



Implementation of resolutions and decisions

Report by the Director-General

This document presents progress reports on the implementation of resolutions and decisions of the Executive Board and the Health Assembly. The Board is invited to note the reports.

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I. HEALTH SYSTEMS DEVELOPMENT

1. Concerned with the slow pace of health systems development in countries, the Executive Board established an ad hoc working group on health systems development for the future.¹ The report of the group² led to the adoption of resolution EB100.R1 in May 1997, which requested the Director-General, *inter alia*, “to launch a major initiative for research, advocacy, capacity-building and direct country support for health systems development ...”. In parallel, resolution WHA50.27 on strengthening health systems of developing countries was adopted during the Fiftieth World Health Assembly in May 1997. In response to resolution EB100.R1, an external advisory group was set up “to ensure that the initiative reflects the best concepts and practices and is implemented in a timely and cost-effective manner”. The advisory group met twice - in November 1997 and April 1998. The Executive Board considered a plan of action for the initiative at its 101st session in January 1998 and, in decision EB101(4), requested that a progress report on the initiative should be submitted to its 102nd session.

2. The challenge confronting countries and WHO is the development of health systems that respond to the health needs of people and contribute to the achievement of the goal of health for all. Such a challenge calls for elaboration of a framework in which to reorient all levels of WHO towards a people-centred approach in order to demonstrate that health is pivotal and central to human development and well-being. This global initiative is intended to bring together different programmes and levels of the Organization to provide countries with coherent policy advice and technical support in developing comprehensive, equitable and sustainable health systems.

3. WHO’s approach at all three levels is based on building up the capacity of national authorities to develop and manage the development of their health systems. To implement this approach WHO will: (i) consider regional and country variations in the development of health systems; (ii) form strategic alliances or partnerships with other sectors that have a major impact on health; (iii) create an enabling environment to sustain effectiveness of health systems; and, (iv) give priority to support those most in need through advocacy, research and enhanced capability.

PROPOSED OUTLINES OF OBJECTIVES AND OPERATIONAL STRATEGIES

4. **Objective 1.** Refocus WHO towards a coherent, consistent, coordinated and comprehensive approach, reconciling health-for-all policy and primary health care strategy with the agenda of health systems development and reform processes in order to respond to countries’ needs.

(i) Create a shared vision, values and common goals through participatory events that include all levels and different programmes of the Organization, e.g. creation of a steering committee involving regional offices and technical programmes;

(ii) draw up appropriate staff profiles to acquire the knowledge and skills needed to support the new approach (by December 1999);

(iii) streamline managerial processes, procedures and structures to facilitate rapid interprogramme actions (by December 1999);

(iv) determine and implement criteria for prioritizing countries based on urgency of need;

¹ Decision EB98(11).

² Document EB100/1997/REC/1, Annex 2.

- (v) develop more effective tools for sectoral assessment, health sector reform, performance measures and master investment plans for use by all levels of WHO, to enable strategic and comprehensive targeting of support (by March 2000);
- (vi) improve processes of communication at all levels for joint planning, country assessments, sector-wide approaches and monitoring and evaluation of health sector reforms (by December 1999);
- (vii) provide active human, organizational and management support to priority country offices to achieve the objective (by March 2000);
- (viii) ensure adequate financial support for the initiative from both regular and extrabudgetary sources.

5. **Objective 2.** To develop national capacity so that countries can themselves create sustainable, effective and equitable health systems, building on the existing basis, and focusing on better performance.

- (i) Promote and support improved and overall system frameworks, tools, methods and training for:
 - assessment of health systems, their strengths, weaknesses, strategies
 - policy coordination and regulatory functions of ministries of health
 - standard-setting and performance measurement
 - improved performance of health workers and provision of individuals and communities with knowledge and information to manage their own health;
- (ii) facilitate the exchange of experiences and ideas between like and unlike countries, e.g., establish technical exchange networks across countries and regions;
- (iii) create resource institutions and WHO collaborating centres in developing countries, focusing on health systems development for individual, and networks of, countries;
- (iv) identify, apply and disseminate innovative and successful examples of health systems development processes and elements, including, for example, financing options, leadership development and change management, strategies for the use and maintenance of equipment and supplies, assessment and use of technology.

6. **Objective 3.** To create awareness across sectors of the importance of effective, comprehensive and integrated health systems to promote health and delivery of care.

- (i) Prepare and use *The world health report 1999* as a strategic document for WHO to lead and coordinate at international level the “whole system” approach, to set the framework for increased awareness and a new approach by countries and the international community;
- (ii) initiate a global advocacy (marketing) campaign using *The world health report 1999* as a basis, with clear messages for different target audiences - country, regional and international, including political leaders and communities - on the importance of sustainable health systems.

7. **Objective 4.** To mobilize bilateral and multilateral agencies, donors, international and regional banks and nongovernmental organizations in support of international action and new investments in health systems development.

- (i) Lead partnerships to work together towards a shared vision, and establish and support strategic alliances with key stakeholders, particularly the international and regional financial institutions, keeping in mind WHO's values;
- (ii) mobilize financial and human resources at national and international levels within a comprehensive and coordinated approach to health systems development;
- (iii) achieve better coordination and complementarity of sector-wide approaches among donor and bilateral and multilateral technical agencies for a more integrated approach to capacity-building at country level;
- (iv) work with international partners and countries for the better use of existing national resources and reduced dependency on external financing over time.

8. **Objective 5.** To commission and support research to add to the body of knowledge on health systems development.

- (i) Prepare, assess, analyse and disseminate information on
 - expected long-term effects of changes affecting health systems
 - impact of those changes
 - lessons learned, identifying best practices and promoting replication of successful experiences;
- (ii) use results to raise awareness of government leaders, ministers of health, finance, education, environment, etc., business leaders and communities to allow new possibilities to be considered, and to design and support agendas for action which correspond to the needs of countries.

9. Some of the actions to be undertaken in the remainder of 1998 are:

- formation of a steering committee of WHO staff, including regional offices and other programmes (by July 1998);
- meeting of steering committee (by August/September 1998);
- drafting of detailed plan of action based on consultations with regional offices, other WHO programmes and the external advisory group (by September/October 1998);
- consultation with health policy-makers, and major bilateral and multilateral partners (by November/December 1998);
- finalization of detailed proposal for the initiative for consideration by the Executive Board at its 103rd session in January 1999 for forwarding to the Fifty-second World Health Assembly in 1999.

II. QUALITY OF BIOLOGICAL PRODUCTS MOVING IN INTERNATIONAL COMMERCE

1. Resolution WHA50.20 requests the Director-General *inter alia* to review the relation between WHO technical reports, requirements and guidelines and World Trade Organization agreements as they apply to international trade in biological medicinal products.
2. The significance of the links between trade liberalization and public health was recognized by WHO before the conclusion of the Uruguay Round of multilateral trade negotiations. Indeed, these trade agreements have cast a new light on WHO's quality and safety standards for pharmaceuticals, biologicals and food products, among others, which can be viewed as facilitating trade while protecting public health.
3. In view of the number of programmes involving trade-related issues, the Director-General established in 1995 a coordinating group for WHO/WTO cooperation in order to harmonize work on such programmes. Meetings of the group provide a means for keeping abreast of developments and avoiding duplication of effort. Included amongst its activities has been a discussion of issues relating to WHO standard-setting in the biologicals field, including vaccines. A paper is being prepared on this topic.¹
4. WTO is a new organization and many of its norms and procedures are as yet undetermined. One of its multilateral agreements, the Agreement on Technical Barriers to Trade (TBT) recognizes the contribution of international standards to facilitating trade. It is designed to promote their development and to ensure that national standards do not create unnecessary obstacles to trade. Thus, it encourages WTO Members to use internationally agreed standards as a basis for their own technical regulations; national criteria based on these standards will not constitute a discriminatory barrier to imported goods.
5. TBT, however, does not specify *a priori* which standards are to be taken as the international norm. In contrast, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) stipulates, for example, that the guidelines, requirements and standards set for food safety and quality by the Codex Alimentarius Commission are the international reference. In the event of a trade dispute under the remit of TBT, WTO's Dispute Settlement Body would determine whether a relevant international standard existed, whether that standard was appropriate to apply under the circumstances, and whether a national technical regulation not based on the international standard constituted a restriction to trade.
6. In the case of biologicals, the crucial question is which standards would a WTO Dispute Settlement Body determine to be the international norm. In reality, there seems to be little choice because, apart from WHO, there is no other neutral standard-setting body in this field to which WTO could turn.
7. Should the Requirements and Guidelines published by WHO be selected as the international norms in the event of a dispute, then some changes in WHO's standard-setting process may be needed, especially in relation to transparency of the process of establishing requirements.
8. WHO requirements and guidelines are drawn up through extensive global consultation involving independent experts from both developing and developed countries, and established by the Expert Committee on Biological Standardization. Members of the Expert Committee are scientists from national control agencies, academia, research institutes, public health bodies and the pharmaceutical industry acting as individual experts and not as representatives of their respective organizations or employers. The decisions and recommendations of the Committee are based entirely on scientific principles and considerations of public health. In comparison, the procedure for establishing international standards for food safety and quality involves the Codex Alimentarius

¹ Draft document: Pharmaceutical regulatory issues - the World Trade Organization and technical barriers to trade.

Commission, an intergovernmental body open to all Member States of WHO and FAO, which are invited to participate in the standard-setting process.

9. An independent review of WHO's remit and activities in the field of biological substances, which were determined more than 50 years ago, is currently under way. It will consider some of the aspects related to WTO activities in recommending action that will assist in harmonizing standards and requirements and enable WHO to meet the challenge of the rapid growth in volume, as well as complexity, of biologicals. Nevertheless, it must be kept clearly in mind that WHO's goal in setting standards is to promote and protect public health, not to facilitate international trade.

III. ACTION BY THE EXECUTIVE BOARD

The Board is invited to note the reports.

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