WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTÉ

REGIONAL OFFICE FOR THE WESTERN PACIFIC
BUREAU RÉGIONAL DU PACIFIQUE OCCIDENTAL

REGIONAL COMMITTEE

Forty-fifth session
Kuala Lumpur
19-23 September 1994

WPR/RC45/17

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Provisional agenda item 20.1

CORRELATION OF THE WORK OF THE WORLD HEALTH ASSEMBLY, THE EXECUTIVE BOARD AND THE REGIONAL COMMITTEE

Consideration of resolutions of the Forty-seventh World Health Assembly and the Executive Board at its ninety-third and ninety-fourth sessions

Resolutions adopted by the Forty-seventh World Health Assembly of interest for the work of WHO in the Western Pacific Region are hereby presented to the Regional Committee for comment, together with a note on their implications for Member States of the Region and for WHO's programme of cooperation. Health Assembly and Executive Board resolutions directly related to other items on the provisional agenda of the current session of the Regional Committee form part of the documentation for those individual agenda items (e.g., resolution EB94.R2 is attached to document WPR/RC45/19). Resolutions of the ninety-third session of the Executive Board are reflected in the resolutions of the subsequent World Health Assembly.

WHA47.12 - Role of the pharmacist in support of the WHO revised drug strategy

Attention is drawn to operative paragraphs 2(2) and 2(3), which urge Member States to make full use of the expertise of the pharmacist at all levels of the health care system, particularly in the development of national drug policies, and to provide training facilities which equip pharmacists to assume responsibilities for all pharmaceutical activities, particularly those related to the quality assurance of drugs.

The resolution reaffirms the continued efforts of the Regional Office, through the ASEAN Technical Cooperation in Pharmaceuticals Project (ASEAN TCDC Project), to provide training to pharmaceutical personnel in different pharmaceutical fields. With limited funding, the ASEAN TCDC Project was able to conduct two training activities under the 1993 workplan. These were; Training in Drug Evaluation, held in Manila, Philippines, and Training in Quality Assurance and Non-pharmaceutical Analytical Methods, held in Kuala Lumpur, Malaysia. Training was also given in the use of resources in the ASEAN region using the TCDC (Technical Cooperation among Developing Countries) approach. In view of the success of the TCDC concept among the ASEAN countries, the 13th Working Group Meeting of the ASEAN Technical Cooperation in Pharmaceuticals decided to expand its scope to include non-ASEAN member states. In this regard, it is planned to hold a Biregional TCDC meeting in the area of essential drugs in Kuala Lumpur, Malaysia, in December 1994. The meeting is intended to enhance existing ASEAN activities, with a view to defining the knowledge and expertise upon which the role of the pharmacist is based.

WHA47.13 - Implementation of WHO's revised drug strategy: Rational use of drugs; and WHO's Action Programme on Essential Drugs

Attention is drawn to operative paragraph 2(1), which urges Member States to commit themselves to the development and implementation of national drug policies to improve equitable access to essential drugs of good quality at affordable cost, and to intensify efforts to promote the rational use of drugs.

Except for some developing countries in the South Pacific, many countries in the Region have national drug policies which emphasize the various aspects of drug management. The Regional Office continued to collaborate with Member States in the further development of drug policies according to their priorities and development status. Activities in China, the Lao People's Democratic Republic and Viet Nam, as well as two South Pacific countries, are geared towards the implementation of the national drug policies such as updating and revision of essential drugs lists,

strengthening of drug regulatory authorities, review and revision of drug procurement procedures and rational use of drugs.

Attention is also drawn to operative paragraph 3, which calls upon bilateral and multilateral agencies, nongovernmental organizations and other collaborators to strengthen their technical and financial support to the Action Programme on Essential Drugs.

In this regard, the Regional Office pursued efforts to encourage others, such as the Japan Pharmaceutical Manufacturers Association (JPMA), to support activities in line with the WHO Revised Drug Strategy. Collaboration was established with JPMA in the area of drug quality control. Some pharmaceutical industry associations in the ASEAN region have also expressed interest in participating in the ASEAN TCDC Project. This will be further discussed during the Biregional TCDC Meeting in Malaysia planned for December 1994.

WHA47.16 - WHO ethical criteria for medicinal drug promotion

Attention is drawn to operative paragraph 5, which urges Member States to develop and implement national mechanisms and, where relevant, to control drug promotion in accordance with the principles embodied in the WHO Ethical Criteria and as proposed in the WHO Certification Scheme.

Two countries in the Region are now implementing national mechanisms to control and monitor drug promotion and advertising. The Philippine Government, with WHO support, established the Drug Information Center (DIC) in 1993. It disseminates unbiased and up-to-date information to health providers, policy-makers and consumers. A similar activity was carried out in Brunei Darussalam when WHO collaborated with the Government in establishing a Drug/Poison Information System. In the ASEAN region, the ASEAN member states continued the exchange of information on drug regulatory matters which started in 1992.

Efforts to develop and update national drug formularies or essential drugs lists are now being pursued in China and Viet Nam. A comprehensive list of pharmaceutical products should be included as well as prescribing and dispensing information, and estimated costs of treatment. Other countries have organized training programmes for various groups of health personnel to inform and educate them on the rational use of drugs.

WHA47.17 - Implementation of WHO's Revised Drug Strategy
Safety, Efficacy and Quality of Pharmaceuticals

Attention is drawn to operative paragraphs 2 and 3, which urge Member States to provide the resources and manpower needed to strengthen their national regulatory capability, and which request governments and pharmaceutical manufacturers to cooperate in order to ensure complementary support of public health goals.

The resolution reaffirms WHO's efforts to support governments of this Region in upgrading manpower capabilities, particularly in the area of drug quality and regulatory control. A number of fellowships and training in the areas of Good Manufacturing Practices and the use of the WHO Basic Tests are provided for in the 1994-1995 regional programme budgets of Cambodia, the Lao People's Democratic Republic and Viet Nam.

Through collaboration with the Japan Pharmaceutical Manufacturers Association (JPMA), WHO provided training in the fields of chemical, biological and microbiological quality control. In 1993, Cambodia, China and Malaysia benefited from this training scheme. JPMA has also provided funds for a meeting on the production and utilization of ASEAN Reference Substances.

The topic of the Technical Discussions in conjunction with the forty-fifth session of the Regional Committee is "Drug quality assurance". This will provide an opportunity for Member States in the Region to discuss and exchange information on their country situations with regard to quality assurance.

世界卫生大会决议
RESOLUTION OF THE WORLD HEALTH ASSEMBLY
RÉSOLUTION DE L'ASSEMBLÉE MONDIALE DE LA SANTÉ
РЕЗОЛЮЦИЯ ВСЕМИРНОЙ АССАМБЛЕИ ЗДРАВООХРАНЕНИЯ
RESOLUCION DE LA ASAMBLEA MUNDIAL DE LA SALUD

FORTY-SEVENTH WORLD HEALTH ASSEMBLY **WHA47.12**

Agenda item 19 10 May 1994

Role of the pharmacist in support of the WHO revised drug strategy

The Forty-seventh World Health Assembly,

Noting the preliminary report by the Director-General on implementation of WHO's revised drug strategy;

Recalling resolutions WHA37.33, WHA39.27 and WHA41.16 on the rational use of drugs;

Noting in particular the need to encourage the fulfilment by all concerned parties, including health personnel involved in prescription, dispensing, supply and distribution of medicines, of their responsibilities with respect to rational use of drugs as specified in WHO's revised drug strategy;

Recognizing the economic benefits and the therapeutic advantage of advocating and reinforcing the rational use of drugs;

Recognizing that the pharmacist can play a key role in public health and particularly in the field of medicines, and that the rational use of drugs is contingent upon the availability to the whole population at all times of essential drugs of good quality at affordable prices;

Emphasizing the need for the utmost vigilance to ensure the detection and prevention of the manufacture, export or smuggling of falsely-labelled, spurious, counterfeit or substandard pharmaceutical preparations;

Concerned about the continued poor state of development of pharmaceutical services in many countries as emphasized in WHO meetings on the role of the pharmacist held in New Delhi in 1988 and Tokyo in 1993;

Appreciating the contribution made by organizations representing pharmacists, in collaboration with WHO, in pursuit of the goal of health for all;

Stressing the importance of collaboration between pharmacists and all other health professionals involved in patient care and the safe and effective administration of medicines,

1. CALLS UPON pharmacists and their professional associations everywhere, through their contributions to regulatory control, pharmaceutical manufacture and community service, to support WHO's policies as embodied in WHO's revised drug strategy and develop the profession at all levels in accordance with the reports of the above-mentioned meetings, and, in particular:

(1) to provide the oversight necessary to assure the quality of pharmaceutical products and services at the time of manufacture, importation or exportation and at all stages of the distribution chain;

(2) to manage drug procurement and supply systems and in so doing, to cooperate in efforts to detect and prevent the distribution of falsely-labelled, spurious, counterfeit or substandard pharmaceutical preparations;

(3) to provide informed and objective advice on medicines and their use to the public, and provide technical advice to other health professionals, to drug regulatory bodies, health planners and policy-makers;

(4) to promote, in collaboration with other health professionals, the concept of pharmaceutical care as a means of furthering the rational use of drugs and of actively participating in illness prevention and health promotion;

(5) to support relevant research and training programmes;

2. URGES all Member States, in collaboration with national organizations representing pharmacists, where such exist:

(1) to define the role of the pharmacist in the promotion and implementation of the national drug policy within the framework of health-for-all strategy;

(2) to make full use of the expertise of the pharmacist at all levels of the health care system and particularly in the development of national drug policies;

(3) to provide training facilities to equip pharmacists to assume responsibilities for all activities cited in 1(1) to 1(4) above;

3. REQUESTS the Director-General:

(1) to support Member States in their efforts to develop drug regulatory and pharmaceutical services;

(2) to encourage Member States to assess their needs for pharmaceutical services and manpower, and for relevant training facilities;

(3) to encourage regular publication of the *World Directory of Schools of Pharmacy*;

(4) to report on progress made to the Executive Board at its ninety-seventh session in January 1996.

Twelfth plenary meeting, 10 May 1994
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FORTY-SEVENTH WORLD HEALTH ASSEMBLY **WHA47.13**

Agenda item 19 10 May 1994

Implementation of WHO's revised drug strategy: Rational use of drugs; and WHO's Action Programme on Essential Drugs

The Forty-seventh World Health Assembly,

Having considered the report of the Director-General on the implementation of WHO's revised drug strategy;

Recalling resolutions WHA39.27 and WHA41.16 on the rational use of drugs, and resolutions WHA43.20 and WHA45.27 on the Action Programme on Essential Drugs;

Noting the activities of WHO in pursuance of the revised drug strategy and its intensified direct collaboration and support to countries in drug policy formulation, standard setting, regulation, procurement and use as well as the related logistics, financing, information, operational research, human resources, education and training capacity building and institution strengthening;

Recognizing the efforts of WHO in collaboration with governments and other bodies to improve access to essential drugs and the rational use of drugs, within the framework of national drug policies;

Aware of the role of the community in the rational use of drugs;

Recognizing also the need for continued action by all interested parties to achieve all the objectives of a comprehensive national drug policy;

Appreciating that the Action Programme on Essential Drugs will be subject to a detailed review by the Executive Board at its ninety-fifth session in 1995, with a view to optimizing the collaboration between all technical programmes in this field;

Emphasizing the need for an adequate response to new economic challenges and the changing balance of the public and private sectors in health care, including the provision of drugs, and assessment of the viability and long-term effects of new financing strategies and other measures;

Mindful of problems with counterfeit drugs and drugs of poor quality,

1. REAFFIRMS the crucial importance of WHO's leadership and coordination, through its Action Programme on Essential Drugs, in the development, support and evaluation of national drug policies within the framework of national health policies;

2. URGES Member States:

(1) to commit themselves to the development and implementation of national drug policies to improve equitable access to essential drugs of good quality at affordable cost, and to intensify efforts to promote the rational use of drugs;

(2) to accelerate the education and training of the necessary human resources, and to strengthen the implementation of drug policies and programmes;

(3) to evaluate progress regularly using performance indicators developed by the Action Programme on Essential Drugs or other suitable mechanisms;

3. CALLS ON bilateral and multilateral agencies, nongovernmental organizations and other collaborators to strengthen their technical and financial support to the Action Programme;

4. REQUESTS the Director-General:

(1) further to strengthen the leadership and advocacy by the Action Programme in mobilizing and coordinating a global collaborative effort to improve access to essential drugs and ensure the rational use of drugs;

(2) to encourage contacts with bilateral and multilateral aid agencies, with organizations and bodies of the United Nations system, bilateral and multilateral agencies, with consumers, industry, nongovernmental organizations and other collaborators;

(3) to ensure that the concept of the revised drug strategy is fully reflected in WHO's work towards reform in the health sector;

(4) to ensure that adequate financial and human resources are provided under the regular budget and from extrabudgetary sources, as necessary, to implement the programme, and to meet increased demands from Member States;

(5) to assist Member States in their efforts to ensure that available drugs are of good quality, and in combating the use of counterfeit drugs;

(6) to report on the current state and the progress made in the drug sector throughout the world by publishing periodically up-to-date information on the world drug situation;

(7) to report to the Forty-ninth World Health Assembly, and subsequently biennially, on progress achieved and problems encountered in the implementation of WHO's revised drug strategy, with recommendations for action.

Twelfth plenary meeting, 10 May 1994
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FORTY-SEVENTH WORLD HEALTH ASSEMBLY **WHA47.16**

Agenda item 19 11 May 1994

WHO ethical criteria for medicinal drug promotion

The Forty-seventh World Health Assembly,

Recalling resolutions WHA41.17, WHA43.20 and WHA45.30;

Noting the continued need to improve the quality of drug promotion through the use of the concepts embodied in the WHO Ethical Criteria for Medicinal Drug Promotion;

Having considered the report of the Director-General[1] on the outcome of the CIOMS/WHO Consultation on the WHO Ethical Criteria,

1. THANKS the Council for International Organizations of Medical Sciences (CIOMS) for having convened the consultation in collaboration with WHO, and for the valuable report adopted by consensus and which covers a wide range of issues and the action to be taken;

2. APPRECIATES the commitment of the participants - drug regulatory authorities, pharmaceutical manufacturers and distributors, health professionals, universities and teaching institutions, professional associations, patient and consumer groups, and the professional and general media - to a common responsibility, based on fundamental ethical principles, for the well-being of patients individually and the public collectively;

3. ENDORSES the report of the consultation and reaffirms:

(1) that the regulation of drugs must ensure not only the safety, efficacy and quality of drugs but also the accuracy of the information provided pursuant to their regulation;

(2) that patients, pharmacists and prescribers should have access to appropriate and understandable information about drugs and their side-effects;

(3) that the promotion of drugs must be accurate, fair and objective, and presented in such a way as to conform to legal requirements and also to high ethical standards;

(4) that promotional claims should not be stronger than valid, up-to-date scientific evidence warrants, every effort being made to avoid ambiguity;

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[1] Document A47/7.

(5) that information for patients and prescribers which appears in leaflets of drugs in the manufacturing country should be supplied by the manufacturer to the countries to which the same drugs are exported;

4. CALLS UPON all concerned parties to continue to collaborate in order to promote further and implement the principles embodied in WHO's Ethical Criteria for Medicinal Drug Promotion, by rapidly adopting, as appropriate, measures based on the CIOMS/WHO recommendations;

5. URGES Member States to develop and implement national mechanisms, where relevant, to control drug promotion in accordance with the principles embodied in the WHO Ethical Criteria, and as proposed in the WHO Certification Scheme;

6. REQUESTS the Director-General:

(1) to implement the recommendations of the CIOMS/WHO consultation applicable to WHO, giving special attention to:

(a) wide dissemination of the WHO Ethical Criteria to all Member States and all other concerned parties;

(b) measures to develop and disseminate educational materials on the WHO Ethical Criteria, and methods to monitor their implementation;

(c) monitoring the implementation of the WHO Ethical Criteria and collecting information on voluntary, self-regulatory national and international codes and guidelines that relate to the promotion of medicinal drugs, in consultation with all concerned parties;

(d) carrying out studies or surveys of current promotional practices as necessary, and analysis of the effectiveness of the Ethical Criteria;

(e) support to Member States, as appropriate, in strengthening drug regulatory capacity and mechanisms regarding the labelling and promotion of medicinal drugs;

(f) dissemination of national experience in the promotion of medicinal drugs;

(g) alert Member States to the importance of this role for universities and other educational institutions and assist them in educational programme development;

(h) periodical review of the WHO Ethical Criteria in consultation with interested parties;

(2) to report regularly, through the Executive Board, on progress made and problems encountered by WHO and Member States, as part of the reporting on the implementation of the revised drug strategy.

Thirteenth plenary meeting, 11 May 1994
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FORTY-SEVENTH WORLD HEALTH ASSEMBLY WHA47.17

Agenda item 19 11 May 1994

Implementation of WHO's Revised Drug Strategy Safety, Efficacy and Quality of Pharmaceuticals

The Forty-seventh World Health Assembly,

Having reviewed the report of the Director-General on the implementation of WHO's Revised Drug Strategy;

Recalling resolutions WHA37.33, WHA39.27 and WHA41.16;

Noting that pharmaceutical trade is becoming more complex as more countries manufacture and export pharmaceutical and biological products and active ingredients, and as new technologies are applied to their production;

Aware, therefore, that countries need to develop the capability to assure the quality of all such products - both brand name and generic and both domestically manufactured and imported - on their national markets;

Aware, moreover, of an unacceptable prevalence of substandard and counterfeit pharmaceutical products in international trade which threatens to erode confidence in the health-care system because such products may be inefficacious or toxic;

Aware also of the important role of the community in drug control,

1. REAFFIRMS the principles embodied in WHO's Guiding Principles for small national drug regulatory authorities and the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce;

2. URGES Member States to provide the resources and manpower needed to strengthen their national regulatory capability;

3. REQUESTS governments and pharmaceuticals manufacturers to cooperate in order to ensure complementary support of public health goals;

4. REQUESTS the Director-General:

(1) to maintain the normative activities that provide standards to assure the quality, safety and efficacy of pharmaceutical and biological products, including vaccine and sera, having regard to the evolution of new technology;

(2) to ensure the continued and timely provision of independent information to support effective registration, to control excessive claims in advertising and to promote the rational use of drugs;

(3) to provide complementary support and training at country level to assist in strengthening regulatory capacity;

(4) to promote and support the biennial International Conference of Drug Regulatory Authorities as a means of fostering understanding and collaboration between officials in countries at all stages of development.

Thirteenth plenary meeting, 11 May 1994
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