



WORLD HEALTH ORGANIZATION

FIFTY-THIRD WORLD HEALTH ASSEMBLY
Provisional agenda item 12.8

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Revised drug strategy

Report by the Secretariat

1. Resolution WHA52.19 (1999) on the revised drug strategy addresses challenges in the areas of international trade agreements, access to essential drugs, drug quality, and rational use of medicines. The resolution builds on the original revised drug strategy, adopted by the Health Assembly in resolution WHA39.27 (1986), and updated at successive Health Assemblies. This strategy identified principles and goals for WHO's work in the pharmaceutical sector. Current work on key areas highlighted in resolution WHA52.19 are summarized in the following paragraphs.

2. **National drug policies.** By the end of 1999 nearly 106 Member States had framed national drug policies and 146 had drawn up national lists of essential drugs. Support continues to be provided for policy development, implementation and monitoring, with a particular focus on moving from policy to implementation and on evaluating policy impact. The document entitled Indicators for monitoring national drug policies has been revised and issued as a second edition. Meanwhile, core indicators for monitoring national drug policies are being field-tested. They will constitute a highly practical tool for monitoring not only implementation of drug policy, but also the impact of WHO's work in this area. Additionally, new *Guidelines for developing national drug policies* will be published shortly. Tools and strategies to ensure the introduction of a gender perspective into national drug policies are also being developed. Support for implementation of national drug policy also extends to collaboration on drug financing, and drug management and supply. At global level, a database on the world drug situation has been compiled.

3. **Pharmaceuticals and trade.** Advice is being provided to countries on the new international economic environment, within the framework of national drug policies. Guidance is being prepared in response to queries from Member States about the relationship between international agreements and such subjects as drug prices, innovation and local production, the use of exceptions, transfer of technology, licensing arrangements, and the transition period for least developed countries. An updated bibliography on globalization, patents and drugs – of use to countries in researching such issues themselves – has been finalized. Simultaneously, methods for monitoring the pharmaceutical and public health implications of new agreements are being developed together with WHO collaborating centres in Brazil, Thailand and the United Kingdom of Great Britain and Northern Ireland. Cooperative work is also proceeding with UNAIDS on trade agreements and access to HIV-related drugs. A contact group has been set up of interested parties from WHO, WIPO, UNCTAD and WTO.

4. **Drug quality.** Mechanisms are being devised to extend the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce to cover control of starting materials and to provide guidance on quality issues related to trade. At the same time, monographs are being drafted for inclusion in *The international pharmacopoeia* for drugs listed in the Model List of Essential Drugs, including antimalarial and antituberculosis drugs. Basic tests are also being

developed for these drugs. More recent work has involved assembling screening tests for antimalarial and antituberculosis drugs. These activities accord with a step-by-step approach to quality control.

5. A major training and technical cooperation project to strengthen WHO good manufacturing practices (GMP) is well under way. GMP basic training modules and a model inspection certificate for national inspection of pharmaceutical manufacturing sites of starting materials and finished pharmaceutical products are being drafted. The aim is to ensure compliance with WHO's GMP. Implementation is being planned in collaboration with Member States.

6. **Drug information and drug promotion.** The eleventh Model List of Essential Drugs was published in *WHO drug information* in late 1999 and the full report of the Expert Committee on the Use of Essential Drugs (held in November 1999) will be produced late in 2000. Publication of the WHO Model Formulary is also expected in 2000. Meanwhile, WHO and interested parties are working on ways to operationalize WHO's *Ethical criteria for medicinal drug promotion* and develop tools to monitor their implementation. A project to examine critically evidence of inappropriate drug promotion worldwide is also moving ahead.

7. **Drug donations.** WHO continues actively to promote implementation of good donation practices as the basis of its strategy to improve drug donations. Good practices are described in the revised Guidelines for drug donations issued in August 1999 and cosponsored by 15 organizations with experience in emergency humanitarian relief.¹ A scheme has been launched for organizations and pharmaceutical companies to endorse the guidelines publicly. The WHO website lists 11 pharmaceutical companies, three pharmaceutical umbrella organizations and eight nongovernmental organizations which have endorsed the guidelines, and provides information on how unhelpful donations can be reported to WHO. Infringements of good donation practices will be treated on a case-by-case basis and repeated infringements publicized.

8. **Expanding partnerships.** WHO is increasingly working in collaboration with bodies such as UNICEF, the World Bank, other organizations of the United Nations system, *Médecins sans Frontières*, and nongovernmental organizations and with the private sector on access to essential drugs. This work should maximize the impact of WHO pharmaceutical policies and programmes and broaden support for the revised drug strategy.

9. **Looking to the future.** WHO areas of responsibility outlined in resolution WHA52.19 will be reflected in the broader WHO strategic plan for essential drugs and medicines policy, 2000-2003, which is being prepared at all levels of WHO and with a wide range of development partners. In particular, the strategy outlines work to be undertaken to increase access to drugs for treating priority health problems: malaria, childhood illness, HIV/AIDS and tuberculosis – diseases that particularly affect poor and vulnerable populations, keep them entrapped in poverty, and substantially slow development. Emphasis is being placed on securing adequate financing for essential drugs (through government revenues and social health insurance), making essential drugs affordable (for governments and consumers), and establishing reliable supply systems for essential drugs (through a mix of public and private services). Indeed, the competing demands that many Member States face for medicines for priority health problems mean that national essential drugs programmes are needed more than ever before.

¹ Document WHO/EDM/PAR/99.4.

ACTION BY THE HEALTH ASSEMBLY

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

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