



WORLD HEALTH ORGANIZATION

FIFTY-SIXTH WORLD HEALTH ASSEMBLY
Provisional agenda item 14.8

A56/16
17 March 2003

WHO medicines strategy: progress report

Report by the Secretariat

BACKGROUND

1. In 1975, the Health Assembly introduced the concepts of “essential drugs” and “national drug policy” (see resolution WHA28.66). The Declaration of Alma-Ata in 1978 identified provision of essential drugs as one of the eight elements of primary health care. On 21 October 2002, WHO commemorated the twenty-fifth anniversary of the first WHO Model List of Essential Drugs, which stated that a limited range of medicines selected to meet priority health needs would lead to better health care, better drug management, better use of financial resources, and thereby greater access to care.

2. When the first Model List was produced in 1977, the national drug policy concept was scarcely known. Few countries had what would today be considered an essential medicines list. The approach to selection of medicines for health services was relatively informal. Independent, unbiased information on medicines was limited, with little attention paid to systematic teaching about rational prescribing and generic prescribing. Publicly available price information was virtually non-existent, and few countries encouraged generic substitution. Regulation of drug promotion was haphazard, with no international criteria for ethical promotion. A network of national centres monitored the safety of medicines, but it had limited membership and insufficient support structures. Standards for good manufacturing practices had been developed, but were rarely adhered to outside industrialized countries.

3. Today, more than 100 countries have national drug policies in place or under development, and 156 Member States have national or provincial essential medicines lists. More than 130 countries have developed national treatment guidelines and/or formulary manuals to provide objective guidance on rational medicines use. More than 80 countries have introduced the essential medicines concept into curricula for medicine and pharmacy students. The WHO Guide to good prescribing¹ has been translated into 18 languages. Generic competition is encouraged in scores of countries. More than a dozen countries provide price information on public web sites. WHO, with other partners, maintains pricing services for essential medicines, for active ingredients, and for HIV-related medicines. The WHO Programme for International Drug Monitoring now includes 76 Members and Associate Members, and a global effort has been mounted to assure the quality of pharmaceutical production worldwide.

¹ De Vries TPGM et al., Guide to good prescribing: a practical manual. Geneva, World Health Organization, 1994 (document WHO/DAP/94.11).

4. WHO's work on pharmaceuticals is guided primarily by the WHO medicines strategy: framework for action in essential drugs and medicines policy 2000-2003¹ (see resolution WHA54.11). The strategy aims to maximize the potential of essential medicines² to save lives and improve health status and has four strategic objectives: to promote rational use; to increase quality and safety of pharmaceuticals; to improve access to essential medicines; and to provide support for development and implementation of national medicines policies. This report highlights some of the key developments and activities of 2002.

RATIONAL USE

5. The WHO Expert Committee on the selection and use of essential medicines met in April 2002 to produce the twelfth WHO Model List of Essential Medicines.³ This was the first meeting under new procedures. These involve linking selection directly to treatment guidelines, preparing systematic reviews of the clinical evidence for proposed choices, making this evidence publicly available before decision-making meetings, allowing stakeholders to comment on proposed changes in the list, making final decisions in a closed meeting of independent experts, and publicly documenting the reasons for each decision.

6. The twelfth WHO Model List of Essential Medicines includes 12 antiretroviral medicines. Information on antiretroviral agents appears in the first WHO Model Formulary.⁴ Other efforts to promote the most effective use of HIV/AIDS medicines included the preparation and drafting of a handbook on access to HIV-related treatments for use by nongovernmental organizations and community-based organizations, in collaboration with UNAIDS and the International HIV/AIDS Alliance.⁵ Also, the preparation of three training modules on the role of pharmacists in HIV prevention and care was in progress in collaboration with the International Pharmaceutical Federation.

7. Promotion of rational use of medicines included developing guidelines for national tuberculosis programmes on use of fixed-dose combination antituberculosis medicines. A new model for containing antimicrobial resistance was piloted at four sites in India and two sites in South Africa. Work was also initiated to harmonize medicines for reproductive health included in the draft UNFPA Interagency Reproductive Health Medicines and Commodities List, and those included in the WHO Model List of Essential Medicines. Cost-effectiveness analysis was undertaken of HIV-related interventions in Africa.

¹ Document WHO/EDM/2000.1.

² As part of the revised procedure for updating the Model List, the term "essential medicines" is used in preference to "essential drugs". This reflects the common use of the term "medicines" to describe pharmaceutical preparations used in clinical health care practice.

³ *The selection and use of essential medicines. Report of the WHO Expert Committee, 2002, including the 12th Model List of Essential Medicines.* Geneva, World Health Organization (WHO Technical Report Series, No. 914, in preparation).

⁴ Couper MR, Mehta D, eds., *WHO model formulary.* Geneva, World Health Organization, 2002. Also available at <http://mednet3.who.int/mf/modelFormulary.asp>

⁵ UNAIDS, WHO, The International HIV/AIDS Alliance. *Handbook on access to HIV/AIDS-related treatment: a collection of information, tools and other resources for NGOs, CBOs and PLWHA groups.* Geneva, UNAIDS, in press; a pre-publication text is available at <http://www.unaids.org/publications/documents/health/access/ngotoolkit/>

8. International, regional and national courses were held in 2002 on: promoting rational medicines use (Manila, 4-15 March; Tehran, 14-17 June); promoting rational medicines use in the community (Bangkok, 3-16 November); promoting drugs and therapeutics committees (East London, South Africa, 5-13 February; Mumbai, India, 23 September – 2 October; Amman, 10-19 December); application of pharmacoeconomics (Antalya, Turkey, 2-13 September; Bali, Indonesia, 24-26 September; Vilnius, 15-19 October); and rational medicines selection (Algiers, 16-27 September).

9. In 2001, the Pharmacy-based Hypertension Management Model, elaborated by the EuroPharm Forum Network of pharmaceutical associations and the Regional Office for Europe, was tested and implemented in Estonia, Latvia, Lithuania, Portugal, Slovenia and Spain. Evaluation in 2002 showed that pharmacists can contribute to improved use of health care services by screening patients for high blood pressure, undertaking regular measurement of blood pressure and counselling patients. Also in the European Region, a survey funded by the European Union to ascertain pharmacists' smoking habits and their interest in smoking cessation activities was carried out in 12 countries of the European Union. Results were published in February 2002 in a research report, which shows that community pharmacies are increasingly involved in smoking cessation activities.¹

QUALITY AND SAFETY

10. The Tenth International Conference of Drug Regulatory Authorities took place in Hong Kong Special Administrative Region, China, in June 2002. Recommendations covered herbal medicines, homeopathy, regulatory reform, medicines safety, counterfeiting, access to medicines and vaccines, regulation of clinical trials, harmonization, new technologies and e-commerce. The document on the impact of implementation of International Conference on Harmonisation (ICH) guidelines in non-ICH countries² was distributed at the meeting.

11. Several activities were undertaken to enhance the impact of the work of medicines regulatory authorities. This included support to medicines regulatory authorities on computer-assisted medicines registration, and field-testing of a common data collection tool (to assess medicines regulatory functions) in Bhutan, Brazil, Bulgaria, India, Islamic Republic of Iran, Japan, Malaysia, Morocco, Poland, South Africa, Sri Lanka, Tunisia, Ukraine and Viet Nam. An International Comparative Study on Regulatory Drug Information to compare information on medicines approved by national authorities, was completed in 26 countries.

12. A project to increase access to HIV/AIDS medicines of assured quality, including antiretroviral agents, is creating a unified pre-qualification programme for organizations of the United Nations system. A list of pre-qualified suppliers was issued in March 2002.³ The project has been expanded to first-line medicines for the treatment of tuberculosis (on behalf of the Global Drug Facility) and antimalarial agents (on behalf of Roll Back Malaria). Three training workshops were held in 2002 to assist drug regulatory authorities: in Africa (on generics, South Africa, June), the Americas (United States of America, April) and Asia (India, September), which concentrated on the evaluation and registration of antiretroviral agents.

¹ Teraesalmi E et al., Pharmacists against smoking: research report 2001. Copenhagen, World Health Organization, 2001 (document EUR/01/5015372, also available at <http://www.euro.who.int/document/e75099.pdf>).

² Document WHO/EDM/QSM/2002.3.

³ See <http://www.who.int/medicines/organization/qsm/activities/pilotproc/pilotproc.shtml>

13. Work to promote quality of multiple-drug, fixed-dose combination antituberculosis medicines included collection of samples, collation of technical information and testing of draft monographs. Screening tests for antituberculosis medicines and all single-dose antimalarial medicines were also prepared. Pharmacopoeial monographs are being drafted for antiretroviral agents and collaboration with the IAEA was initiated on developing specifications for radiopharmaceutical materials.

14. Training in good manufacturing practices was held in Viet Nam (20-27 July 2002). A national training course for inspectors and manufacturers of medicines on implementation of good manufacturing practices and inspection was held in Addis Ababa (3-7 June 2002) and also in Harare (27-29 October 2002). Efforts to improve medicines safety also focused on producing a multicountry plan to fight counterfeits in the Greater Mekong subregion, at a meeting in Thailand (11-13 November 2002).

15. Pharmacovigilance was promoted through issue of a document on safety of medicines: a guide to detecting and reporting adverse drug reactions – why health professionals need to take action¹ and a publication on the importance of pharmacovigilance.² A workshop in Australia on pharmacovigilance, in November 2002, attended by 28 participants from 16 countries, was held to increase understanding among Western Pacific countries of matters related to the reporting of medicines safety. Three more countries – Latvia, Peru and Ukraine – became full members of the WHO Programme on International Drug Monitoring (established in 1968 in the wake of the thalidomide disaster and formalized into a WHO programme in 1970), bringing the total number of Member countries to 68. An international board was established for the WHO Collaborating Centre for International Drug Monitoring (Uppsala, Sweden).

ACCESS

16. WHO continues to promote differential pricing to improve affordability of essential medicines. An analysis of evidence on the effectiveness of a variety of alternative mechanisms for achieving prices related to purchasing power of individuals and countries was carried out in cooperation with the Department for International Development of the United Kingdom of Great Britain and Northern Ireland.

17. To provide support to countries in conducting their own price surveys and improving the quality and availability of price information, a manual for surveying medicines prices, price composition and the affordability of key treatments in low- and middle-income countries was prepared in collaboration with Health Action International. As a standard basis for monitoring medicines price variation and trends, it will contribute to national pharmaceutical policy-making.

¹ Document WHO/EDM/QSM/2002.2.

² *The importance of pharmacovigilance*. Geneva, World Health Organization, 2002 (also available at <http://whqlibdoc.who.int/hq/2002/a75646.pdf>).

18. Work on medicines financing included publication of case studies from the Americas on health insurance systems and access to medicines.¹ In Europe, with the support of the European Union Health Monitoring Programme, a project started to map out patterns in medicines consumption, expenditure and pricing in 15 western European countries. Additionally, technical support was provided to the national country pharmaceuticals programmes of Bulgaria, Romania and Turkey for review of reimbursement policies.

19. With respect to international trade agreements and access to medicines, WHO continues to provide policy and technical support to Member States. A meeting was held in Yaoundé in May 2002 with member countries of the African Organization for Intellectual Property to discuss the Doha Declaration, the Revised Bangui Agreement, and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

20. WHO issued a document² analysing the question of use of the TRIPS agreement's provisions on compulsory licensing by countries with insufficient or no pharmaceutical manufacturing capacity. The underlying public health principle is that the people of a country that does not have the capacity for domestic production of a needed product should be no less protected by compulsory licensing provisions (or any other TRIPS safeguards), nor should they face any greater procedural hurdles, than people living in countries capable of producing the product. Other work relating to international trade agreements and health included a report on the network for monitoring the impact of globalization and TRIPS on access to medicines.³ This document outlines model indicators for studying the impact of globalization and TRIPS on access to essential medicines in relation to changes in pricing, generic competition, investment in research and development, and technology transfer.

21. Considerable work was undertaken to improve medicines procurement. International training courses on procurement of antituberculosis medicines were held in Nairobi (September 2002) and in Jakarta (June 2002). Practical guidelines on pharmaceutical procurement for countries with small procurement agencies⁴ were published to demonstrate how such agencies can minimize costs and ensure product quality.

22. The initial phase of a multicountry study on best practices in public sector medicines supply in Africa was completed. Additionally, a tool was devised to study the involvement of faith-based nongovernmental organizations in medicines supply and distribution.

¹ Zerda A et al., eds, *Health insurance systems and access to medicines: case studies from Argentina, Chile, Colombia, Costa Rica, Guatemala and the United States of America*. Washington, D.C., World Health Organization and Pan American Health Organization, 2002.

² Correa CM, Implications of the Doha Declaration on the TRIPS agreement and public health. Geneva, World Health Organization, 2002 (document WHO/EDM/PAR/2002.3).

³ Network for monitoring the impact of globalization and TRIPS on access to medicines: report of a meeting, February 2001, Bangkok, Thailand. Geneva, World Health Organization, 2002 (document WHO/EDM/PAR/2002.1, Health economics and drug series, No. 11).

⁴ *Practical guidelines on pharmaceutical procurement for countries with small procurement agencies*. Manila, World Health Organization, 2002.

POLICY

23. Strengthening of human resources capacity in pharmaceuticals continued. In Africa, by the end of 2002, national programme officers had been recruited for Cameroon, Chad, Ethiopia, Ghana, Mali, Nigeria, Rwanda, Senegal, Uganda and the United Republic of Tanzania. In the Eastern Mediterranean Region, a national programme officer was recruited for Afghanistan.

24. In Africa, national programme officers are working with their ministry of health counterparts on pharmaceutical situation surveys to ascertain whether existing national drug policies require modification or reinforcement. By the end of 2002, surveys had been carried out in Ethiopia, Ghana, Mali, Nigeria, Uganda and the United Republic of Tanzania. Also in Africa, WHO continues to work with Health Action International on a six-year programme (2001-2006) to improve national drug policy implementation.

25. The joint WHO-India Essential Medicines Programme was started in 1997, based on experience with the medicines policy programme of Delhi State Capital Territory. By the end of 2002, the programme supported the public sector in 11 other states in India, with intensive capacity-building programmes. An essential medicines programme was launched in Afghanistan. It is focusing on issues relating to medicines donations, updating the national list of essential medicines and developing the pharmaceutical capacity of the Ministry of Health.

26. The 2002 WHO international drug policy course on tackling issues relating to national drug policy development and implementation was held in Tashkent, from 27 October to 8 November. It was organized in collaboration with the Ministry of Health of Uzbekistan, the United States Agency for International Development and Boston University School of Public Health (United States of America) and attended by 40 people, including participants from all the Newly Independent States and several countries of central and eastern Europe.

ACTION BY THE HEALTH ASSEMBLY

27. The Health Assembly is invited to note the information contained in this report, which was discussed and noted by the Executive Board at its 111th session in January 2003.

= = =