Mexico


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1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

The primary legislation for the advertising of medicinal products is the General Health Law (*Ley General de Salud*) (HL) and its Regulations (*Reglamento de la LGS en Materia de Publicidad*) (HLR). These norms are supplemented by guidelines published by the Regulatory Agency, the Federal Commission for Protection against Sanitary Risks (COFEPRIS). This agency is part of the Ministry of Health and controls the advertising of medicinal products.

Industry Codes of Practice complement this regulation. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the following self-regulatory instruments (the Codes):

- The Code of Ethics and Transparency of the Pharmaceutical Industry (Code of Ethics & Transparency).
- The Code of Good Practices of Promotion (Code of GPP).
- The Code of Good Practices of Interaction of the Pharmaceutical Industry with Patient Organisations (Code of GPI).

The latest versions of these Codes have been in force since April 1, 2013. Affiliate members of the National Chamber of the Pharmaceutical Industry (CANIFARMA) are required to follow these Codes. CETIFARMA supervises members' and adherents' compliance.

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.

Additionally, other general legislation may be relevant for the advertising of medicinal products, particularly, the Federal Law for the Protection of Consumers and the Industrial Property Law.

1.2 How is "advertising" defined?

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 or consumption of products and services*".

An advert is, according to this Article, "*the message directed to the public or a section of the same, with the purpose of informing about the existence or characteristics of a product, service or activity for its commercialisation and sale or to motivate a conduct*".

For the Code of GPP, promotion means any activity undertaken, organised or sponsored by a pharmaceutical company or under its authority (subsidiaries, foundations, associations, institutes, agencies, etc.) that supports the prescription, dispensing, sale and acquisition or administration of its medicines, complying with applicable rules, regulations and standards.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

The Code of Ethics & Transparency requires members to strictly comply with the applicable legal provisions, and their personnel to have at least a broad knowledge of all of the applicable provisions.

Concerning advertising and promotional activities, the above Code requires them to give accurate and objective explanations on the characteristics, functions, advantages or disadvantages of their products or services.

The Code of GPP requires that the information provided to healthcare professionals is accurate, balanced, fair and objective, and sufficiently complete to enable them to form their own opinion of the therapeutic value of the medicine.

Under no circumstances can promotional material be distributed in a final version, to which no further amendments will be made, if it has not been certified and authorised by the medical authorities of the laboratory and the person in charge of confirming its compliance with the Codes. These authorities must certify that the material's final form has been examined; that it abides by the provisions of the Code of GPP and by the applicable standards on advertising practices; and that it complies with commercial authorisations and, in particular, with the information of the marketing authorisation in effect. Presentations must be true and faithful to the medicine's stated characteristics.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

The Code of Ethics & Transparency requires members to act in accordance with sound trading practices and in strict compliance with the prevailing legislation. In this regard, members are required to establish the proper measures and monitoring procedures to verify that their associated members abide by the regulations applied to the different activities they perform.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Article 79 of the HLR sets forth that the advertisement of medicinal products must be approved. Approval applications should be filed before COFEPRIS. These applications must include all of the characteristics of the intended advertising.

There is also the possibility of submitting only a notice rather than an approval application when the advertising is only directed to healthcare professionals.

The regulations allow companies to have a previous opinion by an authorised expert. This opinion may be filed along with the approval application to speed up the process.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

COFEPRIS has specific authority to order the suspension of an advertising activity in breach of legal framework. This order has to be followed by both the responsible party and the media channel within a term 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 to not 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.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

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 to each one, which can range from 2,000 to 16,000 times the minimum wage (around 9,000.00 USD to 73,000.00 USD). The responsibility for imposing these penalties falls directly on the Ministry of Health, through COFEPRIS.

Regarding the strictness on the imposition of these fines, in our experience it has been steadily increasing. COFEPRIS constantly monitors advertising activities throughout the country, particularly regarding drug-like products. COFEPRIS has been directing 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.

As for any important examples where action has been taken against over-the-counter pharmaceutical companies, it is worth mentioning that COFEPRIS has imposed large fines against specific over-the-counter medication manufacturers for using misleading advertising related to its products, inciting the public to self-medicate and taking their products at the first symptom without consulting a doctor.

Regarding the possibilities for competitors to take direct actions related to advertising infringements, the HL and the HLR, regarding advertising, both contemplate the possibility of a so-called "people's action", which is a complaint filed before COFEPRIS regarding a breach of the provisions of the law. Issues related to unfair competition will be directly addressed in question 1.9 below.

The Industry Codes of Practice empower CETIFARMA to supervise and impose monetary sanctions on members in breach of these Codes.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

COFEPRIS's supervisory and enforcement functions are supplemented by the Codes enforced by CETIFARMA. This self-regulatory process, therefore, does not preclude the statutory powers of COFEPRIS, which, at its discretion, may or may not take into account findings from the self-regulatory body.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

Actions based on unfair competition derived from advertising activities can be taken based on the provisions set forth by the Industrial Property Law before the Mexican Institute of Industrial Property (IMPI) either by the directly affected party or by the authority itself.

If there is a firm unfair competition decision, the affected party can claim damages and lost profits before a Civil Court.

Additionally, Article 32 of the Federal Law for the Protection of Consumers establishes the possibility of filing a complaint before the Bureau of Consumer Protection (PROFECO) regarding false or tendentious advertising, which can impose a fine on the responsible party and an order to stop the specific advertising activities.

There is also the possibility of filing a civil action under article 6 *bis* of the Commercial Law, which establishes the possibility of initiating civil actions derived from unfair competition acts. This action for unfair competition under the Commercial Law may be applicable for cases that cannot be claimed before an administrative authority and are not contemplated in the Industrial Property Law.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company

responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

According to Article 42 of the HLR, prescribing information about products to healthcare professionals is subject to approval before publication. This information is approved while granting marketing authorisation for the corresponding product. Any publication should have the marketing authorisation number of this product.

The Code of GPP sets forth that information about medicinal products must be grounded on scientific evaluation and related empirical evidence, which must be kept at the disposal of healthcare professionals, if required. It must not induce confusion by means of distortion, unjustified pressure, omission or any other means.

This Code also states that, when scientific information is provided and is not part of the prescribing information duly approved or authorised in the marketing authorisation of a product, it should be strictly limited to a scientific audience, avoiding the promotion, directly, indirectly or through a third party, of any unauthorised directions of use.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

With respect to results of clinical trials, the Code of GPP sets forth that when they are being published in specialised or widespread distribution magazines, pharmaceutical companies have to request the disclosure of any conflicts of interest from the authors.

With respect to scientific information that is not part of the prescribing information duly approved or authorised in the marketing authorisation of a product (off-label information), this Code requires that providing this information must be strictly limited to a scientific audience, avoiding the promotion, directly, indirectly or through a third party, of any unauthorised directions of use.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.

According to the HLR, any advertising of medicinal products to the public should be approved by COFEPRIS. The product must have a marketing authorisation. The Code of Ethics & Transparency requires members to promote responsible prescription and discourage self-medication. It should be analysed, therefore, on a case-by-case basis, whether a press release is or is not an advertising activity.

The Code of GPP states that when a company, directly or indirectly, finances, sponsors or organises the publication of promotional materials in journals or magazines, it must be expressly stated that the material is not presented as an independent editorial matter and the sponsorship of the company must be clearly displayed.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

As mentioned above, the Code of GPP sets forth that information of medicinal products must be grounded on scientific evaluation and related empirical evidence, which must be kept at the disposal of healthcare professionals, if required.

When scientific information is provided that is not part of the prescribing information duly approved or authorised in the marketing authorisation of a product, it should be strictly limited to a scientific audience, avoiding the promotion, directly, indirectly or through a third party, of any unauthorised directions of use.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

The above case law is not relevant to Mexico, as it is not an EU Member State.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

With respect to private institutions, it is advisable to first obtain the medicine's approval before sending them information, in order to avoid this being perceived as advertising of an unauthorised medicine.

With respect to public institutions, they have to follow the National Compendium of Health Supplies (*Compendio Nacional de Insumos para la Salud*) issued by the Ministry of Health. This is essentially a list of products that can be acquired by public insurers. To have a product listed in this compendium, it is required to have been approved, among other requirements.

Such products are acquired mainly through public tender processes, unless they have to be directly acquired from exclusive rights holders, for example, in the case of patented products.

The Code of Ethics & Transparency requires members to fully and loyally comply with the precepts of the legal framework applicable to public tender processes. The Code mandates that during the acquisition process, through public bidding or any other procedure of government acquisition, there should be no attempt to either exert undue influence upon the decision-making process, or to gather confidential information from government officials acting on behalf of a government office or entity.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

The Code of GPP allows accredited healthcare professionals to be hired to participate in clinical trial studies and other research. The Code states that under no circumstances can healthcare professionals, whatever their accreditation, be hired in order to induce the use, prescription (products and/or indications), purchase or recommendation of a specific product or to influence the results of a clinical study. The standards mentioned below in question 5.4 would also apply.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

According to Article 42 of the HLR, advertisements directed to healthcare professionals can only be published in specialised media, and they must be based on the approved prescription information of the corresponding medicinal product.

The Code of GPP states that the relationships between pharmaceutical industry personnel and healthcare professionals should encourage the development of a medical practice committed to patients' well-being, based on truthful and accurate information and tested and up-to-date scientific evidence in order to contribute to the appropriate use of approved medicines.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

The Code of GPP requires that the medical and scientific departments of its members ensure that the information provided to healthcare professionals is accurate, balanced, fair and objective, and sufficiently complete to enable the recipients to form their own opinion of the therapeutic value of the medicine.

Members must take scientific and moral responsibility for the content of the information provided by them, or others by an agreement (outsourcing).

According to the Code of GPP, when promotional material refers to published studies, these must be faithfully reproduced or clear, easily accessible references must be given. A faithful reproduction is one that reflects the full meaning and content of the original source in an objective manner, without adding or excluding any information that could mislead or confuse the recipient.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The Code of Ethics & Transparency requires members to refrain from taking undue advantage of their clients, or any product, individual, company, commercial brand or symbol, through mass media advertising.

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

There is no specific provision referring to "head to head" clinical trial data before comparative claims; however, the Code of GPP states that the information must be grounded on scientific evaluation and related empirical evidence, which must be kept at the disposal of healthcare professionals, if required. It must not induce confusion by means of distortion, unjustified pressure, omission or any other means.

As mentioned above, when promotional material refers to published studies, these must be faithfully reproduced or clear, easily accessible references must be given. A faithful reproduction is one that reflects the full meaning and content of the original source in an objective manner, without adding or excluding any information that could mislead or confuse the recipient.

As an example of this, when the effectiveness and safety of different active principles are compared for advertising purposes, information such as the statistical appraisal of the results must not be omitted. Statistics, conclusions or any other data derived from different studies using different methodologies, must not be mixed or compared, unless resulting from systematic reviews or meta-analysis where the homogeneity criteria is specified. Adaptations that may introduce bias or confusion are unacceptable.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Comparative advertisements are further contemplated in both the Industrial Property Law and the Federal Law for the Protection of Consumers. Both of these laws contain provisions related to actions that can be filed against the party responsible for the comparative advertisement.

According to Article 386 subsection III of the Industrial Property Law, it is possible to use another company's brand name in advertising as long as the comparison is intended to inform the public, and it is not tendentious, false or exaggerated.

Article 32 of the Federal Law for the Protection of Consumers also penalises unfair practices in comparative advertisements, including unfair use of trademarks, and contemplates the possibility of filing a complaint before the Consumer's Bureau for such activities.

The Code of Ethics & Transparency calls members to compete fairly, avoiding unfair practices. Market competition must be fair and respect intellectual rights, or any other member's rights.

The above Code requires members to refrain from discrediting competitors or spreading any false or inaccurate information about their activities or products. The Code of GPP states that claims or comparisons while providing information shall not be included unless scientifically tested. All information, claims or comparisons included in promotional material must be substantiated and fair. In particular, any comparison between different medicines must be scientifically sustained and must comply with the regulations of fair competition standards. Comparisons must not be denigrating and must be grounded on equivalent elements and relevant evidence.

As to the referral to a competitor's product that has not been approved in Mexico, there are no clear specific provisions in this regard, provided that it does not have a well-known trademark in Mexico. Thus, our recommendation would be to submit the ad before COFEPRIS for an opinion or authorisation, in order for it to determine whether the ad implies a risk to public health.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

The Code of GPP sets forth guidelines for these activities. Public institutions may have their own particular guidelines.

The Code states that congresses, lectures, symposia, meetings and other similar scientific or educational events sponsored, financed or supported by pharmaceutical companies or any other third party must have, as a main purpose: scientific exchange; medical education; and/or information about medicines.

Whenever support for continuing education or independent educational programmes is being provided, the education of healthcare professionals should be encouraged, primarily, to improve their knowledge of patient care. In each case, programmes must comply with the guidelines of the applicable laws: they must have strict scientific content sustained, if required,

on clinical evidence; and, most importantly, they must be accredited and certified by the corresponding academic authorities.

Support in general will not be offered, under any circumstance, in order to have any kind of influence on the decision-making process involved in prescribing medicines or buying, including, excluding or modifying official product catalogues.

3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

Although there is no legal provision specifically forbidding teaser ads of medicinal products, the Code of Ethics & Transparency requires members, while providing information or advertising, to give accurate and objective explanations on the characteristics, functions, and advantages or disadvantages of the products or services.

In addition, the Code of GPP mandates that all promotional material, including advertising in printed, audio-visual or electronic media, must be legible and in strict accordance with the terms established in the marketing authorisation and with the ethical principles included in the Codes.

Therefore, there is a chance that teaser ads would be considered in breach of the Codes, as information to healthcare professionals must not induce confusion by means of distortion, unjustified pressure, omission or any other means and could be considered misleading for the consumers.

Additionally, promotional activities to consumers should inform the patient or consumer about the properties of the medicines he/she is using, of the importance of concluding the treatment prescribed by the physician, and about the risks of substituting the prescribed medicine for another one without knowledge and proper medical supervision.

3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

Provided that the indication for the combination use was expressly authorised for Product A, the holder of the MA for Product A can certainly rely on the approved use of Product B with Product A in Product A's SmPC to promote the combination use. However, the holder of Product B cannot promote such combination use until expressly authorised in the SmPC for Product B.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

Yes. According to the Code of GPP, samples are provided directly to healthcare professionals in fair amounts and without cost in order to support the medical treatment, so that they may get to know and be familiar with the product.

According to Article 49 of the HLR, providing samples of products for free does not require approval, provided that they meet the requirements of the approved medicinal product. These samples should be contained in a package with a lesser number of units than the approved product.

Sampling of prescription-only medicinal products is not permitted to the general public. Any sample of a medicinal product must not be given out to minors. Samples must also contain the wording "*Not for sale*".

The Code of GPP establishes guidelines for sampling. It prohibits members from offering or supplying samples with the aim of seeking or rewarding prescription practices. The Code also forbids any trade of samples.

In addition, according to Article 464 *ter* of the HLR, the sale of medical samples is a crime punishable with one to nine years in prison and a fine equivalent to between 81,746.00 USD and 204,355.00 USD.

Members are required to have full 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.

We always recommend that our clients have strict control on product samples since there have been cases where said samples have been re-sold.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

The Code of GPP essentially states that companies must act responsibly regarding sponsorships and donations. No gifts of significant commercial value may be offered to healthcare professionals, or incentives of any kind, as an inducement to use, prescribe, purchase or recommend a specific product or influence the results of a clinical study.

No gifts, bonuses, pecuniary advantages, benefits in kind, or any sort of incentive may be offered or promised to healthcare professionals, administrative staff or government employees involved in the cycle of prescription, purchase, distribution, dispensing and administration of medicines, except in the case of inexpensive promotional aids related to the practice of medical or pharmaceutical activities.

The Code delineates inexpensive promotional aid as one that does not exceed the equivalent of 10 times the minimum wage (around 40.00 USD).

The Code allows pharmaceutical companies to grant financial aid or scholarships to a healthcare professional in order to attend scientific or educational events, in accordance with the health institutions where the professional develops their activities.

Under no circumstances will funding be offered to induce healthcare professionals to use, prescribe, buy or recommend a specific product, or to influence the results of a clinical study. The same criteria may be applied to independent educational programme funding.

4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.

Donations are part of the promotional, socially responsible activities of companies, according to the Code of Ethics &

Transparency. These would be granted to non-profit organisations and institutions in order to support altruistic and social projects, as long as they refrain from using donations as a means to promote products from the donor companies.

The Code of GPP states that donations of medical equipment must not be associated with promotional practices; instead, they must be properly channelled through the corresponding institution and must not be made in a personal capacity.

According to their guidelines, companies will make information available to the public concerning the donations granted in order to promote transparency.

In Mexico there is no specific monetary limit regarding donations, but donations must comply with the formalities established in the Mexican legislation, specifically the Mexican Tax Regulation.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

The Code of GPP states that the provision of objects such as books or material on optical, magnetic and electronic support, and scientific material is acceptable provided their commercial value does not exceed the overall equivalent of 50 times the minimum wage (around 200.00 USD). The provision of any good or service of any kind, however, should not be for the inducement to use, prescribe, purchase or recommend a specific product.

According to the Code, promotional activities directed to healthcare professionals, therefore, should only help them to sustain their therapeutic decisions.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

As far as we know, there are no specific rules for this sort of practice regarding the private sector. Even though discounts could have implications derived from our anti-trust law, several conditions, such as relevant market power, would have to coincide before a violation to the provisions of this law takes place.

Additionally, the Code of Ethics & Transparency prohibits members from: making arrangements with competitors to manipulate or increase price levels, potential markets, territories or client distribution; restricting or conditioning production; impeding distribution or commercialisation channels; or encouraging the exclusion of any product from sale points.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?

The HLR states that the advertising of medicinal products cannot be approved when it promotes consumption of those in exchange for another product or service.

We have participated as advisors in cases where COFEPRIS objects to corporate advertising, arguing that programmes related to providing additional medical or technical services or equipment is a violation of provisions in the health law. Several modifications to the terms of the advertisements were made as a consequence of objections by the authority.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

There is no legal provision specifically forbidding or prohibiting offering refund schemes to patients; however, the implementation of any of these types of schemes is subject to the approval of the competent authorities, applicable regulations and compliance with the provisions of the Industry Codes of Practice.

4.8 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply?

Although many pharmaceutical companies have already implemented their own patient access schemes or managed access agreements in Mexico, patient support programmes are not broadly developed in the Mexican legal framework; therefore, the approval of these programmes by COFEPRIS must be carried out on a case-by-case basis in accordance with the provisions of the HL, its Regulation regarding Advertising, the Federal Law for the Protection of Consumers and the Federal Law on Protection of Personal Data.

These rules are complemented by guidelines published by COFEPRIS and the self-regulatory instruments issued by CETIFARMA, specifically the Code of Ethics & Transparency, the Code of GPP and the Code of GPI. Additionally, other general legislation may be relevant for the advertising of medicinal products, particularly the Federal Law for the Protection of Consumers and the Industrial Property Law.

4.9 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?

Yes, collaboration agreements with members of the pharmaceutical industry are a common practice in Mexico. There are no specific rules for these sorts of agreements; however, the Code of Ethics & Transparency, the Code of GPP and the Code of GPI set forth general guidelines applicable to these activities.

4.10 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

As mentioned above, the Code of GPP states that whenever support for continuing education or independent educational programmes is being provided, the education of healthcare professionals should be encouraged, primarily, to improve their

knowledge of patient care. In each case, programmes must: comply with the guidelines of the applicable laws; have strict scientific content sustained, if required, on clinical evidence; and, most importantly, be accredited and certified by the corresponding academic authorities.

Support, in general, will not be offered under any circumstances in order to have any kind of influence on the decision-making process involved in prescribing medicines or buying, including, excluding or modifying official product catalogues.

According to the above Code, funding and support in kind, granted by the pharmaceutical industry for continuous educational medical programmes, must be exclusively designated for scientific and academic purposes.

Pharmaceutical companies may grant financial aid or scholarships to enable a healthcare professional to attend scientific or educational programmes, in accordance with the health institutions where these professionals develop their activities.

Under no circumstances will funding be offered to induce healthcare professionals to use, prescribe, buy or recommend a specific product, or to influence the results of a clinical study. The same criteria may be applied to independent educational programme funding.

Members must notify CETIFARMA of these events, in due form, at least two months prior to the event.

4.11 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

On July 18, 2016, several decrees were enacted in accordance with a Constitutional Amendment for Anti-bribery Matters in Mexico. These decrees were aimed at implementing, amending and supplementing various laws and acts, which together comprise the new National Anti-Corruption System.

The main mandatory anti-bribery rules and provisions currently in place applicable to private parties, whether individuals or corporations (including pharmaceutical companies), are contained in: (i) the Mexican Federal Constitution; (ii) the Federal Anticorruption Law for Government Procurement; (iii) the Federal Criminal Code; and (iv) the international anti-corruption conventions to which Mexico is a party (the United Nations Convention Against Corruption, the Inter-American Convention Against Corruption and the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions).

The General Act of Administrative Responsibilities (GAAR) came into force in Mexico on July 19, 2017, repealing the Federal Anticorruption Law for Government Procurement. The GAAR sanctions, among other corrupt activities, the acts of private parties related to administrative liabilities when interacting with public officials, such as bribery, illegal participation in administrative procedures, influence peddling, collusion and undue contracting of former public officials. Some of the main administrative liabilities considered under the GAAR include the disqualification from public acquisitions for no less than three months and no more than 10 years, and the suspension of activities for no less than three months and no more than three years.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

The Code of GPP allows members to provide proper hospitality to healthcare professionals, medical researchers or experts participating in events. This should not be extended to persons who are not involved with the corresponding event; thus, they would not be provided with financial aid or any other kind of support.

According to the Code, the concept of proper hospitality includes the reasonable cost or payment of round-trip travel expenses, lodging and meals and eventual registration fees. CETIFARMA may determine whether the hospitality is reusable according to its standards.

The Code prohibits organising or sponsoring events outside the country that are directed to healthcare professionals residing in Mexico, unless:

a) More than 80% of the invited healthcare professionals come from abroad and the prospective venue is more convenient for the majority of the participants.
b) Justified motives exist in terms of security or costs.

In these cases, the Code must be respected, as well as the specific legal provisions applied by the host country.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

According to the Code of GPP, members may grant financial aid or scholarships to healthcare professionals in order for them to attend scientific or educational events, in accordance with the health institutions where these professionals develop their activities.

As mentioned above, hospitality means the reasonable cost or payment of round-trip travel expenses, lodging and meals and eventual registration fees.

Members will only pay for reasonable out-of-pocket expenses incurred individually by a consultant attending a scientific conference or a third party's meeting in their capacity as a healthcare professional or in representation of a member. Under no circumstances can healthcare professionals, whatever their accreditation, be contracted in order to induce the use, prescription, purchase or recommendation of a specific product or to influence the results of a clinical study.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

The Code of GPP holds members responsible for verifying that the events they support are in compliance with the Codes.

CETIFARMA may supervise this compliance and sanction breaches to the Codes.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

The Code of GPP states that accredited healthcare professionals may be contracted on a consultancy basis to provide their support and scientific knowledge, such as: helping in the development of medical products; participating in clinical studies or other research; and giving lectures or presentations to the sales departments, in meetings, or to train laboratory staff.

Remuneration to healthcare professionals must not exceed the market value of the services provided. The location and circumstances of a consultants' meeting must be consistent with the consultancy services provided.

Government employees or staff from regulatory bodies must not be assigned for consultancy services when a conflict of interest is involved.

Pharmaceutical companies must compel healthcare professionals contracted as consultants to disclose this activity, to avoid conflicts of interest.

5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

As mentioned above, the Code of GPP allows the hiring of accredited healthcare professionals to participate in clinical trial studies and other research. The standards mentioned above in question 5.4 would apply.

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

As mentioned above, the Code of GPP allows the hiring of accredited healthcare professionals to participate in clinical trial studies and other research. The standards mentioned above in question 5.4 would apply.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Yes, but subject to approval by COFEPRIS. Pursuant to Article 43 of the HLR, any visual or audio advertisement must bear the following message: "*Consult your physician.*" Advertisements should mention applicable precautions, and when the use of the medicine represents any danger in the event of an existing pathology.

The Code of GPP requires that members' promotional activities directed towards consumers must be undertaken with the aim of generating a new culture with regard to the rational and appropriate consumption of medicines, encouraging the guidance of healthcare professionals authorised to prescribe.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

Pursuant to Article 310 of the HL, only non-prescription medicines can be advertised to the general public, and the objective of said advertisements is to inform the public about the characteristics of the products, their therapeutic properties and the form of use.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

The Code of GPP states that promotional campaigns should:

- Discourage self-prescription and product recommendations among consumers.
- Promote respect for a physician's prescription in terms of proper dosages and methods of use.
- Respect the procurement and supply procedures of prescription medicines, if required by law.
- Respect a physician's prescription of a specific product, in such a way that a pharmacy employee is not induced to modify it for the benefit of a particular company.
- Inform patients/consumers about the properties of the medicines they are using, the importance of concluding the treatment prescribed by a physician, and about the risks of substituting the prescribed medicine for another one, without knowledge and proper medical supervision.
- Appoint a person responsible for pharmacovigilance matters in order to compile, collect and analyse all of the information provided by medical representatives, or any other source, concerning the doubts and side effects of the medicines they commercialise.

COFEPRIS's advertisement guidelines state that this Regulatory Agency will not approve an ad providing disease awareness to be followed by another ad of an over-the-counter medicinal product related to that disease, unless both ads are approved jointly.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

The Code of Ethics & Transparency requires members to promote responsible prescription and discourage self-medication. It should be analysed, therefore, on a case-by-case basis, whether or not a press release for a prescription-only medicine is an advertisement activity.

The Code of GPP states that material related to medicines and their uses, whether promotional or not, which is sponsored by a pharmaceutical company, must clearly indicate that it has been sponsored by that company.

According to the Code of GPP, in Mexico it is possible for a press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

There are no specific legal or code provisions in this regard. Members are responsible, however, for verifying that their brochures/reports are, in general terms, in line with the Codes. CETIFARMA may supervise this compliance and sanction breaches to the Codes.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

The Code of GPP establishes that collaboration between the pharmaceutical industry and patient organisations must have a written agreement in place that includes, at least:

- the activities to be undertaken, and the cost, source and destination of funding; and
- direct and indirect support and any other relevant non-financial aid.

In these agreements, members have to follow their applicable guidelines, codes of ethics and conduct, their transparent practices and the deontological instruments approved by CETIFARMA and CANIFARMA.

The Code requires members to set forth criteria and procedures for the approval and implementation of these kinds of collaborations.

Any other kind of sponsorship provided by social, governmental or private sector organisations should not be excluded.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

The Code of GPP states that in no case can health professionals be offered items with significant monetary value or incentives of any kind to use, prescribe, purchase or recommend a product or influence the outcome of a clinical trial. The delivery of objects such as books or materials on optical, magnetic, electronic and scientific equipment are excluded from this, if the secured value of these articles as a whole is less than 50 times the daily minimum wage, equivalent to 200.00 USD.

6.8 What are the rules governing company funding of patient support programmes?

Patient support programmes are not broadly developed in the Mexican legal framework; therefore, the approval of these programmes by COFEPRIS must be carried out on a case-by-case basis in accordance with the provisions of the HL, its Regulations regarding Advertising, the Federal Law for the Protection of Consumers and the Federal Law on Protection of Personal Data.

These rules are complemented by guidelines published by COFEPRIS and the self-regulatory instruments issued by CETIFARMA, specifically the Code of Ethics & Transparency, the Code of GPP and the Code of GPI.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

The General Health Law Regulation for Health Research (*Reglamento de la Ley General de Salud en Materia de Investigación para la Salud*) and the Official Mexican Standard for Health Research in Human Beings (NOM-012-SSA3-2012), both of which regulate clinical trials conducted in Mexico, establish that the principal investigator must deliver to COFEPRIS a partial or final technical-descriptive report, as appropriate, on the progress or execution of the research and will be responsible for delivering a copy of each report to the heads of the Research, Ethics or Biosafety Committees of the institution or establishment where the investigation is carried out.

The General Health Law Regulation for Health Research also states that the principal investigators may publish partial and final reports of the clinical trials and disseminate their findings by other means, always taking care that the confidentiality to which the research subjects are entitled is respected, as well as that which has been agreed with the sponsors of the study. In addition to giving due recognition to the associated researchers and the technical personnel who participated in the investigation, a copy of these publications must be delivered to the corresponding health institutions.

The Code of GPP, which is a self-regulatory code of practice, requires members to publish positive and negative research results, particularly concerning adverse side effects. They should ensure the protection of participants' data according to applicable norms.

When results are being published in specialised or widespread distribution magazines, pharmaceutical companies will request that authors disclose the presence or absence of any conflicts of interest.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

The applicable regulations do not expressly provide or require disclosure about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations. However, the Code of GPP and the Code of GPI allow CETIFARMA to require members to record any valuable support given to healthcare professionals, institutions or patient organisations. According to their guidelines, members will provide information concerning donations granted available to the public on a yearly basis in order to promote transparency.

Such requirements apply only to CETIFARMA's members, regardless of whether they have been granted a marketing authorisation or not, or if they are foreign companies.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Please see the answer to question 7.2 above.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

The interactions of the pharmaceutical industry with health professionals can generate conflicts of interest, as well as supporting

studies, invitations to conferences and other promotional activities. In order to face these situations that may create doubts or uncertainties, CETIFARMA should be consulted, so that in the scope of their capacity and in adherence to the Code of Ethics and current regulations, they can advise and guide on the kind of behaviour to follow or apply.

8 Digital Advertising and Social Media

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

The Health Law Regulations apply to any advertising activity, including ads through electronic means and other forms of technological media.

COFEPRIS is in charge of monitoring ads on the Internet. It has been strongly monitoring drug-like products, known as "miracle products" (products with non-proved health-related claims).

The Code of GPP states that the 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, and the sponsor must be clearly identified.

Companies must adopt the proper measures to ensure that the promotion of prescription medicines on their websites will only be accessible to healthcare professionals.

COFEPRIS issued guidelines for digital advertising that apply to any product subject to be monitored/approved by COFEPRIS. These guidelines clarify that digital advertising campaigns must be approved by COFEPRIS before being used on any digital media.

8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

The Code of GPP requires members to adopt the proper measures to ensure that the promotion of prescription medicines on their websites will only be accessible to healthcare professionals. Such websites must have a precaution stating that it is only addressed to healthcare professionals empowered to prescribe drugs.

8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

There is no clear, specific provision in this regard. The Code of Ethics & Transparency, however, requires members to act in accordance with sound trading practices and in strict compliance with the prevailing legislation. In this regard, members are required to establish the proper measures and monitoring procedures to verify that their associated members abide by the regulations applied to the different activities they perform.

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

There is no clear, specific provision in this regard. As mentioned above:

- The Code of Ethics & Transparency requires members to act in accordance with sound trading practices and in strict compliance with the prevailing legislation.
- The Code of GPP seeks to ensure transparency in the promotion of medicines and compliance with the ethical principles and the prevailing laws and regulations. This Code requires that members' promotional activities directed towards consumers must be undertaken with the aim of generating a new culture with regard to the rational and appropriate consumption of medicines, encouraging the guidance of healthcare professionals who are authorised to prescribe.
- Members must adopt the proper measures to ensure that the promotion of prescription medicines on their websites will only be accessible to healthcare professionals.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

Digital advertising campaigns must be approved by COFEPRIS before being used on any digital media; however, COFEPRIS does not provide clear, specific provisions regarding medicinal products. Therefore, we advise to bear in mind that:

- The Code of Ethics & Transparency requires members to act in accordance with sound trading practices and in strict compliance with the prevailing legislation.
- The Code of GPP seeks to ensure transparency in the promotion of medicines and compliance with the ethical principles and the prevailing laws and regulations. This Code requires that members' promotional activities directed towards consumers must be undertaken with the aim of generating a new culture with regard to the rational and appropriate consumption of medicines, encouraging the guidance of healthcare professionals authorised to prescribe.

Additionally, we recommend that companies adopt the proper measures to ensure that the promotion of prescription medicines through electronic means will only be accessible to healthcare professionals.

Conversely, mobile medical applications are a new area that COFEPRIS may address in the future with particular regulations, especially if they represent health risks.

8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?

There are no specific provisions in this regard; therefore, social media activity by company employees must abide by the self-regulatory instruments issued by CETIFARMA, specifically the Code of Ethics & Transparency, the Code of GPP and the Code of GPI, which require members to act in accordance with sound trading practices and in strict compliance with the prevailing legislation.

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

No. However, the Health Law Regulations and self-regulatory instruments issued by CETIFARMA described above apply to any advertising activity, including advertising and promotional activity conducted virtually.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

COFEPRIS signed the "Alliance for Digital Advertising" with the Mexican Association of Pharmaceutical Advertising Agencies (AMAPF), the Internet.mx Association and the Interactive Advertising Association (IABMX), with the objective of strengthening the Code of Ethics & Transparency and excluding any information that could mislead or confuse the recipient on the Internet.

The alliance will promote collaborative actions on digital advertising and encourage self-regulation, in favour of the final consumers of medicines.

Likewise, COFEPRIS has committed to promote the Code of Ethics & Transparency for the dissemination of pharmaceutical advertising, as well as promote and strengthen the population's access to objective information on the different products and services offered on the web.

COFEPRIS has strengthened the figure of Copy Advice as a free, voluntary, confidential and non-binding mechanism of pharmaceutical advertising, prior to the formal request for authorisation and dissemination, which has reduced time and will optimise resources for pharmaceutical industries.

In June 2019, COFERIS issued a decree through which it decided to revoke the following relevant guidelines on pharmaceutical advertising:

- Guidelines for the administrative simplification of digital advertising procedures and authorisations (2014).
- Guidelines that establish the criteria for the processing of advertising authorisations for medicines (2014).
- Guidelines that establish the criteria for the processing of advertising authorisations for medicines, homeopathic medicines and herbal remedies (2017).
- Guidelines that establish the criteria to which the publicity that promotes healthy habits in order to avoid a possible health risk must be subject (2017).
- Guidelines that establish the criteria for the processing of advertising authorisations for over-the-counter medicines, homeopathic medicines and herbal remedies (2017).

It is important to note that in the decree of reference, it was stated that the revocation of said guidelines was due to the fact that they did not comply with the formality and publicity requirements provided by the General Law of Regulatory Improvement. Therefore, COFEPRIS stated that all procedures in the matter of drug advertising must be resolved in accordance with the current regulations on advertising.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

As a consequence of the revocation of all of the latest relevant guidelines on pharmaceutical advertising, COFEPRIS will have to reassess the content of the applicable regulation, which is expected to be strengthened by both industry associations and regulatory authorities.

The United States–Mexico–Canada Agreement (USMCA), which substitutes the North American Free Trade Agreement (NAFTA), entered into force on July 1, 2020, which includes favourable amendments related to pharmaceuticals and regulatory matters.

On March 8, 2018, 11 countries signed the free trade agreement formerly known as the Trans-Pacific Partnership (TPP), which has been renamed the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The signing members are Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. The CPTPP includes several provisions that will certainly have a positive impact in terms of pharmaceutical advertising, particularly those included in the chapter for Regulatory Coherence and Intellectual Property.

On July 1, 2020, and as a result of the entry into force of USMCA, the new Federal Law for Protection of Industrial Property was enacted. The new Industrial Property Law represents an important legislative change, as it is aimed at matching the domestic law with the standards set by the new trade and cooperation agreements signed by Mexico in recent years, and it came into force on November 5, 2020.

Due to the above, amendments to the health laws are expected in the near future.

Another relevant change that could have a certain impact on drug promotion strategies is that, although, in the past, the acquisition of medicines for public health institutions was exclusively the responsibility of the Mexican government, on July 31, 2020, the Mexican government and the United Nations Office for Project Services (UNOPS) executed an agreement for the acquisition of medicines and medical supplies for the period 2021–2024, with the purpose that said dependency was in charge of implementing, tendering and contracting all of said activities, as well as managing the respective contracts with third parties. However, due to problems in the effectiveness of said mechanism, at the end of 2021 it was announced that two consolidated acquisitions would be carried out, one by INSABI for the acquisition of certain medicines, including innovative medicines, and another by UNOPS.

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Recently, COFEPRIS has been targeting companies that promote the sale of prescription drugs through digital means, both innovative medicines approved in Mexico but manufactured and acquired abroad, and generics that have not been authorised in Mexico, and which are characterised by having prices considerably lower than those available in Mexico to individuals. Said acquisitions are made unlawfully through import permits for purported personal use, and in many other cases they do not even register the same as it is a minimum quantity. In these cases, the affected companies have filed so-called "popular actions", claiming the illegal importation and commercialisation of their products and the generics on the ground of unfair competition, non-compliance with the regulatory requirements and, of course, infringement of industrial property rights.

Taking into consideration that COFEPRIS is the Regulatory Agency in charge of regulating the advertising of medicinal products, the Specialised Court on Environmental Matters and Regulation of the Federal Court of Administrative Justice is the competent authority for the resolution of appeals that are filed against decisions on advertising matters. However, there are cases in which, even when it comes to acts issued by COFEPRIS, the appeal is filed and resolved by the Specialised Court on Intellectual Property Matters, since issues related to the protection of intellectual property rights are involved; therefore, for its challenge, the right and main claim of each case must be analysed.

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