pharmaceuticals. Consumer empowerment to enable individuals to take responsible treatment decisions and better availability of independent drug information are sorely needed. Even though its resources are limited, WHO will try to support systems of effective, comparative and unbiased drug information. It will also rally and train core groups in developing countries to undertake and evaluate sustainable community education in the rational use of drugs.

Expected outcomes for 2000–2003

12.1: Effective systems of drug information *that are accessible to all health workers and the general public, through provision of training materials and regional and national training courses, and technical support to international networks of drug information centres.*

✓ WHO will continue to work with the International Society of Drug Bulletins, including on development of practical guidelines for establishing and running a drug information bulletin in a developing country.

12.2: Public education in rational drug use and consumer empowerment *through operational research, and development and provision of new training materials and courses.*

✓ Work will focus on developing an international training course on public education in rational drug use in developing countries, and establishing a network of national core groups undertaking interventions in public education in rational drug use. Standard research tools to assess drug use in communities will be updated. □

Country progress indicators	1999 Status		2003 Target
	No./No. reporting	%	
Countries with public education on rational drug use	n.a.*	n.a.	na.a
Countries with drug information centre/service accessible to consumers	n.a.*	n.a.	n.a.

**Data will be collected in 2000.*

Monitoring progress

6.1 Monitoring, evaluation and indicators

Monitoring and evaluation ^f help determine what has been achieved (or not achieved). Accordingly, they provide important information as to whether planning and strategies are satisfactory, or whether they need to be modified or even reworked.

In other words, monitoring and evaluation are crucial to successful implementation of national drug policies, programmes and strategies, and to achieving the pharmaceutical objectives of access to and rational use of quality drugs in particular.

Pharmaceutical indicators can greatly facilitate the tasks of monitoring and evaluation since they serve as simple, objective and standard measures for assessing and describing pharmaceutical sectors and activities. Moreover, they can be compared over a period of time and used to determine and assess pharmaceutical trends.

WHO has identified and grouped pharmaceutical indicators into three levels (see Figure 9 in Chapter 5) in order to make the tasks of monitoring and evaluation easier for ministries of health, aid agencies, NGOs and other stakeholders.^{77, 78}

WHO used level I indicators to collect information on pharmaceutical structure and process for the *World Drug Situation 2000 survey*, and to develop a database of pharmaceutical country

information. This set of indicators can also be used as a checklist by countries when they are monitoring the activities and components of their pharmaceutical sectors, or as a tool for rapid assessment of a pharmaceutical sector.

The level II indicators can be used to collect systematic data for describing the outcome and impact of national drug policies and national drug programmes.

6.2 Country progress indicators for the WHO Medicines Strategy

Indicators selected for monitoring implementation of the *WHO Medicines Strategy 2000–2003* reflect a pragmatic balance between those factors which are most *meaningful* for assessing country progress, and those which are most *measurable* in terms of reliability, time and cost. Table 6 lists the 26 country progress indicators — selected from among level I and level II indicators — corresponding to the target outcomes of the *WHO Medicines Strategy 2000–2003*.

WHO will use them to analyse country, regional and global pharmaceutical situations and progress. They are linked to WHO's key medicines strategies to be implemented during the two biennia (2000–2001 and 2002–2003). They also represent pharmaceutical components and strategies that are key to the delivery of effective health services.

"Monitoring is an integral part of day-to-day management in successful drug programs. Systematic monitoring, based on program objectives and linked to specific activities, is essential for improving program performance and achieving long-term program goals."

Management Sciences for Health/World Health Organization, 1997.⁵⁰

^f "Monitoring" refers to reviewing, on a continuous basis, the degree to which activities are completed and targets are being met. This allows corrective action to be taken during implementation. "Evaluation" refers to analysing progress towards meeting established objectives and goals. It provides feedback on whether plans have been met and the reasons for success or failure; it should also provide direction for future plans.³⁹

The country progress indicators provide information on structure, process and outcome:

Structure — Does a country have the necessary structures and mechanisms in place for improving its pharmaceutical sector including: a national drug policy document; a national drug policy implementation plan; a recently updated essential drugs list; computerized drug registration; national guidelines on drug donations; laws and regulations on herbal medicines; and inclusion of traditional medicine in the national drug policy and national health policy.

Process — Has a country established the necessary procedures for implementing pharmaceutical strategies including: generic substitution at private retail outlets; provision of public health insurance that reimburses drug costs; use of an essential drugs list and competitive tender for public procurement of drugs; participation in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce; basic drug regulation and quality assurance.

Outcome — Has a country established the necessary procedures for implementing pharmaceutical strategies including: improving the availability of essential drugs and increasing the percentage of the population with access to essential drugs.

In brief, these country progress indicators will help assess overall progress in the pharmaceutical sector that has resulted from the combined efforts of government, local NGOs, the local private sector, WHO and others. They have already been used to derive and identify a complementary set of indicators for the *WHO Programme Budget 2002–2003*.⁷⁶ This second set of indicators will be used to monitor and evaluate WHO performance — in Regional Offices, at WHO Headquarters

and within individual countries — in contributing to country progress in essential drugs and medicines work.

6.3 Indicator values for the WHO Medicines Strategy

The indicator values in Table 6 reflect the areas of work of countries and all sectors working to achieve the objectives of pharmaceutical policies and programmes. They do not give the whole picture, but nevertheless provide important information for reviewing the performance of governments and others, and in assessing improvements (or otherwise) within a country's pharmaceutical sector.

Most of the 26 country progress indicators use data obtained from the *World Drug Situation 1999* survey and the WHO database of pharmaceutical country information as their baseline. Target values for 2003 have been set as expected progress for each target outcome. These values will be used as a reference point when identifying country pharmaceutical strategies and activities to be promoted and supported.

Most of the country progress indicator values simply indicate whether a country has certain structures and mechanisms in place (yes/no), and has established certain procedures (yes/no). For some country progress indicators, data have been grouped and classified by range of percentage (for example, percentage of population with access to essential drugs) and according to date of updating (for example, a national drug policy updated within the last 10 years).

Several variables have been grouped together as the minimum criteria necessary for ensuring implementation of a particular component of a pharmaceutical strategy or plan. These composite indicators based on several variables are clearly more robust than indicators based on a single variable. The indicators with composite variables are:

Table 6 Country progress indicators for components of WHO Medicines Strategy 2000–2003

▼ Components and Numbered Country Progress Indicators	▼ Indicator type	1999 status		▼ 2003 target
		▼ No./No. reporting	▼ %	
Component 1: Implementation and monitoring of national drug policies				
1. Countries with an official national drug policy document — new or updated within the last 10 years	S	66/151	44%	55%
2. Countries with a national drug policy implementation plan — new or updated within the last 5 years	S	39/107	36%	43%
Component 2: Health system development supported by essential drugs policies and programmes				
3. Countries with a national drug policy included in the national health plan	S	n.a.*	n.a.	n.a.
4. Countries with a national policy on traditional medicine	S	31/46	n.a.	n.a.
Component 3: Access strategy and monitoring for essential drugs				
5. Countries where less than 50% of the population has access to essential drugs	O	30/187	16%	14%
6. % of key drugs available in health facilities (measured in countries with comprehensive programmes)	O	n.a.*	n.a.	80%
Component 4: Financing mechanisms and affordability of essential drugs				
7. Countries with public drug expenditure per capita of less than US\$2.00	P	39/94	41%	35%
8. Countries with generic substitution allowed in private pharmacies	P	83/134	61%	75%
9. Countries with public health insurance covering drug costs	S + P	71/111	64%	70%
Component 5: National and local public sector drug supply systems and supply capacity				
10. Countries with public sector procurement based on a national list of essential drugs	P	70/132	53%	60%
11. Countries with at least 75% of public sector procurement carried out by competitive tender	P	79/88	90%	95%
12. Countries implementing the 1999 interagency guidelines on drug donations	P	n.a.*	n.a.	80%
Component 6: Norms, standards and guidance for pharmaceuticals				
13. Countries participating in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce	P	142/191	74%	80%
Component 7: Drug regulation and quality assurance systems				
14. Countries operating basic drug regulatory system (key legislation and drug regulatory authority functions)	S + P	92/135	68%	75%
15. Countries with basic quality assurance procedures (good manufacturing practices and sampling to test drugs)	S + P	87/139	62%	75%
16. Countries with laws and regulations covering herbal medicines	S	48/60	n.a.	n.a.
Component 8: Information support for pharmaceutical regulation				
17. Countries with computerized drug registration	S	n.a.*	n.a.	n.a.
18. Countries with adverse drug monitoring/registration system	S	56/191	29%	35%
Component 9: Guidance for control and use of psychotropics and narcotics				
19. Number of substances reviewed and recommended for classification for international control	n.a.	2/3**	66%	83%
Component 10: Rational drug use strategy and monitoring				
20. Countries with basic system (including legislation) for regulating pharmaceutical promotion	S + P	58/142	41%	50%
21. Countries with national drug information centre able to provide independent drug information to prescribers and/or dispensers	S + P	57/136	42%	50%
Component 11: Rational drug use by health professionals				
22. Countries with treatment guidelines updated within the last 5 years	S	55/86	64%	70%
23. Countries with national list of essential drugs updated within the last 5 years	S	127/175	73%	75%
24. Countries that include the concept of essential drugs in basic curricula for medicine and/or pharmacy	P	88/100	88%	90%
Component 12: Rational drug use by consumers				
25. Countries with public education on rational drug use	P	n.a.*	n.a.	n.a.
26. Countries with drug information centre/service accessible to consumers	S + P	n.a.*	n.a.	n.a.

Key

- S country progress indicator that provides information on structure
- P country progress indicator that provides information on process
- O country progress indicator that provides information on outcome
- S + P composite country progress indicator that provides information on both structure and process
- * data will be collected in 2000 and the 2003 target set
- ** i.e. UNDCP accepted two out of three of WHO's recommendations concerning substances for international control

"Evaluation is different from monitoring. The word is derived from value... Evaluation involves taking a step back to look at the program as a whole, to assess progress toward achieving goals by fulfilling objectives."

Management Sciences for Health/World Health Organization, 1997.³⁰

Country progress indicator no. 9 Countries with public health insurance covering drug costs meaning that: not only does a public health insurance system exist but that it reimburses patients' drug costs.

Country progress indicator no. 14 Countries operating basic drug regulatory system including: a law on drug registration; a law on drug manufacturing or importation of drugs; inspection of either retail outlets or manufacturers; drug registration by the drug regulatory authority; a drug registration list.

Country progress indicator no. 15 Countries with basic quality assurance procedures including: request for proof of good manufacturing practices when an application for drug registration is made; either sampling of drugs for public procurement or sampling of drugs at retail outlets; drug quality testing.

Country progress indicator no. 20 Countries with basic system (including legislation) for regulating pharmaceutical promotion including: law on drug promotion which was established less than 10 years ago; regulation of drug promotion by the government or co-regulation of drug promotion by the government and the pharmaceutical industry; regulation of drug advertisements.

Country progress indicator no. 21 Countries with drug information centre able to provide independent information to prescribers and/or dispensers meaning that: not only does such a centre exist but that it actively provides

information as requested by prescribers and/or dispensers.

Country progress indicator no. 26 Countries with drug information/service accessible to consumers meaning that: not only does such a centre exist but that it actively provides information as requested by consumers.

During implementation of the *Medicines Strategy 2000–2003*, the criteria for composite indicators will be refined further, and additional composite indicators identified.

6.4 Improving the monitoring/evaluation process and tools

The process of monitoring and evaluating country and global pharmaceutical situations continues to evolve and to be improved. Determining which indicators and how many indicators should be used is a challenging and very complex process, and engenders much debate. Determining which indicators are the most useful depends on continuous field testing and continuous development of methodology for collecting and processing information.

The culture of monitoring among countries and stakeholders must also be promoted. Reliable, relevant data and information needs to be collected and the results reported to policy-makers and other players responsible for decisions relating to health systems planning, national drug policy implementation and allocation of technical, human and financial resources. □

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