Baker McKenzie.

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

BRAZIL

Brazil

Henrique Frizzo

Introduction

The pharmaceutical sector is highly regulated in Brazil. The National Health Surveillance Agency (ANVISA) has broad jurisdiction and is the main agency involved with the control and regulation of health-related products. Since its creation in 1999 by Law 9,782, the agency has increased the level of surveillance in the sector.

ANVISA has issued a series rulings to regulate the areas under its competence. Together with Law 6,360/76 and Decree 8,077/13, ANVISA's rulings form the basis for the regulation of pharmaceutical products and medical devices. Law 6,437/77 is also worth mentioning, as it provides for penalties applicable to those who violate regulatory legislation.

Pharmaceutical Advertising Legislation

The Regulatory Framework

With few exceptions, advertising and promotional activities are generally a non-regulated area. The pharmaceutical and therapies sectors are among the areas whose advertisement and promotional activities are subject to regulation.

The Brazilian Federal Constitution has a specific provision allowing Federal Law to impose certain limits and control over the advertisement of tobacco, alcoholic beverages, pesticides, drugs and therapies.

Such law was enacted in 1996. In this sense, Federal Law 9,294 was enacted to establish restrictions on the use and advertising of tobacco, alcoholic beverages, medicine, therapies and pesticides, as determined by the Federal Constitution, as well as sanctions for violation of these

provisions. With regard to medicines and therapies, Article 7 sets out that:

- except for anodynes and over-the-counter (OTC) drugs, medicines and therapies can only be advertised in scientific, medical and specialized publications, addressed directly and specifically to healthcare professionals (HCPs) and medical institutions;
- the advertisement of medicines and therapies shall not contain statements that cannot be scientifically evidenced, nor use testimony of professionals who are not legally qualified to provide such; and
- the advertisement must contain a warning about the need to consult a doctor in case the symptoms persist.

This law is regulated by Decree 2,018/96, which requires the Ministry of Health's authorization for advertising OTC medicines.

In addition to Law 9,294/96, ANVISA, in its capacity of regulatory authority that ensures compliance in connection with the promotion of medicines, issued Resolution RDC 96/08, which provides for strict regulations on the advertisement, publicity, information and other promotional and marketing practices related specifically to medicines.

ANVISA's Resolution RDC 96/08 creates broader rules for advertising techniques and requirements, participation of celebrities and indirect advertisement, among others. Due to its broadness, the validity of ANVISA's Resolution RDC 96/08 has been questioned by the companies and industry associations, on the basis that ANVISA has exceeded its constitutional and legal limits by legislating in areas beyond its competence, such as consumer protection and telecommunication.

Although most decisions affirm that the regulation of advertisement by ANVISA is legal, there are still judges that interpret differently. In this sense, the courts are not entirely unanimous in this regard, but

there is a clear tendency that indicates that the regularity of ANVISA's actions will be accepted at all times further on.

Although Resolution RDC 96/98 does not apply to medical devices, there are a number of regulations issued by ANVISA that can be applicable to these products:

- Resolution RDC No. 185/2001, which sets forth the requirements for the registration, labeling and instructions of use of medical devices
- Resolution RDC No. 16/2013, which provides for Good Manufacturing Practices requirements
- Resolution RDC No. 55/2005, which governs the recall of medicinal products (drugs) but can be used as best practice in analyzing device issues together with RDC 23/2012, which provides for notification of field actions regarding medical devices that are subject to registration
- Resolution RDC No. 40/2015, which provides for the enrollment of low-risk medical devices and provides for labelling requirements

In general, for medical devices, the main rule is that the advertisement, marketing or promotional activity must be in line with the product specifications, according to the documents and studies submitted for the product approval by ANVISA (i.e., must be compatible with the registration dossier).

To complement the legal framework, Ordinance 344/98 establishes general rules for the commercialization and advertising of substances and medicines subject to special control (narcotic, psychotropic and immunosuppressant medicines).

There are other statutes that set forth additional rules for the marketing and promotion of drugs and medical devices. The codes of conduct and ethics codes of industry associations and healthcare professional

councils[1] are also a valuable source of information on admitted practices. Even when a certain code is not directly applicable, it should serve as guidance for the ethical relationship between drugs and medical device manufacturers and healthcare professionals.

The main industry associations for the pharmaceutical sector are INTERFARMA and SINDUSFARMA, and for medical devices, the ABIMED and ABIMO. As the code of ethics of these entities is in constant development, is always important to verify the applicable rules in the moment of approving a specific marketing/promotional activity.

Permitted and Prohibited Practices

Besides the general prohibition on direct marketing of medical products under prescription, Brazilian legislation generally aims at avoiding a *quid pro quo* between HCPs and the industry.

Therefore, the relationship between industry and HCPs and/or medical institutions must always be conducted in a transparent and documented way. Fair market practices and adequate remuneration, considering the time spent on the services, are also crucial elements.

Another core principle regarding the promotion of medical products is the compatibility between the claims and the information contained in the medical product registration. Such claims must be supported by evidence presented at the time of the product's registration with ANVISA. All marketing and promotional materials must clearly refer to the supporting evidence for the claims.

The health legislation, especially the controversial Resolution RDC 96/08 from ANVISA, covers a broad range of subjects, but transparency in the promotional practices is a core element. Despite the fact that ANVISA's Resolution RDC 96/08 only regulates the

[1] The Federal Council of Medicine (*Conselho Federal de Medicina*) ethics code is not applicable to the industry, only to doctors and physicians, but can be used to understand the admissible practices.

promotion of drugs, it can also be used as a best practice guide for the medical devices sector.

Note that the rules outlined below are applicable to private practice HCPs only, as dealings with governmental officials involve another set of regulations, including anticorruption provisions.

The issue of a physician's possible public function is a broad concept that is not fully defined in Brazilian law. The main consideration is that a physician who works for a governmental or a public-funded entity should not have any decision-making powers. This includes holding administrative/managerial functions within the institution or participating in the elaboration of technical specifications for public bids/tenders.

The difficulties in defining the limits to public practice HCPs should result in a careful review of this practice, and each situation should be analyzed on a case-by-case basis.

Gifts, Seminars, Hospitality and Entertainment

Concerns about the relationship between medical professionals and the industry spurred major regulators (ANVISA and the Medicine Federal Council) and associations (ABIMED, INTERFARMA, etc.) to issue stricter rules on marketing and promotional activities. The restrictions on these practices are outlined below:

Gifts

ANVISA Resolution RDC 96/08, Article 5, provides that pharmaceutical companies cannot offer gifts, benefits or anything else of value to physicians who can prescribe medicines, whether or not the intent was *quid pro quo*.

However, low-value gifts (pens, notebooks, etc.) are still authorized. Prescription pads cannot contain the company logo or promote a drug. Materials containing scientific information such as magazines and medical journals can be freely distributed.

Note that industry codes of conduct and the physicians' professional councils impose additional restrictions on marketing activities and that anti-corruption laws also apply to public practice physicians.

Among industry codes, it is worth mentioning that the INTERFARMA code of conduct prohibits the granting of gifts, such as pens and notepads, that are unrelated to the medical practice.

The ABIMED code of conduct provides that it is allowed to grant gifts that have an educational value, provided that such gifts (i) are related to the training of how to use certain product; (ii) are of low amount; and (iii) are related to the medical practice or provide benefits to a patient. Except for scientific books and anatomic models, the limit on gift amount is BRL100.

Seminars, Hospitality and Entertainment

Any contribution, including travel expenses, meals and hospitality to support healthcare professionals' attendance in medical conferences and scientific events (national or international) is allowed. However, the support or sponsorship may not be conditional on the prescription, distribution and/or advertisement or promotion of any kind of medicine. In addition, any such relationship must be clearly declared by the physician and the company in the prospectus, brochure or leaflets of the seminar, as well as in the application form.

The sponsor relationship and the payment of costs related to admission, hospitality and meals must be duly documented. The healthcare professional and the company must also disclose any potential conflict of interest. A clause to this effect should be included in the relevant instrument governing the sponsorship.

Since a medical professional's decision as to the best treatment for that specific case must be free of any commercial interest, any such events must have a real scientific or educational nature. However, legislation does not provide the level of education and entertainment that is considered acceptable. The legislation is also not clear about restrictions on entertainment, but most industry codes prohibit

pharmaceutical companies from providing or paying for entertainment.

The rules do not clarify how the sponsorship can be implemented, but best practice recommends that a company should reimburse expenses rather than give funds to the healthcare professional. Finally, the payments cannot be extended to relatives, spouses or any other person.

There is a recent trend among associations to further restrict the sponsorship of healthcare professionals to attend third-party seminars. The INTERFARMA code of conduct provides that the selection of the professional that will be sponsored must be based on objective criteria, which leads to certain confusion on how the choice must be conducted.

In addition, the ABIMED code of conduct provides that the sponsorship of healthcare professionals to participate in third-party events will be prohibited starting 2018.

Other Promotional Activities

ANVISA Resolution RDC 96/08 regulates the advertising of prescription medicines on the Internet. It provides that the online promotion of such medicines shall only be accessible to professionals qualified to prescribe or distribute medicines, by means of an electronic registration system, and a liability statement setting out the legal restrictions on access shall be provided.

Any prescribing information/package insert that is published over the Internet without restricted access, must be up-to-date and correspond to the one approved by ANVISA. It cannot present designations, symbols, figures, drawings, slogans or any advertising arguments related to the medicine.

Therefore, companies can include any information on a website, except information about prescription medicines, which shall only be available for physicians.

ANVISA Resolution RDC 96/08 forbids "off-label promotion." Off-label promotion is the marketing of a medicine for use not approved by ANVISA. This is because all statements contained in the advertising or publicity regarding the medicine's or medical devices' effect, indications, usage, adverse reactions, efficacy, security, quality and other characteristics must be compatible with the information registered with ANVISA. Independent websites are also forbidden to disclose off-label data, which is likely to be in the pharmaceutical company's interest. Penalties can be imposed for such conduct.

Companies can provide information about unauthorized medicines to health professionals, but only if the disclosure of the information is for scientific purposes; such unauthorized medicines may not be promoted. Moreover, such information must be strictly disclosed to health professionals or health students.

There are no guidelines for the disclosure of off-label information at scientific meetings, but all disclaimers must be provided in a very clear manner, including a warning that the specific indication is not registered with the regulatory authority, as well as the current level of the trials.

Price comparisons directed at consumers can only be done between interchangeable medicines (generic and reference medicines). When directed to professional prescribers, the price comparison can be done between non-interchangeable medicines, based on market information, as long as they have the same active ingredients. Note that the comparison must be made between the treatment costs or, in the case of continuous use of medicine, between the defined daily doses. Price comparison is forbidden with biological medicines.

Samples

ANVISA Resolution RDC 60/09 imposes various restrictions on the distribution of free samples of drugs, such as the obligation to deliver the samples directly to the HCP by means of written acceptance.

It is prohibited to distribute free samples of biological medicines that require special attention for conservation and transportation, as registered with ANVISA, as well as compounded drugs and formulas.

Free samples must contain at least 50 percent of the contents of the original presentation registered with ANVISA and commercialized by the company, with the exception of antibiotics and contraceptives, which are subject to a special treatment.

Free samples must present the same traceability and authenticity mechanisms defined by the sanitary authority for the original medicine and the package can only differ from the original medicine in terms of its size and volume. Any modification of the package material must be approved at the registry.

Statements on the labeling and the layout of the samples, as well as the prescribing information/package inserts, shall be identical to those approved by ANVISA to be included in the original package.

The registration holder must hold all documents related to the manufacture, distribution and pharmacovigilance for at least two years after the expiration of a certain batch of samples.

Consequences of Breach

Infractions of advertising, promotional and marketing rules can subject the company and individuals involved to serious administrative sanctions. In addition to these penalties, the parties involved may also be subject to criminal and civil liabilities.

Law 6,437/77 establishes penalties for infractions of sanitary legislation, which are:

- warning;
- fine;
- product apprehension, destruction or interdiction;

- suspension of the sale/manufacture of the advertised medicine;
- partial or complete interdiction of the company;
- prohibition of advertising;
- cancellation of the operation authorization;
- cancellation of the operation license; and
- intervention in the company that receives public resources.

Fines vary according to the seriousness of the infraction:

- in less severe infractions, from BRL2,000 to BRL75,000;
- in serious infringements, from BRL75,000 to BRL200,000; and
- gross and severe infractions, from BRL200,000 to BRL1.5 million.

In the event of recurrence, the fine may be doubled.

Law 9,294/96 establishes different penalties from those set out in Law 6,437/77. Breaching the provisions of Law 9,294/96 subjects the breaching company to the following penalties: warning; suspension of any other advertisement of the product for a period of up to 30 days; an obligation to publish a correction; seizing of the product; punitive fine of BRL5,000 to BRL100,000; and suspension of the radio/TV programs for 10 minutes for each minute or fraction of the duration of the advertisement transmitted in breach of the law.

While the penalties addressed by Law 6,437/77 are generally imposed as a result of breaches to sanitary legislation, the penalties established by Law 9,294/96 are applicable to breaches regarding the advertising of medicine and therapies. The rule to be used is determined on a case-by-case basis.

If the unlawful act involves the corruption of public officials, then the company can be subject to Law No. 8,429/92 (the "Improbity Law"), as well as the relevant provisions of the Criminal Code. If the act or omission is also considered a violation of the rules of the Consumer Defense Code, the infringing company and individuals may be subject to criminal and civil liabilities.

Furthermore, if any unlawful act is committed against the government, the company can be held liable under Law 12,846/13 (the "Anti-Corruption Law").

Finally, in addition to these consequences, irregular marketing and promotional activities can also be considered a violation of competition rules.

It is also worth mentioning that INTERFARMA code of conduct also provides penalties that can be applicable to its associates, especially fines in similar amounts as those applicable by ANVISA and the removal of the company from INTERFARMA.

The ABIMED code does not provide for penalties to associates that breach the code's provisions; however, compliance thereof is mandatory.

Enforcement

ANVISA has consistently increased enforcement activities over the years. The chart below shows the increase in the number of fines imposed over the years[2]:

Year	Number of fines applied	Amount of fines (BRL)
2012	1,449	34,614,900
2013	1,930	30,376,530
2014	2,383	36,376,500

[2] *Relatório de Gestão 2014*

Criminal and Civil Liability

In addition to the administrative penalties mentioned, companies and individuals involved in an act or omission considered a violation of the relevant sanitary, consumer and anti-bribery provisions can be subject to severe criminal and civil liability.

As an example, if patients (either individually or organized under patient associations) believe they have suffered damage, they may sue the medical device company that breaches the laws or rules on promotion of medical devices and claim indemnification for damages.

Likewise, if the district attorney determines that the breach of the laws or rules on the promotion of medical devices is a threat to the society or public order, a public civil lawsuit may be brought against the medical device company.

It is considered a crime under Article 7, item VII of Law 8,137/1990 to induce consumers by providing a false or misleading declaration about the product being advertised. The penalty in such case is imprisonment for two years to five years, plus a fine.

Furthermore, the general principles of providing accurate and clear information to consumers must be obeyed in view of criminal implications since the Brazilian Consumer Defense Code (CDC) establishes several crimes in the case of an advertiser's noncompliance. The CDC considers it a crime to:

- not inform consumers through publicity about the risks or hazards offered by the product;
- give false or misleading information, or abstain from giving information about the nature, characteristic, quality, durability, price or warranty of the product;
- produce abusive or misleading publicity;

- produce publicity that could induce consumers to behave in prejudicial or dangerous ways to their health or safety; and
- abstain from organizing empirical, scientific and technical data that supports the publicity.

Depending on the infraction, the following penalties may apply: one month to two years' imprisonment, fine, temporary suspension of rights, and community service. If convicted, the company may be required to publicize the crime and the corresponding sentence in the local media.

As stated under Article 273, paragraph 1-B, item I of the Brazilian Criminal Code, responsible individuals may be subject to imprisonment for 10 years to 15 years, plus a fine, if products that require sanitary registration are exposed to sale without it. Products intended for pharmaceutical and medical purposes are expressly included in this provision.

Moreover, granting benefits to government officials and healthcare professionals from the public sector who are involved in procurement is considered corruption, and such is established under Articles 317 and 333 of the Brazilian Criminal Code. According to the code, corruption consists of offering or promising to offer to public employees any benefit related to an express or implied request or suggestion to the public employee to perform or refrain from performing, or even delay or expedite any act within the scope of his duties. Any gratuity or gift granted in order to obtain advantages in the sale of medical devices to public entities is considered bribery in Brazil. In such cases, the penalty is imprisonment up to 12 years, plus a fine.

The criminal consequences provided here apply to individuals involved in the infringement (typically the statutory directors of the company) but not to the company in its capacity as a legal entity. With very few exceptions, Brazilian laws typically do not deal with crimes committed by legal entities. However, there are several statutes,

including the Brazilian Clean Companies Act, that imposes penalties to companies that commit corrupt acts.

Contracts with Healthcare Professionals and Medical Institutions

Service relationships with healthcare professionals (usually with the key opinion leaders), and partnerships and cooperation arrangements with medical institutions must be analyzed carefully for possible irregularities. In fact, observing the necessary formalities can be as important as complying with the rules.

Transparency in the relationship is important, as flaws in documentation can raise suspicions of fraud and unlawful behavior. This becomes more important when the healthcare professional is also a public servant or when the medical institution is government-owned.

The INTERFARMA and the ABIMED codes of conduct also have specific provisions for the types of relationships described below.

Research and Consulting Contracts

Using healthcare professionals or medical institutions to conduct clinical trials and clinical studies is common and necessary in the industry.

Another common practice in the industry is the retention of healthcare professionals as marketing, medical or research and development consultants.

Because of the importance to the industry of retaining such services, legislation does not prohibit such practices. On the other hand, there are few rules for these kinds of arrangements. Because of the risk that relationships between the industry and healthcare professionals can be used to violate advertisement and promotional activities legislation, as well as to disguise corrupt practices, companies should monitor such activities closely.

The main consideration is to keep relationships transparent and at arm's length, ensuring that the contracted services are being performed. When arrangements are directly with healthcare professionals or medical institutions, it is always important to document the relationship and abide by fair market practices.

Contracted healthcare professionals or medical institutions must be chosen for their expertise in respect of the services to be provided under the agreement. No commercial reason may be used as grounds for the choice, and the healthcare professional or medical institution shall not be obligated to use/prescribe the company's products (i.e., no *quid pro quo* intent).

The services agreement must be documented in a formal instrument, detailing the services to be performed, the consideration to be paid for the services and other customary provisions in this type of arrangement. One important clause that should be included is the reciprocal obligation of the company and the healthcare professional (or medical institution) to disclose the relationship whenever a potential conflict of interest arises. As the activities performed by the healthcare professional might involve relationships with several regulatory authorities, the usual anti-corruption and compliance clause should be included in the instrument.

The consideration for services must be commensurate with market practices. Preferably, the healthcare professional or medical institution may only be remunerated for specific services, and the company must obtain something objective in return. The amounts paid must be by reference to a fair market value. Documentary evidence of the performance of services (such as the reports and schedule of appointments) must be kept by the company.

Reimbursement for accommodation, meals and transportation can only be paid for expenses directly related to the services provided, and the amounts must be reasonable and not exaggerated. It is recommended not to offer the amounts covering the expenses in

advance, but rather to reimburse the expenses upon presentation of the respective receipts.

Entertainment-related expenses are not reimbursable and the payment of lodging must be limited to attending, for example, the seminar, meeting or event. For longer trips, the company may pay for expenses related to the day before and the day after the event.

Finally, if the healthcare professional is also a government official, even on a part-time basis, or the medical institution is government-owned or funded, additional precautions should be taken, as the risks of an improper relationship increase significantly.

Speakers' Contracts and Exhibitors' Agreements

A company may offer financial support to organizations promoting conferences and to healthcare professionals attending such conferences. Such third-party conferences must be of a professional/scientific or charitable nature. The same principles that relate to service agreements apply, thus formalization in a written document, lack of *quid pro quo* intent and transparency (publicity) of the relationship must be taken into account.

The hospitality offered to the healthcare professional (travel costs, meals, overnight stay and registration fees paid by the company) must remain an accessory and be necessary to the attendance of the healthcare professional, must be reasonable in level and must not benefit other persons (e.g., spouse of the HCP). Payment or reimbursement of expenses related to entertainment is not acceptable. This applies to conferences and training. For longer trips, the company can pay for expenses related to the day before and the day after the event.

RDC 96/08 provides that in relation to conferences concerning medicines, the sponsoring of a healthcare professional must be disclosed to the organizers of the conference. The sponsorship must also be disclosed in the event program and at the beginning of each lecture presented by the healthcare professional. Finally, the

sponsorship must be registered in the conference records and the companies may not advertise drugs in the events' materials.

The entity responsible for the organization of the event/seminar must inform ANVISA three months in advance about the possibility of sponsored events. Hence, it is recommended to highlight obligations in relevant agreements with the organizer.

Donations to Medical Institutions, Charitable Organizations and NGOs

Donations to charitable organizations, medical institutions and non-governmental organizations are allowed, but should be reviewed carefully by the appropriate personnel within the company. The same rule of transparency, formalization and lack of *quid pro quo* intent applies.

It is recommended to have an agreement, a letter-agreement or similar written instrument in place outlining the major characteristics of the donation. Also, the donation should be made in goods or payment of necessary services (such as work), rather than monetary grants. Reimbursement of expenses is also acceptable as long as there is a provision ensuring good use of the money (for instance, request for three price proposals).

In addition, the donation should not be conditional on future purchases or business. For instance, the donation of a machine should not be dependent on any future relationship with the donating company. Any hidden intent can be considered a fraudulent attempt to circumvent the legislation. We are aware of a practice involving the donation of funds to a supposed charitable organization, which then sponsored lawsuits against the government, ultimately benefiting the pharmaceutical company[3].

Finally, companies should be aware of donations to medical institutions or other legal entities that can be used for one's personal

[3] The law enforcement authorities considered such practice as fraud against the public health financing system.

benefit. Donating diagnostic equipment to a medical institution is different from donating several computer tablets/notebooks to the institution (as they will ultimately be used by the officer of the institution).

The INTERFARMA code of conduct also provides that donations cannot make the institution dependable on the donor to pay its administrative costs, so as to preserve the independence of such institutions.

Recommendations

Advertising and promotion of medical products in Brazil can entail some potential (and severe) risks. In addition to the administrative sanctions that can be imposed by regulatory authorities, mainly ANVISA (which has been intensifying its enforcement activities), the broad range of legal matters involved in the marketing practice can bring about criminal and civil liabilities due to violations of anti-corruption statutes, consumer defense provisions, and sanitary and competition legislation. The following recommendations can mitigate the risks connected with a company's promotional and advertising efforts:

- Review the gifts and benefits policies.
- Know the local regulations, as they change frequently and can impact some ongoing practices.
- Never make any benefit conditional on the prescription of drugs or the purchase of equipment (avoid *quid pro quo* practices).
- Always be transparent.
- Formalizing and gathering evidence of the performances of the arrangements is crucial. It is not only important to be honest, but also to look honest.

- Look for the real value of the healthcare professionals and medical institutions as services providers.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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