

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.
<p>With respect pharmaceuticals, Decree 677 of 1995 establishes the main principles of advertising and promotion but Decree 334 of 2022 and Resolution 1896 of 2023 governs advertising, non-advertising information, promotion, and marketing of pharmaceuticals, biologics, medicinal gases, radiopharmaceuticals, homeopathic and phytotherapeutics through websites, digital platforms, and other media. This regulation covers both, over-the-counter (OTC) and under prescription drugs.</p> <p>Decree 4725 of 2005 governs the promotion and advertising of medical devices. Devices classified as customizable for dental, ear, or eye care have specific rules.</p> <p>Law 1480 of 2011 establishes rules for consumer protection and applies to pharmaceuticals and medical devices when advertising and promotion is directed to the final consumer. This law must be strongly considered along with the specific regulations for each type of product.</p> <p>Regarding industry and self-regulatory codes, most relevant are held by ANDI and AFIDRO, two Colombian associations that brings together associates in these industries.</p>
2. How is ‘advertising’ defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?
<p>For pharmaceuticals, ‘advertising’ is defined as any form of communication carried out to promote or disseminate marketing of medicines by means of information that influences consumption decisions of these products.</p> <p>There is an additional term that becomes relevant for pharmaceuticals and that is non-advertising information, meaning all the technical and scientific information of the drug duly approved within its marketing authorisation. This is relevant because even prescription drugs may provide this type of information through their official websites with domain (.com.co) following rules stated at article 13 of Decree 334/2022.</p> <p>In turn, ‘promotion’ is defined as all informative and persuasive activities carried out to induce the prescription, dispensation, supply, acquisition, or use of pharmaceuticals.</p> <p>Regulation on medical devices does not expressly define these terms. In practice, the Regulatory Authority applies definitions established under Law 1480 of 2011 that defines ‘advertising’ as any form and content of communication intended to influence consumer decisions and defines promotions as temporary offers of products under special favourable conditions or free of charge as an incentive for the consumer. Promotions can also include offering products with additional content than usual, free of charge or at a reduced price, as well as those made through incentives such as raffles, sweepstakes, contests and other similar, in cash, in kind or with accumulation of points.</p>
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?
<p>The National Institute for Drug and Food Surveillance, herein referred as to INVIMA, regulates, and enforces advertising and promotion of pharmaceuticals and medical devices, with respect to sanitary regulations.</p> <p>The Superintendency of Industry and Commerce (SIC) regulates and enforces advertising and promotion of any type of products and services, including pharmaceuticals and medical devices, with respect to consumer care protection.</p> <p>The powers and jurisdictions of these authorities are separate and not exclusive.</p>
4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, for example food supplements, special nutritional

products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?
No. Aside from the scope indicated in the first answer, food supplements and special nutritional products have their own regulation.
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 (advertisement) in your country and if so, which ones?
<p>No. Advertising of prescription drugs is restricted to healthcare professionals (HCP) and technical or scientific media. Only non-advertising information is allowed through the website of the manufacturer, importer or marketing authorisation holder, prior report to INVIMA.</p> <p>Regarding OTC drugs, it is possible to promote or advertise them directly to the public, prior report to INVIMA.</p> <p>Concerning medical devices, only those classified under risk I can be advertised or promoted directly to the public. It is not possible to advertise or promote medical devices under risk IIa, IIb and III directly to the public without prior authorisation from INVIMA.</p>
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?
<p>It is allowed and regulated for OTC drugs through Resolution 1896 of 2023 and it must disclose the following mandatory sentences:</p> <ul style="list-style-type: none"> • It is a medicine. • Do not exceed its consumption. • Marketing authorisation number. • Read indications and contraindications on the label. • If symptoms persist, consult your doctor. <p>Advertising must be clear, objective, truthful and without exaggerating the product properties. It shall not mislead by assertion or omission, nor induce its indiscriminate, unnecessary, or inappropriate use. Specific rules and restrictions are listed under articles 15 and 17 of Resolution 1896 of 2023.</p> <p>For medical devices, it is not regulated but it is allowed if authorised by INVIMA. Advertising must be in accordance with the information approved on the marketing authorisation and must adhere to the truth without exaggerating its benefits.</p> <p>In all cases, information and affirmations must be scientifically and technically supported.</p>
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)?
<p>Yes, only for advertising or promotion activities of medical devices under risk IIa, IIb and III addressed to the public and or through massive media. The material must be submitted to INVIMA for evaluation and approval paying the agency fee and can take six months approximately.</p> <p>With respect to OTC drugs, there is no need to request prior approval from INVIMA, but advertising or promotion activities addressed to the public and/or through massive media must be informed or reported to INVIMA whose surveillance will be done subsequently.</p> <p>Also, non-advertising information to be disclosed on the websites com.co of the manufacturer, importer or marketing authorisation holder shall be reported to INVIMA either for OTC or prescription only drugs.</p>
8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?
No. Off-label information and unauthorised pharmaceuticals or medical devices cannot be promoted or advertised in Colombia.
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?
<p>Regulations on pharmaceuticals and medical devices restricts comparative advertising if it is pejorative, imputes, defames, or causes damage to third parties but it does not provide specific guidelines for the industry. Accordingly, comparative advertising is ruled by consumer care protection directives which settle the following conditions:</p> <ul style="list-style-type: none"> • The comparison must be between goods, services or establishments that satisfy the same needs or have the same purpose. • The comparison must refer to objective or verifiable characteristics of the activities, establishments and goods or services, therefore it must be made between one or more essential, relevant, verifiable, and representative characteristics thereof. • Subjective judgements or appraisals do not constitute a valid term of comparison for the consumer. • Real characteristics of products compared must be informed and shall not mislead as to the same. • Comparison must be made between products analogues, meaning those of the same characteristics, quality and uses. <p>According to this, it would not be possible to refer to a competitor product or indication that has not been authorised yet.</p>
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?
<p>HCPs are defined as individuals or companies providing healthcare services in Colombia and there are no regulations restricting advertising or promotional activities directed to them unless any of those include gifts, perks, or any donation to the HCP, not bound or caused by a contractual relationship duly established between the manufacturer and the HCP.</p>
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?
<p>The same rules stated under Questions 5, 6 and 7 applies to these types of activities depending on whether addressed exclusively to other HCPs or to the public in general. Additionally, advertising directed to the public through influencers, testimonials and HCPs shall attend the Good Practices of Influencer Advertising Guide published by the consumer care protection authority SIC, which provides specific guidelines on the correct way to publish messages and content on social networks and the internet to protect consumers.</p>
12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?
<p>Yes. Recommendations or endorsements must be verifiable and supported on scientific, technical, and statistical data when applicable and should be readily identifiable as commercial publications or paid advertisement to not affect credibility.</p>
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.
<p>Yes, it is possible to provide HCPs with samples of pharmaceuticals or medical devices duly authorised in Colombia and labelled as 'sample not for commercial use'. Samples exceeding the value of one monthly salary within a six-month frame should be reported as a transfer of value.</p> <p>Regarding donations, gifts, or money, article 106 of Law 1438/2011 expressly forbids giving any type of benefits whether in cash or in kind to HCPs unless linked to the fulfilment of a contractual or labour relationship formally established with the HCP.</p> <p>Any transfer of value (in kind or cash) shall be reported to the Ministry of Health according to the amount limits and procedure established by Resolution 2881/2018.</p>

14. What rules govern the offering of hospitality to healthcare professionals?
<p>There are no specific laws governing the offering of hospitality to HCPs, but Resolution 2881/2018 provides the rules and procedure to report hospitalities as value transfers and the monetary limits subject to that report. Additionally, hospitality shall not consist of a gift, perk, or benefit to the HCP as stated in article 106 of Law1438/2011.</p> <p>In practice, the industry establishes its policies for this activity based on the transfer of value rules, the general restriction of giving gifts and perks to HCPs, their compliance rules, ethics code, and/or self-regulatory codes such as those established by the associations ANDI and AFIDRO, when applicable.</p>
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?
<p>Donations are not considered promotional or advertising but should be addressed to attend or improve healthcare services, or for social and humanitarian purposes and not to conditionate the prescription, use or purchase of the product.</p> <p>Donations are governed by Decree 218 of 2019, Decree 4725 of 2005 and local guides issued and updated by INVIMA.</p>
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?
<p>Yes. Pharmaceutical laboratories or medical devices manufacturers or their licensees can support or sponsor scientific or educational meetings aimed to promote new products and technologies among HCPs, to educate and train on new trends to improve people's health and quality of life.</p> <p>Any transfer of value made to HCPs or Health Institutions shall be reported according to the rules and procedures settled by Resolution 2881/2018.</p>
17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.
<p>In Colombia, there are no rules governing patient organisations. The founding or sponsoring of these organisations and their programs must attend principles of transparency and ethics. Any transfer of value must be reported according to the provisions of Resolution 2881/2018.</p>
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?
<p>Yes, it is possible, and parties shall be jointly and severally liable for the fulfilment of the regulations on the advertising of these products in Colombia. Co-promotion is not regulated but parties can engage in jointly agreements to develop these activities.</p>
19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?
<p>Yes, it is mandatory as provided by Resolution 2881/2018. This resolution establishes the activities, amounts, people, and requirements subject of transfer of value.</p>
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?
<p>Penalties for infringement consumer protection rules on advertising includes fines up to US\$500,000 approximately for 2024, temporary or definitive prohibition to produce, distribute or offer certain products to the public, restriction to advertise without prior evaluation and authorisation from the authority. These penalties are imposed by the consumer care protection authority SIC.</p> <p>Penalties for infringement of the sanitary regulations on advertising includes fines up to US\$2m approximately for 2024, seizure of products, suspension, or cancellation of the marketing authorisation, temporary or definitive closure of facilities. These penalties are imposed by the Health Agency INVIMA.</p>

<p>Both SIC and INVIMA, are truly active enforcing their regulations and SIC announces publicly its sanctions when parties involved in the process are key actors in the relevant industry.</p>
<p>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?</p>
<p>INVIMA regulates and enforces advertising and the promotion of pharmaceuticals and medical devices, with respect to the sanitary regulations.</p> <p>SIC regulates and enforces advertising and promotion of any type of products and services, including pharmaceuticals and medical devices, with respect to consumer care protection.</p> <p>Competitors can take directions in relation to promotion (advertising). Depending on the infringement, these may be unfair competition actions, trademark infringement actions, civil court actions and even report to the Health Agency any violation so that the authority pursues the investigation directly.</p>
<p>FUTURE DEVELOPMENTS</p>
<p>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?</p>
<p>Not for the moment. As of 1 January 2024, Resolution 1896/2023 came into force, so no new developments on pharmaceutical advertising are anticipated.</p>