LEXOLOGY

# Q&A: the promotion and sale of pharmaceuticals and medical devices in Mexico

**OLIVARES**

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## Advertising and promotion

*Regulation*

**Summarise the rules relating to advertising and promotion of medicinal products and medical devices, explaining when the provision of information will be treated as promotional. Do special rules apply to online advertising?**

The primary legislation on advertising of medicinal products and medical devices is the General Health Law Regulation regarding Advertising (RLGSMP) and opinions issued by the Advertising Council. The Intellectual Property Law and the Federal Consumer Protection Law also have provisions on advertising.

The Federal Commission for Protection against Sanitary Risk (COFEPRIS) and the Federal Consumer Bureau (consumer legal framework) are the regulatory authorities in this field.

The National Chamber of the Pharmaceutical Industry has a code of ethics that includes provisions on advertising. Although these provisions are not mandatory, failure to comply can result in a suspension of rights as a member of the chamber or exclusion from it.

The RLGSMP defines advertising as an activity covering all creation, planning, performance and distribution processes of advertising to promote the sale or consumption of products and services. Thus, we consider that providing information will be treated as advertising when it promotes the sale or consumption of products.

Electronic advertising falls under the general rules for advertising in article 2 of the RLGSMP. COFEPRIS is increasing its monitoring of online advertisements for medicinal products and medicinal devices, which to date has been less stringent than advertising on television and radio. The Integrity, Ethics and Transparency of Health Supplies Companies Code (CIETEMIS) states that online promotion of prescription-only medicines addressed to healthcare professionals must be duly approved by the corresponding authorities. The advertising must be disclosed on scientific websites. The sponsor must be clearly identified.

*Inducement*

**What regulations exist to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product or medical device?**

There are several bodies of law that refer in general terms to the relationship between the pharmaceutical industry and healthcare professionals, such as the Health Law and Health Law Regulations (including those that concern the regulatory control of healthcare activities, establishments, products and services). Industry codes of practice complement these regulations.

The CETIFARMA has issued the Integrity, Ethics and Transparency of Health Supplies Companies Code (CIETEMIS).

Affiliate members of the National Chamber of the Pharmaceutical Industry (CANIFARMA) are required to follow this code. CETIFARMA supervises members' and adherents' compliance.

These bodies of law and codes set important sanctions to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend the use of particular products.

*Reporting transfers of value*

**What requirements apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices?**

CIETEMIS allows CETIFARMA to require members to record any valuable support given to healthcare professionals, institutions or patient organisations. According to their guidelines, members will make information concerning donations available to the public on a yearly basis to promote transparency.

*Enforcers*

**Describe the bodies involved in monitoring and ensuring compliance with advertising controls for medicinal products and medical devices, distinguishing between any self-regulatory framework and control by the authorities.**

In accordance with the General Health Law, COFEPRIS is in charge of monitoring and ensuring compliance with advertising controls.

The primary legislation for the advertising of medicinal products and medical devices is the General Health Law and its regulations. These norms are supplemented by guidelines published by COFEPRIS. This agency is part of the Ministry of Health and controls the advertising of medicinal products and medical devices.

These regulations are complemented by the industry's code of practice.

CETIFARMA supervises its members' and adherents' compliance with its code of practice, CIETEMIS. There are also opinions issued by the Advertising Council, which include representatives from the Ministry of Health, the academic and scientific communities, the business sector, the media, and consumer groups.

*Sanctions*

**What are the possible financial or other sanctions for breach of advertising and promotional controls for medicinal products or medical devices?**

COFEPRIS has specific authority to order the suspension of an advertising activity in breach of the legal framework. This order must be followed by both the responsible party and the media channel within a period of 24 hours. COFEPRIS may warn companies with approved products to modify ads that are presumably in breach of the legal

framework. If not modified, or the modification is considered not to comply with the legal provisions, COFEPRIS may suspend the advertising activities and impose a fine. The decision and orders issued by COFEPRIS may be appealed before itself or the federal courts.

The penalties for failing to comply with the rules related to advertising are the suspension of advertising activities ordered either to the responsible party or directly to the media, and the imposition of a fine on each party, which can range from 2,000 to 16,000 units of measure for sanctions. The responsibility for imposing these penalties falls directly on the Ministry of Health through COFEPRIS.

COFEPRIS constantly monitors advertising activities throughout Mexico, particularly regarding drug-like products. COFEPRIS directs the efforts of coordination agreements related to publicity and the enforcement of the same. There has also been a strong coordinated effort between COFEPRIS and pharmaceutical companies tending to the self-regulation of advertising, which is still monitored. COFEPRIS has imposed large fines against specific over-the-counter medication manufacturers for using misleading advertising related to their products, inciting the public to self-medicate and take their products at the first symptom without consulting a doctor.

## Sale and supply

*Regulation*

**Are there special rules governing the dispensing or sale of particular types of medicinal products or medical devices?**

Despite the marketing authorisations requirement to sell products, prescription medicines, such as antibiotics, can be dispensed only if the consumer gives the received written prescription to a pharmacy. Dispensing over-the-counter medicines does not require a specific permit. Psychotropic and narcotic drugs are prescribed using a special notebook monitored by the Federal Commission for Protection against Sanitary Risk (COFEPRIS) and dispensed through local pharmacies authorised by COFEPRIS.

*Online supply*

**What laws and guidelines govern online dispensing, sale and supply of medicinal products and medical devices?**

Unless they are over-the-counter products, medicines must be made available only through authorised drug stores and prescription medicines can be sold to patients only with a physician’s prescription. Dispensers must keep the original prescriptions regarding antibiotics.

*Pricing and reimbursement*

**What are the controls imposed on pricing of medicines and medical devices and reimbursement by national social security systems that are applicable to manufacturers, distributors and pharmacists?**

Price control in the private sector is based on a self-regulated maximum retail price (MRP) scheme covering patented products, overseen by the Ministry of Economy. Under price control, each product’s MRP must not exceed an international reference price, estimated as the average price in six major markets, plus a market factor. There are no established sanctions for violations of the MRP.

In 2008, the government created the Committee for the Negotiation of Drug Prices (CNDP). Until 2018, recommended prices for patented and unique drugs (or those with exclusive distributors) for all public institutions were negotiated with the CNDP under the supervision of the Ministry of Public Function and the Mexican Antitrust

Authority.

Under that scheme, price reviews and eventual changes were done annually. The new administration is implementing modifications frequently, which may impact the frequency of price changes. The austerity measures that have recently been taken by the government will continue and may result in more frequent price reviews.

Public insurers dispense medicinal products prescribed by their healthcare professionals. Products are prescribed from a basic medicinal products list, which public insurers base on the national formulary issued by the Ministry of Health. Public insurers acquire those listed products mostly by public tender processes. The Mexican Institute of Social Security is the largest public sector buyer of drugs.

For direct purchasing of patented products, the CNDP analyses the effectiveness of the drugs and relevant therapeutic alternatives, and the feasibility and implications of an eventual substitution with equivalent medicines. The CNDP also conducts an economic evaluation of the cost-effectiveness of patented medicines compared with potential substitutes.

For the Institute of Social Security for State Workers (ISSSTE), a prescribed medicinal product can be dispensed in a private drug store registered with a public insurer, provided that this is not available within ISSSTE facilities and under certain conditions. ISSSTE reimburses the cost of such products according to previous agreements.

In the private sector, most payments are made on an out-of-pocket basis. Private insurers are improving the level of pharmaceutical coverage as the private market in medicines has grown considerably.

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