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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2016

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A practical cross-border insight into pharmaceutical advertising

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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*".

Ad means, 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.) which 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? If so, what aspects should those SOPs cover?

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.

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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 which 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 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? To what extent may competitors take direct action through the courts?

The penalties for failing to comply with the rules related to advertising are the suspension of advertising activities ordered either to the responsible party or directly to the media, and the imposition of a fine to each one, which can range from 2,000 to 16,000 minimum wages (around US$9,000 to US$73,000). The responsibility for imposing these penalties falls directly on the Ministry of Health, through COFEPRIS.

Regarding the strictness of 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 imposed large fines against the manufacturers of 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 coordination effort between COFEPRIS and pharmaceutical companies tending to the self-regulation of advertising, which is still monitored.

Regarding the possibilities for competitors to take direct actions related to advertising activities, the General Health Law and the Regulations of the Health Law Regarding Advertising both contemplate the possibility of a so-called "people's action", which is a complaint filed before COFEPRIS regarding a breach in 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 to 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.

Actions can be brought 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 Consumer Protection establishes the possibility of filing a complaint before the Bureau of Consumer Protection (PROFECO) regarding false or tendentious advertising, which can impose a fine to the responsible party and order to stop the specific advertising activities.

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.

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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?

According to the HLR, any advertising of medicinal products to the public should be approved by COFEPRIS. The product must have a marketing authorisation. Prescription-only medicines cannot be advertised to the general public. 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 advertisement 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 on 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 related 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 Formulary (*Cuadro Básico de Insumos para la Salud*) that is 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 formulary 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.

In addition, the Committee for the Negotiation of Drug Prices (CNDP) supports public acquisitions through a process of transparent negotiation between public insurers and pharmaceutical companies, particularly regarding patented products. The Committee evaluates the cost-benefits of new medicines and therapies in view of other comparable products in the market.

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 for 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.

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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?

In February 2014 COFEPRIS issued detailed guidelines regarding the approval of ads for non-prescription medicinal products (COFEPRIS's advertisement guidelines). According to these guidelines, COFEPRIS will not approve ads comparing products with the same therapeutic indication or questioning the quality of products with marketing authorisation.

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 213 subsection X 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 on 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. It must not be denigrating and comparisons 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 an 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.

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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 a 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 are chances 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 as 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.

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 punished with one to nine years in prison and a fine equivalent to between US$81,746.00 and US$204,355.00.

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 of the re-sale of said samples.

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

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 medicine or pharmaceutical activities.

The Code delineates as inexpensive promotional aid that one that does not exceed the equivalent of 10 times the minimum wage (around US$45).

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 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?

Donations are part of the promotional, socially responsible activities of companies, according to the Code of Ethics & Transparency. These would be granted to not-for-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.

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

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 equivalent of 50 minimum wages overall (around US$225). 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?

The CNDP mentioned above is a price-negotiating commission formed by several public offices (including major institutes of health) which negotiates prices for drugs with single manufacturers (such as drugs under patent rights) where prices are reduced through volume acquisitions. The offer of discounts in these negotiations is permitted and encouraged.

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 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?

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?

Patient access schemes/patient adherence programmes are not broadly developed in the Mexican legal framework. Companies such as Pfizer, Novartis and GSK have implemented their own patient adherence programmes.

4.8 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 a 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 education 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.

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.

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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 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 in presentations for 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 in regard to rational and appropriate consumption of medicines, encouraging the guidance of healthcare professionals authorised to prescribe.

As mentioned above, in February 2014 COFEPRIS issued detailed guidelines regarding the approval of ads for non-prescription medicinal products.

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 tend to:

- Discourage self-prescription and product recommendations among consumers.

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- 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?

As mentioned above, prescription-only medicines cannot be advertised to the general public. 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.

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 which will include, 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 daily minimum wages equivalent to US$200.00.

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 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 protection of participants' data according to applicable norms.

When results are being published in specialised or widespread distribution magazines, pharmaceutical companies will request from the authors to 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, what information should be disclosed, from what date and how?

The Codes of GPP and 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 make information concerning donations granted available to the public on a yearly basis in order to promote transparency.

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, 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.

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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 which may create doubts or uncertainties, the 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 The Internet

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-proven health-related claims).

The Code of GPP states that internet promotion of prescription-only medicines addressed to healthcare professionals must be duly approved by the corresponding authorities. The advertising must be disclosed on scientific websites. The sponsor must be clearly identified.

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

Recently, 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 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 in regard to rational and appropriate consumption of medicines, encouraging the guidance of healthcare professionals authorised to prescribe.
- Members must adopt the proper measures to ensure 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?

Recently, 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. They are required to have a community manager responsible for monitoring the content used in digital media and ensuring it complies with the approved one. However, these guidelines do not provide clear, specific provision 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 in regard to rational and appropriate consumption of medicines, encouraging the guidance of healthcare professionals authorised to prescribe.

Additionally, we recommend companies adopt the proper measures to ensure 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.

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?

Several amendments to the Industry Codes of Practices by

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CETIFARMA were approved in 2013. Most of these amendments are related to the questions answered above.

In February 2014, COFEPRIS issued detailed guidelines regarding the approval of ads for non-prescription medicinal products. Most of these guidelines are in line with the Codes. As a development, we would highlight the non-approval of an ad providing disease awareness if it is followed by another ad of a medicinal product related to that disease, unless both ads are approved jointly.

Recently, as mentioned above, COFEPRIS issued guidelines for digital advertising that apply to any product subject to be monitored/approved by COFEPRIS.

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

As a consequence of compliance practices, there is the expectation that the rules governing pharmaceutical advertisements will be strengthened by both industry associations and regulatory authorities.

A likely adoption of the Trans-Pacific Partnership Agreement in 2015 or 2016 could lead to major changes in the rules for pharmaceutical advertising.

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

Since 2011, COFEPRIS has been targeting manufacturers of drug-like products, known as "miracle products" (which are not approved as medications and make health-related claims). Strong enforcement has been observed.

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Mr. Luna has participated in questioning the constitutionality of certain provisions of the Industrial Property Law and the Federal Copyright Law. He is also the sponsor of an important proposal to modify the system of litigation and enforcement of intellectual property rights in Mexico. Mr. Luna has spearheaded a 10-year litigation strategy that has incorporated regulation changes and lobbying, which has resulted in precedent for patent linkage regulations and life terms of pipeline patents in Mexico. This work has resulted in billions of US$ of protected revenues for the R&D pharmaceutical industry in Mexico. As a result of his involvement, Mr. Luna has been selected as the delegate to represent AMIFF, the industry association for R&D pharmaceutical companies that do business in Mexico, in the Trans-Pacific Partnership negotiations.

His commitment to just and fair law extends to his overall promise of client satisfaction; he lobbies to change the law to allow for proper patent protection and best serve his clients. Mr. Luna is also the author of several articles on patents, litigation and regulatory issues. He is a part-time professor at the Universidad Nacional Autonoma de México (UNAM).

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Languages: English and Spanish.

Recent publications:

Getting the Deal Through: Life sciences 2014, Mexico Chapter, 2013.

ICLG: Patents 2014, Mexico Chapter, 2013.

ICLG: Pharmaceutical Advertising 2013, Mexico Chapter, 2013.

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He also represents life sciences companies before Mexican Courts handling the following relevant cases:

- Restoration of patents life term granted under provisions of article 12 Transitory (*pipeline patents*).
- Infringement actions of patents covering pharmaceutical products declared final and beyond appeal against generics companies.
- First case in México where the revocation of the marketing authorisation of a pharmaceutical product in violation of a formulation patent listed in the Linkage Gazette was resolved.
- First case in México of a use patent being effectively enforced in México related to public tender.
- The unconstitutionality of article 167 *bis* of the Health Supplies Regulation, as it does not provide the right of the titleholder of a patent to be heard during the prosecution of the marketing authorisation.
- First case in México enforcing the linkage system in order that the local regulatory agency consider a use patent included in the Linkage Gazette for allopathic medicines.

Languages: English, Spanish

Recent publications:

"COFEPRIS ordered to cancel marketing authorisation", *Managing Intellectual Property* [March, 2015].

Getting the Deal Through: Healthcare Enforcement & Litigation 2015 and 2016.

Practical Law: Global Guides 2015/2016 Life Sciences.

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Our *Life Sciences Industry Group*'s mission is clear – we are changing the regulatory landscape for companies doing business in Mexico.

We have a legal-technical team of professionals that focuses on regulatory matters and associated litigation, marketing authorisations, M&A, corporate and licensing structuring, financial and transactional support, privacy, FCPA and anti-bribery compliance, among other services.

We represent many of the world's leading innovators involved in the research, development and manufacture of pharmaceuticals, biotech products, agricultural goods, chemicals and medical devices, as well as food and beverages.

We have developed an unrivalled base of legal knowledge mixed with hands-on experience. We have enabled clients to reduce legal risk in various areas of their business and help them maintain a competitive advantage in a Mexican market that has recently seen much regulatory change and market consolidation. This pace of change is set to continue and we are looking forward to shaping it.

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