



WHO Medicines Strategy
Countries at the core

2004—2007



World Health Organization

Expanding access to essential medicines

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

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

Most of these interventions depend on essential medicines. Yet today, almost 2 billion people – one-third of the global population – do not have regular access to essential medicines (Figure 1). In some of the lowest-income countries in Africa and Asia, more than half of the population have no regular access to essential medicines.

In developing countries, where an estimated 42 million people are infected with HIV/AIDS, life-

saving antiretroviral medicines (ARVs) are available to only 300 000 of the 5–6 million people currently in need of treatment – a crisis that WHO has declared to be a global health emergency.

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

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

Challenges in expanding access to essential medicines

Essential medicines save lives,

reduce suffering and improve health, but only if they are of good quality and safe, available, affordable, and properly used. However, in many countries today not all these conditions are being met. If access to essential medicines is to be expanded, each of the problems outlined below must be tackled.

- **Unaffordable medicine prices** – especially for newer products such as ARVs and artesimin-based antimalarial drugs – limit access to medicines in resource-poor settings. In developing countries today, because of high prices, medicines account for 25%–70% of overall health care expenditure, compared to less than 15% in most high-income countries.
- **Irrational use of medicines** is a major problem worldwide. It is estimated that half of all medicines are inappropriately prescribed, dispensed or sold and that half of all patients fail to take their medicine properly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards.

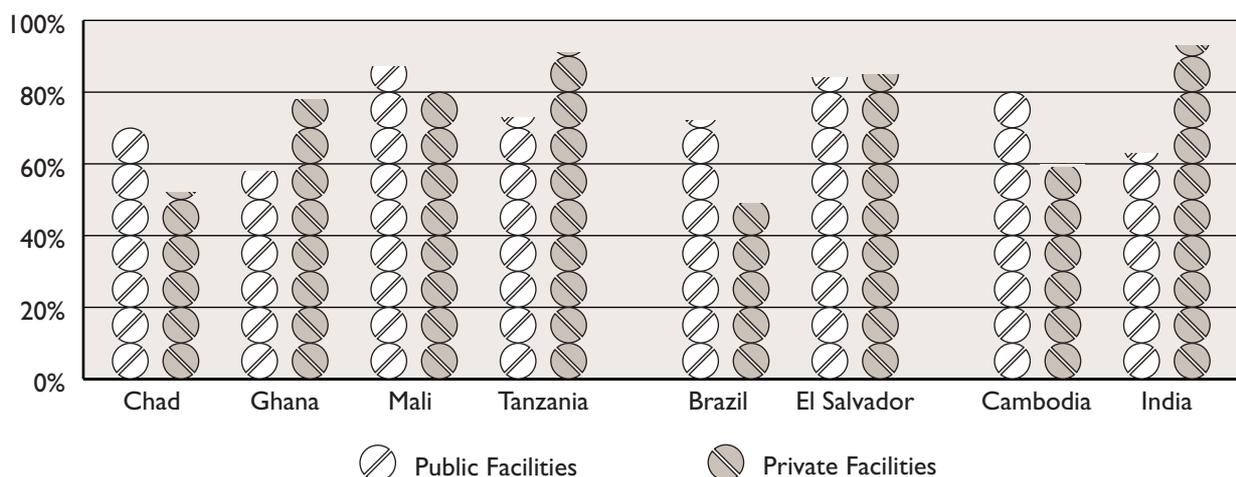


Figure 1:
On average, only 70% of essential medicines are available – this is not good enough, and often the situation is far worse

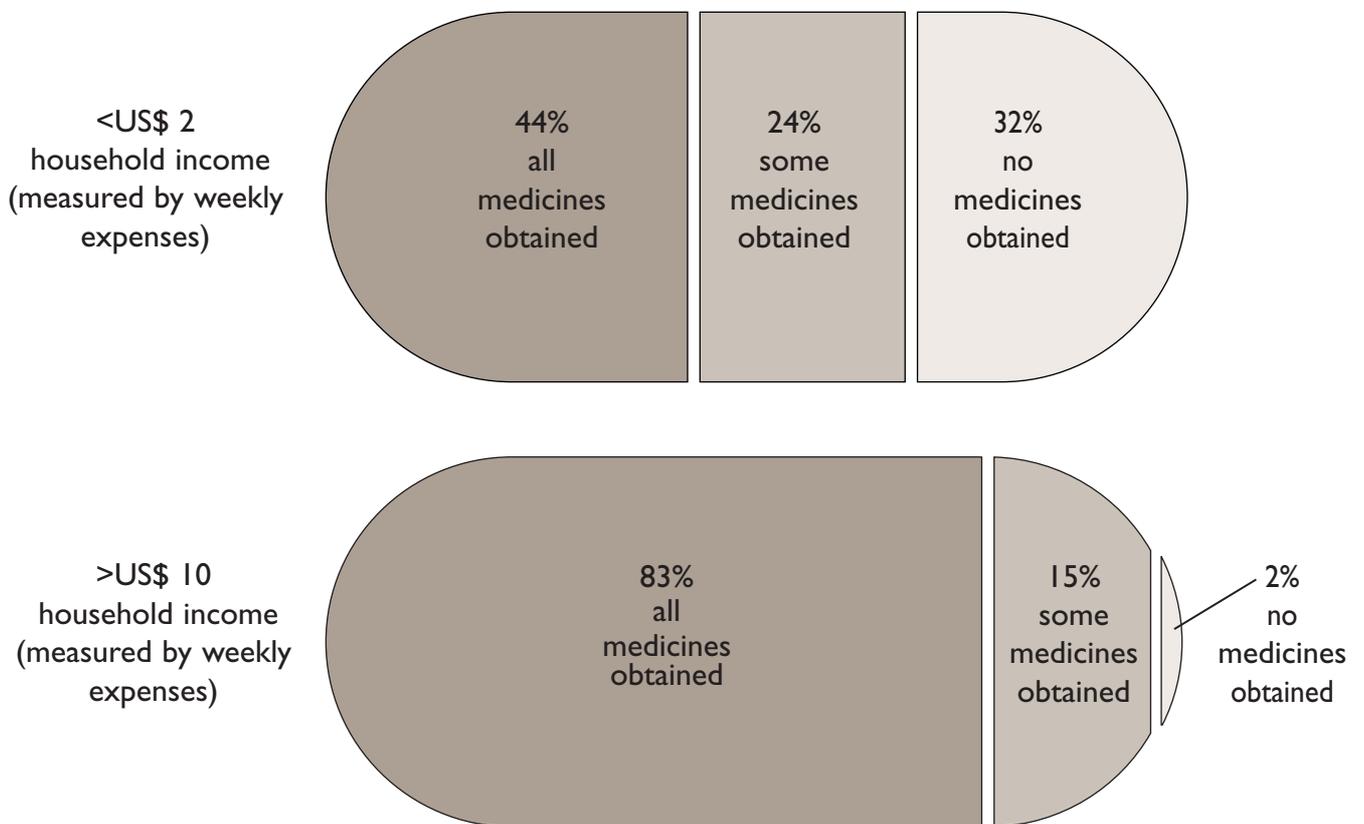


Figure 2:

In some countries, one-third of people in poor households do not receive any of the medicines they need to treat acute illnesses

- Elsewhere, **unfair health financing mechanisms** which leave households responsible for the cost of the essential medicines they need, place the heaviest burden on the poor and sick who are least able to pay. In some countries, one-third of people living in poor households receive none of the essential medicines they need for acute illness (Figure 2).
- The persistence of **unreliable medicines supply systems** is one of the main reasons why many countries are unable to ensure a regular, sustainable supply of essential medicines. Failures at any point in the supply system can lead to shortages of medicines and avoidable suffering and deaths. In addition, inefficient procurement systems

have been found to pay up to twice the global market price for essential medicines and lead to unnecessary waste of resources.

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

In addition, the sale of counterfeit and substandard medicines remains a global concern. Unfortunately, many countries lack the safety monitoring capacity that would help them to identify counterfeit medicines or medicines of poor quality (Figure 3).

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



Figure 3:
The WHO Programme for International Drug Monitoring provides a forum for WHO Member States to collaborate in monitoring drug safety – but coverage remains to be significantly extended in Africa

WHO Medicines Strategy: a coherent response

With the launch of the *WHO Medicines Strategy 2004–2007: Countries at the Core*, WHO is continuing to respond to the medicines challenges of the 21st century through a wide range of initiatives. The strategy provides a framework for WHO, countries and partners to maximize pharmaceutical potential to reduce excess mortality and morbidity, especially among impoverished populations (Figure 4).

The new strategy is based on four key objectives: improving access to essential medicines; and strengthening national medicines policy, the quality and safety of medicines, and their rational use.

For the period 2004–2007, the focus is on expanding access to quality essential medicines – particularly scaling up access to ARVs to meet the WHO target of ensuring that 3 million people in developing countries have access to treatment for HIV/AIDS by 2005. Emphasis is also being placed on efforts to improve medicines financing, supply systems

and quality assurance. The detailed planning of this strategy is outlined in the table on pages 8–11. WHO's strategic priorities for medicines over the next four years include:

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

- Continued support to ensure that all countries develop a national medicines policy and that these are implemented, monitored and regularly updated, in line with broader health and development objectives.
- Supporting countries in their efforts to use public health

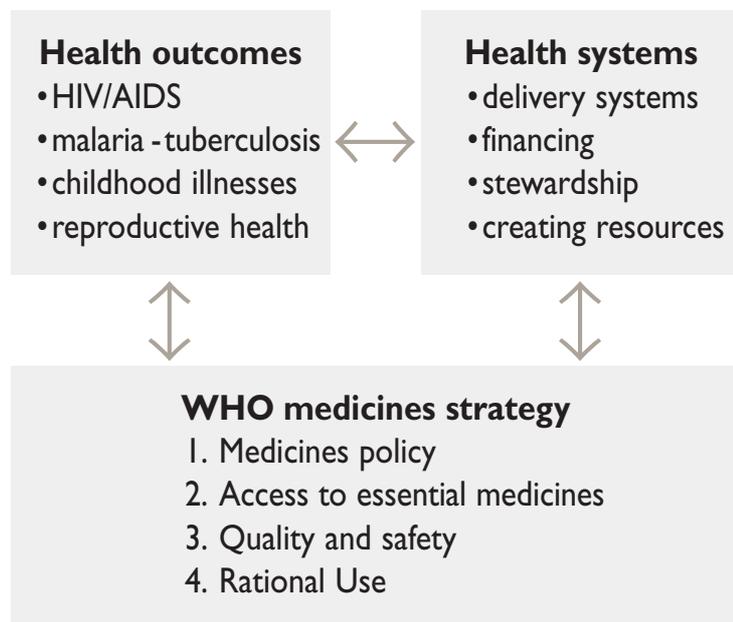


Figure 4:
The WHO Medicines Strategy provides the pharmaceutical foundation for improved health outcomes and stronger health systems

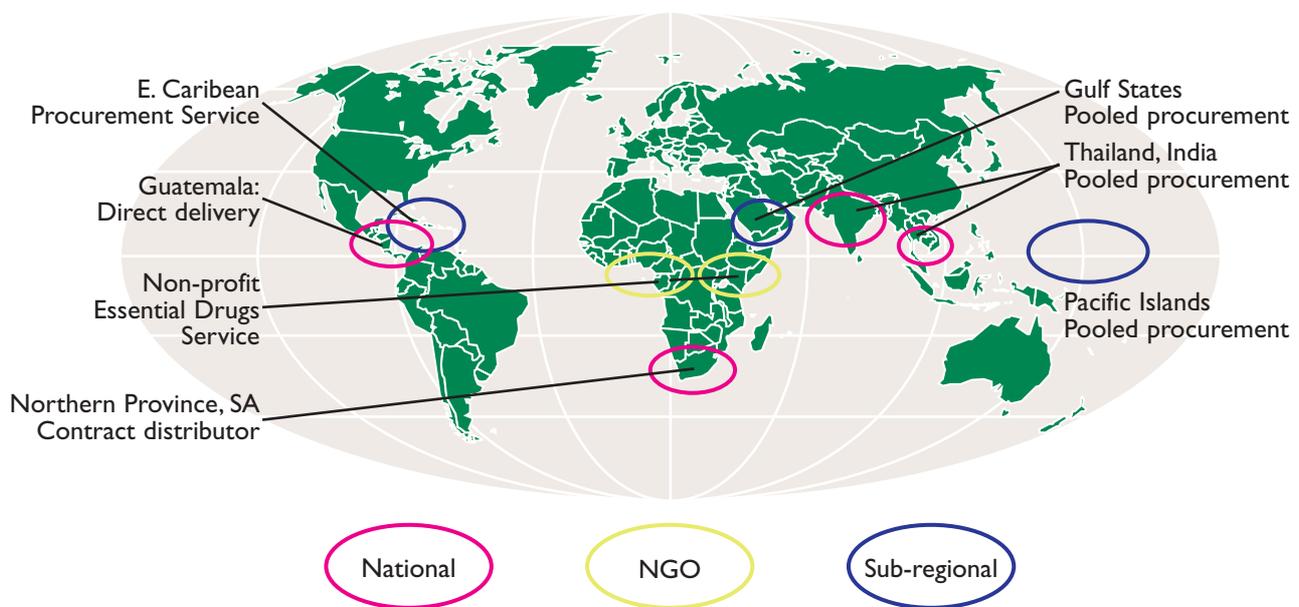


Figure 5:
Reliable health and supply systems – effective medicines distribution channels have been established in every region and can provide lessons to help guide future efforts to scale up access to essential medicines

safeguards in international, regional and bilateral trade agreements, to improve access to priority medicines.

- Promoting and monitoring access to essential medicines as a fundamental human right.
- Development of an agenda of priority needs for public investment in medicines R&D, especially for neglected diseases.
- Promotion of ethical practices and development and use of anti-corruption measures in the pharmaceutical sector.
- Implementation of WHO's strategy for traditional medicine to ensure affordable access, protection of intellectual property rights, and guidance on safety, efficacy and quality assurance.

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

- Expanding access to quality essential medicines for priority diseases, especially HIV/AIDS, through development and use of standard treatment guidelines, prequalification of new

medicines, market intelligence on prices, and guidance on issues such as patents.

- Strengthening medicines supply systems through country assessments, promotion of 'best practices', and medicines supply management training (Figure 5).
- Promoting establishment of sustainable ways of financing medicines expenditure through health insurance schemes.

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

- Ensuring the quality, safety and efficacy of priority medicines, especially for HIV/AIDS, tuberculosis and malaria, by establishing standards and training tools.
- Support to national drug regulatory authorities through assessment, information exchange and capacity building.
- Support to ensure that countries are able to carry out post-marketing safety monitoring of new medicines such as ARVs

and antimalarials which are scheduled for wide-scale use among populations.

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

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

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Tracking progress

Regular monitoring and evaluation underpins every aspect of WHO's work in essential medicines. A package of core indicators has been developed to assess the pharmaceutical situation at country level. Every four years, WHO conducts a global survey to assess structures and processes in the pharmaceutical system at the national level. Data from this are used to identify priority areas of work, plan the *WHO Medicines Strategy*, and set targets. The *WHO's Medicines Strategy 2004–2007* includes 47 country progress indicators (see table on pages 8–11) which will be used to monitor progress and determine whether the strategic targets have been met.

Surveys involving central warehouses, public health facilities,

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

Operational capacity

WHO is well placed to fulfill its mission in essential medicines – working in partnership with Member States and through effective coordination between WHO headquarters, regional offices, and country offices (Figure 6). At the

regional level, essential medicines teams coordinate the work of WHO throughout the region. In over 30 countries, medicines advisers play a key support role – liaising with Ministries of Health and helping coordinate the work of a wide range of public and private sector partners.

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

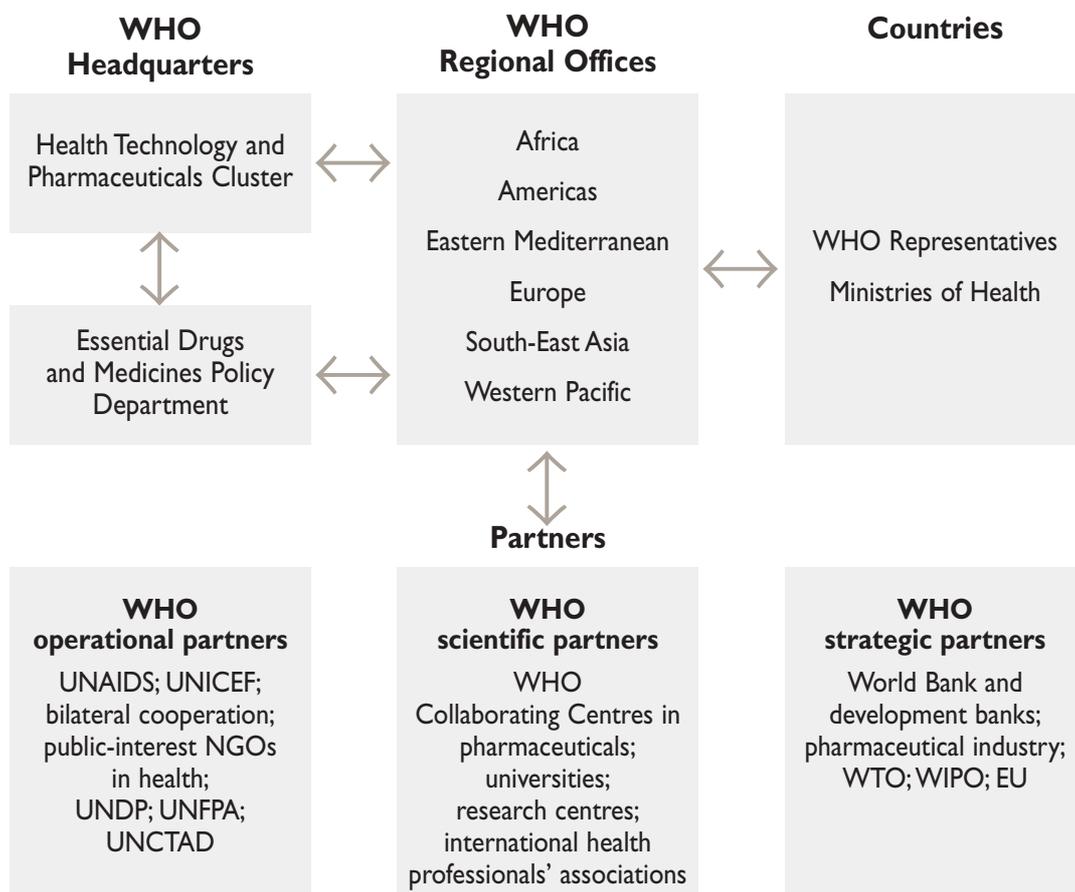


Figure 6:

WHO's interaction with countries and partners is central to development of its evidence and knowledge base

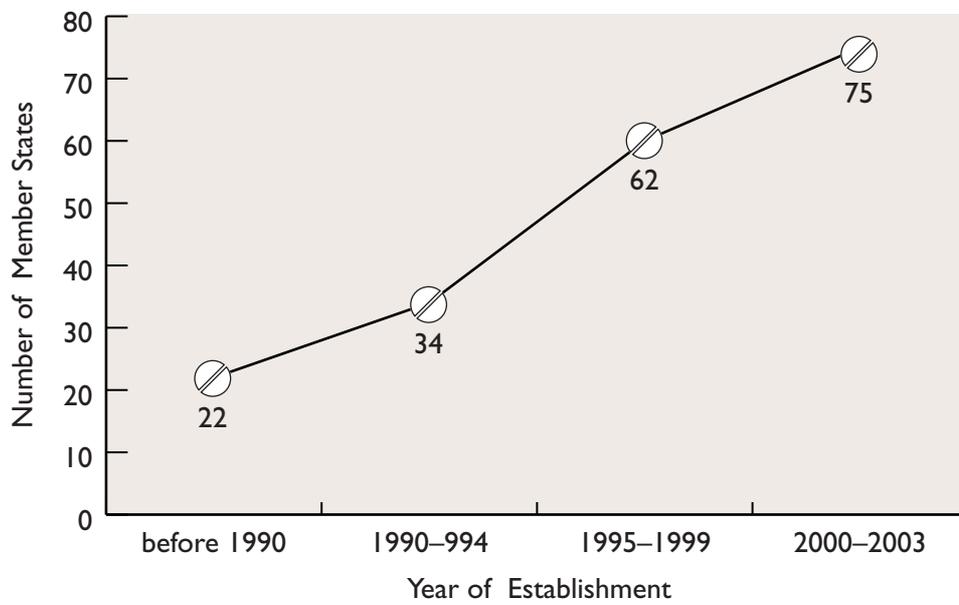


Figure 7:
The number of countries that regulate herbal medicines is increasing steadily (see back cover)

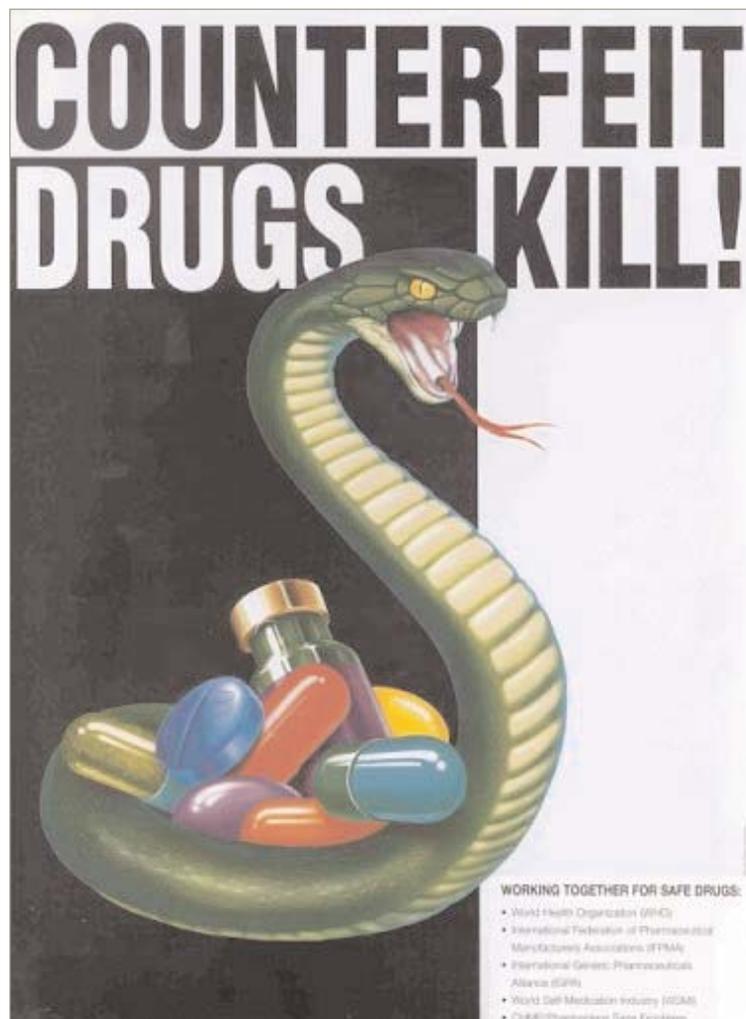


Figure 8:
Poster used in campaign to raise awareness of the dangers of counterfeit medicines (see back cover)

OBJECTIVES, COMPONENTS & EXPECTED OUTCOMES

Policy: Commitment among all stakeholders to medicines policies based on the essential medicines concept, and to coordinated implementation, monitoring and evaluation of policies

1. Implementation and monitoring of medicines policies

Advocate and support the implementation and monitoring of medicines policies based on the concept of essential medicines. Monitor the impact of trade agreements on access to quality essential medicines. Build capacity in the pharmaceutical sector.

- 1.1 Medicines policies developed, updated and implemented taking into consideration health, development and intersectoral policies
- 1.2 Implementation of medicines policy regularly monitored and evaluated
- 1.3 Public health aspects protected in the negotiation and implementation of international, sub-regional and bilateral trade agreements
- 1.4 Human resources capacity increased in the pharmaceutical sector
- 1.5 Promotion of innovation based on public health needs, especially for neglected diseases
- 1.6 Gender perspectives introduced in the implementation of medicines policies
- 1.7 Access to essential medicines recognized as a human right
- 1.8 Ethical practices promoted and anti-corruption measures identified and implemented in the pharmaceutical sector

2. Traditional medicine and complementary and alternative medicine

Adequate support provided to countries to promote the safety, efficacy, quality and sound use of traditional medicine and complementary and alternative medicine (TM/CAM).

- 2.1 TM/CAM integrated into national health care systems where appropriate
- 2.2 Safety, efficacy and quality of TM/CAM enhanced
- 2.3 Availability and affordability of TM/CAM enhanced
- 2.4 Rational use of TM/CAM by providers and consumers promoted

Access: Equitable financing, affordability and delivery of essential medicines in line with Millennium Development Goals, Target 17

3. Fair financing mechanisms and affordability of essential medicines

Guidance provided on financing the supply and increasing the affordability of essential medicines in both the public and private sectors.

- 3.1 Access to essential medicines improved, including medicines for HIV/AIDS, malaria, TB, childhood illnesses and non communicable diseases
- 3.2 Increased public funding of medicines promoted along with cost-containment mechanisms
- 3.3 Increased access to medicines through development assistance, including the Global Fund
- 3.4 Medicines benefits promoted within social health insurance and pre-payment schemes
- 3.5 Medicines pricing policies and exchange of price information promoted
- 3.6 Competition and generic policies implemented

4. Medicines supply systems

Efficient and secure systems for medicines supply promoted for both the public and private sectors, in order to ensure continuous availability of essential medicines.

- 4.1 Supply systems assessed and successful strategies promoted
- 4.2 Medicines supply management improved
- 4.3 Local production assessed and strengthened, as appropriate and feasible
- 4.4 Good procurement practices and purchasing efficiency improved
- 4.5 Public-interest NGOs included in national medicine supply strategies, where appropriate

INDICATORS 2004–2007	1999		2003			2007
	#Reporting	%	Target	#Reporting	%	Target
Countries with an official national medicines policy document – new or updated within the last 10 years	67/152	44%	55%	62/123	50%	59%
Countries with a national medicines policy implementation plan – new or updated within the last 5 years	41/106	39%	43%	49/103	48%	61%
Countries having conducted a national assessment of their pharmaceutical situation in the last 4 years	na	na	na	47/90	52%	58%
Countries integrating TRIPS Agreement flexibilities to protect public health into national legislation	na	na	na	32/105	30%	45%
Countries that provide both basic and continuing education programmes for pharmacists	54/85	64%	na	34/110	31%	35%
Countries promoting research and development of new active substances	na	na	na	21/114	18%	22%
Countries providing free medicines for pregnant women at primary public health facilities	na	na	na	54/106	51%	60%
Countries that provide HIV/AIDS-related medicines free at primary public health facilities	na	na	na	60/104	58%	65%
Countries with medicines legislation requiring transparency, accountability and code of conduct for regulatory work	na	na	na	84/114	74%	80%
Countries with national TM policy*	25	na	na	39/127*	31%*	37%
Countries regulating herbal medicines*	48	na	na	82/127*	65%*	75%
Countries with a national inventory of medicinal plants as a means to provide intellectual property right protection for traditional medical knowledge	na	na	na	9/39	23%	33%
Countries with national research institute in the field of TM/CAM*	19	na	na	56/127*	44%*	51%
Countries where less than 50% of the population has access to essential medicines	29/184	16%	14%	15/103	15%	14%
Countries with public spending on medicines below US\$ 2 per person per year	38/103	37%	35%	24/80	30%	20%
Percentage of key medicines available in public health facilities	na	na	na	22 ¹	77 ²	na
Countries with public health insurance covering the cost of medicines	71/111	64%	70%	79/117	68%	73%
Countries with a pricing policy for maximum retail mark up in the private sector	na	na	na	36/75	48%	55%
Countries in which generic substitution is allowed in private pharmacies	83/135	61%	75%	99/132	75%	81%
Countries with public sector procurement limited to national essential medicines list	71/133	53%	60%	84/127	66%	74%
Countries providing continuing education to pharmacists and pharmacy aides/assistants	39/103	38%	na	31/111	28%	32%
Countries with local production capability	na	na	na	36/122	30%	na
Countries with at least 75% of public sector procurement carried out by competitive tender	81/88	92%	95%	58/70	83%	87%
Countries with NGOs involved in medicines supply	na	na	na	29/64	45%	na

* Data collected from Traditional Medicine Survey

¹ Based on 22 countries that have completed the Level II survey

² Average

OBJECTIVES, COMPONENTS & EXPECTED OUTCOMES

Quality and Safety: The quality, safety and efficacy of all medicines assured by strengthening and putting into practice regulatory and quality assurance standards

5. Norms and standards for pharmaceuticals

Global norms, standards and guidelines for the quality, safety and efficacy of medicines strengthened and promoted.

- 5.1 Pharmaceutical norms, standards and guidelines developed or updated
- 5.2 Medicines nomenclatures and classification efforts continued
- 5.3 Pharmaceutical specifications and reference materials developed and maintained
- 5.4 Balance between abuse prevention of and appropriate access to psychoactive substance achieved

6. Medicines regulation and quality assurance systems

Instruments for effective drug regulation and quality assurance systems promoted in order to strengthen national drug regulatory authorities.

- 6.1 Medicines regulation effectively implemented and monitored
- 6.2 Information management and exchange systems promoted
- 6.3 Good practices in medicine regulation and quality assurance systems promoted
- 6.4 Post-marketing surveillance of medicines safety maintained and strengthened
- 6.5 Use of substandard and counterfeit medicines reduced
- 6.6 Prequalification of products and manufacturers of medicines for priority diseases
- 6.7 Safety of new priority and neglected medicines enhanced
- 6.8 Regulatory harmonization monitored and promoted, as appropriate, and networking initiatives developed

Rational Use: Therapeutically sound and cost-effective use of medicines by health professionals and consumers

7. Rational use by health professionals and consumers

Awareness raising and guidance on cost-effective and rational use of medicines promoted, with a view to improving medicines use by health professionals and consumers.

- 7.1 Rational use of medicines by health professional and consumers advocated
- 7.2 Essential medicines list, clinical guidelines and formulary process developed and promoted
- 7.3 Independent and reliable medicines information identified, disseminated and promoted
- 7.4 Responsible ethical medicines promotion for health professionals and consumers encouraged
- 7.5 Consumer education enhanced
- 7.6 Drug and therapeutics committees (DTCs) promoted at institutional and district/national levels
- 7.7 Training in good prescribing and dispensing practices promoted
- 7.8 Practical approaches to contain antimicrobial resistance developed
- 7.9 Identification and promotion of cost-effective strategies to promote rational medicine use of medicines

INDICATORS 2004 – 2007	1999		2003			2007
	#Reporting	%	Target	#Reporting	%	Target
Countries using the WHO Certification Scheme as part of the marketing authorization process	na	na	na	87/135	64%	75%
Countries using INNs in medicines registration	na	na	na	108/131	82%	90%
Number and types of pharmaceutical specifications and reference materials developed by WHO HQ	na	na	105	96	na	50
Number of substances reviewed and recommended for classification for international control	2/3	66%	na	5/5	100%	80%
Countries implementing basic medicines regulatory functions	70/138	51%	56%	90/130	69%	74%
Countries with a computerized medicines registration system	na	na	na	72/135	53%	60%
Countries with basic quality assurance procedures	95/122	78%	80%	111/137	81%	85%
Countries monitoring adverse drug reactions	56/191	29%	35%	72/192	38%	45%
Countries with >10% of tested medicines failing quality tests	na	na	na	20/71	28%	25%
Number of products assessed and approved	na	na	na	93	na	na
Countries participating in training programmes for introducing new therapies for priority and neglected medicines, e.g. malaria and HIV/AIDS	0	na	na	7	na	20
Number of countries participating in harmonization initiatives supported financially and technically by WHO	na	na	na	15/191	8%	18%
Countries where promotion of rational use of medicines is coordinated at national government level	na	na	na	93/127	73%	75%
Countries with national list of essential medicines updated within the last 5 years	129/175	74%	75%	82/114	72%	75%
Countries with treatment guidelines updated within the last 5 years	60/90	67%	70%	47/76	62%	65%
Countries with a national medicines information centre able to provide independent information on medicines to prescribers and/or dispensers	62/123	50%	59%	53/129	41%	50%
Countries with a medicines information centre/service accessible to consumers	na	na	na	45/127	35%	40%
Countries with basic system for regulating pharmaceutical promotion	92/132	70%	80%	83/113	73%	76%
Countries that have implemented a national consumer education campaign in the last two years	na	na	na	72/120	60%	60%
Countries with DTCs in the majority of regions/provinces	na	na	na	32/96	33%	40%
Countries that include the concept of essential medicines in basic medicine and/or pharmacy curricula	na	na	na	72/88	82%	85%
Countries with national strategy to contain antimicrobial resistance	na	na	na	37/113	33%	40%
Countries that have undertaken a national assessment/study of the rational use of medicines	na	na	na	57/97	59%	60%





Source: David Walton/Partners In Health

Saving lives with the right (to) medicines

Achievements 2000–2003

WHO provides **policy guidance and country support** to help improve access to essential medicines and assure their safety, quality, and rational use. During implementation of the *WHO Medicines Strategy 2000-2003*, over 120 countries worldwide have been supported in this way.

Achievements included:

- **Support to efforts to expand access to medicines – including for HIV/AIDS, tuberculosis and malaria, and other priority diseases** – through progress on critical issues such as selection, regulation, quality assurance, prices, and monitoring of trade agreements.
- **Establishment of a new “prequalification” programme** for priority medicines which has been extended from HIV/AIDS medicines to cover medicines for tuberculosis and malaria.
- **Launch of the WHO *Traditional Medicines Strategy*** to support the safe and informed use of traditional and complementary medicine and protect traditional medicines knowledge. National efforts to regulate herbal medicines and promote their safety have recently accelerated, partly in response to WHO guidance and support to countries in this important area (Figure 7).
- **Implementation of a global system for monitoring country progress** in medicines, including household surveys to investigate the use of medicines and the impact of poverty on access to essential medicines.
- **Expansion of information on comparative medicine prices worldwide** to ensure that countries and consumers do not have to pay more than necessary for essential medicines.
- **Revision of essential medicines selection process** to ensure a more evidence-based, independent and transparent selection process. Reasons for selection are published on the WHO Medicines Library website, together with comparative information on prices and the WHO Model Formulary.
- **Launch of intensified training programmes** on: good manufacturing practices (GMP); quality assurance and registration of generic drugs, especially ARVs; and rational use of medicines.
- **Launch of a campaign to raise awareness about the dangers of counterfeit and substandard medicines** (Figure 8).

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