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THE ADVERTISING OF MEDICINAL PRODUCTS IN MEXICO

MINISTRY OF PUBLIC HEALTH AND SOCIAL WELFARE

DRUG CONTROL DEPARTMENT

The Advertising of Medicinal Products in Mexico

In the Republic of Mexico the advertising of medicinal products is controlled by the Ministry of Public Health and Social Welfare, through the Drug Control Department.

For many years the view has been held that in Mexico, as in most of the Latin American countries, it is not possible to accept the unrestricted publication of advertisements which laboratories and their publicity agencies make about the medicinal products they put on the market.

It is said that we should have the same tolerant attitude as that shown by some European health authorities, and by the health authorities of the United States of America, which do not regulate the advertising of medicinal products but permit the enterprises concerned to be themselves responsible for, and to regulate, the tone and content of their advertisements.

If the reasons for these differences are examined, it will be seen that the liberal attitude of the health authorities abroad is logical: the cultural level of their population is high and, moreover, the better organization of their chemical and pharmaceutical industries and their publicity agencies has enabled them to exercise a higher degree of self-criticism and of respect for the social precepts of their governments.

Now let us consider the situation in our own country.

Foreign countries have looked upon Mexico and, generally speaking, all the Latin American countries as a favorable ground for every type of commercial advantage. It is therefore only to be expected that, as far as medicinal products are concerned, we should receive, as a result of this trade, the benefits which the genius of the chemical and pharmaceutical industries of the above-mentioned countries has given to the world; however, while under their influence medicinal products of great value in medicine, surgery and public health have been introduced into Mexico, it is nevertheless true that they have brought us thousands of medicinal products containing active substances in sub-therapeutic doses or in illogical associations or medicinal products whose fanciful composition and the imaginary pharmacodynamical action attributed to them have served to exploit the credulity both of the ill-informed medical practitioner and of sick people who cling to every hope of improving their condition.

Those fortune-hunting manufacturers registered their products without difficulty in our country and even earned immense profits from selling them, thanks to misleading publicity which presented these products as true panaceas whereas, from a technical point of view, they only raised false hopes of health and longer life.

Confronted with this flood of medical products of foreign origin, many Mexican laboratories hastened to register medicinal products of doubtful value and make exaggerated claims for them.

In both cases, exaggerated publicity and even deceitful publicity were absorbed without difficulty, not only by part of the lay population but even by members of the medical profession, whose technical education has unfortunately not always been uniformly high.

For many years the health authorities did not always have a very clear conception of public health and considered their task complete when they had merely provided fuller facilities for the establishment in our country of trade in pharmaceutical specialities, regardless of their origin, composition, or effectiveness.

Among the many benefits of the social revolution which shook Mexico in the second decade of this century was that of awakening a greater spirit of public service in our authorities, with the result that the situation concerning the registration and advertising of medicinal products that had prevailed until then came to be considered objectionable and even harmful to public health.

As a result of this new spirit the Health Code and the Regulations governing medical products have since contained more exacting technical provisions for the registration of medicinal specialities; in the matter of advertising the manufacturer and his publicity agencies are required to submit drafts of advertisements so that the proper authorities can examine them and, where appropiate, approve them, and register them in numerical order for the purpose of keeping a better control over them.

However, the health authorities do not seek to place obstacles in the way of the chemical and pharmaceutical industry: when publicity concerning medicinal products is submitted for approval, they try not to follow rigid, inflexible, or despotic rules and are always attentive to technical changes that justify greater concessions and freedom in the advertising of medicinal products in Mexico.

There was further reason for adopting these official measures: the Indian population that still lives in our territories has engaged in the pharmaceutical trade on a large scale, either because the leading elements among them are in favor of the continued use of primitive curative measures such as phytotherapy or because modern non-indigenous technicians seek to find in ancient and modern herbal medicine therapeutic

agents that have the great publicity impact of being autochthonous, magical or hitherto unknown.

It might be asked whether the chemical and pharmaceutical industry has internal pressures that facilitate or guide the publicity that it makes about its medicinal products.

Laboratories that produce medicinal products draw up the texts of their advertisements, bearing in mind -

a) pharmacological and clinical therapeutic works and even drafts of advertisements sent to them by the manufacturers of products that are not produced in the country;

b) the degree of competition on the market with products similar to the medicament being advertised;

c) the need to initiate, sustain, or increase the sales of a product; this determines the forcefulness and tone of the publicity;

d) the laboratory's ability or capacity for publicity or the necessary or obligatory assistance from publicity agencies.

Judged by these factors, some laboratories may be considered to have high scientific standards: the publicity they make for their products is generally satisfactory in the matter of precise and logical indications based on prior experiments in animals or in man and also of dosage and warnings of toxicity.

On the other hand there are laboratories which, without carrying out any experiments on animals, and with only empirical administration in man, without any orientation in modern clinical experimentation, request the registration of medicinal products which, sometimes, might well be called magical. But what is worse, their advertisements are exaggerated or frankly misleading or frankly fraudulent.

Now the laboratories in the first group, unlike those in the second, do not present any problems for the health authorities.

The problem is all the more difficult because the undeniable success of advertisements as a means of promoting sales, incites all laboratories to seek an ever-growing number of consumers of their products. They therefore apply for permits for radio, television, and press advertisements of great suggestive force.

The health authorities have thus been justifiably constrained to pursue now and in the near future the policy explained above - the compulsory registration of advertisements with the Ministry of Public Health and Social Welfare.

For the purpose of this meeting it might be of interest to comment on the main points of this procedure.

I. Publicity can only be made in respect of medicinal products (Article L89 of the current Health Code) that are already registered with the Ministry of Public Health and Social Welfare and provided that the publicity has been approved by the Ministry, save in certain exceptional cases.

II. When a product has been registered in accordance with the data submitted by the manufacturer and the examination made in the Drug Control Department, a basis of publicity is determined for each product, stating the indications recognized for the product. Whether this basis of publicity is Popular (Popular product) or Exclusively for medical literature (Ethical product) is also specified. This basis of publicity is forwarded to the person concerned in the letter of provisional approval of the product.

III. Whenever the persons concerned are not in agreement with the basis of publicity given by the Ministry, they are required to request its revision or expansion as soon as possible and must cite the grounds or scientific works in support of their request.

IV. Publicity for medicinal products and comparable products comprises three main classes:

Medical publicity designated by the abbreviation P. Med.

Popular publicity designated by the abbreviation P. Pop.

Special publicity designated by the abbreviation P. Esp.

V. Medical publicity comprises that registered as Literature exclusively for Medical Practitioners: pamphlets, vademecums, cards, inserts, stickers, circular letters, scientific works, etc., medical press, medical literature, dental literature, medical samples with or without literature; that is to say, all publicity directed to medical practitioners and other professionals specified in Article 253 of the current Health Code.

VI. General or popular publicity comprises that directed at the general public through the press, radio and television, posters, brochures, handbills, cards, exhibits, free samples, gifts that display indications or formulas, etc.; that is to say, all publicity aimed at the public (Sub-section III of Article 607, and Articles 210 and 215 of the current Health Code).

VII. Special publicity comprises that carried out by mass circulation media (such as the daily press, the radio, employed occasionally and subject to a permit limited to fifteen days) for the purpose of informing medical practitioners and pharmacists that a given product is already on sale or that there is a distributor of it. This class of publicity also includes gifts to medical practitioners such as book matches, pencils, kleenex, etc.; these are also authorized but must not contain indications or dosage.

VIII. The publicity must be submitted beforehand for examination and, where appropriate, approval to the Food, Beverages and Drug Control Division (Drug Control Department of the Ministry of Public Health and Social Welfare).

IX. Applications for the approval of publicity must contain the following information:

a) Name of the product.

b) Pharmaceutical formula.

c) Definitive registration number allotted by the Ministry of Public Health and Social Welfare; number of the letter of definitive approval, issued by the same Department, granting registration, and the number of the file of the product.

d) Basis of publicity approved by the Ministry of Public Health and Social Welfare for the product in question (to be given textually).

e) Class of publicity for which a permit is requested; the class should be in accordance with the basis of publicity for the product, referred to in (d).

f) Formula of the preparation.

g) Dosage and route of administration.

h) Instructions for use.

i) Any hazard in handling the product, where applicable, including indications.

j) Name and signature, as well as the domicile, of the owner of the product, or of his legal representative.

k) Name and address of the publicity agency.

1. Together with the above-mentioned application the full text of the draft or description of the advertisement, or both, must be submitted in quadruplicate as well as, where applicable, the instructions, samples or designs which it is intended to send with them.

2. Examination of the text of advertisements and registration of the product may be applied for simultaneously, so that, when the definitive registration is granted, both the products and the advertisements may be put on the market at the same time.

X. The text of the approved advertisements will be given an official number and will be delivered at the Advertising Approval Section directly to the duly accredited representative of the laboratory or of the publicity agency, within the following time limits:

a) Within not more than 5 days after the text has been submitted to the above-mentioned Section, in the case of press, radio, television, cinema and medical press advertisements.

b) Within not more than 15 days after the text has been submitted to the above-mentioned Section, in the case of popular or special advertisements.

c) Within not more than 30 days, in the case of medical advertisements.

XI. In the event that words or phrases, etc., in the text of the advertisements submitted for examination and approval are rejected, such changes are not to be considered definitive or unappealable but are subject to confirmation, modification, or substitution; for this purpose the persons concerned (medical representatives in the case of ethical or popular advertisements for medicinal products; publicists in the case of toilet or beauty products) must, within not more than eight days calculated from the day on which they received the approved drafts, register their disagreement to the head of the Technical, Advisory and Advertising Section and to the Approving Physician and establish the scientific veracity of their statements or propose new phrases or expressions in substitution of those not admitted. The appeal may be settled immediately or within 5 days, the period needed for the examination of the scientific documentation presented.

XII. In the case of medicinal products for which advertisements are to be sent exclusively to medical practitioners, the advertisements must always adhere to the basis of publicity given for the product in question and be consonant with accepted clinical therapeutic knowledge. The terminology used must not contain exaggerations that induce false conceptions. When numerical or statistical data or bibliographical references to very recent literature are mentioned, the supporting documentation must be produced. However, as medicine is constantly progressing and in order to allow the distribution of reputable scientific works, the content of these works may be transcribed in part or in whole even when

they do not correspond to the approved basis of publicity, provided that their origin is stated. In these cases the Ministry of Public Health and Social Welfare adds suitable notes to the advertisement, informing medical practitioners that the data have been obtained from experiments on animals or simply that the ideas expressed in the literature are the sole responsibility of the authors mentioned in the attached bibliography. These notes have to be printed in characters not smaller than those used for the general text. The purpose of this provision is to enable medical practitioners to make a better assessment of the indications suggested when administering the medicaments in question to their patients. In any event a manufacturer may be ordered to apply for a change in the basis of publicity if it is believed that it will be more suitable for his product.

This type of medical advertisement must not be inserted into packages of the product.

XIII. In the case of popular medicinal products the text of advertisements must also be drawn up bearing in mind the approved basis of publicity and in a phraseology which is easily understandable by the public so that it may know exactly the type of disorder in which the medicament may be useful. They must not contain qualifying phrases which may lead to deceit or fraud or be exaggerated to the point of promising marvellous results, being unequalled, the only one in the world, etc.; nor may they include any type of testimonial letter. General advertisements for the press must contain the phrase "Consult your physician", but not those for the radio, cinema, television.

XIV. Advertisements for popular "hygienic" products may refer to prophylactic and preventive medicine aspects but must not give the impression of absolute security.

XV. When the indications in the text of the draft for which approval is sought are not within the basis of publicity, and the lack of correspondence to it mentioned in paragraph XII is not justified, the text will be completely rejected and this decision will be announced by official letter. However, the persons concerned shall be entitled to request the expansion or reconsideration of the basis of publicity, giving the scientific grounds, reports, or clinical experiments on which their request is based.

XVI. In order to be disseminated, every advertisement shall contain the following, in addition to what the person concerned has asked for and what has been approved by the Ministry of Public Health and Social Welfare:

a) The name of the product or products that are being advertised shall appear textually at least once.

b) The number or numbers of the medicament, in the form laid down.

c) The entry in the register of advertisements, expressed as follows:

P. MED 801/60 - that is to say, the abbreviation P. MED means medical publicity; the number 810 is the official number allotted to it (in numerical order); and the figure 60 after the oblique stroke is that of the year. This is followed by the abbreviation SSA for the Ministry of Public Health and Social Welfare.

d) The notes or indications decided upon by the Ministry of Public Health and Social Welfare shall also appear in every case (addiction-producing drugs, dangerous drugs, etc.)

e) Every advertisement approved for distribution to medical practitioners must bear the note - "Literature exclusively for Medical Practitioners" - except medical samples which, in lieu thereof will bear the note "Medical Sample. Not for Sale".

f) Popular medicinal products which are to distributed free to the public must likewise bear the note "Free Sample. Not to be sold".

XVII. In order to keep a check on advertisements the owners of products or medicaments or, where applicable, their representatives, as well as publicity agents, must deliver to the Ministry of Public Health and Social Welfare within 20 days immediately following the beginning of publicity a copy of the draft of the advertisement with the seal and signature of the radio station, of the channel concerned in the case of television, of the recording company in the case of recordings, etc., depending upon the publicity medium used.

XVIII. In the case of printed advertisements, the person concerned shall be required to submit within the time limit mentioned above two copies of the proofs, photographs, etc., together with a copy of the approved draft advertisement. In both cases failure to present these copies within the time limit laid down will result in the cancellation of the permit for the advertisement in question.

XIX. The Ministry of Public Health and Social Welfare may at any time suspend advertising which is contrary to the conditions or requirements attached to its approval, or which departs from the approved text or which, in the opinion of the Ministry, is no longer in accord with the latest medical knowledge.

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