



20 October 1978

EXECUTIVE BOARD

Sixty-third Session

Provisional agenda item 19



INDEXED

ACTION PROGRAMME ON ESSENTIAL DRUGS

The Director-General has the honour to transmit herewith the report of the Board's Ad hoc Committee on Drug Policies, which contains proposals for a comprehensive action programme on essential drugs as outlined in resolution EB61.R17 and subsequently endorsed by the World Health Assembly in resolution WHA31.32. In addition, the Director-General wishes to draw the attention of the Board to the following information:

1. A circular letter (C.L.16.1978) was sent on 28 June 1978 to all Member States transmitting a copy of resolution WHA31.32. As at 15 October 1978, 20 governments had expressed interest in participating in consultations and negotiations for the establishment of the proposed action programme and had designated representative(s) for this purpose.
2. Comprehensive surveys have been undertaken in some of the countries most seriously affected by the shortage of essential drugs. A common list of essential drugs is being developed by five South Pacific countries. Moreover, representatives of seven African countries are meeting in November 1978 to consider how the proposed action programme could help most effectively in meeting their urgent needs.
3. The dialogue with pharmaceutical industries, either private or state-owned, is progressing in order to ensure their collaboration. It is not possible, at this preliminary stage, to predict how far such industries, particularly those engaged in production from raw materials to finished products, will contribute to the aims of the action programme. However, it is interesting to note that the new role of WHO in pharmaceuticals is becoming a subject of great interest in industrial circles.
4. After the discussions at the Thirty-first Health Assembly (May 1978), a number of major drug manufacturers (e.g., Bayer, Ciba-Geigy, Cyanamid, Hoechst, Hoffmann-La Roche, Sandoz) pledged their collaboration through the provision, to governments of the least developed countries, of selected products suitable for use in extending and improving the health care coverage of the population. These selected products would be made available under specially favourable conditions in economic packages, taking into account the requirements of primary health care and tropical climatic conditions, with uniform labelling, including generic names and possibly an emblem indicating the special character of the action programme, as the products should not move into the private commercial sector or be re-exported. The conditions would be more favourable if the requirements could be planned for a period of 3-5 years. The products concerned fall into the following categories: amoebicides, analgesics and antipyretics, antibiotics, anti-infectives, antimalarials, antischistosomes, antitrypanosomals, antituberculosis drugs, cardiovascular drugs, and vaccines. Further offers of collaboration are expected.
5. It is clear that these positive reactions from some drug manufacturers can be of no help without the political will of the governments to identify and tackle the problems in their own countries, and without the commitment of additional financial resources from the international community. In fact, as pointed out in the attached report, the first step should be the assessment of drug requirements in both the short and long term, taking into account countries' present and planned health programmes and distribution systems. The types and quantities of essential drugs needed could then be determined for a period of 3-5 years and the improvement of the supply position would become a key factor in extending health care coverage to the whole population.

ANNEX

REPORT OF THE AD HOC COMMITTEE ON DRUG POLICIES OF THE EXECUTIVE BOARD  
ON THE ACTION PROGRAMME ON ESSENTIAL DRUGS

The Ad hoc Committee on Drug Policies was established by the Board at its sixty-first session (January 1978) to study and follow up the action programme on essential drugs proposed in resolution EB61.R17.<sup>1</sup> The Committee met in Geneva on 23 January 1978 and from 3 to 5 May 1978 under the chairmanship of Professor D. Jakovljević.

1. INTRODUCTION

1.1 The Ad hoc Committee recalled that the Executive Board, in proposing the action programme on essential drugs, had emphasized that urgent international action is required to alleviate the situation in developing countries, where large segments of the world's population do not have access to the most essential drugs and vaccines that are indispensable to ensure even minimum health care. In fact, for many diseases affecting millions of people in these countries, effective prophylactic and therapeutic agents already exist, but are not available in sufficient quantities and are not effectively distributed or utilized. Furthermore, at present some of them are too expensive for the less developed countries. In many cases, locally available natural resources could be better utilized.

1.2 In the coming decades, the development of primary health care systems in the developing countries will require the concomitant development of pharmaceutical supply systems, including local production wherever feasible, adapted to the real needs of the majority of the population. Efforts will also be required in information, education and training in the proper use of drugs in the communities. In this perspective, the action programme on essential drugs proposed in resolution EB61.R17, when implemented, can make a significant contribution to "Health for all by the year 2000".

2. REVIEW OF ACTIVITIES

2.1 The Ad hoc Committee felt that the reorientation of WHO's programme in the drug field, following the adoption by the Twenty-eighth World Health Assembly of resolution WHA28.66 in 1975, had increased awareness of the main problems of relating pharmaceutical supply to health needs at the global and regional levels. The two regional meetings on drug policies and management for participants from the South-East Asia and Western Pacific Regions, held in Colombo and Manila in March 1978, had demonstrated the countries' wide acceptance of the new programme and their interest in the planned activities.

2.2 WHO staff had visited a number of developing countries to initiate surveys of national pharmaceutical supply systems, and this had led to the formulation of local projects in some countries. The Ad hoc Committee considered that, in the further development of this programme, WHO should give careful consideration to the proper balance of actions in the developing countries necessary, on the one hand, to achieve urgent improvements in the supply position and, on the other hand, to build up national capabilities. Otherwise, results could be counter-productive. For example, in some countries the provision of finished pharmaceutical products could inhibit or delay the step-by-step expansion of local production, starting with the simplest operations and moving towards the more complex ones. Conversely, the establishment of local production without a feasibility study of the health, economic, technological and logistic aspects could lead to inadequate quality or excessive cost of the products, which might not be suitable to meet the health needs of the population.

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<sup>1</sup> WHO Official Records, No. 244, 1978, p. 11.

2.3 The Ad hoc Committee reviewed the background document (document A31/Technical Discussions/1) for the Technical Discussions to be held during the Thirty-first World Health Assembly on "National policies and practices in regard to medicinal products; and related international problems". This document reviewed the world situation, particularly in developing countries, and underlined the necessity of formulating national drug policies in the light of local health priorities. The Ad hoc Committee noted the trends towards increasing self-reliance and technical cooperation among developing countries (TCDC) in this field. Section 5 of the document, describing the technical and administrative components of drug policies and management of the pharmaceutical supply system, was considered to provide a very suitable framework for the development of the action programme proposed in resolution EB61.R17.

### 3. OBJECTIVE OF THE PROGRAMME

3.1 The Ad hoc Committee discussed the development of the action programme and the need to provide a definition of its objective. In accordance with the Board's resolution, the following definition is proposed:

"The action programme on essential drugs is a global programme of international cooperation initiated by WHO and co-sponsored by (other UN agencies agreeing to participate) with the objective of strengthening the national capabilities of developing countries in the selection, supply and proper use of essential drugs to meet their real health needs, and in the local production and quality control, wherever feasible, of such drugs. The immediate aim of the action programme is to make essential drugs and vaccines available under favourable conditions to governments of the less developed countries in order to extend essential health care and disease control to the vast majority of the population".

3.2 To achieve this objective, it will be necessary at country level for individual governments to formulate a national drug policy linked with country health programming and to build up the infrastructure required to implement it. This will call in turn for the provision of additional resources of all kinds, involving the full collaboration of governments and agencies participating in the financing and execution of the proposed action programme. As the programme is primarily oriented towards the health sector of development, WHO should serve as the executing agency, in association with other United Nations organizations as appropriate, and should be responsible for its management.

### 4. ACTIVITIES IN THE COUNTRIES

4.1 The first step in the formulation of a national drug policy aimed at meeting the real health needs of the majority of the population must be to identify these needs, using all available health information, and to ensure that, once identified, they are reviewed regularly. Consideration should then be given to the extent to which the existing pharmaceutical supply system can meet the health needs, and to the steps necessary to improve its efficiency. At the same time, in some countries, it will be necessary to consider the role of traditional medicines in relation to modern drugs.

4.2 At the request of the government concerned, the proposed action programme could provide adequate support for a comprehensive survey of the country situation as outlined above, which could lead to further cooperation in strengthening the national technical and managerial capabilities and in building up the required facilities in the following main areas:

4.2.1 Drug selection and requirements. The selection, for the various levels of health care, of the most essential drugs of proven efficacy, acceptable safety and reasonable cost, that could best meet the needs of the majority of the population, is a prerequisite for extending the coverage of the population. Epidemiological surveys and clinical pharmacological expertise are required in drug selection and in determining the quantities required at different levels, particularly at primary health care level, taking into account local conditions.

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4.2.2 Quality assurance. Once the most essential drugs and vaccines have been selected, there is a need for quality assurance of the products imported or produced locally. The building up of an effective quality assurance system requires personnel properly trained in drug procurement, analytical control and pharmaceutical inspection, as well as adequate equipment for quality control.

4.2.3 Distribution and logistics. In many developing countries, the main problem is to ensure that the "right" drugs are always available to the population that needs them, particularly in rural areas. The building up of an efficient distribution system requires careful planning and the provision of adequate storage facilities, inventory control, transportation facilities and skilled personnel at all levels, including the primary health care level.

4.2.4 Local production. The establishment or strengthening of local production of essential drugs and vaccines, where appropriate, requires long-term planning, taking into account the types of products and the quantities required, technical manpower, types of buildings and equipment for production and quality control, quantity, grade and cost of raw materials, etc. Feasibility studies could determine the capital investment required and the annual running costs so that the cost of local production can be compared to the cost of equivalent imported products.

4.2.5 Natural resources. The use of drugs of natural origin, particularly medicinal plants, can be improved through the proper evaluation of their usefulness in health care, the development of appropriate technology for the collection, cultivation, processing and establishment of specifications for widely used crude drugs, and the introduction of good practices for the production, quality control and distribution of finished products. Suitably trained personnel and adequate equipment are required for these activities.

4.2.6 Research and development. Among the priority areas for drug research and development in the developing countries are the following: the stimulation of research and development involving drugs and vaccines most relevant to these countries' health needs; the better utilization of locally available natural resources, including traditional medicines, for pharmaceutical production; and the development of appropriate technology for packaging and formulating the most essential drugs in the country.

4.3 In all these areas, information transfer, educational and training activities, and the development of technical cooperation among developing countries (TCDC), would require adequate support from the action programme. The programme could also help to improve the supply position of the least developed countries, where the lack of essential drugs and vaccines is the main constraint in developing national programmes for the extension of essential health care and disease control to larger segments of their population.

## 5. RESOURCES

5.1 In view of the scale and scope of the proposed action programme, the following resources would be required for its implementation, in addition to those available to WHO through its regular budget:

5.1.1 Financial resources made available to the action programme by cooperating parties (see below), which could be channelled through a special fund, the "Essential Drugs Fund", through the WHO Voluntary Fund for Health Promotion and through similar funds of other agencies.

5.1.2 Resources in kind (essential drugs and vaccines, raw materials, equipment, etc.) made available to the action programme by cooperating parties and administered by the executing agency through special protocols covering operations in each country.

5.1.3 Technical personnel, seconded by cooperating parties to the action programme.

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5.2 In order to mobilize the widest possible support for the action programme, the Ad hoc Committee considered that, in addition to the co-sponsoring United Nations organizations, the following cooperating parties should be invited to participate:

5.2.1 Governments willing to contribute to the action programme in cash or in kind: governments providing technical support for the action programme; and governments whose countries are directly affected by the shortage of essential drugs and vaccines to meet the real health needs of the people through the implementation of national programmes of health care.

5.2.2 Those intergovernmental, nongovernmental and industrial organizations willing to contribute in cash or in kind, or to provide technical support for the action programme.

5.3 In this context, the Committee urged that steps be taken, as soon as possible, to establish a dialogue with the pharmaceutical industry to secure its active collaboration in the programme.

## 6. ADMINISTRATION

6.1 The Ad hoc Committee was informed of the technical and administrative structures of other special programmes for which WHO is the executing agency, but felt that it would be premature to make detailed proposals. However, it considered, on the basis of the experience gained in those programmes, that it would be appropriate to outline a possible management structure for the action programme so that negotiations could be initiated with potential cooperating parties (see Annex 1).

6.2 It is envisaged that there would be a "Joint Coordinating Board" (or "Committee") representative of the parties cooperating in the action programme, responsible for reviewing and approving the proposed plans of action and budgets for the programme and evaluating progress. In addition, the co-sponsoring United Nations organizations would be represented in a "Standing Committee" (or a "Steering Committee") intended to guide and coordinate their contributions to the action programme. Finally, there would be a "Technical Advisory Committee" (or "Panel"), comprising technical experts serving in their personal capacities, to review and evaluate the action programme from the technical point of view and to provide the Joint Coordinating Board with a continuous independent technical evaluation of all programme activities.

## 7. CONCLUSIONS

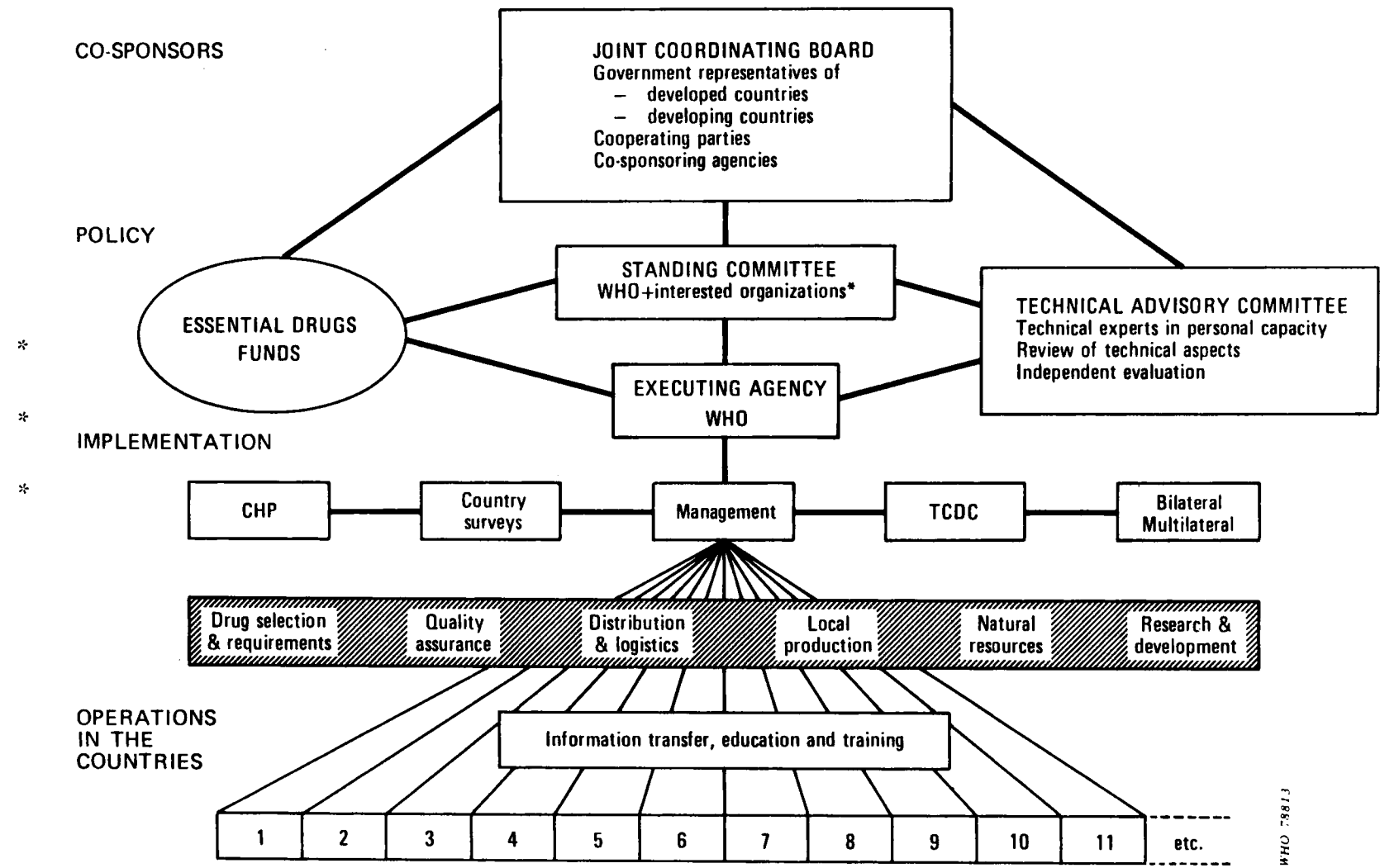
The Ad hoc Committee, having studied the information provided by the Secretariat on the reorientation of WHO activities and on possible ways of implementing the action programme on essential drugs proposed in resolution EB61.R17, arrived at the following conclusions:

7.1 When implemented, the proposed programme can make an important contribution to the extension and improvement of health care to those segments of the world's population which, at present, are denied access to even the most indispensable drugs and vaccines.

7.2 The meetings on drug policies and management held in the South-East Asia and Western Pacific Regions in March 1978 provided valuable information on the present situation in the developing countries concerned and on the acceptance of the proposed programme. Similar meetings should be convened in the other regions to extend the available base information and increase general awareness of the serious problems of access to essential drugs in the developing world.

7.3 Consultations and negotiations should be undertaken as soon as possible with the appropriate governments, agencies, and other parties to establish the action programme, including further discussions with the pharmaceutical industry to explain more clearly the aims of the proposed programme and to enlist the industry's active cooperation in its implementation.

ACTION PROGRAMME ON ESSENTIAL DRUGS: SUGGESTED STRUCTURE



\*Efforts will be made, in due course, to solicit UNDP, UNICEF, UNIDO, UNCTAD and the World Bank to participate.

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