

PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES
Authors: Att. Patricio Quevedo & Att. Thais Cedeño Bermudez
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>In Ecuador, the regulatory body that governs the promotion and advertising of pharmaceuticals and medical devices are:</p> <ul style="list-style-type: none">• the Organic Health Law and its Regulations;• the Organic Consumer Defense Law and its Regulations;• the Regulation for the Advertising and Promotion of Medicines in General, Medicinal Products, Homeopathic Medicines and Medical Devices.
2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?
<p>In Ecuador, there is a legal distinction between the promotion and advertising of pharmaceuticals or medical devices. According to the Regulation for the Advertising and Promotion of Medicines in General, Homeopathic Medicines and Medical Devices, 'promotion' is defined as 'informative and persuasive activities carried out by manufacturers and distributors of medicines, processed natural products for medicinal use, homeopathic medicines, and medical devices, aimed at prescribers with the purpose of inducing the prescription, supply or acquisition of these products, through the medical visit'.</p> <p>On the other hand, advertising refers to 'any form of computerized, written, visual and other offers, directed to the general public, intended to promote the prescription, dispensation, sale, and use or consumption of medicines, processed natural products for medicinal use, homeopathic medicines, and over-the-counter medical devices'.</p> <p>In other words, promotion refers to sales strategies that include advertising exclusively directed towards healthcare professionals and may involve actions like medical visits, educational talks, and deliverance of informational materials. Advertising, on the other hand, is focused on the public and can take the form of print, television, radio, digital advertisements, among others, aiming to influence the purchasing decisions of medicines and medical devices.</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 authorities in charge of regulating and supervising the promotion and advertising of pharmaceuticals and medical devices are:</p> <ul style="list-style-type: none">• the Ministry of Public Health (MOH); and• The National Agency of Regulation and Sanitary Control (ARCSA). <p>The Ministry of Health is the governing body of the National Health System (public and private) and is the state entity responsible for directing public policy, creating regulations and controlling all health-related activities, as well as the operation of establishments through its zonal units (zonal coordinating divisions in the territory) and through its controlled agencies.</p> <p>For supervision, most of the state powers are delegated to the National Agency for Regulation, Control and Sanitary Surveillance, an entity dependent from the Ministry of Public Health, which is responsible for controlling and monitoring the promotion and advertisement of pharmaceutical products and products for human use and consumption in general. ARCSA also authorises pharma companies to operate and grants sanitary registrations to products in the country. In any administrative case pertaining to enforcement of limitations in promotion and/or advertising it will be ARCSA who will act as controlling agency with the capacity of imposing sanctions.</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?
<p>In general, there are general advertising and promotion rules that apply to all products, such as the prohibition of misleading advertising, misleading advertising, and minimum labelling requirements. These can be further developed in the case of specific products, such as processed foods etc.</p> <p>The same advertising and promotion rules for pharmaceuticals apply to medical devices, they are within the same group such as processed natural products for medicinal use and homeopathic pharmaceuticals.</p> <p>A notable case exists with respect to baby food (formula) as a replacement of breast feeding. Ecuador has strong policies that limit any type of advertisement of such products, especially if they induce purchase with comparison to breast feeding.</p> <p>It is important to state that any prescription requiring medication in Ecuador cannot be advertised through any medium. The only available mechanism for pharma companies in that regard is to promote those products to prescribers.</p>
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>Advertising directly to the public is only possible for over-the-counter (OTC) medication or devices.</p> <p>Advertising of medicines in general, natural processed products for medicinal use, homeopathic medicines, medical devices, shall not be allowed by any means in the following cases:</p> <ul style="list-style-type: none"> • those classified as products for sale under medical prescription, in accordance with the provisions of the Ecuadorian sanitary registration certificate; • those pharmaceuticals containing psychotropic or narcotic substances; and • those products whose sale is determined by medical prescription or whose use is suspended for reasons of public health, epidemics, or sanitary emergencies.
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>No, in Ecuador the advertising of pharmaceutical and health products through digital platforms on the internet is not regulated. Still, the prohibition for advertising of prescription medications is construed as very broad, so it would be debatable that while specific regulations relating to those channels are absent, advertisement is still not allowed. However, the regulator has not clarified the issue fully up to this point.</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>No, ex ante authorisations are not required. ARCSA conducts ex post controls.</p>
8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?
<p>No, in Ecuador it is not allowed to advertise information about unauthorised pharmaceutical products. In fact, it is forbidden to advertise through containers, labels, labels, packaging, inserts or leaflets of other products that accompany medicines, processed natural products for medicinal use, homeopathic medicines, OTC medical devices.</p> <p>Off-label information may specifically contradict a prohibition in secondary regulations, that specifically bans messages: '[...] Inducing indiscriminate use of the product, or responses not scientifically demonstrated. Suggesting that the use of the product should be permanent'.</p>
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?

According to Article 18, paragraph 'd' of the relevant regulation for advertisements, the use of offensive comparative advertising directed at other brands, products, services, companies or organisations is prohibited.

While the comparison shall be offensive and which translates to misleading or denigratory, there is no clear regulation to fully explain what information is considered non-offensive in this context. This lack of clarity amplifies the possibility that a company may be exposed to risks of unfair competition and reputational damage when engaging in comparative advertising. The practice is extremely uncommon in Ecuador in general.

In fact, comparative advertising is prohibited when it affects the image of other products, or when it is detrimental to the good name of the products or prestige of third parties, or when it attempts to create a situation of rejection towards the products of competitors or their users, an argument that may be used to determine that comparative advertising is offensive.

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?

In Ecuador, according to Article 193 of the Organic Health Law, health professions are those persons whose third or fourth level university training is specifically and fundamentally aimed at providing professionals with knowledge, techniques and practices related to individual and collective health and the control of its conditioning factors.

It is possible to have direct promotion towards health professionals. In Ecuador these people are known as 'medical visitors', and for this they must be registered with the Ministry of Public Health and carry the corresponding card during the medical visit. Medical visit is essentially the only allowed way to promote pharmaceutical products.

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 governing promotional and advertising activity carried out virtually. In principle, the rules on advertising are of general application, including advertising in digital and traditional media.

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?

Yes, in Ecuador, according to Article 18, paragraph 'n' of the relevant advertising regulations it is stated that, the advertising of medicines and medical devices is prohibited if images and names of health professionals recommending the use of the medicine or medical device are used.

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 health professionals with samples of medicinal products. Medical visitors may only give and promote medicines, processed natural products for medicinal use, homeopathic medicines, and medical devices to health professionals authorised to prescribe, these are: dentists, physicians and obstetricians.

Different rules apply to the public sector, however. It is not possible for health professionals to be visited by medical visitors within the public health centres, and it is prohibited for them to receive donations in money or gifts. Any donations must be made through the health centre through public donation alliances.

In addition, according to the codes of ethics of each health professional, it is forbidden to receive a percentage from the prescription of medicines, medical devices, medical appliances, eyeglasses, etc, as well as financial remuneration to intermediaries of any kind between professionals and patients.

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

<p>There is no specific rule regarding the offering of hospitality to health professionals. However, the offering of these things, at least for public service health professionals, may fall under the criminal type of bribery, or a violation of the Organic Law of the Public Servant.</p> <p>However, in general, the codes of ethics of each health professional restrict or limit certain actions that may fall under 'hospitality', such as obtaining money for advertising pharmaceuticals or medical devices, or from intermediaries.</p> <p>There is no specific standard that divides what could be considered as lawful hospitality from what could be considered as a way of exerting undue influence.</p>
<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>
<p>No, donations have not been considered as a promotional and advertising instrument in our local legislation.</p> <p>In the case of medicines, there is a secondary regulation in force to authorise the importation by exception and importation by donation of medicines, biological products, medical devices and biochemical and diagnostic reagents. This regulation provides rules for making donations to public institutions, which shall be done after an official request.</p>
<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>
<p>Yes, pharmaceutical laboratories and medical device manufacturers, as well as their licensees, may support scientific or educational meetings in Ecuador. There is no express regulatory difference between these two sectors from the perspective of product promotion rules. In principle, the express prohibition is that they cannot advertise through the direct delivery, to the public or users, of samples of medicines, processed natural products for medicinal use, or homeopathic medicines. In other words, they can 'sponsor' educational events and symposiums, but they cannot deliver products directly and free of charge as advertising.</p>
<p>17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.</p>
<p>In Ecuador, there are currently no specific regulations applicable to the relationship between the pharmaceutical industry and patient organisations.</p>
<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>
<p>No, co-promotion is not regulated in Ecuador. Likewise, it is not possible to delegate promotional activities, since only the holders of the health notifications for medicines may exercise promotions through visits to prescribers.</p>
<p>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</p>
<p>No, there is no specific process in place to report any transfers of value currently.</p>
<p>ENFORCEMENT</p>
<p>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>
<p>Penalties for infringement consumer protection rules on advertising includes fines up to US\$500,000. The penalties that may be incurred are a fine of ten basic unified salaries (US\$4,600) and temporary or definitive foreclosure of the corresponding establishment for non-compliance with Article 143 of the Organic Health Law.</p> <p>It is not usual for ARCSA to apply such sanctions as it has limited resources for enforcement in general. If it does so, usually the foreclosure is temporal and not exceeding five business days. The sanctions are rarely announced publicly, a typical exception being cases surrounded by media attention.</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?

The authority in charge of applying sanctions in this case is ARCSA as an agency attached to the Ministry of Public Health.

Competitors have several options. They may choose to report the issue to ARCSA, but can also build an antitrust case (unfair competition falling within the jurisdiction of the antitrust authority) or claim regular damages before civil judges.

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?

No, currently there are no bills in the National Assembly (legislative body) or the Ministry of Public Health (administrative resolutions) that attempt to expand or develop the field of pharmaceutical or medical device promotion.