executive committee of the directing council

PAN AMERICAN SANITARY ORGANIZATION

working party of the regional committee

WORLD HEALTH ORGANIZATION

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Topic 14: PROGRESS REPORT ON DRUG REGISTRATION AND RELATED PROBLEMS (INTER-AMERICAN REGULATIONS ON INSCRIPTION, REGISTRATION, AND CIRCULATION OF DRUGS)

The 28th Meeting of the Executive Committee, in Resolution XIV, (a) approved in principle a proposal of the Pan American Medical Confederation designed to achieve uniformity of legislation in the American states on the registration of drugs; (b) requested the Director to consult the Pan American Union, the WHO and, as appropriate, the International Union for the Protection of Industrial Property, with a view to determining the most suitable procedure for the attainment of uniformity in the legislation of those American countries which require the registration of drugs; and (c) requested the Director to submit a report to a future meeting of the Executive Committee.

The Director proceeded with a study of the procedures for attaining the goal approved by the Executive Committee. A search of the records showed that the Pan American Sanitary Conference had devoted many hours to a study and discussion of not only the problem of drug registration but the entire need for improved food and drug services in the Americas. These problems were discussed at length following the presentation of papers on the subject of food and drug controls during the Fifth Pan American Conference of National Directors of Health (Washington, 1944) and the XII Pan American Sanitary Conference (Caracas, 1947). The latter meeting adopted a long resolution on the subject of food and drug services in which it made a number of specific recommendations for international action as well as individual action by the Member Governments. The most essential points covered were (a) the creation of an international committee to study the problem of food and drug services, prepare a bromatological code, prepare standards for drugs, etc.; (b) the need for repression of international traffic in fraudulent and dangerous foods and drugs; and (c) the development of courses for the training of national personnel. As no funds were provided for carrying out the recommendations for international action, the resolution was never implemented, at least in these respects.

The review of the previous discussions as well as some study of the extent of the problem today has led the Director to conclude that it is necessary to approach the specific problem of the attainment of uniformity in legislation on drug registration only after a broad consideration of the entire problem of food and drug services. This is necessary because there is no machinery by which the necessary scientific and technical information on pharmaceutical products, which is a sine qua non for administration of a useful registration program, can be made available on a continuing basis to a large number of American republics. It seems apparent that the first step is to develop the necessary machinery for the distribution of such data for use by those governments desiring to develop, on a purely voluntary basis, a national drug control program, including specifically, registration procedures.

Therefore, the Director does not believe that an international conference to consider uniform legislation is practical until there is a solution of the basic problem of making available sound technical and scientific data for all countries desiring to use it. To this end, he has prepared a tentative proposal for a gradual development of international efforts in the food and drug field (Annex I). This document has been transmitted to the Pan American Union, the WHO, and through the latter to the International Union for the Protection of Industrial Property. The Pan American Union does not consider that it can appropriately pass upon the merits of the action contemplated, because of the highly technical nature of the problem presented. The WHO forwarded the proposal to the International Union, which has the matter under consideration. The WHO also referred the matter to its Study Group on the Use of Specifications for Pharmaceutical Preparations. The report of this Study Group will be submitted to the next meeting of the WHO Executive Board, immediately following the Tenth World Health Assembly.

In view of the foregoing, the Executive Committee may wish to adopt a resolution along the following lines:

Proposed Resolution

The Executive Committee,

Having examined the report of the Director (Document CE31/6) on the progress of the studies on drug registration and related problems, undertaken by the Bureau in accordance with Resolution XIV of the 28th Meeting of the Committee;

Considering the resolution adopted by the Pan American Medical Confederation aimed at the achievement of the maximum uniformity of legislation in the American states for the registration of pharmaceutical products;

Considering the necessity of first making available a continuing source of reliable scientific and technical data on food and drug problems, standards, and registration procedures; and

Having studied the Director's proposal for the development of international efforts in the food and drug field (Document CE31/6, Annex I),

RESOLVES:

To take note of the report presented by the Director on the progress of studies on drug registration and related problems, and to approve his proposal for the gradual development of international efforts in the food and drug field, as contained in Document CE31/6, Annex I.

Annex I: Proposed International Collaboration for the Development and Improvement of National Food and Drug Services in the Americas

PROPOSED INTERNATIONAL COLLABORATION FOR THE DEVELOPMENT AND IMPROVEMENT OF NATIONAL FOOD AND DRUG SERVICES IN THE AMERICAS

It is believed advisable to proceed slowly and carefully, step by step, in planning and developing whatever international efforts should be made in the food and drug field. This is particularly important because of the many complex problems and diverse interests involved in a problem which has medical, public health, economic, and political aspects. Moreover, the food and drug problems vary a great deal from country to country throughout the Americas. But something needs to be done to solve the problem, especially for those countries in which a national food and drug service has not been found practical. The steps which should be taken are outlined below.

1. There should be a detailed and careful assessment of the nature and extent of food and drug problems in the Americas. Much has been written and more has been said concerning these needs. Few facts are available and these are frequently out of date. It is suggested, therefore, that expert consultation in this field be obtained by the PASB so that a survey of the situation in each country may be made and a report submitted to the Director.

2. On the basis of present knowledge, it is anticipated that the results of this survey will show the need for establishing, under the aegis of the PASB, cooperative food and drug services to fill the requirements of those countries which may wish to pool their resources.

3. These services initially would be based on the needs reported in the survey, subject, of course, to the practical limits of any international activity. The survey report may show a need for only very narrow and restricted services; on the other hand, it may show a need for more comprehensive international collaboration in the field. Some of the activities which are likely to require consideration are:

(a) Establishment of a clearinghouse to provide to governments, and through them to industry and interested groups, information on food and drug laws, regulations, and practices of American countries; and publication of information and data on research developments, regulatory decisions of governments, administrative procedures on drug registration, and similar information.

(b) Review and analysis of current legal requirements on exportation, importation, manufacture, and supply of foods, drugs, cosmetics, and therapeutic devices; and development of legislative standards for recommendation to governments on registration of drugs and on other activities related to foods and drugs.

(c) Within the framework of such standards as may be prepared by the WHO, development of recommended standards for safety, purity, potency, sanitation, identity, quality, packaging, etc., of foods and drugs.

(d) Expert consultation to advise and assist countries in the development of national food and drug activities.

(e) Training programs for national scientific, technical, and administrative personnel, including development of a fellowship program in collaboration with universities and food and drug agencies.

(f) Laboratory services including (1) development of standard laboratory methods, and (2) upon request of governments, testing (or review of national laboratory testing procedures) and reference laboratory services.

4. The Directing Council of PASO might wish to consider sponsoring an international conference to consider the following with respect to services such as those proposed above if the proposed survey bears out the necessity for the proposed international collaboration for the development and improvement of national food and drug services:

(a) Scope and nature
(b) Organization
(c) Financing
(d) Location
(e) Relationship to PASB