BRAZIL

Law and Practice

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Contents

1. Pharmaceutical Advertising: Regulatory Framework p.3
1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines p.3
1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines p.3

2. Scope of Advertising and General Principles p.4
2.1 Definition of Advertising p.4
2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information p.4
2.3 Restrictions on Press Releases Regarding Medicines p.4
2.4 Comparative Advertising for Medicines p.5

3. Advertising of Unauthorised Medicines or Unauthorised Indications p.5
3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications p.5
3.2 Provision of Information During a Scientific Conference p.5
3.3 Provision of Information to Healthcare Professionals p.6
3.4 Provision of Information to Healthcare Institutions p.6
3.5 Information About Early Access or Compassionate Use Programmes p.6

4. Advertising Pharmaceuticals to the General Public p.6
4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public p.6
4.2 Information Contained in Pharmaceutical Advertising to the General Public p.6
4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry p.7

5. Advertising to Healthcare Professionals p.8
5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals p.8
5.2 Reference to Data Not Included in the Summary of Product Characteristics p.8
5.3 Advertising of Combination Products p.8
5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals p.8
5.5 Medical Science Liaisons p.9

6. Vetting Requirements and Internal Verification Compliance p.9
6.1 Requirements for Prior Notification/Authorisation p.9
6.2 Compliance With Rules on Medicinal Advertising p.9

7. Advertising of Medicinal Products on the Internet p.9
7.1 Regulation of Advertising of Medicinal Products on the Internet p.9
7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals p.10
7.3 Provision of Disease Awareness Information to Patients Online p.10
7.4 Online Scientific Meetings p.10
7.5 Use of Social Media p.10

8. Pharmaceutical Advertising: Inducement/Anti-bribery p.10
8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals p.10
8.2 Legislative or Self-Regulatory Provisions p.11

9. Gifts, Hospitality, Congresses and Related Payments p.11
9.1 Gifts to Healthcare Professionals p.11
9.2 Limitations on Providing Samples to Healthcare Professionals p.11
9.3 Sponsorship of Scientific Meetings p.12
9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events p.12
9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions p.12
9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions p.13
9.7 Payment for Services Provided by Healthcare Professionals p.13
9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations p.13

10. Pharmaceutical Companies: Transparency p.13
10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value p.13
10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market p.14

11. Pharmaceutical Advertising: Enforcement p.14
11.1 Pharmaceutical Advertising: Enforcement Bodies p.14
11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements p.14
11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe p.14
11.4 Relationship Between Regulatory Authorities and Courts p.14
11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising p.15

12. Veterinary Medicines p.15
12.1 Advertising Veterinary Medicines p.15

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1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The manufacturing, distribution, marketing, import and export of medicinal products in Brazil are mainly regulated by the National Sanitary Surveillance Agency ("ANVISA" or the "Regulatory Agency").

The advertising of pharmaceuticals, as well as of other products that may affect human health, as provided for in paragraphs 3 and 4 of Article 220 of the Federal Constitution, are subject to legal and regulatory restrictions. The limits that the Regulatory Agency has in the imposition of restrictions on the advertising of non-prescription drugs are the subject of heated debate between the regulated sector and the government, including a few judicial discussions.

The main legal instruments that essentially regulate advertising and the promotion of medicinal products in Brazil are as follows.

Laws and Decrees

- 6.360/76 regulates the sanitary surveillance to which medicinal products and their ingredients, medical products, cosmetics and cleaning products are subject – the implementation of this law is regulated by Decree 8.077/2013;
- 6.437/77 defines violations of the federal sanitary legislation and establishes the corresponding penalties;
- 8.078/90 the Consumer Protection Code;
- 9.294/96 imposes restrictions on the advertising of medicinal products, products for smoking, alcoholic beverages, therapies, and crop-protection products – the implementation of this law is regulated by Decree 2.018/96; and
- 9.782/99 sets forth the statutory competence of the Regulatory Agency, ANVISA – the implementation of this law is regulated by Attachment I of Decree 3.029/99.

Resolutions and Other Ancillary Regulations Issued by ANVISA

- RDC 096/2008 (as amended by RDC 023/2009) regulates advertising and promotional actions in all their forms and media (some concepts are defined in Normative Instruction ANVISA 05/2009);
- RDC 060/2009 regulates the production, distribution and control of free samples; and
- Ordinance 344/98, issued by the Ministry of Health before ANVISA was created, remains in force and regulates medicinal products containing substances under special control (narcoleptics, anorexigenic drugs, antiretroviral drugs, immunosuppressants, and others), including their advertising and promotion.

Resolutions of the Federal Council of Medicine – "CFM"

- 2.217/2018 – Medical Profession Code of Ethics.
- 1.939/2010 – prohibits medical doctors from participating in the supply, to patients, of coupons or cards that give discounts on medicines.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Self-regulatory codes in Brazil, in general, apply only to members of class associations that have enacted these codes. Pharmaceutical Class Associations that have enacted self-regulatory codes to date are:

- INTERFARMA (Brazilian Association of Research-Based Pharmaceutical Industries);

- ABIMIP (Brazilian Association of Manufacturers of Non-prescription Drugs); and
- SINDUSFARMA (Pharmaceutical Employers Union of the State of São Paulo).

Brazil also has a National Council of Self-Regulation in Advertising ("CONAR") that enacted a code regulating public advertising and, in the case of pharmaceutical products, applies exclusively to non-prescription drugs that may be advertised to the public in general. In fact, the CONAR code has a chapter specifically directed at the advertising of non-prescription medicines. CONAR's code applies to any advertisement in Brazil, even if the advertiser is not a member of the council.

As a rule, decisions from self-regulatory bodies are not made public, but competent authorities and the judiciary may (and do) use decisions issued by self-regulatory bodies as a basis for their decisions, if these decisions are brought to their attention.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

ANVISA defines the advertising/publicity of pharmaceutical products in Resolution RDC 096/2008, as: "the array of information and persuasive techniques and activities with the objective of publicising knowledge, making a product or trademark more widely known or the object of prestige, aiming to influence the public by means of actions intended to promote and/or induce the prescription, dispensing, purchasing and use of a medicinal product".

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Initially, it is important to keep in mind that advertising of prescription drugs to the lay public is prohibited in Brazil. That said, as a rule, information will usually be seen as "advertising" if it includes products' trade marks and standard promotional messages.

The category of "information" includes disease awareness campaigns, related leaflets and other information (including electronic information), directed to patients and/or to the general public, which are widely used in Brazil. This includes health-related campaigns by private industries and does not qualify as advertising.

In fact, Brazilian health authorities implement several campaigns each year especially related to vaccines, AIDS prevention, hepatitis, influenza, COVID-19, and tropical diseases. In disease awareness campaigns, it is prohibited to mention any specific trade mark or name of a medicinal product. The campaigns must simply provide an incentive for the population to consult with healthcare professionals for diagnosis or to go to doctors or health clinics (private or public) for vaccinations.

2.3 Restrictions on Press Releases Regarding Medicines

Press releases are allowed in Brazil and widely used. Although there is no specific legislation regulating this issue, in some cases, health authorities have argued that some releases (or articles published in lay media) were, in fact, disguised "advertising". Because of that, in preparing press releases the use of trade marks or trade names should be avoided in favour of using the name of the active ingredient.

2.4 Comparative Advertising for Medicines

Comparative advertising is allowed and RDC 096/2008 sets forth the rules to guide authorised comparisons.

Price Comparisons

Price comparisons are only allowed between medicines considered as interchangeable under applicable law and regulations. As a rule, only reference products and generics would be interchangeable. In the case of Brazil, even though "similar products" (generics bearing trade marks) must demonstrate bio-equivalence to the reference product, the use of comparative advertising is still the subject of some discussion.

Comparative Advertising

Comparative advertising, in general, must also abide by several different pieces of legislation and regulations, including:

- the Industrial Property Law;
- the Class Associations' Codes of Ethics; and
- the National Code of Self-Regulation in Advertising.

Self-Regulation and the Code of Conduct

CONAR's National Code of Self-Regulation in Advertising states that all comparative advertising must focus on objective aspects of the products and that the advertiser must be able to prove the conclusions of the comparisons. Also, it is forbidden to deprecate the compared brand or to create confusion between the products.

The INTERFARMA Code of Conduct, for instance, prohibits comparative advertising using third-party brands without their prior consent. However, it does allow comparisons between active ingredients even if indirect identification of brands could be possible. Any decision to engage in comparative advertising must be carefully evaluated.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The provision of information about unauthorised medicines and/or unauthorised indications (off-label) are, as a rule, not allowed in Brazil. Some information may be provided in medical events or through press releases but, as mentioned, the use of trade marks should be avoided.

3.2 Provision of Information During a Scientific Conference

Information on unauthorised medicinal products and/or off-label information can only be published as scientific information. That said, in order to avoid allegations of disguised advertising, if the product already has a trade mark, its use should be avoided. The INTERFARMA Code of Conduct sets forth that information on unregistered products or off-label indications may only be used in the context of medical and scientific information at congresses, symposiums or other scientific events.

If any company does disclose information on unauthorised medicines, the audience must be duly and previously informed that the product is not yet available in the market and that its use has not been approved by the regulatory authorities. There are no specific rules for international conferences.

3.3 Provision of Information to Healthcare Professionals

Although Brazilian pharmaceutical legislation and ancillary regulations strictly prohibit the advertising of medicinal products that have not been registered by ANVISA, products that have not yet been authorised may be discussed at scientific events (congresses, symposiums, etc), whether the event is sponsored solely by the company responsible for the product or not. These discussions must be restricted to technical information, eg, important findings in ongoing clinical studies, and should not use product trade marks to avoid being perceived as an inducement to prescribe.

It should be noted that the legislation does not mandate a previous request from the healthcare professional for such information. However, the INTERFARMA Code of Conduct states that this type of information, in principle, can only be sent if requested by the professional.

The same rules apply to off-label information. In this case, too, it is advisable not to use the trade mark of the product, but rather just the name of the active ingredient.

3.4 Provision of Information to Healthcare Institutions

See **3.3 Provision of Information to Healthcare Professionals**.

3.5 Information About Early Access or Compassionate Use Programmes

There is no specific regulation on the publication of the availability of compassionate programmes.

It is important to say that while the production, distribution and sale of medicinal products that are not yet registered by ANVISA are prohibited, it is possible for an individual to import non-registered products for their own use, independent of previous authorisation. For this, it is only necessary to provide the importer with a specific prescription from a medical doctor duly registered to practise medicine in Brazil.

Importation for groups of patients can only be made through "compassionate use" or "expanded access" programmes that depend on ANVISA's previous authorisation but, as a rule, no public information is released. These types of programmes are mainly used in relation to patients who have participated in clinical studies, for access to the study drugs after the end of the study, while the product is undergoing registration.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Only over-the-counter (OTC) pharmaceuticals can be advertised to the general public in Brazil. Prescription-only products can only be advertised to prescribing professionals. While no restrictions apply for OTC medicines, advertising guidelines must be followed.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertisement of medicinal products to the public in Brazil must always include the following generic warnings: "If the symptoms persist, consult a doctor", and "This is a medicinal product, and its use involves risks. Consult with a doctor and a pharmacist. Read the insert/leaflet".

The above-mentioned warnings must be included. Additional warnings regarding a specific active ingredient may be required by health authorities in relation to any product.

Restrictions on Advertising Non-prescription Medicinal Products

The following restrictions also apply to the advertising of non-prescription medicinal products:

- there can be no use of expressions such as "shown in clinical studies" or "scientifically proven";
- the advertising piece cannot suggest that the product would make healthy habits and visits to doctors unnecessary;
- there can be no use of celebrities stating or insinuating that they make use of the product;
- the piece cannot use language that relates the product to excessive intake of alcohol or food;
- there may be no language relating the use of the product to physical, intellectual, emotional or sexual performance or to a person's looks/complexion, except if the product has been approved by ANVISA for these specific properties;
- the piece cannot present visual representations of changes in the human body caused by illnesses or lesions in an abusive, frightening or misleading way; and
- the piece cannot include messages, symbols or images of any nature directed at children or teenagers.

Restrictions on Advertising to Professionals

Even considering that advertising of a medicinal product can only be made to prescribing professionals, the advertising cannot:

- foster indiscriminate use of medicinal products;
- suggest or stimulate diagnosis; and/or
- suggest that a medicinal product is tasty, yummy or delicious.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There is very little legislation and/or ancillary regulation on the subject but, as a rule, direct interaction with patients is not allowed (except for through "call centres" or "access/adherence programmes"), while interaction with patient organisations is allowed. The INTERFARMA Code of Conduct, unlike the legislation, does expressly address the issue. For instance, the code expressly prohibits the industry from interfering with the administration of the organisation or participating in it. The code also prohibits an industry from being the sole contributor to any organisation.

Because of the high level of judicialisation of health treatment in Brazil, health authorities have been keeping a close watch on the relationship between the industry and patient associations.

Authorities believe, and in some cases found it to be true, that some donations made to patient support groups were being used to pay legal fees and the expenses necessary for patients to sue the government in order to receive treatment (medicines or medical treatment) not yet available in the public system or not yet registered in Brazil. Note that under the interpretation of the constitution by the courts, the government is obliged to provide medicines, for free, for those that cannot pay for them.

Most police investigations made over the past decade ended without finding hard evidence on the alleged financing of patient associations for the purpose of subsidising judicialisation, but a

few cases are still ongoing. Most of these cases refer to "high-cost" and "high-complexity" medicines.

The judicialisation of health is a big issue in Brazil.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

This is regulated under RDC 096/2008. The required information in advertising to healthcare professionals is:

- brand name;
- name of the active ingredient as it appears in the Common Brazilian Denomination – "DCB";
- ANVISA product registration number;
- indications;
- contraindications;
- warnings related to adverse reactions and interactions with other substances;
- dosage;
- prescription and dispensing classification; and
- date of printing.

Where a promotional piece on a prescription drug highlights the benefits of the product, the piece must also highlight at least one contraindication and one frequent drug interaction.

For vaccines, the advertisement must convey the necessary number of doses for complete immunisation.

Products containing substances under special control, as defined in Ordinance 344/98 (see **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines**), are subject to further regulation.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertising to prescribing professionals may contain information related to data held on file or to clinical studies that have not been included in the registration package, or even phase 4 studies. The information, however, must conform to the information (indications, dosage, etc) already approved by ANVISA and must be available for consultation if requested by healthcare professionals or by the authorities. Information that does not conform to the registration package will be deemed as promotion of unauthorised use (off-label).

5.3 Advertising of Combination Products

Pharmaceutical products in Brazil may only be promoted for the indications that are approved by ANVISA, and such indications are those included in the registration package. That said, for it to be possible to promote any product, even in combination with another product, it would be necessary to amend the product registration to include this "combined use indication" in the product registration package and have it approved by ANVISA. Advertising of these combined products is subject to the same standard regulations.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

These are generally considered as scientific information and, as such, reprints may be distributed to healthcare professionals. There are no specific restrictions, but the reprint should not come in a format that resembles a promo-

tional piece. For the distribution of reprints, a company must have the authorisation of the author or of the media, as the case may be.

5.5 Medical Science Liaisons

There are no specific regulations related to medical science liaisons (MSLs) who – in Brazil – are under the same rules applicable to pharmaceutical representatives. Although most MSLs are themselves healthcare professionals, they cannot discuss unauthorised medicines or off-label indications.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

No prior authorisation applies to advertising of medicines. However, RDC 096/2008 sets forth that the organisers of scientific events at which the advertising and promotion of medicinal products will take place, must inform ANVISA three months in advance of any such event, indicating the date and place of the event and the professional categories that will be invited to the event. There are no specific regulations regarding medical science liaisons' (MSLs') reporting lines.

6.2 Compliance With Rules on Medicinal Advertising

There are no arrangements or standard operating procedures (SOPs) required by law or regulation in Brazil, in relation to advertising or promotional activities.

Companies are free to establish these according to their own policies. Companies are also free to not even implement any SOPs to guide their promotional activities.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

The internet is regarded as just another form of media and, as such, the same legislation and regulations that apply to the advertising of medicinal products in traditional media in Brazil also apply to advertising on the internet, meaning that only advertising of OTC medicines is allowed.

If companies have internet sites that carry or include any type of promotion or advertisement of medicinal products, they need to ensure that advertising and promotion of prescription products can only be accessed by prescribing professionals.

RDC 096/2008 has only a few regulations that are specific to internet advertising. These regulate, for example, how warnings must appear (even indicating the type of font or requiring the use of bold fonts and capital letters in some specific cases).

In addition, CONAR recently issued its Digital Influencer Advertising Guidelines and a Guide of Good Practices for Digital Advertising for Minors, which are also applicable to advertising of any medical product using digital influencers or digital platforms, mainly regarding its clear identification as an explicit advertisement.

It should be stressed that ANVISA does monitor the health-related sites of pharmaceutical companies, pharmacies, distributors, clinics, etc, to make sure these rules are followed. However, exercising control over the content of internet sites is difficult as they exist in vast numbers and most of them contain a lot of information and

countless different pages and/or links. That said, it is not common to see violation notices or fines applied for non-compliance with internet rules.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

As the promotion/advertising of prescription medicines can only be made to healthcare professionals, any website containing adverts of these products must have access controls and restrictions.

7.3 Provision of Disease Awareness Information to Patients Online

Online disease awareness campaigns are allowed and, in fact, are very common in Brazil. The Brazilian health authorities are among the more common users of these campaigns and implement several of them each year especially related to vaccines, AIDS, hepatitis, influenza, and tropical diseases. These campaigns can be found on the internet sites of the Ministry of Health, the State Health Department and even municipal health departments.

Note that in online disease awareness campaigns, and/or material provided through this channel, no specific medicinal product or trade mark should be mentioned. The campaigns should simply provide an incentive for the population to consult with healthcare professionals for diagnosis or to go to doctors or health clinics (private or public) for diagnosis or vaccination.

7.4 Online Scientific Meetings

The rules applicable to scientific meetings or congresses also apply to online events. Although there are no specific rules issued to online scientific meetings in Brazil, the sponsor should implement the same filters and controls required at presential events of the same nature. That said, these online meetings may or may not be considered international depending on their scope and content. No previous authorisation is needed.

In the same manner applicable to the online advertisement of prescription-only drugs, access to online materials must be subject to appropriate controls and restrictions during and after the online meeting or congress. No specific regulation applies to the use of social media by pharmaceutical companies' employees.

7.5 Use of Social Media

See **7.1 Regulation of Advertising of Medicinal Products on the Internet**.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

There is no anti-bribery/anti-corruption legislation or regulations specifically applicable to the interaction between pharmaceutical companies and healthcare professionals/organisations, or to the pharmaceutical industry in general.

In Brazil, bribery and corruption are regulated by:

- the Penal Code, as amended by Federal Law 10.467/2002;
- Federal Law 12.846/2013, which penalises actions against national or foreign public administrations (penalties apply to both individuals and organisations); and
- Federal Law 8.249/1992, applicable specifically to public workers/agents.

Anti-bribery/anti-corruption authorities will only investigate breaches related to advertising of pharmaceutical products to the extent that the breach constitutes an action of corruption or bribery.

8.2 Legislative or Self-Regulatory Provisions

As per applicable regulations, especially Resolution RDC 96/2008, pharmaceutical companies are not allowed to grant, offer, promise or distribute gifts, benefits and advantages to:

- professionals who prescribe or distribute medicines;
- those who directly sell medicines to consumers; and
- the public in general.

The rules apply to both individuals and/or organisations.

INTERFARMA also expressly regulates the issue in basically the same way as RDC 96/2008. Violation of the INTERFARMA code will subject the company to administrative penalties, eg, suspension or exclusion from the association and a pecuniary penalty that may be extremely steep.

It should be noted that the Federal Medicine Council, which regulates the medical profession in its Code of Conduct and Resolution 1.939/2010, prohibits physicians from participating in any advertisements or promotion of medical information for any promotional purposes and, also, to register patients or enrol them to participate in promotional actions, such as discount programmes.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Companies may offer gifts to healthcare professionals. However, as per the applicable regulations, only gifts of nominal value can be offered and these gifts must be of an "institutional" nature, meaning they cannot bear marks or signs that link them to any specific product. Some class associations like INTERFARMA, also require that the gifts:

- be related to the medical practice, which excludes all kinds of office supplies and gifts of a personal-use nature that are not considered directly related to the medical practice;
- are of a symbolic value (around USD50); and
- are limited to three per year per doctor.

9.2 Limitations on Providing Samples to Healthcare Professionals

Samples may be provided to healthcare professionals, with a few exceptions:

- samples of non-prescription products;
- biological products; and
- products prepared in compounding pharmacies.

The procedures related to the distribution of samples are clearly regulated in RDC 096/2008 and RDC 060/2009. Products containing substances under special control, eg, narcoleptics, which are included in Ordinance 344/1998 (controlled substances) are subject to additional regulations.

A free sample package must contain 50% of the quantity of an original package. However, in the case of products for chronic diseases and a few others, like contraceptives, samples

must have the same quantity of the registered original. Samples of antibiotics must contain a complete treatment for one patient. Applicable regulations require that free sample packages are clearly and indelibly marked with the words "free sample".

The distribution of free samples is limited to ambulatories, hospitals, medical doctors' offices, and dentists' offices. The prescribing professional receiving the samples must sign a document indicating receipt of the samples.

Regulations on samples, especially RDC 060/2009, require that holders of the product registration must keep on file, for a minimum of two years after each lot's expiry date, all documents related to the production, distribution, and pharmacovigilance data of the free samples, even if not distributed, and must send ANVISA, annually, information on the production and distribution of free samples.

9.3 Sponsorship of Scientific Meetings

The sponsorship of scientific events by pharmaceutical companies is allowed and is also regulated under RDC 096/2008, although there is no direct or specific regulation that directly mentions hospitality.

The INTERFARMA Code of Conduct is more detailed than the ANVISA regulation and does indicate that locations of primarily touristic appeal are not permitted. No approval from the local affiliate is required.

There is no specific threshold applicable, but the venues and activities must not be excessive or inappropriate for a healthcare event. Under the INTERFARMA Code, events should take place in the country where the organiser is located, except if the choice of a foreign country is justifiable for reasons of security or logistics.

It should be noted that payment or any type of remuneration, direct or indirect, for the time invested in participation cannot be made to participants. Also, payments for travel, accommodation, food, etc, are limited to the participant and cannot be extended to family members or other invitees of the doctor.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Pharmaceutical companies are allowed to organise and sponsor cultural, sports and other events, provided they are under the corporate trade marks of the companies concerned. These types of events cannot be organised using the names or trade marks of prescription-only drugs.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

There is no specific regulation in Brazil with direct and clear wording on this.

However, throughout the applicable legislation and ancillary regulations it is made very clear that promotional actions towards prescribing professionals should not be (or be understood to be) in exchange for prescriptions of any product. In this case, also, it is advisable that grants and donations are regulated by contracts indicating the reason for the grant or donation.

In relation to healthcare institutions, these donations must also be of an institutional nature. In addition, they must clearly not be linked to any requirement or for the effect of serving as an incentive for the recipient institute to promote, advertise or standardise the use of any medicinal product of the donor.

Donations should be covered by contracts that should have a specific clause to make this as evident as possible. The contracts may, and should, define the specific purpose of the donation and include clauses that give the donor the right to audit the use of the donations.

From a regulatory point of view, there is no difference between monetary or equipment donations. Some donations may be subject to taxation and specific rules will apply.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Usually, rebates or discounts are granted to distributors and retailers. The industry is allowed to grant discounts and rebates, provided they are within commercial market practices and in line with the rules set forth in RDC 096/2008.

9.7 Payment for Services Provided by Healthcare Professionals

Companies may hire healthcare professionals to render any reasonable and justifiable professional services such as consulting services and review of dossiers, etc. Payment for the services must be within market practices.

When hiring professional services from healthcare professionals, a contract should be executed clearly defining the services to be provided. If a healthcare provider is hired to give classes and/or presentations at the start of any such class or presentation, the doctor must indicate that they are receiving payment for that service as disclosure of potential conflict of interest.

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Healthcare professionals linked to either government institutions or private companies must observe transparency and the conflict-of-interest norms set forth in their respective employment agreements and in the applicable law. Usually, government employees are prevented from rendering services to any private companies even if there is no apparent conflict of interest. Government employees may give speeches and/or presentations but cannot be paid for these. In some cases, prior authorisation or notification may apply, mostly for healthcare professionals, employed by private companies.

Furthermore, organisers of scientific events at which the advertising and promotion of medicinal products will take place, are also required to inform ANVISA three months in advance of any such event, indicating the date and place of the event and the professional categories that will be invited to the event.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Resolution RDC 096/2008 requires that healthcare professionals disclose to events' organisers and participants any sponsorship by companies and/or eventual conflicts of interest.

There is no obligation to disclose the amount or details of any sponsorship. Speakers at events, symposiums, congresses, etc, must, however, disclose if they are sponsored by any compa-

ny at the start of their presentation and in the records of the event, if they exist.

It is important to point out that INTERFARMA's Code of Conduct recommends making the public the recipient of sponsorships and donations.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

See **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value**. In cases where the donor is a foreign company not subject to Brazilian Law, authorisations and notifications, if any, should be addressed by the grantee.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

Enforcement of advertising rules is mainly exercised by ANVISA. The ANVISA department that holds the authority for supervising and judging advertising/promotional violations is located under the General Management in Charge of Sanitary Inspection and Supervision ("GGFIS").

As regulated by RDC 096/2008, the authorities also have the power to request that, if corrective statements are required, these will be issued and published by the companies.

Any final administrative decision, as per Brazilian law, may be submitted to the judiciary if the regulated entity/individual believes the administrative decision does not conform to the law. Enforcement may also be sought through class associations such as INTERFARMA, ABIMIP or SINDUSFARMA.

Finally, in the case of non-prescription medicines, enforcement may be sought through CONAR.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Proceedings may be initiated ex officio by the regulatory authority, or by a competitor. Most of the time, the basis is some indication or evidence that the advertising rules have been breached by the accused party. Proceedings can be started before ANVISA and/or before any of the class associations mentioned.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

Penalties imposed by ANVISA will range from:

- a warning;
- the prohibition of advertising; the obligation to provide a rectifying message; suspension from new advertisements; and/or
- the payment of a fine that may range from BRL2,000 to BRL1.5 million.

The penalties imposed will depend on ANVISA's evaluation of the gravity of the violation.

11.4 Relationship Between Regulatory Authorities and Courts

There is no relationship between the regulatory authority and the courts. However, the courts will tend to confirm decisions of the regulatory authority or class associations, as they realise that these bodies have a better technical knowledge of the field.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Recently, there has been a wave of comparative OTC advertisements and, given the speed necessary to block irregular advertising, CONAR has taken the lead in ruling these cases. The most significant decisions were about the veracity of the comparisons and the irregular use of trade marks in the advertisement (one leading case is: CONAR representation 240/19).

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

The manufacturing, importation, distribution, and sales of veterinary medicines are regulated and supervised by the Ministry of Agriculture, Livestock and Supply. The advertising of veterinary products is very different from that of human medicines and is only marginally regulated by Law-Decree 467/1969, by Federal Decree 5.053/2004 and by the Brazilian Advertising Self-Regulation Code. These rules are enforced by the authorities by means of warnings, fines or cancellation of the company's registration.

Lopes Muniz Advogados is recognised as a multi-field action firm, known for solutions that grant security to its clients and give them the confidence they need to face their legal challenges. In the field of life sciences, the firm renders services in the areas of pharmaceutical and biological products, other health-related products (medical devices), food and food supplements. The firm's work model is based on specialised teams, led by one or more partners, that have hands-on participation in finding solutions and in determining strategies for each case, assuring high-quality legal advice. The firm's life sciences area is composed of a team of lawyers with recognised experience in regulatory and sanitary legislation.

Authors

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