



ICLG

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2013

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A practical cross-border insight into pharmaceutical advertising

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■ Preface by Tom Spencer, Counsel, GlaxoSmithKline Plc.

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Brazil



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1 General - Medicinal Products

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

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 authority of the regulatory agency – ANVISA, 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, advertising and promotion of medicinal products in Brazil are 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 79.094/77;
- 6.437/77 – defines violations to 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.

Resolutions of ANVISA:

- RDC 096/2008 (as amended by RDC 023/2009) – regulates advertising and promotional actions in all their forms and media.
- 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 products campaigns; and
- 1.974/2011 – sets forth criteria for the participation of members of the medical profession in promotion and advertising.

Other Regulations:

- The National Code of Self Regulation in Advertising – sets forth a series of basic rules to be followed by all advertisers and media – CONAR.
- Codes of Conduct of Class Associations such as INTERFARMA (Brazilian Association of Research Based Pharmaceutical Industries).

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 publicizing knowledge, make more widely know 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?

There are no legal requirements related to this matter. 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 even 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 in which 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 from the decision that considered that a certain promotion/advertisement breaches the applicable regulations and/or from the decision to request a corrective statement, which appeals will be judged by the ANVISA Board of Directors.

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 will vary from warnings to suspension of sales and prohibition of advertising, corrective statements, as mentioned in question 1.6 above and may be accompanied by a fine that will 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 of 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 with any self regulatory process or body, be it the National Code of Self Regulation in Advertising – CONAR, or in 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 in the law and in the regulations they issue, but may use the decision of any such self regulatory body 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. The action would be brought by the owner of the violated industrial property right or copyright or by a licensee if the License 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 health 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’s 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 in 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 not be 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 practice medicine in Brazil. The same rules apply to off-label information and for these types of discussions, 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 be published? If so, in what circumstances?

Information on unauthorised medicinal products can only be published as scientific information.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

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

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

Yes, provided the information is part of a strictly scientific publication. A previous request from the health 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 Brazil?

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

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

As publicity of unauthorised medicinal products is prohibited and only scientific information is allowed, they can be sent only to health professionals. Also, in the advertising of medicinal products, as regulated by RDC 096/98, it is prohibited to create expectation of sales.

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

Yes. Companies can hire health professionals to render any reasonable professional services.

3 Advertisements to Health Professionals

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

This is regulated in RDC 096/98. Required information in advertising to health professional is the following:

- (1) brand name; (2) name of 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 of 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 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 in the SmPC?

Studies not included in the SmPC may be used as reference in advertisement to health professionals. However, they must have been published in scientific publications, preferably with high evidence levels and should be available to be sent to health professionals and to the authorities if requested.

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”.

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 are made?

No. Any such comparison must be based in 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 which had not yet been authorised in Brazil?

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

In the case of price comparison, 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 the comparison must be based in the cost of the treatment.

Comparative advertising of medicinal products is regulated, as mentioned above, by RDC 096/98 of ANVISA. 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 doctors?

Scientific papers may only be distributed to healthcare professionals. As mentioned above, promoters/sponsors of medical events, what includes 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 permitted 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 health professionals with samples of products? If so, what restrictions apply?

Yes, except for non-prescription products, biological products and products prepared in compounding pharmacies. The procedures and restrictions are clearly regulated in RDC 096/98 and in 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 that must have the same content of the registered original; and antibiotics that must have 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 the receipt of the samples.

As per articles 11 and 12 of RDC 060/2009, owners of the product registration must keep in file, for a minimum of two years after the each lot expiration date all documents related to the production, distribution and the pharmacovigilance data of the free samples and must send to ANVISA, yearly, information on the production and distribution of free samples.

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

Only gifts of nominal value can be given to practitioners and 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 institutions 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 will 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 the 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 doctors 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 market international 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 violation of, among other rules, article 5 of RDC 096/98 that 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 without disputing whether or not the Law-Decree mentioned above would still be in force.

It is important to point also out, 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, at the start of his/her presentation, as well as in the annals of the event if it is the case.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

The same rules already mentioned above, although in RDC 096/98, there is no direct reference to hospitality. The INTERFARMA Code of Conduct, on the other hand, does indicate that locations of primarily touristic appeal are not permitted.

5.2 Is it possible to pay for a doctor 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 that limit payment only to those doctors that 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.

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 doctors to attend?

There are no regulations directly related to this matter.

5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? 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 doctors to take part in post marketing surveillance studies? What rules govern such studies?

Yes. See answer to question 5.4 above.

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

Yes. See answer to question 5.4 above.

5.7 Is there a requirement in law and/or self-regulatory code for companies to make publicly available information about donations, grants, benefits in kind or any other support provided by them to health professionals, patient groups or other institutions? If so, what information should be disclosed, from what date and how?

No such requirement exists in the law or regulation in Brazil.

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 is regulated by RDC 096/98.

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

- “If the symptoms persist consult with a doctor”; and the generic phrase
- “This is a Medicinal Product and its use involves risks. Consult with a Doctor and a Pharmacist. Read the insert/leaflet”,

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

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

- (1) there can be no use of expressions such as “shown in clinical studies” or “scientifically proven”; (2) 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 make use of this or that product; (4) the piece cannot use language that relates the products with excessive intake of alcohol or food; (5) there shall be no language relating the use of the product with the 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:

- (1) the piece cannot 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 the private industry. In fact, Brazilian health authorities have made several of them during 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 health 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.

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 funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

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 in to 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.

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 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.

Judicialisation of health is a big issue in Brazil.

7 The Internet

7.1 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 the advertising made through 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 for Internet advertising setting forth, for example, how warnings have to appear indicating even 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 too 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.

7.2 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 health professionals?

There is no specific requirement related to access security. The most usual is that sites/pages intended for health professionals will be accessed by the use of logins and passwords and logins are usually the doctors’ (dentists’) registration number in their respective professional association which some companies check to verify they are correct.

7.3 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 that they were included on the site with the purpose to try to avoid the legislation.

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

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

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

8 Developments in Pharmaceutical Advertising

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

On February 14, 2012, the Brazilian Association of Research Based Pharmaceutical Industries – INTERFARMA, signed an agreement to regulate the relationship between its members and the Federal Council of the Medical Profession – CFM, the National Medical Association – AMB, and the Brazilian Cardiology Society.

This agreement provides for the creation of a Technical Chamber, composed of doctors and representatives of the companies, inside the Federal Council, that will follow-up on the compliance with the terms of the agreement.

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

The State of São Paulo Regional Council of the Medical Profession has made known its opinion contrary to the Agreement mentioned above and is pressuring the Federal Council to denounce it. The regional council believes that doctors are still receiving “many favours and sponsorships from the pharmaceutical companies” and the Ethics Code of the Medical Profession should be much stricter.

8.3 Are there any general practice or enforcement trends that have become apparent in Brazil over the last year or so?

No, there are not.

8.4 Has your national code been amended in order to implement the 2011 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals and the 2011 EFPIA Code on relationships between the pharmaceutical industry and patient organisations 2011 and, if so, does the change go beyond the requirements of the EFPIA Codes or simply implement them without variation?

The EFPIA Code (and all its regulations) does not apply in Brazil. The changes were considered and used in the updating of the INTERFARMA Code (as were those of PhRMA and of the IFPMA), but this code only applies to INTERFARMA members.

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