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 promotion and advertising of pharmaceuticals and medical devices are regulated by Laws No 6,360 of 1976, No 8,078 of 1990 ('CDC' or 'Consumer Defense Code'), No 9,294 of 1996 and by Resolution RDC No 96 of 2008 issued by the National Health Surveillance Agency (ANVISA). They are further regulated by the Brazilian Code of Advertising Self-Regulation issued by the National Council of Advertising Self-Regulation ('CONAR' and the 'CONAR Code'), industry codes such as INTERFARMA (Pharmaceutical Research Association) code of conduct, ABIMED (Brazilian Association of Industry of High Technology Medical and Hospital Equipment, Products and Suppliers) code of conduct, as well by codes issued by professional councils, such as the Dentistry Code of Ethics.

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

'Advertising' is generally defined under the CONAR Code as 'all activities designed to encourage the consumption of products and services and promote institutions, concepts or ideas'.

Advertising of pharmaceuticals is broadly defined under ANVISA's Resolution RDC No 96/2008 as 'a set of information and persuasion techniques and activities aiming at disseminating knowledge, making a certain product or brand better known and/or prestigious, exerting influence on the public through actions intended to promote and/or induce the prescription, dispensing, acquisition and use of a drug'.

There is no legal definition of advertisement of medical devices, the definition of advertising of pharmaceuticals is used analogously for regulatory purposes. In practice, companies adopt a more loose interpretation of the legal framework and restrictions when dealing with medical devices.

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 promotion and advertisement of pharmaceuticals and medical devices are regulated and enforced by: (1) ANVISA; (2) consumer defense authorities (including administrative agencies such as Procons, SENACON and Consumer Public Prosecutors); (3) CONAR; and (4) professional class councils, depending on the type of product.

There is no official relationship between the supervisory and enforcement functions by the competent authorities and self-regulatory bodies or industry associations. Breaches may be investigated by them independently. The competent authorities cannot base their decisions on the findings identified by a given self-regulatory body or the industry association, but the findings or existence of investigations by such may trigger or complement the authorities' investigations of alleged breaches. Sanctions may be applied by all the different authorities and entities responsible for supervision and enforcement of advertisement rules.

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?

In addition to pharmaceuticals, the general advertisement rules and restrictions provided for under Federal Law No 6,360 of 1976 also apply to pharmaceutical inputs, medical devices, cosmetics, sanitisers and other products subject to health surveillance authorities (which include food supplements, cannabis products and special nutritional products). Besides, Federal Law No 9,294 of 1996 also restricts advertisement of smoking products, alcoholic beverages and agricultural therapies and agrochemicals.

In any event, it should be highlighted that both Federal Law No 6,360 of 1976 and No 9,294 of 1996 only set forth general rules and restrictions regarding the promotion of the products indicated above. Similarly to

ANVISA's RDC No 96 of 2008 applicable to drugs, several specific pieces of regulation on specific products contain limitations and rules on their respective promotion and advertisement. For instance, ANVISA's RDC 327 prohibits any, and all, advertisement of cannabis products.

Certain 'Schedules' of the CONAR Code relating to 'special category of advertisement' apply to different classes of products.

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?

Federal Law No 6,360/1976 restricts the promotion and advertisement of prescription drugs to healthcare professionals and prohibits such activities in relation to the general public.

Over-the-counter drugs may be advertised to the general public subject to compliance with extensive and detailed rules on their marketing and promotion set forth in ANVISA's Resolution RDC No 96/2008 and in the Brazilian Advertisement Self-Regulating Council's (CONAR) Code. Also, the Consumer Defense Code sets forth that advertisements shall be published in such a way that consumers are able to easily and immediately identify them as advertisements of products and services.

The CONAR Code regulates only the advertising of non-prescription medicines (OTC). The Code requires that the packaging, labeling and advertising of medicines must comply with the relevant regulation and provides for various restrictions regarding advertising.

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?

The promotion (and advertising) of pharmaceuticals and medical devices through the internet is shyly provided for in ANVISA's regulation (ie, few rules on how warnings shall appear) and in CONAR's regulation (few rules on the advertisement of non-prescription drugs on the internet). Such regulation, however, does not contain specific provisions concerning social media. In practical terms, the legal framework on advertisement of medical products and pharmaceuticals applies irrespective of the communication means, which include social media.

In any case, it is a reality that social media is a highly used tool for advertising medical devices and pharmaceuticals in the country. One sign is the fact that a great portion of cases brought to CONAR's attention and jurisdiction concern advertising on social media, including those of pharmaceuticals and medical devices.

CONAR has published a manual, 'Digital Influencer Advertising Guidelines', for contents generated by digital influencers, which is highly based on guidelines issued by international organisations such as the International Council for Ad Self-Regulation (ICAS), the International Chamber of Commerce and the European Advertisement Standards Alliance, among others. The guidelines contain several rules on the identification of posts as advertisements and challenges or other engagement activities through social media.

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)?

Promotions (and/or advertisements) do not receive prior approvals from regulators before use, surveillance and control occur after the fact.

ANVISA must be informed by an event's organisers, with up to three months advance notice, about regional, national and international scientific events in which the advertisement or promotion of drugs is allowed, with the indication of the professional category participating.

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

No, they may not be advertised to the general public. The promotion of information on unauthorised pharmaceuticals and/or off-label information is expressly prohibited. The law only authorises promotion of pharmaceuticals which have received a marketing authorisation, being certain that any promotion must match the information registered with ANVISA.

It is possible, however, to include such information in scientific materials directed to the professionals authorised to prescribe the type of product.

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?

ANVISA's Resolution RDC No 96/2008 and industry association codes govern comparative advertisements. According to ANVISA's rules, price comparisons with other drugs must be exclusively between drugs that are interchangeable or that have the same active ingredient.

Additionally, INTERFARMA's Code of Conduct states that comparative promotional materials must comply with the principles established by the association and respect some limitations, especially with respect to the use of third-party brands without the consent of their respective owners, which is not allowed. This prohibition does not encompass comparative advertising between active ingredients and other characteristics linked to the composition of medicines, even if it allows for the indirect identification of the companies and INTERFARMA's members, as long as properly based on comparative studies.

In relation to medical devices, ANVISA's legislation is silent about comparative advertisements. However, ABIMED's Code of Conduct states that companies are prohibited from engaging in illegal or unethical competition practices aimed at undue advantage, including, but not limited to, practices that target the abuse of economic power, illegitimate restriction and prejudice to free competition, as well as the creating and maintaining of barriers to entry or competition in the market.

The CONAR Code allows comparative advertisements, with certain limitations:

- the main purpose must be to enlighten the consumer and its defence;
- the basic principle of the comparison is objectivity, since subjective, psychological or emotional data does not constitute a valid basis for comparison in the eyes of the consumer;
- the comparison claimed or made is verifiable;
- in case of consumer goods, the comparison is made with models manufactured in the same year, and the comparison between products from different times is reprehensible, unless it is a reference to demonstrate evolution, which, in this case, must be characterised;
- there is no confusion between competing products and brands;
- there is no unfair competition, damage to the image of the product or to another company's brand;
- no unjustified use is made of the corporate image or prestige of third parties;
- when a comparison is made between products whose price is not the same, this must be clearly indicated in the advertisement.

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 are only defined on INTERFARMA's Code of Conduct. Such document indicates that a 'healthcare professional' is a professional qualified to prescribe or dispense medications, limited to doctors, dentists and pharmacists.

Under ANVISA's Resolution RDC No 96/2008, the following information must be included in advertising to healthcare professionals: (1) brand name; (2) name of the active ingredient as written in the Common Brazilian Denomination; (3) registration number; (4) indications; (5) counter-indications; (6) warnings related to adverse reactions and interactions with other substances; (7) dosage; (8) prescription and dispensing classification; and (9) date of printing.

Where the promotional piece on a prescription-only medicine highlights the benefits of the medicine, the piece must also highlight at least one counter-indication and one frequent medicine interaction.

For vaccines, advertisements must provide the necessary number of doses for complete immunisation.

Products containing substances under special control are subject to further regulation.

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 activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia.

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?

The inclusion of medical endorsements in medicine advertising is forbidden. Resolution 1,974/201 of the Federal Council of Medicine prohibits medical doctors from 'participat[ing] in advertising of companies or products associated with medicine'.

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.

It is possible to provide healthcare professionals (HCPs) with samples of medicinal products. ANVISA's Resolution RDC No 60/2009 provides for the requirements for the distribution of free samples of drugs as follows: (1) they may be distributed by companies only to the prescribing professionals; (2) by means of documented acceptance; and (3) in outpatient clinics, hospitals, medical and dental offices.

Companies cannot offer free samples of biological products that require special conditions for their transportation and products prepared in compounding pharmacies.

The free sample packages must contain 50 per cent of the original content, except for: products for chronic diseases and contraceptives, which must have the same content of the registered original; and antibiotics, which must have a complete treatment for the patient.

The registration holder of the product must keep on file, for a minimum of two years, all documents related to the production, distribution and pharmacovigilance data of the free samples and must send information on the production and distribution of free samples to ANVISA annually.

Regarding gifts or donations of money, this is not allowed. According to Article 5 of ANVISA's Resolution RDC No 96/2008, which governs the promotion of medicines, 'companies cannot grant, offer, promise or distribute gifts, benefits and advantages to prescribers or dispensers, those who sell the product directly to the consumer, as well as to the general public'.

INTERFARMA's Code of Conduct reinforces such prohibition. However, certain items may be exempt from this prohibition, such as pens and notepads (made available at in-person seminars/events with the company logo and not the logo of the product) and items essential for the safe use of the product prescribed by the HCP.

It is worth highlighting that stricter guidance may apply to HCPs acting in the public practice, in view of the risks associated with potential violations of the Brazilian Anti-Corruption Law (LAC). In 2023, a Swiss company with operations in Brazil, settled with Brazilian authorities for violation of LAC in connection with offerings such as the financing of office remodeling and payment of flight tickets to public HCPs.

ABIMED's Code of Conduct determines that companies are permitted to offer, distribute and/or deliver samples and/or demonstration products to HCPs or HCOs, as long as permitted by applicable laws, regulations and standards and in compliance with the rules and other requirements set forth in the Code. Also, the Code establish that the laws, regulations and standards applicable to drugs samples will be applicable to samples of medical devices with due interpretation and adaptation, taking into account their particularities, characteristics and differences.

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

Except for Article 5 of ANVISA's Resolution RDC No 96/2008, which prevents companies from providing, offering, promising, or distributing small gifts, benefits or advantages to prescribing or dispensing HCPs, there is no specific provision regarding offering of hospitality.

However, according to INTERFARMA's Code of Conduct, supporting expenses in relation to transportation, meals, and accommodation are allowed, but some limitations apply: the expenses must be limited to the

event and the period that the event will occur; the expenses must be related solely to the invited HCP; the values must be modest; and the location suitable for the exchange of information. Thus, there is no limitation as regards to the location of the event, but it must be appropriate/adequate to the event's scientific purpose.

The support cannot be conditioned to the prescription, sale or promotion of a medicine or a company by the HCP.

Finally, in events, the invited HCPs may not receive any kind of compensation, direct or indirect, for the time invested in monitoring the event, except when such compensation corresponds to services legitimately provided as a result of a contractual obligation previously agreed.

In the same sense of INTERFARMA's Code of Conduct, ABIMED's Code of Conduct establishes that companies may provide hospitality (stay and meals during the stay) and logistical (transport) support, provided that objective criteria of modesty, reasonableness, necessity and professionalism are observed and that such support does not consist of undue advantages or anything of undue value or influence.

As referred above, hospitality expenses that are not strictly associated with medical events may pose risks of violation of the Brazilian Anti-Corruption Law.

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?

If we take into account CONAR's Code definition, which qualify as advertisement 'all activities designed to […] promote institutions, concepts or ideas', donations may indeed be characterised as a promotional tool because they may result in enhancing the knowledge of the brand of the manufacturer, which equals to the promotion of an institution.

In any case, donations to HCOs must comply with a legitimate interest and always be aimed at meeting the real needs of the assisted community or society. There is no monetary limitation, but the donation amount must be reasonable in relation to the aim of the donation.

It is highly recommended that companies formalise each donation by means of an agreement (letter agreement or similar written instrument) outlining the clear purpose, type, amount of the donation and other conditions that donors and recipients must comply with.

Cash donations are usually allowed. However, donations of products or services are preferred over cash to avoid further risks. In addition, companies are encouraged to address guidance for the recipients on the use of these resources in line with the purpose of the donation and should consider including additional monitoring or auditing measures on that aspect and anti-corruption clauses.

Donations to public HCOs require extra caution. In this context, companies must pay close attention to specific requirements from legal provisions issued at federal, state and local levels, as additional conditions may apply. At the federal level, Decree No 10,314/2020 governs donations of products and services to public federal entities (including HCOs). Some of the measures required by this Decree are the registration of the products or services on a website of the government and restrictions on the publicity or advertising these donors can carry out with these types of donations. At local level, specific requirements may apply depending on the legal framework applicable for each state/municipality.

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?

Yes, they can. Both INTERFARMA's and ABIMED's Code of Conduct allow pharmaceutical laboratories or medical device manufacturers or their licensees to support scientific or educational meetings.

The main difference between the pharmaceutical and the medical devices sectors relates to the fact that promotional rules applicable to pharmaceutical products are more robust and more strictly applied when compared to medical devices. Also, from an industry association perspective, the rules for events organised by medical device manufacturers are subject to ABIMED's Code of Conduct as an industry standard and rules for events organised by pharmaceutical laboratories are subject to INTERFARMA's Code of Conduct.

Special attention should be given regarding the hiring of public officials for these scientific or educational meetings. In cases where a company or INTERFARMA member intends to engage a Public Agent or Politically Exposed Person, as outlined in the preceding section, strict adherence to prevailing legislation is imperative. The company or INTERFARMA member must ensure that the Public Agent or Politically Exposed Person fulfils the requirements of their institution. Additionally, a written declaration is to be

obtained, confirming that the services to be provided or sponsorship to be received aligns with the policies and regulations of the institution to which they are affiliated.

Finally, it is imperative for companies and their supporters to diligently maintain accurate records of sponsorships, donations, and any other types of support – be it financial or non-financial – that they extend to Patient Associations.

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

There is no express legal or regulatory provision governing the relationship between pharmaceutical companies and patient associations. However, certain practices may be considered irregular by law enforcement authorities, mainly if the relationship results in, or is perceived as, an inducement of prescription-only medicines or a disguised promotional activity, or if the patient association is used by the company as a vehicle to influence doctors or induce prescription.

However, it should be highlighted that the industry codes provide for some rules applicable for the interactions between companies and the patient associations. Both, INTERFARMA's and ABIMED's Code of Conduct, emphasise the importance of engaging with such entities for legitimate purposes, including technical training, raising awareness on health-related issues, and disseminating information on disease prevention and treatment.

INTERFARMA's Code of Conduct, for example, establishes that companies:

> 'may interact with Patient Associations and other similar organizations that are legally constituted. Such interaction may occur through support, financial or otherwise, for projects that aim, but are not limited to, technical training, awareness of the population on health-related issues and/or dissemination of adequate information on the treatment, prevention and diagnosis of diseases, Advocacy actions (understood as actions that aim at demonstrating the position of civil entities and institutions on decisions to formulate public policies) and information on quality of life'.

The Code also states that the companies should implement control mechanisms that aim at ensuring that the relationship takes place in an ethical, clear and transparent manner, with legitimate objectives and in accordance with the other rules provided for in the Code of Conduct and in the legislation.

ABIMED's Code of Conduct in the same way provides that companies 'may interact and contribute financially or through products and/or services with reputable Patient Associations, to support a legitimate action of an educational, research and/or medical treatment/clinical condition clarification, such as actions raising awareness of issues related to health, diagnosis, prevention and treatment of pathologies'. Additionally, the Code states that under no circumstances may the support of a Patient Association be aimed at obtaining undue advantages, such as, but not limited to, obtaining a commitment to purchase, use, recommend or advertise a certain product.

Overall, both codes prioritise ethical and transparent engagements with Patient Associations, emphasising legitimate objectives and compliance with established rules and regulations.

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. The contract with the advertisement agency must be carefully drafted to ensure compliance by the third-party service provider with the applicable regulation, since all parties involved in the advertisement may be held liable for unlawful materials or campaigns.

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

Although there is no specific legal provision addressing requirements in relation to transfers of value to HCPs, HCOs and patient organisations, there are some rules governing disclosure of some sponsorships, grants and donations. Companies must pay close attention to specific requirements from legal provisions issued at federal, state and local levels.

Article 42, section 1 of ANVISA's RDC Resolution No 96/2008 sets forth that any sponsorship of a company to any events, symposia, congresses, meetings, conferences and similar, public or private, whether partial or total, must be clearly stated at the time of registration of participants and in the annals, if applicable.

As a general rule for donations of products and services to federal entities (including public HCOs), Decree No 10,314/2020 requires the registration of the products or services the company wishes to donate on a special website of the government.

Furthermore, with regard to local regulation, the State of Minas Gerais requires pharmaceutical, orthosis, prosthetics, equipment and implant companies to report on a specific website any type of grants to HCPs registered with the professional council within the State of Minas Gerais made directly or by third parties, such as gifts, tickets, event registration, lodging, financing of research stages, consulting, lectures, continued and permanent education, social and recreational events, commission, bank transfers or payments in cash, financing of clinical guidelines or articles of opinion and financing of societies and professional associations for purposes of conflict-of-interest analysis (State Law No 22,440/2016, regulated by Decree No 47,334/17).

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?

Under sanitary rules, the penalties for failing to comply with the rules governing the advertising of drugs include warning; fine (from BRL 2,000 up to BRL 1.5m); prohibition of advertising; suspension of the sale of the advertised product; imposition of rectifying message; product apprehension, destruction or interdiction; and suspension of advertising. ANVISA has responsibility for enforcement, and whenever violations are detected, the rules are strictly enforced.

From a consumer defence point of view, the penalties for violation of advertisement rules include fines, prohibition or suspension of the advertising and imposition of a counter-advertisement. In the case the misleading or abusive advertisement constitutes crimes against consumers, then the penalty is imprisonment from three months up to one year and payment of a fine.

PROCONs and SENACON may actively impose penalties and other sanctions if they find any violations. The penalties applied are public.

The violators of the rules established in the CONAR Code will be subject to the following penalties: (1) warning; (2) recommendation to modify or correct the advertisement; (3) recommendation to the media to suspend the broadcasting of the advertisement; and (4) disclosure to the media of CONAR's position as regards the advertiser, the agency and the medium for non-compliance with the measures determined by the entity.

There are several cases in which ANVISA or PROCONs have fined companies because of misleading or abusive advertising, and in terms of Superior Courts, there have been many cases in which the legality of those fines was recognised. Finally, the Public Prosecutor can file a collective lawsuit, asking for damages due in relation to abusive advertising, and each consumer might, individually, file lawsuits asking for any damages they might have suffered due to abusive and/or misleading advertising.

The violators of the rules established in the CONAR Code will be subject to the following penalties: (1) warning; (2) recommendation to modify or correct the advertisement; (3) recommendation to the media to suspend the broadcasting of the advertisement; and (4) disclosure to the media of CONAR's position as regards the advertiser, the agency and the medium for non-compliance with the measures determined by the entity. CONAR's Superior Committee has responsibility for the enforcement of the decisions of the Ethical Council in a regular process. In the past years, there were several important examples of actions being taken against pharmaceutical companies under the CONAR Code.

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?

ANVISA, consumer defence authorities (including administrative agencies such as Procons, SENACON and Consumer Public Prosecutors, CONAR and professional class councils, depending on the type of product, are responsible for enforcement. The rules are generally strictly enforced.

Anyone (including competitors) can present a complaint to the authorities about advertising infringements. A competitor can also file a lawsuit with regard to such infringements.

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. We are not aware of any significant developments in the field of pharmaceutical or medical device promotion expected in the next year or so. The enforcement on social media has become apparent in the country in the recent past years.