WORLD HEALTH ORGANIZATION

EXECUTIVE BOARD
103rd Session
Provisional agenda item 3

EB103/4
25 November 1998

Revised drug strategy

Report by the Chairman of the ad hoc working group

BACKGROUND

1. In January 1998 the Executive Board at its 101st session considered the Director-General's report on the revised drug strategy. The Board recognized progress made and commended WHO on 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, it adopted resolution EB101.R24 on the revised drug strategy. The Fifty-first World Health Assembly was invited to consider the resolution in May 1998. Views differed on a number of points in the resolution and the Health Assembly therefore agreed to establish a drafting group.

2. The drafting group was chaired by Professor J.-F. Girard (France). Despite many hours of discussion in the drafting group, no consensus was reached on language for the resolution and the Health Assembly decided to refer the resolution back to the Executive Board for further consideration at its 103rd session.[1]

3. At its 102nd session, immediately after the Health Assembly, the Executive Board decided to establish a two-tier method of work, in order to draft a resolution for consideration at its 103rd session in January 1999: an ad hoc working group open to all Member States wishing to participate, which included a subgroup to assist WHO in its contacts with relevant interested partners.[2] The Board decided that the subgroup would comprise the chairman of the drafting group established during the Fifty-first World Health Assembly, and two Member States from each region, of which at least one would be currently entitled to designate a person to serve on the Executive Board. The regional committees were invited to nominate their representatives to the subgroup. Those nominated were Cape Verde, China, Indonesia, Islamic Republic of Iran, Jamaica, Japan, Poland, South Africa, Switzerland, Thailand, United States of America and Yemen.

4. The ad hoc working group and the subgroup met from 12 to 16 October 1998 (list of participants attached at Annex). The meetings were chaired by Professor J.-F. Girard (France). The ad hoc working group elected Ms S. Kizildeli (Turkey) and Dr T.J. Stamps (Zimbabwe) as Vice-Chairmen. A total of 59 Member States, including subgroup members, participated in the meeting.

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[1] Decision WHA51(10).

[2] Decision EB102(14).

ISSUES

5. In order to assist the ad hoc working group in exploring the complex issues raised by resolution EB101.R24, one full day was devoted to a technical briefing in which relevant interested partners were invited to participate. The technical briefing covered globalization and pharmaceuticals, including the question of how trade agreements could interfere with or support public health, and strategies for ensuring access to pharmaceuticals.

6. Presentations on globalization and pharmaceuticals were made by representatives of WIPO, WTO, The South Centre, Health Action International, the International Federation of Pharmaceutical Manufacturers' Associations, and the International Pharmaceutical Generic Alliance. A presentation on strategies for ensuring access to pharmaceuticals was made by the WHO Secretariat and reactions were invited from members of the ad hoc working group, including the subgroup, and from those who had made presentations on the globalization and pharmaceuticals issue.

7. The ad hoc working group identified a number of new topics not covered by resolution EB101.R24, which it felt should be the subject of further work by the Secretariat, in particular on access to drugs, transfer of technology and local production, new drugs, counterfeit drugs, human resources, and gender issues. Issues discussed under the topic of access to drugs included supply systems, drug financing, drug insurance, price information and pricing policies, generic drugs, procurement methods, and related matters. However, in order to conclude on the issues in resolution EB101.R24 on which there had been diverging views at the Health Assembly, the ad hoc group decided to concentrate on those topics currently included in the resolution.

8. By the last day of the meeting the ad hoc working group had reached consensus on the text of a resolution to be forwarded to the Executive Board, although, because of lack of time, certain points raised during the deliberations were not included in the text (e.g. the addition of "transitional countries" in preambular paragraph 10, the addition of preambular paragraphs concerning gender inequalities in health care, and the need to improve access for vulnerable groups). The Secretariat was requested to provide information on the financial implications of the resolution, which will be provided separately.

ACTION BY THE EXECUTIVE BOARD

9. The Board is invited to consider the following draft resolution as proposed by the ad hoc working group:

The Executive Board

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

The Fifty-second 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;[1]

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;

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, and further concerned that the evaluation of the impact of the guidelines has not yet been completed;

Concerned about the situation in which (a) one third of the world's population has no guaranteed access to essential drugs, and (b) poor quality pharmaceutical raw materials and finished products continue to move in international trade;

Noting that there are trade issues which require a public health perspective;

Recognizing that the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) provides scope for the protection of public health;

Taking note of concerns of many Member States about the impact of relevant international agreements, including trade agreements, on local manufacturing capacity and on access to and prices of pharmaceuticals in developing and least developed countries;

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 abuse,

1. URGES Member States:

(1) to reaffirm their commitment to developing, implementing and monitoring national drug policies and to taking all necessary concrete measures in order to ensure equitable access to essential drugs;

(2) to ensure that public health interests are paramount in pharmaceutical and health policies;

[1] Document EB101/10, Chapter VII, and Corr.2.

(3) to explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs;

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

(5) to enact and enforce legislation or regulations in accordance with the principles of the WHO Ethical Criteria for Medicinal Drug Promotion, to encourage the pharmaceutical industry and the health community to establish an ethical code, and to monitor drug promotion in collaboration with interested parties;

(6) 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;

(7) 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;

(8) to promote and support education of consumers in the rational use of drugs and its inclusion into school curricula;

(9) to evaluate progress regularly, making use of indicators developed by WHO or other suitable mechanisms;

(10) 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 methodology 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 starting materials;

(4) to establish and develop a model inspection certificate for the national inspection of pharmaceutical manufacturing sites of starting materials and finished pharmaceutical

products to ensure compliance with WHO Good Manufacturing Practices, and to collaborate with Member States, at their request, in implementation;

(5) to strengthen and expand the provision of independent information on market prices of starting materials of assured quality for production of essential drugs;

(6) to continue the development and dissemination, also using electronic media such as the Internet, of independent information on safety of pharmaceutical products and instances of counterfeit drugs or medicines, on drug selection and on rational prescribing;

(7) to cooperate with Member States, at their request, and with international organizations in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximize the positive and mitigate the negative impact of those agreements;

(8) 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;

(9) to report 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.

ANNEX

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