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ACTION PROGRAMME ON ESSENTIAL DRUGS

The Action Programme on Essential Drugs was developed as a result of resolutions EB61.R17, adopted by the Executive Board in January 1978, and WHA31.32, adopted by the World Health Assembly in May 1978 (see Annex 1). A subsequent resolution, WHA32.41, adopted by the World Health Assembly in May 1979, urged Member States to take action in accordance with the two above-mentioned resolutions and to participate in the Action Programme.

Subsequently, after having reviewed the progress achieved in promoting and cooperating in the Programme, it was decided within WHO that to meet the challenge posed by the complex nature of the problems involved, particularly in relation to the pharmaceutical industry, and to clearly identify WHO's role, a global strategy for implementation of the Programme needed to be developed followed by a plan of action.

The attached paper outlines the present situation with regard to the Action Programme in the Western Pacific Region.

## I. INTRODUCTION

The effective use of pharmaceuticals constitutes one of the most important elements of a health care programme. In recent years, there has been a tremendous increase in the number of pharmaceutical products marketed. In most developing countries, however, only a limited number of patients enjoy the benefits derived from access to such products; for the majority, they are inaccessible to a greater or lesser degree, depending on the prevailing socioeconomic situation. It is clear that, for limited financial resources to be used to the greatest effect, the drugs made available must be restricted to those of proven therapeutic value and of acceptable safety, which satisfy the health needs of the population. To attain the goal of health for all by the year 2000 through primary health care, the Member States of WHO accordingly decided to launch an Action Programme on Essential Drugs in conformity with resolutions of the Executive Board and the World Health Assembly.<sup>1</sup>

The Programme is primarily directed towards supporting governments in improving their pharmaceutical procurement and supply systems, in particular in ensuring the availability of essential drugs of adequate quality at the lowest possible cost for national health needs.

Because of the intersectoral nature of a pharmaceuticals production and supply system, there are many constraints on the development of the Programme, including the higher priority accorded to industrial or economic development than to health care, and the influence of private pharmaceutical establishments on decision making at the highest level. These constraints have to be taken into consideration in implementing the Programme.

## 2. PRESENT SITUATION AND ACTION TAKEN

### 2.1 Formulation of national drug policies, including the selection of essential drugs

As a result of the information campaign conducted by WHO, most Member States now acknowledge the importance of formulating national drug policies. However, in practice, few have as yet formulated clear policies. Almost all developing countries have established a list of essential drugs for the public sector. In 1979, in order to encourage the selection of essential drugs at national level, the WHO Regional Office for the Western Pacific published and disseminated

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<sup>1</sup>Resolutions EB61.R17, WHA31.32 and WHA32.41, WHO Handbook of Resolutions and Decisions, Vol. II, 4th ed., 1981, pages 74-76.

a list of essential drugs for countries or areas of the South Pacific. This common list led most of them to formulate their own national essential drug lists. Generally, therefore, countries or areas of the Western Pacific Region are now at the stage of revising their national lists of essential drugs.

## 2.2 Procurement of essential drugs

The drug procurement plans in developing countries are often based on available financial resources rather than on health needs, and consequently drugs are still in short supply in those countries. To improve the situation in the South Pacific area, the establishment of a joint purchasing service, the South Pacific Pharmaceutical Service, has been promoted, through WHO cooperation.

Exchanges of information on drug supply sources and prices are being conducted among ASEAN countries.

## 2.3 Quality assurance

Quality assurance has received lower priority, owing to the absence or inadequacy of quality control facilities. As a result, drugs of doubtful quality are being sold in developing countries. The ASEAN countries are exchanging information in this area within the framework of technical cooperation among developing countries. In the South Pacific, no country or area has a quality control or assurance laboratory but, as a part of the South Pacific Pharmaceutical Service, the establishment of a sub-regional quality assurance laboratory has been proposed.

## 2.4 Logistics and distribution

In most developing countries, the drugs purchased are not stored correctly owing to the shortage of qualified pharmacists and the lack of warehouses. The distribution of drugs from the centre to the periphery is hampered by problems of transportation and logistics particularly among the archipelagoes of the South Pacific. The ASEAN countries have decided to provide training and to promote the exchange of expertise in this field through the medium of technical cooperation among developing countries.

## 2.5 Information on the adequate use of drugs

Although lists of essential drugs have been established in most developing countries, unbiased information on the adequate use of these drugs is still not widely available. An exchange of information is needed. The ASEAN countries have agreed to promote drug information exchange in the context of technical cooperation among developing countries.

## 2.6 Manpower development

The shortage of pharmacists and other types of health worker is a serious constraint on the formulation and implementation of essential drug programmes, particularly in some countries of the South Pacific which have recently become independent. Training courses for health workers other than pharmacists are needed in order to offset the lack of qualified technicians to instruct the public on the proper use of essential drugs.

## 3. PLANS FOR THE FUTURE

A global strategy for the Action Programme on Essential Drugs was agreed upon by a working group which met in New Delhi in December 1980 and subsequently, with some amendments, by the WHO Global Programme Committee.<sup>1</sup> In order to develop the Action Programme in the Western Pacific Region according to the objectives adopted by the Global Programme Committee, the activities to be implemented have been identified.

### 3.1 Objectives

The objective of the Programme is to ensure the regular supply of the most effective and safe essential drugs, of established quality, to all people, at a cost they can afford, through the development of appropriate infrastructures for drug supply systems, as part of national socioeconomic and health development.

The medium-term objective is to strengthen the capabilities of developing countries in the selection, supply, distribution, production, quality assurance and proper use of essential drugs, to meet their real health needs.

The short-term objective is to make available to developing countries essential drugs of recognized quality at a cost their governments can afford, in order to extend primary health care to the majority of the population.

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<sup>1</sup>The Global Programme Committee is composed of the Director-General, the Deputy Director-General, the Regional Directors and the Assistant Directors-General. It meets in Geneva twice a year, in January and May.

### 3.2 Approaches

#### 3.2.1 Formulation and implementation of national drug policies

In the Western Pacific Region, WHO will collaborate by:

- (1) promoting the formulation of national drug policies, based on health needs, in those countries or areas where such policies are not yet definitely established;
- (2) encouraging the revision of national lists of essential drugs;
- (3) supporting the construction of warehouses, particularly in countries or areas of the South Pacific and the Indochinese Peninsula, in order to improve drug storage conditions;
- (4) facilitating shipping transport services in order to improve national drug distribution systems in the South Pacific;
- (5) designating collaborating centres, mainly for the South Pacific, which will perform drug stability tests under tropical and oceanic conditions;
- (6) establishing and facilitating national drug assurance laboratories and, if necessary, subregional laboratories for areas such as the South Pacific or some countries of ASEAN;
- (7) advising on the improvement of drug legislation in countries where national drug policies have been formulated but which still have implementation problems;
- (8) providing training in the control of dangerous drugs for countries or areas where such drugs are handled;
- (9) renovating facilities for the manufacture of drugs in countries of the Indochinese Peninsula;
- (10) encouraging developed countries to produce improved medicines for tropical diseases.

#### 3.2.2 Cooperation among Member States of the Western Pacific Region

There are some components of national drug policies which could be better implemented through technical cooperation among developing countries.

In the Western Pacific Region, two programmes for technical cooperation among developing countries have been initiated: a joint procurement and quality control scheme for the South Pacific (South Pacific Pharmaceutical Service) and technical cooperation among ASEAN countries on pharmaceuticals, adopted at the Meeting of the ASEAN Ministers of Health in July 1980.

WHO will continue to promote such cooperation in the Region.

### 3.2.3 Strengthening of the manpower capabilities required for implementation of the Programme

The strengthening and development of qualified manpower capability will be a key factor in the achievement of Programme objectives. The characteristics of each country should be taken into account when collaborating in training courses or providing fellowships.

Since manpower development is mainly the responsibility of Member States, WHO will collaborate in the Region by:

- (1) providing expertise for the evaluation of manpower needs;
- (2) organizing workshops and seminars;
- (3) mobilizing funds and other resources for training purposes, including fellowships.

### 3.2.4 Development of guidelines and manuals

To offset the shortage of qualified manpower, further efforts will be made to develop guidelines and manuals in relation to the procurement, storage and distribution of essential drugs, drug utilization, drug legislation and regulatory control, quality assurance systems, basic tests, and quality control laboratories.

### 3.2.5 Collaboration with other United Nations agencies

With the aim of pooling the collaborative expertise and funds available within the United Nations system, the following United Nations agencies and institutions will be invited to participate in the Programme:

- UNICEF - in a joint WHO/UNICEF programme on the provision of essential drugs for primary health care, and in joint purchasing schemes;
- UNDP - by providing financial support;
- UNIDO - by cooperating in the development of the pharmaceutical industry.

### 3.2.6 Mobilization of funds from international and regional financial institutions and other potential contributors

The widest possible support will be mobilized for implementation of the Programme, including resources from such agencies as the Asian Development Bank, the South Pacific Bureau for Economic Cooperation and the Japan Shipbuilding Industry Foundation.

### 3.2.7 Dialogue with the pharmaceutical industry

The industry will be encouraged to provide essential drugs at low cost, as well as information on their use. However, it is important to recognize that the industry is profit-oriented, its objective being to increase its share of the market, whereas WHO's goal is to promote social and health development.

WHO will continue its dialogue with the industry at global and regional levels, with contact being maintained between all those taking part in the Programme to ensure a unified approach. In the Western Pacific Region, China, Japan and Republic of Korea are considered to be good sources for the supply of essential drugs.

RESOLUTION OF THE EXECUTIVE BOARD OF THE WHO

Sixty-first Session

EB61.R17

20 January 1978

DRUG POLICIES AND MANAGEMENT - ESSENTIAL DRUGS

The Executive Board,

Recalling resolution WHA28.66;

Having considered the report of the Expert Committee on the Selection of Essential Drugs<sup>1</sup> and the report of the Director-General on Drug Policies and Management;<sup>2</sup>

Realizing that large segments of the world's population do not have access to the most essential drugs and vaccines that are indispensable to ensure effective health care;

Recognizing the importance of an adequate supply of essential drugs and vaccines to meet the real health needs of people, particularly in developing countries, through the implementation of national programmes of health care;

Deeply concerned by the high proportion of health budgets spent on pharmaceuticals by governments of developing countries, thereby limiting the remaining funds available for the provision of adequate health care to the whole population;

Stressing the need to provide essential drugs of adequate quality, in sufficient quantity and at reasonable costs to meet the health needs of these countries;

Considering that local production of essential drugs and vaccines is a legitimate aspiration which developing countries have expressed on many occasions, and that considerable progress has been achieved in some countries;

Convinced that urgent international action is required to alleviate this situation through the establishment of an action programme of technical cooperation on essential drugs aimed at strengthening the national capabilities of developing countries in the field of selection and proper use of essential drugs to meet their real needs, and in local production and quality control, wherever feasible, of such drugs;

1. REQUESTS the Director-General:

(1) to continue to identify the drugs and vaccines which, in the light of scientific knowledge, are indispensable for basic health care and disease control in the vast majority of the population, and to update periodically this aspect of the report of the Expert Committee on Essential Drugs;

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<sup>1</sup> WHO Technical Report Series, No. 615, 1977.

<sup>2</sup> Document EB61/WP/2.

EB61.R17

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- (2) to cooperate with Member States in formulating drugs policies and programmes that are relevant to the real health needs of populations, aimed at ensuring access of the whole population to essential drugs at a cost the country can afford;
- (3) to foster technical cooperation among developing countries for the formulation and implementation of appropriate programmes on drugs, including the local production of essential drugs and vaccines;
- (4) to stimulate bilateral and multilateral cooperation in order to provide generous support to countries for the implementation of their programmes on drugs, including the local production of essential drugs and vaccines;
- (5) to maintain a dialogue with the pharmaceutical industry in order to assure its collaboration in meeting the health needs of large under-served segments of the world's population;
- (6) to appeal to governments and the pharmaceutical industry to participate in WHO's action programme of technical cooperation aimed at making available to governments of the less developed countries essential drugs and vaccines under favourable conditions in order to extend population coverage;
- (7) to assist in the development of a system of quality control of the products provided under such a programme of technical cooperation.

Seventeenth meeting, 20 January 1978  
EB61/SR/17

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RESOLUTION OF THE WORLD HEALTH ASSEMBLY

THIRTY-FIRST WORLD HEALTH ASSEMBLY

WHA31.32

23 May 1978

ACTION PROGRAMME ON ESSENTIAL DRUGS

The Thirty-first World Health Assembly,

Recalling resolutions WHA28.66 and EB61.R17;

Having considered the progress report by the Director-General<sup>1</sup> on Drug Policies and Management;

Realizing that large segments of the world's population do not have access to the most essential drugs and vaccines that are indispensable to ensure effective health care;

Recognizing the importance of an adequate supply of essential drugs and vaccines to meet the real health needs of the people, through the implementation of national programmes of health care;

Deeply concerned by the high proportion of health budgets spent on pharmaceuticals by governments, particularly of developing countries, thereby limiting the remaining funds available for the provision of adequate health care to the whole population;

Stressing the need to provide essential drugs of adequate quality, in sufficient quantity and at reasonable costs to meet the health needs of these countries;

Considering that local production of essential drugs and vaccines is a legitimate aspiration which developing countries have expressed on many occasions, and that considerable progress has been achieved in some countries;

Considering that the establishment of a pharmaceutical industry in countries where it does not exist requires transfer of appropriate technology and investment and that most developing countries cannot afford this without international cooperation;

Recognizing the importance of objective information about pharmaceuticals and the risk of uncontrolled promotional activity by manufacturers, particularly in developing countries;

Convinced that collective purchases of large quantities of pharmaceuticals would substantially reduce their costs;

Convinced that urgent international action is required to alleviate this situation through the establishment of an action programme of technical cooperation on essential drugs aimed at strengthening the national capabilities of developing countries in the field of selection and proper use of essential drugs to meet their real needs, and in local production and quality control, wherever feasible, of such drugs;

Highly appreciating the steps already taken by the Director-General to make available essential drugs and vaccines necessary for the extension of the health care coverage of the population;

1. ENDORSES resolution EB61.R17.

<sup>1</sup> Document A31/12.

WHA31.32

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2. URGES Member States, particularly developing countries to:

- (1) establish adequate drug procurement, storage and distribution systems in order to make available drugs of adequate quality, at reasonable prices, to the population;
- (2) establish national drug lists or formularies by international nonproprietary names (generic names) including essential drugs selected on the basis of the health needs of the countries and taking into account the criteria of the WHO Expert Committee on the Selection of Essential Drugs (Technical Report Series No. 615);
- (3) enact legislation as appropriate covering drug registration, use or prescription by generic names, control of drug information, including therapeutic indications and mention of side-effects, price regulation and definition of the type of drugs authorized for use or prescription by different levels of health workers;
- (4) collaborate in the exchange of information on drug policies and management through bilateral or multilateral programmes and WHO.

3. REQUESTS the Director-General:

- (1) to continue to identify the drugs and vaccines which, in the light of scientific knowledge, are indispensable for primary health care and control of diseases prevalent in the vast majority of the population, and to update periodically this aspect of the report of the Expert Committee on Essential Drugs;
- (2) to cooperate with Member States in formulating drug policies and management programmes that are relevant to the health needs of populations, aimed at ensuring access of the whole population to essential drugs at a cost the country can afford;
- (3) to improve existing WHO supply services for drugs, including vaccines, and medical equipment through closer collaboration with UNICEF, and to ensure that developing countries take full advantage of such services;
- (4) to ensure collaboration with UNDP, the World Bank and regional Development Banks and Funds, UNICEF and UNIDO with a view to ensuring that technical expertise and financing are made available to interested countries to establish local production, wherever feasible, corresponding to their health needs, it being understood that financing should be independent of the source of technology;
- (5) to develop further the dialogue with pharmaceutical industries in order to assure their collaboration in meeting the health needs of large underserved segments of the world's population;
- (6) to study how prices of pharmaceutical products are determined and possible strategies for reducing such prices including the development of a code of marketing practices, with special emphasis on pharmaceutical products essential for the populations of developing countries;
- (7) to take appropriate steps to cooperate with Member States in developing quality control systems for drugs, either imported or locally produced, and to establish regional quality control networks;
- (8) to foster exchange of information among Member States on drug policies and management and on technical aspects of pharmaceutical products;
- (9) to submit to the sixty-third session of the Executive Board a comprehensive action programme as outlined above aiming at fostering technical cooperation among developing countries and to stimulate bilateral and multilateral cooperation in this programme;
- (10) to invite governments directly interested in the implementation of this action programme in their own countries, governments willing to provide support, relevant United Nations agencies and other appropriate cooperating parties to participate;
- (11) to submit a report on the progress achieved in the implementation of this action programme to subsequent sessions of the Executive Board and World Health Assembly.