

*executive committee of
the directing council*



PAN AMERICAN
SANITARY
ORGANIZATION

*working party of
the regional committee*

WORLD
HEALTH
ORGANIZATION



28th Meeting
Washington, D. C.
June 1956

CE28/4 (Eng.)
18 May 1956
ORIGINAL: SPANISH

Topic 14: INTER-AMERICAN REGULATIONS ON INSCRIPTION, REGISTRATION, AND
CIRCULATION OF DRUGS

(Topic proposed by the Government of Cuba)

The IV General Assembly of the Pan American Medical Confederation approved the following motion:

FIRST: That the Medical Associations Members of the Pan American Medical Confederation, after study of the existing legislation in their countries on the registration of pharmaceutical products, approach their Governments, through the Ministries or Departments of Public Health, with a view to obtaining necessary modifications in the said legislation in order to achieve the maximum possible uniformity in the legislation enacted in this respect within the countries of America.

SECOND: That the basic standards annexed to the present Motion be recommended as a guide for the study that is to be made.

THIRD: That the Pan American Medical Confederation, through its Executive Committee, approach the Governing Council of the Organization of American States for the purpose of calling an Inter-American Convention with a view to formulating a Code that will fulfill these aspirations.

Annexes: I and II

PAN AMERICAN MEDICAL CONFEDERATION
Central Executive Committee
Avenida de los Presidentes No. 506
Vedado, Havana, Cuba

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WHEREAS: The free flow of drugs is essential to public health, to the medical profession, and to the patient, inasmuch as the health or life of a human being may depend on the ready availability of these substances.

WHEREAS: Although existing legislation in each country regulates the manner in which drugs are made available to physicians and patients, many and varied difficulties are nevertheless encountered: length of time consumed in processing applications for registration of the product; high cost of registration; exacting requirements already superseded by modern techniques; and complete lack of uniformity in legislation from one country to another.

WHEREAS: No international congress has ever been held to deal with matters of such interest as those affecting registration of pharmaceutical products, and one of the objectives of the Pan American Medical Confederation is to foster in every way possible the solution of problems related to the health of the people and the proper practice of medicine.

IT IS THEREFORE PROPOSED:

That the IV General Assembly of the Pan American Medical Confederation approve the following:

M O T I O N

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BASIC STANDARDS FOR SECURING MODIFICATIONS IN LEGISLATION ON THE
REGISTRATION OF PHARMACEUTICAL PRODUCTS

1. PRODUCTS SUBJECT TO REGISTRATION FORMALITIES

- a) Products to be sold under proprietary names.
- b) Specialties, unless sold under generic names.
- c) Products to be sold with generic name, only if they represent new drugs.
- d) New formulations affecting registered products, provided the changes in formula imply a modification of the chemical, pharmacological or therapeutic nature or identity of the product.
 - 1) If a product remains the same therapeutically, it should not be necessary to resubmit the product because of the change in formula for registration. A notification of the change in formula to the department of health should suffice.

2. DOCUMENTS AND/OR MATERIAL FOR APPLICATION

- a) Descriptive data:
 - 1) Name of the product.
 - 2) Qualitative and quantitative formula expressed in weight or volume.
 - 3) Prophylactic and/or therapeutic indications.
 - 4) Counter-indications, if any.
 - 5) Dosage.
 - 6) Mode of administration.
 - 7) Method of assay, if not given in any official pharmacopoeia or compendium.
- b) Certificate of origin and free sale issued by the local health authorities.
- c) Typewritten draft of the labelling.

d) Samples of the product (if the product is to be supplied in different sizes, only samples of the smallest size would be submitted). No special labelling requirements will be imposed in regard to samples for registration.

1) In those countries where reregistration is required, additional samples or trade packages should not be required. This same purpose could be served by supplying labels and/or cartons.

3. VALIDITY OF REGISTRATIONS

It is desirable that registrations be permanent without prejudice to the right of the Governments to establish annual fees to keep the registration alive or to the right of the Governments to revoke the registrations on grounds of public health or safety.

Revocation of licences will not affect the sales of stocks already in the country.

4. PERIOD WITHIN WHICH HEALTH DEPARTMENT REGISTRATION APPLICATION SHOULD BE PROCESSED

A period of not more than 60 days should be established for processing an application for Health Department registration, subject to extension of not over 60 days.

5. LABELLING REQUIREMENTS

Registered products shall be labelled in the language of the country of destination. Basically, the data to be included on the labelling should be as follows:

a) Name of the product. The rule under which the name is to be trademarked prior to Health Department registration should be abolished inasmuch as trademark questions are of a purely private character, and should not be raised ex officio by the public authorities. Manufacturers should be free to adopt any name for their products under their own responsibility as to misappropriation of any name already registered as a trademark by a third party, subject only to the requirement that the generic name or pharmacopoeia designation be used.

b) Formula (active ingredients).

c) Dosage.

d) Common indications.

e) Counter-indications, if any.

f) Warning statements as may be necessary to prevent improper use.

- g) Name and address of manufacturer.
- h) Rx statement for ethical products.
- i) Special finishing such as safety bands shall not be required.
- j) If package literature is supplied with a given product, authorities should permit its use as long as the statements contained therein do not conflict in any way with the requirements outlined above.

The requirement that the registration number be indicated on the labels should be abolished inasmuch as the importation of non-registered products would be a violation of the local laws, for which both the manufacturer and the importer could be prosecuted. If this requirement is maintained, rubber-stamping of registration number at point of importation should be permissible.