Baker McKenzie.

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

CHILE

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Valentina Venturelli

Legislation on Medical Product Advertising

Pharmaceutical advertising is mainly regulated by the Sanitary Code (Decree with Force of Law (D.F.L.) No. 725/67) and Decree No. 3-2010 of the Ministry of Health, which approved the Regulations for the National Control System of Pharmaceutical Products for Medical Use.

Other rules pertaining to this matter are scattered in several other laws and rules that are stated below.

The rationale behind the Chilean legal provisions on advertising of medical products is to prevent healthcare professionals and consumers from receiving misleading information about medical products which could lead to health risks for consumers in the market.

The Regulatory Framework

Pharmaceutical advertising is mainly regulated by the Sanitary Code (Decree with Force of Law (D.F.L.) No. 725/67) and Decree No. 3-2010 of the Ministry of Health (D N° 3/10) dated 25 January 2010, which approved the Regulations for the National Control System of Pharmaceutical Products for Medical Use.

Pharmaceutical advertising is also regulated in the following pieces of legislation:

- Supreme Decree No. 404/83, corresponding to the Regulation on Narcotic Drugs
- Supreme Decree No. 405/83, which corresponds to Regulations on Psychotropic Products
- Consumer Protection Law No. 19.496 (Consumer Law)

- Antitrust Decree Law No. 211 which regulates Free Competition
- Unfair Competition Law No. 20.169
- Ethics Code of the Medical Association of Chile
- Public Procurement Law No. 19886

Definition of Advertising

Article 199 of D N° 3/2010 defines advertising as "... set of procedures or activities used to raise awareness, highlight, distinguish directly or indirectly to the public, through any means or diffusion procedures, the features, terms of distribution, sale and use of the products referred by this regulation."

Advertising to consumers and other activities intended to raise awareness of a pharmaceutical product will only be allowed in relation to over-the-counter (OTC) pharmaceutical products and in accordance with the terms established in the corresponding sanitary registration (Article 100 of the Sanitary Code).

Even though promotions are not defined as such, the Sanitary Code establishes in article 100 that promotion to professionals, within the therapeutic utility indications of the corresponding sanitary registration, cannot be made through mass media directed to the general public. Such promotion may include the provision of medical samples to the said professionals in accordance with the terms of each sanitary registration, to be provided free of charge to those persons who use their services.

The differentiation between advertising and promotion to professionals is relevant because, as mentioned above, according to the Sanitary Code, advertising can only be carried out in relation to OTC pharmaceutical products. Advertising regarding prescribed pharmaceutical products is strictly prohibited, except for promotions

targeted at professionals who are authorized to prescribe pharmaceuticals.

Permitted and Prohibited Practices

The Institute of Public Health (ISP) is the public institution responsible for granting sanitary registrations for pharmaceutical products. Being a titleholder of a sanitary registration (marketing approval registration) is a legal requirement to import, manufacture and distribute these products in Chile.

In this sense, the advertising and/or promotion of pharmaceutical products does not require prior approval by the ISP but is nonetheless subject to various conditions.

For example, products sold under medical prescription may be announced to qualified professionals authorized to prescribe and dispense the same, through advertisement intended to publicize their entry into or presence in the market. This advertisement should contain only the official name adopted by the ISP in the sanitary registration, together with identification on the main label, the name of the manufacturing laboratory or importer and the badge of the establishment, if any, or fully replicate approved labels or packages in their sanitary registration or in a later resolution issued by ISP.

The promotion of pharmaceutical products which require medical prescription for sale should be directed solely to professionals legally authorized to prescribe pharmaceutical products, and pharmaceutical chemists who are responsible for dispensing medications.

The scientific information that is delivered to the professional to promote prescription products must be true, accurate, complete and verifiable, and must be in line with the therapeutic use and properties approved when the sanitary registration was issued. It must also state the formula, the indications, interactions, contraindications, precautions and warnings, as well as collateral and side effects, dose and risk of toxicity and its treatment. All information must be supported by recognized scientific literature, submitted when the

sanitary registration of the product is granted as well as in its subsequent amendments. Information on side and collateral effects must be backed up by studies that indicate their occurrence and that are available for professionals upon request.

Information regarding the demonstrated bioavailability of products sold under a medical prescription in appropriate cases must be stated in information brochures for professionals. These brochures must also state whether the product is a therapeutic equivalent with respect to other previously registered pharmaceutical products.

When it comes to the advertising and/or promotion of OTC pharmaceutical products, it is mandatory to only use a complete and accurate reproduction of tags and labels, patient information brochures, text, and attachments that have been approved by the ISP by the time in which the sanitary registration was granted or when it is expressly requested to the ISP in connection to a product that is already registered.

Furthermore, the advertising or promotion of pharmaceutical products can only refer to the therapeutic indication(s) approved by the ISP when granting a sanitary registration. This advertising or promotion should also include use directions or indications, precautions, contraindications, interactions, side effects or adverse reactions and other warnings as appropriate. If the pharmaceutical product has other therapeutic indication(s) but the same have not been previously approved by the ISP, advertising or promotion of such indications would be considered illegal.

Advertising and promotion of pharmaceutical products cannot contain titles, figures, references or interpretations that are not verifiable or, in any way, are not in accordance with the nature of the product or its approved properties.

It is strictly prohibited to donate, deliver or distribute freely pharmaceutical products for advertising and promotional purposes, except for medical samples that correspond to a unit of a registered

medicinal product that is exclusively distributed free of charge to professionals who are legally

entitled to prescribe them. These products must also have labeling identical to the registered product, which may include information for the professional.

Advertising and promotion of simple homeopathic preparations listed in the Chilean Pharmacopoeia, in Wilmar Schwabe Pharmacopoeia, or others recognized by the Ministry of Health of Chile for pharmaceutical products, and that are presented by their generic name, and also others that respond to trading names that are simple or form mixtures, herbal medicines, which are labeled and finished pharmaceutical products with active substances that are exclusively herbal drugs or preparations of vegetables, and products for parenteral administration, whatever their composition, properties or effects, cannot include statements or indicate certainty of results that are not scientifically verifiable.

In order to control advertising or promotion, the ISP can request from manufacturers and importers any information, clinical studies, scientific literature and any other item used for such purposes, and may also request this information or data from any corporation (company) or person that holds the same.

The amendments to the promotion authorized by the sanitary registration may be requested by the titleholder, and shall be approved or rejected by resolution issued by the ISP within 10 working days of receipt. The ISP may also, based on a grounded resolution, modify the authorized promotion by providing notice to the holder of the sanitary registration of at least five working days, so that they can take appropriate action.

All kinds of economic incentives are forbidden if they intend to encourage the use of a certain product by the professionals entitled to prescribe and dispense pharmaceutical products or to the sales

assistant of retail establishments or to any other person involved in the sale or administration of pharmaceutical products.

Article 100 of the Sanitary Code establishes that an incentive is understood as any payment, gift, service or economic benefit provided to the aforementioned persons by pharmaceutical laboratories, drugstores (warehouses), importers, distributors, pharmaceutical establishments in general or by their representatives.

Notwithstanding, the donation of pharmaceutical products to not-for-profit care establishments will be allowed, if they are duly included in the Pharmaceutical Products National Form.

Consequences of Breach

The ISP has the authority to suspend or prohibit advertising and promotion of pharmaceutical products based on a grounded administrative decision or resolution.

The sanitary registration of a pharmaceutical product may be canceled if significant changes are confirmed in terms announced in the labeling, advertising or promotion to the professional, that have not been ISP-approved in the sanitary registration.

The sanitary registration of a pharmaceutical product may also be canceled if the proven breach of the provisions relating to advertising and promotion actually compromises public health.

Breaches of the legal standards set by the Sanitary Code and D 3/10 are sanctioned by the ISP, prior to the fulfillment of administrative proceedings, in accordance with the provisions of Section X of the Sanitary Code and other provisions in the legislation.

All decisions issued by the ISP on matters referred to in the aforementioned dispositions can be challenged before the Ministry of Health by filing a complaint appeal within five days from the date on which the respective resolutions were served or notified.

In accordance with Sanitary Code, the breach of any of the rules in D 3/10, except for those provisions that have a special sanction, are punishable with a fine that ranges from one tenth of a monthly tax unit (approximately USD6.5) to 1,000 tax units (approximately USD65,670). Repeat offenses may be subject to a maximum penalty of up to twice the original fine.

The aforementioned breaches may all be punished with: the closure of facilities, buildings, houses, buildings or places of work where the offense was committed; cancellation of operating licenses or permits issued; or cessation of work and confiscation, destruction and distortion of products, where appropriate.

Competitors can enforce their rights against breaches of rules on advertising of pharmaceutical products established in the Sanitary Code and D 3/10, either by filing an action before the Antitrust Court or a Civil Court if the offense can be considered an act of unfair competition, for which you can claim compensation for damages and the cessation of acts of unfair competition, among other actions. Obviously, those affected can also file actions before the ISP in order to seek the respective administrative responsibilities.

Professional Codes of Conduct[1]

The Code of Ethics of the Medical Association of Chile requires the physician to abide by the following principles:

- Sustain independent professional relationship with companies that manufacture or distribute goods of pharmaceutical or clinical use. The decisions that affect their patients should always ensure their best interest, and should never pursue personal benefit.

[1] The Code of Ethics of the Medical Association of Chile is only mandatory for those physicians who are members of the Association of professionals. It is not mandatory in Chile for an MD to become a member of the Association to practice medicine.

- Only accept modest gifts or invitations to meetings or conferences provided by companies of pharmaceutical or clinical products, when they do not limit or restrict their professional independence.

- Only accept full or partial funding of vocational training programs from medical product companies or private health institutions when these programs are taught by recognized academic institutions, and the funding is disclosed to all concerned parties. In any case, the acceptance must never compromise professional freedom of the physician to ensure the interests of the patient.

According to the Code of Ethics of the Medical Association, the acceptance of funding from companies of pharmaceutical clinical products, in whole or in part, for activities outside the medical profession, such as travel for tourism purposes, or similar activities, is a breach of professional ethics.

Likewise, the professional who accepts donations that are not in line with those which, according to custom, are acceptable, considering the amount and nature of the donation, also commits the same offense.

Physicians must inform the Medical Association of Chile of any activities of companies of pharmaceutical or clinical products which aim to restrict their professional independence or condition their medical action to favor the interests of these companies.

Penalties for breach of the rules of professional conduct set forth in the Code of Ethics of the Medical Association of Chile are as follows:

- Warning
- Censorship
- Fine
- Suspension of its membership

- Ineligibility to hold office positions within the organization
- Expulsion from the Medical Association of Chile

Criminal and Civil Liability

The Criminal Code of Chile establishes misdemeanors and criminal offenses against public health. Article 313 d reads as follows:

> "*The person who manufactures or knowingly in any capacity sells medicinal substances that are deteriorated or adulterated in their kind, quantity, quality or proportions, in order to be hazardous to health due to their harmfulness or the erosion of their healing properties, shall be punished by imprisonment in its medium degree up to a maximum fine of six to 50 monthly tax units.*
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> *If the manufacture or sale is clandestine, this shall be considered as an aggravating circumstance.*"

This is an offense that is punishable with a penalty that ranges from a fine of 50 UTM (USD3,284 approximately) up to a penalty of incarceration (ranging from 541 days to three years and one day to 819-1,095 days).

With regard to civil liability, in the case of a pharmaceutical product that causes damage to health, the affected individuals have the right to sue the manufacturer or distributor to seek compensation, based on tort regulations set in the Chilean Civil Code.

Additionally, Consumer Laws also enable consumers to bring legal actions against the manufacturer or distributor of a pharmaceutical product. Such an action can be filed both individually or collectively, in order to seek compensation and the imposition of fines.

Responsibility of Public Officers in Public Procurement Processes[2]

Public Procurement Law No. 19886 does not establish any offense when it comes to procurement fraud, so in order to determine criminal responsibility of a public officer, it is necessary to resort to general criminal law provisions.

Bribery

Bribery is defined as the active or passive conduct of a public officer that seeks unlawful retribution for the fulfillment of their position or post. It also entails an active or passive conduct of a person that seeks to give a public officer unlawful retribution in the fulfillment of their position or post. Provisions 248 to 251 of the Criminal Code state and describe the different kinds of bribery that are considered an offense.

Bribery by the fulfillment of a duty (provision 248 of the Criminal Code): Any civil servant who solicits or accepts gratuities in excess of those afforded to his position, or a benefit for himself or any third party for performing or having performed activities within the scope of his responsibilities, shall be punished with suspension as applicable and a fine ranging from 50 percent to 100 percent of the solicited or accepted gratuities or bribes.

Bribery by the infringement of a duty (provision 248 bis of the Criminal Code): Any civil servant who solicits or accepts any bribe for himself or any third party to not perform or fail to perform any activity within the scope of his responsibility or to engage or for having engaged in any activity that constitutes a breach of his duties, shall be punished with lesser imprisonment in its minimum to medium degrees and exceptionally or completely disbarred from any temporary civil service positions or duties, and fined in a sum amounting to 100 percent to 200 percent of the solicited or accepted bribes.

[2] This part is based on Transparency and Integrity Manual of the State Administration, published by the Government of Chile. Available from: www.serviciocivil.gob.cl/sites/.../141009_Manual_transparencia.pdf.

Bribery by committing a public administrative felony (provision 249 of the Criminal Code): Any civil servant who solicits or accepts bribes for himself or a third party for committing any of the felonies or misdemeanors indicated herein or in paragraph 4 of Title III shall be exceptionally disbarred from permanent civil service positions and completely disbarred from temporary civil service positions, or else completely disbarred from permanent civil service positions, and fined a sum amounting to 100 percent to 300 percent of the solicited or accepted benefit.

The foregoing is notwithstanding the penalty applicable to the crime committed by the civil servant, which shall not be lower, in any case, than the lesser imprisonment in medium degree.

Bribery (provision 250 of the Criminal Code): Whoever offers or consents to give any civil servant a bribe, for his benefit or the benefit of a third party, to engage in actions or fail to act indicated in Articles 248, 248-bis and 249, or for having incurred or committed the same, shall be penalized with the same monetary fine and disbarment as provided therein.

With regard to bribes consented to or offered in connection with the actions or failures to act indicated in Article 248-bis, the briber shall be further sanctioned with lesser imprisonment in the medium degree in case of the benefit offered, or lesser imprisonment in the minimum degree in case of the benefit consented to.

In the case of bribes consented to or offered in connection with felonies or misdemeanors indicated in Article 249, the briber shall also be sanctioned with lesser imprisonment in the medium degree in case of the benefit offered, or lesser imprisonment in its minimum to medium degree in case of the benefit consented to. In these cases, the briber may not also be sanctioned for the responsibility he may have had in the felony or misdemeanor committed by the civil servant.

Recommendations

The only materials that can be used in advertising or promotion are brochures for promotion to professionals and information brochures for patients, as well as advertising texts previously approved by the ISP in the corresponding sanitary registration.

Promotional materials for pharmaceutical products share the same general advertising requirements applicable to all products in order to prevent consumers from receiving information that is false, misleading or error- inducing. However, the provisions governing the advertising of these products provide additional requirements and thus, the ISP monitors very closely any promotional materials used in connection to these kind of products.

In this respect, before investing in any promotional material or advertising for pharmaceutical products, it is highly advisable to check thoroughly that the material only uses the scientific denominations that correspond to the registered product, along with the name of the producer, or alternatively, an exact reproduction of the labels approved by the sanitary registration granted by the ISP, and makes reference only to therapeutic indications in the same.

Failure to follow these recommendations could result in the potential cancellation or suspension of sanitary registrations, as well as fines and potential liability to consumers.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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