



WORLD HEALTH ORGANIZATION

MEETING OF INTERESTED PARTIES

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Essential medicines: access, quality and rational use – highlights of 2000

1. The *WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2000-2003*¹ is being implemented with WHO's full range of partners in pharmaceuticals. The strategy incorporates four main objectives (policy; access; quality and safety; and rational use) and 26 country progress indicators corresponding to the Strategy's target outcomes.

POLICY

2. **Direct policy and technical support to countries** remains the priority in essential drugs and medicines policy. Strengthened support included preparations for a five-person essential drugs and medicines policy unit in the Regional Office for Africa and for appointing WHO national essential drugs advisers in seven countries. Specific country support on **national drug policy development, implementation and monitoring** was given to Chad, China, Colombia, the People's Democratic Republic of Laos, Mongolia, Namibia, Oman, Papua New Guinea, Romania and the former Yugoslav Republic of Macedonia. International two-week courses on developing and implementing national drug policy were held in Lebanon (with the Inter-ministerial Council for Health Reform in Lebanon and Boston University) and Brazil (with the National School of Public Health). In the Philippines, a regional course helped countries share the latest economic and political perspectives on health systems in their region, thereby encouraging them to update their national drug policies.

ACCESS

3. Through the *WHO Medicines Strategy*, the work of UNAIDS and other organizations of the United Nations system on access to HIV-related drugs, and the Director-General's round tables with the pharmaceutical industry and public interest groups, a **global framework for expanding access to**

¹ Document reference WHO/EDM/2000.1. See also summary version: *WHO Medicines Strategy: 2000-2003. WHO Policy Perspectives on Medicines, No. 1. December 2000*. Geneva, World Health Organization, 2000 (document reference WHO/EDM/2000.4).

essential drugs emerged. **Work to increase access¹ to HIV-related drugs** was undertaken with UNAIDS, UNICEF and other partners. Support was provided to 12 African countries, including under the International Partnership Against HIV/AIDS in Africa, to integrate access to HIV-related drugs in national essential drugs programmes. Work was also undertaken on: financing and price reduction for HIV-related drugs; information on prices and patent status of HIV-related drugs; the impact of the Trade Related Aspects of International Property Rights Agreement (TRIPS) on access to HIV-related drugs in francophone Africa; and quality-related issues for generic HIV-related drugs. With respect to malaria, work on the quality and availability of antimalarials was undertaken with Roll Back Malaria and an action paper developed with the research-based pharmaceutical industry on access to antimalarials. Work was also intensified on access, quality and rational use of drugs for tuberculosis and childhood illness.

4. WHO-sponsored research on **promoting generic drugs** established that four factors are key to developing national generic drug markets: appropriate legislation and regulations; reliable quality assurance capacity; professional and public acceptance of generic drugs; and economic incentives and information for prescribers and consumers. WHO plans to follow up this research with policy guidance for developing countries on how to promote a larger role for generic drugs in creating access to affordable health care.

5. The **differential pricing concept** was pursued through negotiations with pharmaceutical companies on individual products and a policy development process. Together with WTO, an international workshop was held in April on *Differential Pricing and Financing of Essential Drugs*, in Høsbjar, Norway. In order to compare drug prices, a project was initiated with several nongovernmental organizations and a private foundation to develop standardized **drug price survey methodology**. Existing **drug price information** continued to be made widely available through work with partners on three price information services on essential drugs, HIV-related drugs and starting materials.

6. WHO also continued **helping countries to develop their own informed approaches to health and trade**.² For example, policy guidance on patent issues and revision of national pharmaceutical legislation to incorporate safeguards of the Agreement on TRIPS was given to China, Costa Rica, Islamic Republic of Iran, South Africa, the Southern African Development Community (SADC), and at a joint ASEAN-WHO workshop in May on the TRIPS Agreement. Concurrently, WHO initiated monitoring and analysis of the impact of trade agreements on health with four collaborating centres.

7. Work also continued on identifying **best practices in financing and optimal resource allocation** based on a mix of funding channels. In May the Regional Office for South-East Asia working group on drug financing met in Nepal to review prepayment schemes for health and drugs, and to propose strategies for developing national social health insurance systems and improving drugs benefits in health insurance schemes in the region. Considerable activity also took place in the countries of Central and Eastern Europe and Western Europe regarding **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 guidance in making reimbursement decisions.

¹ See *Access to Essential Drugs. WHO Policy Perspectives on Medicines, No. 2*. Geneva, World Health Organization, 2001 (document reference WHO/EDM/2001.1).

² See *Globalization, TRIPS and Access to Pharmaceuticals. WHO Policy Perspectives on Medicines, No. 3*. Geneva, World Health Organization, 2001 (document reference WHO/EDM/2001.2).

8. At operational level an international study was started to analyse successful **drug distribution strategies** within the context of health sector reform and privatization. Country support was provided to Armenia, Georgia and Kyrgyzstan, among other countries, and training to make **supply systems** (for example, in Peru and Tajikistan) more effective and to rebuild supply systems (for example in Kosovo) continued. WHO also participated in 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.

QUALITY AND SAFETY

9. **Provision of information and guidance** included: producing the first draft of screening tests for antimalarials and anti-tuberculosis drugs; drafting and/or review of 10 new quality assurance guidelines; and outlining guidance on good trade and distribution practices. A new version of the *WHO Pharmaceuticals Newsletter* was issued, incorporating material from the Uppsala Monitoring Centre. Increasingly, quality and safety information is being made available on the WHO web site.

10. Several courses were held, including one on **drug regulation and quality assurance** in Ghana for African drug regulatory authorities, and another in Zimbabwe for drug analysts, both in September. Also in September, WHO and the national drug regulatory authorities of Spain and Portugal cosponsored the Annual Conference of Ibero-American Drug Regulatory Authorities in Costa Rica.

11. In terms of **supporting the work of drug regulatory authorities**, the **WHO Multicountry Working Group on Effective Drug Regulation** completed its study of effective approaches to drug regulation, and collaborative projects were undertaken with the European Agency for the Evaluation of Medicinal Products to develop computerized drug registration systems. WHO also ran a workshop, in December, to improve **monitoring and control of drug importation** for all countries of the South-East Asia Region and Tunisia. Another workshop — on **harmonizing drug registration** — was held in South Africa in November for SADC representatives. A comprehensive joint ASEAN-WHO project — ASEAN Drug Regulatory Harmonization: A Tool to Ensure Drug Quality, Safety and Efficacy — was developed. WHO also continues to participate as an observer in the Steering Committee of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

12. A further 120 **International nonproprietary names (INNs)** were selected and all INNs translated into Arabic, Chinese, French, Latin, Russian and Spanish. Additionally, an internet-based exchange service was established for all those involved in applying INNs.

13. Six **psychoactive substances** were assessed and a recommendation made to the United Nations Commission on Narcotic Drugs to place four of the drugs assessed under international control. Other activities included development and promotion of balanced drug control policies and guidelines to improve access to opioid analgesics.

14. Activities to promote **good manufacturing practice (GMP)** implementation included: finalizing the WHO GMP basic training modules; production of a GMP video and CD-ROM, and of GMP campaign materials in all six official languages of the United Nations; and organization of national GMP workshops in Cambodia, China, the Philippines and South Africa. **Combating counterfeit drugs** included awareness-raising through a technical briefing at the Fifty-third World Health Assembly.

RATIONAL USE

15. Over 190 **treatment guidelines** were evaluated and summarized. The summaries are being made available on the WHO web site, as a CD-ROM and in hard copy. Standard procedures and a checklist for developing WHO treatment guidelines, and standard procedures for linking the *WHO Model List of Essential Drugs* with WHO treatment 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.

16. Changes for **modernizing the WHO Model List of Essential Drugs** were proposed including: standardized and transparent application review procedures and reporting; close linking of selection of essential drugs to WHO treatment guidelines; evidence-based rather than consensus-based decisions; separation of safety-efficacy evaluation from cost considerations; “real-time” rather than two-yearly updates; and electronic publication in all major languages.

17. **Promoting rational drug use** courses were held in Nigeria and Indonesia in July and October respectively, in collaboration with the International Network on Rational Use of Drugs. In Peru, a drug selection workshop was held in June. 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, health professionals from ministries of health and health insurance institutions met to compare national approaches to rationalizing drug use through formulary and guidelines development, innovative use of drug information and information technology, and local structures for prescribing support.

18. The first version of a manual on establishing and running **drug and therapeutics committees** was produced. New modules on **public education in rational drug use in the community** were tested at a first international two-week course in Thailand in October. Development and implementation of community-based intervention projects to promote more rational use of antibiotics for infectious diseases at household level also continued.

CROSS-CUTTING AREAS OF WORK

19. The *WHO Strategy for Traditional Medicine 2001–2005* was produced to enable traditional medicine to play a far greater role in reducing excess mortality and morbidity, including mainstreaming traditional medicine in national health systems. Specific activities relating to traditional medicine focused on treatment with traditional medicine for major diseases such as HIV/AIDS and malaria, and normative work.

WORKING COLLABORATIVELY

20. At headquarters **collaboration between programmes and clusters on drug issues** was enhanced on quality assurance, safety and efficacy, evaluation of treatment guidelines, increasing access to essential drugs for priority diseases and drug development.

21. The **Interagency Pharmaceutical Coordination (IPC) Group** expanded to include all four United Nations agencies most concerned with access, quality and rational use of pharmaceuticals – UNFPA, UNICEF, UNAIDS, WHO – and the World Bank.

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

23. **Significant collaboration to extend the impact of WHO's work in pharmaceuticals** took place with the European Commission, WIPO, WTO, the Council of Europe and many others.

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