PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

Authors: Att. Andrea Abascal

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.

In Chile, promotion and advertising of pharmaceuticals are strictly regulated in the Sanitary Code and in the Supreme Decree No 3, of 2010, issued by the Health Ministry (DS No 3).

It is important to point out that, regarding drugs, in Chile it is only permitted to advertise over-the-counter (OTC) pharmaceuticals.

Regarding Medical Devices, there's no sanitary regulation that prohibits or limits its promotion or advertising, nevertheless they are subject to the Consumers Law regulation, which is contained in Law No 19,496.

The regulations set forth by the Advertisement Ethic Autoregulation Council (CONAR, per its acronym in Spanish) is not mandatory but nevertheless is complied with by companies.

It is also important to bear in mind regulation issued by pharmaceutical associations, such as the Chamber of Pharmaceutical Innovation (CIF, per its acronym in Spanish) or the Industrial Association of Pharmaceutical Laboratories (ASILFA, per its acronym in Spanish). These regulations are important, especially regarding such topics that are not strictly regulated, but are subjects of concern, such as patient organisations engagement, or value transfer, for instance.

Finally, and regarding physicians, it should be noted that there is a Physicians Association, which has its own Code of Conduct that is mandatory for its members. The number of physicians enrolled in this Association is high, so it is relevant to consider their regulations.

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

It is important to point out that according to the regulation set forth in the Sanitary Code, advertisement is targeted to consumers and promotion is targeted to healthcare professionals. This difference will be of capital importance to distinguish the regulations that apply to each of them. In general terms, the advertising regulation is stricter than the promotion regulation.

Regarding pharmaceuticals, advertising is only permitted regarding OTC drugs, and is defined in article 199 of DS No 3, as the set of procedures or activities performed to make known, highlight, distinguish directly or indirectly to the public, through any means or procedure of dissemination, the characteristics, conditions of distribution, sale and use of the products referred to in these regulations. Advertisements should be previously approved by the Public Health Institute (ISP, per its acronym in Spanish). Therefore, no advertisement can be published without such previous approval.

In Chile, promotion refers to the information given to the healthcare professionals to familiarise themselves with the drugs. Promotion is an activity that is not limited just to OTC drugs as it is with advertisements, and it can refer to a wide array of drugs as long as it complies with the regulation set forth. DS No 3 defines such information as the set of procedures and activities aimed at professionals legally authorised to prescribe or dispense pharmaceutical products, with the purpose of informing them about the products referred to in this regulation, in accordance with what is authorised in the respective health registration.

Regarding medical devices, there are no specific sanitary regulations about advertising or promotion. Nevertheless, they will be subject to the general regulation about advertisement, contained in the Consumers Law.

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?

Regarding pharmaceuticals, the regulatory authority is the Public Health Institute (ISP) which will have to approve the advertising that any company would issue. ISP will also be the authority that will supervise the compliance of said regulation.

Regarding medical devices, as mentioned, there are no sanitary regulations regarding advertising, but as long as they are subject to consumers' law, the authority in charge of supervising compliance with consumer law will be the national consumer service.

Authorities will only intervene regarding infringements of the official regulation. Any self-regulatory processes, as those imposed by CIF, ASILFA, or the Physicians Association, are not supervised by authorities, but its compliance can be relevant to prove diligence of the companies, if needed.

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?

Regarding food supplements or nutritional products, they are not subject to the advertising regulation contained in DS No 3, but they will have to comply with the regulation set forth in Supreme Decree No 977 of 1996, issued by the Health Ministry. In these cases, the authority in charge of supervising the compliance with the regulations will be the Regional Ministerial Secretary of Health.

Any food product will have to comply with the labelling regulation regarding its calories, fat and sugar content. This regulation establishes that if the food product contains certain levels of calories, fat and sugar, in addition to complying with the labelling regulation it will have special limitations in terms of advertising. These limitations are related to the restriction of advertising to children under 14 years of age, and the prohibition of the use of animated images or figures that are attractive to minors.

In addition, such products labelled as 'high in' calories, fat and/or sugar, will have to include a special message that promotes a healthy lifestyle in their advertisment.

Regarding special nutritional products, there are specific regulations regarding the kind of nutritional messages than can be used when advertising such products. It is also important to bear in mind that there are also special requisites about labelling.

Infant formula for children between zero and 12 months of life cannot be the object of an advertisement.

Finally, it is important to note that only pharmaceutical products can be linked with advertisements that enhance therapeutic properties.

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?

As previously explained, advertising of pharmaceuticals refers to the activity of known drugs to the general public, and is only permitted regarding OTC drugs, and only with previous approval by the ISP.

Promotion, which refers to the act of giving information about the drugs to healthcare professionals, can be made regarding any kind of pharmaceuticals as long as it complies with the specific regulation set forth for promotion. In this case, the main restriction is the usage of mass media to make the promotion, as this transforms the information as available for the general public, thus it becomes advertising, and, as such, should comply with all the regulation set forth for advertising.

Regarding medical devices, as explained at Question 3, there are no specific regulations.

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?

There are no specific limitations regarding the advertisement of pharmaceutical and medical devices through the internet and social media, as long as, regarding pharmaceuticals, it refers to OTC drugs and is previously approved by the ISP.

Regarding promotion, the only limitation is the use of mass media, but there is no regulation about performing promotional activities through the internet or social media, provided that this media is targeted only to healthcare professionals and not to the general public, and that it complies with the regulation about information for healthcare professionals.

Nevertheless, it is important to consider that the National Consumers Service has issued certain regulations applicable to advertisements made by influencers, which will apply to any kind of advertisement.

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)?

Regarding OTC drugs, which are the only pharmaceuticals that can be the object of advertisements, the advertisement itself should be previously approved by the ISP. In order to get such approval, the company will have to complete a form which contains the full advertising that the company wishes to publish. Then, an advertising committee will review it and can approve, reject, or approve with modifications.

Regarding promotion, there is no need for a specific authorisation, but it can only refer to the therapeutic indications approved in the sanitary registry and cannot be made through mass media targeted to 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?

Unauthorised pharmaceutical and off-label information cannot be the subject of advertising, unless the advertising only refers to uses for which the drug is approved in Chile.

Nevertheless, off-label information can be given to healthcare professionals, being that it is their responsibility for the potential off-label use.

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?

Under Chilean law, comparative advertising is lawful, provided that it is based on a truthful and demonstrable background, and furthermore, that it is not misleading, denigratory or misleading with respect to the competitor. It is possible to refer expressly to another company's information.

It is important to highlight that, in Chile, advertising is only permitted regarding OTC pharmaceuticals registered in Chile, and it is not possible to use as a comparison a product or indication that is not authorised in Chile since it must be strictly adhered to the information set forth in the information brochure authorised by the ISP.

In case of information presented to healthcare professionals, comparations should be based on studies that confirm the information.

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?

Healthcare professionals in Chile are those regulated under articles 112 et seq of the Sanitary Code which establishes that only those who have the respective degree granted by the University of Chile or another University recognised by the state and are legally authorised to practice their professions may perform activities related to medicine, dentistry, chemistry and pharmacy or others related to the preservation and restoration of health.

DS No 3 regulates promotion to healthcare professionals, pointing out that it can be made to such professionals that are legally authorised to prescribe, and it can be based solely on the authorised information.

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?

There is no specific regulation regarding activities conducted virtually, they will have to meet all the requirements as it would be held in person. As such interactions will be with healthcare professionals it should not be considered as advertising but as promotion.

It is important to consider that when dealing with healthcare professionals, as promotion is considered as a way of providing information, the rules are more flexible, there is no need to get previous approval from ISP, and it can refer to any kind of drug, not just OTC.

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?

There is no legal limitation to the inclusion of endorsement by healthcare professionals in promotional and advertising materials. Nevertheless, it is important to consider that the Ethics Code of the Physicians Association contains specific regulation on this matter.

This Code of Ethics is not mandatory for those physicians who are not members of the association, but it is important to bear in mind that, in Chile, the number of physicians that joined the association is high.

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.

The provision of samples of medicinal products to healthcare professionals is permitted but strictly regulated.

Samples are permitted but should comply with specific regulation regarding its labelling and they can only be provided to healthcare professionals at their offices or at scientific meetings or congresses. The healthcare professional should give the sample directly to the patient in their medical cabinets.

Regarding giving gifts, and donations, it is important to distinguish between giving drugs as gifts, and/or money to healthcare professionals, it is prohibited, as it is considered advertising.

Regarding medical devices, there is no regulation that limits such activities.

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

There is no legal regulation that applies specifically to the offer of hospitality to healthcare professionals. Nevertheless, at this point it is important to consider that the Physicians Association Code of Ethics establishes that physicians can accept such kinds of offers as long as they are modest and do not affect their independence. In these cases, is important to consider also the criteria established by IFMPMA, which determines in its Code of Conduct that hospitality should not exceed what participants would normally pay for themselves.

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?

Yes. The Sanitary Code establishes in Article 100 that it prohibits the donation of pharmaceutical products made for advertising purposes, as well as incentives of any kind that induce to favour the use, prescription, dispensation, sale or administration of one or more pharmaceutical products to any person.

The same article sets the scope of 'incentives', pointing out that it will be considered as such any payment, gift, service or economic benefit given or made to persons by pharmaceutical laboratories, drugstores, importers or distributors of medicines or pharmaceutical establishments, by those who represent them or, in general, by those who have any interest in favouring the use of one or more products or devices.

Regarding donations of pharmaceutical products, it should be authorised by ISP, and the patient receiving such donation will have the right to receive it whilst the therapeutic benefit persists.

Donation of pharmaceuticals to healthcare establishments will only be permitted if the establishment is non-profit making and if the drugs are contained in the National Drug Formulary.

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?

Laboratories can support scientific or educational meetings. Considering that scientific or educational meetings are focused on healthcare professionals it is not classed as an advertisement activity, so the rules governing them are those regarding the provision of information.

Such information can be provided in any format, being only prohibited by the use of mass media. Limitations about advertising are focused only on such information that goes to the general public, so as long as the information provided on scientific, or education meetings is targeted just to healthcare professionals it can be considered as information and not as an advertisement.

Regarding medical devices, there is no regulation, so manufacturers and licensees can support any scientific or educational meetings.

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

There are no specific legal rules governing such relationships. Nevertheless, it is important, on this topic, to consider the regulations set forth by pharmaceutical associations and healthcare professionals associations.

It is possible to provide funding to such organisations, but pharmaceutical organisations, such as the Chamber of Pharmaceutical Information (CIF, per its acronym in Spanish) have special rules for their members, in the sense of informing and making public some information linked with the finance of patient organisations.

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 and advertising activities to a third party who will have to comply with all the regulations applicable. Co-promotion is not regulated, so it should be possible if it accomplishes all the regulations about advertising.

It is always important to keep in mind that any advertising related to pharmaceutical products should be previously approved by the ISP.

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

The report of value transfer is not legally regulated; thus, it is not mandatory. Nevertheless, there are private regulations that promote its report. For instance, the CIF have its regulations about it, encouraging its members to comply with such regulations, and promoting the report of value transfer as a standard in the industry.

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?

Any infringement of the regulation regarding pharmaceutical advertising will be the object of a sanitary investigations, whose fines can go from UTM 1/10 to UTM 1,000, or UTM 2,000 if there is a recidivism (from US$7 to US$67.000, or US$134.000 in case of recidivism). The fines can be complemented with sanctions such as closure of establishments, cancellation of the authorisation to function, stoppage of work, suspension on the distribution of products, destruction of products, and seizure of goods. Once the summary is finished and the fine is imposed, the expedient becomes public.

Advertisement is a matter of concern to the ISP so they are constantly reviewing it and imposing fees. Also, they are very strict in the revision of the advertisement submitted for its approval.

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?

Competitors can file complaints before the ISP to start a supervision process that may finish with a fine. It is something to expect from competitors once a complaint is filed; the ISP should investigate without the support of the complainant, who can keep intervening, but it is not mandatory. It happens that competitors file the complaint from an anonymous source or at least not under their name.

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?

Regarding publicity and advertisement of medical products, currently the Chilean Parliament is discussing a new law, as it has been since 2015. This law, as it is now conceived, will prohibit any publicity regarding drugs, and will strictly regulate some activities.

This law contains extensive new regulations regarding pharmaceutical products, incorporating norms about pricing, denomination, labelling and fraction of drugs. There are also innovations regarding intellectual property and pharmaceutical investigation, among others.

It is important to note that this law has been discussed for several years, and we cannot predict when, or if, it will be approved. Nevertheless, in the short run, there are low possibilities for its approval.