

## SUPPORT OF DRUG CONTROL BY THE PAN AMERICAN HEALTH ORGANIZATION<sup>1</sup>

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*All Governments face the need to assure safe and effective pharmaceutical products for their people. This report summarizes what PAHO is doing in the Americas to help in the performance of this task.*

Because of the harm that badly prepared food and drugs can cause, it has been recommended for some time that the Governments maintain supervision of production in order to guarantee that the public receives safe foods as well as safe and effective drugs and therapeutic substances. It has also been recognized in recent years, that the Governments should prevent the distribution of harmful cosmetics and protect the public from dangerous items such as insecticides, caustic agents, solvents, etc., which may be found in the home or contaminate foods.

The volume of products governed by consumer protection laws is enormous. For example, the present retail value of pharmaceutical products consumed annually by the Latin American people has been estimated at US\$1.9 billion. The annual value of food consumed is naturally much greater.

Numerous problems arise in connection with food and drugs. With respect to food the most important relate to the following matters:

- a) Contamination from harmful bacteria, such as *Salmonella*.
- b) Residues of pesticides and chemical substances used on vegetables and fruits.
- c) Safety of chemical substances (food additives) used by food processors.
- d) Antibiotic residues in food (for example,

penicillin in milk from cows treated for mastitis with this drug).

- e) Safety of new foods and new forms of food preparations such as frozen foods, pre-cooked foods, and other "convenience foods."
- f) Safety of coloring agents added to foods.
- g) Lack of food hygiene.
- h) Standards for the composition of essential foods such as bread, cheese, jelly, etc.
- i) Methods for deceiving the public, such as inexact weights and deceptively large packages.

In practice, PAHO's work to alleviate these problems is very closely linked with its work in drug control. A full description of these activities may be found in the *Annual Report of the Director, 1971*.<sup>3</sup>

With respect to drug control, the most important considerations are as follows:

- a) Drug efficacy and safety.
- b) Adulterated drugs and drugs that are defective due to failure to follow proper procedures during manufacture.
- c) Unstable drugs and the loss of potency by drugs while still in distribution channels.
- d) False claims for the curative powers and safety of drugs.
- e) Restriction of the sale of habit-forming drugs such as narcotics and psychotropic drugs.

To the extent that available resources have permitted, the Pan American Health Organization has assisted countries in formulating adequate consumer protection laws and in establishing effective government agencies to

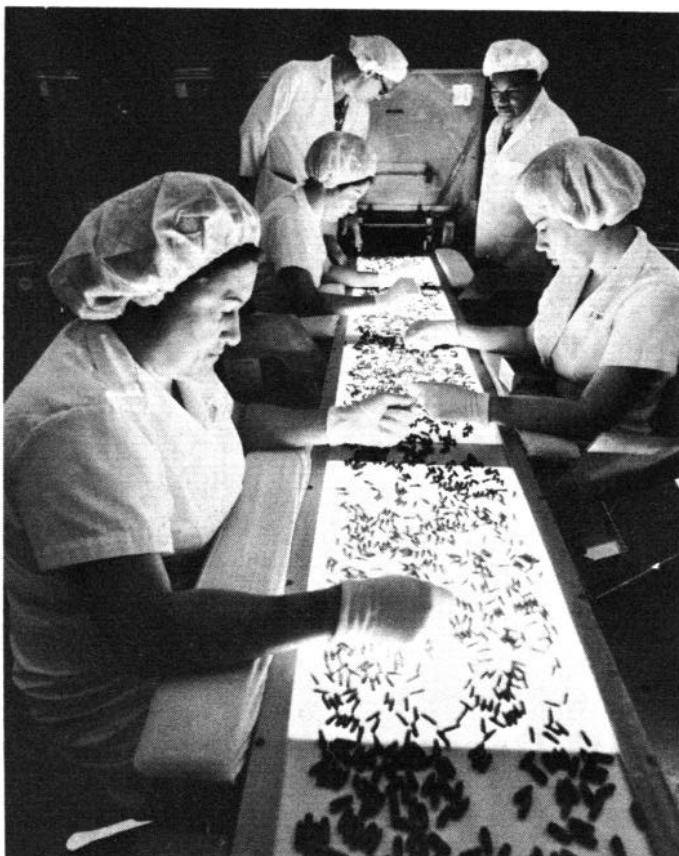
<sup>1</sup>Paper presented at the Seminar on Drug Control in the Americas (Maracay, Venezuela, 15-20 November 1970). Also published in Spanish in *Boletín de la Oficina Sanitaria Panamericana*, Vol. LXXIII, No. 3 (September 1972), pp. 231-236.

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<sup>3</sup>*Official Document PAHO 116* (1972), pp. 82, 256, 322-323.

implement these laws. In the important area of drug control, PAHO lends support as follows:

1. General advisory services have been furnished to the Governments, and adoption of the following principles has been recommended:



This inspection unit in Puerto Rico is examining drug capsules for defects as they pass by on a conveyor belt before being filled with drugs.

a) Each country should enact a comprehensive drug law. We have suggested that the laws of the various countries should be uniform to facilitate international commerce in drugs manufactured in the Americas, and to guarantee the preparation of drugs of uniformly high quality.

b) Each country should have a well-coordinated agency to administer its drug laws. The drug control agency should form part of the national health services and should preferably be directed by a person with well-defined authority so far as compliance with the appropriate legislation is concerned.

c) The agency's inspectors, analysts, and administrators should have the specialized training which will enable them to cope with the

complex problems currently facing drug control agencies.

d) The Governments should support the drug control agencies with sufficient funds to enable them to carry out high-level control activities.

e) Countries which are unable, because of their limited technical resources, to establish national drug analysis laboratories, should send drug samples to centers of recognized competence, such as the Specialized Analysis Laboratories of the University of Panama. An alternative course of action might be to join with other countries to establish a group laboratory.

2. In addition to providing general advisory services, PAHO has answered requests for technical advice on special aspects of drug control. In the past 10 years, it has sent technical advisers for this purpose to Argentina, Brazil, Chile, Costa Rica, Mexico, Panama, Peru, Uruguay, and Venezuela, and to the English-speaking countries of the Caribbean. The experts have remained in these countries from one week to three months. In each case, PAHO has provided the Government with a report of the experts' findings.

It is interesting to note that although different advisers have participated in these studies, their opinions and recommendations have been uniform and consistent. In general, the reports have pointed out the need to improve the organization of national drug control agencies, supplement the training of personnel, and increase the funds available for control activities.

3. On numerous occasions, PAHO has provided government agencies with reagents, laboratory texts, and other items. To the extent that resources permit, the Organization fulfills the technical assistance requests presented by the countries.

4. Since personnel is the most important element in any organization, PAHO has devoted a large part of its activities and available funds to training government health officials. This same course of action has been followed in connection with drug control, and over the years PAHO has sponsored the award of fellow-

ships for the training of numerous analysts and other drug control officials in the countries of the Region. These fellowships have made possible the training of personnel in scientific institutions throughout the world. Activities have been concentrated, however, in the U.S. Food and Drug Administration and the Food and Drug Directorate of Canada.

Recently an intensive five-week training course was offered in Washington, D.C., for drug analysts from nine Latin American countries and the Caribbean area, the U.S. Food and Drug Administration being responsible for the training. This was PAHO's first attempt at sponsoring a group training program for drug analysts.

PAHO's concern with the need for high-level training of analysts and other drug control officials has led it to sponsor the establishment of a regional institute for drug quality. The proposal to create this institute was first formulated in a report prepared in 1965 by Dr. C. A. Morrell, former director of Canada's Food and Drug Control Laboratory. This proposal was supported on various occasions by the Ministers of Health, most recently at the Special Meeting of Ministers of Health of the Americas (Buenos Aires, October 1968).

The creation of this institute is still in the planning stage for lack of the necessary funds. Nevertheless, it is expected that the realization of this project will have an important and lasting effect upon the drug control situation in the Americas. The institute will provide the following benefits:

a) It will facilitate high-level training for drug analysts in Latin America and thereby increase the effectiveness of this personnel.

b) It will serve both as a training center for senior drug control administrators and inspectors and as a forum for the exchange of ideas and experiences among officials charged with applying the drug laws. This training will enable administrators and inspectors to better orient the personnel under their supervision.

c) It will improve the professional prestige of drug analysts, drug control administrators, and inspectors in the Member Countries, and thereby increase the scope of their activities

and their effectiveness in verifying the quality of drugs in each country.

d) It will prompt each Latin American drug manufacturer to make sure its analysts are as well trained as the Government's, thus improving drug quality at the production site.

e) It will act as an information center, providing national laboratories with reliable analytical procedures obtained from a world-wide array of scientific publications.

f) It will aid countries in solving unusual analytical problems.

g) It will carry out research to establish examination procedures uniformly applicable to new drugs introduced in Latin America.

h) By fostering uniformity of analytical procedures and standards, the institute will have a beneficial effect in facilitating uninterrupted trade of drugs between countries, thus giving support to Latin American Common Market principles.

i) It will improve Member Governments' capacity to examine drugs and guarantee their quality. This in turn will increase the confidence of government administrators of treatment centers, social security systems, and other services which make large-scale drug purchases based on relative prices offered by competing suppliers.

j) It will benefit the Latin American scientific community, particularly in the country where the institute is established. This beneficial effect will be felt in diverse branches of biomedical research.

It should be pointed out that the proposed institute will not act as a control laboratory for any country, nor will it have juridical powers of any kind. Its purpose will be simply to facilitate the task of national drug control agencies; all its activities will therefore be aimed at supporting and strengthening the work of national authorities.

5. Since 1965, PAHO has sponsored annual meetings of officials responsible for control of food and drugs in Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama. The meetings have promoted these neighboring countries' traditional cooperation in resolving their common health problems, and have

caused attending officials to form a better idea of the area's food and drug quality problems. These officials have submitted proposals to their Governments for application of uniform procedures dealing with these problems. PAHO believes that its support of these regional meetings has proved very worthwhile.

In connection with its advisory activities in Central America and Panama, PAHO sponsored the establishment of the University of Panama's Specialized Analysis Laboratories. This facility performs an important role in food and drug analysis within the area, and the Central American countries accept its analyses as official for purposes of meeting their legal food and drug registration requirements.

Another regional drug control project being studied would affect the Caribbean area. The Ministers of Health of Barbados, Guyana, Jamaica, Trinidad and Tobago, and the other English-speaking countries of the Caribbean met in 1969, and again in April 1970, to examine health matters of regional interest. At the second meeting they approved a resolution requesting that PAHO carry out a study to determine the feasibility of establishing a drug analysis laboratory in the Caribbean to serve the interested countries of that area. The necessary data on this matter have been collected, and conclusions based on the data are to be presented to the Health Ministers of the Caribbean at their third annual conference.

#### SUMMARY

In the drug control field, PAHO furnishes Member Governments with general advisory services and materials such as chemical reagents and laboratory texts. It also supplies special technical advice upon request, sending advisers to the requesting country to deal with particular problems. Besides this, PAHO sponsors annual meetings for Member Countries' food and drug control officials, and has adopted a number of principles to serve as guidelines in drug control work.

A major effort is also made to help the Governments train officials in this field. Until now this PAHO training program has acted primarily through fellowships that enable personnel from one country to study at scientific institutions throughout the world. For the future, plans are being made to create a Regional drug quality institute. This institute is expected to have an important and lasting effect on the drug control situation in the Americas.