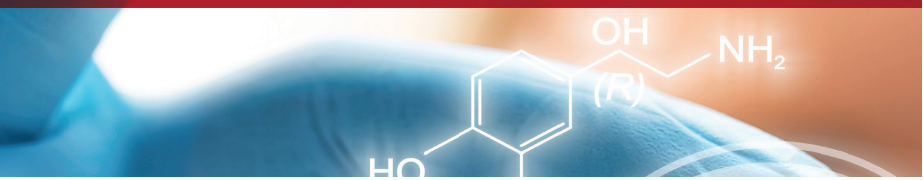
Baker McKenzie.

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



ARGENTINA

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Introduction

The pharmaceutical industry is heavily regulated in Argentina. The main sanitary authorities at the national level are the National Ministry of Health (MOH) and the National Administration of Drugs, Food Products and Medical Technology (ANMAT). Additionally, each province has its own provincial Ministry of Health and, in some cases, even municipal permits may be required.

In general terms, the MOH is in charge of drafting and enforcing health and environmental public policies, as well as coordinating and monitoring the activities of provincial sanitary authorities.

Most sanitary legislation (e.g., registration of pharmaceuticals and medical devices, authorizations to commercialize pharmaceuticals and medical devices, promotion of pharmaceuticals and medical devices, imports and clinical trials) is passed by ANMAT, a decentralized and independent governmental body that controls, at the national level, the processes of authorization, registration and surveillance of medical devices, pharmaceuticals and food products. Even though ANMAT has economic independence, it follows technical and scientific rules and instructions issued by the MOH.

Regulatory Framework

The main laws and regulations applicable to the promotion of pharmaceuticals and medical devices are as follows:

- Law 16,463 (Pharmaceuticals Law)
- Executive Order/Regulatory Decree 9763/64 (Regulating Pharmaceuticals Law)

- MOH Resolution 20/05 (Advertisement of Over-the-Counter ["OTC"] Pharmaceuticals)
- ANMAT Disposition 4980/05 (Advertisement of OTC Pharmaceuticals)
- MOH Resolution 627/07 (Good Practices in the Promotion of Prescription Drugs)
- ANMAT Disposition 1631/09 (Advertisement of OTC Pharmaceuticals)
- ANMAT Disposition 2845/11 (Program for Control and Fiscalization of Advertisement of Products under Sanitary Surveillance)
- Law 24,240 (Consumer's Protection Law)
- Law 22,802 (Commercial Loyalty)
- Law 25,156 (Competition Law)
- ANMAT Disposition 6516/2015 (Notification Regime for Promotion)

In all cases, corresponding amendments and regulatory decrees are included.

Permitted and Prohibited Practices

In Argentina, promotion and advertising of pharmaceuticals and medical devices are permitted, though heavily regulated.

First and foremost, promotion of pharmaceuticals and medical devices that have not previously obtained the corresponding authorization for commercialization (i.e., product registration with ANMAT) is strictly forbidden.

Rules on promotion and advertisement of pharmaceuticals and medical devices vary depending on the condition of sale (OTC/prescription pharmaceuticals) or indicated use (for patients/consumers' direct use/for use with the intervention of a healthcare provider for medical devices).

Promotion to the general public of prescription pharmaceuticals (as opposed to OTC pharmaceuticals) and medical devices which, due to their intrinsic nature and proposed use, may not be directly used, or are not indicated for direct use by patients and/or non-professional consumers ("prescription medical devices") is forbidden.

Consequently, pharmaceutical and medical device companies are only allowed to advertise registered prescription pharmaceuticals and medical devices to the medical community.

General Rules

In general terms, the content of promotional materials should be consistent with the information on the product submitted to ANMAT at the time of product registration. Information should be objective, true, accurate and shall avoid misleading or confusing language.

Additionally, applicable regulations indicate that advertisements must be based on scientific and technical evidence (which shall be available to ANMAT).

Pharmaceutical and medical device companies are required to keep a registry of the advertisement materials and the supporting information.

Authorization of Promotional Materials

In principle, previous authorization by sanitary authorities is not required for promotional materials of OTC pharmaceuticals and medical devices. Pursuant to Ministry of Health Resolution 20/05, the content of any such advertising shall be subject to subsequent supervision by the sanitary authority.

In contrast, and according to Ministry of Health Resolution 627/07 (Good Practices for the Promotion of Prescription Pharmaceuticals) ("Resolution 627/07"), express authorization of ANMAT for public (mass media) advertisements directed to the medical and/or pharmaceutical community is required for prescription pharmaceuticals. In addition, the need for mass media advertising must be justified.

In the case of medical devices, due to the absence of specific legislation regulating the advertisement of prescription medical devices, express authorization of ANMAT for promotional materials directed to the medical and/or pharmaceutical community could be required if Resolution 627/07 is applied by way of analogy.

Notification of Promotional Materials

Pursuant to ANMAT Disposition 6516/2015, all publicity addressed to the general public regarding promotional materials of OTC pharmaceuticals and medical devices must be notified to ANMAT.

Same requirements apply under the same disposition to prescription pharmaceuticals addressed to healthcare professionals.

In the case of alleged infringement of the current legislation on promotion matters, ANMAT shall request that the circulation of the publicity and/or promotional materials involved be stopped.

Certain Marketing Practices

Samples

In the case of pharmaceuticals, according to Disposition 4980/05, free samples of OTC pharmaceuticals may be supplied to the general public only through physicians or pharmacists, who shall be responsible for their distribution.

The supply of free samples to minors is forbidden. Based on Resolution 627/07, delivery of samples of prescription pharmaceuticals is also permitted to medical professionals only.

In the case of medical devices, Disposition 4980/05 provides that, depending on the product's risks, free samples of medical devices may be supplied to physicians, dentists, pharmacists and any government entity authorized to that effect.

Hospitality and Gifts

As a preliminary comment, it is important to note that Law 17,132 (Practice of Medicine) prohibits physicians from obtaining benefits from manufacturers, distributors or sellers of pharmaceuticals, cosmetics, dietary products, prostheses or any other elements used in the diagnosis, treatment or prevention of illnesses.

Additionally, because in Argentina most physicians render services both in the private and the public sector (e.g., in hospitals and as teachers at public universities), a physician may qualify as a public official. Consequently, from an anti-corruption perspective, benefits to physicians will also be prohibited (anti-corruption regulations are mainly contained in the Argentine Criminal Code).

Pharmaceuticals: Resolution 627/2007 prohibits pharmaceutical companies from directly or indirectly granting, offering or promising incentives or benefits of any nature to healthcare professionals.

Medical Devices: There are no regulations that expressly prohibit companies that manufacture medical devices from offering or giving physicians hospitality, gifts or any kind of benefit, except when the physician qualifies as a public official (in such case, sanctions set out in anti-corruption regulations shall apply). However, as already mentioned, Resolution 627/07 may be applied by way of analogy and as a consequence, medical device companies could be sanctioned if they offer or give any incentive or benefit to a healthcare professional.

Scientific and/or Educational Events

According to Resolution 627/07, pharmaceutical companies may grant fellowships, sponsorship and/or invite physicians to participate in congresses, symposia or scientific events if they publicly inform

physicians of the terms and conditions that will enable them to participate in such events, as well as the selection mechanisms (which should be equitable/fair and transparent). Again in this case, no express regulation exists for medical device companies, but Resolution 627 could apply by way of analogy.

In any event, any expenses related to a congress, symposium or scientific event that a pharmaceutical company will be financing, shall be reasonable and not lavish, and strictly related to the event (in this sense, the recommendation is to avoid using luxurious venues and avoid paying for entertainment or leisure activities).

Consequences of Breach

In the event of a breach of the regulations regarding promotion and advertisement of pharmaceuticals and/or medical devices, the technical director and/or the pharmaceutical or medical device company may be subject to various penalties that vary depending on the type of infringement, its relevance and whether there is repeat infringement.

From a Health Regulations perspective, the technical director and the titleholder of the product registry will be jointly and severally liable under Law 16,463 for the following penalties:

- Warnings
- Fines
- Total or partial, temporary or final, business closure, depending on the relevance of the infringement or whether or not there is repeat infringement
- Suspension or disqualification in the exercise of the activity or professional practice for up to three years (if the infringement is egregious, possible permanent disqualification)
- Seizure of infringing products

- Cancellation of the authorization to sell and manufacture the products

Professional Codes of Conduct

Local chambers of commerce, to which health-related companies may belong (there are specific chambers for pharmaceutical companies and specific chambers for medical device companies), have enacted codes of conduct/ethics for purposes of self-regulating the industry.

These codes mainly address interactions with healthcare professionals and rules on marketing practices and promotion of pharmaceuticals and/or medical devices. These codes may not override Argentine legislation. In general terms, these codes have a more lenient approach by comparison to the Argentine Regulatory Framework.

Criminal and Civil Liability

Depending on the case and type of infringement, additional penalties to the ones described above under "Consequences of Breach" may apply from a Consumers' Protection Law and/or Commercial Loyalty perspective.

In addition, if healthcare professionals qualify as public officials, criminal sanctions contained in the anti-bribery provisions of the Argentine Criminal Code may also apply. For example, if pharmaceutical companies engage in certain prohibited practices such as offering, promising or giving benefits to healthcare professionals, the anti-bribery provisions mentioned may apply.

Finally, the Argentine Criminal Code contains a special chapter for offenses against public health. The provisions in this chapter are mainly aimed at sanctioning the individuals or companies that commercialize false or contaminated pharmaceuticals.

Public Procurement

In general terms, administrative acts (including public contracts) must comply with several requirements to be valid:

- They must be performed by a competent administrative agency/body (i.e., the agency/body that is legally authorized to issue the administrative act).
- They must be based on applicable law, taking into consideration factual circumstances (both the law and the facts serve as grounds for any administrative act).
- The purpose must be clearly defined and physically and legally possible.
- The opinion of the state's attorney must be requested when rights or legitimate interests could be affected.
- The reasons and findings for its issuance must be precisely stated.
- They must follow the rules that grant relevant powers to the issuing agency and must always bear in mind the public interest directly or indirectly involved.
- As a general rule, they must be in writing.
- They must comply with general and particular rules governing public procurement contracts, both at the national and provincial levels.

Contracts with Healthcare Professionals and Medical Institutions

Pharmaceutical and medical device companies are permitted to engage healthcare professionals for service agreements (e.g., consulting and speaker services). Payments to physicians for such services are not

prohibited. However, the fees to be paid for the services should be reasonable, taking into consideration the type of service as well as market practices.

Additionally, prior to executing a services agreement with a healthcare professional, an analysis of the nature of the healthcare professional (whether he or she is a public official) should be conducted, considering that public officials could be subject to conflict of interest.

Recommendations

The promotion and advertisement of pharmaceuticals and medical devices is heavily regulated in Argentina. Thus, special consideration should be taken when drafting promotional and advertisement materials for each product.

In order to lower the risks of facing sanctions, pharmaceutical companies should bear in mind the following recommendations:

- Do not structure benefits to physicians unless the selection mechanism described under "Permitted and Prohibited Practices: Scientific and/or Educational Events" has been complied with or unless this benefit is in consideration for a service rendered by the physicians.
- Do not give benefits that are linked to a sales transaction.
- Draft a company code of conduct.

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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