directing council

PAN AMERICAN HEALTH ORGANIZATION

XIII Meeting

regional committee

WORLD HEALTH ORGANIZATION

XIII Meeting

Washington, D. C.
October 1961

CD13/24 (Eng.)
30 August 1961
ORIGINAL: SPANISH

Topic 15: ADVERTISING OF MEDICINAL PRODUCTS

Background

At the XV Pan American Sanitary Conference, held in San Juan, Puerto Rico, 21 September-3 October 1958, careful attention was given to two important problems concerning medicinal products: (a) their control and registration, and (b) advertising. While the second of these problems, which was raised by the delegation of Panama, really involves points complementary to the first, the Conference felt that it deserved to be the object of a special study and, in Resolution XXII, instructed the Director of the Pan American Sanitary Bureau to include on the agenda of the XI Meeting of the Directing Council a topic on the problems arising from the advertising of medicinal products.

The Directing Council, after carefully examining the matter at its XI Meeting, adopted Resolution XXX, as follows:

"The Directing Council,

Bearing in mind that at both the XV Pan American Sanitary Conference and the X Meeting of the Directing Council, the Member Governments of the Pan American Health Organization expressed their deep and constant concern over the problems arising from the misleading advertising of medicinal products directed to the general public;

Taking into account the fact that at present there are no available means of control that are easily applied and are acceptable to all the governments; and

Considering that, in conformity with Resolution XXV of the X Meeting of the Directing Council, the Pan American Sanitary Bureau already has under study the problem of drug registration in the Member Countries,

RESOLVES:

1. To instruct the Director to study the present situation of the control of advertising directed to the general public and to inform the next meeting of the Council on the progress and studies made with respect to the following points:

(a) Nature of the control of advertising in the different countries;

(b) Measures of self-regulation within industry; and

(c) Practical problems arising from the application of various legislations or activities for the control of advertising.

2. To recommend that the Governments of the Member Countries adopt measures to prohibit false or misleading advertising of medicinal products."

In compliance with this decision, the Director consulted all Member Governments of the Organization in regard to the three points set forth in the first operative paragraph of the resolution, and reported to the XII Meeting of the Directing Council on the progress of the study that was under way (Document CD12/16). The Council then approved Resolution XXII, as follows:

"The Directing Council,

Having examined Document CD12/16 on the advertising of medicinal products, presented by the Director of the Pan American Sanitary Bureau,

RESOLVES:

1. To take note of Document CD12/16.

2. To instruct the Director of PASB to continue the study of the present situation with respect to the control of advertising of medicinal products, in accordance with Resolution XXX of the XI Meeting, and to report the results to the XIII Meeting of the Directing Council.

3. To reiterate its recommendation that the Governments of the Member Countries adopt measures to prohibit false or misleading advertising of medicinal products."

The Governments of the following countries have replied to the inquiry made: Argentina, Bolivia, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Mexico, Panama, Paraguay, Peru, the United States of America, Uruguay, and Venezuela.

Information has also been received from Antigua, Barbados, British Guiana, British Honduras, Dominica, Grenada, Jamaica, Netherlands Antilles, Saint Kitts, Saint Lucia, Surinam, Trinidad and Tobago, and the Virgin Islands (U.K.).

In some cases the Governments answered by sending copies of the pertinent legislation; in other cases, a summary of that legislation was sent, accompanied by a commentary on the difficulties encountered in its application; and finally, in at least one case, the explanation of the legislative measures adopted was accompanied by a broad discussion of the problem.

The fact that not all the countries provided the same kind of information and that the data requested from some Governments have not yet been received has made it impossible to carry out a complete, comparative study.

Nevertheless, the information obtained is perhaps sufficient to indicate the main aspects of the important questions raised, in the field of public health, by the advertising of medicinal products.

Characteristics of the Control of Advertising: Nature and Extent of the Problem

The advertising of medicinal products gives rise to a problem of a medico-juridical nature, since any criterion chosen to resolve it must have as a basis the goal of protecting the health of the population, as well as a legislative provision to put it into effect. The origins of this problem, which is world-wide in scope, are very remote, but in most of the countries the legislation bearing on it dates from after 1940. This is understandable because it has been in this century that the risks of free advertising of medicinal products have become most clearly defined and have seen the most rapid development. Two factors have powerfully influenced this process: the multiplicity of the pharmaceutical preparations that are put on sale, which in some countries amount to more than 40,000; and the increasing diversity and effectiveness of the publicity media.

Measures Adopted by the Countries of the Americas

The advertising of medicinal products has been a matter of concern to the Governments of all countries of the Americas. All of them have regulations to deal with this matter, although the nature and degree of detail of the measures adopted vary. In some cases, there are special laws on the matter, but in others these conditions are covered by measures of a broader nature, such as those dealing with production, registration, or trade in pharmaceutical products.

The extent to which each of these legislative measures is applicable also varies according to the political and administrative structure of the various countries. In countries with a federal constitution, the states or provinces generally enjoy full autonomy in the regulation of advertising, a fact which, in some cases, makes difficult or impossible the exercise of effective control on the part of the authorities of the national government.

A study of the various legislative provisions in force allows one to note the acceptance, in many cases, of various points of view that can serve as a guide for the solution of the problem raised by the advertising of medicinal products.

First of all, it is to be noted that most of the provisions in this field are of a restrictive or prohibitive nature. This is because publicity is, in principle, a lawful and beneficial activity that constitutes one of the essential factors of commercial prosperity in the modern world. In general, whoever produces an article for public consumption has a right to make that article known. But there are cases in which the advertiser, in exercising this right, inclines toward poor taste, passes the bounds of ethics, and even enters fully into the field of the unlawful.

It is very easy to reach this point in the advertising of medicinal products, since, to a degree unsuspected by many, the health or even the life of individuals may be put at risk. It is not enough that a product be harmless in its content. The most innocuous of preparations may produce pernicious and even fatal effects if it causes a patient, convinced of its curative power, to delay his visit to the doctor until all possibilities of cure have been lost.

These dangers to the health of the public impose upon Governments the necessity for carefully studying where the perils of advertising begin, because that is just where the first limits must be set.

From the various laws compared in the course of this study, it is seen that the following standards are, to a greater or less degree, earning acceptance in the countries of the Americas:

1. Distinction between advertising intended for professional people and that intended for the lay public. While freedom is respected for the first class mentioned, important restrictions are established for the second.

2. Requirement that the texts of advertising directed at the public be submitted to competent authorities for prior approval.

3. Prohibition of the announcement to the public of products that must be sold under prescription or those intended for the cure of certain diseases, such as leprosy, cancer, tuberculosis, syphilis, and gonorrhea.

4. Prohibition of street advertising.

5. Prohibition of advertising medicinal specialties without indicating the basis of their composition.

6. Prohibition of all expressions that attribute a preferential quality to a product, such as "irreplaceable," "the best," "magic," or "miraculous."

7. Prohibition of statements that encourage self-medication or abortive practices.

8. Prohibition of the use of testimonials of individuals, doctors, dentists, etc., assuring cure of a disease.

9. Prohibition of distribution to the public of "medical samples." These must be clearly marked as such and can be distributed only to professional people; they must be devoted to experimentation.

10. Necessity for foreign products to be subjected to the same requirements as national products, with respect to the obtaining of licenses to permit their announcement and sale.

11. Prohibition against the use of advertising submitted for approval in a means of publicity other than that for which authorization was requested.

12. Prohibition of any erroneous statements, which are taken to include any statement that does not reveal the formula, content, name of the manufacturer, etc.

Penalties for Violations

The penalties imposed on violators of the established standards, vary from one country to another and according to the gravity of the infraction. Starting with a mere warning or fine, they may extend to cancellation of the license to sell and even accusation before the courts of law. There is also considerable variation among the various countries as to the agencies charged with enforcing the established regulations and as to the extent of responsibility in cases of violation. In some cases, in addition to considering as directly responsible for infractions related to the advertising of pharmaceutical specialties those persons, companies, or corporations that order the advertising, it is prohibited to printers to accept orders that do not bear the signature of accredited persons located within the country.

Means of Self-regulation within the Industry

From the answers received, it appears that, in the majority of the countries, express measures of self-regulation have not been established in the industry. In many cases, professional ethics, for which the Pharmaceutical Colleges assume responsibility, effectively takes the place of such measures of self-regulation.

Among the replies received, there is one that explains in detail the criteria which the laboratories that produce medicaments follow in preparing the texts of advertising for approval by the public health authorities. In the preparation of these texts, the laboratories take into account:

a. The work of their own research departments.

b. Pharmacological and clinical-therapeutical work, and proposals for advertising sent by the manufacturers of products that are not made within the country.

c. The degree of competition existing in the market with respect to products similar to the medicament advertised.

d. The need for beginning, maintaining, or increasing the sales of a product, which sets the measure for the scope and the tone of the advertising.

e. The aptitude or capacity of each laboratory to give public information, or the necessary or required collaboration of publicity agencies.

Problems in the Application of the Various Legal Provisions or Activities to Control Advertising

Despite the fact that, as has already been said, the countries of the Americas have adopted measures for controlling the advertising of medicinal products, this matter continues in many cases to be a serious problem. Even though legislative measures may be well conceived, they are not always easy to apply, owing to such diverse reasons as the difficulty of exercising control in certain remote areas of some countries, and the characteristics of modern publicity techniques, which often get around all the barriers set up by the legislator.

In the printed advertising that appears in newspapers, magazines, pamphlets, and other national publications, it is relatively simple to ascertain whether the texts that appear coincide with those that have been approved in advance. This check is made periodically, taking advantage of newspaper clipping services.

It is very difficult, however, to exercise effective control over the advertising conducted by loudspeakers in small and remote communities. It is also very difficult, in most cases, to check on the advertising done over radio and television.

Similarly, various Governments point out the difficulty of controlling the advertising that appears in magazines, pamphlets, etc., of products manufactures abroad.

The loudspeaker, radio, and television have come to aggravate the problem of the advertising of medicinal products, not only for the reasons already mentioned but because they represent a powerful means for reaching the masses of the people, by-stepping even the barrier that written advertising meets in illiteracy. Moreover, it is most unlikely that any legislative formula, however thorough, will cover all the means that modern publicity will find for reaching the public. The frequent interruption of a radio program to announce the name of a product, or the repeated flashing of this name on movie screens or on strategically-located neon signs, may prove more effective than the most elaborate of advertising claims. These difficulties of control undoubtedly influenced the decision of one European country, Denmark, to prohibit all advertising of medicinal products through motion pictures, radio, highway billboards, luminous signs, or placards in public vehicles or in public places.

Final Considerations

The problems raised by the advertising of medicinal products are very complex, and for a broader study of certain aspects, such as that of self-regulation in the industry, the cooperation of professional pharmacists would be necessary.

Nevertheless, it is appropriate to set forth the following final considerations:

a. Any purely legislative approach to the problem of the advertising of medicinal products can lead only to an incomplete solution. Advertising would be to no avail if it did not find the field enriched by credulity, and the most appropriate means for combating credulity is health education.

b. Legislation with respect to the advertising of medicinal products must be essentially dynamic, since the media of publicity change every day.

c. While the problem of the advertising of medicinal products is of world-wide importance, the means used for solving it must be adapted to the political, social, and above all, cultural circumstances of each country.

It is very difficult, however, to exercise effective control over the advertising conducted by loudspeakers in small and remote communities. It is also very difficult, in most cases, to check on the advertising done over radio and television.

Similarly, various Governments point out the difficulty of controlling the advertising that appears in magazines, pamphlets, etc., of products manufactures abroad.

The loudspeaker, radio, and television have come to aggravate the problem of the advertising of medicinal products, not only for the reasons already mentioned but because they represent a powerful means for reaching the masses of the people, by-stepping even the barrier that written advertising meets in illiteracy. Moreover, it is most unlikely that any legislative formula, however thorough, will cover all the means that modern publicity will find for reaching the public. The frequent interruption of a radio program to announce the name of a product, or the repeated flashing of this name on movie screens or on strategically-located neon signs, may prove more effective than the most elaborate of advertising claims. These difficulties of control undoubtedly influenced the decision of one European country, Denmark, to prohibit all advertising of medicinal products through motion pictures, radio, highway billboards, luminous signs, or placards in public vehicles or in public places.

Final Considerations

The problems raised by the advertising of medicinal products are very complex, and for a broader study of certain aspects, such as that of self-regulation in the industry, the cooperation of professional pharmacists would be necessary.

Nevertheless, it is appropriate to set forth the following final considerations:

a. Any purely legislative approach to the problem of the advertising of medicinal products can lead only to an incomplete solution. Advertising would be to no avail if it did not find the field enriched by credulity, and the most appropriate means for combating credulity is health education.

b. Legislation with respect to the advertising of medicinal products must be essentially dynamic, since the media of publicity change every day.

c. While the problem of the advertising of medicinal products is of world-wide importance, the means used for solving it must be adapted to the political, social, and above all, cultural circumstances of each country.