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 advertising and promotion of pharmaceutical products is subject to the regulations issued by the National Administration of Medicine, Food and Medical Devices (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) (ANMAT), through Disposition No 4980/2005, and by the National Ministry of Health, through Resolution No 627/2007.

Law 16,463 (commonly known as the Medicines Law) provides a general prohibition on advertising, meaning that any form of public announcement on products that are sold under prescription is forbidden. Therefore, prescription medicines can only be promoted to healthcare professionals who are authorised to prescribe or dispense medicine and they cannot be advertised to the general public.

The Argentine Chamber of Medical Specialities (CAEMe) is a chamber that gathers laboratories whose members are international pharmaceutical companies located in Argentina. It has its own Code of Pharmaceutical Marketing Practices and interactions with Healthcare Professionals (the 'CAEMe's Code') that sets out rules that must be followed by its members in relation to advertising and promotion of pharmaceutical products.

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

'Advertising' – both of pharmaceutical products and medical devices – is defined by ANMAT (more precisely in Disposition No 4980/2005) as a technique that, applied in an organised way through the media in general, aims to inform or promote the characteristics, advantages or qualities of goods or services to provoke and obtain their acquisition.

Given the prohibition on advertising by the Medicines Law, only OTC products can be advertised to the general public and any advertising must be carried out in accordance with, and under the limits and parameters set out in, ANMAT Disposition No 4980/2005.

Pharmaceutical products available only by prescription can only be promoted to healthcare professionals subject to several limits. In this sense, Resolution No 627/2007 establishes good practices for the promotion of prescription medicine and sets out the limits for such promotion.

The legal difference between advertising and promotion of pharmaceutical products lies in the nature and scope of communications. 'Medicine/Medication advertising' refers to the disclosure of information about medications intended for the general public, while 'Medical/Medication promotion' involves actions directed at healthcare professionals, such as doctors or pharmacists, with the aim of influencing the prescription, dispensing, or sale of these medications. Both are regulated by the health authority to ensure ethical and safe practices in the healthcare field.

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 authority that controls and supervise the advertising and promotion of pharmaceutical products is ANMAT. There has been a recent judicial case that has reinforced ANMAT's authority to control the advertising and promotion of these products, excluding other authorities such as the Fair-Trading Decree No 274/2019 (*Laboratorio Elea Phoenix SA v EN M Desarrollo Productivo re Direct Appeal*, file No. 34794426/20).

It is worth noting that under ANMAT Disposition No 6516/2015, marketing authorisation holders of products sold under prescription, must notify ANMAT about any promotion of products to healthcare professionals, together with the promotional material in the format in which it will be delivered.

Notification of such promotions must be made within 48 hours from dissemination of the material.

There is no relationship between self-regulatory process and the supervisory and enforcement function of the competent authorities.

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?

The other products subject to advertising regulations established by ANMAT Disposition No 4980/2005 are: dental products; diagnostic reagents; cosmetic products; medical devices; household sanitary products; dietary supplements and food products as determined by the regulatory authority.

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?

Given the prohibition on advertising by the Medicines Law, only OTC products can be advertised to the general public and any advertising must be carried in accordance with the parameters set out in ANMAT Disposition No 4980/2005.

The parameters for advertising include, among others, that it:

- must be for the proper use of the medicine, including its characteristics in an objective, truthful, precise and clear way, without any misleading information;
- must not be misleading, indirect, subliminal or unfair;
- must not lead to fear or anguish, suggesting that the health of someone may be affected if they do not use it;
- must provide any scientific information included in the advertising or promotion to the ANMAT to review, if requested;
- cannot be intended for the patient to use more than strictly necessary;
- must include the following wording 'read the package leaflet carefully and if in doubt consult your doctor and/or pharmacist'; and
- must be in Spanish, in clear and accessible language.

As for medical devices, according to Disposition No 4980/2005, only medical devices which, by its intrinsic nature and proposed use may be used or indicated for its use directly by the patient, can be advertised to the general public.

Medical devices of which condition of use is to be used exclusively by professionals or sanitary institutions cannot be advertised to the general public, even though the products may be used or indicated for its use directly by the patient.

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?

No, it is not specifically regulated, so general advertising and promotion regulation would apply to any advertising or promotion that wants to be made through the internet and social media.

Thus, the rules set out in ANMAT Disposition No 4980/2005 on advertising apply equally to the internet or social media advertising. OTC products can be advertised on the internet or social media, provided the advertisement complies with all the requirements set out in the disposition.

Since prescription medication can only be promoted to healthcare professionals, if the internet or social media is used to promote it, the marketing authorisation holder must put in place the necessary mechanisms or measures to guarantee that only healthcare professionals have access to it. The marketing authorisation holder is responsible for any access by the general public to information on prescription medications.

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)?

Under ANMAT Disposition No 6516/2015, marketing authorisation holders of products sold under prescription must notify ANMAT about any promotion of products to healthcare professionals, together with

the promotional material in the format in which it will be delivered. Notification of such promotions must be made within 48 hours from dissemination of the material.

This presentation is considered as a sworn statement and must be signed by the legal representative or an attorney-in-fact and the technical director. In the case of an infringement of promotional regulations, ANMAT will send the relevant notifications to the companies' owners of the products to stop them from further disseminating the material.

Each new campaign that uses the same promotional material must be notified to ANMAT.

There is no need to make this notification for OTC products, however, it is important to take into consideration that ANMAT uses a real time automated capture system for monitoring advertisements targeted at the general public.

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

The general principle is that it is not possible to promote a product that is not registered in Argentina, even to healthcare professionals. No pharmaceutical products can be advertised or promoted for indications not approved by the ANMAT, meaning that no off-label promotion of products is allowed.

Resolution No 627/2007 establishes that any promotion of medicines not authorised for commercialisation is forbidden. It also states that all the contents of the promotion of a medicinal product must match the data, characteristics, and identifications listed on the registration certificate (marketing authorisation). ANMAT Disposition No 4980/2005 has similar provisions for the advertising of OTC products.

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?

Section 10 of Annex II of ANMAT Disposition No 4980/2005 expressly refers to comparative advertising. If the rules are complied with, comparative advertising will be legal and valid.

Comparative messages must not:

- create confusion with the comparison;
- ridicule or denigrate the other product;
- distort the image of other products;
- attack the good name or prestige of third parties;
- try to create a rejection of the competitor's products or its users;
- mention active ingredients not contained in the advertised product; or
- mention possible adverse or collateral side effects of active ingredients not contained in the advertised product.

Considering the general principle that it is not possible to promote a product that is not registered in Argentina, even to healthcare professionals, pharmaceutical products cannot be advertised, promoted for indications not approved by the ANMAT, or compared to products not registered.

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?

There is no specific definition of healthcare professionals and healthcare organisations.

National Law 17,132, which is in force for the city of Buenos Aires and certain other provinces, sets out the rules for the practise of medicine, dentistry, and their collaborative activities. It states general parameters of these practises and regulates the requirements a person must meet to be a doctor, a dentist or a collaborator in those activities.

CAEMe's Code defines Healthcare Professionals saying that notwithstanding provisions contained in the legal rules in force, a Healthcare Professionals is 'any member of the medical, dental, pharmacy or nursing professions, or any other person who, in the course of his or her professional activities, may perform or

condition the activities of prescribing, recommending, purchasing, distributing, dispensing or administering a medicinal product'.

With regard to the regulation on promotional (advertisement) restrictions toward healthcare professionals, it is prohibited to offer gifts, bonuses, benefits, or cash to healthcare professionals to induce prescription, recommendation, dispensation, supply, sale, administration, or consumption of medicinal products.

Resolution 627/2007 permits pharmaceutical companies to sponsor healthcare professionals to attend medical congresses and other scientific events in Argentina or abroad. They must publicly inform the professionals of the conditions for entry and select attendees using equitable and transparent mechanisms. Companies may not use the promise of prescribing a particular product to grant entrance to the event.

CAEMe's Code prohibits companies from sponsoring international events, unless the location makes sense from a security or logistics perspective (for example, most participants are foreign nationals).

At the time of designing their medicinal products promotion, companies should consider that their first priority is the safety of the patients.

CAEMe's Code permits gifts of nominal value that relate to the practise of medicine, pharmacy, or scientific educational activities. Gifts must be of modest value and cannot be delivered on a frequent basis to the same recipient.

The following gifts are prohibited:

- cash or cash equivalents such as gift certificates and vouchers;
- gifts for the personal benefit of a healthcare professional, such as CDs, DVDs, sports or entertainment tickets, and electronic items; and
- any other gifts that give an impression of preferential treatment.

CAEMe's Code permits companies to provide promotional aids, such as pens or pads of paper, at medical visits and events attended by healthcare professionals.

Promotional items provided during medical visits must be related to:

- the practise of medicine or pharmacy and/or provide a benefit for patients;
- the scientific and/or educational activity attended by a healthcare professional. Promotional items that may be delivered during medical visits, may also be offered at events.

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?

As mentioned above, the rules set out in ANMAT Disposition No 4980/2005 on advertising apply equally to the internet or social media advertising. OTC products can be advertised on the internet or social media, provided the advert complies with all the requirements set out in the disposition.

Since prescription medication can only be promoted to healthcare professionals, if the internet or social media is used to promote it, the marketing authorisation holder must put in place the necessary mechanisms or measures to guarantee that only healthcare professionals have access to it.

There are no specific rules or regulations on the virtual interaction with healthcare professionals.

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?

Annex II, point 5 of Disposition 4980/2005, expressly refers to the possibility of healthcare professionals to endorse products. However, it clarifies that such endorsement must not exceed the authorised indications of the product by ANMAT. Advertisements that include healthcare professional's endorsement should also mention the registration number of the involved professional.

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.

In Argentina, it is legally allowed to provide free samples of medications to healthcare professionals in accordance with the regulations established by the Ministry of Health and ANMAT (Resolution No 627/2007

and Disposition No 4980/2005). Nevertheless, free samples distributed through healthcare professionals to the public, are given under their responsibility.

CAEMe's Code determines that a reasonable number of free samples may be offered to healthcare professionals authorised to prescribe medicinal products.

Each sample must bear a statement identifying it as such, by way of illustration 'Free Sample – Sale Forbidden', 'Sample with no commercial value' and/or any other term that confirms it is a sample, and not the dosage form licensed for sale.

The delivery of samples of medicinal products containing psychotropic or narcotic substances, as defined in the international agreements, is forbidden, the same applies to medicines that may cause dependency or give rise to public health problems for improper use, and of any other medicinal product as determined by regulatory authorities.

Regarding gifts or donation of money, section 15 of Resolution 627/2007 provides that granting, offering, or promising healthcare professionals any type of incentives or benefits of any nature, such as bonuses, pecuniary advantages, in kind, or of any other kind, is prohibited. Therefore, is not possible to donate money or provide gifts of significant value.

CAEMe's Code permits gifts of nominal value that relate to the practise of medicine, pharmacy, or scientific educational activities. Gifts must be of modest value and cannot be delivered on a frequent basis to the same recipient.

As mentioned above, the following gifts are prohibited:

- cash or cash equivalents such as gift certificates and vouchers;
- gifts for the personal benefit of a healthcare professional, such as CDs, DVDs, sports or entertainment tickets, and electronic items; or
- any other gifts that give an impression of preferential treatment.

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

There are no specific rules regarding offering hospitality to healthcare professionals.

CAEMe's Code provides that the offer or delivery of hospitality independent from a scientific event or with no legitimate business purpose is contrary to the guidelines established in the Code.

According to such Code, hospitality should always be secondary to the main purpose of the event and limited to provision of the necessary means for attendance and participation in such event. The concept of hospitality, pursuant to such Code, includes payment of actual travel, registration, accommodation and meal expenses by member companies, which must be reasonable and limited to the days on which the scientific or professional event is planned to be held. In addition, according to such Code, hospitality will not include the sponsorship or organisation of entertainment or leisure activities (such as sports events, music events etc) and it should not be extended to persons other than healthcare professionals.

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, in principle they are not considered as a promotional or advertising tool; however, this should be further analysed on a case-by-case basis. There is no specific regulation on donations.

CAEMe's Code provides that donations, grants or benefits in cash or in kind to institutions, organisations, associations or foundations related to healthcare areas that provide social or humanitarian assistance services, or conduct research, education or training services, are allowed provided they comply with certain parameters established therein, such as that they are documented and they do not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer medicinal products, among others.

According to CAEMe's Code, donations and/or grants to individual healthcare professionals are not allowed.

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?

Ministry of Health Regulation 627/2007 permits pharmaceutical companies to sponsor healthcare professionals to attend medical congresses and other scientific events in Argentina or abroad. They must publicly inform the professionals of the conditions for entry and select attendees using equitable and

transparent mechanisms. Companies may not use the promise of prescribing a particular product to grant entrance to the event.

There is no specific regulation on the matters as regards to medical devices.

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

There is no regulation in relation to interaction or engagement with patient organisations. However, in principle, general principles apply meaning that it is not possible to unduly benefit these organisations nor is it possible to promote prescription pharmaceutical products to them.

CAEMe's Code provides guidance on interactions for its members with patient organisations, which must be followed. The main considerations are:

- No member company can request to be the sole funder of a patient organisation.
- The members' obligations and fees (if any) must be stated in a written agreement to be signed by the parties.
- Member companies will not influence the editorial content of patient organisations' material to favour their commercial or promotional interests.
- When member companies hold meetings with patient organisations, they must ensure that the venue and location are appropriate and conducive to the development of the meetings, and meals or refreshments provided by them must be modest.

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 or advertising activities to a third party (eg, an agency) through an agreement, but any promotional or advertising activity they perform must always comply with Disposition No 4980/2005 and Resolution No 627/2007, and all applicable legislation on promotion and advertising of medical products.

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

There is no national law that obliges pharmaceutical companies to report, inform or make public transfers of value paid to healthcare professionals.

However, in 2016, the legislators of the city of Buenos Aires, passed a law providing that the manufacturers, importers, and distributors of pharmaceutical and biological products that granted or provided goods, services, benefits, or awards with monetary value to healthcare professionals within the city of Buenos Aires should inform the local health authority.

Although the law was published and came into force, it was never regulated and therefore complying with it is not possible for pharmaceutical companies.

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 most common infringements when promoting and advertising medicines are:

- advertising or promoting medical products that are not authorised by ANMAT;
- offering rewards or benefits to healthcare professionals;
- misleading advertising;
- indirect advertising of prescription medication to the general public;
- not complying with all the requirements set out in Ministry of Health Regulation No 627/2007 or ANMAT Disposition No 4980/2005 in relation to promotion or advertising material.

When there is an infringement of any of the advertising and promotion rules, the Medicines Law applies, and the punishment will include a monetary fine. The fines vary in scale as follows:

- Mild infringements: ARS1,000 to 10,000.
- Moderate infringements: ARS10,001 to ARS50,000.

- Serious infringements: ARS50,001 to ARS300,000.
- Very serious infringements: ARS300,001 to ARS1m.
- When imposing fines, the ANMAT will take into consideration the sanctioned party's prior infractions.

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 enforcement authority in relation to infringements regarding advertising and promotion of pharmaceutical and medical device products is ANMAT. ANMAT is quite active in controlling advertising and promotion of these type of products.

Typically, the action taken by competitors is to file a denounce before ANMAT that its competitor is infringing the advertising or promotion rules for ANMAT to follow up on that. Only when the company is considered injured or damaged by the advertisement or promotion of another company will it file a judicial complaint. In such scenario the company shall evidence the damage caused to it by the advertisement and claim compensation for such damages.

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?

Currently, there are no developments in the field of pharmaceutical or medical device promotion. Nor do we have evidence of new general trends regarding practices or regulatory enforcement in Argentina during 2023.

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