Distribution and marketing of drugs in Brazil: overview

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DISTRIBUTION
Pre-conditions for distribution

1. What are the legal pre-conditions for a drug to be distributed within the jurisdiction?

Authorisation
The distribution of medicinal products is regulated by the National Sanitary Surveillance Agency (ANVISA).

Pharmaceutical products can be marketed and distributed if the following requirements are met:

- They are registered with ANVISA.
- Their price is approved by CMED (Chamber of Drug Market Regulation).
- They are manufactured or imported by establishments duly authorised by the federal government.
- They are manufactured or imported by establishments duly licensed by the local authorities (municipal or state government).

To obtain approval to launch and distribute drugs on the market, the applicants must submit to ANVISA regulatory data of the potential candidate, such as details of the manufacturing process, clinical trial results, and safety and efficacy data. If all data complies with the requirements established by ANVISA, a marketing authorisation is eventually granted, formally allowing the medicinal products to enter the market.

Exceptions
There are exceptions to the requirement for a marketing authorisation, for example, if the new drug is intended to be exclusively used in a clinical trial or if it is required to meet the prescription for a specific patient. In these cases, it can be supplied and imported in Brazil without being previously approved, if the importation is formally authorised by ANVISA.

2. Do any types of named patient and/or compassionate use programmes operate? If so, what are the requirements for pre-launch access?

The National Sanitary Surveillance Agency's (ANVISA) Resolution No. 38 of 13 August 2013 sets out pathways through which patient access to experimental drugs is provided before these drugs are officially approved and available for purchase.

Under the compassionate use programme, ANVISA provides authorisation for individual access to an experimental drug without agency registration for the treatment of patients with serious or rare diseases. The expanded access pathway is an alternative that provides group access to an experimental drug. These specific pathways provide the possibility of importing new, unregistered drugs, if needed.

According to ANVISA, the authorisation approval for compassionate use is evaluated depending on the severity of the illness. The absence of satisfactory treatment alternatives available for the patient's condition is assessed before issuing an authorisation. The patient's doctor must submit a formal request to obtain the drug for the entity funding the programme and the entity must place a corresponding request with ANVISA.

The entity funding the treatment must provide for the complete treatment and medication at no cost for the patient under the expanded access, compassionate use or post-study programmes (chapter VIII, section 18, Resolution No. 38/2013).

Licensing

3. What is the procedural structure regarding licensing a drug for distribution?

See Question 1.

4. Is there a simplified licence proceeding, or relaxed licensing conditions, for drugs which have already been licensed for distribution in another jurisdiction?

When dealing with a drug with a foreign licence, marketing authorisation from the National Sanitary Surveillance Agency (ANVISA) is still required. However, some over-the-counter drugs can be marketed by only giving notice to ANVISA, regardless of any previous licences held abroad.

With imported drugs and active pharmaceutical ingredients, in addition to the usual registration requirements, the applicant must also show evidence proving that the product is already registered in the country of origin (Article 18, Law No. 6,360, 23 September 1976) and further complies with the good manufacturing practice (GMP) standards in that country.

Regarding parallel imports, a product manufactured in accordance with a process or a product patent that has not been placed on the internal market directly by the patentee or with its consent can represent a violation of the patent holder's exclusive rights, therefore allowing the patent holder to enforce its exclusive rights (section 43, item IV, Brazilian Industrial Property Law). Whether implicit consent can avoid the parallel importer's liability for patent infringement is always a hot topic before the courts, so all situations must be examined on a case-by-case basis.
5. **Is virtual drug distribution possible from your jurisdiction?**

The sale of drugs through the internet can only be undertaken by accessing websites from pharmacies and drugstores with fixed commercial establishments that are open to the public.

The service provider must also provide for a direct and immediate method of communication between the patient and a pharmacist.

Drugs subject to special control (ANVISA’s Ordinance No. 344, 12 May 1998) cannot be sold on the internet, as provided by ANVISA’s Resolution No. 44/2009.

Brazil-based pharmacies can attend online orders with some restrictions. According to the law, only licensed Brazilian pharmacies can sell prescription drugs online. An internet pharmacy must post its National Sanitary Surveillance Agency’s (ANVISA)’ authorization number on its website. Personal importation of medicines is legal where the patient has a valid prescription and where the frequency and quantities are clearly limited in the prescription signed by the medical doctor.

6. **What is the procedure to appeal (legal remedy) a licensing decision?**

It is possible to proceed with an administrative appeal against refusals to grant a licence for a drug within ten days starting from the day immediately after the publication of the rejecting decision.

The appeal is filed before National Sanitary Surveillance Agency (ANVISA) and the authority that made the appealed decision has a five-day period to reconsider. If it upholds the decision, the appeal is subject to a formal analysis. One of the five directors of ANVISA is then assigned the appeal and acts as a case rapporteur when the appeal is heard by the board of directors.

The board of directors does not have a statutory maximum period to render its final administrative decision. However, parties often apply for an injunction (by filing a writ of mandamus) ordering the board of directors to decide within a specific deadline.

It is not possible to file a second administrative appeal from the final decision issued by ANVISA’s board of directors after analysis of the technical appeal, but such decisions may be subject to judicial control.

7. **What are the costs of obtaining licensing?**

There are fees to be paid to the National Sanitary Surveillance Agency (ANVISA) to obtain a marketing authorisation. These fees vary depending on the type of product and on the size of the applicant (ANVISA’s Ordinance No. 45 of 27 January 2017).

For example, if the applicant is a large company, the costs can vary from BRL11,000 (generic drug) to BRL160,000 (new drug).

**Distribution to consumers**

8. **What are the different categories of drugs for distribution?**

For distribution to consumers, medicinal drugs can be classified into the following categories:

- Drugs that can only be dispensed under a medical prescription (with retention).
- Drugs that can only be dispensed under a medical prescription (without retention).
- Drugs that can be sold without a prescription, known as non-prescription products or over-the-counter drugs, which present a remote risk of causing side effects to patients.
- Drugs exclusively used in hospitals.
- Drugs subjected to special control, where the medical prescription must be notified to the health authority.

In considering whether a drug can be sold without the need for a prescription, the National Sanitary Surveillance Agency (ANVISA) takes into account, among other issues, whether the product is likely to, if incorrectly used:

- Present a substantial risk to the patient.
- Lead to addiction.
- Be used for illegal purposes.

9. **Who is authorised to distribute prescription drugs and over-the-counter drugs to consumers?**

**Prescription drugs**

Prescription drugs are sold in licensed pharmacies, under medical prescription. This licence is obtained from the National Sanitary Surveillance Agency (ANVISA).

Pharmacist technicians can perform activities that are not exclusive to pharmacists, including dispensing or selling prescription medicines (ANVISA’s Resolution No. 44, 17 August 2009). However, pharmacist technicians must be under direct supervision of the registered pharmacist technically responsible (or a substitute, also a pharmacist), whose presence is required during working hours of the commercial establishment. The sale of prescription medicines can only be made on the presentation of a prescription issued by a registered physician.

**Over-the-counter drugs**

Over-the-counter drugs are sold freely in licensed pharmacies, drugstores and some large supermarkets, without the need of a medical prescription.

10. **What drugs can an attending physician distribute and under what circumstances?**

Physicians can distribute free samples of marketed drugs to any patient, provided that it follows the medical prescription.

11. **Who is authorised to prescribe prescription drugs to consumers?**

Depending on the legal attributions of each profession, only physicians (medical doctors), dentists (for dental use only), veterinarians (for veterinary use only) and nurses (for medicines established by public health programmes and approved by the health institution) can prescribe drugs.

12. **Is direct mailing/distance selling of drugs permitted in your jurisdiction?**

ANVISA’s Resolution No. 96/2008, which deals with the advertising and promotion of drugs, does not expressly mention the possibility of using e-mails as a way to buy or sell drugs.
There are also no particular rules referring to marketing medicinal products by mail order. However, this may be possible provided all requirements for the acquisition of a particular drug on the internet are met (see Question 5).

13. What regulatory authority is responsible for supervising distribution activities?

The regulation of the medicines distribution sector is conducted on three levels:

- The federal government.
- The state governments.
- Municipalities.

The federal government enacts laws and regulations of general applicability, which are enforced and complemented by actions of the state governments and municipalities. At the federal level, the health and pharmaceuticals sectors are regulated and supervised by the Ministry of Health, through the National Sanitary Surveillance Agency (ANVISA).

14. What is the procedure to appeal (legal remedy) a distribution decision?

The National Sanitary Surveillance Agency (ANVISA), and other authorities within the National Sanitary Surveillance System, can impose penalties if a regulated entity does not comply with the regulatory requirements (including in relation to distribution activities). Such penalties can be imposed in a preventive manner if non-compliance involves a future risk of breach, or after the breach has taken place.

In the event of a breach, the regulated entity is summoned with an infraction notice and a defence can be generally filed within ten or 15 days. However, this depends on the decision-making authority and the specific provision that had allegedly been breached.

A company can appeal a decision imposing any penalties within the same deadline set for a defence.

If the decision is maintained, it can be appealed to a superior authority at the government level within 20 days from the date the decision was acknowledged or from publication.

All legal deadlines are set out in Law No. 6,437/1977, which sets out the penalties for infringing sanitary federal statutes and corresponding regulations, including criminal sanctions.

15. What are the legal consequences of non-compliance with consumer distribution laws?

The consequences of non-compliance with consumer distribution laws include:

- Suspension of the authorisation to distribute.
- Suspension of the product registration licence.
- Fine.
- Warning letter.
- Suspension of advertisement.
- Ban of the establishment.

In addition, the falsification and adulteration of drugs may be punishable with imprisonment under the Brazilian Penal Code, Decree-Law No. 2,848/1940.

Wholesale distribution

16. What is the legal regime regarding wholesale distribution of drugs?

Distributors of pharmaceuticals must comply with the relevant regulations (Good Distribution Practices), more specifically ANVISA's Resolution No. 39/2013, amended by ANVISA's Resolution No. 217/2016, and hold the appropriate licences. Such distributors must obtain:

- A licence to operate.
- An authorisation to operate.
- A special authorisation for medicines under special control, if necessary.

It is necessary to pay a fee to obtain these licences and to present a certificate of the technical responsibility of the responsible pharmacist. It is also necessary to undergo an inspection carried out by the local health authority. These distributors must obtain a document called “Certificate of Good Distribution Practices”, which is issued by the National Sanitary Surveillance Agency (ANVISA) to operate legally. This certificate is a statement confirming that the distributor complies with all established good practices established, and allows the distributor to operate.

17. What regulatory authority is responsible for supervising wholesale distribution activities?

Regulatory authority

The distribution and promotion of medicinal products by wholesale distributors are subject to the legal regulation of the National Sanitary Surveillance Agency (ANVISA).

Supervision

ANVISA can issue legal provisions on human health issues (Article 24, section XI, Brazilian Constitution and Article 7, Law No. 9,782/1999). These enable ANVISA to:

- Proceed with the surveillance and regulation of medicines and medical goods.
- Supervise the entities that manufacture and distribute them.
- Provide for the registration of medicinal products.

Companies that apply for permission to distribute drugs must comply with the requirements of Good Distribution Practice and Storage established by ANVISA. Under these rules, a distributor must comply with certain procedures to control the quality and keep track of the medicinal products distributed.

Rights of appeal

The procedure is the same as for appealing a distribution decision (see Question 14).

18. What are the legal consequences of non-compliance with wholesale distribution laws?

See Question 15.

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19. What is the general legal regime for the marketing of drugs?

Legal regime
The main legal instruments governing the marketing, advertising and promotion of medicinal products are:

- The Brazilian Constitution of 1988, which provides the legal basis for advertisement regulations.
- Law No. 5,991 of 17 December 1973, which provides for the sanitary control and sales of drugs, active pharmaceutical ingredients, and medical devices.
- Law No. 6,360 of 23 September 1976 (amended by Law No. 13,097 of 2015), which regulates sanitary surveillance and sets out general rules for the advertising of drugs, medical products and other health-related products.
- Decree No. 8,077 of 2013, which regulates Law No. 6360/1976 that provides further provisions on the advertising of medicinal products.
- Law No. 9,294 of 15 July 1996, which regulates the advertising of drugs.
- Decree No. 2018 of 1 October 1996, which regulates Law No. 9,294/1996.
- Law No. 6,437 of 20 August 1977, which defines violations of federal health law and imposes respective sanctions.
- ANVISA’s Resolution No. 96 of 17 December 2008 (amended by RDC 23/2009), which regulates the advertising and promotional practices of prescription drugs and over-the-counter drugs.
- ANVISA’s Normative Ruling No. 5, of 20 May 2009, which provides further clarifications on Resolution No. 96/2008.
- ANVISA’s Resolution No. 60 of 26 November 2009, which regulates free samples.
- ANVISA’s Ordinance No. 344 of 12 May 1998, which imposes specific restrictions on the advertising and promotion of medicinal products containing substances under special control (such as anorexigenic drugs, immunosuppressant drugs, and other drugs).
- Law No. 8,078 of 11 September 1990 (Consumer Protection Code) (CDC), which contains general provisions on the advertising of products in general.

Limits to marketing activities
To market medicines, entities must have been granted the necessary authorisations by the sanitary authorities.

Besides the general prohibition on direct marketing of medical products under prescription, the legislation aims to keep the relationship between industry and healthcare professionals or medical institutions transparent and fully documented.

Additionally, an advertisement for drugs cannot differ from or exceed the information provided in the registration dossier submitted to the National Sanitary Surveillance Agency (ANVISA) for record-keeping and evidentiary purposes.

20. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?

The Advertising Self-Regulation Code, enforced by the Advertising Self-Regulation Council (CONAR) and adopted in 1978, regulates ethical rules related to advertisements and defines rules applicable to over-the-counter drugs. CONAR’s objective is to eliminate misleading advertisements and campaigns that may be offensive or abusive in content, or could, among other things, distort competition.

There are also Codes of Conduct of class associations such as the Association of Research Based Pharmaceutical Industries (INTERFARMA).

Finally, the following resolutions of the Federal Council of Medicine are also relevant:

- Resolution 1,931/2009, which the Medical Profession Code of Ethics.
- Resolution 1,939/2010, which prohibits participation of doctors in medicinal products campaigns.
- Resolution 1,974/2011, which sets out the criteria for the participation of members of the medical profession in the promotion and advertising of drugs.

The National Sanitary Surveillance Agency’s (ANVISA) advertising regulations are not related to any self-regulatory bodies such as CONAR or INTERFARMA, whose decisions are not made public. ANVISA only investigates matters of non-compliance with the law and its regulations, but can use the decisions of any self-regulatory body to support its decision.

Marketing to consumers

21. What is the legal regime for marketing to consumers?

Legal regime
Generally, advertising is subject to supervision by a self-regulatory body, the Advertising Self-Regulation Council (CONAR). The limitations on advertising to consumers are regulated by ANVISA’s Resolution No. 96/2008. Law No. 6360/1976 provides that the marketing of medicinal products is subject to authorisation by the Ministry of Health.

Products
Only over-the-counter drugs can be directly advertised to end consumers in all types of media (Law No. 9,294/1996). Prescription drugs can only be advertised to healthcare professionals.

22. What kinds of marketing activities are permitted in relation to consumers and the products which may be advertised to them?

Law No. 6,360/1976 limits the advertising and marketing of prescribed medicines to healthcare professionals and prohibits such activities in relation to consumers.

To avoid self-medication and the indiscriminate use of drugs, there are several provisions regulating the advertising of over-the-counter drugs.

Although it is not possible to advertise prescription drugs to the public, disease awareness campaigns are allowed. However, the campaign must not mention a specific product or have any marketing nature.
It is possible to issue press releases concerning prescription products in non-scientific journals. In this case, the release cannot be "advertising" in its nature.

It is also possible to describe products and research initiatives in corporate brochures or annual reports.

23. Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers (for example, "buy-one-get-one-free")?

Under ANVISA's Resolution No. 60/2009, free samples can only be distributed by entities to prescribing professionals (doctors and dentists), exclusively in ambulatories, hospitals, clinics and medical offices.

Additionally, an entity can only distribute free samples of drugs registered with the National Sanitary Surveillance Agency (ANVISA), except for biological products, products prepared in compounding pharmacies, and non-prescription drugs.

The concession of discounts is not prohibited under ANVISA's Resolution No. 96/2008. However, promotional material offering such discounts must comply with this Resolution.

24. Are there particular rules of practice on the use of the internet/social media regarding drugs and their advertising?

ANVISA's Resolution No. 96/2008 contains specific regulations on internet advertising.

Entities are free to convey whichever information they wish on their websites, but cannot advertise or publish promotional materials related to prescription products, which is not permitted.

Online promotion of prescription medicines can only be accessible to professionals qualified to prescribe or distribute medicines. This is possible by means of an electronic registration system, and a liability statement setting out the legal restrictions on access must be provided.

The National Sanitary Surveillance Agency (ANVISA) often monitors websites of pharmaceutical companies, pharmacies, distributors, clinics and so on.

25. What regulatory authority is responsible for supervising marketing activities to consumers?

Regulatory authority

The National Sanitary Surveillance Agency (ANVISA) is the authority responsible for supervising advertising and marketing activities related to drugs.

Supervision

The supervision of these activities is done by ANVISA's department called the General Management of Inspection, Quality Monitoring, Control and Supervision of Raw Materials, Medicines and Products, Advertising and Publicity (CGIMP).

According to Resolution No. 96/2008, ANVISA can also request the issuance of a corrective statement.

Rights of appeal

Violators can appeal a decision of ANVISA that considered an advertisement or promotion as contravening the regulations, or a decision to request the issuance of a corrective statement.

An appeal is decided by the ANVISA's board of directors and any final administrative decision can be subject to a judicial procedure.

26. What are the legal consequences of non-compliance with consumer marketing laws?

Law No. 6,347/1977 establishes penalties for failing to comply with the rules governing the advertising of medicines. The National Sanitary Surveillance Agency (ANVISA) is responsible for enforcing these rules.

These penalties include warnings to suspensions of sales, prohibition of advertising and corrective statements. They can be also accompanied by a fine, the value of which depends on whether the failure was considered by the authority as "light", "serious" or "very serious".

Infringers may also be subject to administrative procedures and penalties established by the Advertising Self-Regulation Council (CONAR).

Marketing to professionals

27. What kinds of marketing activities are permitted in relation to professionals?

Advertisements, visits by representatives, distribution of free drug samples or other gifts and sponsoring of meetings and seminars are all permitted, provided that this interaction does not influence a physician's prescription decisions inappropriately.

28. Are there any restrictions on marketing to professionals?

Marketing activities

There are some restrictions related to marketing to professionals. For example, pharmaceutical companies cannot provide professionals with off-label information using the trade mark of the product.

Additionally, advertising medicinal products that are not registered by the National Sanitary Surveillance Agency (ANVISA) is not permitted. A common practice used to overcome this prohibition is to conduct campaigns with medical societies on the awareness and prevention of diseases, without specifically mentioning products.

Frequency

The frequency of sales representatives' visits to medical doctors is not regulated by ANVISA's Resolution No. 96/2008. However, health institutions and class associations can issue specific rules establishing criteria for receiving sales representatives, provided that other conditions set out in Resolution 96/2008 are respected.

Provision of hospitality

There is not a direct mention of hospitality in ANVISA's Resolution No. 96/2008.

Any contribution, including travel expenses, meals and hospitality to support healthcare professionals' attendance at medical conferences and scientific events (national or international) is allowed. However, it is important that the relationship is clearly declared by the physician and the company, in the prospectus, brochure or leaflets of the seminar and in the application form.

The Association of Research Based Pharmaceutical Industries' (INTERFARMA) Code of Conduct contains some restrictive rules related to payments made to a professional when attending a scientific meeting. For example, payments cannot benefit family
members, companions or other persons invited by the hired professional.

29. What information is it legally required to include in advertising to professionals?

The information that must be included in advertising to healthcare professionals is regulated in ANVISA’s Resolution No. 96/2008. Under this resolution, the promotional material must contain the:

- Brand name of the medicine.
- Name of the active ingredient.
- Registration number granted by the National Sanitary Surveillance Agency (ANVISA).
- Therapeutic indications, including the dosage.
- Side effects.
- Interactions and contraindications.
- Warnings and precautions.
- Proof of safety and efficacy by scientific sources.
- Date of printing.

30. Are there rules on comparisons with other products that are particularly applicable to drugs?

ANVISA’s Resolution No. 96/2008 sets out the rules on comparative advertising of medicinal products. Generally, comparative advertising is regulated by different instruments, including the Code of Ethics and the Advertising Profession and the Advertising Self-Regulation Codes.

Products that are not authorised by the National Sanitary Surveillance Agency (ANVISA) cannot be mentioned in advertising.

Price comparison is only allowed between interchangeable products. If the products are not interchangeable, the price comparison can only be made to professionals, under specific conditions.

31. What other items, funding or services are permitted to be provided to professionals?

Discounts
No incentives to prescribing professionals can be (or be understood as) an exchange for ensuring the prescriptions of a particular product.

Free samples
The restrictions on free samples are regulated in ANVISA’s Resolution No. 60/2009.

It is possible to provide professionals with samples of products, except for:

- Non-prescription products.
- Biological products.
- Products prepared in compounding pharmacies.

Samples can only be distributed in clinics, hospitals, medical and dentists’ offices. The prescribing professional must sign a document indicating receipt of the samples.

Generally, the amount offered in a free sample package must be 50% of the original and must clearly include the term “free sample”.

Sponsorship of professionals
A scientist or physician must report to the conference organisation if they have received financial support.

If a pharmaceutical company sponsors scientific events, this support must be made clear in all communication materials.

Resolution No. 96/2008 prohibits linking sponsorship of events (medical or health congresses, symposia, conferences and meetings) within assurance in prescribing or dispensing a medicine.

Other promotional items or activities
The advertisement and indirect sale or the granting, offer, promise or distribution of promotional gifts, benefits and advantages to professionals are prohibited.

Only institutional gifts that are not related to any specific product can be given to professionals.

32. What regulatory authority is responsible for supervising marketing activities regarding professionals?

Regulatory authority
The National Sanitary Surveillance Agency (ANVISA) is the authority responsible for supervising advertising activities and deciding on possible violations arising from marketing activities related to drugs.

Supervision
The supervision of these activities is carried out by ANVISA in the same way as for marketing to consumers (see Question 25).

Rights of appeal
The rights of appeal are the same as for marketing to consumers (see Question 25).

33. What are the legal consequences in case of non-compliance with professional marketing laws?

The consequences are the same as for non-compliance with consumer marketing laws (see Question 26).

ENGAGEMENT WITH PATIENT ORGANISATIONS

34. What kinds of activities are permitted in relation to engagement with patient organisations? What are the restrictions that are imposed on relationship with patient organisations?

Generally, meetings with, and funding of, patient organisations are permitted and no specific requirements must be observed. Health authorities have been looking very closely at this issue.

The Association of Research Based Pharmaceutical Industries’ (INTERFARMA) Code of Conduct provides that companies can interact with patient associations and other similar organisations with the purpose of raising the population’s awareness of health-related issues and/or providing the public with proper information on the treatment, prevention, and diagnosis of diseases.

Resolution No. 96/2008 provides that the organisers of scientific events in which advertising and promotion of medicinal products are allowed must report to the National Sanitary Surveillance Agency (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.

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35. Are there notable recent developments or regulatory projects in the field of distribution and marketing of drugs?

No changes are expected for 2018 in the field of distribution and marketing of drugs in Brazil. However, a review of Resolution No. 96/2008 is scheduled to take place by 2020.

An opinion from the Federal Attorney General’s Office from 2009 indicates that most of the restrictions established in Resolution No. 96/2008 are unconstitutional. Some stakeholders have successfully challenged attempts to enforce such provisions.
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