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Pharmaceutical Advertising 2023

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Mexico: Trends and Developments

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Trends and Developments

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Pharmaceutical advertising in Mexico can be categorised in terms of legal compliance, general compliance on consumer protection laws, and specific compliance due to the regulatory nature of pharmaceutical products and/or services.

However, before discussing the specific rules which may be applicable to such types of advertising, it is worth noting a fairly new pharmaceutical advertising topic due to a recently enacted law (currently being challenged) regarding paying for advertisements when there is an agency involved, and how the law intends to establish specific requirements and limitations on the manners for buying specific advertising products, such as pharmaceutical advertisements.

The Transparency Law

On 3 June 2021, the "Law for Transparency, Prevention and Combating Improper Practices in Advertising Contracting" (the "Transparency Law") was published in the Official Daily and became effective on 1 September 2021. As mentioned, the purpose of the law is to prevent certain commercial practices by publishers, specifically practices which involve monetary considerations to the agencies (hired by advertisers), for such publishers to gain more business with such agencies.

Although the law is aimed at publishing activities which are carried out in Mexico, it contains an express prohibition which may have extraterritorial effect, as it mentions that any advertisement in Mexico paid for outside Mexico by a foreign company is subject to compliance with the Transparency Law. However, in the authors' opinion, if there is an agreement not subject to Mexican law, or if the company is not a Mexican company and its services are understood to be provided through the internet, the Transparency Law would not be applicable.

A particular point of the Transparency Law is that sanctions due to breaches are imposed following an investigation procedure in accordance with Economic Competition Law procedures, and such investigation is also carried out by the Economic Competition Authority. The Transparency Law would thus be enforced taking into account economic competition procedures and principles, and breaches would only be investigated following a third-party claim.

The Transparency Law has become relevant considering there are no other specific laws which establish other contractual requirements for marketing/advertising activities in Mexico. Because of this, the Transparency Law has been challenged by many players through "amparo" suits. Such challenges have been ruled in favour of the companies, and recently, in January 2023, the Supreme Court ruled on a specific procedure, deeming the Law unconstitutional. Although this consideration of the Transparency Law as being unconstitutional only applies to such amparo challenges, this is a precedent which may be taken into account by other jurisdictional authorities in Mexico. The Telecommunications Institute has also challenged the Transparency Law, stating that it gives the Economic Competition Authority too much power in overseeing mat-

ters normally given to the Telecommunications Institute only.

Because of the aforementioned issues, and all amparo procedures and rulings currently being challenged, in the authors' opinion the Transparency Law will be ruled as unconstitutional by the Supreme Court, and will be requested to be repealed. Meanwhile, and until it is repealed, some of the rules and requirements established by the Transparency Law are worth noting:

- advertising spaces cannot be contracted by agencies on their own – such spaces should be contracted in the name and on behalf of the advertiser;
- a specific type of agreement must be executed, in which it is understood that a specific and specialised power of attorney is granted to the agency for the agency to contract on behalf of the advertiser for such advertising spaces;
- any rebate offered by the publisher to the agency must be replicated in the agreement between the advertiser and the agency;
- neither the agency nor third parties used by the agency to provide services to the advertiser can receive remuneration, commission or considerations by the publisher;
- an agency cannot provide services (simultaneously) to advertisers and to publishers;
- although the agency is the party paying the publisher, the publisher must bill the advertiser directly;
- an agency that buys programmatic digital advertising on behalf of the advertiser should inform the publisher of the identity of the advertiser and other information mentioned in the law after the broadcasting of the advertising;
- an agency must inform the advertiser of any financial relationships between them (or their group) and the publisher; and
- the economic sanctions arising from the Transparency Law may be 2% to 4% of the gross income of the infringer.

Consumer Protection for Pharmaceutical Advertising

It should be noted that there are no specific rules for the pharmaceutical advertising industry; however, the general rules regarding advertising are helpful for understanding how a pharmaceutical advertisement may be analysed or considered compliant by the Consumer Protection Agency (PROFECO) in charge of overseeing compliance with the Consumer Protection Law.

In general terms, pharmaceutical advertising must comply with the following rules:

- the information or advertising related to products or services must be truthful, verifiable, clear and free of texts, dialogues, sounds, images and other descriptions that induce or may induce error or confusion due to being misleading or abusive; and
- misleading or abusive information or advertising is that referring to characteristics or information related to a product or service that may or may not be true, and which induces error or confusion in the consumer due to the inaccurate, false, exaggerated, partial, artificial or biased manner in which it is advertised.

The authority of PROFECO in relation to advertising includes the following:

- requesting a service provider to suspend the advertising that breaches the provisions of

the Consumer Protection Law, wherever it is published;
- requesting correction of the advertising that breaches the provisions of the Consumer Protection Law; and
- imposing economic sanctions, in accordance with the law.

Economic sanctions may range from USD9,500 to USD260,000, and, depending on how severe the breach was, may go as high as 10% of the gross income of the infringer.

Economic sanctions imposed by PROFECO take into consideration the following:

- the damage caused to the consumer or to society in general;
- the intentional nature of the breach;
- whether it is a repeat offence; and
- the economic condition of the provider.

Since the definition of misleading advertising and the elements that qualify for it are established in a broad manner in the Consumer Protection Law, PROFECO has issued certain guidelines to help understand what is covered by unlawful advertising, and identifies specific types of advertising which are not allowed, as follows.

- Misleading advertising by action – texts, dialogues, sounds, images, trade marks and other descriptions that induce or may induce error or confusion.
- Misleading advertising by omission – advertising that is silent about characteristics of the good, product or service which are necessary for the consumer to have the appropriate information make a decision.
- Misleading comparative advertising – comparing goods or services must, for obvious reasons, not be misleading, and must be considered lawful, since it should aim to provide the consumer with additional (and better) information.
- Denigratory advertising – advertising that discredits a good, product or service of others. In this case, advertising will be unlawful or misleading when the information is not truthful, or is considered abusive since it will induce the consumer to change their consumption habits in an unlawful manner.
- Adhesive advertising – advertising that induces or is likely to induce confusion with the goods, products or services of other suppliers. This is a type of misleading advertising to the extent that it takes advantage of the prestige acquired by another supplier, in such a way that the message makes the consumer believe that the advertised good or service corresponds to the type (characteristics) of those advertised by a competitor, taking advantage of the prestige of others.
- Concealed advertising – a type of misleading advertising intended to hide its advertising nature, being hidden under an informative veil by means of which an attempt is made to make the consumer believe that they are being given an informative message of an objective nature, not vitiated by the persuasive and subjective interest that characterises the advertising message. The objective of this type of advertising is clear: to make the consumer/recipient of the concealed advertising give it the same credibility that they would give to an informative message, thus reducing consumer defences against advertising.
- Exaggerated advertising – this may be considered as misleading advertising, and is unlawful since it constitutes subjective information that cannot be verified and is normally used as a technique to exalt goods, products or services. It corresponds to civil fraudulent misrepresentation, and does not contain

objective information. Additionally, "over-promising" advertising which aims to surprise consumers and generate expectations is a classic example of the information provided with "miracle products".

PROFECO will look for the following to determine if a specific type of advertising is in fact unlawful:

- false information, when the information does not correspond to reality and may induce the consumer to make an erroneous decision, which they would not have made otherwise, as well as when the supplier does not deliver the good or perform the service in accordance with the terms and conditions offered or implied in the advertisement;
- inaccurate, imprecise information in relation to the characteristics or qualities of the product, good or service;
- exaggerated information which leads to deception of the consumer, where the consumer does not recognise such exaggeration at first sight and takes the advertising message seriously, and which may influence the consumer's decision to consume;
- partial information provided in an incomplete manner, where such omission relates to fundamental data required for a consumer's proper decision; and
- artificial or tendentious information where the advertising is intended to cautiously disguise the message sent – eg, inserting texts or legends that are not visible to the naked eye.

Rules for Pharmaceutical Advertising

For services and/or products of a pharmaceutical nature, there are two relevant laws establishing specific requirements and limitations: the General Health Law and the Regulations of the General Health Law on Advertising Matters. Their requirements and limitations as regards pharmaceutical advertising are discussed below.

Product advertisements

Cosmetic products cannot be attributed the same effects as medical products. The Ministry of Health must be notified when advertising cosmetic products, and advertising of any type of surgery must comply with all the requirements established in the General Health Law.

Any advertising related to health matters, disease treatments, rehabilitation of disabled people, health professionals and health products and services is subject to the prior authorisation of the Ministry of Health.

The advertising of raw materials for health, surgical materials, hygienic products and alcoholic beverages is also subject to the prior authorisation of the Ministry of Health.

The aforementioned advertising must adhere to the following principles:

- the information contained in the message regarding quality, origin, purity, conservation, nutritional properties and use benefits must be verifiable;
- the message must contain guiding and educational content;
- the elements comprising the message, if applicable, must correspond to the characteristics of the respective health authorisation;
- the message must not lead to behaviours, practices or habits which are harmful to physical or mental health, or imply a risk or threat to the safety, physical integrity or dignity of people, particularly women;
- the message must not undermine or contravene the principles, provisions or regulations established by the Ministry of Health in

prevention, disease treatment or rehabilitation matters; and
- the message must be drafted according to the applicable legal provisions.

Regulatory matters related to pharmaceutical advertising

Advertising must be consistent with the characteristics or specifications of the product or service, and it cannot:

- attribute to the product or service preventative, therapeutic, rehabilitation, nutritious, stimulative or other qualities that do not correspond to its function or use;
- indicate or suggest that the use or consumption of a product or service is a factor in determining a change of behaviour of individuals; or
- indicate or lead to believe, explicitly or implicitly, that the product has ingredients or properties which it lacks.

Advertising which attempts to put at risk the security or physical or mental integrity of people is forbidden.

Disclaimers or sanitary messages appearing in the advertisements of products, services or activities are subject to the following:

- written disclaimers in advertisements transmitted on TV should be shown for one quarter of the total length of the advertisement;
- the disclaimer should appear in a contrasted colour;
- the disclaimer should be located horizontally, with "Helvetic" font and in a size of 40 points per letter, proportional to a 14-inch TV screen;
- audible disclaimers should be pronounced in the same rhythm and tone as the advertisement; and
- for advertisements transmitted over the internet, the disclaimers should comply with the aforementioned obligations and principles.

Regulatory matters related to pharmaceutical products or services

For health services, the following applies:

- health services advertisements should inform on the characteristics and purposes of the services, and the means to access them;
- the advertisements cannot include techniques or treatments which are preventative, curative or rehabilitative, unless with the respective authorisation from the Ministry of Health; and
- health professionals (as doctors) should, when they advertise, include within the advertisement the university where they obtained their degree and their professional ID number.

For food, food supplements and non-alcoholic beverages, the following applies.

- Such advertising must not contravene the provisions on nutritional, hygienic and health education.
- Food, food supplements and non-alcoholic beverages cannot be advertised as stimulants or as though they are able to modify the physical or mental state of individuals, unless with the respective authorisation from the Ministry of Health.
- Advertising of food, food supplements and non-alcoholic beverages may not:
  (a) induce or promote harmful habits to health;
  (b) state that the product fulfils by itself the nutritional requirements of a human being;
  (c) attribute higher nutritional value to industrial food;
  (d) perform comparisons aimed at disparaging the properties of natural foods;

(e) express or suggest, through real or fictional characters, that ingestion of these products provides people with extraordinary abilities or characteristics;
(f) be directly or indirectly associated with the consumption of alcoholic beverages or tobacco; and
(g) declare properties that cannot be verified, or imply that the products are useful in preventing, alleviating, treating or curing a disease, disorder or physiological state.

- The advertising should include disclaimers about the condition of the products and messages promoting an equal alimentation and the promotion of healthy habits.
- Advertising of baby milk formulas should:
  (a) promote breastfeeding, for which they should clearly indicate the benefits thereof;
  (b) expressly indicate that the use of baby formula is recommended only in certain cases; and
  (c) include information on the correct handling of the formulas, their preparation and specific care.
- Advertising of food supplements should include a disclaimer indicating the relevant authorisation of such food supplement.

Health supplies

Regulations provide a series of restrictions and rules related to the following products, which are considered health supplies.

Medicines

- The advertising of medicines directed to the general population may include descriptions of human diseases, diagnosis, treatment, prevention or rehabilitation expressed in the terms of their sanitary registration and in language appropriate to the target public. These messages must always identify the issuer with the brand of the product or its corporate name.
- The advertising should be in a visual form for printed material, and in audible form for radio, with the legend "Refer to your doctor" as well as express the corresponding precaution when the use of the medicine represents any danger in the presence of any coexisting clinical or pathological condition.

Herbal remedies

- Herbal remedies should be limited to advertising a symptomatic effect based on the information expressed on the label, and should refrain from advertising them as curative.
- In addition to the "Refer to your doctor" legend, they should also include the following additional precautionary legend which the Ministry of Health determines, based on the health risk that the product represents: "This product has not been scientifically proven to have preventative or curative properties."

Generic exchangeable drugs

Only pharmaceutical specialties included in the Catalog of Interchangeable Generic Drugs referred to in the Regulation of Health Supplies may use the following legends, acronyms, denominations and adjectives in their advertising:

- the acronym "GE" (Generic Exchangable), its symbol or logo;
- the denomination "interchangeable generic drug", or the expressions "generic" or "interchangeable"; and
- any other expression, word, image or symbol whose purpose is to induce in the consumer the idea that the advertised medicine is a substitute for the original or innovative product.

Medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental supplies, surgical and healing materials and hygiene products

The Ministry of Health authorises the advertising of these types of products in accordance with the characteristics and purposes for which they have been registered, and they shall be subject to the indications or uses approved by the Ministry.

- When granting or reviewing the registration of the product, the Ministry of Health shall specify in the advertising grounds whether it can be directed to the general population or only to health professionals or technicians.
- The advertising of the product should include messages that avoid self-treatment, when required due to their characteristics.
- Hygienic products may not be advertised when they:
  (a) promote practices that are harmful to health due to the inadequate use of such products; and
  (b) attribute preventative, therapeutic or rehabilitative qualities to the treatment of a certain disease, except in those cases where such circumstances have been fully proven.
- In general, all advertisements should:
  (a) be clear, concise and easily understandable for the sector of the public to which it is directed;
  (b) contribute, by means of the use of legends, to hygiene education; and
  (c) express in the precautionary message, if applicable, whether the use or consumption of the product represents a health risk.

It is important to mention that the following advertising always requires a specific advertisement permit issued by the Ministry of Health:

- provision of health services;
- food supplements and biotechnological products;
- medications and herbal remedies; and
- medical equipment, prosthetics, functional aids, diagnostic agents, dental supplies, surgical and healing materials, and hygienic products.

Conclusion

As can be seen from the topics discussed in this article, Mexico has strict regulatory requirements for pharmaceutical advertising. Because of this, it is always suggested that before carrying out any type of advertisement in this sector, the specific product and service is assessed in order to determine the relevant limitations and requirements.

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Bello, Gallardo, Bonequi y García was established in 2001 and has become a significant player in the Mexican legal market, meeting the growing need for specialised legal services. The versatility of its lawyers allows BGBG to provide personalised services in each of its practice areas, including technology, media and telecommunications (TMT). BGBG was created as a boutique law firm for TMT practice, and since its formation has been providing ongoing legal services to all types of companies within the TMT, technology, media, entertainment and communications industries. The firm's TMT practice, which handles all matters related to advertising and regulatory sectors, is one of the biggest standalone practices in Mexican law firms, and its team devotes almost all of its time to this specialised area. It has been recognised by independent national and international publications as a top-tier and leading practice.

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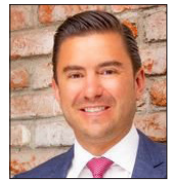

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