PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

In México, the promotion and advertising of pharmaceuticals and medical devices are first of all regulated by the General Health Law ('Health Law'), which establishes the health control of the advertising of activities, products and services (ie, the orientation, education, sampling, inspection, and, where applicable, the security measures and sanctions that may be imposed by the Ministry of Health through the Mexican Federal Commission for the Protection against Sanitary Risks, Comisión Federal para la Protección contra Riesgos Sanitarios or 'COFEPRIS'), and the Regulations of Health Supplies (the 'Regulations') that regulates health supplies, as well as the establishments, activities and services related to health supplies. Furthermore, there is a specific regulation on the advertising of the products, services and activities considered by the Health Law, that is, the Regulations of the General Health Law on Advertising (the 'Advertising Regulations'), which of course contain specific provisions on the advertising of all the pharmaceutical products and medical services, among others.

In addition, the Ministry of Health issued an agreement establishing the guidelines to be observed by public establishments that provide healthcare services to regulate their relationship with manufacturers and distributors of medicines and other healthcare suppliers, derived from the promotion of products or the performance of academic, research or scientific activities, which was published in the Federal Official Gazette on 12 August 2008, in order to reinforce the self-regulation system of the Pharmaceutical Industry, as defined below.

In Mexico, the pharmaceutical industry, along with infant formula, medical devices and healthcare supply companies (jointly hereafter, the 'Pharmaceutical Industry'), has adhered to the National Chamber of the Pharmaceutical Industry (Camara Nacional De La Industria Farmacéutica or 'CANIFARMA'), whose main objective is to promote business practices within an ethical and transparent framework with integrity, through the Council of Ethics and Transparency of the Pharmaceutical Industry (Consejo de Ética y Transparencia de la Industria Farmacéutica or 'CETIFARMA').

CETIFARMA is the responsible body for the development of a self-regulatory system, and in 2012, along with COFEPRIS, executed the self-regulation agreement for healthcare supplies and advertising ethics as another contribution to the self-regulatory system, which was updated in 2018.

Furthermore, it is important to consider that, by joining CANIFARMA, any pharmaceutical company inherently accepts adherence to the Code of Ethics and Transparency of the Pharmaceutical Industry (Código de Ética, Integridad y Transparencia de Empresas de Insumos para la Salud or 'CIETEMIS') issued in 2021, and to the Code of Good Promotional Practices (the 'Promotional Code') executed on 2016, both issued by CETIFARMA and enacted by the members of the Pharmaceutical Industry. Both codes are based on several international initiatives and directives.

Finally, the general principles of consumer protection regarding advertisements and promotional activities contained in the Federal Law on Consumer Protection (the 'Consumer Law') must be taken into account because they complete the regulatory framework applicable to pharmaceuticals and medical devices in Mexico.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

According to the Advertising Regulations, advertising is defined as an activity comprising the entire process of creating, planning, executing and disseminating advertisements in the media for the purpose of promoting the sale or consumption of products and services. Advertising is distinguished from the sales and commercial promotional activities of the products, which are understood to be related exclusively to the price of the products, services and activities; however, when the brand of the product or service is referred to in the promotion, certain wording should be included.

On the other hand, the Promotional Code of CETIFARMA defines promotion as every activity carried out, organised or sponsored by a pharmaceutical company or third parties under its control, intended to foster the prescription, supply, sale and acquisition or consumption of drugs and other health supplies, (eg, medical

devices).

At all times, the promotion of medical devices and pharmaceuticals, and authorised information to disseminate among the general public must be of products authorised by the health authority.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

The Ministry of Health, through COFEPRIS, is the regulatory authority entrusted with the enforcement of the existing regulatory framework by analysing and reviewing the advertising material and campaigns, and then granting, when appropriate, permits or authorisation for the advertising of medical devices and pharmaceuticals. In addition, CETIFARMA, as a self-regulatory body, may also enforce the promotion and advertisement of pharmaceuticals and medical devices, along with the associated members of CANIFARMA and other related trade associations.

Both COFEPRIS and CETIFARMA have their own sanctions for the breach of their respective codes and regulations, which can vary depending on the activity and the seriousness that led to the sanction.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

The Advertising Regulations also include and regulate the advertising of other products, such as food, food supplements, alcoholic beverages, tobacco, herbal remedies, cosmetics, psychotropic substances and narcotics, as well as medical devices and pharmaceuticals. Depending on the type of product, an advertising authorisation or a notice to be filed before COFEPRIS is required.

Additional considerations, such as specific wording to be included in the advertisement, specific schedules for the broadcast of the advertisements, specific media for its publication, defined content of the advertisement (eg, not including athletes or famous individuals) and requirements to be complied with according to the type of audience to which the advertisement will be addressed, shall apply, depending on the type of product.

The advertisement of psychotropic substances, and narcotics, as long as they have a therapeutic effect, may be authorised, may only be addressed to healthcare professionals (HCPs) and should always comply with the requirements for pharmaceuticals subject to prescription.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisements) in your country and, if so, which ones?

As per the Health Law and Advertising Regulations, only over-the-counter (OTC) products that do not require a prescription, as well as herbal remedies, may be advertised to the general public. The advertisements of these products may only include the description of the diseases, the diagnosis, treatment, prevention or rehabilitation, as provided by the marketing authorisation, in a language that may be understood by the general public, and should always include the brand of the product and the company name, as well as the wording ‘Consult your physician’.

Pharmaceuticals subject to prescription may only be advertised to HCPs through specific media exclusively dedicated to the health sector, including pharmaceutical dictionaries and guides, and should be based on the prescription authorised in the marketing authorisation, and the marketing authorisation number of the product must be included at all times on the respective advertisements.

By contrast, as for the advertisement of medical devices, either to the general public or HCPs only, this depends on the terms of the marketing authorisation and the characteristics and aim for which they were registered. Additionally, the Ministry of Health may determine that a medical device may only be advertised to HCPs.

On the other hand, the information provided at scientific seminars shall always be used with the authorisation

of the authors and/or sponsors, and always be quoted.

As for the telephone messages and electronic communications, these may only be used for promotional purposes, once the express authorisation by the health authority has been obtained, and such activities can only be performed in strict compliance with Mexican data protection law.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

According to the Advertising Regulations, advertisements may be disseminated through television, film, radio, billboards, traffic signs, advertisements posters, newspapers, magazines, direct mail, catalogues, brochures, flyers and point-of-sale material, as well as any other means of communication, whether printed, electronic, telephone, computer, telecoms or other technologies, and they shall all comply with the requirements mentioned previously.

It is important to consider that the advertising of information addressed to the HCP through the internet and social media must ensure at all times that access to the information has all the security needed to ensure that only the HCP may access the information, according to the Advertisement Regulations and the Promotion Code, which expressly provide that it is the responsibility of the company to ensure that information uploaded to media such as the internet may only be accessed by HCPs.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

Yes, advertisements regarding OTC pharmaceuticals and medical devices require prior authorisation from COFEPRIS, for which the interested party must physically submit the corresponding application form to COFEPRIS, containing every aspect related to the product being advertised, such as the means of advertising, the period during which the product is going to be advertised, the actual content of the ad or the promotional campaign and so on.

Additionally, the interested party shall pay the corresponding duties, which may vary, depending on the media through which the product will be advertised, from approximately US$30 for a flyer, catalogue or similar means, and up to US$1,500 for advertisements on television and the internet.

Once the form has been submitted, COFEPRIS will analyse all the information provided and determine whether authorisation is granted or denied.

As for prescription-only pharmaceuticals, a notice must be submitted to COFEPRIS, which may be done online through DIGIPRIS, COFEPRIS electronic platform, where some self-managed filings may be submitted. It is important to note that COFEPRIS has continuously been updating the platform in order for the public to be able to file the different notices online and to avoid long waiting times that were common before.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

According to the applicable Health Law and the Advertisement Regulations, in order to be able to advertise the pharmaceuticals and/or medical devices, as mentioned above, the relevant products must have marketing authorisation granted by the authority; therefore, at no time may such products be advertised.

Furthermore, according to CIETEMIS, information regarding clinical trials must be kept confidential between the research team, sponsors, committees to which the annual reports are submitted and the authority.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

The Advertising Regulations generally prohibit the comparison of products with different ingredients in order to avoid risks or the causing of damage to the health of the general population.

However, the Promotional Code allows the comparative advertisement of pharmaceutical and medical devices, as long as different requirements are met, such as the fact that the information provided is not biased, that it is always scientifically contrasted, that it is based on compared elements and relevant evidence and, that it is unequivocally indicated that the quoted pharmaceutical trademarks of the competitors

belong to them.

On the other hand, the Regulations of the Consumer Law allow the comparative advertising of products and services, which is defined as one that compares and confronts the comparison of one or more products, goods or services that are similar or identical to each other, whether or not they are of the same brand. Comparative advertising may be used, as long as the complete information, the author and the veracity of the information are clear, truthful and verifiable.

It is important to note that, if the rules regarding comparative advertising are not complied with, in the event of an inspection by the authority, through the monitoring of media or a claim filed by a consumer, such a breach may be considered a particularly severe cause for the imposition of a sanction if, after a procedure for the infraction of law is solved, the comparative advertising was in breach of the Regulations.

Whenever a pharmaceutical brand is quoted by another company, it should all be clearly stated that it is the property of the relevant company.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

In Mexico, the Health Law provides that the professionals that may prescribe pharmaceuticals are doctors, homeopathic physicians, surgeon dentist and veterinarians in the area of their competence, and those who have a bachelor's degree in nursing. In addition, for the exercise of professional activities in the fields of medicine, pharmacy, dentistry, veterinary medicine, biology, bacteriology, nursing, physical therapy, social work, chemistry, psychology, optometry, sanitary engineering, nutrition, dietetics, pathology and its branches, and any other branches established by other applicable legal provisions, professional degrees or certificates of specialisation are required that have been legally issued and registered by the competent educational authorities.

From this, it can be interpreted that a HCP is a person who has obtained a professional degree for the practice of the aforementioned medical fields; therefore, those are the only individuals to which the advertisement may be addressed when it refers to the HCP.

Moreover, the Promotional Code provides that an HCP is any member of the medical, odontology-pharmaceutical or nursing professions, who is authorised to prescribe, recommend or supply a pharmaceutical product.

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

There are no specific rules governing promotional (advertising) activity conducted virtually, including online interactions with HCPs, different from the ones previously mentioned, because the Advertising Regulations apply to all kinds of advertising, including those through different media. The HCP who attends said virtual meetings, congresses and symposia, must have a medical-related degree and, in the event of a foreign HCP, he/she may participate in the congresses and symposia, as long as the prior requirements for this kind of events are met, and the foreign HCP does not prescribe, suggest or induce the consumption of the pharmaceutical due to the lack of a Mexican professional degree or completion of the homologation process of his/her medical degree in Mexico.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?

According to the Health Law, promotion materials may include HCPs' endorsements, as long as the HCP joins medical associations, which are in charge of guaranteeing their professionalism and ethical practice.

The Advertising Regulations provide that the Ministry of Health will promote colleges, associations and national boards regarding joining those dedicated to advertising in order to issue ethical codes for the manufacture, production and dissemination of advertising material.

On the other hand, the Consumer Law and its Regulations provide that the endorsement of a product in an

advertisement or information about a product is allowed, as long as, where the endorsement is granted by a professional organisation or association, the wording or information included is based on the appropriate documentation that supports the qualities and properties of the products, and any other requirements provided by law, with scientific, objective and reliable evidence.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Yes, according to the Supply Regulations, samples of pharmaceutical products may be provided to HCPs (those authorised to prescribe in Mexico), as long as some requirements are met: the samples are free of charge; they are not or do not contain any psychotropic or narcotic substance; they contain a statement that says they are free samples; and their aim is to improve the patients' health. The samples do not need marketing authorisation, as long as the products for sale comply with the legal requirements and they contain fewer units than the original packaging sold to the public.

It is important to note that samples of pharmaceutical products that require a medical prescription are not permitted.

According to the Promotional Code, the delivery of free samples in hospital centres must be carried out according to the procedures of the hospital, and they should be granted in order to get to know the product and the possibility to start treatment. Moreover, the free samples must comply with the following: they may not be offered to induce or compensate for prescription practices; they shall include the warning 'Prohibited for sale'; there must be a strict follow-up of all the samples from their manufacturing to their storage; and they are delivered by the regional distributors and medical representatives to the HCPs, for which notification must be provided to CETIFARMA, and may be subject to further inspection.

Furthermore, there should be a list of addresses of the HCPs that receive the free samples, and such a list must be maintained and updated at all times. A certified professional must be in charge of the compliance of the foregoing.

14. What rules govern the offering of hospitality to healthcare professionals?

The provision of hospitality to HCPs is regulated under CIETEMIS and the Promotional Code, both issued by CETIFARMA. Hospitality may be granted at all times to HCPs, medical researchers or medical consultants that participate in the events, but never to third parties external to the meetings, who may not receive any hospitality at all.

The definition of hospitality considers the payment of reasonable costs for transportation, accommodation and meals and, if applicable, the registration to the educational or scientific event, but it could never include entertainment activities, such as social, recreational or sports activities.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

From a sanitary perspective, according to the Promotional Code, donations made to the organisations of HCPs, either directly or indirectly, must at all times be made only for educational or academic purposes, and not for organisational purposes, for example, changes to the board of directors.

Any donation or sponsorship made by pharmaceutical companies must be mentioned at the events, and all the donation or sponsorship must be included or mentioned in the documents or papers to be published.

Notification of any event sponsored by pharmaceutical companies for scientific and/or educational purposes, either directly or through third parties, must be provided according to the guidelines and forms issued by CETIFARMA, for these purposes: historical events (which are those that are held every year, for which notification must be provided annually within the first bimester) and episodic events (which are not part of an annual programme), and the companies must register each event.

It is important to take into consideration that, according to the Promotional Code, non-compliance with the said obligations will be considered an infringement of CIETEMIS and the Promotional Code, and may lead to the imposition of different sanctions by CETIFARMA.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from

the perspective of rules on the promotion of products?

Yes, they can all support scientific or educational meetings, as long as they satisfy the aforementioned requirements, and according to the Promotional Code, there is no difference between the two sectors.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

CIETEMIS regulates the interactions between pharmaceutical companies and patient organisations (POs), which must execute an agreement covering the objectives, scope and activities involved, as well as the timetable in which they will be carried out. As for funding, the agreement shall consider the amounts, sources and destination of financing, direct or indirect support in kind and any other type of non-financial collaboration, which may not be conditioned. They should also include an accountability clause describing the support received by POs.

Interactions with HCPs and POs are defined by CIETEMIS, which provides that the patients' rights must be respected, POs must be recognised as independent representation bodies, with their own policies and work programmes, and that the information to be provided must relate to therapeutic options, the promotion of self-care practices and easy-to-understand scientific information. The interaction may be carried out directly or through third parties, but at all times, pharmaceutical companies will be responsible for such interactions, and such interactions will never be directly with patients.

Pharmaceutical companies may support the educational programmes of the POs, either for the production or acquisition of teaching or pedagogical materials, but under no circumstances may they be used for the promotion of a specific product of the company; such support must be considered as a transfer of value.

According to the Mexican Health Law and its Advertising Regulations, the promotion of the prescription of products is not allowed within POs.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

It is possible to delegate promotional advertising to a third party, such as subsidiaries, foundations, associations, institutes, agencies or third parties linked to them, but pharmaceutical companies will always remain responsible or liable for interactions with the POs, and they must ensure that the decisions of HCPs and their independence are respected.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

Yes, it is mandatory in Mexico to report transfers of value, that is, any legitimate payment, contribution, support or fee based on legality and ethical principles, that a healthcare supply company makes, directly or indirectly, in cash or in kind to an HCP, a medical or HCPs association or organisation, a healthcare service institution, whether public or private, or a PO, from a sanitary and tax perspective.

Medical samples, commercial transactions between companies and distributors, or services to other professionals are not considered transfers of value.

From a sanitary perspective, the employment of consultants, the employment of HCPs, scientific societies, organisations or associations, the support granted to POs, which need to be documented in an agreement, are considered as transfers of value.

From a tax perspective, donors must, of course, comply with the tax law and regulations regarding the registration of the association or organisation as an authorised donor, and in order to be able to continue receiving transfers of value, they must comply with tax obligations, such as reporting every transfer of value received.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

General sanctions imposed by the sanitary authority for the breach of the Health Law and the Advertising Regulations may range from the suspension of the broadcast of the advertisements to economic fines ranging from US$12,000 to US$100,000.

As for the sanctions that may be imposed by CETIFARMA for the breach of CIETEMIS and the Promotional Code, these may range from a temporary or definite suspension of benefits as an affiliated party of CANIFARMA to a private admonition; an economic sanction of approximately US$50,000 to US$250,000; and a public admonition broadcast through CANIFARMA media or any other media defined by CETIFARMA, when the breach affects the image and credibility of the pharmaceutical industry.

COFEPRIS does actively pursue infringements of the Health Law and its Advertising Regulations, although it is limited by budgetary and human resource constraints. However, its resolutions are not made public, unless the gravity and severity of the breach pose a risk to the health of the general population.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

From a sanitary perspective, COFEPRIS is the authority entrusted with the enforcement of the Health Law and its Regulations and Advertising Regulations, CETIFARMA, in turn, is the industry self-regulating body responsible for the enforcement of CIETEMIS and the Promotional Code.

Competitors that take action against companies that infringe the codes normally take such action through CETIFARMA as the self-regulatory body to which the companies have adhered, although the law provides a means through what is called a 'popular action', by means of which competitors may claim breaches of the law, thereby obliging the authority to initiate administrative proceedings and investigations ex officio against possible breaches.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

To the best of our knowledge, no significant development in the field of pharmaceutical and medical device promotion is expected in the coming years. Recently, the authority has developed a procedure for filing advertising notices only, and, as of 2023, they can be easily submitted through the online platform DIGIPRIS and do not require a response from the authority; however, the advertisement is subject to surveillance. As for advertisement authorisations for drugs, herbal remedies and medical devices, they must be submitted in person. It is important to take into consideration that, as of 2024, the governmental duties to be paid for such authorisations have increased drastically.