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Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

VENEZUELA

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Venezuela

Dianne Phoebus

Introduction

Health-related products and services are highly regulated in Venezuela. The People's Ministry of Health and the corresponding divisions are the motors behind the regulation. In addition, health-related products and services are also subject to increased regulation and restrictions through the equivalent of the Consumer Protection Agency.

Regulatory Framework

The advertising and promotion of pharmaceutical products is governed by the following laws and regulations:

- Rules for the Promotion and Advertising of Medicines, published in Official Gazette No. 37.966, dated 23 June 2004 (Promotion Rules)
- Law on Medicines, published in Official Gazette No. 37.006, dated 3 August 2000 (Law)
- Rules of the Pharmaceutical Products Review Board of the Rafael Rangel National Institute of Hygiene (Pharmaceutical Review Board) relating to Advertising and Promotion of Pharmaceutical Products (Review Board Rules)
- The Organic Law on Fair Prices published in Special Official Gazette No. 6.202, dated 8 November 2015 (Fair Price Law), printed again in the Official Gazette No. 40.787, dated 12 November because of a substantive error.
- Administrative Order No. 077/2014 which establishes the procedure for the authorization of the promotions requested before the National Superintendence for the Defense of the

Socio Economic Rights published in Official Gazette No. 40.571, dated 30 December 2014 (Administrative Order No. 077).

- Law Governing Social Responsibility in Radio, Television and Electronic Media published in Official Gazette No. 39.610, dated 7 February 2011
- Partial Regulations on Television Transmissions published in Official Gazette No. 35.096, dated 20 November 1992
- Technical Rules on Definitions, Time and Conditions of Advertising, Propaganda and Promotion in the Services of Radio, Television and Subscription Transmission published in Official Gazette No. 38.352, dated 6 January 2006
- Code of Ethics of the National Association of Announcers and the Venezuelan Federation of Advertising Agencies, dated 26 July 2007 (ANDA Code of Ethics)

There are no express legal provisions regarding advertising and promotion of medical devices. Resolution No. DM-0010-99 issued by the People's Ministry of Health (Ministry of Health) on 3 December 1999, regulates the manufacture, importation, marketing and distribution of medical equipment in Venezuela. It does not, however, include provisions relating to advertising of medical equipment. As a matter of practice, health authorities apply the provisions regarding the promotion and advertising of pharmaceutical products to medical devices. Because of this analogous application by the authorities, this chapter specifies the rules and regulations applicable to pharmaceutical products.

Permitted and Prohibited Practices

All advertising and promotion of pharmaceutical products must be authorized by the Ministry of Health, taking into consideration the opinion of the Pharmaceutical Review Board. Only pharmaceutical products which have been approved and registered in Venezuela can

be promoted and advertised. Furthermore, all promotion and advertising dealing with pharmaceutical products must comply with the specific, applicable provisions dealing with the advertising and promotion of these products. This applies to all sections below dealing with advertising and promotion, in addition to the specific information provided under each heading.

In addition, the Fair Price Law establishes that the National Superintendence for the Defense of the Socio Economic Rights (Sundde) has competence to fix the general conditions of the offers, promotions and advertising of goods and services. In this sense, the Sundde issued Administrative Order No. 077 which establishes the procedure for the authorization of the promotion of goods and services. Promotions without Sundde approval will be sanctioned with the closure of the business or a fine (Article 46). It is not clear whether or not these provisions apply to pharmaceutical products. However, taking into account the severe sanctions for violations, requesting authorization should be seriously considered.

Permitted Practices

The advertising and promotion of pharmaceutical products should be informative, educational, true, up-to-date, can be proven and should be in Spanish. Under no circumstances can spoken, written or graphic publicity and promotion contradict the officially approved use conditions and restrictions.

The use conditions are:

- instructions for the pharmaceutical product
- dosage and age group which is the target of the product
- means of administration and use

The use restrictions are:

- warnings and precautions

- contraindications
- adverse reactions and interactions
- those that deal with special types of patients (such as those suffering from kidney, liver or heart problems)

Advertising and promotion of pharmaceutical products should not promote unreasonable self-medication or abuse.

Such advertising and promotion can include price comparisons as long as such comparisons are reliable.

Pharmaceutical companies can promote their company's name through the media, identifying themselves as sponsors of a message or as companies which provide health information aimed at the rational use of medicine or healthcare. Only non-prescription drugs can be mentioned in such promotion.

Non-prescription drugs can be advertised and promoted through all types of media once the advertising and promotion have been approved by the Ministry of Health and the approved texts, conditions and use restrictions have been complied with.

Prescription drugs can only be advertised to medical professionals and not to the general public. The only exception to this prohibition are notices published in newspapers which advise the general public that a certain medicine is available.

Scientific and technological information included in advertising and promotion must be supported by bibliographies, which must be approved by the company's scientific director or consultant as well as the sponsoring pharmacist. Only generic names can be used in the comparison of pharmaceutical products; product names cannot be used.

A pharmaceutical company's sponsoring of health professionals for scientific educational events, either national or international, cannot be conditioned on the promotion of any pharmaceutical product.

Free (or underpriced) promotional and advertising items are permitted only when they are related to the health professional's work and they benefit the patient.

Prohibited Practices

The following are prohibited in Venezuela:

- The promotion and/or advertising of unregistered pharmaceutical products.
- The use of promotional information and material in the text of the labels, packages or patient information leaflets of medicines; labels, packages or patient information leaflets must strictly abide by the text approved by the Ministry of Health.
- The promotion and advertising of medicines by offering or granting economic or material benefits to the health professional or any other person or company responsible for prescribing and supplying medicines.
- The distribution of free samples of prescription or non-prescription medicines to the general public as a means of promotion, with the exception of free distribution by official health entities or institutions during health campaigns.

In addition, the following are prohibited in the promotion and advertising of pharmaceutical products:

- unfair competition
- preaching of benefits based on what a product is not or does not contain

- use of qualifiers such as “harmless” regarding the use of the medicine
- use of quality claims in connection with the medicine’s characteristics and properties

Promotional Claims

Claims made in advertising must be supported. If the claims are false, deceiving or subliminal, the Fair Price Law sanctions the responsible company for false or misleading advertising (Article 47).

Special care must be taken in connection with advertising targeting children, the elderly and the gravely ill, as well as other persons who are not capable of fully understanding the information being presented.

Use of Scientific Publications and/or Expert Opinion

In Venezuela, there are no provisions regarding references to scientific publications or expert opinions in connection with the promotion of pharmaceutical products. Venezuelan law does not prohibit the use of expert terminology when promoting pharmaceutical products to consumers/patients. However, the Fair Price Law requires that the information regarding goods sold to consumers be truthful, precise and understandable.

Comparative Advertising

Pharmaceutical companies can use comparative advertising as long as such advertising does not include false declarations or disadvantages or risks of competitors’ products since this would be deemed unfair competition, which is prohibited in Article 17.1 of the Antimonopoly Law, published in Official Gazette No. 40.549, dated 26 November 2014 (“**Antimonopoly Law**”). Furthermore, this type of advertising could be considered a violation of the Rules for the Promotion and Advertising of Medicines. ANDA’s Code of Ethics also provides certain general guidelines for comparative advertising.

"Before and After" Photographs

There are no specific legal provisions regarding the use of "before and after" photographs in advertising. However, any such advertising must consider Article 4 of the Administrative Order No. 077 which indicates as false and misleading any type of information or communication which uses texts, dialogs, sounds, images or descriptions which, directly, indirectly or by omission, could mislead, confuse or induce errors. The Fair Price Law provides sanctions for false or misleading advertising.

Advertising via Electronic Means

The derogated Law for the Defense of the People's Access to Goods and Services specifically regulated advertising through electronic media. Actually, the Fair Price Law is applicable to the economic activities via electronic means (or media), but there is no specific regulation regarding advertising through electronic media. However, the Fair Price Law establishes severe sanctions for those who conduct activities in violation of the regulations via electronic means in which this law is referred to (e.g., resale of goods priced higher than regulated). We emphasize that all advertising and promotion of medical products must also comply with the legal provisions dealing specifically with this subject.

Use of Testimonials

Companies that sell pharmaceutical products can use personal testimonials as long as the information is true.

Contests, Raffles, etc.

There are no provisions that prohibit pharmaceutical companies from offering contests, raffles or other mechanisms in connection with the offer, promotion or sale of such products, nor are there express prohibitions regarding the participation of health professionals in this type of activity.

Based on the above, companies could use contests, drawings, gifts, vouchers, prizes or similar methods associated with the offer, promotion or sale of products as long as the activities comply with the provisions of the Fair Price Law, Administrative Order No. 077 and with the regulations issued by the Ministry of Commerce and/or Sundde on these activities.

Promotional Activities for Health Professionals and Public Employees

- Gifts – gifts are not permitted except those of nominal value which are normally given during traditional celebrations (e.g., Christmas).

- Gimmicks – free (or underpriced) promotional and advertising items are permitted only when they are related to the health professional's work and they benefit the patient.

- Hospitality – a meal or reception of reasonable value provided as a courtesy and without corrupt connotations would most likely be considered legal by a judge. Meals and receptions offered by pharmaceutical companies (related to seminars, for example) are permitted as long as there is no connection between the meal and reception on the one hand, and the duties of a public employee or the obligations of the host on the other.

- Sponsorship of training, investigations, employment or events – there are no specific legal provisions regarding these activities. However, the Rules for the Promotion and Advertising of Medicines indicate: hospitality provided by a pharmaceutical manufacturer or supplier in a scientific educational event must be moderate; and a pharmaceutical company's support of health professionals in scientific educational events, either national or international, cannot be conditioned on the promotion of any pharmaceutical product.

- Product discounts – as indicated above, free (or underpriced) promotional and advertising items are permitted only when they are related to the health professional's work and they benefit the patient. By the same token, pursuant to Venezuelan legislation, a public employee cannot accept gifts or any other benefit based on the promise to take or abstain from taking a certain action.

Consequences of Breach

The Law on Medicines and other legal instruments contain sanctions for failure to comply with the legal provisions on the promotion and advertising of pharmaceutical products, without prejudice to the civil and criminal sanctions provided in other laws. Furthermore, the sanctions in the Fair Price Law could also be applied to the extent that the promotion and advertising of pharmaceutical products violate this law.

Professional Codes of Conduct Law on the Practice of Medicine (Official Gazette No. 39.823, dated 19 December 2011)

The practice of medicine is providing preventive-curative medical attention to the population by medical professionals through the promotion of health, the prevention of illness, the reduction of risk factors, preventive diagnosis, early treatment and restoration of health, among other activities. Pursuant to the Law on the Practice of Medicine, a health professional violates this code when, while providing professional services, he/she covers up for or sponsors individuals or companies which illegally practice medicine.

Deontological Code

Pursuant to this code, the respect for the life and integrity of the human being as well as the promotion and preservation of health as elements of social well-being should always be a priority to medical doctors. It is, therefore, considered contrary to medical ethics for a doctor practicing the profession to act as a commission agent on

behalf of companies that manufacture or sell pharmaceutical or biological products.

Public Employees Code of Ethics (Official Gazette No. 36.268, dated 23 August 1997)

If a health professional carries out public functions and qualifies as a public employee pursuant to Venezuelan legislation, this professional would be subject to certain limitations arising out of the legal provisions which apply to public employees. Pursuant to the Public Employees Code of Ethics, such employees must refuse under any circumstances and never ask for themselves or for others, payments, benefits or privileges arising out of their responsibilities.

Law Against Corruption (Official Gazette No. 6.155, dated 19 November 2014)

Public employees who, through their work, receive for themselves or for others, payouts or other benefits that are not to them, or accept a promise to that effect, shall be punished with imprisonment and a fine.

Law on the Statutes of the Public Employee (Official Gazette No. 37.522, dated 6 September 2002)

Soliciting or receiving money or any other benefit due to their condition as a public employee is cause for dismissal.

Code of Conduct for the Public Servant (Official Gazette No. 36.496 dated, 15 July 1998)

The following are guiding principles of duty and conduct of public servants regarding ethical values which must govern public service: honesty, equality, decorum, loyalty, vocation for service, discipline, effectiveness, responsibility, punctuality, transparency and neatness.

Specifically regarding honesty, public servants should, in the course of their duties, refuse gifts, invitations, favors, handouts, payment for trips, use of transportation or any type of praise, or material or

immaterial benefits offered by groups or persons interested in obtaining any type of favorable decisions.

Criminal and Civil Responsibility

False or Misleading Advertising under the Fair Price Law

If the company uses false or misleading advertising, it will be sanctioned with a fine of between 500 and 30,000 tax units. The value of a tax unit as of August 2018 is less than USD 1 (calculated at the official exchange rate of approximately USD 1/VES 60) (Article 47). If the company is a special contributor in accordance with the Tax Law, the sanction will be between 12% and 20% of the annual net income.

Lack of Authorization of Promotions under the Fair Pricing Law

If the company uses a promotion without Sundee's authorization, it could be sanctioned with the closure of the business for up to 48 hours and can be fined between 500 and 10,000 tax units (Article 46).

Additionally, the Fair Price Law establishes severe sanctions for those who undertake via electronic means activities considered violations of the Law (e.g., resale of goods higher than the regulated prices).

Failure to Register a Product under the Organic Health Law

The marketing of pharmaceutical products without the corresponding registration shall be sanctioned with a fine, confiscation or destruction of the products, and/or permanent or temporary closure of the establishment, depending on the circumstances (Articles 65, 66 and 67).

Unfair Competition under the Antimonopoly Law

Companies who commit unfair competition are subject to a fine of between 10% and 20% of their annual gross income. In case of recidivism, the fine will be 40% of their sales (Article 49).

Contracts with Healthcare Professionals and Medical Institutions

Contracts between pharmaceutical companies and health professionals are permitted depending on the nature of the contract and are subject to certain limitations:

- Pursuant to Article 19 of the Law on the Practice of Medicine, no person authorized to practice medicine can sell medicines or other products of therapeutic use, or suggest to patients that they acquire products from certain pharmacies or establishments.
- It is considered professionally immoral for an active medical professional to work as a commissioned agent on behalf of companies that manufacture or sell pharmaceutical or biological products.
- Under no circumstance can a health professional accept limits imposed by their employer on his or her professional independence; health professionals should give priority to providing physical and spiritual health to the patients that they examine and treat.
- A contract between a health professional and a public or private entity is considered a violation of the law and ethical principles, if such a contract means that the health professional would be working in two different entities during the same working hours (for example, a health professional that is hired to work at a public hospital and a private clinic during the same hours).
- Health professionals should notify the Ministry of Health and the Medical Board when they resign and accept another position in the medical or health profession.

As mentioned above, if the health professional exercises public functions and qualifies as a public employee pursuant to Venezuelan law, the professional would be subject to certain limitations arising

out of the applicable legislation. Under these circumstances, a contract could not be used by a pharmaceutical company to obtain benefits that arise out of the health professional's position as a public employee.

Recommendations

As evidenced, health-related products and services are heavily regulated in Venezuela, and the promotion and advertising of pharmaceuticals and medical devices does not escape from this regulation. Furthermore, the trend is moving toward increased rather than decreased regulation in this area, and in this regard the legal panorama changes rapidly. Based on this, recommendations regarding the promotion of pharmaceutical products and medical devices include the following:

- Ensure that you are aware of the latest regulatory development.
- Ensure that any products to be promoted are registered with the Ministry of Health and that the registrations are current.
- Ensure that all dealings with government officials and employees (including doctors who work part-time in public institutions), are transparent and well-documented.
- Provide training to the entire chain of employees and representatives who could be involved in the promotion of the products.

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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