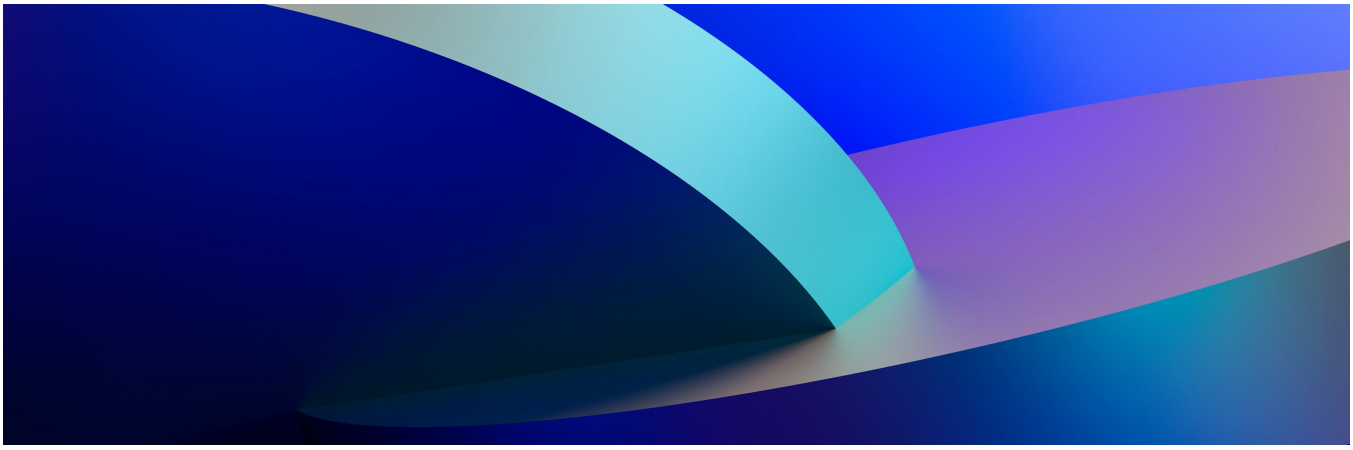

Pharmaceutical advertising regulation and medical device advertising in Mexico

1. Which laws are applicable regarding advertising of medicines and medical devices?

- The primary legislation for medicines and medical devices advertisement is The General Health Law (*Ley General de Salud*) (“ GHL”), and its Regulations (*Reglamento de la Ley General de Salud en materia de publicidad*) (“ HLR”). These norms are supplemented by The Federal Consumers Protection Law (*Ley Federal de Protección al Consumidor*), The Rules of the Federal Consumer Protection Law (*Reglamento de la Ley Federal de Protección al Consumidor*) and a variety of Mexican Official Standards (“ NOMs”) covering specific technical issues such as manufacturing best practices, post – marketing controls, surveillance of labelling, among others.
- Also, the Law for the Transparency, Prevention and Combat to Unduly Practices in Publicity Hiring (*Ley para la Transparencia, Prevención y Combate de Prácticas Indebidas en Materia de Contratación de Publicidad*) must be obey.
- The Federal Commission for the Protection against Sanitary Risks (“COFEPRIS”), is the agency in charge of the surveillance and authorisation of medicines and medical devices advertisement.

2. Are there any other legal regimes such as self- regulatory codes of conduct that govern the advertising of medicines and medical devices?

2.1 Medicines

Three industrial associations have issued Codes of Practices for the implementation of the regulation for medicines advertisement:

- The Council of Ethics and Transparency of the Pharmaceutical Industry (“CETIFARMA”): i) The Code of Ethics and Transparency of the Pharmaceutical Industry; ii) The Code of Good Practices of Promotion (Code of GPP); and iii) The Code of Good Practices of Interaction of the Pharmaceutical Industry with Patient Organizations.

- The Nacional Advertisement Regulation Council (“ CONAR”): i) Advertisement Ethics Codes; and ii) Sectorial Ethics Code.
- The Over-the-Counter Medicines Association (“AFAMELA”): AFAMELA Advertisement Ethics Code.

2.2 Medical devices

Medical Devices Companies follow CETIFARMA and CONAR self-regulatory codes.

3. What kind of licenses/approvals/fees (if any) are required for medicines and medical devices to be advertised to the general public and healthcare professionals?

On a general basis, Article 79 of HLR sets forth that the Advertisement of medicines, including vitamins and herbal remedies, and medical devices to the general public requires a permit granted by COFEPRIS, as well as an advertisement to health services, unless these are carried out by a private practitioner (single individuals). Advertisement to health professionals, only require a notice to be filed before COFEPRIS.Promotional activities also only require a notice.

- For medicines, the advertisement authorization is based on the classification made by the risk analysis of the product in the GHL. While over-the-counter medicines (“ OTCs”) can be advertised to the general public, prescription medicines are limited to advertisements targeted only to healthcare professionals.
- For medical devices, the general rule is that the authority indicates in the premarket clearance that advertisement is limited to healthcare professionals, except when at the moment of filing the pre- market clearance application the applicant requests to be authorized to advertise the product to the general public and includes evidence that proves the advertisement does not present a risk to public health. Only in this case medical devices can make advertisement to general public an advertisement permit application can be filed.

Article 195 of the Federal Rights Law sets forth the services provided by the health authority shall be paid for each product, type of message and event in accordance with the following:

Television and internet: 1,729.96USD

- Cinema, video: 240.76 USD
- Radio: 171.07 USD
- Print Press: 57.02 USD
- Brochures: 39.28 USD
- Outdoor advertisement: 304.12 USD

The abovementioned fees are estimation and apply both for medicines and medical devices.

4. Does the law in Mexico regulate the advertising of prescription-only and over-the-counter medicines differently?

Yes, only over the counter medicines can be advertised to the general public; the purpose of said advertisements is to inform the public about the characteristics of the products, their therapeutic properties and the form of use.

Prescription-only medicines advertisement can only be targeted to healthcare professionals. The purpose of this restriction is to prevent the misuse of medicines, avoiding potential harms to the population’s health.

5. What are the main restrictions applicable to the advertising of medicines and medical devices to the general public?

5.1 Medicines

According to article 44 of the HLR medicines advertisement will not be authorized to the general public when:

- It is presented as a definitive solution as preventive, curative or rehabilitative treatment of a
- certain disease;
- It indicates or suggest its use in relation to symptoms and conditions different that those expressed in the premarket clearance;
- Disrupt the information authorized by COFEPRIS;
- Promote its consumption through draws, raffles, competitions collectibles, or events in those who chance is involved;
- Promote consumption by offering any other product or service in return;
- Use statements or testimonials that may confuse the public or that are not supported.
- Use cartoons techniques that can confuse or induce minors to consume the products;
- Neglect the preventive messages command by regulation, when applicable.

The fine for the violation of this article range $83,000.00 to $110,666.66 USD.

5.2 Medical devices

According to article 55 of the HLR medical devices advertisement will not be authorized to the general public when:

- They promote unhealthy practices if the product is not use properly;
- It is presented as a definitive solution in the preventive, curative or rehabilitative treatment of a certain disease, unless this has been completely proved.

6. What are the main restrictions applicable to the advertising of medicines and medical devices to healthcare professionals?

According to article 42 of the HLR, advertisements directed to healthcare professional can only be published in specialized media, including specialty pharmaceutical dictionaries and directories of medicines, and the must be based on the approved prescription information of the corresponding medicine or medical device. In all cases the premarket clearance number of the product shall be included prior publication.

In the case of web pages containing information targeted to healthcare professionals, the responsible of the content must file an advertisement notice before COFEPRIS and explain the digital security mechanisms to prevent access from non-healthcare professionals' users.

The Code of GPP states that the relations between pharmaceutical industry personnel and health care professionals should encourage the development of a medical practice committed to patients' well-being, based on truthful and accurate information, tested, and up-to-date scientific evidence.

7. What information must appear in advertisements directed only to healthcare professionals for medicines and medical devices?

7.1 Medicines

According to article 42, medicines advertisement shall include the following information:

- The distinctive denomination; if applicable;
- Generic denomination;
- The pharmaceutical form and formulation;
- Therapeutic indications;
- Pharmacokinetics and pharmacodynamics;
- The contraindications;
- General precautions;
- Restrictions of use during pregnancy and lactation;
- Secondary and adverse reactions,
- Drug and non-drug interactions;
- Alterations in the results of laboratory tests;
- Precautions regarding effects of carcinogenesis, mutagenesis, teratogenesis and on fertility;
- Dosage and administration route;
- Manifestations and management of overdose or accidental intake;
- The presentation or presentations;
- Storage and handling recommendations; Protection messages;
- Laboratory name and address;
- The premarket clearance number issued by COFEPRIS.

If any of the above data does not exist, that circumstance must be expressly stated.

All the information in the guides to prescribe a medicine should be authorized previously in the medicine premarket clearance.

7.2 Medical devices

Medical devices advertisement shall include the following information:

- The premarket clearance issued by COFEPRIS.
- The references to support the scientific information.

8. What information must appear in advertisements directed to the general public?

8.1 Medicines

The advertisement of medicines directed to the general public shall comply with the indications approved by COFEPRIS in the premarket clearance of the product. This must include the message either in visual, print, hearing for radio, and print and hearing for cine and television the following caption: “Consult your physician”, and also the precautions messages when the use of the medicine can represent any danger in the presence of a disease pattern, breastfeeding or pregnancy status.

8.2 Medical devices

For medical devices, the advertising shall include captions that prevent self-treatment; according with article 56 of HLR, the advertisement directed to the general public shall be brief, concise and easy to understand, contribute to hygienic education, and state if the use of the product represents a risk for health.

9. Please summarise the requirements for scientific data indicated in advertisements. Are there any restrictions on the data on which the promotional claims are based (data on file, retrospective analyses, such as subgroup analyses or meta-analyses etc.)?

- Pursuant article 11 of HLR, the advertiser shall prove the statements made on the advertisement about the quality, origin, purity, conservation, nutritious properties and benefits which requires technical and scientific information requested by the Minister of Health.
- Scientific data must not be presented to audiences that do not have the professional knowledge to interpret it.
- All scientific data shall comply with the obligation set forth for the process of data in the General Health Law Rules for Clinical Research (*Reglamento de la Ley General de Salud en materia de Investigación Clínica*).

10. Are there specific rules for comparative advertisement of medicines and medical devices?

According to Mexican laws comparative advertisement is permitted, if the comparison has been made between equals, intended to inform the public, and it is not tendentious, false or exaggerated.

The Industrial Property Law and the Federal Consumer Protection Law contains provisions related to actions that can be filed against the party responsible for harmful comparative advertisement.

11. Are there specific provisions for advertisement of medicines and medical devices on the internet/in social media postings?

There are no specific provisions for advertisement of medicines and medical devices on the internet or social media. Internet and social media posting shall comply with all the applicable advertisement regulation.

Moreover, Article 2 of the HLR defines advertising as, "*the activity comprehending any process of creation, planning, execution and circulation of ads in media channels which aims to promote the sales of consumption of products and services*", and a broadcast medium as "*the one used to spread the commercials or information to the general population including television, cinema, radio, mail or any other communication system either print, electronic, digital or by any other technologies*". The general scope of application applies therefore to all advertising, regardless of whether it is published on internet or social media platforms.

12. Please describe the enforcement mechanism. Which bodies monitor compliance with the advertisement provisions and what are the legal consequences (e.g. penalties) for non-compliance?

COFEPRIS Surveillance Department monitors the compliance of medicines and medical devices advertisement provisions, by remote and on-site surveillance programs.

In very specific cases COFEPRIS and the Federal Prosecutor for the Consumer Protection **(PROFECO)** may coordinate actions against a violation of the corresponding laws and regulations.

Both authorities may order the suspension of an advertising in breach of legal framework to modify such ads. If not modified or the modification is considered not to comply with legal provisions, COFEPRIS and PROFECO may suspend the advertising activities, seize the advertise product and/or impose a fine according to articles 110, 111 and 112 from the HLR which may vary from $27,666.66 to $221,333.333 USD depending on the severity of the violation.

13. Any future developments in Mexico?

In 2021 the Official Mexican Standard NOM-241-SSA1-2021 Good Manufacturing Practices for Medical Devices (*Norma Oficial Mexicana NOM-241-SSA1-2021, Buenas Prácticas de Fabricación de Dispositivos Médicos*) was issued, which establishes the minimum requirements for the design, development, manufacture, storage, and distribution of medical devices based on their risk level. The purpose is to ensure that these devices comply with the quality, safety, and functionality requirements to be used by the final consumer or patient. It is worth mentioning that at the time of the publication of such Official Mexican Standard, it was determined that it would enter into force 18 months after its publication in the Official Gazette of the Federation (*Diario Oficial de la Federación*). Therefore, the Official Mexican Standard entered into force in June 2023, which is a legal provision that should not be overlooked when dealing with medical devices.

On the other hand, on May 10, 2023, the Decree amending, adding, and repealing several legal provisions of the General Health Law was published in the Official Gazette of the Federation (*Diario Oficial de la Federación*). This decree is relevant because it includes within the term Medical Devices the following: medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical and healing materials, and hygienic products.

Another relevant point of the Decree is that it empowers the Ministry of Health to classify within the category of Medical Device any input that, due to its characteristics and use, can be considered as such. Likewise, the Decree distinguishes between the manufacturing process of surgical materials, healing, and hygienic products from the provisions applicable to medicines.

Additionally, the GHL recognizes the classification of low-risk medical devices, which do not require an authorization. This is an important issue since previously the aforementioned classification was only provided for by Agreements.

Finally, the Decree includes the typification of the behaviors constituting a crime in relation to medical devices in relation to what was already foreseen for medicines.

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