Legal 500
Country Comparative Guides 2024

Brazil
Pharmaceutical Advertising

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Brazil.

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Brazil: Pharmaceutical Advertising

1. What laws are used to regulate advertising on medicines in your jurisdiction?

A set of laws, ordinances, regulations and self-regulations governs the advertising of medicinal products in Brazil, including:

- Brazilian Federal Constitution
- Law No. 6.360/77 – provides for sanitary surveillance to which medicines, drugs, pharmaceutical and related products, cosmetics, and other products are subject to.
- Law No. 6.437/77 – defines violations of the federal health legislation and establishes the respective sanctions.
- Law No. 8.078/90 – the Consumer Protection Code.
- Law No. 9.294/96 – provides for restrictions on the use and advertising of tobacco products, alcoholic beverages and medicines.
- Decree No. 2.018/96 – regulates Law No. 9.294/96
- Law No. 9.782/99 – provides for the national health regulatory system and creates the Brazilian *Health Regulatory Agency* – ANVISA.
- Law No. 12.964/2014 – Brazil's Internet Bill of Rights (*Marco Civil da Internet*).
- Law No. 13.709/2018 – the Brazilian Data Protection Law.
- ANVISA ordinance RDC No. 60/2009 – regulation on free drug samples.
- Ministry of Health ordinance No. 344 – technical regulation on substances and drugs subject to special control.
- Federal Council of Medicine – CFM (Brazilian Medical Association) resolutions, including:
    - Resolution No. 1.939/2010 – prohibits the participation of doctors in promotions related to the provision of coupons, discount cards and other documents provided for in the resolution for the purchase of medicines.
    - Resolution No. 1.974/2011 – establishes the criteria of advertising in medicine, conceptualising the advertisements, the dissemination of medical matters, sensationalism, self-promotion and prohibitions.
    - Resolution No. 2.217/2018 – Code of Medical Ethics.
    - Resolution No. 2.386/2024 – regulates procedures and rules in relation to doctor's association with pharmaceutical industries, healthcare and medical equipment' suppliers (will be in force in March 2025).
- The Brazilian Advertising Self-Regulation Council (CONAR)'s *Self*-Regulatory *Advertising* Standards – instructs all advertisers and media outlets.
- The Brazilian Advertising Self-Regulation Council (CONAR)'s Digital Influencer Advertising Guidelines – instructs on the application of the rules of the Brazilian Advertising Self-Regulation Code (CBAP) to the commercial content on social media, in particular, contents generated by Users known as “Digital Influencers” or “Influencers.”
- Codes of Conduct of class associations such as INTERFARMA (Brazilian Association of Research-Based Pharmaceutical Industries) and ABIMIP (Brazilian Association of Manufacturers of Non-Prescription Drugs).

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

Yes.

a. If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

They apply to any companies, agencies and/or individuals that advertise medicines.

b. What is the legal status of the self-regulatory codes?

Although they are not a legislation made, approved and sanctioned following the legal venue for all enforceable legislation, the individuals/companies that advertise in Brazil tend to comply with their dispositions as well as Tribunals use to indicate them as a reference due to the widely adoption of the rules by the peers in the market.

3. Is there a statutory or generally accepted definition of “advertising”? a) What does the definition cover? – does it include patient

information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

There is no statutory definition but any content that has a commercial message (either direct or indirectly) must comply with the advertising rules.

a. What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

N/A

b. Does the definition apply equally to all target audiences?

N/A

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

There are no specific legislation concerning press releases of if they should be considered as advertising. However, health authorities have argued that press releases were in fact a form of advertisement. Therefore, it is advisable to conduct a legal review and oversight on the terms of release, even if the product is already registered.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

There are no specific processes prescribed to be followed within companies. However, all advertising shall abide by the legislation and companies must consider it within their internal procedures for approving advertising of medicines.

6. Do companies have to have material approved by regulatory bodies prior to release?

There are no requirements to approve advertising in advance by a regulatory or industry authority before use.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

There are no specific legislation relating to comparative advertising for medicines. Comparative advertising was foreseen in ANVISA's RDC No. 96 which prescribed that comparative advertising and unauthorised products could never be mentioned in advertisements. However, this ordinance was declared invalid by the Superior Court of Justice (Special Appeal No. 2035645 – DF). The INTERFARMA Code of Conduct prohibits comparative advertising with the use of third-party brands without permission. However, it allows comparisons between ingredients even if brands can be indirectly identified.

Also, the Brazilian Advertising Self-Regulation Council (CONAR)'s *Self*-Regulatory *Advertising* Standards foresee that injurious comparisons with competitors will not be tolerated. Any comparison will only be admitted when easily perceptible by the Consumer or based on clinical or scientific evidence. Scientific jargon with irrelevant data or statistics of dubious or limited validity, which may suggest a scientific basis that the product does not have, should not be used.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

Off-label or unauthorized medicinal products' information can only be published as scientific information at congresses, symposia or other scientific events, avoiding, in any case, the use of trademarks, and declaring to the audience that the product has not yet been registered and, as such, is not available in the market.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, and include the information that must or must not be included.

The advertisement of prescription-only medicines to the general public is strictly prohibited.

As for over the counter medicines, advertising is allowed with some legal limitations/conditions (Law No. 9.294/96 and Decree No. 2.018/96), namely:

- Authorization from the Ministry of Health;
- Registration of the product, when it is mandatory, with the competent health surveillance agency;
- The text, figure, image, or projections cannot give rise to false interpretation, error or confusion as to the composition of the product, its purposes, mode of use or origin, or proclaim therapeutic properties not proven at the time of registration with the competent health surveillance agency;
- Contraindications, indications, cautions and warnings on the use of the product must be expressly declared;
- Medicine fits into other possible requirements that may be set by the Ministry of Health;
- Contains warnings about its abuse, as directed by the classification authority;
- Advertising cannot have statements that are not scientifically proven, nor may it use statements from professionals who are not legally qualified to do so;
- All medicine advertising must contain a warning indicating that, if symptoms persist, the doctor should be consulted;
- In the advertising of dietary products, the inclusion or mention of indications or expressions, even subjective, of any therapeutic action or treatment of metabolic disorders is prohibited;
- Advertising of generic drugs is allowed in advertising campaigns sponsored by the Ministry of Health and in the premises of establishments authorized to dispense them, with indication of the reference drug.

The Brazilian Advertising Self-Regulation Council (CONAR)'s *Self*-Regulatory *Advertising* Standards also provides guidance for advertising of over the counter medicines, namely:

- The packaging, labelling and advertising of popular medicines must comply with the relevant legislation;
- it must not contain any claims as to the action of the product that are not based on clinical or scientific evidence;
- it should not be done in such a way as to suggest a cure or prevention of any disease requiring treatment under medical supervision;
- it should not be done in such a way as to result in a use other than the therapeutic actions contained in the documentation approved by the Health Authority;
- will not offer the consumer prizes, participation in contests or similar resources that induce the consumer to use unnecessary medicines;
- it should avoid any inference associated with excessive use of the product;
- it should not be done in such a way as to induce the use of products by children, without supervision by parents or guardians to whom, in fact, the message will be addressed exclusively;
- must not encourage the Consumer to commit physical, gastronomic or alcoholic excesses;
- it should not show a character in dependence on the continuous use of medication as a simplistic solution to emotional problems or mood states;
- it must not mislead the Consumer as to the content, package size, appearance, uses, speed of relief or therapeutic actions of the product and its classification (similar/generic);
- it must be careful and truthful about the use of the written or spoken word as well as visual effects. The choice of words should correspond to their meaning as generally understood by the general public;
- it must not contain statements or dramatizations that cause fear or apprehension in the Consumer, that he is, or may become, without treatment, suffering from any serious illness;
- It should emphasize the uses and actions of the product in question. Injurious comparisons with competitors will not be tolerated. Any comparison will only be admitted when easily perceptible by the Consumer or based on clinical or scientific evidence. Scientific jargon with irrelevant data or statistics of dubious or limited validity, which may suggest a scientific basis that the product does not have, should not be used;
- it must not contain any offer to return money paid or other benefit, of any nature, for the purchase of a drug due to a possible ineffectiveness;
- the advertising of dietary products must be subject to the rules relating to medicines in general. It must not include or mention indications or expressions, even subjective, of any therapeutic action;
- Reference to studies, whether scientific or consumer, should always be based on research done and interpreted correctly;
- Any endorsement or attestation, as well as the simple reference to professionals, educational or research institutions and health establishments, must be supported by appropriate documentation, required at any time;
- Drug advertising will not offer remote diagnosis;
- It will not contain statements that are injurious to the activities of health professionals or to the value of their care or treatment;
- When offering the sale of the product by telephone or electronic address, it must explain the corporate name and physical address of the advertiser in order to facilitate inspection action and complaints.

10. Are there any restrictions on interactions

between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

In Brazil, interactions between the pharmaceutical industry and patients or patient organizations are subject to several regulatory frameworks aimed at ensuring transparency, protecting public health, and preventing undue influence or conflicts of interest.

The Brazilian Advertising Self-Regulation Council (CONAR)'s *Self*-Regulatory *Advertising* Standards emphasizes responsible marketing and prohibits misleading or coercive advertising practices. Specifically, it includes restrictions on advertising directed at the general public, which would encompass patient groups. Advertising that could potentially lead patients to demand specific medications from their healthcare providers is prohibited.

INTERFARMA's Code of Conduct provides guidance on interactions with patient organizations, such as:

- Pharmaceutical companies must ensure that any sponsorship or support of patient organizations is transparent and does not exert undue influence over the organization's actions or advocacy efforts.
- Any financial or non-financial support (such as grants or consulting arrangements) must be disclosed publicly.
- Companies are prohibited from directly funding activities or events that involve patient advocacy or education in a way that could promote their own products or create conflicts of interest.
- Patient organizations should have autonomy in their operations and decision-making, and the support they receive should be for educational or research purposes, rather than for promotional purposes.

Thus, while patient organizations can receive sponsorship or support from pharmaceutical companies, such support must be clearly separated from any promotional or commercial activities and must align with the overarching goal of patient welfare and public health. The sponsorship should also follow the guidelines set by CONAR and INTERFARMA' Code of Conduct.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example, can companies provide information about clinical trials, or reprints of scientific journal articles?

The advertising must contain clear identification of the product or service (clearly identify the product being promoted, as well as the pharmaceutical form, name of the responsible company), scientific support claim (all claims made about the product must be substantiated by reliable, scientifically valid data). The source of this data should be clearly referenced, indications and contraindications, clinical trial information and reprints can be included but adhering to some requirements and all communication must be clear and transparent.

The advertising cannot contain misleading or false claims, cannot promote off-label use, cannot have unverified claims, cannot use testimonials, cannot exaggerate scientific data and cannot show an unbalanced presentation of risk and benefit.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

It is possible, but only gifts of nominal value, without references to any specific product. The INTERFARMA Code of Conduct states the following requirements for such gifts: (a) they have to be related to the medical practice, excluding office supplies; (b) they must have a symbolic value (around R$ 50); and (3) they must be limited to three per year per doctor.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

Yes, it is possible, except for non-prescription medicinal, biological and compounding pharmaceutical products, in which the provision of free samples is not allowed. Products containing substances under special control are subject to additional regulations.

Free samples can only be distributed to hospitals, and medical doctors' and dentists' offices. The healthcare professional responsible for prescribing the product must sign a document indicating the receipt of the samples.

Holders of the product's registration must retain for at least two years after each lot's expiration date all documents related to the production, distribution and pharmacovigilance data of the free samples, and must annually send information regarding the production and distribution of free samples to ANVISA.

14. Are pharmaceutical companies permitted to

sponsor scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Yes, pharmaceutical companies in Brazil are permitted to sponsor scientific meetings, congresses, and the attendance of healthcare professionals at these events. However, there are strict regulations governing such sponsorships to ensure transparency, ethics, and the protection of public health.

Pharmaceutical companies must disclose their sponsorship publicly, ensuring transparency about financial support provided to healthcare professionals attending such events.

There is a prohibition on direct payment, i.e. pharmaceutical companies are not allowed to make direct payments to healthcare professionals to attend scientific meetings. Invited professionals may not receive any kind of compensation, direct or indirect, for the time invested in monitoring the event, except when such share corresponds to services legitimately provided as a result of a contractual obligation previously agreed.

Sponsorship should not create a conflict of interest, such as influencing the healthcare professional's medical judgment. As such, any involvement of healthcare professionals in sponsored events must align with the principles of medical independence.

Any support for professionals to participate in events, national or international, cannot be conditioned to the prescription and/or dispensing, sale or promotion by such professionals of any type of product subject to sanitary surveillance.

It will not be allowed to hold events in places whose eminently tourist or entertainment appeal may detract from the scientific and/or educational character of the event.

Expenses with transport, meals and accommodation must be limited to the occasions inherent to the event itself and be directed exclusively to the invited professional, and may be extended to the days immediately before and after the official schedule, if logistical and transport aspects justify such concession. It is prohibited to offer first class tickets. The payment or reimbursement of any expenses related to family members, companions or persons invited by the professionals is expressly prohibited, as well as refund, payment or provision of any entertainment and/or leisure activity.

For events taking place abroad, the same reasoning applies, along with local regulations applied by the hosting country. INTERFARMA's Code of Conduct also establishes that the events must take place in the same country in which the organizing Company is headquartered, unless the choice for a foreign country is justified by security and/or logistical reasons, as in the case of events that bring together participants from different countries, in the case of a satellite symposium at international congresses, and in case the relevant resource or experience that is the object or subject of the event is located outside the country of the professional's practice.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

There is no specific restriction on the organisation of cultural, sports or other non-scientific events. Pharmaceutical companies may support cultural, sports and non-scientific events, since all other provisions related to advertising be complied by the companies.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

There is no provision prohibiting the payment of services provided by healthcare professionals. Healthcare professionals, including doctors, are allowed to receive compensation for the services they provide, but the nature of the payment must correspond directly to the professional services rendered, such as medical consultations, examinations, surgeries, and other health interventions. The payment must be clear, fair, and reflect the value of the services provided, without any form of overcharging or misleading representations. Moreover, from March 2025, doctors who have any relationship with pharmaceutical industries, or who produce medical products and supplies, equipment for exclusive medical use or for common use with other professions, or even with companies that act as intermediaries for the sale of these products, are required to inform them to Regional Council of Medicine in which they have an active registration, the name of the company(ies) in which they will provide services, and are required to notify the Council when their relationship ends.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

It is possible, but only gifts of nominal value, without references to any specific product. The INTERFARMA Code of Conduct states the following requirements for such gifts: (a) they have to be related to the medical practice, excluding office supplies; (b) they must have a symbolic value (around R$ 50); and (3) they must be limited to three per year per doctor.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

There is a set of bills tabled in the Brazilian Congress aiming to regulate the transparency and publicity of financial relationships between the healthcare industry and professionals. Currently, Resolution No. 2.386/2024 from the Federal Council of Medicine – CFM regulates procedures and rules in relation to doctor's association with pharmaceutical industries, healthcare and medical equipment' suppliers but it does not obliges to disclose monetary information, only the exiting relationship between healthcare industry and professionals. The Resolution will be in force by March 2025.

19. Are there any restrictions (whether by law or Codes of Practice) on advertising for medicines on social media directed to healthcare professionals or directed to the general public?

Although there are no specific regulations in this regard, Brazil's Civil Rights Framework for the Internet (Law No. 12.964/2014) establishes guarantees, rights and obligations on both providers of internet services and its users.

Also, the Brazilian Advertising Self-Regulation Council (CONAR)'s Digital Influencer Advertising Guidelines establishes that any advertisement must be clearly identified as an advertisement. If this is not evident in the content, an explicit mention of the advertising identification by using the following expressions is necessary to ensure compliance with this principle: publicidade [advertisement], publi, publipost, or others, among other recommendations for a clear and transparent advertising.

20. Is advertising on the internet for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

All regulation applies for advertising on the internet but specific rules must be observed. For instance, the display of manipulated products for advertising is not permitted. Further, over-the-counter medications may be advertised on social media, but they may not: Promote results or cure diseases; Insinuate that they are tasty, delicious or aromatic; Include imperative terms, such as “take”, “use” or “have”; Show people using the medications; Advertise the products as new or launched if they have been on the market for more than two years. Furthermore, the advertisement must include the commercial name of the medication, the name of the active substance and the registration number with Anvisa. Moreover, the display of people posing as health professionals is not permitted and people who are not experts in medicine or pharmacy may appear in the advertisement, but they may not state that they use the medication or recommend it.

21. Are there any anti-bribery rules that apply to communications between pharmaceutical companies and healthcare professionals or healthcare organisations?

There is not specifically applicable legal or regulatory provision related to anti-bribery/anti-corruption regarding interactions between pharmaceutical companies and healthcare professionals and/or organisations or the pharmaceutical industry in general. However, bribery and corruption are the object of: (1) the Brazilian Penal Code (Decree No. 2.848/1940, as amended by Federal Law No. 10.467/2002); and (2) Federal Law No. 12.846/2013 on the legal liability on companies' actions against national or foreign administrative systems.

22. What are the rules (whether statutory or self-

regulatory) which govern the offering of benefits or inducements to healthcare professionals?

As indicated in Question 1, a set of rules governing the offer of benefits or inducements to healthcare professionals and must be complied by the healthcare industry.

23. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

Bodies indicate in the answer of the Question 1, including Brazilian *Health Regulatory Agency* – ANVISA, Federal Council of Medicine – CFM and Brazilian Advertising Self-Regulation Council (CONAR) may enforce their own provisions beside judicial tribunals (State Tribunals and Federal Tribunals, depending on the nature of the grounds).

24. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Companies can initiate proceedings against competitors for advertising infringements based on several legal grounds, primarily revolving around unfair competition, consumer protection laws, and advertising regulation. The legal framework for such proceedings is mainly governed by the Brazilian Civil Code, the Brazilian Industrial Property Law (Lei nº 9.279/1996), the Consumer Protection Code (Código de Defesa do Consumidor – Law No. 8.078/1990), and specific regulations under the National Health Surveillance Agency (ANVISA) for medicine-related advertising.

Proceedings can be initiated before administrative bodies like CONAR and ANVISA or judicial bodies, such as **civil courts**, under Brazilian legislation.

25. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Penalties, sanctions and measures range from the warning and recommendation to change the practise to monetary penalties and compensation for damages.

26. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

Self-regulatory bodies such as CONAR have as primary function to ensure that advertising complies with ethical and legal standards, as well as advertising codes. When a complaint is lodged with CONAR, they can investigate the issue and issue recommendations or decisions regarding the advertisement. CONAR's decisions are binding on its members but do not have the force of law in the broader legal system.

Government Competent Authorities, such as ANVISA and Ministry of Health, are responsible for enforcing public health and safety regulations regarding the advertising of medicines, medical devices, and health services. Although their regulations and decisions are binding, carry legal force and can directly affect a company's operations, they can be challenged before a legal court that may decide that a resolution is illegal or not valid, for example. This type of situation occurred recently when the Superior Court of Justice ruled that ANVISA's RDC 96/2008 (which established advertising rules for medicines) was invalid.

In cases where self-regulation by CONAR or government actions by ANVISA or other authorities do not adequately resolve the issue, judicial proceedings may be initiated. Also, typically, a lawsuit is deemed appropriate when additional legal remedies are necessary, such as financial compensation. A court, usually a civil or public law court, may be called upon to resolve disputes regarding the legality of an advertisement, especially if there are violations of broader public health laws, consumer protection laws, or constitutional rights. It is worth noting that it is not mandatory to first initiate a proceeding with a self-regulatory bodies or Government Competent Authorities to seek judicial remedy. Brazilian legislation assures that any individual or company have the right to seek the judicial system regardless of first trying to obtain a position of other administrative bodies.

27. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past

two years.

On August 13, 2024, the Superior Court of Justice ruled that ANVISA Resolution No. 96/2008 is illegal because it exceeds ANVISA's powers provided by law.

RDC No. 96/2008 was a very strong legal tool in connection with medicine advertisement with detailed requirements, obligations and specifications, more restricted than the applicable legislation. However, ANVISA's performance must be guided by the limits imposed by federal laws, which means that the agency cannot create rules that are not provided for in the legislation approved by the National Congress.

In this sense, by ruling in Special Appeal No. 2035645 – DF, with appellant ANVISA and defendant ASPEN PHARMA INDUSTRIA FARMACEUTICA LTDA, the 1st Panel of Superior Court of Justice, having as reporting judge assistance of justice Regina Helena Costa, the Panel has decided that ANVISA has normative power limited to the faithful execution of the law. There is lack of attribution of ANVISA to impose obligations in terms of advertising medicine, being Law No. 9.294/96 and Decree No. 2.018/96 the legislation that regulates medicine advertising.

In view of that, the Panel ruled as illegal the provisions of RDC No. 96/2008 that, contrary to regulations enshrined in federal law, especially the Law No. 9.294/1996, impose obligations and conditions on the advertising pieces of Medicines.

This decision issued by the Superior Court of Justice has substantial impact in the advertising of medicine in Brazil since the pharmaceutical companies are no longer required to follow the additional rules imposed by RDC No. 96/2008, which was more restrictive.

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