



WORLD HEALTH ORGANIZATION

FIFTY-SECOND WORLD HEALTH ASSEMBLY

(Draft) A52/38
24 May 1999

Second report of Committee A

(Draft)

Committee A held its seventh meeting on 22 May 1999 under the chairmanship of Dr M. Taha bin Arif (Malaysia) and Dr A.J.M. Sulaiman (Oman).

It was decided to recommend to the Fifty-second World Health Assembly the adoption of the attached resolutions relating to the following agenda item:

13. Technical and health matters

Two resolutions entitled:

% Towards a WHO framework convention on tobacco control

% Revised drug strategy

Agenda item 13

Towards a WHO framework convention on tobacco control

The Fifty-second World Health Assembly,

Being deeply concerned by the escalation of smoking and other forms of tobacco use worldwide, which resulted in the loss of at least 3.5 million human lives in 1998 and is expected to cause at least 10 million deaths a year by 2030 if the pandemic is not controlled, with 70% of these deaths occurring in developing countries;

Having considered the report of the Director-General to the Health Assembly on the Tobacco Free Initiative, and the outline of expected activities;

Recognizing the leadership of the Director-General and WHO in the field of tobacco control;

Recalling and reaffirming resolution WHA49.17 requesting the Director-General to initiate development of a WHO framework convention on tobacco control in accordance with Article 19 of the WHO Constitution;

Recognizing the need for multisectoral strategies, including the involvement of other multilateral organizations and nongovernmental organizations, to foster international consensus and action on development of the WHO framework convention on tobacco control and possible related protocols;

Being mindful of the many constraints, including resource constraints, faced by a number of countries in the development and implementation of the WHO framework convention on tobacco control and possible related protocols;

Being also mindful of the fact that tobacco production is a significant source of earnings in many developing countries;

Being aware of the urgent need to speed up work on the proposed WHO framework convention on tobacco control and possible related protocols so that they may serve as a basis for multilateral cooperation and collective action on tobacco control;

Desiring to complete preparation of the draft text of the framework convention for consideration by the Fifty-sixth World Health Assembly,

1. DECIDES:

(1) in accordance with Rule 42 of its Rules of Procedure, to establish an intergovernmental negotiating body open to all Member States to draft and negotiate the proposed WHO framework convention on tobacco control and possible related protocols;

(2) to establish a working group on the WHO framework convention on tobacco control open to all Member States in order to prepare the work of the body referred to above. This group will prepare proposed draft elements of the WHO framework convention on tobacco control. The working group will report on progress to the Executive Board at its 105th session. It will complete its work and submit a report to the Fifty-third World Health Assembly;

(3) that regional economic integration organizations constituted by sovereign States, Members of the World Health Organization, to which their Member States have transferred competence over matters governed by this resolution, including the competence to enter into treaties in respect to these matters, may actively participate, in accordance with Rule 55 of the Rules of Procedure of the Health Assembly, in the drafting and negotiations of the intergovernmental negotiating body referred to under paragraph (1) and in the preparatory work of the working group referred to under paragraph (2);

2. URGES Member States:

(1) to give high priority to accelerating work on development of the WHO framework convention on tobacco control and possible related protocols;

(2) to provide resources and cooperation necessary to accelerate the work;

(3) to promote intergovernmental consultations to address specific issues, for example, public health matters and other technical matters relating to negotiation of the proposed WHO framework convention on tobacco control and possible related protocols;

(4) to establish, where appropriate, relevant structures, such as national commissions, for the WHO framework convention on tobacco control and mechanisms to examine the implications of a framework convention on tobacco control within the context of health and economic issues, especially its effects on the economy of agriculturally dependent States;

(5) to facilitate and support the participation of nongovernmental organizations, recognizing the need for multisectoral representation;

(6) to consider further development and strengthening of national and regional tobacco policies, including the appropriate application of regulatory programmes to reduce tobacco use, as contributions to development of the framework convention and possible related protocols;

3. REQUESTS the Director-General:

(1) to promote support for development of the WHO framework convention on tobacco control and possible related protocols among Member States, organizations of the United Nations system, other intergovernmental, nongovernmental and voluntary organizations, and the media;

(2) to complete the technical work required to facilitate negotiations on the WHO framework convention on tobacco control and possible related protocols;

(3) to convene the working group on the WHO framework convention on tobacco control, and the first meeting of the intergovernmental negotiating body on the basis of progress achieved by the working group;

- (4) to provide the working group on the WHO framework convention on tobacco control and the intergovernmental negotiating body with the necessary services and facilities for the performance of their work;
- (5) to facilitate the participation of the least developed countries in the work of the working group on the WHO framework convention on tobacco control, in intergovernmental technical consultations, and in the intergovernmental negotiating body;
- (6) to invite, as observers at the sessions of the working group on the WHO framework convention on tobacco control and the intergovernmental negotiating body, representatives of non-Member States, of liberation movements referred to in resolution WHA27.37, of organizations of the United Nations system, of intergovernmental organizations with which WHO has established effective relations, and of nongovernmental organizations in official relations with WHO, who will attend the sessions of those bodies in accordance with the relevant Rules of Procedure and resolutions of the Health Assembly.

*Annex***OUTLINE OF EXPECTED ACTIVITIES**

January 1999 to May 2000 (completion of pre-negotiation phase), and targets for negotiation and adoption of the WHO framework convention on tobacco control and possible related protocols (May 2000 to May 2003)

Milestones	Governing and subsidiary bodies	Decision and actions by governing and subsidiary bodies	Action by the Secretariat
January 1999	Executive Board	C Recommend for adoption by the Fifty-second World Health Assembly the resolution "Towards a WHO framework convention on tobacco control"	After the 103rd session of the Executive Board <ul style="list-style-type: none"> • Disseminate information on the process for developing the framework convention • For the Fifty-second World Health Assembly, prepare briefing document(s) on the process • Hold consultations with Member States
May 1999	Fifty-second World Health Assembly	<ul style="list-style-type: none"> • Consider the draft resolution "Towards a WHO framework convention on tobacco control" C Establish the intergovernmental negotiating body and the working group on the framework convention on tobacco control	<ul style="list-style-type: none"> • Hold briefing sessions on the framework convention during the Fifty-second World Health Assembly After the Fifty-second World Health Assembly <ul style="list-style-type: none"> • Support intergovernmental technical consultations on the framework convention • Facilitate participation of least developed countries in the process for developing the framework convention C Provide technical support
May 1999 to January 2000	Working group on the framework convention	C Initiate preparation of proposed draft elements of the WHO framework convention on tobacco control	C Convene the working group on the WHO framework convention on tobacco control C Provide technical support
January 2000	Working group on the framework convention Executive Board	C Submit progress report of the working group on the framework convention to the Executive Board at its 105th session C Consider the progress of the working group	<ul style="list-style-type: none"> • Provide technical support
January 2000 to May 2000	Working group on the framework convention	<ul style="list-style-type: none"> • Continue work based on direction from the Executive Board 	<ul style="list-style-type: none"> • Provide technical support
May 2000	Fifty-third World Health Assembly	<ul style="list-style-type: none"> • Submit report of the working group on the framework convention to the Fifty-third World Health Assembly 	<ul style="list-style-type: none"> • Hold technical briefing during the Health Assembly on alternative negotiation processes
May 2000 (target date)	Intergovernmental negotiating body	<ul style="list-style-type: none"> • Hold the first organizational session 	C Convene the first meeting of the intergovernmental negotiating body based on progress achieved by the working group
May 2000 to May 2003 (Target date for adoption)	Intergovernmental negotiating body	<ul style="list-style-type: none"> • Negotiate the draft framework convention and possible related protocols 	C Provide technical support

Note: Process and content will be driven primarily by Member States, but will also include input from bodies of the United Nations system, other international, regional, or intergovernmental organizations, and nongovernmental organizations.

Agenda item 13

Revised drug strategy

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 are 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 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 that unethical promotion in developed and developing countries and a lack of access to independent, scientifically validated drug information contribute to such abuse,

¹ Document EB101/10, section VII and Corr.1.

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;
- (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 of other suitable mechanisms;
- (10) to continue their funding and material support for the revised drug strategy, especially through 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; to develop and disseminate uniform guidelines on the regulatory control, export, import and transit conditions of pharmaceutical products; and to 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 in order 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.

= = =