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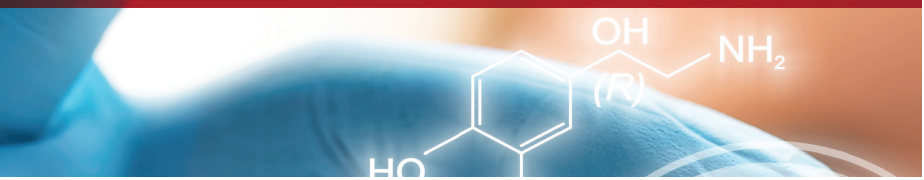
Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



COLOMBIA

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Promoting Medical Products

Introduction

In Colombia, the promotion of medical products must be done in conformity with national statutes, national decrees and resolutions of government agencies that directly regulate the parameters within which such promotion may be performed. In addition, legal norms that address criminal conduct, consumer protection, unfair competition, contests/games of chance and physician conduct also affect how medical products may be legally promoted. Finally, non-binding ethical rules in Colombia should also be considered.

Regulatory Framework for the Promotion of Medical Products

Laws

The promotion of medical devices is governed essentially by Decree 4725 of 2005, and the promotion of drugs by Decree 677 of 1995. In addition, the promotion of over-the-counter (OTC) drugs is governed by Resolution 4320 of 2005 of the Ministry of Social Protection (now named the Ministry of Health and Social Protection). The Ministry of Health and Social Protection and the National Institute of Surveillance of Drugs and Food (INVIMA) regulate the promotion of both types of products.

Rules, Regulations and Codes

Law 1480 of 2011 regulates the promotion of medical products in matters related to consumer protection, and Law 256 of 1996 regulates the promotion of these products in matters related to unfair competition. The Superintendence of Industry and Commerce oversees such matters.

In addition, the Physicians Code of Ethics, Law 23 of 1981, contains provisions relevant to the promotion of such products.

According to this article, any donation, present, benefit or incentive that is offered or granted to an HCP and an HCW, is forbidden and could trigger a violation of anti-bribery and criminal regulation in Colombia.

Also, the Association of Pharmaceutical Laboratories of R&D (AFIDRO) issued in 2015 its code of ethics for the industry, which provides a set of guidelines covering a variety of topics, including some restrictions to certain promotional activities, where current regulations are slightly vague.

Finally, the wrongful promotion of medical products potentially involves certain criminal laws,[1] including types of bribery and extortion, as well as anti-corruption laws.[2]

Marketing Authorization

In order for a medical device or drug to be put on the market in Colombia, a product registration must be obtained. In the case of imported products, their product registration is verified in order to be approved for importation and nationalization.

Market authorization is granted by INVIMA, and medical products are prohibited from being sold without such authorization.

Permitted and Prohibited Practices

Advertising Medical Products

With regard to both medical devices and drugs, consumers must be provided with information regarding the product's safe use.

The promotion and advertising of drugs and medical devices must conform with the information authorized in the product registration

[1] Law 599 of 2000.
[2] Decree 126 of 2010 (addressing corruption in the General System of Social Security for Health); Law 970 of 2005 (approving the United Nations Convention against Corruption); Law 190 of 1995 (addressing bureaucratic corruption).

and conform to current applicable technical norms. The information must be truthful and there must be scientific support. Moreover, the benefits of use may not be exaggerated.

For prescription drugs, information and publicity may only be addressed to physicians or dentists and should specify its instructions, effects, therapeutic uses, contraindications, side effects, risks of administration, risk of dependency, and other precautions and warnings, without omitting any items that are contained in scientific literature or were known by the manufacturers. Likewise, the bibliography in which the information is based should be cited and the principal active ingredient should be identified by its generic name (and for essential drugs, the name and trademark of the drug should also be identified).

According to Colombian copyright law, it is possible to refer to a scientific publication without authorization from the author if it is just a short paragraph and not a significant part or the entirety of the scientific work. Moreover, when citing a scientific publication, it is important to indicate the name of the author and the title of the publication. If the promotion affects the integrity of the publication or the professional expert cited, the author could initiate legal claims based on the rights violated by the use of the work in the promotion. Because of this, it is recommended that the authorization of the author of the scientific publication or the professional expert cited be requested.

Special requirements applicable to OTC drugs are found in Resolution 4320 of 2005.

The supply of scientific data and literature by a medical products device company is considered advertising material. Decree 677 of 1995 and Decree 4725 of 2005 expressly apply their advertising requirements to both scientific information as well as promotional and advertising information. Moreover, Law 1480 of 2011 regarding consumer protection defines advertising as communication of any form and content whose objective is to influence consumer decisions.

Approval

Promotional materials for OTC drugs must be submitted to INVIMA for prior approval. Pre-approval is not required for promotional materials for prescription drugs or for medical devices. However, even where pre-approval is not required, it is possible to present INVIMA with the material in question in advance in order to obtain an opinion of whether it would violate any applicable rules.

Advertising to End Consumers/Patients

OTC drugs and medical devices of class I can be advertised in mass media,[3] according to the specifications of the product registration. Mass media is understood to include the end consumer/patients because mass media is directed to the general public.

OTC drugs may be promoted to end consumers, provided that INVIMA has granted prior authorization of the promotional material.

Prescription drugs and medical devices of classes IIa, IIb and III, may only be advertised or promoted in scientific or technical publications. For pharmaceuticals, such advertising must be exclusively addressed to physicians (or dentists, if applicable), whereas for medical devices, advertising can be extended to other healthcare professionals.

Direct Sales to End Consumers/Patients

Although there is no legal provision that expressly states that any medical device cannot be sold directly to end consumers/patients, Colombian legal norms establish that if done, their use must not endanger the health of the consumer.

A medical device may not be promoted in a manner that would endanger the clinical status, health, or safety of patients or of those

[3] Decree 4725 of 2005, Article 58 (medical devices); Decree 677 of 1995, Article 79 (drugs); Resolution 4320 of 2004 (OTC drugs).

who are in contact with them when the medical device is used in adequate conditions and in accordance with its intended purpose.[4]

OTC drugs may be promoted to end consumers.

Advertising Requirements

Medical product companies are permitted to use expert terminology in advertising to patients if such use is in conformity with the content of the product registration and as long as the information is true.

Generally, according to Colombian law regarding unfair competition,[5] comparative advertising is prohibited in any of the following circumstances:

- Incorrect or false statements or assertions are made.
- The truth is omitted.
- Reference is made to extremes that are neither analogous nor verifiable.

Furthermore, Colombian legal norms that specifically apply to drugs and medical devices prohibit publicity that attributes, defames, causes harm or makes a pejorative comparison with other trademarks, products or services of other businesses or organizations.[6]

With this in mind, medical product companies may generally use comparative advertising if they meet the above-stated conditions. Otherwise, the company could be subject to an unfair competition action or a sanctionatory proceeding before INVIMA.

Likewise, use of "before and after" images is not expressly prohibited. The patient and physician who took the images must authorize their

[4] Decree 4725 of 2005, Article 1.
[5] Law 256 of 1996.
[6] Decree 4725 of 2005, Article 58 (medical devices); Decree 677 of 1995, Article 79 (drugs).

use. Any use of such images must comply with the more general advertising rules affecting medical products, which vary based on the product type and category.

There is also no legal norm in Colombia that addresses whether medical product companies are permitted to advertise the price of medical devices or drugs. Advertisements may not be deceitful, misleading or cause confusion, nor may they discredit the competitor, violate any Colombian Unfair Competition Law,[7] or violate consumer protection laws.[8] The publicity must also comply with health laws in the sense that, among other requirements, class I medical devices and OTC drugs, but not other types of medical devices or drugs, may be advertised in mass media.[9]

- Mass media includes email, TV, radio, Web pages, blogs, posters, videos, etc.

- Prescription drugs, as well as class IIa, IIb and III medical devices, may not be advertised in mass media.[10] As described earlier, prescription drugs may be advertised only in scientific or technical publications directed to physicians (or dentists, if applicable). Class IIa, IIb and III medical devices may be advertised only in scientific or technical publications directed to healthcare professionals, but there is no further definition of specific types of professionals.

According to Colombian legal norms (the unfair competition law and the consumer protection statute) regarding publicity, medical product companies are permitted to use testimonials to promote their products if such testimonials are merely opinions and are not misleading.

[7] Law 256 of 1996.
[8] Law 1480 of 2011.
[9] Decree 4725 of 2005, Article 58 (medical devices); Decree 677 of 1995, Article 79 (drugs).
[10] Decree 4725 of 2005, Article 58 (medical devices); Decree 677 of 1995, Article 79 (drugs).

If a medical product company offers any contest, raffle or other procedure where results are determined by chance, the activity must be authorized by the Regional Entity for Health (*Entidad Territorial para la Salud* or ETESA).

Any such activity would need to respect provisions requiring that medical devices in classes IIa, IIb and III may only be offered in scientific or technical publications directed at healthcare professionals, and that prescription drugs can only be offered in scientific or technical publications directed at physicians (or dentists, if applicable). Likewise, any such activities must respect the prohibition against the promotion or giving of any type of perks or gifts to workers (either employed or contracted) of the entities within the General System of Social Security for Health.[11]

There are fewer restrictions on medical product companies advertising the company itself and not a particular medical product. A medical product company can advertise itself because it has a right as the owner of the commercial name of the company. Advertising of the medical product company's commercial name must not violate third parties' rights as stated in the Andean Community Law.[12]

Promotional Activities

Products

Only the information and usage authorized by the product registration granted by INVIMA can be promoted with regard to said medical product.

It is also worthy to note that patient information sessions about medical products arranged by medical product companies will be understood to be promotion of medical devices or drugs. In this sense, they are not permitted for prescription drugs or class IIa, IIb or III medical devices, which may only be promoted directly to physicians

[11] Law 1438 of 2011, Article 106, as modified by Law 1474 of 2011, Article 133.
[12] Andean Decision 486, 2000, Title X.

(or dentists, if applicable) in the case of drugs, and healthcare professionals in the case of medical devices. Therefore, only OTC drugs and class I medical devices may be promoted in such sessions.

Disease

Similarly, prescription drugs and class IIa, IIb or III medical devices may not be referenced in patient sessions arranged by medical product companies in relation to a disease. The information in such sessions would have to concern the treatment without mentioning the drug or medical device and without having the objective of publicizing it.

Surgery

Additionally, prescription drugs and class IIa, IIb or III medical devices may not be referenced in patient sessions arranged by medical product companies in relation to a surgery. The information in such sessions would have to concern the surgery itself and post-operative treatments without mentioning the drug or medical device and without having the objective of publicizing it.

Gifts, Hospitality and Sponsorships

Medical product companies providing healthcare professionals or medical institutions with gifts, sample products, hospitality, entertainment, sponsorship for training and research, employee positions or events, and discounted products, must comply with the prohibitions on the promotion of drugs and medical devices described above, including the stricter requirements that apply to the promotion of prescription drugs and class IIa, IIb and III medical devices, and the anti-corruption and anti-bribery regulations

Moreover, the aforementioned activities must not violate the Physicians Ethics Code,[13] which prohibits physicians from receiving commercial benefits from pharmacies, laboratories and other similar organizations in charge of objects that could be prescribed by them. In other words, if any of the these activities amount to commercial

[13] Law 23 of 1981, Article 40.

benefits to the physician, accepting such items would amount to a violation of the Ethics Code by the physician.

According with Afidro´s Code of Ethics, any promotional and / or medical useful items, must not individually exceed a sum equal to ten percent (10%) of a current legal monthly minimum wage (ie. approximately USD$20, at current conversion rates), may be branded in accordance with the provisions of the law and may be delivered in minimum quantity, if it relates to the work of the HCP who receives it. In no case these items may consist of gifts, cash or its equivalent for the personal benefit of the HCP, and shall not exceed on the whole, on an annual basis, the amount of fifty percent (50%) of the current legal monthly minimum wage.

With respect to healthcare professionals that are public employees or contractors, generally, the crime of bribery amounts to the offering or giving of money, any benefit, or promise to give a benefit to a public official for the purpose of inducing such officer to perform or expedite his public duties, not perform or delay such duties, or perform actions contrary to such duties.

Thus, the offering or giving, for example, of gifts, hospitality, entertainment and sponsorships to a physician employed or contracted by the government in exchange for the generation of business could constitute bribery.[14] In addition, the aforementioned activities must respect the prohibition against the promotion or giving of any type of perks or gifts to workers (either employed or contracted) of the entities within the General System of Social Security for Health.[15]

Some interpretations state that these activities (the giving of gifts, sample products, hospitality, entertainment, etc.) could be considered as acts of unfair competition when they are considered to contravene healthy commercial customs, good commercial faith, honest industrial and commercial uses, or when they are intended to affect the free

[14] Colombian Criminal Code, Articles 405, 406, and 407.
[15] Law 1438 of 2011, Article 106, as modified by Law 1474 of 2011, Article 133.

decision of the consumer or to deceive clients. The unfair competition caused by those activities would have to be duly proven in an administrative or judicial process and lead to proportional sanctions.

Sample drug products may only be given to physicians.[16]

Donation of drugs and medical devices that are not registered with INVIMA in Colombia may be made in accordance with the provisions of Decree 919 of 2004. An authorization from INVIMA is required in order to make such a donation. Specific requirements to be met include those relating to the product's active ingredients, the packaging and labeling that may be used, the product's useful life, compliance with the product's own specifications, and the product's storage and conservation. The donation of experimental products is prohibited, as is the commercialization, for-profit use or other misuse of donated products.

Colombian law does not specifically regulate donations of medical products that are already registered with INVIMA. There is no express legal requirement to obtain an authorization from INVIMA in order to make this type of donation.

Special requirements apply with regard to the importation for donation of "biomedical equipment" (generally, medical devices that are neither implanted nor for one-time use).[17] Biomedical equipment imported into Colombia in order to be donated must be donated to a healthcare institution. The donation (as wells as importation and acquisition) of used class I and IIa biomedical equipment is expressly permitted under certain circumstances, but the donation (as well as importation and acquisition) of used class IIb and III biomedical equipment is expressly prohibited.

Laws regarding perks and gifts to health system workers, laws regarding the promotion of the medical products, and tax obligations should also be considered in making a donation.

[16] Decree 677 of 1995, Article 76.
[17] Decree 4725 of 2005, Article 37.

Contracts with Healthcare Professionals and Medical Institutions

Colombian law permits medical product companies to engage healthcare professionals in speaking arrangements or other services. However, such engagements must respect the prohibition against the promotion or giving of any type of perks or gifts to workers (employed or contracted) of the entities within the General System of Social Security for Health, and the norms regarding the promotion of medical products. Moreover, the information given by these healthcare professionals must comply with Colombian law.

Liability Under Criminal and Civil Law and Applicable Codes of Conduct

Medical product companies could be the subject of several complaints and sanctions if a law or provision regarding promotion of medical products is infringed. The procedures that could be initiated are the following:

- Sanction Proceeding – INVIMA could initiate a sanction proceeding if the company violates a heath law or regulation that regulates the advertising of medical products or another Colombian health law or regulation. Where a violation is proven, sanctions include the following: Warnings
    - Fines
    - Seizures
    - Suspension or cancellation of product registrations or permits
    - Temporary or permanent shutdown of the establishment, laboratory or building.[18]

[18] Decree 4725 of 2005, Article 80 (medical devices); Decree 677 of 1995, Article 125 (drugs).

- Unfair competition action – This kind of action could be initiated by a competitor if a medical product company engages in misleading publicity or unfair comparative advertising. The action would be initiated before a civil judge or before an administrative authority (the Superintendence of Industry and Commerce). In this type of action, the plaintiff mainly requests the cessation of the act of misleading publicity or unfair comparative advertising, and for compensation for the damages caused.

- Consumer protection action – This action is initiated before the Superintendence of Industry and Commerce by a consumer who considers the promotion or advertising of a medical product company misleading or because the same induces consumer error. Possible sanctions resulting from such an action include any of the following:

    - Fines

    - Permanent or temporary closures of commercial establishments

    - Permanent or temporary prohibition on production, distribution or offering the product to the public

    - Destruction of the product if it is dangerous to consumer health or security. Moreover, mayors may, within their respective jurisdictions, exercise the same administrative powers of control and vigilance exercised by the Superintendence of Industry and Commerce, including the imposition of fines. Decisions by mayors may be appealed before the Superintendence of Industry and Commerce.[19]

- Criminal action – A criminal action could be initiated against a person who, in the promotion of a medical product,

[19] Law 1480 of 2011, Articles 61 and 62.

allegedly commits an act of aggression that could be considered as defamation or slander against another person or company. This act, according to Colombian criminal law, is an offense and is penalized. Moreover, the wrongful promotion of medical products potentially involves certain criminal laws,[20] including types of bribery and extortion (as well as anti-corruption laws).[21]

- Fines: gifts and perks – Administrative agencies in charge of inspection, monitoring and control, may impose fines from 100 to 500 legal monthly minimum salaries for the promotion or giving of any type of perks or gifts, either monetary or in kind, to workers (either employed or contracted) of the entities within the General System of Social Security for Health.[22]

Recommendations

The following are among the strategies that a medical product company could adopt to minimize the risk of violating legal norms regarding the promotion of medical products in Colombia:

- Scrutinize gifts, payments or donations to be made to medical professionals and institutions beforehand to ensure that they are made in conformity with applicable legal norms, especially when being made to government entities, employees and contractors.

- As much as possible, register and keep track of the direct or indirect transfers of value made to any of the actors of the health system (travel expenses, professional fees, hospitality, donations, etc.).

[20] Law 599 of 2000.
[21] Decree 126 of 2010 (addressing corruption in the General System of Social Security for Health); Law 970 of 2005 (approving the United Nations Convention against Corruption); Law 190 of 1995 (addressing bureaucratic corruption).
[22] Law 1438 of 2011, Article 106, as modified by Law 1474 of 2011, Article 133.

- Promote prescription medical products to physicians (or dentists, if applicable) only, and do not promote such products to the general public and/or via mass media.
- Obtain agency approvals for promotions of medical products, where applicable.
- Be aware of rules and guidance related to the promotion of medical products given by the Ministry of Health and Social Protection, INVIMA, the Superintendence of Industry and Commerce, and other applicable agencies and associations.
- Implement policies and procedures directed at ensuring proper promotion practices.

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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