



# WHO Medicines Strategy: 2000–2003



**S**erious illness is a major reason why poor populations remain trapped in poverty. Where public health services and insurance are inadequate, health care and medicines costs push households further into debt and dependency. 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.

Essential drugs and medicines are one of the vital tools needed to improve and maintain health. The WHO Medicines Strategy 2000-2003 is now serving as the basis for coordinated action to bring medicines where they are most urgently needed. The strategy was developed with a country perspective, in broad consultation with over 60 countries, and with the WHO "global medicines family". This family includes not only WHO programmes, but also WHO Expert Committees and Panels, WHO Collaborating Centres, international agencies and academic institutions.

## Essential drugs have a profound impact on:

- ... **health** — Effective drug treatment now exists for most leading infectious diseases, including acute respiratory infections, HIV/AIDS, malaria, tuberculosis, and diarrhoeal diseases, as well as leading noncommunicable diseases such as ischaemic heart diseases and cancer.
- ... **cost-effectiveness of health expenditures** — In many developing countries, medicines represent the largest household health expenditure, and in most countries public pharmaceutical expenditure is second only to spending on staff costs. By focusing pharmaceutical expenditure on essential drugs, the cost-effectiveness of government and out-of-pocket drug expenditure can be enhanced and health impact heightened.
- ... **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 and donors in a country's health system is increased, and provision of resources encouraged.

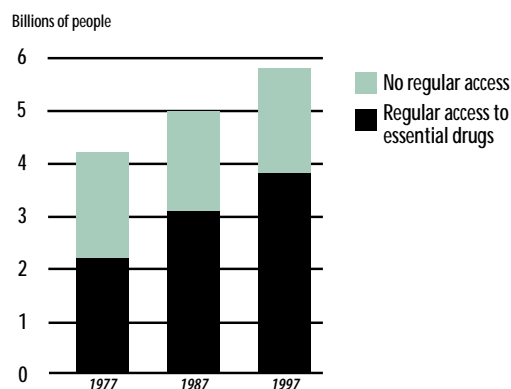
The strategy's starting point was WHO's mission in medicines:

**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.**

## Major progress, yet huge inequities remain

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.

The estimated number of people with access to essential drugs has doubled in only 20 years – but one-third of the world's population still lacks such access



Source: World Health Organization, 1998. *Progress of WHO Member States in Developing National Drug Policies and in Revising Essential Drug Lists.*



Yet at the beginning of the 21st century inequities in terms of access to essential drugs, quality and rational use remain widespread 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. The reasons often include inadequate financing and poor health care delivery. And even if drugs are available, weak drug regulation may mean that they are substandard or counterfeit. Irrational use — for example, high rates of antibiotic prescription, very short dispensing times and incorrect drug use by patients — is of great public health concern too.

## Framework for action

The WHO Medicines Strategy 2000–2003 addresses four objectives: policy, access, quality and safety, and rational use. Among the 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. Detailed planning elements of this Strategy appear in Table 1.

### Objective 1. Policy

*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 be consistent with broader health system objectives, and its implementation should support those objectives. 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, and integration of essential drugs policies and programmes with health systems development.*



### Objective 3. Quality and safety

*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, but enforcement of regulatory standards remains a challenge for every country. WHO's work under the quality and safety objective has four components: norms, standards and guidance for pharmaceuticals; drug regulation and quality assurance systems; information support for pharmaceutical regulation; and guidance for control and use of psychotropics and narcotics.*

### Objective 2. Access

*Access to essential drugs is a key priority for WHO. Four enabling factors need to be firmly in place to increase and ensure sustainable access:*

- ➔ *rational selection based on a national essential drugs list and treatment guidelines*
- ➔ *affordable prices for governments, health care providers and consumers*
- ➔ *sustainable financing through equitable funding mechanisms such as government revenues or social health insurance*
- ➔ *reliable supply systems incorporating a mix of public and private supply services.*

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. geographically accessible), they are readily available in health facilities (i.e. physically available), and affordable (i.e. financially available).

### Objective 4. Rational Use

*The essential drugs concept is now applied worldwide. A growing number of countries, both developed and developing, have used it to help them improve drug use by prescribers, dispensers and the general public, and to contain drug expenditure.*

*The challenge now 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 is working to support three components: rational drug use strategy and monitoring; rational drug use by health professionals; and rational drug use by consumers.*

Table 1: WHO Medicines Strategy 2000–2003 — objectives, components and expected outcomes

Objectives	Components	Expected outcomes
<b>Policy:</b> Ensure commitment of all stakeholders to national drug policies, to coordinated implementation, and to monitoring policy impact	1. <b>Implementation and monitoring of national drug policies</b> 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. <b>Health system development supported by essential drugs policies and programmes</b> 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
	3. <b>Access strategy and monitoring for essential drugs</b> 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. <b>Financing mechanisms and affordability of essential drugs</b> 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. <b>National and local public sector drug supply systems and supply capacity</b> 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
<b>Quality and Safety:</b> Ensure the quality, safety and efficacy of all medicines by strengthening and putting into practice regulatory and quality assurance standards	6. <b>Norms, standards and guidance for pharmaceuticals</b> 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. <b>Drug regulation and quality assurance systems</b> 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. <b>Information support for pharmaceutical regulation</b> 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. <b>Guidance for control and use of psychotropics and narcotics</b> 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
	10. <b>Rational drug use strategy and monitoring</b> 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
<b>Rational use:</b> Ensure therapeutically sound and cost-effective use of drugs by health professionals and consumers	11. <b>Rational drug use by health professionals</b> 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. <b>Rational drug use by consumers</b> 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



Table 2: 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	▼ %	
<b>Component 1: Implementation and monitoring of national drug policies</b>				
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%
<b>Component 2: Health system development supported by essential drugs policies and programmes</b>				
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.
<b>Component 3: Access strategy and monitoring for essential drugs</b>				
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%
<b>Component 4: Financing mechanisms and affordability of essential drugs</b>				
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%
<b>Component 5: National and local public sector drug supply systems and supply capacity</b>				
10. Countries with public sector procurement based on a national list of essential drugs				
11. Countries with at least 75% of public sector procurement carried out by competitive tender	P	70/132	53%	60%
12. Countries implementing the 1999 interagency guidelines on drug donations	P P	79/88 n.a.*	90% n.a.	95% 80%
<b>Component 6: Norms, standards and guidance for pharmaceuticals</b>				
13. Countries participating in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce	P	142/191	74%	80%
<b>Component 7: Drug regulation and quality assurance systems</b>				
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.
<b>Component 8: Information support for pharmaceutical regulation</b>				
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%
<b>Component 9: Guidance for control and use of psychotropics and narcotics</b>				
19. Number of substances reviewed and recommended for classification for international control	n.a.	2/3**	66%	83%
<b>Component 10: Rational drug use strategy and monitoring</b>				
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%
<b>Component 11: Rational drug use by health professionals</b>				
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%
<b>Component 12: Rational drug use by consumers</b>				
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

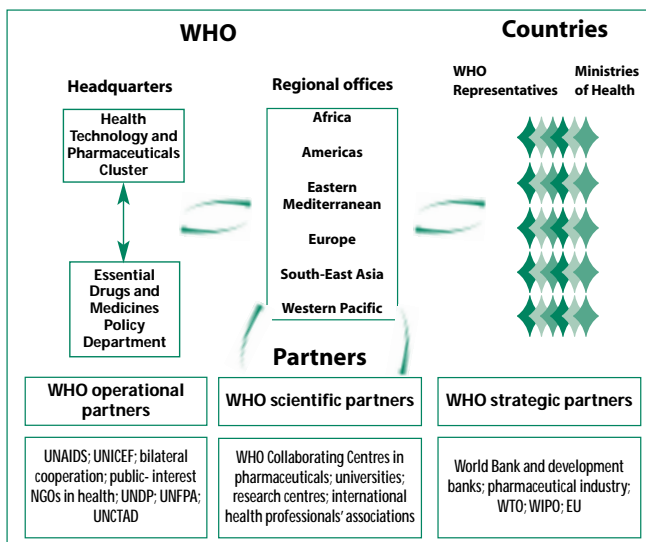
\* data will be collected in 2000 and the 2003 target set

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

## Implementing the strategy with countries

WHO has always had a strong country presence in medicines. It works with countries through the coordinated efforts of its WHO Representative offices in countries, its pharmaceutical advisers in each regional office, and its regional focal points located within the Essential Drugs and Medicines Policy Department at Headquarters. This diverse concentration of expertise is a valuable resource for countries who are striving hard to develop their pharmaceutical sector. Additionally, many donors and development agencies are keen to use this expertise when providing their own country support.

WHO's interaction with countries and partners is central to its activities



At the same time, country work is a vital resource for WHO itself. Only by undertaking such work can the Organization develop its evidence and knowledge base, and maintain its position as the world's leading authority on public health issues.

However, the unfinished agenda and new challenges of the pharmaceutical sector, together with the demands imposed by this new strategy, mean that the quality and impacts of WHO's country work must be stepped up. Over the next four years, WHO will therefore:

- ➔ expand its network of pharmaceutical advisors in priority countries, especially in Africa and Asia
- ➔ increase support to regional and subregional pharmaceutical networks
- ➔ further integrate planning, implementation and information-sharing among WHO country, regional and headquarters staff working in pharmaceuticals

- ➔ expand direct country support relationships with key development partners such as the World Bank, bilateral donors and the Rockefeller Foundation.

## Monitoring and evaluation to improve performance

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.

The *WHO Medicines Strategy: 2000-2003* incorporates 26 country progress indicators (see Table 2,) which will be used to monitor and evaluate country, regional and global pharmaceutical situations and progress. The indicators selected 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.

Monitoring and evaluation results will contribute to the ongoing evolution of WHO work in medicines policy, and will also be reported to responsible policy-makers and other players responsible for decisions relating to health systems planning, national drug policy implementation, and allocation of technical and financial resources.

The *Medicines Strategy* provides the pharmaceutical foundation for improved health outcomes and stronger health systems – linking across WHO clusters and areas of work

