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Mexico
Pharmaceutical Advertising

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Mexico.

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Mexico: Pharmaceutical Advertising

1. What laws are used to regulate advertising on medicines in your jurisdiction?

Two key legal instruments regulate advertising of medical products in Mexico: (i) the General Health Law ("LGS" by its acronym in Spanish), which includes a specific section dealing with advertising requirements for health-related products and services, and (ii) the Secondary Regulations for Health-related Advertising ("RMP" by its acronym in Spanish), which further elaborate on specific requirements.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

Yes. There are two main codes of practice:

a. The Code of Integrity, Ethics and Transparency of Medical-Products ("CIETEMIS" by its acronym in Spanish), issued by the Council of Ethics and Transparency of the Pharmaceutical Industry ("CETIFARMA" by its acronym in Spanish), a body which was created under the National Chamber of the Pharmaceutical Industry ("CANIFARMA"). This Code applies to companies, both generic and innovative, who became members of CANIFARMA, and
b. The Code of Practice of the International Federation of Pharmaceutical Manufacturers & Associations ("IFPMA"). This Code applies in Mexico to those innovative companies who became members of the Mexican Association of Pharmaceutical Research Industries ("AMIIF" by its acronym in Spanish), by Resolution of AMIIF.

Both codes regulate the (promotional) interactions with Health Care Professionals ("HCPs"), health institutions and Patient Organizations.

a. If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

The Codes of Practice described above were designed to apply only to companies.

However, the existence of the CIETEMIS Code, and the organic collaboration between CANIFARMA and members of the National Academy of Medicine ("ANM" by its acronym in Spanish), prompted the creation of the Committee of Ethics and Transparency in the Physician-Industry Relationship ("CETREMI" by its acronym in Spanish), who has issued recommendations for HCPs, in their interaction with the pharmaceutical industry.

b. What is the legal status of the self-regulatory codes?

In general, the codes are contractually mandatory only to those companies who became members of the respective organization that issued them. However, members of AMIIF also decided to adhere and make mandatory for them in Mexico, the IFPMA Code.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

Yes, and it is very broad. Article 2, Section IX of the RMP defines advertising as any activity involving the creation, planning, execution, and dissemination of material, through media channels, aiming to promote the sale or consumption of health-related products and services.

a. What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

The definition of advertising in the RMP covers all type of advertising materials, whether printed, electronic, telephonic, digital, or through other technologies, as well as all channels, including media platforms (television, cinema, radio); billboards; transportation advertising; lighted signs; posters; printed means (newspapers, magazines, catalogues, brochures, flyers); direct mail, point-of-sale materials, etc.

The RMP also includes in the definition of advertising, the following types of information provided to HCPs: (i) medical information that refers to human diseases, their

prevention, treatment and rehabilitation, and (ii) scientific information that refers to the pharmacology of active ingredients and therapeutic uses of products.

That makes it difficult to find material that is fully excluded from the scope of regulated advertising.

However, there is a statutory exemption, known as the "catalogue exemption", which excludes altogether from the scope of the RMP, that material which only refers to the price of the product.

b. Does the definition apply equally to all target audiences?

Yes, the definition applies to all audiences. But there are different rules for each of the two target audiences: (i) HCPs and (ii) the public in general. Prescription drugs are only allowed to be advertised to HCPs and are subject to an Advertising Notice. In contrast, OTC drugs can be advertised to the public in general but are subject to an Advertising Permit.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Not as such. The same rules and restrictions apply to press releases, which means that no advertising of prescription drugs can be made to the public in general. Having said that, it has been tolerated recently to report in the media over the approval of new types of medicines, which in some cases has been done by the local regulator itself. In those cases, only the disease and the generic name are used, avoiding any reference to the commercial name and the respective pharma company.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Yes, there are. However, only the Codes of Practice refers to the internal approval of advertising material, requiring the existence of a Compliance Committee.

6. Do companies have to have material approved by regulatory bodies prior to release?

It depends on the prescription status and targeted audience. Prescription drugs are only allowed to be advertised to HCPs and are subject to an Advertising Notice. In contrast, OTC drugs can be advertised to the public in general but are subject to an Advertising Permit.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Although the RMP does not allow comparative advertising of products with different substances, the CIETEMIS Code does allow it, provided that (i) the comparison is scientifically supported, (ii) the statistical significance of the respective results is not misconstrued, (iii) the same methodology is used for comparing, exempt for meta-analysis with clear homogeneity criteria, and (iv) confusing adaptations are avoided.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

In general, it is only allowed to make advertisement of (i) approved medications and (ii) approved indications. In the first case, this has resulted in a heavy restriction for orphan drugs, which are not supported by a marketing authorization ("MA"), but simply by a recognition letter. In the second case, this means that off-label advertising is not allowed and is subject to different consequences, the most serious one being the cancellation of the MA.

Having said that, the CIETEMIS code allows the presentation of information not yet authorized, to an audience strictly scientific, provided no actual promotion of the product is done.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, and include the information that must or must not be included.

Prescription drugs are only allowed to be advertised to HCPs and are subject to an Advertising Notice. In contrast, OTC drugs can be advertised to the public in general but are subject to an Advertising Permit. The information provided to HCPs must be based on the Information to Prescribe ("IPP" by its acronym in Spanish) and the information provided to both HCPs and

the public must be fully consistent with the MA.

At the same time, the RMP contains certain prohibitions for the advertising of medicines, including the following: (i) promoting the product through raffles or contests, (ii) conditioning the use of the product to the purchase of another service or product, (iii) using testimonials that mislead the public, and (iv) failing to include the legend of "Consult your physician".

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

The LGS and RMP do not refer to patients, but they would be considered part of the public in general. In contrast, the Codes of Practice have plenty of provisions focusing on the interaction with Patient Organizations ("POs").

The CIETEMIS Code allows sponsoring educational programs and providing didactic materials for such events. However, while the name of the company can be included, references to specific products cannot. Other relevant provisions include the following:

a. Any collaboration with POs must be documented in agreements, which shall include a transparency clause.
b. Companies shall investigate deviations of POs and in some cases shall report these to CETIFARMA.
c. Companies shall have internal Policies for Interactions with POs, where they will respect independence of POs and shall never condition support.
d. Companies shall not participate in the elaboration of didactic materials but can review them for accuracy and avoidance of errors.
e. Any sponsored material must disclose the financial support.
f. Hospitality can only be directed at the PO and never at individual patients.
g. No support is allowed if the intention is to influence the inclusion or exclusion of products in either public or private product formularies.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example, can companies provide information about clinical trials, or reprints of scientific journal articles?

Information provided to HCPs must be based on IPPs, which can therefore refer to clinical trials. Companies can provide reprints of scientific journal articles.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

Both the mandatory regime, which includes the General Law of Administrative Responsibilities and the CIETEMIS Code, currently forbid companies from providing any gift in exchange of favoring its business.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

Yes, they are, except for controlled products (psychotropic and narcotics). The CIETEMIS Code also requires (i) samples to be labeled properly ("Commercialization of this sample is forbidden"), (ii) companies to abide to each public institution rules, (iii) companies shall maintain a documented system of control for samples, (iv) submitting periodic reports to CETIFARMA, including identification of deviations, and (v) companies shall appoint a person to be responsible for overseeing the use of samples.

14. Are pharmaceutical companies permitted to sponsor scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Yes, they are. Hospitalities are regulated predominantly through the Codes of Practice, which include the following provisions: (i) the interaction shall be documented in an agreement, (ii) the interaction shall be previously approved by the management of the public health institution, who will define the individual who will attend, (iii) supports shall not be granted to companions, (iv) hospitalities will not be provided for days prior or after the event, (iv) companies shall not sponsor or finance social, recreational, sporting or any other type of activities other than educational and/or scientific, and (v) educational events shall be held in appropriate venues.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

The CIETEMIS Code requires that (i) educational and/or scientific activities must use at least 80% of the scheduled time of each event, so that entertainment, sports, or recreational activities can not prevail over the former, and (ii) companies shall not organize simultaneous educational/scientific and promotional activities during the development of the academic program, to avoid impeding the educational objectives of the event.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

The CIETEMIS Code provides that (i) companies may employ HCPs as consultants, to participate in training programs for the company's personnel, for continuing medical education activities and specialized advisory boards, (ii) the selection of HCPs shall be based exclusively on their expertise, (iii) the number of HCPs must be fully justified by the company in terms of the scope of the project, (iv) the fees shall be determined in accordance with fair market value, and (v) the place and circumstances of any meeting with consultants must be consistent with the contracted services.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

The CIETEMIS Code provides that (i) donations will be formalized in writing, specifying commitments, their scope, validity, and accountability of the beneficiary, (ii) it is forbidden to make any donation with the purpose of influencing the decisions of HCPs to favor the donor company's business, (iii) companies must establish internal policies for the evaluation, approval, and allocation of donations, (iv) donations will not be granted to individuals and (v) companies shall not condition the granting of donations to the recommendation of use or acquisition of medicines.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

Transparency is not currently a legal requirement. In fact, under the current legal framework, privacy triumphs over transparency. Nevertheless, the CIETEMIS Code requires companies to (i) promote a transparency culture internally and externally, (ii) establish internal transparency policies, and (iii) document and report transfers of value to CETIFARMA in an aggregate manner. This applies to any company that is a member of CANIFARMA.

19. Are there any restrictions (whether by law or Codes of Practice) on advertising for medicines on social media directed to healthcare professionals or directed to the general public?

The definition of “advertising” provided by the RMP include online advertising. Therefore, the same rules that apply to medication advertising in other media apply to online platforms.

20. Is advertising on the internet for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

The restriction on advertising prescription drugs extends to online platforms. Only over-the-counter drugs may be advertised online, in accordance with the terms described previously and in compliance with the MA, the IPP, and the labeling information approved by COFEPRIS.

Companies should restrict online access to content directed at healthcare professionals, as failure to do so may be interpreted as non-compliance with health advertising regulations.

21. Are there any anti-bribery rules that apply to communications between pharmaceutical companies and healthcare professionals or healthcare organisations?

Information exchanged between companies and governmental entities or public institutions may be

considered public interest information under the General Law of Transparency and Access to Public Information. As a result, these authorities are obligated to disclose all communications with private parties, including pharmaceutical companies, and make such communications available to requesters.

In contrast, communications between private entities can only be disclosed through a court order. Such an order must be well-founded, justified, and clearly outline the nature and context of the legal proceedings that led to the request.

22. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

The CIETEMIS Code promotes transparency, integrity and ethical behavior. It forbids interactions aimed at unduly influencing the cycle of prescription, acquisition, distribution, dispensing and administration of medicines, as well as the inclusion or exclusion in public or private product formularies.

23. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

The Federal Commission or the Protection against Health Risks (COFEPRIS) enforces the mandatory rules and CETIFARMA enforces the CIETEMIS Code.

24. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Any individual can file a complaint before COFEPRIS, in relation to alleged infringements of advertising rules. This usually triggers an inspection procedure. Competitors are frequent users of the system, which is abused nowadays. COFEPRIS decides whether to move an inspecting procedure to a sanctioning procedure.

Any member of CANIFARMA can initiate a claim before CETIFARMA, who will investigate and decide if a sanction is applicable.

25. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Sanctions include warnings, administrative fines, and revocation of a marketing authorization. The most common sanction is an administrative fine, which is determined within a range that is defined for specific obligations.

At the same time, COFERIS can impose safety measures during inspection procedures, which can include product seizures, prohibitions of use, suspension of advertising, and sanitary alerts.

26. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

They are completely independent.

27. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

The enforcement made by COFEPRIS has increased, as additional tools and staff has been dedicated to monitoring online advertising. In contrast, although there has been an increase of sanctions imposed by CETIFARMA, they have consistently stated that they will favor positive incentives, like their certification system, rather than negative incentives, like their sanction system.

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