



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



## 25th PAN AMERICAN SANITARY CONFERENCE 50th SESSION OF THE REGIONAL COMMITTEE

Washington, D.C., 21-25 September 1998

*Provisional Agenda Item 4.11*

CSP25/17 (Eng.)

4 August 1998

ORIGINAL: ENGLISH-SPANISH

### WHO REVISED DRUG STRATEGY

The resolution on the WHO revised drug strategy, proposed by the Executive Board in January 1998 to the World Health Assembly in May 1998, was sent back to the Executive Board for further consideration. In order to address this complex subject again, the Executive Board decided to initiate a broad consultation by means of an ad hoc group open to all Member States, and a subgroup made up of representatives of each of the Regional Committees to assist WHO in its contacts with the interested parties.

This document provides the Pan American Sanitary Conference with information on the revised drug strategy and the resolution of the Executive Board, and on the ad hoc advisory group set up by the Director of PAHO to analyze this topic. The Conference is requested to:

- comment on the WHO revised drug strategy;
- comment on the suggested approaches for the development of a draft resolution that will be proposed by the Executive Board of WHO to the World Health Assembly;
- select two Member States (of which at least one will be a member of the Executive Board of WHO) to form part of the subgroup of the ad hoc working group on the revised drug strategy.

It is suggested that the Conference not repeat the discussion on Resolution EB101.R24 that caused such contention and about which consensus could not be reached in the World Health Assembly.

## 1. Background

The World Health Assembly in 1986 (Resolution WHA39.27) adopted the World Health Organization's revised drug strategy. This strategy requires that WHO support the Member States in the formulation and implementation of policies and national programs on essential drugs; in the expansion of regulatory roles and in supporting drug regulation and quality assurance; in the dissemination of information on drugs; in the training of health workers; and in the promotion of collaborative research.

Since that time, WHO has implemented the revised drug strategy, submitting progress reports every two years to the meetings of the Governing Bodies of WHO. In 1996, the Assembly, in Resolution WHA49.14, instructed the Director-General to “report to the Fifty-first World Health Assembly on the progress achieved and problems encountered in the implementation of WHO’s revised drug strategy.”

In January 1998, the Executive Board at its 101st Session considered the Director-General’s report on the revised drug strategy. The Board recognized the progress made and commended WHO for its work in promoting the essential drugs concept and national drug policies and in improving drug regulation. In order to address specific constraints on access to drugs, rational use of drugs, and drug quality, Resolution EB101.R24 (see Annex A) on the revised drug strategy was adopted. The Fifty-first World Health Assembly was invited to consider the resolution in May 1998. Several Member States indicated their concerns regarding some points of the resolution. Failing to reach agreement, Committee A of the Fifty-first World Health Assembly decided, therefore, to establish a drafting group to review the resolution.

The following three points of Resolution EB101.R24 led to the most discussion in the drafting group, and no consensus was reached on language:

. . . (b) new world trade agreements may have a negative impact on local manufacturing capacity and the access to and prices of pharmaceuticals in developing countries. . . [preamble].

1. Urges Member States:

. . . (2) to ensure that public health interests rather than commercial interests have “primacy” in pharmaceutical and health policies. . .

2. Requests the Director-General:

. . . (6) to cooperate with Member States in analyzing the pharmaceutical and public health implications of agreements the application of which is overseen by the

World Trade Organization and in developing appropriate policies and regulatory measures. . .

The Health Assembly, taking into account the discussions of the matter in Committee A and in the drafting group, decided to refer the matter back to the Executive Board for further consideration.

Subsequently, the Executive Board at its 102nd Session decided to establish an ad hoc working group open to all Member States wishing to participate. This working group would explore the complex issues raised by Resolution EB101.R24 on the revised drug strategy (Decision EB102(14), see Annex B). The working group would take note of the outcome of contacts pursued by WHO with other partners, including the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), industry, and nongovernmental organizations, in order to draft a resolution for consideration by the Executive Board at its 103rd Session in January 1999.

## **2. Actions in the Region of the Americas**

### **2.1 *Ad Hoc Consultation on the WHO Revised Drug Strategy***

The Director of the Pan American Health Organization (PAHO), with a view to better informing the Pan American Sanitary Conference (WHO Regional Committee for the Americas) on the revised drug strategy in the context of the debate in the World Health Assembly, formed an advisory group to:

- analyze the controversial aspects of the aforementioned resolution in greater detail;
- examine the various points of view for the purpose of reporting to the Conference and facilitating discussion of the revised drug strategy;
- contribute to the participation of the Region of the Americas in the subgroup to be convened by WHO on 12-13 October 1998 to prepare a new draft resolution.<sup>1</sup>

The advisory group, with members from six countries of the Region, met in Washington, D.C., on 29-30 July. In its discussions the advisory group took into account Resolution EB101.R24 and Document EB/RDS/CR/1 (Revised Drug Strategy) (see Annex C).

The advisory group carried out a comprehensive review of the various topics discussed in the resolution with respect to the activities carried out by WHO in the area of

---

<sup>1</sup> This draft resolution will be submitted for the consideration of the Executive Board at its 103rd session in January 1999.

drugs and to the progress made and difficulties encountered by various countries in implementing drug policies, giving special emphasis to discussion of the paragraphs that gave rise to the intense debate in the World Health Assembly in May 1998.

The advisory group recognized with satisfaction the work carried out by WHO with regard to the revised drug strategy, especially with respect to the development of national drug policies; strengthening of regulation and quality assurance; implementation of WHO's ethical criteria for drug promotion; preparation of guidelines on drug donations; development and promotion of independent information on drugs; education of health professionals to foster the rationalization of drug prescription and care; and consumer education.

Based in part on the recommendations of the advisory group, the PAHO Secretariat considers that the following points should be taken into account in drafting a new resolution:

- governments should formulate and implement drug policies to improve access to essential drugs of good quality, safety, and efficacy;
- the need for government regulations of the pharmaceutical sector is recognized since, due to its characteristics, self-regulation is not sufficient. There are basic strategies to improve drug access that are not directly related to international trade agreements;
- there is a need to strengthen the drug regulatory authorities so that they carry out their responsibilities effectively, including taking the necessary measures to respond to and implement agreements reached at global, regional, and subregional levels;
- there should be coordination at the national level among the different government sectors, particularly between health and trade ministries, in order to insure that public health interests are taken into account in international trade negotiations;
- WHO and WTO should meet at the highest level to establish open lines of communication and to define clearly the roles and responsibilities of each organization in providing information and technical cooperation to Member States in matters of health and trade. It is expected that in an open and consultative manner with WTO and other international organizations, WHO would advise ministries of health regarding the health implications of the trade agreements;
- while health and trade interests should not be seen in opposition, appropriate weight must be assigned to each;

- when necessary to protect public health, governments should make use of existing mechanisms provided in international agreements;
- WHO resolutions dealing with pharmaceuticals should not be divisive but rather pursue the consensus of the different sectors concerned in order to facilitate their adoption and implementation.

Complementary to the indications above, the Secretariat considers that mechanisms such as the following should be taken into account in the formulation of policies and programs to improve access to drugs:

- the inclusion of drug policy in health sector reform, including the development of financing mechanisms;
- the definition of roles and greater collaboration among health professionals, consumers, industry, and governments;
- an increase in the activities to harmonize regulation in the pharmaceutical area;
- the development of innovative mechanisms for drug supply through the alliance of the public and private sectors, and greater dissemination of drug and therapeutic guidelines.

## ***2.2 Selection of Two Member States Entitled to Designate a Representative to Serve in the Subgroup of the Ad Hoc Working Group on the WHO Revised Drug Strategy***

In accordance with decision EB102(14), the Regional Committees of WHO are each requested to select two Member States to participate in the subgroup of the ad hoc working group on the revised drug strategy. At least one of the Member States selected must be a member of the Executive Board. The subgroup will meet in Geneva on 12-13 October 1998 and subsequently before or during the 103rd Session of the Executive Board, to consider the revised drug strategy.

**RESOLUTION OF THE EXECUTIVE BOARD OF THE WHO**  
**RÉSOLUTION DU CONSEIL EXÉCUTIF DE L'OMS**  
**RESOLUCION DEL CONSEJO EJECUTIVO DE LA OMS**

---

101st Session  
Agenda item 9

EB101.R24  
27 January 1998

## **Revised drug strategy**

The Executive Board

RECOMMENDS to the Fifty-first World Health Assembly the adoption of the following resolution:

The Fifty-first World Health Assembly,

Recalling resolutions WHA39.27, WHA41.16, WHA43.20, WHA45.27, WHA47.12, WHA47.13, WHA47.16, WHA47.17, and WHA49.14;

Having considered the report of the Director-General on the revised drug strategy;<sup>1</sup>

Noting the activities of WHO to further the implementation of the revised drug strategy, in particular through support to the development and implementation of national drug policies; the strategy to review and assess the effectiveness of the WHO Ethical Criteria for Medicinal Drug Promotion; the flow of market information; guidelines for drug donations; and model drug information;

Recognizing with satisfaction the progress made, and approving WHO's comprehensive response to current and new challenges in the pharmaceutical sector;

---

<sup>1</sup> Document EB101/10, Chapter VII.

Commending the strong leadership shown by WHO in promoting the essential drugs concept and national drug policies, which are contributing to the rational use of resources in the pharmaceutical sector and to improved health care;

Noting with satisfaction that a number of Member States have adopted guidelines for drug donations that were based on the interagency guidelines issued by WHO, but concerned that inappropriate drug donations, such as donations of expired, mislabelled, inessential products, continue to be common;

Concerned about the situation in which one third of the world's population has no guaranteed access to essential drugs, in which new world trade agreements may have a negative impact on local manufacturing capacity and the access to and prices of pharmaceuticals in developing countries, and in which poor quality pharmaceutical raw materials and finished products continue to move in international trade;

Concerned also that drugs continue to be irrationally used by prescribers, dispensers and the general public, and because unethical promotion in developed and developing countries and a lack of access to independent, scientifically validated drug information contribute to such abuses,

1. URGES Member States:

(1) to reaffirm their commitment to develop, implement and monitor national drug policies to ensure equitable access to essential drugs;

(2) to ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies and to review their options under the Agreement on Trade Related Aspects of Intellectual Property Rights to safeguard access to essential drugs;

(3) to establish and enforce regulations that ensure good uniform quality assurance standards for all pharmaceutical materials and products manufactured in, imported to, exported from, or in transit through their countries;

(4) to enact and enforce legislation or regulations in accordance with the principles of the WHO Ethical Criteria for Medicinal Drug Promotion, and to monitor drug promotion in collaboration with interested parties;

(5) to develop or maintain national guidelines governing drug donations that are compatible with the interagency guidelines issued by WHO and to work with all interested parties to promote adherence to such guidelines;

- (6) to promote the rational use of drugs through the provision of independent, up-to-date and comparative drug information, and to integrate the rational use of drugs and information about commercial marketing strategies into training for health practitioners at all levels;
  - (7) to promote and support consumer education on the rational use of drugs and its inclusion into school curricula;
  - (8) to evaluate progress regularly, making use of indicators developed by WHO or other suitable mechanisms;
  - (9) to continue their funding and material support for the revised drug strategy especially by the provision of extrabudgetary resources to WHO;
2. REQUESTS the Director-General:
- (1) to support Member States in their efforts to develop and implement policies and programmes that achieve the objectives of the revised drug strategy, including the development of tools, guidelines and methodologies for evaluation and monitoring;
  - (2) to adopt a comprehensive strategy to implement the WHO Ethical Criteria for Medicinal Drug Promotion and to continue to review its effectiveness with all interested parties;
  - (3) to extend the guidelines incorporated in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce to cover pharmaceutical starting materials; develop and disseminate uniform guidelines on the regulatory control, export, import and transit conditions of pharmaceutical products; and develop standards of practice for entities involved in international trade in pharmaceuticals and pharmaceutical raw materials;
  - (4) to strengthen and expand the provision of independent information on market prices of raw materials of assured quality for production of essential drugs;
  - (5) to continue the development and dissemination, also using electronic media such as the Internet, of independent information on pharmaceutical product safety and instances of counterfeit drugs or medicines, on drug selection and on rational prescribing;
  - (6) to assist Member States to analyze the pharmaceutical and public health implications of agreements overseen by the World Trade Organization and to develop appropriate policies and regulatory measures;



(7) to review and update the revised drug strategy to reflect current and continued challenges in the pharmaceutical sector and the principles articulated in the renewed health-for-all policy;

(8) to report comprehensively to the Fifty-third World Health Assembly on progress achieved and problems encountered in the implementation and renewal of WHO's revised drug strategy, with recommendations for action.

Sixteenth meeting, 27 January 1998  
EBIOI/SR/16



**World Health Organization  
Organisation mondiale de la Santé**

EXECUTIVE BOARD  
102nd Session

EB102/DIV/3  
19 May 1998

**EB102(14) Revised drug strategy**

The Executive Board decided to establish an open-ended ad hoc group to explore the complex issues raised by resolution EB101.R24 on the revised drug strategy. The group will take note of the outcome of contacts pursued by WHO with other partners, including the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), industry and nongovernmental organizations in order to draft a resolution for consideration by the Executive Board at its 103rd session in January 1999.

The Executive Board established a two-tiered method of working, as follows: (1) the ad hoc working group on the revised drug strategy will be open to all Member States wishing to participate and will meet in Geneva; (2) a subgroup will be created comprising the chairman of the drafting group that had been established during the Fifty-first World Health Assembly, and two Member States from each region, of which at least one will be a member of the Executive Board. This subgroup will assist WHO in its contacts with relevant interested partners; (3) the Director-General and his staff will prepare a concise and comprehensive report on which discussions and decisions should be based at the regional committee meetings to be held in September and October 1998; (4) the regional committees will nominate their representatives to the subgroup; (5) the ad hoc group will meet shortly after the regional committee meetings and prior to or shortly after the opening of the 103rd session of the Executive Board in January 1999 in order to finalize the draft resolution to be considered by the Executive Board.

The Executive Board noted that adequate financial resources will need to be provided for the aforementioned activities, and that the work of the Secretariat and Member States on this issue may need to continue beyond January 1999.