

UN Instrument

*Fifty-second World Health Assembly, Geneva, Switzerland, 24 May 1999
WHA52.19 Agenda item 13*

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. 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;

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

- (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.

Ninth plenary meeting, 24 May 1999

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