

*directing council*



PAN AMERICAN  
HEALTH  
ORGANIZATION

XXXI Meeting

*regional committee*

WORLD  
HEALTH  
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XXXVII Meeting

Washington, D.C.  
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Provisional Agenda Item 26

CD31/8 (Eng.)

15 July 1985

ORIGINAL: ENGLISH

REPORT ON THE PROGRESS OF THE IMPLEMENTATION OF THE ORGANIZATION'S  
ESSENTIAL DRUG PROGRAM

At its 95th Meeting, the members of the Executive Committee expressed their concern regarding the continuing difficulties encountered by Member Governments in ensuring the availability of essential drugs to all sectors of the population at reasonable cost. In the discussion following the presentation of the attached progress report of the Organization's essential drugs program (Document CE95/4, annexed) the complex nature of the pharmaceutical sector and the existing industrial, commercial and professional interests were mentioned as elements that must be considered in any comprehensive approach toward improving the present situation. The need for intersectoral action at the national and international levels and the utilization of TCDC/ECDC mechanisms were highlighted.

The Executive Committee approved Resolution XXI which, inter alia, reiterates the recommendation that Member Governments formulate intersectoral policies and implement national programs on essential drugs, and requests the Director to continue promoting cooperation by the Organization in this area. This resolution is, therefore, presented to the Directing Council for its consideration, as follows:

THE 95th MEETING OF THE EXECUTIVE COMMITTEE,

Having seen the report on the progress of the implementation of the Organization's essential drug program (Document CE95/4),

RESOLVES:

To recommend to the XXXI Meeting of the Directing Council that it adopt a resolution along the following lines:

## THE XXXI MEETING OF THE DIRECTING COUNCIL,

Having seen the report on the progress of the implementation of the Organization's essential drug program (Document CD31/8); and

Considering that the Program is progressing in accordance with the recommendations approved by the XXIX Meeting of the Directing Council of PAHO,

## RESOLVES:

1. To recommend that the Member Governments:
  - a) Formulate intersectoral policies and implement national programs on essential drugs, recognizing the importance of such drugs for the extension of coverage of health services and the need to rationalize expenditures for these drugs;
  - b) Ensure that drugs marketed are of good quality and available at reasonable cost to all sectors of the population, and promote and monitor the rational and wise prescription and use of marketed drugs;
  - c) Give emphasis to the analysis and formulation of pharmaceutical policies, to the strengthening of controls and quality assurance, to the development of systems for the supply of essential drugs, to the encouragement of domestic production where this is economically feasible and where countries are able to meet quality standards, and to manpower training, operations research, and evaluation mechanisms;
  - d) Examine the possibilities held forth by TCDC/ECDC for solution of the problems involved in making drugs accessible to populations in the Region.
2. To request the Director:
  - a) To continue promoting cooperation by the Organization in the development and implementation of program activities relating to essential drugs;
  - b) To mobilize extrabudgetary resources for strengthening the Regional program and improving its capability for technical cooperation in support of national programs on essential drugs;
  - c) To support TCDC/TCC activities directed at finding ways to improve the supply of drugs of adequate quality at the lowest possible prices in the countries of the Region.

*executive committee of  
the directing council*

PAN AMERICAN  
HEALTH  
ORGANIZATION



*working party of  
the regional committee*

WORLD  
HEALTH  
ORGANIZATION



95th Meeting  
Washington, D.C.  
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CE95/4 (Eng.)  
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ORIGINAL: SPANISH

REPORT ON THE PROGRESS OF THE IMPLEMENTATION OF THE ORGANIZATION'S  
ESSENTIAL DRUG PROGRAM

Resolution XXX of the XXIX Meeting of the Directing Council requested the Director to establish a program of technical cooperation to advise the Member Countries on all matters relating to drug policies and programs. In response to this request, the Secretariat, after identifying basic problem areas, has selected strategies and initiated activities designed to support the countries in their efforts to ensure the quality and availability of essential drugs together with their appropriate prescription and use. The lines of work being pursued by the Program are the following:

- . Analysis and formulation of drug policies
- . Production of essential drugs
- . Supply systems for essential drugs
- . Quality control and assurance

The report details the Regional Program's activities in these lines of work. It is important to note that special emphasis has been placed on the promotion and execution of activities in the Central American Isthmus, since essential drugs form one of the seven critical areas included in the Plan of Priority Health Needs for Central America and Panama agreed on by the Ministers of Health of the subregion and supported by the Governing Bodies of PAHO and WHO.

Introduction

The Technical Discussions of the XXIX Meeting of the Directing Council of PAHO held in 1983 considered the topic "Policies for the Production and Marketing of Essential Drugs". After studying the report of these discussions, the Directing Council approved Resolution XXX that

requests the Director "to provide, as budgetary resources permits, technical and financial assistance in establishing, in keeping with the recommendations formulated in the Report of the Technical Discussions, a cooperation program at the regional, subregional and national levels, with a view to advising the Member Countries in all matters relating to the implementation of drug policies and programs". The Director was also asked to present to the XXXI Meeting of the Directing Council a report on progress in the implementation of PAHO's essential drug program. This document has been prepared to meet that request.

#### Activities of the Regional Essential Drugs Program

In response to the mandate to set up a broad program of technical cooperation in the field of essential drugs, the Secretariat has identified the basic problem areas and selected strategies designed to provide sustained support to Member Countries in their efforts to ensure: a) the marketing of drugs of recognized efficacy and safety; b) the availability of quality drugs at reasonable cost for all segments of the population, with emphasis on primary care, and c) rationalization of the prescribing and appropriate use of drugs. The Program's lines of action are as follows:

- 1) Analysis and formulation of drug policies
- 2) Quality control and assurance
- 3) Supply systems for essential drugs
- 4) Production of essential drugs

The principal common components of these lines of action are: development and utilization of human resources, development of information systems, promotion of research and establishment of evaluation mechanisms.

As the Ministries of Health of Central America and Panama had identified essential drugs as one of the seven critical areas to be covered in the Priority Health Needs Plan for the subregion, the Director asked the Secretariat of PAHO to pay special attention to the development of activities in the Isthmus. Accordingly, in June 1984, the Program coordinated a meeting of the National Groups of the Essential Drugs Priority Area, with a view to defining the subregional projects and preparing the respective profiles. Later, these groups prepared profiles of national projects along the same lines. The Program is presently collaborating with the national groups in the adjustment and development of the proposals for their submission to financing and technical cooperation agencies.

The Regional Program activities, started in 1984 in accordance with the lines of work referred to above, are set forth in the following:

## Analysis and Formulation of Drug Policies

Promotion of consistent intersectoral policies at national and subregional level is one of the priorities of the Essential Drugs Program, since in many countries the existing policies are often out of step with the priority health needs and inconsistent with the complexity and development of the world pharmaceutical market.

Legislation is the instrument by which policies can be translated into concrete actions. PAHO has begun a comparative study of current drug legislation in selected countries of the Region, dealing with the priority fields of the Program, with a view to providing the countries with information that will enable them to modernize and expand the scope of their legislation.

Bearing in mind that identification of the drugs that are essential for the different levels of public sector health care is the first step toward rationalization of expenditure on drugs and their use, the Regional Program has published a monograph on Preparation and Use of Drug Formularies. This monograph contains the guidelines for the drawing up and use of national formularies and is the product of the experience built up by the Secretariat and Member Countries in this field.

The final report of the Technical Discussions of the XXIX Meeting of the Directing Council includes a recommendation to the Governments that they promote self-sufficiency in the pharmaceutical sector. To this end PAHO has coordinated a study on the production of raw materials in the three Latin American countries--Argentina, Brazil, and Mexico--whose pharmaceutical industries are the most technologically developed and have the greatest degree of vertical integration. The findings of this study provided the basis for proposing a regional strategy aimed at complementary integration of the production capacity in those countries and expansion of their markets with a view to obtaining economies of scale that would also benefit the other countries of the Region. The proposals were discussed at the International Preparatory Meeting for the Development of Industrial Chemical and Pharmaceutical Production held in Oaxtepec, Mexico, in July 1984, and attended by representatives of the three countries concerned and Spain, and are set forth in the final report of that meeting.

The recommendations and agreements on action resulting from that meeting include collaboration in trade and industrial production, together with exchange of information on international raw material prices, the promotion of research and the training of human resources. The resolutions adopted by the meeting were supported by a declaration of the Ministers of Health of Argentina, Brazil, and Mexico presented during the September 1984 Meeting of the PAHO Directing Council, and subsequently subscribed to by Spain as well.

To ensure proper follow-up of the resolutions adopted, it was decided to set up a Technical Secretariat composed of representatives of the countries involved. At this moment the governments are in the

process of appointing the professionals to fill these positions, whose first task will be to draw up the work program for the agreed activities.

In Colombia, a preliminary study was made of the pharmaceutical sector that served as the basis for an interinstitutional workshop for analyzing the development of the national drug policies, held in Medellín in March 1984. As a follow-up to this workshop, PAHO helped with the development of a national drug program coordinated by the Colombian National Health Institute.

PAHO and WHO continued their technical cooperation to the Government of Nicaragua in its efforts to formulate and establish a national drug policy, giving priority to coordination of the assistance being provided by the various bilateral and multilateral agencies in the pharmaceutical sector.

PAHO has been collaborating with the Government of Argentina in the performance of the studies needed for the establishment of a national drug supply program known as the Drug Assistance Fund (Fondo de Asistencia de Medicamentos--FAM) that is designed to meet the needs of the economically underprivileged groups at no cost to the beneficiaries.

Various countries have expressed their special concern to PAHO about the problems connected with the price of drugs in the market. PAHO has responded to this concern by collaborating with the national authorities in making a diagnosis of the situation and formulating alternatives for better control of this item. PAHO has provided specific technical assistance in this area to Colombia, Ecuador, Honduras, and Peru.

The document prepared by the PAHO Secretariat for the Technical Discussions is available as Scientific Publication No. 462 entitled "Production and Marketing Policies for Essential Drugs". This publication can be useful to Member Governments in clarifying conceptual aspects and for support in determining national and regional policies and strategies in the sphere of essential drugs.

#### Quality Control and Assurance

This program line includes three types of services falling within the competence of the central normative level of the Ministries of Health, namely, the evaluation and registration of drugs, inspection of production plants and distribution facilities, and laboratory analyses. Drug quality is one aspect of the total question in which WHO and PAHO technical cooperation is already traditional and their leadership acknowledged. Despite the support provided, the national services in the majority of the countries of the Region have not yet reached the level of development that is desirable. The Regional Program accordingly decided to approach the matter using different strategies so as to speed the development of these services. As part of this new approach, the public sector supply systems have also been included in the scope of the

technical cooperation. In cases where there are parallel quality control services their integration is being encouraged, while in the other instances the conclusion of service agreements between the institutions involved is being prompted. This will make possible better utilization of the existing resources and rationalization of investments and expenditures, and at the same time serve to expand the drug quality evaluation program to those accessible to the population of the countries.

Another of the strategies used consisted in the organizing of a Latin American network of official health sector drug control laboratories, formed to begin with by institutions from 11 Latin American countries. This initiative was decided upon at a workshop held in Buenos Aires, Argentina, in December 1984, with the collaboration of the National Institute of Pharmacology and Bromatology. The laboratory network will foster communication and the integration of related institutions, the execution of continuing education programs, performance of collaborative research, organization of an information system, harmonization of methodologies, the setting up of bilateral agreements for the provision of complementary services, and the exchange of experts within the mechanism for intercountry technical cooperation. The network will also make it possible to coordinate the regional program for the manufacture of reference substances for pharmaceutical preparations. A tangible outcome has been the joint formulation of the network's program of activities for 1985.

Execution of the tripartite United Nations Development Program/Pan American Health Organization (UNDP/PAHO) projects with the Governments of Guatemala and Brazil was continued in the course of 1984. The first of these focuses primarily on the evaluation and registration services and the laboratory services through institutional development of the "Laboratorio Unificado de Control de Alimentos y Medicamentos" (LUCAM) and expansion of its operating capacity so as to be able to meet, in addition to the demand of the central normative level, that of the Guatemalan Social Security Institute and the National Supply Service. The second concentrates on development of the scientific and technological infrastructure and training of manpower for the National Institute for Quality Control in Health (INCQS). The possibility is presently being studied of extending the project under way in Guatemala, which is due to end in mid-1985, for a further two years in order to allow continuity of the process and consolidation of the results obtained so far. The collaboration was continued with the Caribbean Regional Drug Testing Laboratory in Kingston, Jamaica, which performs specialized pharmacological and microbiological analyses of Jamaica, pharmaceutical products imported into or produced in the subregion.

The Regional Program and the Specialized Analysis Laboratory of the University of Panama, designated in 1985 as a WHO Collaborating Center, have collaborated in the organizing of training and refresher courses and workshops in registration, pharmaceutical analysis and post-marketing surveillance of drugs.

Finally, direct advisory services have been provided to the following countries interested in developing and setting up national drug testing programs, design of specific projects and diagnostic studies: Argentina, Mexico, Colombia, Ecuador, Haiti, and Chile. Special mention should be made of the technical cooperation with the countries of the Central American Isthmus in the preparation of profiles of subregional and national projects, redefining of terms of reference, subsequent development of these profiles and the search for and initiation of negotiations with national and international financing agencies within and outside of the United Nations system.

### Supply Systems

The Regional Program is placing great emphasis on the training and use of human resources for administration of the drug supply systems. The collaboration of subregional and national institutions has been of considerable importance in the development of this activity. Subregional training courses for instructors (train the trainers) in drug supply administration were held in March 1984 at the "Universidad Javeriana" in Colombia for representatives of Andean countries, and in November 1984 in the Central American Institute of Public Administration (ICAP) for the Central American Isthmus and the Dominican Republic. The subregional activity led to the organization of national courses in 1984 in Bolivia, Ecuador, Peru, and Venezuela with the collaboration of the Hipólito Unanue Agreement. Similar courses are planned for 1985-1986 in the Central American area. With PAHO cooperation, the "Central de Medicamentos" in Brazil held a regional-scale course on the political, technical and administrative aspects of an essential drugs program.

The manual "El Suministro de Medicamentos" has been published in Spanish under the auspices of UNICEF, the Agency for International Development (AID) and the Pan American Health and Education Foundation (PAHEF) and is distributed by the PAHO Expanded Textbook and Instruction Materials Program as Manual No. 1 in the PALTEX series for health program executive personnel. This valuable publication is used in the courses sponsored by PAHO and has been distributed to the governmental officials concerned.

In the English-speaking Caribbean the Barbados Drug Service (BDS) has been designated a WHO Collaborating Center in Drug Supply Systems Administration, in recognition of the significant experience it has built up in the planning and launching of a national program of pharmaceutical services. PAHO received valuable assistance from BDS technicians in the advisory services provided to Dominica for the preparation and publication of its national drug formulary, and also in the work done in St. Vincent and the Grenadines and that started recently in Saint Lucia to improve their drug supply systems. However, PAHO has not yet developed a specific work plan with the BDS for support in its sphere of competence to the Caribbean countries.

In Central America and Panama, PAHO is continuing to cooperate with the Ministries of Health and/or social security institutions in the rationalization of their supply procedures. In order to support a joint procurement system for essential drugs, PAHO financed a feasibility study that forms the basis for one of the subregional projects in the drug area within the framework of the Priority Health Needs Program. A broad diagnostic study is presently being made of the public sector supply systems in the countries of the subregion that will make it possible to align the cooperation activities in this field on the real needs of the countries.

Up-to-date knowledge regarding the prices of drugs and chemicals used in pharmaceuticals enhances the negotiating power of the national institutions vis-à-vis their suppliers, thus enabling them to obtain lower prices on their purchases of pharmaceutical products. The Regional Information Systems and Essential Drugs Programs are collaborating with the Hipólito Unanue Agreement in the basic design of an information system that will serve the governments as an instrument for achieving this objective. This will entail developing a uniform system design, standardized classifications of pharminochemical products and drugs, and a similar data base for the countries forming the systems.

### Production

The production of essential drugs is a new area of technical cooperation for the Regional Program and was established in response to specific recommendations included in the final report, and Resolution XXX of the Technical Discussions of the XXXIX Meeting of the PAHO Directing Council. The actions focused on supporting the making of studies for diagnosis of the situation concerning drug production in existing public sector laboratories and the preparation of profiles of subregional and national projects for raising productivity, developing administrative and technical capability, training human resources and increasing the installed capacity of these institutions. During this first year of technical cooperation the accent was on meeting the requests of the governments of the countries of the Central American Isthmus within the framework of the PAHO initiative on Priority Health Needs. Profiles were prepared for one subregional project and seven national projects for technical cooperation and investment and these were submitted to national and international technical cooperation and financing agencies, including the Inter-American Development Bank (IDB).

The chief purpose of these projects is to ensure the timely and uninterrupted supply of at least 50 essential drugs that are critical for the first level of care by the end of the first year of execution. One of the profiles also envisages support for developing the national industry belonging to the private sector as the principal source of supply for the public sector. Agreements with the Central American Bank of Economic Integration (CABEI) and coordinated activities with the United Nations Industrial Development Organization (UNIDO) made it possible to prepare the initial studies and to proceed subsequently with the preparation of the projects.

PAHO and the Member Governments also indentified high-volume parenteral solutions as one of the lines of work requiring priority attention. The Regional Program has already begun gathering information of this subject, with a view to developing a line of action that considers the needs of the less developed countries of the Region who are entirely dependent on imports of these products to cover the demand of their health services.

### Research

Development of the national drug programs, including the activities directed toward rationalization of drug therapy, requires scientific and technological structures that will serve as a basis for the setting of policies and decision-making. Pharmacology is one of the fundamental components of this basis.

With a view to ascertaining the present status of basic pharmacology, the Program, in conjunction with PAHO's Office of Research Coordination, sponsored a meeting held in April 1984 to study trends and prospects in research on pharmacology in Latin America, with participation by scientists of international standing from the Region. This meeting identified areas of priority interest warranting PAHO support through existing national centers of excellence. Regarding clinical pharmacology, a study was made to identify institutions and academic units actively involved in research, teaching or practice of this discipline. The findings of this study were presented at the XX Latin America Congress of Pharmacology and Therapeutics held in Quito, Ecuador, in November 1984. The reports produced will serve as a basis for defining future technical cooperation in this field.

The Program has promoted studies of the use and consumption of drugs, with a view to quantifying and evaluating the demand so that better use can be made of national resources. The first PAHO-financed study is being carried out in Barbados. At the Regional Workshop on Postregistration Surveillance of Drugs, held in February 1985 with the collaboration of the University of Panama, model research protocols were drawn up for use by the participants in their respective countries.

### Program Resources

The Program is coordinated at central level by the Regional Adviser on Drugs and is carried out with the support of a technician (pharmaceuticals) and short-term consultants. The regular budget for 1984-1985 is \$412,000, to which are added additional funds in the amount of \$395,000 for a total of \$807,000, compared with \$246,000 for the previous two-year period, which has made it possible to start and maintain a set of activities in the program lines mentioned in this report. PAHO and USAID have signed a joint four-year project in the amount of \$3 million, financed by USAID, to support the development of the public sector supply systems and the quality of drugs in the Central American Isthmus.

The Drugs Program only has specialized personnel in Brazil and Guatemala, countries where UNDP-financed projects for developing national drug quality programs are being carried out. In the other countries, the Program's actions are coordinated by the PAHO advisers designated for the purpose by the Field Offices. However, the lack of specialized personnel in the field affects the execution of certain of the activities, limiting their impact.

The governments' growing interest in coming to grips with the multifaceted drug question and the recognition of its complexity is generating a significant demand for technical assistance that is impossible to quantify at this moment. This demand will have to be channeled through the established programming mechanisms and incorporated as appropriate, with allocation of the funds required, into the AMPES of the countries concerned, thereby making it possible to respond more efficiently to the requests submitted for technical cooperation.