

## **Progress reports**

### **Report by the Secretariat**

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## **I. RATIONAL USE OF MEDICINES**

1. In resolution WHA60.16, the Health Assembly requested the Director-General to strengthen WHO's leadership in promoting rational use of medicines by undertaking evidence-based advocacy; supporting countries to implement national programmes; strengthening coordination of international support; promoting international research on sustainable interventions; and promoting discussion among health authorities, professionals and patients.

2. This approach has been approved by all six WHO regions, but implementation has not yet begun and resources are being sought.

3. Technical support to countries on various aspects of promoting rational use of medicines has continued on the basis of specific requests and involving discussion among health authorities, professionals and patients. Areas of support have included the following:

- review of essential medicines lists, development and implementation of clinical guidelines, monitoring medicine-use practices, undertaking focused interventions, and training health professionals and consumers;
- publication of new WHO recommendations for the management of infections in childhood – oral rehydration solution and zinc treatment for diarrhoea, and a three-day instead of a five-day course of antibiotics for pneumonia, both these measures being based on research findings and having the potential to reduce irrational use of antibiotics;
- preparation of a technical document entitled “Pharmacological treatment of mental disorders in primary health care”,<sup>1</sup> which provides evidence-based information on the use of psychotropic medicines for common mental and substance-use disorders in primary care, particularly in low- and middle-income countries;
- continued operation of the tuberculosis control strategy (known as DOTS), currently operating in 183 countries, which had treated 31.8 million cases by 2006. In addition, 46 000 patients with multidrug-resistant tuberculosis in 56 countries have been treated with quality-assured second-line tuberculosis medicines after approval of the Green Light Committee. However, over-the-counter availability and misuse of tuberculosis medicines remain major concerns that health authorities and professionals must address jointly with consumers.

## **J. BETTER MEDICINES FOR CHILDREN**

4. In resolution EB121.R2, the Executive Board decided to establish a temporary subcommittee of the Expert Committee on the Selection and Use of Essential Medicines, in order to prepare a list of medicines for children. The subcommittee met in July 2007 and September 2008, and in October 2007

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<sup>1</sup> *Pharmacological treatment of mental disorders in primary health care*. Geneva, World Health Organization, in press.

the Expert Committee approved the report<sup>1</sup> of the July 2007 meeting containing the first WHO Model List of Essential Medicines for Children. In preparing the List, the Expert Committee took account of the priority diseases identified in resolution WHA60.20 and WHO treatment guidelines. Many important research and produce gaps were identified. At its September 2008 meeting, the subcommittee recommended further work to maintain and expand the List, but noted that this could be done only by an appropriately constituted Expert Committee rather than by the subcommittee. The subcommittee's report will be considered at the March 2009 meeting of the Expert Committee.

5. In order to promote application of the List and treatment guidelines, WHO has received donor support from the Government of the Netherlands and the Bill & Melinda Gates Foundation for a three-year programme of work commencing in 2009 that includes promoting national standards for medicines for children, the availability of child-specific medicines, and developing strategies with Member States to enhance access to, and ensure better use of, essential medicines for children.

6. Work on the List has involved several departments. The List includes "ideal" fixed-dose combinations for treatment in HIV/AIDS; similar specifications for tuberculosis medicines; and medicines suitable for use in neonates. In WHO regions, work has begun to promote national adoption of the List, on a multicountry survey of availability of medicines for children in Africa, and on organizing regional workshops in the South-East Asia and Western Pacific Regions.

7. A two-day pre-conference was held before the 2008 International Conference of Drug Regulatory Authorities to discuss regulation of medicines for children. As a result, an international regulatory working group will be formed to review existing standards for regulation of these medicines and to enhance the availability of quality medicines for children. WHO's Expert Committee on Specifications for Pharmaceutical Preparations is producing a guidance document on the development of paediatric medicinal products, to be included in the Committee's report, as agreed at its October 2008 meeting.

8. Funding was received for a formulary based on the List as a source of independent information on essential medicines for children. Developed in consultation with Member States, it can be adapted to national needs. Work has begun on updating key treatment guidelines on medicines for children, including the Integrated Management of Childhood Illness guidelines.

9. WHO's advocacy campaign, known as Make Medicines Child Size, launched in December 2007, has been endorsed by pharmaceutical industry, through the International Federation of Pharmaceutical Manufacturers & Associations, civil society organizations including *Médecins Sans Frontières* and Caritas Internationalis, professional associations and organizations such as UNICEF, the European Medicines Agency and the National Institutes of Health in the United States of America. WHO worked closely with UNICEF to develop the List and will shortly publish the first report on sources and prices of medicines for children.

## **K. HEALTH TECHNOLOGIES**

10. In resolution WHA60.29 the Health Assembly requested the Director-General to provide support to Member States in the prioritization, selection, and use of health technologies, in particular

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<sup>1</sup> WHO Technical Report Series, No. 950, 2007.

medical devices. It calls for extensive efforts to disseminate evidence-based guidance on health technologies as an aid to the prioritization of needs and allocation of resources in order to increase equity, quality and safety in health services. This report summarizes the progress made as a result of collaborative efforts between WHO and international, regional and national partners.

11. The extensive deliberations of the Executive Board at its 118th, 120th and 121st sessions shaped and gave a major impetus to a process of consultation with United Nations organizations and industry, and to mobilization of resources. Funding was obtained in April 2008 from the Bill & Melinda Gates Foundation for a period of three years, which enabled the Secretariat to begin work on guidelines and tools, including norms, standards and a glossary of definitions. These instruments will include a medical device nomenclature system; an inventory management system; guidelines for decision-makers on the procurement and donation of health technologies, particularly medical devices; and guidelines and associated training modules on preventive and corrective maintenance.

12. Work has commenced on a WHO-recommended standardized nomenclature system with a glossary of definitions. An informal expert consultation was held in January 2008 with participation by nomenclature users, organizations providing nomenclatures and health-technology management professionals. The outcome was an agreement on the requirements and technical specifications for the WHO-recommended system and the identification of a network of main stakeholders.

13. WHO has collaborated with regulatory authorities and industry umbrella organizations in encouraging and facilitating the involvement of Member States in an international exchange of information on regulatory actions in relation to medical devices. Training on regulatory issues pertaining to medical devices was held in October 2007 in the United States of America and China, organized by the Global Harmonization Task Force on Medical Devices and the Asian Harmonization Working Party on Medical Devices, respectively. Regulatory authorities that participated in these events are entitled to be connected to the National Competent Authority Reporting System, an international network on regulatory action that was established to standardize reporting practices and inform health authorities of potential risks associated with the use of certain medical devices.

14. Work has begun on the preparation of guidelines on the formulation of health-technology policies and action plans that are appropriate for specific or priority diseases and levels of care. Next steps include the finalization of a draft guideline document and its validation by experts from Member States.

15. A priority medical-devices project was established in 2007 in collaboration with the Government of the Netherlands. A general methodology has been developed to identify where availability of medical devices for use in the management of the 15 highest-burden diseases worldwide is lacking. A survey is in progress to assess the gap between needs and availability. In addition, a separate activity has been initiated for identifying assistive medical devices (such as wheelchairs) used in the rehabilitation of impairments (such as walking impairment) related to high-burden diseases. The final report will be published in mid-2009.

16. An informal expert consultation, organized with the Region of the Americas (Washington DC, 2008), laid the foundations of the web-based clearing house for health technologies by defining the proposed intended users, the type of information to be included and general management rules for its functioning. A group to oversee implementation was established, including representatives of government organizations, WHO Collaborating Centres, professional associations and industry.

17. The Secretariat organized a process of consultation (Geneva, June 2008) involving health technology-related collaborating centres, relevant organizations of the United Nations system, professional bodies and nongovernmental organizations for the development of guidelines and tools.

**ACTION BY THE EXECUTIVE BOARD**

18. The Board is invited to note these reports.

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