**PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES**

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**GENERAL**

**1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.**

The following legislation governs advertising of pharmaceutical and medical products:

- Law on Pharmaceutical Products, Medical Devices and Sanitary Products (Law No 29,459);
- Regulations for the Registration, Control and Sanitary Surveillance of Pharmaceutical Products, Medical Devices and Sanitary Products (Supreme Decree No 016-2011-SA) and amendments;
- Law on Suppression of Unfair Competition (Legislative Decree No 1044);
- Consumer Protection Code (Law No 29,571);
- Ethical Criteria for the Promotion and Advertising of Pharmaceutical products, Medical Devices and Sanitary products approved through Ministerial Resolution No 474-2020-MINSA (Health Technical Standard No 162-MINSA/2020/DIGEMID).

Advertisements do not require authorisation or supervision before dissemination by any authority. The supervision and control take place after the advertisement has been released (*ex-post* control) and is supervised by the Unfair Competition Commission of the National Institute for the Defence of Competition and the Protection of Intellectual Property (INDECOPI). In compliance with the Unfair Competition Law, the responsibility of proving the veracity and accuracy of objective statements on products and services advertised corresponds is the responsibility of the advertiser.

**2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?**

According to the Law on Suppression of Unfair Competition 'advertising' means any form of communication disseminated by any means or carrier, and objectively suited or designed to promote, either directly or indirectly, the image, trademarks, products or services of a person, firm or entity in the exercise of its commercial, industrial or professional activity, within the framework of a competition activity, promoting the contracting or conduct of transactions to satisfy its business interests.

The same Law defines 'promotion of sales' as any discount designed to incentivise a transaction for goods or services in exceptional and temporary conditions of sale, which appear to be more beneficial than the conditions of the ordinary or standard offer. This may consist of a reduction in prices, increase in quantity, competitions, draws, exchanges and the like.

According to Supreme Decree No 016-2011-SA, 'pharmaceutical promotion' is defined as any informative and persuasive activity deployed by manufacturers, importers, distributors and sellers, through any means of communication, with the aim of inducing the prescription, supply, acquisition or use of their products or devices.

Similarly, the mentioned norm defines 'pharmaceutical advertising' as the set of techniques used by pharmaceutical companies to disseminate information about their products or devices to promote their sale or consumption; the same that can be intended for health professionals or the general public depending on its sales condition.

**3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?**

The regulatory bodies are:

- The Unfair Competition Commission of the National Institute for the Defence of Competition and the Protection of Intellectual Property (INDECOPI);
- The Consumer Protection Commission of INDECOPI; and
- The General Directorate of Medicines, Supplies and Drugs (DIGEMID).

Articles 17.1 and 17.2 of the Law for the Suppression of Unfair Competition establish that advertisers must respect the mandatory rules of the legal system. Consequently, the breach of any sector provision that regulates the performance of the advertising activity regarding its content and scope constitutes an infringement of the Principle of Advertising Legality. Therefore, in cases where there are any special

regulations that establish certain limits or bans on the circulation of advertisements, its non-compliance will constitute an act of unfair competition.
Even though the General Directorate of Medicines, Drugs and Suppliers (DIGEMID) is the national authority on pharmaceutical products and medical devices, being in charge of granting the Marketing Authorisations, as well as their surveillance, the entity responsible for supervising the conduct of advertising activities is INDECOPI, through the Unfair Competition Commission. If DIGEMID identifies an advertising contrary to the legislation, it will notify the Unfair Competition Commission to investigate or initiate a procedure.

**4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?**

Some Food supplements and special nutritional products are considered 'dietary products'. This is a product whose purpose is to complement the normal diet that consists of concentrated sources of nutrients or other substances that have a nutritional or physiological effect, in simple or combined and dosed form. Dietary products are subject to the same rules as the ones applicable to pharmaceutical products. However, depending on the ingredients, these products could be considered as food and beverages, which applies to any substance or mixture of substances intended for human consumption. Their applicable regulation is Supreme Decree No 007-98-SA.

**CONSUMER MARKETING**

**5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisements) in your country and, if so, which ones?**

According to Article 39 of Law No 29,459, the promotion and advertising of pharmaceutical and medical devices duly authorised (that have a granted Marketing Authorisation) for sale with a medical prescription must be addressed exclusively to the professionals who prescribe (physicians) and dispense said products. Consequently, it is prohibited to promote and advertise pharmaceutical and medical devices sold with a medical prescription for the general public. It is not permitted to promote pharmaceutical products that require a medical prescription on internet or social media advertising addressed to the general public. This is in accordance with Section 5.2.(4) of the Ethical Criteria for the Promotion and Advertising of Pharmaceutical Products, which relates to medical devices and sanitary products approved through Ministerial Resolution No 474-2020-MINSA (Health Technical Standard No 162-MINSA/2020/DIGEMID).

Also, in case of health establishments (hospitals, clinics, etc.) Article 195 of the Rules of the Law prohibits the installation of modules or spaces in such places, to carry out promotion and advertising activities or delivery of drugs or other pharmaceutical products. Similarly, and in accordance to the provision in the Rules of the Law, the wording and illustrations in advertisements to physicians and related health professionals should be fully consistent with the approved scientific data sheet for the drug concerned or other sources of information with similar content and the text should be fully legible.

**6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?**

As a general rule, the Law states that advertisements must not contain exaggerations or other inaccurate information on their properties, which may lead consumers to error, and must not encourage self-medication and irresponsible use.

The information provided in a promotion or advertising must coincide with the information authorised along with the Marketing Authorisation. Likewise, according to Supreme Decree No. 016-2011-SA, the promotion and advertisement of drugs and medical devices must include information that appears in the technical specifications (approved scientific data sheet) and/or technical information and must be legible, clear, truthful, accurate, complete and updated.

Advertising carried out regarding a pharmaceutical product sold without a prescription must contain, in addition to the name of the product, the following information in Spanish, in a clear, legible manner and in a distinctive font size:

- dosage;

- concentration or pharmaceutical form thereof.
- main precautions and warnings for use.

The written legends must have a duration proportional to the length of the advertising.

Furthermore, according to Health Technical Standard No. 162-MINSA/2020/DIGEMID, advertising must comply with the following:

- It must not include expressions that suggest that health may be affected by not using the product, nor may it suggest or allude that consumption of the product may prolong or dispense with going to the consultation of a health professional.
- It should not promote self-medication and irrational use of the product.
- The technical and scientific information approved by the health authority (DIGEMID) must be disseminated in an understandable and accessible manner consistent with what is authorised in the health record.
- It cannot be stated that a product is completely harmless or safe if there is no technical or scientific support.
- It cannot be suggested or claimed that a product is safer or more effective compared to others, without verifiable scientific evidence.
- It should not lead to the consumption of the product being considered as a means to achieve a certain status in life or magnify its properties, assuming that its use enhances physical or mental performance.
- The messages, symbols and images that are disseminated must not distort, lead to error or confusion regarding the origin, results, benefits, characteristics, benefits or indications approved by DIGEMID.
- It must not contain exaggerations or inaccuracies about therapeutic, nutritional, cosmetic, diagnostic, preventive or any other properties that are not consistent with those authorised by DIGEMID.
- It must not contain information that guides the consumption of the product to be considered as a means to achieve a certain standard of living or magnify its properties, with its use being attributed to enhancing physical or mental performance.
- It should not be directed at children and mechanisms should not be used that attract the attention of this age group, inducing them to consume it.

When dealing with dietary products, nutritional statements must not be false, ambiguous, misleading or indicate that they have therapeutic activity as if they were medicines. Nor should it be stated, suggested or implied that consumption of the product can replace a balanced and varied diet that provides adequate amounts of nutrients in general.

**7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?**

There are no specific local permits required for contests or promotions. However, it must be indicated the clear indication of the duration of the promotion and the minimum stock of available units of the offered products.

**8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?**

No, it is forbidden.

**9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?**

The acts of comparison consist of advantages presentation of the competing offer. There shall be an unmistakable, direct or indirect allusion on the offer of another economic agent, even by external distinctive sign, to verify the existence of an act of comparison.

The comparison acts, licit or illicit, necessarily generates a harm to the competitor which whom the comparison is made, because it could potentially affect the decision of its clients. Despite that, is harm is justified and becomes a tolerated harm if it has an informative character that benefits the consumers, as long as it complies with the requirements for making comparative advertisement. The lack of informative character in comparative advertising is produced when the advertiser uses non confirmable opinions or

claims, because it would be impossible for the consumer to confirm the alleged advantages advertised. This lack of informative character leads to the competitor being harmed without the consumer benefiting from relevant information, and therefore it is not allowed.

Acts of comparison will be considered lawful when they comply with the following requirements:

- they constitute information that is true in terms of its objective, verifiable condition, in line with reality;
- they constitute information that is accurate in terms of its clear and current condition, presented in such a way that ambiguity or lack of precision is avoided as to the reality which pertains to the economic agent referred to or to what is being offered;
- they are carried out in relevant manner in a way such that, inter alia, unjustified irony, satire, humour or sarcasm is avoided, in view of the circumstances; and,
- they are performed in a relevant context in order to avoid allusions to nationality, beliefs, sexuality or any other strictly personal circumstances of the owners or representatives of another firm, inter alia allusions which do not transmit information allowing the consumer to evaluate the economic agent referred to or what he is offering regarding efficiency parameters.

Provision 157 of the Decision 486 of the Andean Community regarding Intellectual Property states that the registration of a mark does not confer its owner the right to prohibit a third party from using the mark to publicise, including the use of comparative advertising, to offer for sale or to advertise the existence or availability of lawfully marked goods or services, or to advertise the compatibility or suitability of spare parts or accessories that may be used with goods bearing the registered mark, provided that such use is: (1) made in good faith; (2) is confined to the purpose of informing the public; and, (3) is not liable to mislead or confuse as to the corporate origin of goods or services concerned.

Therefore, a name, logo, trademark, trade dress or other designation of a competitor can be used in advertising as long as it is for information purposes.

Also, according to section 5.4.7 of the Health Technical Standard No 162-MINSA/2020/DIGEMID it is possible to make statements about the advantage of comparative use of one medical device with another, for having a better design and technological advance, with verifiable scientific evidence that is in accordance with what is authorised in its registration.

**DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS**

**10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?**

The applicable legislation is Supreme Decree 016-2011-SA and Administrative Directive 208-MINSA/DIGEMID-V.01 (approved by Ministerial Resolution No 413-2005-MINSA) and Ethical Criteria for the Promotion of Medicines approved by the World Health Organization.

According to the mentioned Directive, the installation of stands, modules, offices or other forms of positioning of environments and physical spaces by medical representatives and other agents of pharmaceutical companies is banned in both public and private health establishments.

Also, the mentioned Directive indicates that in medical offices, advertisements (posters) of pharmaceutical products for sale with a medical prescription may not be posted on the walls, which may only be delivered directly to the prescribing professionals, and must contain the information in the technical sheet and in the event that scientific, clinical or pharmacological is alleged, the same must be supported on the information included in the Marketing Authorisation.

**11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?**

No, there are no specific rules.

**12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?**

No for endorsement, but please be aware that according to Article 197 of Supreme Decree 016-2011-SA advertisements for pharmaceutical products and medical devices disseminated in the mass media, should

not publicise testimonies delivered by health professionals, entertainers or others, without being supported by recent, authentic and verifiable experiences.

Article 192 includes several requirements which must be fulfilled regarding introduction advertisements of pharmaceuticals and medical devices for sale with a prescription that, as an exception, are advertised in written mass media. In such cases, the following information must be provided:

- Name of the pharmaceutical product.
- International non-proprietary name of the Active Ingredient.
- Pharmaceutical form.
- The quantity of active ingredient (expressed in dose or concentration unit) of each one.
- Presentation form.
- Marketing authorisation number.
- Name, address and/or telephone of the owner of the marketing authorisation, indicating that there is more information available of the product. If the product is imported, it must also include the name, address and/or telephone of the importer.

**13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.**

Yes, it is possible to provide samples of both products for healthcare professionals. It should be noted that samples must be duly labelled with all the technical and approved information included in the product's correspondent marketing authorisation. Only physicians can directly provide samples to their patients (Administrative Directive 208-MINSA/DIGEMID-V.01)

Medical representatives or other agents cannot directly deliver medical samples to patients. The prescribing professionals, according to their clinical criteria, will deliver the medical samples to the patients, which were distributed by the medical representatives or other agents of pharmaceutical companies. These medical samples should be used only for the purpose of checking the patient's adaptation to the medication and not to influence its acquisition.

Note that according to Directive 208-MINSA/DIGEMID-V.01, medical representatives should not encourage healthcare professionals to perform unethical prescription practices by offering, inter alia, courses, trips, rewards and presents. Travel and accommodations expenses are not prohibited but they should be granted in accordance to the Ethical Criteria for Medicinal Drug Promotion approved by the World Health Organization which indicate that: 'Entertainment or other hospitality, and any gifts offered to members of the medical and allied professions, should be secondary to the main purpose of the meeting and should be kept to a modest level. Any support to individual health practitioners to participate in any domestic or international symposia should not be conditional upon any obligation to promote any medicinal product.'

Any support to individual health practitioners to participate in any domestic or international symposium should not be conditional on any obligation to promote any medicinal product and must be announced as a conflict of interest, when applicable. Likewise, gifts offered to members of the medical and allied professions, should be eliminated from any event, especially those with scientific purposes or therapeutic disclosure.

**14. What rules govern the offering of hospitality to healthcare professionals?**

See response to Question 13.

**15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?**

No, donations made by permit/authorisation holders to healthcare institutions or organisations are not considered as a promotional (advertising) tool. They are regarded as humanitarian.

The following standards regulate donations:

- Law on the Facilitation of Customs Clearance for Donated Goods from Abroad (Law No 28,905);
- Regulation of Law No 28905 (Supreme Decree No 021-2008-EF);
- Donations Directive (Ministerial Resolution No 1000-2019/MINSA, Directive No 277-MINSA/2019/OGCTI);

- Administrative Directive regulating the procedure for issuing technical opinions and authorisation for the entry into the country of donations of pharmaceutical products, medical devices, and sanitary products from abroad (Directorate Resolution No 060-2015-DIGEMID-DG/MINSA).

**16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?**

Yes, pharmaceutical laboratories or medical device manufacturers, as well as their licensees, can support scientific or educational meetings. According to Ministerial Resolution No 474-2020/MINSA, educational and scientific activities (congresses, symposiums, seminars, and others) targeting healthcare professionals should not be primarily used for promotional purposes.

There is no difference between these two sectors regarding the promotion of products.

**17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.**

There are no specific regulations regarding the relationships between the industry and patient organisations, including funding.

**18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?**

Yes, it is possible to delegate promotional (advertising) activities to a third party through a service agreement. There are currently no provisions in existing regulations that prohibit such outsourcing.

**19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?**

From the perspective of health regulations in Peru, it is not mandatory to report transfers of value made by permit/authorisation holders to healthcare professionals.

**ENFORCEMENT**

**20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?**

The Law for the Suppression of Unfair Competition establishes that the administrative responsibility arising from the commission of unfair competition acts through advertising corresponds, in all cases, to the advertiser. However, in some cases the means of social communication (where the ad is disseminated) and/or the ad agency (which created the infringing ad) will also be responsible. Their responsibility is independent from such corresponding to the advertiser.
The determination of the existence of an act of unfair competition shall not require proof of the awareness or knowledge of the person or entity that committed such act. Nor shall it be necessary to prove that such act causes actual harm to the detriment of another competitor, consumers or economic public order; it shall be sufficient to prove that the possibility of such harm may occur.
As already mentioned, ads do not require authorisation or supervision prior to its dissemination by any authority. The supervision of compliance with the above-mentioned law is conducted completely on the advertising that has already been disseminated in the market.
In compliance with the Law for the Suppression of Unfair Competition, the responsibility of proving the veracity and accuracy of objective statements on products and services advertised corresponds to whom has communicated them in his capacity as advertiser.
According to the Law on Supression of Unfair Competition, the sanctions may be as follows:

*Monetary sanctions*
From a warning (no monetary fine) to a US$974,300 (approximately) fine depending on the infringement. For: (1) non-serious infringement without real effects in the market – a warning; (2) not serious infringement – to US$72,300 (approximately); (3) serious infringement – to US$348,000 (approximately); and (4) very serious infringement – to US$974,300 (approximately).
The Unfair Competition Commission may have in consideration to determine the severity of infraction and the application of corresponding fines, among others, the following criteria:

- illicit benefit resulting from the infraction commission
- probability of infraction detection;
- modality and scope of unfair competition act;
- dimension of the affected market;
- market fee of the offender;

- the effect of the unfair competition act on effective or potential competitors in regards to other agents who participate in the competitive process and on the consumers and users;
- length of unfair competition act; and
- recurrence and reiteration in the commission of an unfair competition act.

In order to keep the sanction, the Commission uses a mathematical formula, taking into account the result of criteria before mentioned, as follows: 'The illicit benefit divided between detection probability and the result multiplied by aggravating and mitigating factors'.

*Precautionary measures*
These measures can be ordered at any stage of the proceeding. These are namely ceased from the infringing action, close of an establishment or ban of a website, immobilisation of goods, among others.

*Corrective measures*
These measures are to revert the effects of an infringing conduct or to avoid from happening again forward (eg, cessation of the infringement conduct or publication of a rectification).

*Fines for non-compliance*
If the fine or any measure is not complied with, additional sanctions can be ordered.

**21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?**

The Unfair Competition Commission is the national administrative entity responsible for the verification of compliance with the rules governing advertising. The determination of the existence of an act of unfair competition shall not require proof of the awareness or of the actual committing of such act.

**FUTURE DEVELOPMENTS**

**22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?**

There are currently no anticipated significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year. Additionally, there are no specific general practice or enforcement trends that have become apparent in Perú over the last year or so.