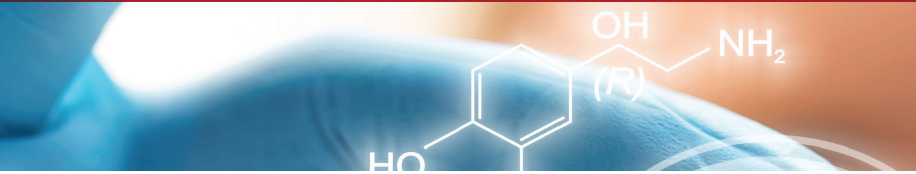


Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



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Peru

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Introduction

In Peru, the promotion and advertising of pharmaceutical products and medical devices is regulated by industry-specific laws and regulations, as well as by general laws on advertising and consumer protection.

Event though the General Directorate of Medicines, Drugs, and Supplies (DIGEMID) is the national authority on pharmaceutical products and medical devices, being in charge of granting the sanitary registrations, as well as of their surveillance, the entity in charge of supervising the conduct of advertising activities is the National Institute for the Defense of Competition and Protection of Intellectual Property (INDECOPI). Thus, if the INDECOPI detects an infringement of industry-specific legislation on pharmaceutical products and medical devices or of general legislation — or is informed of such situation by DIGEMID — it may initiate a proceeding against the advertiser and impose the corresponding fine.

Approval for the advertising of pharmaceutical products and medical devices is not required in Peru. It is an ex-post control that evaluates the quality of the information, so that medical professionals and consumers are provided with accurate, opportune and sufficient information on pharmaceutical products and medical devices.

Medical Product Advertising Legislation

Regulatory Framework

Advertising of pharmaceutical products and medical devices are governed by the following legal bodies:

- Law No. 29459, on Pharmaceutical Products, Medical Devices and Sanitary Products

- Supreme Decree No. 016-2011-SA, Regulations on the Registration, Control and Surveillance of Pharmaceutical Products, Medical Devices and Sanitary Products
- Supreme Decree No. 014-2011-SA, Regulations on Pharmaceutical Establishments
- Ministerial Resolution No. 413-2015-MINSA, Directive that regulates the activities of medical sales representatives or other agents of pharmaceutical companies in health establishments
- Legislative Decree No. 1044, Law on Repression of Unfair Competition
- Law No. 29571, Consumer Protection and Defense Code

The Code of Ethics and Deontology of the Medical Bar Association of Peru also contains several provisions regarding how physicians must guide their conduct regarding the choice and prescription of pharmaceutical products and medical devices (e.g., choose medical procedures as a consequence of medical evidence or product efficiency; reject any incentive from a pharmaceutical company in order to avoid compromising his/her clinical judgment).

Finally, the wrongful promotion of pharmaceutical products or medical devices may also imply infringement of criminal laws regarding bribery and anti-corruption.

Permitted and Prohibited Practices

According to the Law No. 29459, on Pharmaceutical Products, Medical Devices and Sanitary Products, advertising directed at consumers can only be done for over-the-counter (OTC) pharmaceutical products and medical devices. Advertising of pharmaceutical products or medical devices sold under medical prescription can only be directed at medical professionals who prescribe or dispense them.



Rules on advertising of over-the-counter pharmaceutical products and medical devices

- In all cases, the advertising of pharmaceutical products and medical devices must be consistent with the information contained in the Sanitary Registry.
- If the advertising refers to therapeutic indications of pharmacological actions, warnings for its use must also be indicated.
- The advertising must not include exaggerations or inaccuracies regarding the properties of pharmaceutical products or medical devices that could lead consumers to error or that could encourage them to self-medicate.
- If the advertising will be diffused through printed media, panels, vehicles or similar, as well as through the internet, it must include the technical information of the product in a legible and visible manner.

Rules on advertising within medical establishments

- Direct delivery of free samples of pharmaceutical products (sold under medical prescription or over-the-counter products) in order to persuade patients and public in general is prohibited.
- Pharmaceutical companies are not authorized to install modules for the promotion of their products.
- Medical representatives are not allowed to access hospitalization sectors or consulting rooms.

Other rules

- The promotion and advertising of medical devices sold exclusively to professionals, sanitary institutions and

laboratories can only be directed at them, along with the information contained in the sanitary registration.

- The advertising of pharmaceutical products and medical devices for sale under medical prescription must contain the technical information sheet and technical report, as corresponds.
- The delivery of free samples of pharmaceutical products for sale under medical prescription directly to citizens is prohibited. Free samples can only be delivered to the physicians who prescribe them.

Consequences of Breach

In the event of a breach of regulations regarding the advertising of pharmaceutical products and medical devices, INDECOPI would be entitled to initiate sanction proceedings, as a consequence of which INDECOPI could impose fines of up to 700 tax units (equivalent to USD898,000). As well, INDECOPI would be entitled to order corrective measures, including the cessation of advertising, the removal of the effects produced by the acts, and the rectification of the misleading statements.

If as a consequence of the infringement a consumer suffers any damage (e.g., he or she is misled to error regarding the properties of a product), such circumstance may also lead to the infringement of the legal framework on consumer protection, which can lead to fines of up to 450 tax units (equivalent to USD577,500). As well, if as a consequence of the infringement a consumer suffers any damage, such consumer would be entitled to file suit against the company and ask for compensation.



Professional Codes of Conduct

The Code of Ethics and Deontology of the Medical Bar Association of Peru contains the following provisions regarding the relationship between physicians and the healthcare industry:

- In any case, a physician should not use, in clinical practice, information received through advertising without having contrasted such information with independent scientific sources.
- The physician, when choosing a diagnosis or therapeutic procedure, must take into account the best clinical and/or experimental evidence to justify it, critically evaluating the information granted by the healthcare industry.
- The physician should be aware that accepting incentives or special facilities from companies that promote pharmaceutical products or other products for treatment or diagnosis, may affect the physician's clinical judgment in prejudice of the patient.
- The physician who receives remuneration or funding from a pharmaceutical or medical company should not participate in institutional pharmaceutical committees and/or in the acquisition committees, because of the evident conflict of interest involved.

Criminal and Civil Liability

Civil Liability

Once INDECOPI has declared that a piece of advertising regarding pharmaceutical products or medical devices violates or contravenes the requirements stated by Law No. 29459 and its Regulations (e.g., unlawful or misleading advertising) or by Legislative Decree No. 1044, in addition to the sanctions and corrective measures that may be imposed (as noted above), INDECOPI can also initiate, in defense of

collective and diffuse interests of consumers, and with authorization from its Directive Council, a judicial process (civil claim) requiring compensation for damages arising from the advertising declared illegal. INDECOPI is also entitled to initiate a judicial process in case of infringements of consumer protection legislation.

Likewise, consumers who, in a particular case, have been affected as a result of an infringement of consumer protection legislation can initiate, on their own behalf, a civil claim requesting compensation for damages from the responsible parties.

Criminal Liability (Bribery and Anti-corruption)

As already noted, the illegal promotion of pharmaceutical products or medical devices can also lead to the initiation of a criminal investigation and process for an alleged act of bribery.

In this respect, the Peruvian Criminal Code (Legislative Decree No. 635) punishes acts of bribery that involve public officials (e.g., a physician from the public sector), as a consequence of which the Judiciary may sanction the public official who receives the bribe (passive bribery), as well as the private entity (citizen or corporation) who offers the bribe (active bribery), in the terms described below:

- Regarding passive bribery, the Peruvian Criminal Code states that any Peruvian public officer, foreign public officer or any officer of an international organization that requests, accepts or receives donations, promises or any type of advantages to carry out or omit an act in violation of his or her obligations or without violating his or her obligations, constitutes a crime that will be sanctioned with imprisonment, as well as disqualification from future public service.
- Regarding active bribery, the Criminal Code sanctions with imprisonment any person who, under any modality, offers, gives or promises any Peruvian public officer, foreign public officer or any officer of an international organization, a



donation, promise, benefit or advantage in order for them to carry out or omit acts whether in violation or without violating their obligations.

It must be noted that these rules are very rigorous and no exceptions are provided for their application; facilitation payments are generally not acceptable, so a gift or hospitality could be considered as bribery, depending on the circumstances and time on which they were granted.

According to the Peruvian Criminal Code, the penalties that can be imposed on participants in an act of bribery are as follows:

- For private individuals: Up to eight years of imprisonment, depending on the type of bribery committed, as well as secondary penalties. In certain cases, a monetary fine can also be applied.
- For public officers: Up to 15 years of imprisonment, depending on the type of bribery committed, and secondary penalties (e.g., destitution). In certain cases, a monetary fine can also be applied.
- For companies: Placement under judicial supervision and intervention for a maximum period of two years; permanent closure of the establishment; temporary closure for up to five years of the establishment; dissolution and liquidation of the company; suspension of activities for a maximum period of two years; and/or the prohibition to engage in any commercial activities similar to those under which the offense was committed.

Contracts Between Healthcare Professionals and Medical Institutions

Peruvian law does not prohibit pharmaceutical and medical device companies to engage in service agreements with healthcare professionals, for example, to provide research, consulting, speaking

or exhibiting services. In any case, it is recommended to hire healthcare professionals for a specific purpose and for a fixed term.

Notwithstanding the above, take into consideration that some restrictions may apply depending on the condition of the healthcare professional. When he or she qualifies as a public official or is involved with public entities, it must be verified if he or she meets any prohibition or impediment stated by law. In this respect, Law No. 27815, Code of Ethics of the Public Service, prohibits all public officials and servers from maintaining or accepting any situation in which his or her personal, labor, economic and financial interests may be in conflict with the fulfillment of his or her duties and functions.

Moreover, according to Law No. 27588 on Prohibitions and Incompatibilities of Public Servers, and Supreme Decree No. 004-2014-PCM, Regulations of the Law No. 30057 of Civil Service, public officials and servers that fulfill direct public function in connection with any interest of corporations or private institutions, during the time they serve the government and for a year after, are prohibited from doing any of the following conducts:

- Provide services in corporations and private institutions
- Accept paid representations for these
- Join any of their Boards of Directors/Directory
- Acquire any of their shares or participations, and those of their related companies
- Enter into any commercial and civil agreement with these
- Participate as lawyer, representative, adviser, sponsor, expert witness or arbitrator

Regarding private healthcare professionals, it must be verified if he or she is engaged in a labor relationship with another private entity and if, as a consequence of that, is subjected to certain restrictions (for



example, exclusivity and non-compete obligations). Furthermore, compliance standards and ethic codes must be taken into account when executing any agreement.

Recommendations

In order to minimize the risk of infringing the legislation on promotion and advertising of pharmaceutical products and medical devices, companies must take into consideration the following recommendations:

- Only diffuse advertising regarding over-the-counter pharmaceutical products and medical devices.
- Be careful that all advertising material regarding pharmaceutical products and medical devices for sale under medical prescription — which can only be directed at health professionals — are not accessible by the public in general. Thus, in case of doubt on whether media can be accessed not only by health professionals (e.g., a health magazine that is not highly specialized), avoid using it for advertising.
- Verify that the information to be included in the advertising is consistent with the information contained in the Sanitary Registration of the corresponding product. As well, avoid using subjective statements in the advertising (mainly, regarding the properties of the products).
- Implement policies and procedures that gather the rules applicable to the promotion and advertising of pharmaceutical products and medical devices (some of which we have included in prior paragraphs).
- Avoid granting any facilitation payment, as well as any gift or hospitality, to public officials in order to prevent such conduct from being considered an act of bribery.



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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