Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

Mexico

Baker & McKenzie

Mexico

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Introduction

Mexican legal provisions on advertising of medical products[2] have a double goal of protection. They protect healthcare professionals and consumers/patients from (i) receiving misleading information about products and services, and (ii) from health risks resulting from inaccurate health information.

For the same reason this area is jointly overseen by two authorities: (i) the Federal Consumer Protection Bureau (PROFECO), and the (ii) Federal Commission for the Prevention of Health Risks (COFEPRIS). They divide its jurisdiction according to whether the relevant misleading or inaccurate information could represent or not a health risk, in relation to medical products that are commercialized in Mexico.

To determine the medical products that are subject to specific advertising requirements, it is important to define what is understood under Mexican legislation as a medical device and as a medication or pharmaceutical product.

In terms of General Health Law and the Pharmacopeia of the United Mexican States and its Supplements[3] (Pharmacopeia), the following definitions apply:

- Medical Device

Substance, mixture of substances, material, apparatus or instruments (including the computer program necessary for its appropriate use or application), used solely or in combination in the diagnosis, monitoring or prevention of diseases in humans, or auxiliary in the treatment of diseases and disabilities. Additionally, those used in the substitution, correction, restoring or modification of the anatomy or physiological human processes. Medical devices include products of the following categories: medical equipment, prostheses, orthoses, functional aids, diagnosis agents, dental materials, surgical and healing materials and hygienic products.

- Pharmaceutical Product

Any substance or mixture of substances of natural or synthetic origin which has therapeutic, preventive or rehabilitative effect, which is presented in pharmaceutical form and is identified as such due to its pharmacologic activity and its physical and biological characteristics. When a product has nutrients, it will be considered as a pharmaceutical product, so long as it is a preparation that contains, individually or in associated form: vitamins, minerals, electrolytes, amino acids or fatty acids, in concentrations higher than those in natural food and which is also presented in a defined pharmaceutical form, and the instructions for use indicate preventive, rehabilitative or therapeutic effects.

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[1] Based on text originally prepared by Adriana Ibarra-Fernandez and Jose Hoyos.

[2] The Mexican regulation refers to "health supplies" which is a notion that generally includes (i) medicines for human use and (ii) medical devices, but also (iii) herbal remedies. When using the term "medical products" we will refer here to the first two.

[3] *Farmacopea de los Estados Unidos Mexicanos y sus Suplementos.*

The Regulatory Framework

Advertising Legislation

Advertising of pharmaceutical products and medical devices in Mexico is mainly governed by the following legal bodies:

- General Health Law[4]
- Regulations to the General Health Law on Sanitary Inputs[5] (RSI)
- Regulations to the General Health Law on Advertising Activities[6] (Advertising Regulations)
- Federal Law on Consumer's Protection[7] and its Regulations

Professional Codes of Conduct

Articles 99 and 100 of the Advertising Regulations set forth that the Ministry of Health will encourage councils and associations engaged in promoting pharmaceutical products to develop codes of ethics for the production and broadcasting of promotional materials.

In this regard, the most relevant professional codes of conduct that are currently in force and regulate promotional activities are the following:

- The Code of Ethics and Transparency of the Pharmaceutical Industry of the Council of Ethics and Transparency of the Pharmaceutical Industry[8] (CETIFARMA Code of Ethics)
- The Code of Good Promotional Practices for the Pharmaceutical Industry of the Council of Ethics and Transparency of the Pharmaceutical Industry[9] (CETIFARMA Code of Good Promotional Practices)
- The Code of Marketing Ethics of the Association of Manufacturers of Over the Counter Pharmaceutical Products[10] (AFAMELA Code of Marketing Ethics)
- The Code of Interaction with Health Care Professionals of the Mexican Association of Innovative Industries of Medical Devices (AMID Code of Interactions)[11].

Advertising Pharmaceutical Products and Medical Devices

General Provisions

General Health Law and Regulations

Pursuant to the provisions of the General Health Law, all promotional materials that refer to pharmaceutical products and medical devices must comply with the following requirements:

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[4] *Ley General de Salud*, published in the Federal Official Gazette on 7 February 1984, as amended.
[5] *Reglamento de Insumos para la Salud*, published in the Federal Official Gazette on 3 February 1998, as amended.
[6] *Reglamento de la Ley General de Salud en material de Publicidad*, published in the Federal Official Gazette on 2 May 2000, as amended.
[7] *Ley Federal de Protección al Consumidor y su Reglamento*, published in the Federal Official Gazette on 24 December 1992 and 2 August 2006, as amended.
[8] *Código de Ética y Transparencia de la Industria Farmacéutica del Consejo de Ética y Transparencia de la Industria Farmacéutica.*
[9] *Código de Buenas Prácticas de Promoción del Consejo de Ética y Transparencia de la Industria Farmacéutica.*
[10] *Código de Ética Publicitaria de la Asociación de Fabricantes de Medicamentos de Libre Acceso, A.C.*
[11] *Código de Interacción con los Profesionales del Cuidado de la Salud de la Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos.*

- The information that refers to the quality, origin, purity, conservation, nutrimental properties and benefits of the products must be verifiable.
- The content of the message must be instructive and educational.
- The content of the message must correspond to the characteristics of the corresponding sanitary authorization (e.g. off-label promotion is not allowed).
- The message cannot lead to conduct, practices or habits that may be harmful to physical or mental health, or that endanger the physical integrity or safety or the dignity of any person, particularly of women.
- The message cannot distort or contravene the principles, provisions and regulations issued by the Ministry of Health with regards to the prevention, rehabilitation or treatment of diseases.
- The promotional message must be made in accordance with the marketing authorization and applicable laws and regulations.

Promotional materials of pharmaceutical products and medical devices are classified as:

- promotional activities and materials addressed to the general public; and
- promotional activities and materials addressed to healthcare professionals.

In general terms, promotional activities and materials addressed to the general public requires of previous authorization, regardless if the product requires the medical prescription or not.

Promotional activities and materials addressed to healthcare professionals are those that refer to the information, characteristics and use of pharmaceutical products based in the information previously authorized (quality control and clinical).

For medical devices, the Ministry of Health, at the time of issuing the corresponding sanitary registration, will specify whether the promotional and marketing materials corresponding to the specific product may be addressed to the general public or only to healthcare professionals.

For pharmaceutical products, the Ministry of Health, at the time of issuing or reviewing the corresponding sanitary registration, will determine whether the pharmaceutical product requires a prescription or not. If the products requires a prescription, then the promotional and marketing materials can only be addressed to healthcare professionals.

Federal Law on Consumer Protection (FLCP): Misleading advertising through physical and online platforms

Under Article 32 of the FLCP, all information and promotional materials covering goods, products or services which are broadcast by any means must be truthful, verifiable and free of text, dialogue, sounds, images or any other description that may be misleading or confusing.

Information or advertising materials which compare products or services should not be misleading or abusive and should only compare products or services of the same nature.

PROFECO has issued guidelines for the analysis and verification of said advertising (the Guidelines). It is noted that rules contained therein are applicable to online ads and both to providers operating locally or through offshore websites.

The following are key aspects of such regulation:

- If advertising materials refer to the effects or benefits to be obtained by acquiring goods or services, or includes objective statements, PROFECO may request the corresponding technical or scientific information that supports the statement.

- If the advertising materials include "categorical" or "superlative statements" (as such terms are defined by the Guidelines) PROFECO may request companies to provide studies, samples or tests to support such statements.
- Certain specific principles shall be followed by the companies when targeting members of vulnerable populations such as the children, the elderly or the sick. Companies should be able to prove that when preparing the ads, they took into account recipients' lack of experience and the possibility of users relying on company's advertising. Likewise, companies should avoid taking advantage through marketing practices of the psychological or emotional characteristics of the target group.

Penalties for non-compliance include fines up to MXN3,457,496 or up to USD210,000 and 10 percent of the infringer's gross income, in the case of recidivists.

Authorizations and Notices

Pursuant to the Advertising Regulations, promotional materials addressed to the general public require an advertising authorization issued by COFEPRIS, while those addressed to healthcare professionals are subject to filing an advertising notice with such authority.

It should be noted that in both cases, the information contained in the promotional materials must refer to the purposes and indications referred to in the corresponding sanitary registration issued by the sanitary authority.

If an advertising permit is required, the relevant promotional material should include the issuing number of the permit.

Permitted and Prohibited Practices

Promotional Activities Addressed to the General Public

Promotional materials for medications that are addressed to the general public may include the description of diseases and their treatment, diagnosis, prevention or rehabilitation, provided that they are referred to in the corresponding sanitary registration and that the language used is appropriate for the public to which it is addressed. Such messages must identify the sponsor of the advertising information with its corporate name.

This type of promotional materials must include, in visual form for printed materials, auditory for radio messages, and visual and auditory for films and television, the following:

- The precautionary legend "Consult your Physician" (*Consulte a su medico*) or the corresponding to the type of the health supplies
- The corresponding warning legend for the use of the specific health supplies when it represents a risk under the presence of a coexistent pathological or clinical condition.[12]

Promotional materials for medical devices that are addressed to the general public must include: messages that discourage self-treatment, when due to the characteristics of the product such legends are required; must be clear, concise and easily understandable; and must contribute to the hygienic education and express in the warning message, as applicable, that the product may represent a health risk.

[12] For films and television, one of the legends can be included in a visual and the other one in an auditory manner.

Promotional materials for pharmaceutical products that are addressed to the general public will not be authorized when they:

- display the product as a definitive solution for the prevention, treatment or rehabilitation of a determined disease;
- indicate or suggest use for symptoms different than those contained in the corresponding sanitary registration;
- alter the doses authorized by the Ministry of Health;
- promote consumption through lotteries, raffles, contests or other similar activities;
- promote consumption of the product by means of offering other products or services in exchange;
- use declarations or testimonies that are misleading or that are not duly supported;
- use cartoons that could confuse children in the consumption of the products; or
- fail to include the warning legends referred to in the paragraphs above.

Comparing products is allowed, provided that they have the same therapeutic indication, considering identical objective elements of comparison. The points of comparison must be based on verifiable facts, cannot be unfairly or partially selected and, in general, must avoid any comparison that may mislead the consumer.

Promotional Activities Addressed to Healthcare Professionals

Promotional materials addressed to healthcare professionals may be broadcast in media oriented to such sector, including specialized dictionaries and guides of pharmaceutical products, and must be based on the Information to Prescribe (IPP) of such pharmaceutical products.

Promotional materials referring to pharmaceutical products and medical devices will not be subject to authorization or precautionary legends when they only indicate the trademark or name of the product.

Invitations, Gifts, Hospitality to Private Sector

There are no binding provisions governing promotional activities such as hospitality. In contrast, the industry has developed voluntary provisions that do contain more specific provisions on these kinds of promotional activities (e.g., the CETIFARMA and AMID Codes) for affiliate or adherent companies.

There is no threshold or specific amount that gifts or hospitality cannot exceed. The codes simply indicate that hospitality expenses shall not exceed the cost that healthcare professionals would be willing to absorb themselves in similar circumstances. They shall not be luxurious and may include round-trip travel expenses, lodging, meals, and eventual registration fees. Covered expenses may include the day before and the day after the event. These aids may be provided to healthcare professionals, but shall not be extended, under any circumstance, to accompanying persons.

Pharmaceutical laboratories or third parties that organize or sponsor scientific and/or educational events must inform CETIFARMA about the event at least two months prior to the event, using the prescribed form issued by CETIFARMA for this effect.

CETIFARMA may verify that the organization of an event complies with the provisions of the code. Non-fulfillment of this stipulation will be considered as a breach of the abovementioned codes.

Additionally, the health authority, healthcare consumers, or any pharmaceutical company, may file a complaint with the Council of Ethics against a pharmaceutical company established in Mexico for breaching the provisions of the CETIFARMA Codes. The Council may proceed to investigate *ex-officio* any possible breach, when it deems appropriate.

Gifts consisting of books or materials in optical, magnetic or electronic format, as well as scientific material, are acceptable provided their total commercial value does not exceed the equivalent of 50 times the minimum daily wage (USD215).

Invitations, Gifts, Hospitality to Public Sector

Under Mexican legislation, all entities, departments and offices of the public sector as well as all of the officials within these organizations are considered public officials. Additionally, any person administrating government monetary resources is also considered a public official.

Gifts or donations from a single person or entity to a public official cannot exceed 10 times the daily minimum wage for the Federal District[13] (which is approximately equivalent to USD44). Any public official receiving any gift or donation which exceeds this amount from the same person should report such occurrence to the authority appointed by the Ministry of Public Function, to facilitate the return of the goods or to be able to put them at the disposition of this authority.

Hence, no gifts, bonuses, pecuniary advantages, benefits in kind, or any sort of incentive may be offered or promised to healthcare professionals, administrative staff or any other public official involved in the cycle of prescription, purchase, distribution, dispensing and administration of medicines (except inexpensive promotional aids related to the practice of medicine or pharmaceutical activities that do not exceed the threshold).

Nothing may be offered or provided under conditions that may influence healthcare professionals' prescription practices.

All payments, including those characterized as facilitation payments under the Foreign Corrupt Practices Act (FCPA), are considered illegal under Mexican Law.

Donations to charitable organizations may be questionable when the institution is somehow related to a public official who is a decision maker in deals where the company participates. In these cases, a conflict of interest may arise. Moreover, a donation under these circumstances may be considered a bribe. As a general rule, in order to contract with any governmental entity, it is a requirement for a company to previously enter into a public bidding process. However, direct contracting is permitted in specific cases.

Public officials involved in these processes are prohibited from participating in dealings where a conflict of interest might be present. Furthermore, a public official is prohibited from participating in any deal where the involved bidders, or other public officials that participate, are related to that public official in any way (i.e., if an academic, business or family relation exists).

This prohibition includes dealings which may result in a benefit to the public official; his or her wife or husband; his or her relatives; other individuals having a professional, labor or business relationship with the public official; or companies or shareholders of companies in which the public official had participated within two years prior to the contracting process.

Guidelines for Speakers Selection, Training and Utilization

Government employees or staff from regulatory bodies may not be assigned consultancy services if a conflict of interest may exist.

[13] Current daily minimum wage is MXN71.10 as of 01 October 2015, equivalent to USD4.40 at an exchange rate of MXN16.5 per USD.

If the speaker is considered to be a public official, an invitation to participate in a congress would not fall in the abovementioned USD44 cap for gifts. However, the invitation should not have the intention of obtaining a benefit for the company, closing deals with public hospitals that would otherwise not take place, or influence doctors to use the company's products only.

While there are no legal provisions governing invitations to doctors in the private sector, under the CETIFARMA Codes hospitality expenses shall not exceed the cost that healthcare professionals would be willing to absorb themselves in similar circumstances.

Medical Samples

Applicable Legislation

Under Article 49 of the Advertising Regulations, it is not necessary to secure an authorization for samples of pharmaceutical products which are given out free of charge in order for healthcare professionals to learn about the product in question, and which meet the requirements and specifications applicable to products to be retailed to the general public but which contain a lower amount of units. The label should identify the product as "free sample" or "original gift".

The delivery of the samples should not be conditional on a sale or service. A control of the quantities and frequency of deliveries should be in control.

Free samples of pharmaceutical products subject to medical prescription cannot be given out to the general public. Samples of these products and over-the-counter (OTC) pharmaceutical products cannot be distributed to children.

Codes of Conduct

Medical samples should be presentations of pharmaceutical products, provided directly, in fair amounts and without cost to healthcare professionals, so that they may get to know and be familiar with the products and/or initiate a treatment. Commercialization of medical samples is prohibited.

Other relevant provisions include:

- Samples of a product may not be offered or supplied with the purpose of seeking or rewarding prescription practices.
- Samples may not be sold, purchased or commercialized in any form and, therefore, must have a "not for sale" label clearly displayed. Non-compliance with the aforementioned conditions will be reported to CETIFARMA, who will proceed in accordance with the provisions of the Codes. Samples must not be used as gifts or provided to healthcare professionals for purposes other than for free provision to their patients.
- In accordance with the provisions defined in international agreements and determined by the national health authorities, provision of medical samples containing psychotropic or narcotic substances is forbidden.
- Companies must have thorough and up-to-date control of their samples, including their manufacture, storage, delivery to regional coordinators or others, and provision to medical representatives and physicians. Adopted measures on this matter will be reported to CETIFARMA who will proceed, in due time, with the corresponding evaluation and verification. Any deviation identified by the company must be reported to CETIFARMA in order to be informed, in due time, of possible misuses.
- Mailing lists for the delivery of promotional material must be regularly updated. Requests by healthcare professionals to be removed from such lists must be complied with.
- Pharmaceutical companies must appoint a professionally qualified person to supervise compliance with these provisions.

Off-Label Promotion

Under the General Health Law, registered medical devices can only be advertised to be used for the indication specified in the corresponding sanitary registration. Otherwise, a fine up to 10,000 times the daily minimum wage for the Federal District[14] may be imposed.

Any advertisements indicating a use different from that contained in the sanitary registration would be removed from the media and, in certain cases, the sanitary registration of the product could be revoked.

Consequences of Breach

Consequences of Breach for the Public Sector

Offering gifts to public officials, where the value exceeds the mentioned threshold, may be considered a bribe. Under the Federal Criminal Code, individuals found guilty of committing the offense, may face up to 14 years of imprisonment and an administrative fine of up to 1,000 times the daily minimum wage for the Federal District (approximately USD4,300). If the perpetrator is a public official, he/she would be removed from office and disqualified from any public position for up to 14 years, in addition to the abovementioned administrative fine.

In addition, even when receiving a gift is not considered a crime, if the amount exceeds the threshold, such public officials may face the following administrative sanctions under the Federal Law of Responsibilities of Public Officials:

- Public reprimand
- Temporary removal from office for a term between three days and one year
- Removal from office
- Monetary fine
- Temporary disqualification from public service (up to 20 years).

Consequences of Breach for the Private Sector

FLCP

In accordance with the FLCP, one of the functions of PROFECO is to coordinate the corresponding federal, state and municipal authorities in order to ensure the effective protection of consumers against deceitful information or promotional materials.

In order to meet the foregoing, PROFECO has authority to order the suspension of any information or marketing materials that breach the provisions of the FLCP, order the amendment of the marketing materials, and impose the monetary sanctions set in the FLCP.

Health Regulation

The Ministry of Health may order the suspension of broadcasting of advertising materials for herbal remedies, food supplements or cosmetic products which are publicized or are retailed as pharmaceutical products or goods to which therapeutic effects were attributed for preventive treatment, rehabilitation or healing of one or more diseases. Media shall suspend broadcasting the marketing materials within 24 hours following serving of the notice issued to that effect by the Ministry of Health.

In the event that manufacturers, distributors or retailers refrain from or impede the seizure of products, the sanitary authority can request the support of the police force.

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[14] Approximately MXN710,100, equivalent to USD43,090 at an exchange rate of MXN16.5 per US dollar.

The Ministry of Health may also impose fines ranging between 2,000[15] and 16,000 times the minimum daily wage, among others, in the following cases:

- For advertising that may threaten the physical or mental integrity of the population; when warning legends do not appear in materials as provided for in the regulation; or
- When advertising materials of pharmaceutical products addressed to the general public are displayed as definitive solution in the prevention, healing or rehabilitation treatment of a determined illness.

Codes of Conduct

In terms of the Industry Codes, infractions are classified as minor, serious or very serious based on the following criteria:

- If the nature of the breach harms the relationship between associates of CANIFARMA
- If the nature of the breach implies a potential risk for the patients' health
- If the breach has an impact on the medical profession and the scientific credibility of the resulting practice
- If the reputation of the pharmaceutical industry is affected
- If it leads to unfair competition

Once the sanction has been determined, the following aggravating and attenuating circumstances must be taken into account:

Aggravating circumstances: degree of intentionality:

- Disregard of previous warnings
- Recidivism
- Concurrence of several breaches in the same act of infringement
- Financial benefits for the laboratory derived from the breach
- Damage to another laboratory
- Analogous practices to the ones denounced, failing to follow the principles of honesty and truth

Attenuating circumstances:

- Adoption of corrective measures prior to the complaint or during the examination procedures
- Opportunity in the collection of evidence; prompt response to CETIFARMA's requirements

According to the seriousness of the infringement, CETIFARMA will decide between issuing a warning or imposing a monetary sanction.

CANIFARMA will execute the sanction determined by CETIFARMA and will refrain from participating in the proceedings undertaken by CETIFARMA for this purpose.

CANIFARMA may decide, if appropriate, to notify the health authorities about a member's recurring serious or very serious infringements. This will be decided by CANIFARMA's Directive Council. In case of contempt for a resolution, CETIFARMA will notify CANIFARMA's Directive Council, which will proceed according to its regulations. Expulsion of a member from CANIFARMA will be decided in the General Associates' Meeting.

[15] Fine ranging between MXN142,200 (which is equivalent to USD8,618 at an exchange rate of MXN13 per US dollar) and MXN1,137,600 (equivalent to USD68,945).

Criminal and Civil Liability

According to the criminal codes of the different Mexican states and the Federal District, when a product does not deliver the offered results or effects, the affected party may initiate criminal action for fraud. This offense is subject to imprisonment for a term that varies depending on the economic loss caused.

Regarding civil liability, in the event that a medical device or pharmaceutical product causes health injury, the affected individual is entitled to sue the manufacturer or the distributor, in order to claim payment for damages. In addition, please note that Mexican legislation has been recently amended to implement class actions. Hence, a group of individuals who are injured as a result of the consumption of a pharmaceutical product or the use of a medical device may file for class action. Although health regulation was not explicitly included as one of the areas eligible for class actions, the area of consumer protection was indeed included. Thus, medical products, being goods in the market offered by suppliers to consumers, could be reached by class actions.

Recommendations

When granting a marketing authorization for a medical device, COFEPRIS will indicate whether advertising may be addressed to the general public or only to healthcare professionals.

Determining whether pharmaceutical products may be promoted to the general public or to healthcare professionals depends on whether they are OTC medications or pharmaceutical products subject to a medical prescription.

Advertising materials for medical products share with the general marketing requirements the aim of avoiding consumers receiving deceptive information. However, and because medical products may represent a higher risk to the health and lives of the Mexican population, the provisions that govern these products set forth additional requirements, and Mexican health authorities closely monitor any promotional materials of these types of products.

Before investing in any promotional materials for medical products, it is advisable to conduct a review and/or contact COFEPRIS and PROFECO to ensure that all applicable provisions are met. There are pre-review mechanisms for that. Otherwise, a company faces the risk of seizure of its medical products, suspension or termination of broadcast of its marketing materials, as well as imposition of fines.

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This third edition of "*Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance*" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.