PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

Authors: Att. Sergio Antelo, Att. Laura De La Via & Att. Carolina Aguirre

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 promotion and advertising of pharmaceutical products and health products in Bolivia are governed by the following laws:

- Political Constitution of the Plurinational State of Bolivia dated 7 February 2009, which provides in Article 37 that '[the] State has the undeniable obligation to guarantee and support the right to health', which is a supreme function and the first financial responsibility.
- Law No 1737, the 'Medicines Law', dated 17 December 1996, specifically in Chapter XVI, Article 50, which provides that '*the Ministry of Human Development, through the National Secretariat of Health, shall regulate the publication, promotion, propaganda and advertising of medicines*, based on the ethical standards for the promotion of medicines. For the purposes of the Law, publication, promotion, propaganda and/or advertising is understood as *the presentation and disclosure of data and/or information by any means, tending to promote the sale, transfer, and/or use of medicines*' (emphasis added).
- Supreme Decree No 25235 dated 30 November 1998, which created the National Drug Policy, whose objective is to meet the needs of the low-income population through the timely supply of essential drugs of good quality, recognised efficacy and accessible prices. Article 96 of this regulation provides that the publication, promotion, and advertising of medicines shall be governed by the Ethical Norms for the Promotion of Medicines.
- Ministerial Resolution No 060/2015 dated 25 June 2015, which provides for the regulation on the promotion and advertising of medicines.
- The Ethical Norms for the Promotion of Medicines approved by the Ministry of Health and Social Welfare (now Ministry of Health and Sports) through Secretarial Resolution No 0139/94 dated 1 March 1994, paragraph 13, item (b), states that the advertising of medicines in the mass media is subscribed to over-the-counter medicines after analysis by the National Pharmacological Commission and the Unit of Medicines and Technology in Health.

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

Law No 1737 stipulates that the publication, promotion, propaganda and/or advertising of medicines is the presentation and dissemination of data and/or information by any means, aimed at promoting the sale, transfer and/or use of medicines.

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 Ministry of Health and Sports and the Public Agency of Medicines and Technologies in Health (AGEMED).

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, the regulation on promotion and advertising of food supplements or special nutritional products are governed under their own rules, since the state authority that regulates them is different, in this case the Ministry of Agriculture, Livestock and Rural Development, which oversees managing the Agricultural Health and Food Safety Regime, through the National Agricultural Health and Food Safety Service.

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?

In accordance with the Ethical Norms for the Promotion of Medicines, approved by Secretarial Resolution No 136 dated 1 March 1994, the promotion of medicines that require medical authorisation for sale is prohibited (para 13.b).

Likewise, and in addition to the aforementioned, distribution of medical samples for the promotion of medicines to the general public is also prohibited (para 13.b).

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?

Although Bolivia does not have a specific regulation on the promotion of medicines through social media, paragraph 13.b of the Ethical Guidelines for the Promotion of Medicines provides that over-the-counter medicines can be promoted through the mass media (social media being included in this group).

In this regard, the National Pharmacological Commission has the power to approve the inserts of medicines, orienting the information to the user of the medicine, using understandable language, and taking care that it does not induce self-medication (article 14.3 of the Regulations to the National Pharmacological Commission, approved by Secretarial Resolution No 138 dated 14 April 1998).

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)?

As mentioned at Question 6, the authority in charge of authorising drug promotions is the National Pharmacological Commission.

The procedure for their authorisation is carried out through internal meetings of the Commission, who elect subcommittees to review the different items to be authorised and/or rejected (articles 15 to 27 of the Regulations to the National Pharmacological Commission.

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

Unauthorised pharmaceuticals and/or off-label information cannot be promoted.

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?

In Bolivia there are no regulations on comparative advertising. However, and according to Supreme Decree No 29519 dated 16 April 2008, the action of possibly using information of another company (including the trademark) could be understood as an anticompetitive conduct, if that company did not give its consent through a contract.

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 Regulation of the Professional Category in Health issued by the Ministry of Health and Sports of Bolivia, in its second article, defines 'health professionals' as recognition to the post-graduate studies in the areas of clinical and non-clinical specialisation of medical professionals, dentists, biochemists, pharmacists, nurses, nutritionists and social workers, recognition that is granted according to the time of training and is directly related to the function in which it is performed and that is manifested through an economic benefit.

In this regard, the following article of the same regulation categorises health professionals into three categories, according to their academic level, which translates into an economic increase:

- Category I, with a 60 per cent increase over the basic credit.
- Category II, with an 80 per cent increase over the basic salary.

- Category III, with a 100 per cent increase over the basic salary.

On the subsequent point, Bolivia has no restrictions on direct promotion to health professionals; however, it is regulated by the Ethical Norms for the Promotion of Medicines, in paragraphs 9 to 12, which, in general terms, provide as follows:

- The text and illustrations of advertising or literature intended for physicians and health professionals must be entirely compatible with the approved scientific data sheet for the drug in question or with any other source of information of analogous content.
- Advertising or literature is required to contain complete product information in accordance with the approved scientific data sheet for the duration of the product's sanitary registration.
- Medicines to be promoted to health professionals must have a list based on the drug fact sheet contained in the fifth report of the WHO Expert Committee on the Use of Essential Drugs.
- In the case of controlled medicines, an allusive legend should be added.
- Advertisements without advertising claims (reminder advertisements) are allowed, they must include at least the trade name, the international non-proprietary name or approved generic name, the name of each active ingredient, and the name and address of the manufacturer and distributor in order to be able to receive complementary 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?

At the time of the worldwide Covid-19 pandemic, the Bolivian State included a free medical consultation line for infected patients. However, and to this date, unless they are patients with Covid-19, there is no special regulation on virtual meetings or consultations, nevertheless, it is not prohibited, so virtual medical consultations can be made if the private health entity has this service.

Scientific meetings and symposiums are regulated by the Ethical Guidelines for Drug Promotion and Advertising, in paragraphs 19 to 21, such meetings/symposiums are allowed and may be promoted, although this standard does not mention any prohibition on virtual meetings, therefore, using the above logic, they may be held.

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 regulation on this matter. However, ethical regulations may prohibit such conducts.

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.

According to the Ethical Standards for drug promotion and advertising, item 17 states that small quantities of free samples of prescription and legally available drugs may be provided to health professionals *upon request.*

Making donations or pecuniary gifts to physicians, however, is prohibited by the Bolivian Code of Medical Ethics and Deontology, article 60 of which states 'it is forbidden for the Physician to give or receive commissions or other benefit, directly or indirectly, from persons or institutions for patient care'.

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

In terms of hospitality among healthcare professionals, the Code of Ethics and Medical Deontology is the norm that regulates this aspect.

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?

As mentioned in Question 13, donations are prohibited.

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?

According to the Ethical Standards for the promotion of medicines and advertising, section 20 states that 'sponsorship by a manufacturer or distributor of pharmaceutical products must be clearly announced in advance at the meeting and in all proceedings. These should accurately reflect the communications and discussions', meaning that they can support and participate in scientific or educational meetings.

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

There is no regulation on this matter.

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?

Advertising can be delegated to third parties (marketing agencies). However, such third parties must comply with the regulations above mentioned.

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

There is no regulation on this matter.

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?

Law No 453 dated 4 December 2013, 'General Law of the Rights of Users and Consumers', applies. It sets forth regulations to protect society against institutions providing various services (including medical services) regarding misleading advertising or contracts with abusive clauses.

The authority responsible for controlling and supervising entities that provide different services is the Vice Ministry of Consumer Rights' Defense, under the Ministry of Justice.

The penalties/sanctions or fines that the Vice Ministry of Consumer Rights' Defense may issue are carried out through an administrative procedure, where the consumer must submit their complaint and the authority will issue a Sanctioning Resolution against the institution. The institution can then defend itself and appeal the decision up to the Hierarchical Resource, and as a last resort, the contentious administrative proceeding.

In addition, AGEMED may impose sanctions for lack of registries and other infractions relating pharmaceuticals.

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?

See Question 20 above.

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?

Given the difficult political/economic scenario Bolivia is facing, a law on the field of pharmaceutical or medical device promotion is on the back burner, so the possibility of passing a law or proposing a bill on this specific issue is very low.

However, due to the fact that, after the Covid19 pandemic, Bolivia has adopted several initiatives (both in the private and public sector), it is foreseeable that specific regulations regarding pharmaceutical or medical device promotion would be implemented in the near future.