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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2016

13th Edition

A practical cross-border insight into pharmaceutical advertising

Published by Global Legal Group, with contributions from:

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Published by
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London SE1 3PL, UK
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Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

GLG Cover Design
F&F Studio Design

GLG Cover Image Source
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Printed by
Stephens & George
Print Group
June 2016

ISBN 978-1-911367-01-7
ISSN 1743-3363

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1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

It is important to start by pointing out that the manufacture, distribution, marketing, import and export of medicinal products in Brazil are regulated by the National Sanitary Surveillance Agency – ANVISA.

The Federal Constitution sets forth in paragraph 4 of article 220 that advertising of pharmaceuticals, as well as other products that may interfere with public health, is subject to legal restrictions. There is an ongoing discussion, although mainly in relation to non-prescription products, on the extent of the regulatory agency's (ANVISA) authority to impose these restrictions, as some scholars (and a few court decisions) understand that the imposition of any restrictions would depend, first, on the enactment of a law.

That said, the advertising and promotion of medicinal products in Brazil is regulated, essentially, by the following legal instruments:

Laws:

- 6.360/76 – regulates the Sanitary Surveillance to which medicinal products, their ingredients, medical products, cosmetics and cleaning products are subject. The implementation of this law is regulated by Decree 08.077/2013;
- 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 – creates the National Sanitary Surveillance Agency – ANVISA – and sets forth its statutory competence. The implementation of this law is regulated by Attachment I of Decree 3.029/99.

Resolution of 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 5/2009; and
- RDC 060/2009 – regulates free samples.

Note that Ordinance 344/98, issued by the Ministry of Health before ANVISA was created, remains in force (which continues to be amended from time to time to add products to the lists attached to it) and imposes specific restrictions on the advertising/promotion of medicinal products containing substances under special control (narcoleptics, anorexigenic drugs, antiretroviral drugs, immunosuppressant drugs, and others).

Resolutions of the Federal Council of Medicine – CFM:

- 1.931/2009 – Medical Profession Code of Ethics;
- 1.939/2010 – prohibits participation of doctors in medicinal product campaigns; and
- 1.974/2011 – sets forth criteria for the participation of members of the medical profession in promotion and advertising.

Other Regulations:

- Decree 2.108/1996 regulating Radio Advertising;
- The National Code of Self Regulation in Advertising – sets forth a series of basic rules to be followed by all advertisers and media – CONAR; and
- 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).

1.2 How is "advertising" defined?

RDC 096/2008 defines advertising/publicity as the "array of information and persuasion techniques and activities with the objective of publicising knowledge, make more widely known or object of prestige a determined product or trademark, 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".

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Some multinational companies create a "review board" for promotional material; usually with members from legal affairs, medical affairs and regulatory affairs.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

There are no SOPs required by law or regulation. Companies are free to establish them according to their own policies or to not establish them at all.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

No. However, RDC 096/98 determines that the organisers of scientific events at which the advertising and promotion of medicinal products will be allowed, 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 participate in the event.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Yes, they do. The ANVISA department that holds the authority for supervising and judging advertising/promotional violations is the general management in charge of Inspection, Quality Monitoring, Control and Supervision of Raw Materials, Medicines and Products, Advertising and Publicity – GGIMP.

As regulated by RDC 096/98, the authorities also have the authority to request that a corrective statement be issued and published.

Alleged violators have the right to appeal a decision that considers that a certain promotion/advertisement breaches the applicable regulations and/or a decision to request a corrective statement; such appeals will be judged by the ANVISA Board of Directors. Any final administrative decision may be subject to a Judicial Procedure if the regulated entity/individual believes the administrative decision does not conform to the law.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

Applicable penalties are listed in article 2 of Law 6.347/77 and vary from warnings and suspension of sales, to prohibition of advertising and corrective statements, as mentioned in question 1.6 above, and may be accompanied by a fine that can vary from two thousand Reais to one and a half million Reais, depending on whether the failure was considered by the authorities as "light", "serious" or "very serious".

Enforcement of these rules is the responsibility of the GGIMP and it is fairly strict. Due to the size of the country and the market, enforcement usually results from complaints and/or denunciations made by competitors. Although a few cases do exist, it is very uncommon for competitors to take direct action through the courts, but when they do, the complaints usually involve unfair competition and/or violation of intellectual property rights.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

ANVISA's enforcement of advertising regulations bears no relationship whatsoever to any self regulatory process or body, be it the National Code of Self Regulation in Advertising – CONAR, or a Class Association like INTERFARMA, where, as a general rule, the decisions are not made public. Competent authorities will investigate only matters that may constitute a breach of the law and the regulations they issue, but may use the decision of any of the mentioned self-regulatory bodies to support their decision.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

Other actions that can be taken would be, in principle, related to violations of (1) the Industrial Property Law – Law 9.279/96, that are considered acts of unfair competition as a result, for example, of unauthorised use of a trademark and/or trade dress, imitation advertising signs and/or expressions, or (2) the Copyright Law – Law 9.610/98, as a result, for example, of using competitors' sales presentations, manuals, training material, etc. The action can be brought by the owner of the violated industrial property right or copyright or by a licensee if the Licence Agreement so permits. These actions will be filed as claims for civil indemnification and/or a criminal proceeding as the case may be.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

Although Brazilian pharmaceutical legislation and ancillary regulations strictly prohibit the advertising of medicinal products that are not registered by ANVISA, any such product may be discussed at scientific events (congresses, symposia, etc.), independent of whether or not the event is sponsored by the company responsible for the product. These discussions should be restricted to technical information like important findings in ongoing clinical studies, for example, and should not use product trademarks so as to avoid being perceived as an inducement to prescribe.

Note that while it is prohibited to produce, distribute and market medicinal products that are not registered, it is possible for an individual to import non-registered products for his/her own use under a specific prescription from a medical doctor duly registered to practise medicine in Brazil. The same rules apply to off-label information and for these types of discussions; in this case, too, it is advisable not to use the trademark of the product, but instead just the name of the active ingredient.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

Information on unauthorised medicinal products and/or off-label information can only be published as scientific information. In this case, using trademarks should also be avoided. The INTERFARMA Code of Conduct expressly says that information on unregistered, off-label indications or products may only be used when related to medical and scientific information at congresses, symposiums or other scientific events, and provided that the audience is duly and previously informed that the product has not been registered or that the indication is off-label.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply?

Yes, but as mentioned above, only strictly as scientific information, and it is advisable to avoid the mention of trademarks.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

Yes, provided the information is part of a strictly scientific publication. A previous request from the healthcare professional is not required.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

It has not. The European Court of Justice judgments are not applicable in Brazil.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

As publicising unauthorised medicinal products is prohibited and only scientific information is allowed, information on unauthorised medicines or indications can only be sent to healthcare professionals. Also, in the advertising of medicinal products, as regulated by RDC 096/98, to create an expectation of sales is prohibited.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Yes. Companies can hire healthcare professionals to render any reasonable professional services. A contract should be issued clearly delimiting the services to be provided.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

This is regulated in RDC 096/98. The required information in advertising to healthcare professionals is the following:

- (1) brand name; (2) name of the active ingredient as written in the Common Brazilian Denomination – DCB; (3) ANVISA product registration number; (4) indications; (5) counter-indications; (6) warnings related to adverse reactions and interaction with other substances; (7) dosage; (8) prescription and dispensing classification; and (9) date of printing.
- In case the promotional piece on a prescription drug highlights the benefits of the product, the piece must also highlight at least one counter-indication and one frequent drug interaction.
- For vaccines, the advertisement must inform of the necessary number of doses for the complete immunisation.

Products containing substances under special control, as defined in Ordinance 344/98 mentioned above, are subject to further regulation.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Studies not included in the SmPC may be used as reference in an advertisement to healthcare professionals. However, they must have been published in scientific publications, preferably with high evidence levels, and should be available for delivery to healthcare professionals and/or the authorities upon request.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

Healthcare professionals cannot endorse medicinal products in promotional materials. In fact, the Federal Council of Medicine, through Resolution 1.974/2011, prohibits medical doctors to "participate in advertising of companies or products associated with medicine". Some participation is allowed for other professionals like dentists, pharmacists and nurses.

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

No. Any such comparison must be based on studies that have been published, preferably with high evidence levels, and must include the complete bibliographical information.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Unauthorised products can never be mentioned in advertising. RDC 096/98 sets forth the rules for comparative advertising.

In the case of price comparisons, the regulations only allow it between interchangeable products, as defined in the law (Reference Products X Generics), including to the public. However, if the products are not interchangeable, the comparison can only be made to prescribing professionals and only between products that have the same active ingredient and must be based on the cost of the treatment.

Comparative advertising of medicinal products is regulated by RDC 096/98 of ANVISA, as mentioned above. Comparative advertising, in general, is regulated by several different pieces of legislation (Industrial Property; Code of Ethics or the Advertising Profession; and the National Code of Self Regulation in Advertising) and there is an ongoing discussion on whether or not it is possible to use third party brands in comparative advertising. Any decision to do so must be carefully evaluated.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

Scientific papers may only be distributed to healthcare professionals. As mentioned above, promoters/sponsors of medical events, which include congresses, 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 participate in the event.

3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

Yes, as there are no regulations directly related to this matter.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

Yes, except for non-prescription products, biological products and products prepared in compounding pharmacies, in which case provision of free samples is not allowed. The procedures and restrictions are clearly regulated in RDC 096/98 and RDC 060/2009. Products containing substances under special control, e.g., narcoleptics, are subject to additional regulations.

In general terms, the content of a free sample package must be 50% of the original, except for: products for chronic diseases (continuous use) and contraceptives, which must have the same content of the registered original; and antibiotics, which must have a complete treatment for one patient. Free sample packages must clearly and indelibly include the expression "free sample".

Free samples can only be distributed in ambulatories, hospitals, medical doctors' and dentists' offices, and the respective prescribing professional must sign a document indicating receipt of the samples.

As per articles 11 and 12 of RDC 060/2009, owners of the product registration must keep on file, for a minimum of two years after each lot's expiration date, 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.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply?

Only gifts of nominal value can be given to practitioners and they must be "institutional"; that is they cannot be related to any specific product. Some class associations like, for instance, INTERFARMA, also require that the gifts: (1) must be related to the medical practice; (2) are of a symbolic value; and (3) are limited to three per year per doctor.

4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

Yes. However, these gifts or donations must be institutional and cannot be linked to the requirement that the recipient institute promotes/advertises or standardises the use of any medicinal product. Even information leaflets and annual reports on corporate responsibility published by companies to inform of their respective activities in that field cannot be used as advertising vehicles for medicinal products or even mention such products.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

This is not possible. Throughout the applicable legislation and ancillary regulations it is made very clear that no promotional action towards prescribing professionals can be (or be understood as) an exchange for prescriptions of any product.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

Yes. The purchase and sales of medicinal products in Brazil operates on a standard international market basis, and so volume is one of the variables that may impact prices. Regulations strictly related to advertising do not make reference to this matter.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

No, as this is understood by health authorities as a violation of, among other rules, article 5 of RDC 096/98, which prohibits

companies from granting benefits or advantages to prescribing and dispensing professionals, or anyone exercising activities related to the sale of medicinal products to the consumer.

In a specific case, and with the argument above, ANVISA denied the request of a pharmaceutical company that had consulted ANVISA on the possibility to pay for a certain lab test as it would be the only way to determine whether or not patients suffering from a determined illness could benefit from the use of the medication, as it only would work for certain subtypes of viruses.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

The National Code of Self Regulation in Advertising strictly prohibits this type of scheme in relation to non-prescription medications.

In relation to medication sold under prescription, some medical-related institutions argue that parts of Law-Decree 4.113/42 (dating back to February of 1942) are still in force, including article five/XII, which sets forth that it is prohibited to advertise medicinal products with promises of reward (refunds) for the patients that do not have satisfactory results with their use. This piece of legislation is consistent with the prohibition of refund schemes in relation to non-prescription products.

Although such a scheme has been implemented a couple of times in Brazil, in at least one case the programme was terminated early, as the company decided to settle with one medical professional institution, and does not discuss whether or not the Law-Decree mentioned above would still be in force.

It is important to point out, also, that Resolution 1.939/2010, issued by the Federal Council of Medicine, prohibits the participation of doctors in any promotion related to medicinal products, including the filling out of any form or document related to any type of discount to patients.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Yes. There is a specific chapter relating this matter in RDC 096/98. The three basic general rules for sponsoring continuing medical education are: (1) that the sponsoring is clearly not an exchange of prescription or participation of the sponsored doctors in promotional campaign; (2) it being the case, it must be very clear to participants of medical events which company/ies are sponsoring the event; and (3) a speaker in any such event who has relations with pharmaceutical companies or has any financial interest in them (e.g., a shareholder), must clearly inform this potential interest to the event organisers and this must be clearly indicated in the programme and at the start of his/her presentation, as well as in the annals of the event if applicable.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

This is also regulated RDC 096/98, although there is no direct or specific regulation with a direct mention of hospitality. The INTERFARMA Code of Conduct, on the other hand, 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 it must be seen as not excessive or inappropriate for a healthcare event.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

The general answer is yes. Here again the most restrictive rules are set forth in the INTERFARMA Code, which limits payment only to those doctors who render legitimate services that are provided by that professional under a previous contractual obligation; in other words, payment or any type of remuneration, direct or indirect, for the time invested in the participation cannot be given 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. Paying for the healthcare professional's time is not possible, as a general rule. In some circumstances, however, this may be possible. This would be the case of a specific closed company meeting of Advisory Boards, where participants must have written contracts specifying their services.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

There are no regulations directly related to this matter.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

Yes. Any legitimate services not in exchange for prescriptions and/or publicity, which are provided by doctors, can be paid. It is highly advisable that such services are covered in as much detail as possible in a written contract.

5.5 Is it possible to pay healthcare professionals to take part in post marketing surveillance studies? What rules govern such studies?

Yes. See the answer to question 5.4 above.

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

Yes. See the answer to question 5.4 above.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Yes, this type of product can be advertised to the general public in all types of media and the limitations are regulated by RDC 096/98.

Advertisement of medicinal products to the public must always include the following generic warnings:

(1) "If the symptoms persist consult with a doctor"; and

(2) the generic phrase: "This is a Medicinal Product and its use involves risks. Consult with a Doctor and a Pharmacist. Read the insert/leaflet",

which must be included, unless a specific warning related to a specific active ingredient is required by health authorities.

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

- (1) there can be no use of expressions such as "shown in clinical studies" or "scientifically proven"; (2) the advertising piece cannot suggest that the product would make healthy habits and visits to doctors unnecessary; (3) there can be no use of celebrities to say that they use the product; (4) the piece cannot use language that relates the product with excessive intake of alcohol or food; (5) there shall be no language relating the use of the product with physical, intellectual, emotional or sexual performance or to a person's beauty, except if the product has these specific properties approved by the regulatory agency – ANVISA; (6) the piece cannot present in an abusive, frightening or misleading way visual representations of changes in the human body caused by illnesses or lesions; and (7) the piece cannot include messages, symbols or images of any nature directed to children or teenagers.

The following restrictions apply to any advertising of any medicinal product, even if only to prescribing professionals:

- the piece cannot: (1) foster indiscriminate use of medicinal products; (2) suggest or stimulate diagnosis; and/or (3) suggest that a medicinal product is tasty, yummy or delicious.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

Advertising of prescription-only medicines to the public is strictly prohibited.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Yes, disease awareness campaigns are allowed, including by private industry. In fact, Brazilian health authorities implement several campaigns each year especially related to vaccines, AIDS, hepatitis, flu and tropical diseases. In any disease awareness campaign, however, it is prohibited to mention any medicinal product. The campaigns should simply provide an incentive to the population to look to healthcare professionals for diagnosis or to go to health clinics (private or public) for vaccination.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply?

Yes, this is possible. Although there is no specific legal instrument related to this issue, in some cases the authorities have argued that some releases (or articles published in lay media) were in fact "advertising". It is advisable, whenever possible, that press releases to lay media, even in cases where the product is already registered, avoid the use of the trademark in favour of the name of the active ingredient. A legal review of the terms of the release is highly recommended.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

No restrictions apply. However, as the material will be distributed to the public, it should not have the form of advertising and should not serve as an inducement to the consumption of any medicinal product.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

Neither the law nor the ancillary regulations address this. As a general rule, this is permitted and no requirements need to be followed. That said, it is important to point out that health authorities have been looking very closely at this issue, as some health authorities believe that, in some cases, donations are being made to patient support groups to pay for legal fees and expenses necessary for patients to sue the government to receive treatment (medicines or medical treatment) not yet available or registered in Brazil or that are very expensive and not included in government formularies.

In the recent past (2008), the São Paulo State Police and the São Paulo State General Attorney's Office went as far as to carry out investigations to verify whether three pharmaceutical companies were making donations that were directed to financing patient associations' legal costs for filing lawsuits as mentioned above. These investigations ended without finding hard evidence on the alleged financing of patient associations.

The judicialisation of health is a big issue in Brazil.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

As a general rule, providing advantages or benefits to patients in relation to in-market products is not allowed by the Brazilian regulations, as set forth in article 5 of Resolution ANVISA RDC 096/2008. The exception would be to the items/services provided for patients participating in Clinical Trials, in which case these items/benefits should be described in the Clinical Trial Contract and in the Informed Consent Form.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

Clinical trials in Brazil are regulated by Resolution CNS 466/2013. The disclosure of information on ongoing and/or complete trials is made, as a general rule, only to the health authorities and to the respective Ethics Councils through partial and final reports prepared by the Head Investigator. There is no self-regulatory code in Brazil related to clinical trials.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how?

Not as a general rule. Resolution RDC 096/2008, however, requires that the sponsorship by companies of events, symposia, congresses, etc., must be informed to all participants. There is no obligation to disclose the amount of sponsorship. Also, speakers at events, symposia, congresses, etc., if they are sponsored by any company, must disclose such, at the start of their presentation and in the records of the events, if they exist.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Not as a general rule. The INTERFARMA Code of Conduct, however, requires that speakers at events, symposia, congresses, etc., if they are sponsored by any company, must disclose this information. There is no obligation to disclose the amount of sponsorship.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

As mentioned above, there is no obligation to disclose the amount of sponsorship.

8 The Internet

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

The same legislation and regulations that apply to the advertising of medicinal products in Brazil in other media, also apply to advertising on the internet. So, should any company have sites that carry the advertising of medicinal products, they must follow these rules, including the need to ensure that advertising of prescription products can only be accessed by prescribing professionals.

RDC 096/98 has some regulations that are specific to internet advertising, setting forth, for example, how warnings have to appear (even indicating the type of font or requiring the use of bold fonts and capital letters in some specific cases).

ANVISA monitors health-related sites (pharmaceutical companies, pharmacies, distributors, clinics, etc.). Control of the content of internet sites is difficult as there are many and they contain a lot of information. Although some cases do exist, it is not common to see violation notices or fines applied for non-compliance.

8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

There is no specific requirement related to access security. The most common is that sites/pages intended for healthcare professionals must be accessed by the use of log-ins and passwords, and log-ins are usually the doctors' (dentists') registration number in their respective professional association, which some companies check to verify they are correct.

8.3 What rules apply to the content of independent websites that may be accessed by link from a company sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

In principle, the rules are the same; that is, there may be no advertising of prescription products to the general public. Although no specific rules regulate this matter, it would be advisable, as much as possible, to avoid the inclusion of links that will give access to the advertising of prescription products to the public in general. For obvious reasons, links to sites that advertise medicinal products that do not follow the rules will be understood and argued by ANVISA as being included on the site with the intention to try to avoid the legislation.

The most common occurrence of such cases is that companies will include generic disclaimers related to links, in which they state that they are not responsible for the content of links including comments, references, opinions, photos, advice, etc.

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

A website may contain basically anything that the company finds suitable or necessary, with the exception of advertising/promotional material related to prescription products.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

There are no specific regulations controlling the use of social media by life sciences-related companies, or any other company for that matter. The use of social media by companies is regulated by the same legal instruments that apply to other media in relation to promotion and advertising. That said, on April 23, 2014, Law 12.965 was enacted, which sets forth the specific principles, rules and regulations on the guarantees, rights and obligations of internet service providers and users.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

In the last year, the Code of Conduct of ABIMIP (Brazilian Association of Manufacturers of Non-Prescription Drugs) came into force. As the Code presents some incompatibilities with the Code of Conduct of INTERFARMA (Brazilian Association of Research Based Pharmaceutical Industries) and some companies are members of both associations, there have been discussions on how to work around these incompatibilities.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

No. However, a review of Resolution RDC 098/2008 is scheduled to occur. At the end of 2013, the President of the Regulatory Agency issued a *mandamus* (167/13) requesting the review and stating that the Office of The Attorney General had issued an opinion indicating that some of the restrictions included in the Resolution had gone beyond the Agency's constitutional powers and, in some cases, especially in relation to non-prescription drugs, the industry was being successful in getting injunctive relief to suspend the enforceability of some of the rules.

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

No, there are not.

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