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Revised drug strategy

Report by the Secretariat

1. WHO's work on pharmaceuticals is now guided primarily by the WHO medicines strategy,¹ which evolved from the revised drug strategy adopted by the Health Assembly in 1986 (resolution WHA39.27) and subsequent updates (most recently resolution WHA52.19). The medicines strategy places the revised drug strategy within a more operational, responsive and comprehensive framework. It aims to help to save lives and to 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. The strategy was elaborated in consultation with more than 60 institutions, including WHO collaborating centres, agencies in the United Nations system, other international organizations, nongovernmental organizations, and members of WHO expert advisory panels. It is now being implemented with the cooperation of all the partners who were involved in its development.

WHO MEDICINES STRATEGY: FRAMEWORK FOR ACTION IN ESSENTIAL DRUGS AND MEDICINES POLICY 2000-2003

3. The strategy incorporates four main objectives: **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).

POLICY

4. The strategy and its associated activities are designed to cover many components of a national drug policy and an essential drugs programme, and to ensure that WHO's work related to pharmaceuticals is internally consistent and of maximum practical benefit to national programmes.

¹ WHO medicines strategy: framework for action in essential drugs and medicines policy 2000-2003, Geneva, WHO, 2000 (document WHO/EDM/2000). See also summary version: WHO medicines strategy: 2000-2003. WHO Policy Perspectives on Medicines, No.1. December 2000. Geneva, WHO, 2000 (document WHO/EDM/2000.4).

5. WHO continues to promote **national drug policies** and the concept of essential drugs as proven strategies for securing integrated and sustainable supply systems and services for such drugs. At the end of 1999, 66 countries had introduced official national drug policies within the past 10 years, and a further 41 countries were developing such policies, or had developed them more than 10 years ago. In early 2001, after a five-year global consultative process, the text of the second edition of *Guidelines for developing national drug policies* was finalized.

6. WHO's first priority in this strategic area remains the provision to countries of **policy and technical support** and associated activities are being strengthened.

7. In 2000, support for the formulation and implementation of national drug policy was given to Chad, China, Colombia, Lao People's Democratic Republic, Oman, Romania, and other countries. Two-week international courses on this specific subject were held in Brazil (with the National School of Public Health, Rio de Janeiro) and Lebanon (with the Inter-Ministerial Council for Health Reform in Lebanon and Boston University, United States of America). In the Philippines, a regional course allowed countries to share their current economic and political perspectives of health systems, thereby encouraging them to update their national drug policies.

Access

8. A global framework for expanding access to essential drugs has been built on the basis of the WHO medicines strategy, the work of UNAIDS and other United Nations agencies on access to HIV-related drugs, and the outcomes of the Director-General's round tables with the pharmaceutical industry and public interest groups. The framework has four central components: (1) rational selection and use of drugs (defining what is most needed and using it effectively); (2) affordable prices (reducing costs and promoting competition); (3) sustainable financing (through a variety of financing sources for drugs and medical supplies); and (4) reliable health and supply systems (ensuring efficiency, accessibility and quality). Measurement of access to essential drugs is being refined through definition of relevant indicators. Efforts to make prices affordable have included promotion of generic drugs, advocacy for the equity pricing concept, wider dissemination of information about drug prices, and designing methods for surveying drug prices.

9. **Access to drugs.** Access to HIV-related drugs is being increased through work with UNAIDS, UNICEF and other partners. In 2000, support was provided to 12 African countries, for example through the International Partnership against AIDS in Africa to integrate access to drugs for HIV-related conditions into national essential drugs programmes. WHO also collaborated with United Nations and other partners on: financing for, and reduction in price of, HIV-related drugs; providing information on prices and patent status of such drugs; determining the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on access to such drugs in francophone Africa; and quality-related issues for generic HIV-related drugs. A pilot project with UNICEF, UNFPA, UNAIDS and the World Bank on pre-qualification of suppliers for HIV-related drugs is intended to lead to a uniform pre-qualification system for pharmaceutical procurement. With respect to malaria, the Roll Back Malaria programme has undertaken considerable work on quality and availability of antimalarial agents, and an action paper has been written with research-based pharmaceutical industry on access to such drugs. Work has also been intensified on access, quality and rational use of drugs for tuberculosis, childhood illness and other priority health problems.

10. **Generic drugs** can be between 50% and more than 90% cheaper than equivalent branded drugs. However, large markets for generic drugs have developed in relatively few countries. WHO-sponsored research has identified four critical factors for the growth of national markets for generic drugs: appropriate legislation and regulations; reliability of and capacity for quality assurance; professional

and public acceptance of generic drugs; and economic incentives and information for prescribers and consumers.

11. WHO has been championing, with several partners, the concept of **differential pricing** whereby low-income countries would systematically pay less than high-income countries for essential drugs. This idea is being pursued through negotiations with pharmaceutical companies on individual products (for example, antimalarial and HIV-related drugs) and through a broader process of policy formulation. Also, WHO and WTO held an international workshop in early 2000 on “Differential pricing and financing of essential drugs” (in Hosbjar, Norway), which included participants from academia, industry, governments, nongovernmental organizations and consumer groups.

12. WHO continues to make **drug price information** widely available through: the *International Drug Price Indicator Guide* (with Management Sciences for Health), which includes prices and selected references on finished essential drug products for nearly 300 active ingredients in over 500 dosage forms; *Selected drugs used in the care of people living with HIV: sources and prices* (with UNICEF, UNAIDS and *Médecins sans Frontières*), which provides twice yearly information on prices, sources and therapeutic use for more than 36 HIV-related drugs in more than 60 dosage forms, including antiretroviral agents and medicines for opportunistic diseases and palliative care; and the *Pharmaceutical starting materials/essential drugs report* (with WTO and UNCTAD International Trade Centre), which provides prices and source information on active ingredients for more than 200 essential drugs.

13. A project was initiated with several nongovernmental organizations and a private foundation to standardize **methods for drug price surveys**, with the aim of increasing the quantity, quality, comparability and transparency of information. Prices for selected essential drugs will be collected for different subsectors of the health system in several countries. Once tested, the methods will be made widely available to enable data collection to be extended to other countries. A first meeting of the project’s technical advisers was held in the Netherlands in January 2001.

14. Work has continued on the identification of best practices in **sustainable financing** and optimal resource allocation based on a mix of funding channels – public financing, health insurance, donor assistance, development loans and cost-sharing with patients. At the third meeting of the working group on drug financing, organized by the Regional Office for South-East Asia (Kathmandu, May 2000), participants from Indonesia, Nepal, Myanmar and Thailand reviewed prepayment schemes for health and drugs operating in their countries. They proposed strategies for developing national social health insurance systems and for improving drugs benefits in health insurance schemes in the region. They paid special attention to assessing how the Asian economic downturn (starting in 1997) has affected health and drugs financing in Indonesia and Thailand.

15. Considerable activity has also taken place in the countries of both central and eastern Europe (CCEE) and western Europe, with respect to reimbursement for drug expenditure. The health authorities responsible for the pharmaceutical policies of 29 countries created the Pricing and Reimbursement Information Network on Medicines in Europe, to extend use of pharmacoeconomic data in making reimbursement decisions.

16. **Reliable health and supply systems.** Reliable procurement, distribution and dispensing of pharmaceuticals depend on countries effectively dealing with such issues as good management practices, decentralization, the combination of public, private and nongovernmental organizations in supply functions, and integration of supplies for disease-specific programmes. An international study was started to analyse experiences with successful drug distribution strategies in relation to health

sector reform and privatization. In addition, support was provided to Armenia, Georgia and Kyrgyzstan, among other countries.

17. Training to rebuild and to make supply systems more effective has been undertaken. WHO is also contributing to international supply training, such as the Commonwealth Pharmaceutical Society correspondence course and the annual training programme of Management Sciences for Health and the International Dispensary Association. Additionally, a core curriculum and training materials on pharmaceutical care are being developed for undergraduate pharmacy training.

18. Amidst much debate WHO continues to support countries to formulate their own informed approaches to health and **trade**. In June 2000, ministers of health of the Southern African Development Community (SADC) were briefed on the implications for African countries of international trade agreements. Additionally, policy guidance on patent issues and on revision of national pharmaceutical legislation to incorporate safeguards contained in the TRIPS agreement was provided in response to individual requests (from China, Costa Rica, Islamic Republic of Iran and South Africa, as well as from countries of the Southern African Development Community and ASEAN) and in May 2000 at a joint ASEAN-WHO workshop on the TRIPS Agreement and its impact on pharmaceuticals (held in Jakarta). Concurrently, WHO initiated monitoring and analysis of the impact of trade agreements on essential drugs in partnership with four WHO collaborating centres (in Brazil, Spain, Thailand and United Kingdom of Great Britain and Northern Ireland). Finally, after a two-year process, WTO's TRIPS Council accorded WHO observer status on an ad hoc basis. WHO can now monitor all relevant issues under discussion at WTO that may have implications for the health sector.

Quality and safety

19. **Information and guidance.** Much of WHO's work on quality and safety comprises provision of advice based on the best information available. Recent examples include: producing the first draft protocol for screening tests (using thin-layer chromatography) for antimalarial and antituberculosis drugs; drafting and/or review of 10 new quality assurance guidelines; and outlining guidance on global good practices in trade and distribution. A new issue of the *WHO pharmaceuticals newsletter* was published, incorporating material provided by the Uppsala Monitoring Centre (a WHO Collaborating Centre for International Drug Monitoring in Sweden). Increasingly, information on quality and safety is being made available on the WHO Web site for easy reference and the widest possible access.

20. Much of WHO's activity in **national drug regulation** consists of building capacity. Several courses have been held, including one in Ghana on drug regulation and quality assurance for African drug regulatory authorities, and another in Zimbabwe for drug analysts, both in September 2000. In the same month, WHO and the national drug regulatory authorities of Portugal and Spain cosponsored the annual Conference of Ibero-American Drug Regulatory Authorities in Costa Rica. In December 2000 WHO ran a workshop to improve monitoring and control of drug importation for all countries of the South-East Asia Region and Tunisia. At global level, WHO participated in planning for the Tenth International Conference of Drug Regulatory Authorities (to be held in Hong Kong Special Administrative Region of China, November 2001). At operational level, the WHO Multicountry Working Group on Effective Drug Regulation completed its study of the most effective approaches to drug regulation.

21. In the area of **information support for drug regulation**, WHO has undertaken collaborative projects with the European Agency for the Evaluation of Medicinal Products on developing computerized systems. It has helped to strengthen computer-assisted drug registration in several countries. A project to create a WHO model Web site for national drug regulatory authorities was

launched to make drug regulatory information more accessible and more widely available. An additional project – the International Comparative Study on Drug Information – has also been initiated together with the International Society of Drug Bulletins and two WHO collaborating centres.

22. **Harmonization of drug regulation** helps to identify and eliminate duplication of studies undertaken to meet different drug regulatory requirements, promotes more effective use of resources for research and development, speeds up patients' access to safe and effective new medicines, and improves transparency and conformity of standards. A workshop on harmonizing drug registration was held in South Africa in November 2000 for representatives of the South African Development Community. A comprehensive joint ASEAN-WHO project, "ASEAN Drug Regulatory Harmonization: A Tool to Ensure Drug Quality, Safety and Efficacy", will be launched in 2001. WHO's continued participation as an observer in the Steering Committee of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) enabled the organization to continue to liaise between countries that are members of ICH and those that are not.

23. Introduced by WHO in 1950, the system of recommended **International Nonproprietary Names** (INNs) aims at protecting the safety of patients through the identification of each pharmaceutical substance or active pharmaceutical ingredient by a unique name that is universally recognized and accessible as public property. In 2000, a further 120 INNs were recommended. All published INNs are or soon will be, available on the Internet in the six official languages of the United Nations.¹ Additionally, an Internet-based exchange service has been established for all those involved in application of INNs.

24. Certification of **good manufacturing practice** (GMP) is a system for ensuring that pharmaceutical products are consistently produced according to quality standards. Recent activities to promote GMP include: finalizing the WHO GMP basic training modules; production of GMP video and CD-ROM, and of GMP campaign materials in all six official United Nations languages; and organization of national GMP workshops in Cambodia, China, the Philippines and South Africa.

25. **Counterfeit drugs** can prolong treatment periods, exacerbate conditions being treated, cause death, help create drug resistance and are a waste of money. Activities to combat counterfeit drugs included awareness-raising through a technical briefing at the Fifty-third World Health Assembly.

Rational use

26. Over the past 12 years, WHO has produced nearly 200 treatment guidelines. Covering the world's major diseases they are used as the basis for national and institutional treatment protocols and essential drugs lists, training programmes and drug supply systems. In 2000, 192 treatment guidelines were evaluated and summarized. The summaries are being made available in printed and electronic form (on the WHO Web site and CD-ROM). Standard procedures (with a checklist) for preparing treatment guidelines, and for linking the Model List of Essential Drugs with the guidelines and the WHO Model Formulary were also formulated. While the global process for developing treatment guidelines was under review, support was given to Member States, including Armenia, Georgia, several states in India, Kyrgyzstan, Mongolia and Tajikistan.

27. Like the WHO treatment guidelines, the **WHO Model List of Essential Drugs** sets out those drugs that are effective, safe and offer good value for money in comparison with other drugs and

¹ INNs in English, French, Spanish and Russian, as well as Latin, are available at <http://mednet.who.int>.

treatment alternatives. To bring it up to date, various changes are under consideration including: application review procedures and reporting to be standardized and made transparent; selection of essential drugs to be closely linked to WHO treatment guidelines; decisions on inclusion to be based on evidence rather than consensus; evaluation of safety and efficacy to be separated from cost considerations; continual rather than two-yearly updates; and electronic publication in all major languages. A wide consultative process has been started on revising the methods of updating and disseminating the WHO Model List.

28. Training remains an important means of improving rational use skills. Courses to promote rational drug use were held in Indonesia (October 2000) and Nigeria (July 2000) in collaboration with the International Network on Rational Use of Drugs, and a drug selection workshop was held in Peru (June 2000). Additionally, the pharmacy and therapeutics committee responsible for promoting rational drug use in 12 of Colombia's 34 provinces was strengthened. In the European Region, rational use is increasingly promoted through cross-country collaboration. Health professionals from ministries of health and health insurance institutions from 20 European countries met to compare national approaches to rationalizing drug use through development of formularies and guidelines, innovative use of drug information and information technology, and local structures for supporting prescription practices.

29. **Drug and therapeutics committees**, at hospital or provincial level, help to ensure appropriate and efficient drug use. WHO has produced the first version of a manual on establishing and running such committees, and international courses and regional workshops will be held on this subject during 2001.

30. **Public education** is essential if drugs are to be used more rationally and wasteful household expenditure on drugs is to be reduced. New modules on this subject were tested at the first international two-week course on promoting rational drug use in the community in Thailand in October 2000. The long-term aim is to develop a network of trained people, committed to implementing community education in rational drug use, with evaluation of the impact of their work, reporting on experience and sharing of expertise. Design and implementation of community-based intervention projects to promote more rational use of antibiotics for infectious diseases at household level also continued as part of an initiative with several universities and nongovernmental organizations.

Cross-cutting areas of work

31. **Traditional medicine** is an accessible and affordable health care resource for many developing country populations. It is also increasingly used in developed countries. For instance, three-quarters of HIV-positive people in Africa and North America use traditional medicine or complementary and alternative medicine. However, although promising indications of efficacy exist for some herbal products and traditional practices such as acupuncture, substantial work is needed to establish a solid base of evidence. In 2000, the WHO strategy for traditional medicine 2001-2005 was formulated to enable traditional medicine to contribute much more to reducing excess mortality and morbidity. Like the WHO Medicines Strategy, it has four objectives relating to policy, access, quality, safety and efficacy and rational use.

32. In 2000, specific activities relating to traditional medicine focused on treatment for major diseases such as HIV/AIDS and malaria, and on normative work. Work included: selection of three herbal antimalarial formulations for clinical trial; drafting of a Technical Update for HIV/AIDS programme managers on clinical validation of traditional medicine in cooperation with UNAIDS; publication of general guidelines for methodologies on research and evaluation of traditional

medicines;¹ and finalizing of a worldwide review on the Legal Status of traditional and complementary/alternative medicine.

33. **To monitor and evaluate the WHO medicines strategy;** 26 indicators at country level, corresponding to the target outcomes in the strategy, are being used to analyse country, regional and global pharmaceutical situations and progress. They represent pharmaceutical components and strategies that are vital for delivering effective health services.

Working collaboratively

34. The diverse and broad areas of work outlined in the WHO medicines strategy demand collaboration with other bodies. WHO has strengthened its own work on quality assurance, safety and efficacy, evaluation of treatment guidelines, increasing access to essential drugs for priority diseases and drug development. The Organization is a member of the Interagency Pharmaceutical Coordination (IPC) Group, which now includes all five United Nations agencies most concerned with access, quality and rational use of pharmaceuticals (WHO, World Bank, UNICEF, UNFPA and UNAIDS). The group addresses such issues as global and country-level coordination, pharmaceutical procurement practices and improving drug donations. Significant collaboration to extend the impact of WHO's work in pharmaceuticals has been set in train with **other partners**, such as the European Commission, WIPO, WTO and the Council of Europe.

35. The Director-General's **round-table talks** have continued with the research-based pharmaceutical, generic drug and self-medication industries, and with public-interest nongovernmental organizations. The round tables have led to new projects and approaches for tackling health problems by increasing access to antimalarial agents, improving drug quality, developing methods for drug price surveys and documenting and critically evaluating drug promotion.

ACTION BY THE HEALTH ASSEMBLY

36. The Health Assembly is invited to note the report.

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¹ Document WHO/EDM/TRM/2000.1.