



WORLD HEALTH ORGANIZATION

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Quality and safety of medicines, including of blood products

WHO medicines strategy

Report by the Secretariat

1. The four main objectives of WHO's medicines strategy are:

*to frame and implement policy (with the commitment of all stakeholders to national drug policies, coordinated implementation and the monitoring of policy impact); to ensure access (that is, equitable availability and affordability of essential drugs, with an emphasis on diseases of poverty); to ensure quality, safety and efficacy of all medicines (by strengthening and putting into practice regulatory and quality assurance standards); and to promote rational use (namely, the therapeutically sound and cost-effective use of drugs by health professionals and consumers).*¹

EXPANDING ACCESS TO ESSENTIAL MEDICINES

2. Expanding access to essential medicines, especially those for HIV/AIDS, tuberculosis, and malaria, is critical to WHO's global efforts to prevent millions of deaths each year, reduce suffering and help to reduce the economic burden of illness on the poorest families.
3. Scaling up existing interventions for infectious diseases, maternal and child health, and noncommunicable diseases may save more than 10.5 million lives per year by 2015, in turn boosting economic growth and social development.
4. Most of these interventions depend on essential medicines. Yet today, almost 2000 million people, or one-third of the global population, have no regular access to essential medicines – indeed, more than half the population in some of the lowest-income countries of Africa and Asia is in that position. In developing countries generally, lifesaving antiretroviral agents are available to only 300 000 of the five to six million people currently in need of treatment – a crisis that WHO has declared to be a global health emergency.

¹ See document A54/17.

THE CHALLENGES OF MEETING ESSENTIAL MEDICINE NEEDS

5. Unaffordable prices for medicines, especially newer products such as antiretroviral agents and artemisinin-based antimalarial drugs, limit access to medicines in resource-poor settings. In developing countries today, medicines account for 25% to 70% of overall health care expenditure, compared with less than 15% in most high-income countries. Elsewhere, inequitable health-financing mechanisms that leave households responsible for the cost of their essential medicines place the heaviest burden on the poor and sick who are the least able to pay. In some countries, one-third of poor people receive none of the essential medicines needed for acute illness.

6. The lack of reliable and sustainable systems for the supply of medicines is one of the main reasons for the chronic shortage of essential medicines in many countries, resulting in unnecessary suffering and death. Through inefficiency, procurement systems can pay up to twice the market price for essential medicines, thereby wasting valuable resources.

7. The quality of medicines varies greatly, especially in low- and middle-income countries. Most countries have a drug regulatory authority and formal requirements for registering medicines, but one-third of WHO Member States have either no regulatory authority or only limited capacity to regulate their medicines market. In recent assessments by WHO, 50% to 90% of samples of antimalarial drugs failed quality-control tests and more than half the antiretroviral agents tested did not meet international standards. In addition, the sale of counterfeit and substandard medicines remains a global concern.

8. Irrational use of medicines is a major concern worldwide. It is estimated that half all medicines are inappropriately prescribed, dispensed or sold and that half all patients do not follow instructions for their use. The misuse of medicines wastes scarce resources and results in widespread hazards to health.

WHO'S RECENT ACHIEVEMENTS

9. In response to these challenges, WHO provides **policy guidance** and **country support** to help to improve access to essential medicines and assure their safety, quality and rational use. Over the past four years, more than 120 countries have received such support.¹ Recent activities include:

- implementation of a global system for **monitoring country progress**, including household surveys of the use of medicines and the impact of poverty on access to essential medicines;
- launch of the WHO **traditional medicine strategy** to support the safe and informed use of traditional and complementary medicine;
- provision of systematic **guidance on the impact of globalization on access to medicines**, focusing on WTO agreements on patents and other intellectual property;

¹ Highlights of the year 2000 in essential drugs and medicines policy (document WHO/EDM/2001.4); Annual report 2001, essential drugs and medicines policy: extending the evidence base (document WHO/EDM/2002.1); Annual report 2002, essential drugs and medicines policy: supporting countries to close the access gap (document WHO/EDM/2003.1).

- progress in **expanding access to medicines, including those for HIV/AIDS, tuberculosis, malaria, and other high-priority diseases**, by resolution of difficulties in critical areas such as selection, regulation, quality assurance, prices and patents;
- collection of more information on **comparative medicine prices** worldwide to ensure that countries and consumers pay no more than is necessary for essential medicines;
- extension of a “**pre-qualification**” programme for **priority medicines** from HIV/AIDS drugs to medicines for tuberculosis and malaria;
- expansion of the **WHO Programme for International Drug Monitoring** to 72 countries;
- launch of a campaign to raise awareness of the dangers of **counterfeit and substandard medicines**;
- revision of the **essential medicines selection process**¹ to ensure a better evidence-base and greater independence and transparency;
- launch of intensified **training programmes** on good manufacturing practices, quality assurance and registration of generic drugs, especially antiretroviral agents, and rational use of medicines.

RESPONDING TO COUNTRY NEEDS

10. With its medicines strategy,² WHO is continuing to respond broadly to the challenges of the new century. The strategy has four key objectives, which relate to better **access** to essential medicines; stronger **national medicines policy**; **improved quality and safety** of medicines; and their **rational use** (see paragraph 1).

11. Over the next four years, top priority is being given to expanding **access** to high-quality essential medicines, in particular antiretroviral agents in order to meet WHO's target of ensuring access to treatment for HIV/AIDS by 2005 for three million people in developing countries. Emphasis is also being placed on improvement of financing, supply systems and quality assurance.

12. Ensuring implementation and monitoring of **national medicines policies** will remain one of WHO's core activities. Work will focus on supporting countries in formulating their medicines policies in a new international context.

13. WHO will continue to implement its **traditional medicine strategy** in order to ensure affordable access, protection of intellectual property rights, efficacy and quality assurance, and to provide guidance on safety.

¹ Reasons for selection are published on the WHO Essential Medicines Library pages of the WHO web site, together with comparative price information and the WHO model formulary.

² WHO medicines strategy 2004-2007: countries at the core (document WHO/EDM/2004.1), in press.

14. In ensuring equitable financing, affordability and delivery of essential medicines, WHO will concentrate on **expanding access to quality essential medicines** for high-priority diseases, especially HIV/AIDS.

15. To assure **quality and safety of medicines** WHO will support countries in strengthening and implementing regulatory and quality assurance standards, including their work on post-marketing surveillance of new drugs such as antiretroviral and antimalarial agents which are scheduled for widespread use.

16. WHO will promote **therapeutically-sound and cost-effective use of medicines** by health workers and consumers, emphasizing work with health insurance systems to promote the use of essential medicines.

17. Regular monitoring and evaluation underpin every aspect of WHO's work in essential medicines. A package of core indicators has been put together for evaluation of the pharmaceutical sector at the country level. Every four years, WHO conducts a global survey to assess structures and processes in the pharmaceutical system at the national level, and uses the findings to identify priority areas of work, plan its medicines strategy and set targets. The strategy for 2004-2007 includes 44 country-progress indicators which will be used for monitoring and to determine whether the strategic targets have been met.

ACTION BY THE EXECUTIVE BOARD

18. The Executive Board is invited to note the report.

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