Pan American Sanitary Organization

World Health Organization

XV Pan American Sanitary Conference

X Meeting Regional Committee

San Juan, Puerto Rico
September-October, 1958

CSP15/20 (Eng.)
13 September 1958
ORIGINAL: SPANISH

Topic 34: DRUG REGISTRATION AND RELATED PROBLEMS

(Topic proposed by the Government of Venezuela)

A. Background

The Government of Venezuela requested, in a communication dated 27 June 1958, that a topic "Drug Registration and Related Problems" be included on the agenda of the Conference. After recalling the fact that Resolution XXV of the X Meeting of the Directing Council approved the Director's proposal for the gradual development of international efforts in the food and drug field, beginning with a careful assessment of the nature and extent of the problems concerned, the communication stated that "the Government of Venezuela has always shown the greatest interest in the establishment of any international system for mutual aid among the countries of the Americas in dealing with the numerous and complex problems involved in the registration of pharmaceutical and food products; and it considers that the proposal presented by the Director of the Pan American Sanitary Bureau to the X Meeting of the Directing Council sets forth a plan of action which, if carried out in the manner suggested, would undoubtedly bring positive results of benefit to the various national public health administrations in this important field."

In accordance with established practice, the Director requested the Government of Venezuela to prepare a document incorporating its points of view, so as to facilitate the discussion of the topic during the Conference, and at the same time define the scope of any resolution it would like to propose.

B. Document Presented by the Government of Venezuela

"1. The diagnosis, prevention, and treatment of diseases cannot be carried out without the assistance of the diagnostic, preventive, and therapeutic measures which have been developed by the medical and pharmaceutical sciences for that purpose and have received universal acceptance. This requirement is equally true and invariable whether it concerns the private physician or, even more so, the national public health administrations.

2. The effectiveness of the physicians's theraupetic indications and, in consequence, the success of programs of medical care and public health, can be seriously impaired if the diagnostic, preventive, and curative resources to be used do not strictly meet the needs of each case. The existence of reliable, efficacious, and safe pharmaceutical products is, therefore, a prerequisite for obtaining maximum medical action against the symptom or the disease.

3. The physician is responsible for the diagnosis and the therapeutic indication; but it is the pharmacist who is responsible for preparing the prescribed product in such a way as to guarantee its efficacy. In private medical practice these two responsibilities remain separate, but when governments offer medical and pharmaceutical services to the individual, as is true of nearly all the national medical care programs, there is but one responsibility and it falls on the government concerned.

4. The pharmaceutical industry has developed at a tremendous rate in the last decades. The producing laboratories are constantly multiplying and new pharmaceutical products appear on the market by the thousands each year. Likewise, international commerce has expanded to as high a degree, and there has thus been a tendency to attach more importance to economic and commercial interests than to the high purpose that the preparation of therapeutic substances should serve in behalf of the community.

5. The importance of government regulation of pharmaceutical products is seen from the historic fact that many countries, before organizing national medical care and public health services, had already promulgated laws on drug control. With the advent of public medicine, this responsibility of the State became even more urgent and important, since the medical service furnished by the State includes, inseparably, pharmaceutical service.

6. Insofar as this responsiblity is concerned, the situation in the different countries of the Americas varies considerably. It is possible that in all of them there is the same picture of numerous production firms and countless pharmaceutical patents pending official

approval. And even more possible is the fact that some of those governments do not have the necessary means to properly assume this critical responsibility. The results are obvious: inadequately controlled national products, which under free trade conditions, seek an outlet in foreign markets; and an overwhelming number of pharmaceutical preparations, which exist by the tens of thousands, thereby interfering with the proper use of basic drugs by the medical profession and forcing the interested firms to engage in exaggerated advertising and sales promotion, very often at the expense of scientific ethics and principles that go hand in hand with this important activity.

7. For these reasons, it is advisable to establish a system of international cooperation to assist the governments in the solution of their problems in the field of drug registration and control. The purpose of such a system is not to impose international regulations on governments or create obstacles to free trade and to the development of the pharmaceutical industry. Such restrictions exist today only for narcotics because of the serious risks involved in their production, trade, and indiscriminate usage. A desirable initial system for the Americas should offer:

a) information on the legislative standards and routine practices of the different countries in connection with drug control;

b) regular publications on the most important advance in therapeutics and pharmacology and on problems related to this field;

c) regional or continent-wide meetings for the discussion of these problems and the formulation of appropriate recommendations;

d) services of technical personnel and the interchange of scientific information and national standards to assist the different organizations responsible for control;

e) reply to inquiries on technical matters presented by countries; and

f) reply to inquiries on studies and analyses made in other countries on products pending registration, and interchange of information on products already approved.

8. The Pan American Sanitary Bureau could perform these functions through a drug section established within the Division of Public Health."

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The Government of Venezuela, in transmitting the preceding document with a communication dated 26 August 1958, pointed out that "the document summarizes the Government's points of view on the drug registration problem," and added that its reason for requesting that this topic be discussed at the Conference "was solely to take the opportunity afforded by this meeting of the Organization's supreme governing body to reiterate the concern of the American governments with respect to this important subject, and to give a stimulus to the establishment of the initial plan approved by the Council."

C. Supplementary Information

As will be recalled, the 28th Meeting of the Executive Committee considered this topic at the proposal of the Representative of Cuba, a proposal that cited the motion approved on this subject by the IV General Assembly of the Pan American Medical Confederation. At that meeting the Executive Committee, in Resolution XIV, requested the Director of the Bureau to consult the Pan American Union, the World Health Organization, 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. At the 31st Meeting of the Executive Committee, the Director presented a progress report on this matter, together with an annex containing a provisional plan for the development and improvement of national food and drug services in the Americas, a plan that was approved by the Committee. The Directing Council, in turn, at its X Meeting, studied and approved (Resolution XXV) the aforementioned plan (Official Document No. 18, p. 131 and Official Document No. 22, pp. 22, 25, 133-137, 205-206, and 278-280).

In November 1957 the Director attended the Fourth Pan American Congress of Pharmacy and Biochemistry in Washington, D. C. Both in his statement at the inaugural session, and in his remarks at the symposium of the Section on Pharmacy Laws and Ethics, the Director summarized the basic points that guide the thinking of PASO on problems related to drugs and therapeutic agents, as follows:

> "1. It is essential that means be found for assuring that all pharmaceutical agents be safe, pure, and of uniform potency, and that they be readily available to all countries.
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> "2. The individual country is and must be responsible for the safety, purity, and potency of all pharmaceutical products distributed within its borders.
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> "3. The individual government cannot effectively discharge this responsibility without full and accurate technical information on every product marketed.

"4. Many countries find it impractical, for financial and other reasons, to establish their own facilities for obtaining the necessary technical information.

"5. A means must be found for providing the necessary technical information which governments need in discharging their responsibilities in this field."

In a letter dated 11 December 1957 (Annex I), the Secretary General of the Fourth Pan American Congress of Pharmacy and Biochemistry officially forwarded to the Director of the Bureau the resolution adopted by the Congress on this topic.

The Director of the Bureau considers that the policy set forth by the Organizations's governing bodies with respect to this matter is the most appropriate at the present time, and in compliance therewith has included in the proposed program and budget for 1959 and in the provisional draft program and budget for 1960, provisions for conducting the study on the nature and extent of the problems related to food and drugs in the Americas, as well as for training national personnel.

Annex I

CSP15/20 (Eng.)
ANNEX I
ORIGINAL: ENGLISH

Fourth Pan-American Congress of Pharmacy and Biochemistry
Washington, D. C.
3-9 November 1957

11 December 1957

Dr. Fred L. Soper, Director
Pan American Sanitary Bureau
1501 New Hampshire Avenue, N.W.
Washington 6, D. C.

Dear Dr. Soper:

In performing the duties of Secretary-General of the Fourth Pan-American Congress of Pharmacy and Biochemistry according to the mandate of the Heads of Delegations attending this Congress I wish to bring to your attention the fact that the Fourth Pan-American Congress of Pharmacy and Biochemistry resolved:

"1. To declare that the agreement adopted by the General Assembly of the Pan-American Medical Confederation, held in Bogota, Colombia, in 1955, is prejudicial to the professional obligations and responsibilities of pharmacists and the pharmaceutical industry with respect to the public health of the people in the American States. In addition, the agreement is incompatible with the national economies of the countries involved.

2. To request that the Secretary General of the Congress transmit the above statement to the Pan-American Medical Confederation, the Pan-American Sanitary Organization (the specialized agency of the Organization of American States), and the Ministries of Public Health of the American States for consideration and appropriate action."

Furthermore I wish to report that the Fourth Pan-American Congress of Pharmacy and Biochemistry declared:

"That the professionally-owned establishment called a pharmacy should restrict its activities to medicine in general, and those related to health".

Sincerely yours,

(signed)
George B. Griffenhagen
Secretary-General