



THIRTY-SECOND WORLD HEALTH ASSEMBLY

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ACTION PROGRAMME ON ESSENTIAL DRUGS

Progress report by the Director-General

In response to resolution WHA31.32, the Director-General reports here on the progress achieved so far in developing the action programme on essential drugs. The document outlines the objectives of the programme, the proposed technical and administrative components, and the types of resources required; it also emphasizes the need for the formulation of national drug policies. The extent of implementation of the programme will depend on the mobilization of additional resources and on the priority given by the countries themselves to essential drugs within their health development plans. A number of governments have already expressed interest in participating in the programme, and some are willing to provide support. Interest has also been expressed by some major drug industries. The document refers to the integration, within the programme, of current WHO activities in the drug field. Finally, information is provided on developments in each of the WHO regions.

The progress report is intended to keep the Health Assembly informed on the implementation of the policy decisions taken by the previous Health Assembly in 1978.

1. Urgent international action is required to alleviate the situation in many developing countries where large segments of the world's population do not have constant access to the most essential drugs,<sup>1</sup> which are indispensable for primary health care. In fact, for many diseases affecting millions of people, effective drugs and vaccines already exist, but are not available in sufficient quantities and are not effectively distributed or utilized in health care. Without such essential drugs, effective health care cannot be provided no matter what efforts are made to train health workers and to develop the infrastructure.
2. Essential drugs are medicines of the utmost importance that are basic, indispensable and necessary to cater for the health needs of the vast majority of the population. They are selected on the basis of scientific criteria and of the assessment of the community's health needs, not of demand. Drugs considered to be essential differ from country to country depending on many factors, such as the pattern of prevalent diseases and the type of health personnel available. Essential drugs cannot provide for the needs of every individual but should, in a given situation, meet those of the vast majority and be available at all times, together with adequate information on their proper use at different levels of the health care network.
3. The International Conference on Primary Health Care (Alma-Ata, USSR, September 1978) recognized that primary health care required a continuous supply of essential drugs, and that the progressive extension of primary health care to ensure eventual national coverage entailed a large increase in the provision of such drugs. The Conference recommended that governments

<sup>1</sup> The term "essential drugs" is used here to include vaccines.

formulate national policies and regulations with respect to the import, local production, sale and distribution of drugs and biologicals so as to ensure that essential drugs are available at the various levels of the health care system at the lowest feasible cost. These recommendations are consonant with resolution WHA31.32 and with strategies to achieve "Health for all by the year 2000".

4. At its sixty-third session in January 1979, the Executive Board reviewed a comprehensive report<sup>1</sup> on the proposed programme prepared by its Ad Hoc Committee on Drug Policies, after which it adopted resolution EB63.R20.<sup>2</sup> During the Board's discussions, general agreement was expressed with the proposals contained in the Ad Hoc Committee's report. With regard to the suggested administrative structure, for which the Ad Hoc Committee had felt that it would be premature to make detailed proposals, preference was expressed for a decentralized rather than centralized structure, with full involvement of the regions.

5. The objectives of the proposed programme are: (i) to strengthen the national capabilities of developing countries in the selection, procurement, distribution and proper use of essential drugs to meet the health needs of the majority of their population; (ii) to strengthen, whenever feasible, the local production and quality control of such drugs; and (iii) to make essential drugs, including vaccines, available under favourable conditions to governments of the least developed countries in order to extend primary health care and disease control.

6. To achieve these objectives, the right political climate will be crucial and it will be necessary for governments to formulate drug policies within the framework of health policies aimed at meeting the health needs of the majority of the population. At the request of governments, the proposed programme would provide adequate support and cooperation for a survey of the country situation, which could lead to the formulation of strategies and to further technical cooperation in the following main areas: (i) selection of essential drugs and assessment of the requirements at different levels, particularly the primary health care level, taking into account local conditions and plans for extending the coverage of the population; (ii) quality assurance and drug procurement, including intercountry and regional approaches to quality control and purchasing; (iii) building up of efficient drug distribution systems, particularly for rural areas, including storage facilities; (iv) development of local or regional production of the most commonly used essential drugs on a step-by-step basis, starting with the establishment of low-cost formulation units with in-process quality control; (v) better use of natural resources, particularly medicinal plants, through studies of their therapeutic properties and the establishment of local processing facilities; and (vi) research and training activities in fields related to the proposed programme (this component would be very important in stimulating the involvement in the action programme of universities, medical schools, health institutions and research laboratories in developing countries).

7. The extent of implementation of the action programme will depend on resources made available, in addition to those from the WHO regular budget, through the full collaboration of governments and agencies participating in the financing and execution. The following support will be required: (i) financial resources; (ii) resources in kind (essential drugs and vaccines, raw materials, equipment, etc.); (iii) technical personnel; and (iv) training facilities. The mobilization of these additional resources from governments and development aid agencies will depend on the formulation of country and intercountry strategies, plans and projects, with the full involvement of the regional level, and on the priority given by the countries themselves to essential drugs within their health development plans.

8. In response to a circular letter (C.L.16.1978) sent by the Director-General on 28 June 1978 to all Member States transmitting a copy of resolution WHA31.32, the governments of the following 32 countries had, up to 1 March 1979, expressed interest in participating in consultations and negotiations for the establishment of the proposed action programme:

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<sup>1</sup> Executive Board, sixty-third session: Resolutions and decisions (document EB63/48), Annex 7.

<sup>2</sup> Ibid., p. 23.

Australia	Jordan
Belgium	Mexico
Burundi	Mozambique
Cape Verde	New Zealand
Central African Empire	Norway
Congo	Pakistan
Costa Rica	Rwanda
Denmark	Swaziland
Ecuador	Sweden
El Salvador	Switzerland
France	United Kingdom of Great Britain and Northern Ireland
Germany, Federal Republic of	United Republic of Cameroon
Greece	United States of America
Hungary	Venezuela
Iceland	Viet Nam
Italy	
Japan	

Preliminary consultations have been initiated.

9. The dialogue with pharmaceutical industries requested in resolution EB63.R20, in order to ensure their collaboration in meeting the health needs of large underserved populations, is being developed at different levels, particularly through the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), a nongovernmental organization in official relations with WHO. The subject was extensively discussed at the IFPMA General Assembly in October 1978. After explanation of the proposed action programme on essential drugs, some major drug manufacturers offered to provide essential drugs under favourable conditions in economic and specially identified packages for use in the public health sector of the less developed countries, provided that large quantities were ordered (by collective purchasing) and payments were guaranteed. As this component of the proposed action programme is an area in which UNICEF is currently involved in wide operational activities, WHO maintains close contacts with this organization with a view to joint efforts to improve the services available to developing countries for the supply of essential drugs.

10. Close contacts are maintained not only with UNICEF, but also with other United Nations organizations which, within their terms of reference, have developed activities related to essential drugs. WHO is collaborating with UNCTAD and UNIDO in an interregional project, supported by UNDP, entitled "Economic and technical cooperation among developing countries in the pharmaceutical sector". These organizations will also be invited in due course to participate in the action programme.

11. In accordance with resolution WHA31.32, work is continuing on the identification of drugs and vaccines which, in the light of scientific knowledge, are indispensable for the control of the most prevalent diseases and for the extension of primary health care to the vast majority of the population. Comments and proposals for updating the model list of essential drugs contained in the report of the WHO Expert Committee on the Selection of Essential Drugs<sup>1</sup> have been received from members of WHO's expert advisory panels, government officials, nongovernmental organizations in official relations with WHO, scientific institutions, drug manufacturers, regional offices and specialized units of WHO. A second meeting of the Expert Committee will be convened in July 1979 to update the model list on the basis of the comments received, indicate commonly used dosage forms for each drug on the list, and provide information on the proper use of the drugs.

12. Transfer of information on the proper use of essential drugs by prescribers is of course a vital element in the success of the programme. A bulletin entitled Drug information is already issued periodically by WHO and widely disseminated; it is envisaged that this bulletin will include information on the proper use of essential drugs in health care.

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

13. Quality assurance of imported or locally-produced drugs is a problem of great concern to national health authorities in many developing countries. The WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce<sup>1</sup> could provide partial assurance of the quality of imported products, including essential drugs. Up to 1 March 1979, the following 38 countries had agreed to participate in this scheme:

Argentina	New Zealand
Australia	Norway
Austria	Poland
Belgium	Portugal
Congo	Republic of Korea
Cyprus	Romania
Denmark	Senegal
El Salvador	Spain
Egypt	Swaziland
Finland	Sweden
France	Syrian Arab Republic
Iceland	Thailand
India	Tunisia
Iran	United Arab Emirates
Israel	United Kingdom of Great Britain and Northern Ireland
Italy	United Republic of Tanzania
Japan	United States of America
Jordan	Zaire
Liberia	
Mauritius	

14. The first volume of the third edition of the International Pharmacopoeia,<sup>2</sup> to be published in 1979, will describe general methods of analysis, taking into account the various technical and economic constraints, and recommend optimum solutions for drug control laboratories in developing countries. Work on basic tests to be used where well equipped laboratories are lacking is progressing, and the results of field trials will be reviewed by a WHO expert committee at the end of 1979. These general guidelines are particularly relevant to the quality assurance of essential drugs.

15. Within the framework of the proposed programme, UNDP has been approached with a view to obtaining support for a comprehensive interregional project on quality assurance and the strengthening of local capabilities in the formulation of essential drugs, to be implemented in 1980-1983. Guidelines are being prepared for the establishment of low-cost formulation units, with in-process quality control, for the local formulation of 20-30 essential drugs for primary health care, taking into account the need to protect the products from deterioration due to adverse climatic conditions. The draft guidelines will be circulated for comment by the end of 1979.

16. Infectious diseases will not be contained unless the majority of the target population can be given safe vaccines known to have satisfactory potency. For this reason, great emphasis is being placed, within the programme, on improvements in the production and quality control of vaccines. Furthermore, an active research programme directed towards the production of vaccines with increased stability in the countries with high ambient temperatures is in progress. The transfer of technology for production and quality control is at an advanced stage, as there are WHO requirements and standards for the manufacture and control of all vaccines required for immunization programmes for children. Requirements for the production facilities have also been formulated, as well as a detailed description of the

<sup>1</sup> WHO Official Records, No. 226, 1975, Annex 12.

<sup>2</sup> World Health Organization. International pharmacopoeia, 3rd ed., Geneva, 1979, vol. 1 (General methods of analysis).

production of diphtheria/pertussis/tetanus vaccine. Assistance in quality control is given through UNDP's financial support for individual and group training. At the immediate practical level, WHO is able to test and give advice on the suitability of any particular product.

17. The better use of natural resources, particularly medicinal plants, is a component of the proposed programme which is of great interest to many developing countries. While aspects related to the use of medicinal plants in health care are being approached at the regional level, it is felt that general guidelines on the selection and characterization of medicinal plants (crude drugs) should be formulated at the global level. A report will be published in 1979 containing (i) an initial list of medicinal plants widely used throughout the world; (ii) guidelines for their standardization, including nomenclature, specifications, manufacture, labelling and packaging; and (iii) principles for the preliminary investigation of plants considered to have medicinal properties.

18. All the WHO regions are developing activities related to the action programme, the most important of which are outlined below.

#### African Region

19. In the developing countries of the African Region the introduction of the concept of essential drugs has a much greater impact than in countries where drugs are in sufficient quantity and in ready supply. At its meeting in Brazzaville from 9 to 13 October 1978, the Regional Expert Committee on Drug Policies and Management underlined the importance of establishing national lists of essential drugs as soon as possible, according to national needs and the prevailing disease pattern. The Expert Committee acknowledged that the medical profession, as well as the patient, has to be educated to change its attitude towards drug consumption, avoiding complex prescriptions and the use of expensive special products so as to limit treatment to a few effective and simple drugs. The use of nonproprietary names was considered a necessary element of the programme.

20. To assure the quality of the drugs consumed, the Expert Committee recommended that more African countries should join the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce. At the present time, Congo, Mauritius and Senegal have agreed to participate in the scheme.

21. Several studies are in progress concerning the possibility of local production of essential drugs in the Region. In all of them, it has been stressed that the pharmaceutical industry should be established on a subregional basis, within the framework of technical cooperation among developing countries. The African Development Bank has undertaken a joint feasibility study with WHO in order to find the most suitable means of implanting a local pharmaceutical industry, while country studies have so far been carried out in Congo, Ghana and Togo. The Central African Customs and Economic Union (UDEAC) proposed the establishment of a nucleus of drug production in the Central African Empire. A WHO mission visited the countries of the Economic Community of the Great Lakes (Burundi, Rwanda and Zaire) as well as Botswana and Kenya in order to explore the possibilities of harmonizing their programmes on drug procurement.

22. In order to collect the necessary information on a regional basis, a circular letter has been sent to all countries of the Region asking for information on the actual status of local production, quantities available for export to neighbouring countries, price lists, and existing quality control facilities. Five countries have replied giving detailed answers (Congo, Kenya, Malawi, Nigeria, Swaziland). Chad has indicated that it produces vaccine for veterinary use. Eleven countries have indicated the absence of local production of drugs or vaccines (Benin, Botswana, Cape Verde, Central African Empire, Gabon, Guinea-Bissau, Liberia, Rwanda, Seychelles, Sierra Leone and Upper Volta).

23. In order to solve the acute problem of drug shortage, contact was established, in February 1979, with the Association of Pharmaceutical Industries of the Federal Republic of Germany, which showed great interest in supplying the most essential drugs to the whole Region. Crucial elements of such a programme are now being identified by the countries of the Region wishing to participate, including the establishment of a list of 30-40 essential drugs and some 10 vaccines considered as the most urgently needed, estimates of the quantities required over a five-year period, and the location of three subregional quality control laboratories.

#### Region of the Americas

24. "The impact of drugs on health costs: national and international problems" was the subject of the Technical Discussions held during the XX Pan American Sanitary Conference, which was also the thirtieth session of the WHO Regional Committee for the Americas. The Technical Discussions stressed the need to develop realistic national drug policies to provide adequate coverage of the population with products of proved safety and effectiveness and of high quality, at reasonable cost.

25. To ensure an adequate supply of basic drugs to government programmes for the extension of health care coverage and primary health care in the countries of the Region, contact has been established with the Federation of Latin American Pharmaceutical Industries (FIFARMA) in order to identify problems within the public health sector requiring the industries' collaboration and to propose lines of action to solve them.

26. To improve contacts with drug regulatory agencies in the Region, a regional working group on drug control will be convened in May 1979 in the United States. The working group will focus on criteria for drug registration and advertising and on mechanisms for the exchange of information.

27. The regulatory control of drugs and quality assurance programmes utilizing existing or expanded laboratory facilities and the provision of training for drug inspectors and analysts are receiving special attention in Brazil and Guatemala.

28. In the Caribbean area a subregional drug testing laboratory is in the process of being established in Jamaica, with the partial support of the Canadian International Development Agency. It will provide important quality control services for pharmaceutical procurement offices and bulk purchasing programmes in the countries of the area.

#### South-East Asia Region

29. The action programme on essential drugs is starting to take shape in the Region. After the Regional Committee's 1979 session, at which the subject of "Drug policy, including traditional medicine, in the context of primary health care" will be taken up during the Technical Discussions, an action programme will be delineated more closely, and funds have been provided to carry it out. As part of the background paper for these Technical Discussions, an outline for a proposed regional programme on the subject will be prepared.

30. Among the countries moving ahead in essential drugs are Bangladesh, where a list has been formulated for use at the primary level and manufacturing facilities are being established to cope with part of the demand, and Sri Lanka, where a recent pre-feasibility study was carried out on the rationalization and expansion of facilities for the manufacture and control of essential drugs.

31. The problem of adapting the WHO list of essential drugs to the countries' health structure, and particularly of determining which drugs are to be used at each level of health care, is receiving attention in Burma, India, Indonesia and Nepal. In Burma, there is also considerable interest in expanding manufacturing facilities.

### European Region

32. In this Region, the pace of drug innovation has accelerated during the last decades. At the same time, a marked decrease in the number of available new products has recently been noticed and many proprietary preparations of single or combined therapeutic substances have appeared.

33. The concept of essential drugs has been developed at a time when national expenditures on drugs have reached an intolerably high level, and practically all countries of the Region have attempted to lower the drug bill through various measures.

34. In most countries, procedures for more intensive clinical evaluation of drugs are being developed; in that context, it has been noted that new and relatively expensive preparations are sometimes of limited value in the treatment of certain diseases but are still accepted as alternate drugs.

35. Drug use studies, forming the basis of drug policies and management programmes, have been extended in the Region and more countries are expected to be represented at the next meeting (Prague, 22-25 August 1979) of the European drug utilization research group which coordinates the studies. Such meetings provide a forum for extension of the regional programme of action on essential drugs.

### Eastern Mediterranean Region

36. In the Eastern Mediterranean Region, WHO collaboration with countries is expanding in scope in respect of procurement of drugs, drug administration and control, pharmaceutical inspection, drug registration, dissemination and exchange of information, and manpower development. Studies on drug utilization are in progress in Democratic Yemen and Sudan, with the focus on the primary health care level.

37. WHO fellows from 10 countries of the Region participated in two seminars on pharmaceutical inspection held in the Federal Republic of Germany in 1976 and 1977. The objectives of the WHO action programme on essential drugs, especially the need to provide drugs of adequate quality at reasonable price, were referred to at a Symposium on Drug Evaluation and Licensing held in Alexandria in 1978.

### Western Pacific Region

38. This was the first Region to convene a working group on the regional aspects of drug policies and management. The meeting was held in March 1978 in Manila to review and analyse the various aspects of the problem, to identify priority areas for technical cooperation, and to prepare and recommend an action programme for such cooperation within and among the countries/areas of the Region. The Working Group laid the basis for the formulation of the regional medium-term programme on drug policies and management and on pharmaceuticals, which provides guidelines for action up to 1983.

39. A preliminary survey of the situation with regard to drug policies and management in Fiji, Papua New Guinea, Samoa, Solomon Islands and Tonga, which included drawing up national lists of essential drugs, was carried out in July-August 1978. Following this, a survey on drug utilization at the different levels of the health service, especially in rural health centres, was carried out in Papua New Guinea in August-September 1978.

40. These surveys provided the technical input for the Meeting on Technical Cooperation among South Pacific Countries/Areas in Pharmaceutical Supplies, held in Suva, Fiji, from 4 to 8 December 1978 and jointly sponsored by WHO and the South Pacific Bureau for Economic Cooperation. During the meeting, a list of essential drugs for use in the South Pacific was finalized and adopted, and a programme was recommended for the establishment of a South Pacific joint pharmaceutical service, to include bulk procurement, quality control, storage and repacking, delivery of pharmaceuticals, and manpower development. The meeting proposed the establishment of a task force to prepare a paper setting out the political and technical

implications of implementation of the programme, to be considered at a Conference of Ministers of Health of the South Pacific to be held in Manila from 12 to 15 November 1979.

41. Representatives from other countries/areas in the Region will also be invited to attend this Conference so that they are adequately informed of this programme of technical cooperation among developing countries (TCDC). The Conference is expected to consider the implementation of the South Pacific joint pharmaceutical service, the possible structure of the programme from the TCDC viewpoint and its political and administrative relationship to participating international organizations, and possible financing for the programme.

42. Two subregional workshops on drug quality control and management are being planned - one in Suva, Fiji, in December 1979 and another in Kuala Lumpur, Malaysia, in February-March 1980.

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