



WORLD HEALTH ORGANIZATION

FIFTY-FIFTH WORLD HEALTH ASSEMBLY
Provisional agenda item 13.8

A55/12
28 March 2002

WHO medicines strategy

Expanding access to essential drugs

Report by the Secretariat

1. WHO's work on pharmaceuticals is guided primarily by the WHO medicines strategy,¹ which was adopted by the Fifty-fourth World Health Assembly (resolution WHA54.11). The strategy aims to help to save lives and improve health by closing the huge gap between the potential that essential drugs have to offer and the reality for millions of people that medicines are unavailable, unaffordable, unsafe, of poor quality or improperly used.
2. Within the strategy, four factors are crucial to securing and expanding access to essential drugs: (1) rational selection and use of essential drugs; (2) affordable prices; (3) adequate and sustainable financing; and (4) reliable health and supply systems. The priority areas for 2000-2003 are the major diseases of poverty, such as HIV/AIDS, tuberculosis, malaria and childhood illnesses.
3. Overall, considerable progress was made in 2000-2001 on selection and pricing of essential drugs. This work is being consolidated in 2002-2003, but more attention will be paid to drug financing, reliable supply systems, financial sustainability of national drug supply systems, analysis of options for public financing for drugs, expansion of drug benefits in health insurance, development of financing sources, and support for access to medicines in new global mechanisms to address high-priority health problems such as AIDS, tuberculosis and malaria.

SELECTION

4. The first **WHO Model List of Essential Drugs** was prepared by a WHO expert committee in 1977 and revised every two years thereafter. By the end of 1999, 156 Member States had official essential drugs lists. In 1999 the Expert Committee on the Use of Essential Drugs noted that the methods for updating and disseminating the Model List needed to be revised. Hence, following extensive consultations, a revised procedure for updating the Model List has been drawn up.²
5. The twelfth meeting of the WHO Expert Committee on the Use of Essential Drugs, to be held in April 2002, will be the first meeting of the Committee since the new procedures to update and

¹ WHO medicines strategy: framework for action in essential drugs and medicines policy 2000-2003. Geneva, WHO, 2000 (document WHO/EDM/2000.1).

² See document EB109/8.

disseminate the list were discussed at the 109th session of the Executive Board in January 2002. It is already possible to follow most of the new procedures. The meeting will receive an update on the current situation of the new procedures, and discuss the current status of the WHO Essential Medicines Library, WHO Model Formulary and the identification of priority needs for systematic review. Proposed changes to the list and the sections to be reviewed can be found on the WHO web site.¹

6. **WHO clinical guidelines** for prevention, diagnosis, and treatment continue to be regularly updated. During 2000-2001, clinical guidelines for malaria, sexually transmitted infections, tuberculosis, some noncommunicable diseases and antiretroviral treatment for HIV/AIDS were issued. These guidelines will eventually constitute the basis of the WHO Model List of Essential Medicines.

7. Creation of a **WHO essential medicines library** is under way. This collection is intended to link various sources of information on essential medicines in an electronic setting. For each essential medicine electronic links will be made to various elements such as the WHO Model Formulary (available by end of 2002), WHO clinical guidelines, Management Sciences for Health/WHO's *International drug price indicator guide*, the International Nonproprietary Name database and other information on quality (basic tests and *The international pharmacopoeia*).

8. **Cost-effectiveness analysis** helps to expand access to essential drugs by enabling policy-makers and clinicians to make the best use of available resources. Such an analysis of HIV-related interventions in Africa, for example, demonstrated the large variations in cost per life year gained for various preventive and therapeutic interventions. Systematic examination of the evidence on the cost-effectiveness of noncommunicable disease interventions has been initiated, with the focus on specific treatment for certain cardiovascular conditions, risk factors such as high blood lipids, chronic diseases such as diabetes, and cancer.

9. **International, regional and national courses** have been held since 2000 on promoting rational drug use (in China, Indonesia, Islamic Republic of Iran, Kyrgyzstan, Nigeria, Papua New Guinea, Philippines, Tajikistan and Zimbabwe), on drug and therapeutics committees (in Cambodia, Kenya, Lao People's Democratic Republic, Nepal and South Africa), on pharmacoeconomics and drug selection (in Hungary, India and Latvia), and on promoting rational drug use in the community (in Thailand and Uganda). In November 2000, health professionals from ministries of health and health-insurance institutions from 20 European countries met in Copenhagen to discuss the promotion of rational drug use. In October 2001 an intercountry meeting of drugs and therapeutics committees for the Western Pacific Region was held in Malaysia to evaluate ongoing interventions and to design innovative ones for rational drug use in hospitals.

10. **Misuse of antimicrobials and unsafe injections** contribute significantly to irrational drug use. In 2001 WHO issued its global strategy for the containment of antimicrobial resistance.² The document summarized the evidence on interventions to promote rational use of antimicrobials and the roles of international organizations, national governments, the public, industry and other important stakeholders. WHO also hosts a secretariat for the Safe Injection Global Network, which *inter alia* addresses problems caused by unsafe and excessive use of therapeutic injections.

¹ <http://www.who.int/medicines/>

² Document WHO/CDS/CSR/DRS/2001.2.

PRICES

11. WHO is working with partners to maintain three **international price information services**: the *International drug price indicator guide* covering over 300 essential drugs;¹ *Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS*;² and *Pharmaceutical starting materials/essential drugs report*.³ WHO has initiated a review of the feasibility and effectiveness of implementing additional systems for voluntary monitoring of drug prices and reporting global drug prices.

12. In response to requests from Member States, **regional price information services** continue to be supported. They include the *AFRO essential drugs price indicator*, which compares national tender prices for essential drugs;⁴ and *Antiretrovirals in Latin America and the Caribbean*, which provides information on prices, uses and access policies.⁵ The Regional Office for Europe has established a pricing and reimbursement information network on medicines in Europe and initiated discussions with countries about systematically linking national drug price information services for the European Region.

13. **Price survey methods.** A manual for collecting data on drug prices and price composition in low- and middle-income countries, developed jointly by WHO and Health Action International is being prepared. It should support national policy-making by offering a global standard for producing more and better-quality information on drug price variations and trends. Field-testing has been completed in Armenia, Brazil, Kenya, South Africa and Sri Lanka. Further country studies, and publication and distribution of the manual, will take place in 2002.

14. WHO actively promotes the concept of **differential pricing** to increase access to essential drugs. A WHO/WTO workshop on differential pricing⁶ has been much cited in subsequent work by Member States, nongovernmental organizations and the Commission on Macroeconomics and Health. Participants noted that reductions of up to 95% have been achieved for some products; that best prices are obtained through bulk purchasing, competition, skilful negotiation and sound supply management; and that more widespread differential pricing is feasible. They also suggested that mechanisms for differential pricing could include: (1) leaving it to the market; (2) bilaterally negotiated discounts; (3) regional or global bulk purchasing; (4) voluntary licensing with transfer of technology; (5) compulsory licensing; and (6) flexible global systems. Subsequent discussions in international and national forums have highlighted the need for differential pricing arrangements to be closely monitored, sustainable and transparent.

¹ *International drug price indicator guide*, Arlington, Virginia, United States of America, Management Sciences for Health, published annually.

² UNICEF, UNAIDS, WHO and Médecins sans Frontières, *Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS*, Copenhagen, UNICEF, published twice a year.

³ *Pharmaceutical starting materials/essential drugs report*, Geneva, International Trade Centre/UNCTAD/WTO, published irregularly.

⁴ *AFRO essential drugs price indicator*, Brazzaville, WHO, published every two years.

⁵ Available on the PAHO web site (http://www.paho.org/English/HCP/HCA/antiretrovirals_HP.htm).

⁶ WHO/WTO workshop on differential pricing and financing of essential drugs (jointly organized by WHO, WTO, Norwegian Foreign Affairs Ministry and Global Health Council), Høsbjør, Norway, 8-11 April 2001.

INTERNATIONAL TRADE AGREEMENTS AND ACCESS TO DRUGS

15. WHO will continue to provide independent data and **technical assistance to countries** in order to develop informed approaches to dealing with the health implications of trade issues. WHO has provided up-to-date policy and technical support to 50 Member States through regional briefings and direct country support. Between May 2000 and January 2002, six regional briefings on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) were held in China, Costa Rica, Indonesia, Poland, South Africa and Zimbabwe. These meetings brought together, often for the first time, representatives of health ministries, trade ministries, patent offices, nongovernmental organizations, WTO and WIPO. The briefings covered: the background to the TRIPS agreement; its relevance to access to medicines; the role of intellectual property rights in stimulating innovation; principles of model legislation; and a proposed framework for implementing safeguards in the TRIPS agreement at national level and the type of support that this would require. Direct technical support to countries has been provided on request, for example to China, Islamic Republic of Iran, South Africa and Thailand. A network of legal experts with specialized knowledge and understanding of public health and pharmaceutical impact of international trade agreements is being built as a resource for developing countries.

16. In June 2000 WHO was granted observer status at the WTO Council for Trade-Related Aspects of Intellectual Property Rights. In her statement on the declaration on intellectual property rights and public health adopted by the WTO Ministerial Conference, in Doha in November 2001, the Director-General welcomed the conclusion that the TRIPS agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, promote access to medicines for all”. As instructed in the Doha Declaration, that WTO Council is to find an expeditious solution to the problem of WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector which could face difficulties in making effective use of compulsory licensing under the TRIPS agreement. The Council must report to the WTO General Council before the end of 2002.

17. The **network for monitoring the impact of globalization and TRIPS on access to essential drugs** (consisting of WHO collaborating centres in Brazil, Spain, Thailand and the United Kingdom of Great Britain and Northern Ireland) formulated draft model indicators for use in studies measuring the impact of globalization and the TRIPS agreement on access to essential drugs. These indicators cover changes in pricing, generic competition, investment in research and development, and technology transfer. Case studies on trends in drug patenting have also been undertaken by the University of Buenos Aires.

18. **Cooperation with other international organizations** has been strengthened. Trade issues are systematically discussed with other agencies besides WTO, such as UNAIDS, UNCTAD and WIPO, and in the Director-General’s round-table process with public-interest nongovernmental organizations and the research-based industry.

FINANCING

19. Published studies and national health accounts confirm that **pharmaceutical expenditure in developing countries** constitutes 25% to 65% of total public and private health expenditure, and 60% to 90% of out-of-pocket household spending on health. Because of the magnitude of drug expenditure and the unique aspects of managing this critical health resource, WHO devotes considerable attention to drug financing, treating it as an integral component of overall health care financing.

20. Work on **drug financing**, undertaken in more than 35 countries during 2000-2001, included contribution to a publication on drug benefits in Latin American social security systems,¹ a regional workshop on drug reimbursement in the European Region, and country support for quantification of drug needs and managing drug benefits in health insurance programmes.
21. **Drug donations** are provided through WHO for the treatment of onchocerciasis, leprosy, African trypanosomiasis and lymphatic filariasis. These donations are managed according to specific WHO guidelines. In some instances, special safety monitoring or other measures are being taken to ensure safe and effective use of large drug donations.

RELIABLE HEALTH AND SUPPLY SYSTEMS

22. **International, regional or national bulk procurement** can dramatically reduce costs and improve monitoring of drug quality. WHO has supported the Stop TB Secretariat to establish the Global TB Drug Facility, which has led to substantial reductions in prices for antitubercular drugs. In the Region of the Americas, a strategic fund for purchasing medicines and insecticides for targeted diseases (HIV/AIDS, leishmaniasis, tuberculosis and malaria) has been established. The fund provides for supplier prequalification, standardized criteria for inspection, harmonized drug specifications, drug quality surveillance, and technical cooperation with countries to strengthen drug selection, distribution and rational use. In the Western Pacific Region, WHO supports collaborative pharmaceutical procurement involving small Pacific island countries through a pharmaceutical bulk purchasing scheme based in Fiji.
23. A project to increase **access to high-quality HIV/AIDS drugs**, including antiretroviral agents, will create a unified prequalification programme for all United Nations organizations. The first list of prequalified innovator and generic suppliers was published in March 2002 and is being updated periodically. An analysis of measures needed to correct deficiencies will help both regulatory authorities and manufacturers to improve product quality.
24. Work on **drug quality control** has focused on medicines for high-priority diseases. An eight-country field study on the quality of antimalarials and the use of rapid screening techniques for drug quality control is in its final phases. A plan of action is being implemented on the quality, safety and efficacy of the four-drug fixed-dose combination for tuberculosis. Screening tests and monographs for *The international pharmacopoeia* are being prepared for antitubercular drugs (including fixed-dose combinations), antimalarial agents and HIV/AIDS drugs.
25. **Good manufacturing practices** ensure that pharmaceuticals are produced according to established standards. Strong, good manufacturing practices are important for enhancing domestic production. Since the start of a major initiative to improve such practices, 240 people from more than 40 countries have been trained; relevant training materials have been translated into Spanish.

¹ Zerda A., Velásquez G., Tobar F., Vargas JE. *Sistemas de Seguros de Salud y Acceso a Medicamentos*, Buenos Aires, ISALUD, 2001, ISBN 92 75 32353 4.

EXPANDING ACCESS TO OPIOID ANALGESICS

26. Overemphasis on the dependence-producing characteristics of opioid analgesics can lead to excessive fear of addiction, underuse for legitimate medical purposes, and enactment of unduly restrictive regulations on distribution and use. In 2000, WHO issued a report entitled “Achieving balance in national opioids control policy” which advocates balanced control approaches.¹ A special issue of the newsletter *Cancer Pain Release* was produced in collaboration with the WHO Collaborating Centre for Policy and Communications in Cancer Care, United States of America, to promote a more balanced approach.² Regulatory barriers to access to opioid analgesics have been lowered in several countries, including China, India, Italy and Mexico.

27. Import-export controls can limit the efforts of humanitarian organizations to supply countries in emergency situations with emergency medical kits containing opioid analgesics. To help to overcome this obstacle, WHO promotes the application of simplified controls in emergency situations, by widely disseminating model guidelines for the international provision of controlled medicines for emergency health care.³

ACTION BY THE HEALTH ASSEMBLY

28. The Health Assembly is invited to consider adoption of the draft resolution contained in resolution EB109.R17.

= = =

¹ Document WHO/EDM/QSM/2000.4.

² New WHO opioid guidelines put into action, *Cancer Pain Release*, 2001, **14**(1).

³ See resolution WHA49.18, also endorsed by the Commission on Narcotic Drugs in its Resolution 7 (XXXIX).