



# Brazil



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## REGULATORY OVERVIEW

### 1. What is the regulatory framework for the authorisation, pricing and reimbursement of drugs, biologicals and devices (as they are termed in your jurisdiction)?

#### Legislation

The Brazilian regulatory framework regarding pharmaceuticals is in a constant state of change. The current national regulatory framework for medicine, drugs, pharmaceutical inputs and related products is extensive and complex compared to ten years ago. The two constitutional clauses that established the foundation for the framework are:

- **Article 196, Federal Constitution 1988 (FC 1988).** This provides for Brazilian health policies and the regulatory framework for medical devices, pharmaceutical products and inputs aimed at reducing the risk of illness and other hazards for the whole population.
- **Article 197, FC 1988.** This enshrines the government's duty to regulate the provision of health services and products, whether directly or through third parties.

The key legislation is:

- **Federal Law No. 6,360 of 23 September 1976.** The main law related to pharmaceutical products in Brazil. It regulates, among other things, the production, commercialisation, advertising, labelling, inspection, quality control, importation and marketing approvals of medicine, biologics, vaccines, drugs, pharmaceutical inputs and related products. This law is regulated by Decree No. 79,094 of 5 January 1977, amended by Decree No. 3,961 of 10 October 2001.
- **Law No. 5,991 of 17 December 1973.** Regulates sanitary control related to the trade of drugs, medicine, pharmaceutical inputs and related products.
- **Law No. 9,787 of 10 February 1999.** Provides that generic medicine can obtain marketing approval provided they are proved to be interchangeable (through bioequivalence studies) with the reference medicine.
- **Law No. 6,437 of 20 August 1977.** Sets out the penalties for infringing food and medicine laws, including criminal sanctions.
- **Law No. 9,294 of 1996.** Imposes restrictions on the use of, and advertising for, smoking products, alcoholic beverages, medicine, therapies and agricultural pesticides.

- **Decree No. 2,018 of 1996.** Places restrictions on the use of, and advertising for, smoking products, alcoholic beverages, drugs, therapies and pesticides under section 4, Article 220 of the Federal Constitution.

#### Regulatory authorities

The National Sanitary Surveillance Agency (ANVISA) (*see box, The regulatory authority*) was established by Law No. 9,782 of 26 January 1999 (Law No. 9,782/99). It is linked to the Ministry of Health, despite operating as a financially autonomous regulatory agency. ANVISA is responsible for regulation and enforcement of food and drug laws in Brazil.

ANVISA's statutory role is to protect public health by regulating the production and marketing of pharmaceutical products, as well as agrochemicals, foodstuffs, cleaning products, and so on. ANVISA also regulates:

- The factories where these products are produced.
- The processes used.
- The raw materials and the technologies related to the final product.

ANVISA's main responsibilities are set out in Law No. 9,782/99. A marketing approval from ANVISA is required to produce or commercialise pharmaceutical products in Brazil, or import pharmaceutical products into Brazil. Every company seeking a pharmaceutical marketing approval must have good manufacturing practices (GMP), following the standards required by ANVISA.

#### Biological products

In 2010, ANVISA updated the regulations for biological products and different regulatory pathways for new biological products and for copies were established (*Resolution No. 55 of 16 December 2010*). For new biological products, the usual pathway, based on a full dossier submitted by the applicant, is required. For similar biological products, the following two regulatory pathways were introduced:

- **Individual development pathway.** A reduced dossier can be submitted. The applicant must submit full data regarding quality issues but this does not have to be comparative. The number of non-clinical and clinical studies submitted can be reduced, depending on how much data is available on the pharmacological properties, safety and efficacy of the originator product. At least one comparative Phase III study (equivalence, superiority or non-inferiority) with the originator biological product is mandatory (except for hemoderivatives, vaccines and biological products for oncological use).



- **Comparative pathway.** A comparator product must be submitted. The applicant must use comparability in terms of quality, safety and efficacy between the comparator product and the similar biological medicine.

## PRICING AND STATE FUNDING

### 2. What is the structure of the national healthcare system, and how is it funded?

Although the Constitution establishes that health is everyone's right, the Brazilian national healthcare system is in practice not comprehensive and assists mostly poor citizens. Most middle-class Brazilians rely on private medical insurance, which is often subsidised by employers (including all branches of government). Law No. 9,656 of 3 June 1998 establishes the rules for private insurances and healthcare plans.

The regional healthcare network is a unified system, organised according to the following principles (*Article 198 FC 1988, Law No. 8,080 19 September 1990 and Law No. 8,142 of 28 December 1990*):

- Decentralisation, with a single management in each sphere of government.
- Full service, with priority given to preventive activities.
- Participation of the community.

This Unified Healthcare System (SUS) is statutorily defined as comprising "health activities and services, provided by public and federal entities and institutions, both by states and counties, of the direct and indirect administration of the foundations maintained by the government".

Maintained by the federal, state and county executive governments from taxes and contributions, SUS relies on publicly owned facilities, such as hospitals, hiring private contractors for specific needs.

The health activities and services provided by SUS are organised regionally and hierarchically. SUS has a unified management structure, exercised by each government sphere of the following institutions:

- In relation to the Federal Union, by the Ministry of Health.
- In relation to the states, Federal District and municipalities, by the respective health offices.

### 3. How are the prices of medicinal products regulated?

The prices of new medicinal products and new presentations of medicine are strictly regulated in Brazil. Prices are set by the Pharmaceutical Market Regulation Council (CMED), after the marketing approval is issued by ANVISA.

CMED was created by Law No. 10,742 of 6 October 2003, and is composed of members of the Ministries of Health, Justice and Finance and the Chief of Staff to the President. CMED is responsible for monitoring and regulating the pharmaceutical

market and establishing the parameters and criteria for setting and adjusting the prices of medicines in Brazil, to stimulate competition in the market. Prices are reviewed annually in March.

To obtain marketing approval for a product, a company must file the following economic data (*Article 16, VII, Law No. 6,360/76, as amended by Law No. 10,742/03*), which must be taken into consideration by CMED when setting or adjusting prices:

- The price charged by the company in foreign countries.
- The cost of the active ingredients.
- The cost per patient of the treatment with the product.
- The potential number of patients to be treated with the product.
- The price that the company intends to charge in the market, including tax.
- The commercialisation plan, including advertising and sales costs.
- The list of all the competitor products with their respective prices.
- Information on intellectual property, especially patents covering the product.

However, some products are not subject to the analysis of CMED, such as herbal and homeopathic medicines.

### 4. When is the cost of a medicinal product funded by the state or reimbursed to the patient? How is the pharmacist compensated for his dispensing services?

There is no direct or indirect reimbursement to end-users or pharmacists in Brazil. Medicines in Brazil have the same tax burden as other non-essential goods, such as alcoholic beverages or clothes.

However, Article 6, clause D of Law No. 8,080 of 19 September 1990 establishes that SUS has an obligation to provide integral therapeutic assistance, which includes pharmaceuticals. The Brazilian population therefore has the right to receive free medicines.

Federal, state and county authorities have a free distribution programme of medicines in public hospitals (including anti-inflammatory drugs, analgesics, oral contraceptives, antihypertensive drugs, and so on). The National Medicines Policy of the Ministry of Health, established by Ordinance No. 3,916 of 30 October 1998, must adopt "Rename" (the National List of Essential Medicines), which serves as a guideline for state and municipal governments to create their own lists in accordance with each region's needs. The current list is provided by Ordinance No. 2,012 of 24 September 2008.

There are several programmes for patients with chronic diseases (for example, diabetes, asthma, epilepsy and Alzheimer's disease). There is also an HIV/AIDS programme, responsible for the free distribution of antiretroviral medicines, which is recognised as the leading programme worldwide.

The federal government buys nearly 50% of the medicines in Brazil. The distribution is made by the federal, state and county public hospitals.



The purchase of medicines by the Ministry of Health and public health institutions is carried out through competitive bidding in a procurement process under the FC 1988 (*Federal Law No. 8,666/93, as amended*). The supplier with the lowest price, who proves that the medicine meets the legal and technical requirements of the procurement, wins the bid. Federal Law No. 9,787/99 states that a public bid for the purchase of medicines must include the international non-proprietary name (INN).

Some Brazilian states have recently implemented a new system called low-cost pharmacy. Under this system, the federal government buys medicines from the industry and distributes them to patients at a lower cost, through a network of government-owned pharmacies selling directly to users.

## MANUFACTURING

### 5. What is the authorisation process for manufacturing medicinal products?

#### Application

The company must obtain an operating authorisation from the Ministry of Health. Once this authorisation is granted, the company must obtain a licence from the local sanitary surveillance body (state, county or municipalities), which ultimately allows the company to start its manufacturing activities. State and county rules must also be observed.

#### Conditions

To obtain an operating authorisation and licence, the company must (*Articles 2, 50, 51 and 52, Law No. 6,360/76*):

- Specify its industrial activities and the kind of products it wishes to manufacture.
- Prove its technical, scientific and operational capability.
- Satisfy other requirements set out in ANVISA's internal rules.

The company must also obtain approval from the state sanitary surveillance body for the building's projects and plants. County rules must also be observed.

#### Restrictions on foreign applicants

Foreign manufacturers can market medicinal products in Brazil as imported goods, through local subsidiaries or local commercial representatives. To do so, they must obtain a GMP certificate from ANVISA, after ANVISA inspects the manufacturer's premises abroad. The local subsidiaries or local commercial representatives must obtain an operating permission, as well as marketing approval for each imported product. The specific regulation on imported medicinal products is ANVISA's Resolution No. 81 of 5 November 2008.

#### Key stages and timing

It takes roughly between six months to one year to:

- File the operating authorisation request at the Ministry of Health (ANVISA).
- Obtain Ministry of Health approval.
- File the operating authorisation at the local sanitary surveillance body.

- Obtain the licence.
- Publish it in the *Official Gazette*.

#### Fee

ANVISA charges fees for granting and revalidating the operating authorisation, for each type of activity performed by the company (*Annex II, Law No. 9,782/99*). These fees also vary depending on the size of the company, under Resolution No. 222 of 28 December 2006, which is available on ANVISA's website.

#### Period of authorisation and renewals

The operating authorisation is valid indefinitely throughout Brazil. However, it must be renewed if (*Article 50, sole paragraph, Law No. 6,360/76*):

- There is an alteration in activity.
- The company intends to start a new activity not covered by the original operating permission.
- A partner or director in charge of the company's legal representation changes.

### 6. What powers does the regulator have in relation to manufacturing authorisations?

#### Monitoring compliance

ANVISA, as well as state and municipal entities, are responsible for inspecting and enforcing compliance with food and drug laws.

#### Imposing penalties

ANVISA, as well as state and municipal entities, can impose administrative penalties (such as fines) for a statutory sanitary infringement, after due administrative prosecution. Civil and criminal penalties can also be imposed, but only after civil or criminal court proceedings (not directly by ANVISA).

## CLINICAL TRIALS

### 7. Outline the regulation of clinical trials.

The interest in clinical trials has increased sharply in Brazil in the last ten years. The country's medical facilities have received investment from international sources and have benefited from foreign know-how and transfer of technology.

#### Legislation and regulatory authorities

Clinical trials are regulated by the National Health Council, linked to the Ministry of Health, through Resolution No. 196/1996, which sets out the main guidelines for clinical research, particularly concerning the ethical aspects of research involving humans. Through Public Consultation No. 3 of 11 August 2011, the National Health Council published a reviewed version of Resolution No. 196/1996.

The technical requirements are regulated by ANVISA, through Resolution No. 39 of 5 June 2008. The Good Clinical Practice of the Document of the Americas is also adopted, which is a document resulting from the work performed by the PanAmerican Health Organisation/World Health Organisation (PAHO/WHO).



## Authorisations

Every clinical trial to be performed with medicinal and health products in Brazil, regardless of its subject (whether new medicines or new or therapeutic indications, for example), must be submitted for ANVISA's prior evaluation. ANVISA's Division of New Drugs, Research and Clinical Tests (GEPEC) analyses all the required documentation, as well as the sanitary risks involved, before granting the approval. The trial's sponsor or the person in charge of conducting the trials is responsible for preparing the dossier to be submitted to GEPEC's evaluation, fulfilling all the requirements set out in Resolution No. 39/2008.

In addition, as a condition of obtaining ANVISA's approval, the company must file a detailed protocol before the Ethics Committee (CEP) of the institution in which the clinical trial will be performed, to have all ethical aspects of the trial analysed. Every CEP must be registered at the National Ethics Commission (CONEP), linked to the Ministry of Health and the Health National Council. This protocol must contain the freely given and informed consent of the trial subjects (or their legal representatives) on every single detail of the clinical trial, such as objectives, procedures to be adopted, alternative methods to be eventually adopted, risks, assistance offered to the subject, freedom to withdraw from the trial, and so on.

## Consent

The consent is set out in Resolution No. 196/1996, which is based on the World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects of 1964 (and its later versions of 1975, 1983 and 1989), and must contain the following information:

- Rationale aims and methods to be used in the research.
- Any foreseeable risks or discomfort to the subject, as well as benefits that might reasonably be expected, associated with participation in the research.
- Existing alternative methods.
- Medical follow-up and care to be provided to the subjects of research, as well as the identity of those responsible for these actions.
- Assurance of information concerning the methodology, before and during the research, including the possibility of inclusion in a control or placebo group.
- Freedom of the individual to refuse participation or withdraw his consent, at any time during the research, without any penalty or loss of benefits to which he would otherwise be entitled.
- Extent to which confidentiality of records will be maintained, to safeguard the privacy of the research subjects.
- Forms of reimbursement of current expenditure resulting from participation in the research.
- Types of indemnity to cover possible injury resulting from the research.

## Trial pre-conditions

Insurance coverage is not required, but the sponsor must declare himself responsible for assistance in the case of complications or damage caused during the trial, including adverse reactions.

## Procedural requirements

The sponsor must file annual reports about the trial, as well as a final report with the conclusion of the trial, along with a special report concerning adverse reactions.

## MARKETING

### Authorisation and abridged procedure

#### 8. What is the authorisation process for marketing medicinal products?

### Application

The application on form PF1, available at ANVISA's website) for all kinds of marketing approvals must be addressed to ANVISA (*Article 12, Law No. 6,360/76*).

### Authorisation conditions

For a medicine to be registered, it must be proven, by means of scientific and analytical evidence, to be safe and effective for its intended use, and have sufficiently high quality, activity and purity for human use (*Article 16, Law No. 6,360/76*).

ANVISA's resolutions set out the specific and technical requirements for obtaining marketing approvals for:

- New medicines (*Resolution No. 136 of 29 May 2003*).
- Generic medicines (*Resolution No. 16 of 2 March 2007*).
- Non-interchangeable branded drugs (so-called similar medicines) (*Resolution No. 17 of 2 March 2007*).
- Biological products (*Resolutions No. 55 of 16 December 2010 and No.49 of 20 September 2011*).

### Other conditions

Any registration changes must follow the procedures specified in the *Guide for making post-registration alterations and inclusions in medicines*. If medicines are not marketed within a certain period, marketing approval may not be renewed.

### Key stages and timing

The key steps in the procedure for obtaining marketing approval are:

- Filing the application.
- Analysis by ANVISA.
- Filing any additional documentation.
- Publishing the approval in the *Official Gazette*.

The whole process can take around one year.

### Fee

ANVISA charges fees for issuing and revalidating marketing approvals (*Annex II, Law No. 9,782/99*). The fees vary depending on the type of marketing approval and on the size of the company, according to Annex I of Resolution No. 222 of 28 December 2006, which is available on ANVISA's website.





## Period of authorisation and renewals

The marketing authorisation issued by ANVISA for new, similar or generic medicines is valid for a five-year term, and can be renewed for equal and successive periods (*Article 12, paragraph 1, Law No. 6,360/76*). For diet products, the marketing approval is valid for a two-year term (*Article 12, paragraph II, Law 6,360/76*).

## Post-marketing commitments and pharmacovigilance obligations

ANVISA can undertake a control analysis of commercialised batches in official laboratories, to monitor the quality and compliance of the drug with the drug registration. When necessary, ANVISA can require companies to train ANVISA technicians, to enable them to undertake this monitoring. Once the drug expiry date has passed, the company must file:

- A report on the final results and evaluation of the long term stability study for the three batches submitted on registration.
- A declaration containing the definitive expiration date and conservation care.

Pharmaceutical industries also have a stake in the pharmacovigilance system, informing ANVISA of any problems with medicines. Law 6,360 establishes that these companies must notify the sanitary authorities of any adverse reactions caused by medicines.

## 9. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

### Scope of abridged procedure

Medical products seeking marketing approval as generics (*ANVISA's Resolution No. 16 of March 2007*) or similar medicines (*Resolution No. 17 of March 2007*) can benefit from an abbreviated marketing approval procedure.

### Conditions and procedure

Similar medicines must contain the same following characteristics as the reference medicine registered with ANVISA:

- Active ingredients.
- Concentration, dosage form, route of administration, strength and therapeutic, preventive or diagnostic indication.

A similar medicine can only differ in characteristics related to size and form of the product, expiry date, packaging, labelling, excipients and vehicles, and must always be identified by its trade mark.

By law, similar medicines are not considered interchangeable with the reference product (that is, therapeutically equivalent to the reference product, having the same efficacy and safety). However, relative bioavailability and pharmaceutical equivalence assays must be conducted as a requirement for their marketing approval. Similar medicines for which relative bioavailability and pharmaceutical equivalence have been shown are said to be pharmaceutically equivalent to the reference product registered with ANVISA (*Resolution No. 17/2007*).

Generic medicines are products similar to a reference/innovative product, which must be interchangeable with the reference/innovator product. Generics are usually produced after the expiration or waiver of patent protection or other exclusive rights. Their effectiveness, safety and quality must be proven and designated by either:

- DCB, that is, the Brazilian Common Denomination of the drug substance or the pharmaceutically active ingredient approved by ANVISA.
- In the absence of a DCB, the INN of the drug substance, or the pharmaceutically active ingredient recommended by the WHO.

To prove interchangeability for generic medicines, ANVISA requires the submission of bioavailability and bioequivalence assays:

- **Bioavailability.** This indicates the rate and extension of absorption of an active ingredient in dosage form, based on its concentration/time curve in the systemic circulation, or its excretion in urine.
- **Bioequivalence.** This demonstrates the pharmaceutical equivalence of products presented in the same pharmaceutical form, showing:
  - the same qualitative and quantitative composition of active ingredient(s); and
  - comparable bioavailability when studied under the same experimental design.

Further details on the specific procedure to be followed are in ANVISA Resolution No. 16/2007.

## 10. Are foreign marketing authorisations recognised in your jurisdiction?

A Brazilian marketing approval must still be obtained from ANVISA for a medicine with a foreign marketing approval. In the case of imported medicines and inputs, in addition to the usual registration requirements (*see Question 8*), the company must also prove that the product is already registered in the country of origin (*Article 18, Law No. 6,360/76*) and complies with the GMP standards in that country.

## 11. What powers does the regulator have in relation to marketing authorisations?

### Monitoring compliance

ANVISA, as well as the state and municipal bodies, are responsible for inspecting and enforcing compliance with food and drug laws. This includes monitoring the existence or lack of the necessary marketing approval.

### Imposing penalties

ANVISA, as well as the state and municipal bodies, are also responsible for imposing administrative penalties for any statutory sanitary infringement, after due administrative prosecution.



## Parallel imports

### 12. Are parallel imports of medicinal products into your jurisdiction allowed?

IP laws prohibit parallel imports into Brazil. Trade mark and patent rights can be used to oppose parallel imports. An importer can have the IP law enforced against it.

ANVISA is responsible for the pharmacovigilance of imported pharmaceutical products in Brazil, including airports and ports (*Law No. 9,782/99*). ANVISA has been enforcing a very stringent rule which requires the importer of medicines to provide detailed information on, among other things, the source of the drug and the owner of the marketing approval (*Resolution No. 81 of 5 November 2008*). If the importer satisfies the requirements of Resolution No. 81, ANVISA will issue an import licence and release the pharmaceutical products.

## Restrictions

### 13. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

Giving or offering prizes or cash incentives to prescribing medical practitioners and pharmacies is forbidden (*Resolution No. 96 of 17 December 2008*). However, the distribution of institutional gifts, that is, gifts that do not advertise medicine, and of scientific papers, magazines or publications and technical books used for professional updates, are allowed (*Normative Instruction No. 5 of 20 May 2009*).

Free samples, distributed exclusively to prescribing practitioners, must contain at least 50% of the original packaging content, except for antibiotics (enough for complete treatment is mandatory) and contraceptives (full contents of the original package are mandatory). The packaging of these samples must contain the non-removable expression "free sample". Resolution No. 60 of 26 November 2009 prohibits the distribution of free samples of:

- Biological products that require special care for maintenance and transport.
- Medicine prepared by compounding pharmacies.

The distribution of medicine subject to special control is subject to more strict rules (*Ordinances No. 344 of 12 May 1998* and *No. 9 of 29 January 1999*).

Public agents cannot act in favour of a private agent in exchange for compensation (*Law 8.429 of 2 June 1992*). Bribery is considered a crime and punished in Brazil.

### 14. What are the restrictions on marketing medicinal products on the internet, by e-mail and by mail order?

#### Internet

Advertising prescription medicine over the internet is prohibited, unless the advertisement is only accessible by professionals who are able to prescribe or to dispense medicine (*Article 29, Resolution No. 96 of*

*17 December 2008*). Pharmaceutical industries commonly operate restricted-access websites. Advertisements for non-prescription medicine on the internet must contain a warning concerning the active ingredient of the product.

The sale of medicine over the internet can only be undertaken by websites from pharmacies and drugstores with fixed commercial establishments, which are open to the public (*Resolution No. 44 of 17 August 2009*). In the case of prescription medicines, the sale can only be made on presentation of a prescription.

In addition, the company providing the service must provide a direct and immediate method of communication between the patient and a pharmacist. Drugs subject to special control (*Ordinance No. 344 of 12 May 1998*) cannot be sold on the internet.

The site should use only the electronic domain *com.br*, and must show on the main page, among other things, the following data and information:

- Name and registration number in the Pharmaceutical Council of the pharmacist in attendance.
- Alert messages and health recommendations from ANVISA.
- That prescription medicines will only be released on presentation of a receipt, and the means by which it can be presented to the establishment (fax, e-mail or otherwise).

#### E-mail

Resolution No. 96/2008 does not expressly mention e-mail messages, but it can be inferred that the term internet in this resolution includes e-mail messages (*see above, Internet*).

#### Mail order

There are no particular rules referring to marketing medicinal products by mail order. In any event, this is not common in Brazil.

## ADVERTISING

### 15. What are the restrictions on advertising medicinal products?

#### Legislation and regulatory authority

Law No. 9,294 of 1996 and Decree No. 2,018 of 1996 impose restrictions on the use and advertising of smoking products, alcoholic beverages, drugs, therapies and agricultural pesticides, under section 4 of Article 220 of the FC 1988.

The rules relating to the advertising of medicinal products are contained in Resolution No. 96/2008 enforced by ANVISA. Medicines cannot be advertised unless they have a marketing approval from ANVISA.

ANVISA often sets fines for industries perceived as marketing ethical medicines to the general public, even where these involve disguised, non-direct advertising. A common practice used to avoid the advertising rules is to partner with medical societies to campaign for awareness and prevention of diseases, without specifically mentioning products. The National Council for Advertising Self-Regulation (CONAR), founded in 1980, has the authority to enforce the Brazilian Code of Advertising Self-Regulation, adopted in 1978. CONAR's objective is to eliminate the placing of advertisements and



campaigns with misleading, offensive and abusive content, or that could, among other things, distort competition.

### Restrictions

Under Precedent No. 2 of 15 August 1988, prescription-only pharmaceuticals cannot be advertised to the general public, and any such advertising can be immediately withdrawn by CONAR. This precedent is based on Articles 1 and 50, and C, of the Brazilian Code of Advertising Self-Regulation. Prescription drugs can only be advertised to professionals who are able to prescribe or to dispense medicines.

Advertisements must not, among other things (*Article 8, Resolution No. 96/2008*):

- Stimulate and/or induce the indiscriminate use of medicines.
- Suggest or encourage diagnosis by the general public.
- Include images of people using the medicine.
- Employ words that encourage consumption of the medicine, for example, “have”, “take”, “use”, “try”, and so on.
- Advertise a drug as being new, if it has been on the market for more than two years (except for new therapeutic indications).
- Suggest that the patient's health could be endangered if he does not take the advertised medicine.

### Internet advertising

Advertising of prescription medicine on the internet must be accessible only to professionals qualified to prescribe or dispense medicine (*see Question 14*).

## PACKAGING AND LABELLING

### 16. Outline the regulation of the packaging and labelling of medicinal products.

#### Legislation and regulatory authority

Packaging and labelling requirements are set out in ANVISA's Resolution No. 71 of 22 December 2009. This is enforced by ANVISA.

#### Information requirements

Packaging must contain certain minimum information, including:

- The medicine's brand name (except for generics).
- The name of the active ingredient.
- The name and address of the owner of the marketing approval.
- The name of the manufacturer and place where the medicine is manufactured (country, state and city, in the case of imported products).
- The name and registration number of the pharmacist responsible for the medicine.
- The batch number.
- Manufacturing and validity dates.
- Marketing approval number.
- Information regarding the medicine's formulae and composition, including weight and volume.

- Security stamp.
- The storage conditions, indicating the temperature range and storage conditions indicated by the medicine's stability study.
- The telephone number of the customer care service of the marketing approval holder, or the company producing the medicine.

### Other conditions

There are also specific requirements for prescription medicines, and specific warnings regarding children, free samples and routes of administration. All the information that does not fit in the external packaging must be contained in the insert packaging. As well as Portuguese, the packaging must contain information in Braille (*Article 24, Resolution No. 71/09*).

## TRADITIONAL MEDICINES

### 17. Outline the regulation of the manufacture and marketing of alternative or complementary medicinal products.

As with regular medicines, companies must obtain an operating permission to begin manufacturing herbal medicines.

The marketing approval procedure for herbal medicines is set out in ANVISA's Resolution No. 14 of 31 March 2010. The required documentation includes:

- Quality control test results.
- A copy of the operating permission.
- A technical responsibility certificate.
- The packaging insert and labelling information.
- A complete report describing each manufacturing stage and its respective methodologies.
- Complete information regarding the herbal medicine.
- GMP certificate of the Brazilian manufacturer or of the foreign manufacturer, in the case of imported products (ANVISA also inspects foreign companies in order to issue GMP certificates).
- Proof of the product's safety and efficacy.

The marketing approval is valid for a five-year term, after which it must be renewed.

## PATENTS

### 18. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

#### Conditions and legislation

The requirements to obtain patent protection are:

- Novelty.
- Inventive activity.
- Industrial application.



- Descriptive sufficiency.

The IP Law (*Law No. 9,279/96*) sets out the requirements to obtain patent protection.

### Scope of protection

All pharmaceutical products and processes inventions can be patent protected (*Law No. IP Law*), except for:

- Those that are contrary to morals, good customs, public security, public order or health.
- Any substances related to atomic nucleus transformations.
- The whole or parts of living beings, except transgenics.

Patents can only be issued for a pharmaceutical product or process with ANVISA's prior consent (*Article 229-C, IP Law*). ANVISA's role in providing prior consent is controversial. ANVISA generally interprets (*section 4, Resolution RDC No. 45/2008*) prior consent to mean it can (re)analyse whether a pharmaceutical invention complies with the requirements for patentability (*see above, Conditions and legislation*). Some jurists and judges believe that ANVISA's prior consent is limited to assessing whether a patent is contrary to public health (*section 18, I, IP Law*).

Two legal opinions, which bind ANVISA, have been rendered by the Attorney General's Office to limit the ANVISA's examination to public health factors. In 2011, an inter-ministerial working group was created to discuss the application of section 229-C of the IP Law.

## 19. How is a patent obtained?

### Application and guidance

Patents are issued by the Brazilian Patent and Trademark Office (INPI) (*see www.inpi.gov.br*). Guidance is available in Portuguese only.

Fees are due:

- When the application is filed: about US\$130 (as at 1 November 2011, US\$1 was about EURO.7).
- When the technical examination is requested: about US\$328 (application with up to ten claims).
- Annually, before the patent is not issued: about US\$165.
- If and when the patent issued: about US\$130.
- Annually, from the third year of the patent validity until its final term:
  - from year three to year six: about US\$435;
  - from year seven to year ten: about US\$680;
  - from year 11 to year 15: about US\$915;
  - from year 16 onwards: about US\$1,115.

### Process and timing

The key stages are:

- The applicant files the application.

- The application is published for opposition purposes.
- The technical examination is requested.
- INPI conducts the technical examination.
- INPI makes its decision and issues the patent.

### Deposit system

After its filing, the patent application is kept secret for 18 months and, then, published for opposition purposes. The examination of the patent application must be requested within 36 months as from the filing date. Otherwise, the application is dismissed. Once requested, the technical examination is performed by INPI. Then, INPI renders its decision and issues the patent.

## 20. How long does patent protection typically last? Can monopoly rights be extended by other means?

### Duration and renewal

Patent protection lasts for 20 years from the filing date, or at least ten years from when it is granted (*Article 40, IP Law*). It cannot be renewed.

### Extending protection

There is no procedure to renew a patent or extend its term, even where there are delays to the issue of the related marketing approval. If INPI unreasonably delays examination of the patent application for more than ten years, the term of the patent is ten years from its grant (*Article 40, IP Law*).

## 21. How can a patent be revoked?

INPI and any other authorised body can revoke patents using a post-grant opposition procedure, within six months from the issuance of the patent, in the following circumstances:

- If the legal patentability requirements, for example novelty, inventiveness and descriptive sufficiency, have not been met.
- If the patented subject matter extends what was originally claimed.
- If any essential formal requirement was not met during the patent application process.

A patent can also be revoked by a nullity lawsuit before the federal courts at any time during the patent term. A patent can also be revoked through a forfeiture proceeding started by INPI or any interested party in cases of abuse or non-use (*section 80, IP Law*).

## 22. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

### Conditions for infringement

Patent infringements include:

- Using a patented product or process without the patent owner's authorisation.





- Importing, for economic purposes, a patented product or a product that is obtained by a patented means or process, which has been placed on the external market by someone other than the patent owner, or without his consent.
- Supplying a component of a patented product, or material or equipment for carrying out a patented process, if the final application of the component, material or equipment necessarily leads to the exploitation of the subject matter of the patent.

#### Claim and remedies

When a patent is infringed, the patentee can file a civil lawsuit to seek to stop the infringement and obtain compensatory damages.

In addition, patent infringements are criminal offences punishable with imprisonment.

### 23. Are there non-patent barriers to competition to protect medicinal products?

Data package exclusivity (DPE) periods can be used to extend protection, or replace patent protection if there is no patent covering the product. Law No. 10,603/2002 only provides DPE for pharmaceutical products for veterinary use, fertilisers, agrochemicals, their components and similar products.

In relation to drugs for human use, the data package protection is solely based on the rules of unfair competition (*section 195, item XIV, IP Law*). Further, ANVISA must treat data packages submitted to it for marketing approvals as secret. However, the Superior Court of Justice (STJ) has recently suspended a court decision which granted DPE for a human drug, based on the fact that, when Congress converted Provisional Measure No. 69/2002 into Law No. 10,603/2002, it intended to suppress DPE for human drugs. In addition, DPE for human drugs could jeopardise generic drugs in Brazil.

## TRADE MARKS

### 24. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

#### Conditions and legislation

A trade mark application must be filed before INPI and it will mature into registration, if the trade mark at stake is:

- Visually perceptible.
- Distinctive.
- Not statutorily prohibited. Most statutory prohibitions are set out in Article 124 of the IP Law.

#### Scope of protection

Medicinal product brands can be registered as trade marks. However, the products must not have names or designations (*Article 5, Law No. 6,360/76*) that could lead to confusion between brands. ANVISA's rules relating to medicine labelling and commercial names are set out in Resolutions No. 333/2003 and No. 46/2006.

### 25. How is a trade mark registered?

#### Application and guidance

Applications for trade mark registration must be filed with INPI (*see Question 19*).

Fees are due:

- When the trade mark application is filed: about US\$272.
- Before the registration certificate is issued, when fees for the first ten-year period of registration must be paid: about US\$426.
- During the last year of the ten-year registration term, when fees for any renewal application must be paid: US\$610.

#### Process and timing

The key steps in the process are:

- The applicant files the application.
- The application is published for opposition purposes.
- INPI examines the application and makes a decision granting or rejecting the application.
- INPI grants a registration certificate.

### 26. How long does trade mark protection typically last?

#### Duration and renewal

Trade mark protection lasts for ten years.

Trade mark protection is renewable for successive ten-year periods, on payment of renewal fees (*Article 133, IP Law*).

#### Extending protection

Non-registered trade marks can be protected under unfair competition law.

### 27. How can a trade mark be revoked?

A trade mark can be revoked if it was issued contrary to any of the legal requirements, within 180 days after the issuance of the registration certificate and using the administrative procedure (administrative annulment request). After this period, a trade mark can be revoked through a nullity lawsuit, which must be filed within five years from the registration.

In addition, a trade mark registration can be revoked through forfeiture proceedings, on the request of any person with a legitimate interest if:

- After five years from its issuance, the owner has not used the trade mark in Brazil.
- The use of the mark has been interrupted for more than five consecutive years or, within that time, has been used in a modified form that implies alteration in its original distinctive character, as set out on the registration certificate.



However, the registration will not be revoked if its owner demonstrates that the non-use is due to legitimate reasons (for example, a delay in granting marketing approval by ANVISA).

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**28. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?**

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**Conditions**

A trade mark is infringed if someone:

- Reproduces a registered mark wholly or in part, without the authorisation of the trade mark owner.
- Imitates a registered mark in a manner that could cause confusion with another mark.
- Alters the registered mark of a third party already applied to a product placed on the market.

It is also a crime to import, export, sell, offer or exhibit for sale, hide or maintain in stock either:

- A product branded with an illicitly, wholly or partially, reproduced or imitated mark of a third party.
- A product of the infringer's trade or commerce, held in a vessel, container or package and carrying a legitimate mark of a third party.

It is also prohibited to (*Article 195, IP Law*):

- Use fraudulent means to take another's clients for a person's own, or a third party's, benefit.
- Use another person's advertising expression or sign, or imitate it in such a way to cause confusion between products or businesses.
- Unduly use another's commercial name, business title or insignia, or sell, exhibit or offer for sale, or maintain in stock, a product with such references.

**Claim and remedies**

Infringements (*see above, Conditions*) are criminal acts punishable with imprisonment. The trade mark owner can also file a civil lawsuit.

The trade mark owner can file a civil lawsuit seeking damages. Trade mark counterfeited goods can be seized by customs authorities.

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**Patent and trade mark licensing**

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**29. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body?**

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It is mandatory to obtain approval for patent, trade secrets and trade mark technology transfer licences to remit royalty payments abroad. The approval procedure, which is lodged with INPI, is straightforward, but can take several months.

There are a number of limitations imposed on the amount of royalties that can be sent abroad, particularly between

corporations exercising the same control, such as a parent and its subsidiary.

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**Patent and trade mark conventions**

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**30. Is your jurisdiction party to international conventions on patent and trade mark protection?**

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Brazil is a signatory to the:

- WTO Agreement on Trade-Related Aspects of Industrial Property (TRIPS) (implemented in Brazil by *Decree No. 1,335/94*).
- WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) (implemented by *Decrees No. 75,572/75, No. 635/92 and No. 1,263/94*).
- Patent Cooperation Treaty 1970 (implemented by *Decree No. 81,742/78*).

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**PRODUCT LIABILITY**

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**31. Outline the scope of medicinal product liability law.**

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**Legal provisions**

Liability for defective medicinal products can arise under:

- The Consumer Protection Statute (*Law No. 8,078 of 11 September 1990*).
- The Criminal Code (*Decree-Law No. 2,848/1940*, as amended by several subsequent laws, particularly *Law No. 8,072/1990* and *No. 9,677/98*, which classify crimes against public health as serious crimes).
- Law No. 8,137 of 27 December 1990, which defines crimes against consumer relations.

**Substantive test**

A pharmaceutical product is considered to be defective when it is unfit or inadequate for consumption, or when there are contradictions between the product and its packaging information. It can also be considered counterfeit when it has been deliberately and fraudulently mislabelled with respect to identity and/or source, including drugs:

- With correct ingredients but fake packaging.
- With the wrong ingredients.
- Without active ingredients or with insufficient active ingredients.

**Liability**

The following are potentially liable for defective pharmaceutical products (*Article 273, Criminal Code*):

- Anyone who falsifies, corrupts, adulterates or alters a product intended for therapeutic or medicinal uses.
- Anyone who imports, sells, displays for sale, stores for sale or, in any way, distributes or delivers for consumption a falsified, corrupted, adulterated or altered product.



- Anyone who commits these actions with products which:
  - do not have registration from ANVISA;
  - do not comply with the registered formulae;
  - do not have the necessary identity and quality required for their commercialisation;
  - have reduced therapeutic value or activity; or
  - are products of unknown origin, or are acquired from an establishment that does not have the necessary operating authorisation.

The Brazilian or foreign manufacturer, producer, importer and seller of the defective pharmaceutical products are jointly liable (*Consumer Protection Statute*).

### 32. How can a product liability claim be brought?

#### Limitation periods

There is a five-year limitation period for consumers bringing claims for damages caused by defective products. For criminal complaints, the limitation period can rise up to 20 years, depending on the maximum penalty applied to the crime (*Article 109, Criminal Code*).

#### Class actions

Class actions are allowed, and are quite common, for groups of consumers claiming damages (civil liability) for defective products.

#### Foreign claimants

Foreign claimants can bring law suits before the Brazilian courts if any of the following apply:

- The claimants are residents of Brazil.
- The product was used within the Brazilian jurisdiction.
- The producer or the seller of such product is located in the country.

### 33. What defences are available to product liability claims?

There is no liability if any of the following is proven (*Article 12, Consumer Code*):

- The product has not been placed on the market.
- The product has no defect.
- The defect or damage arises exclusively from the consumer's fault.

### 34. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

The claimant can file a civil lawsuit claiming damages (civil liability). The Public Prosecutor's Office is responsible for bringing criminal lawsuits.

## THE REGULATORY AUTHORITY

### National Sanitary Surveillance Agency (ANVISA)

W [www.anvisa.gov.br](http://www.anvisa.gov.br)

**Main areas of responsibility.** Among other activities, ANVISA is responsible for the sanitary control of the production and marketing of products and services subject to sanitary surveillance, including related premises, processes, inputs and technologies, as well as:

- Controlling ports, airports and borders and co-ordinating the National System of Sanitary Surveillance.
- Establishing rules, proposing, monitoring and executing policies and activities concerning health surveillance.
- Authorising the operations of companies manufacturing, distributing and importing medicines.
- Approving the import and export of medicines, granting marketing approval for medicines and granting and cancelling GMP certificates.
- Closing down, as a sanitary surveillance measure, manufacturing plants and those premises involved in the management, importation, storage, distribution and sale of health-related products and services, if the relevant legislation is violated, or if they constitute a likely health risk.
- Examining patent applications related to pharmaceutical products and processes, jointly with INPI (prior consent).

Although it is possible to find some decisions applying punitive damages, this is a controversial issue in Brazil.

## REFORM

### 35. Are there proposals for reform and when are they likely to come into force?

Currently, there are several bills related to IP, food and drug matters being considered by Congress. The most important ones are the following:

- Bill No. 4,961/2005, which aims to amend the IP Law, so that substances or materials isolated from nature which meet the patentability requirements and are not mere discoveries are patentable. This Bill is currently awaiting the opinion of the Chamber of Deputies' Committee on Science and Technology, Communication and Computing. It is doubtful whether it will be adopted into law.
- Bill No. 3,995/2008, which proposes the exclusion from patentability of new therapeutic uses of known compounds and novel polymorphic forms. It is doubtful whether it will be adopted into law.

A rule issued by ANVISA concerns compounding pharmacies, which are very common in Brazil (*Resolution No. 67 of 8 October*).

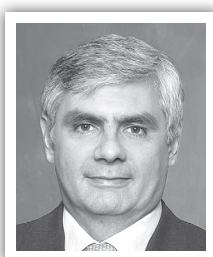


2007). This rule sets stringent requirements, and prohibits the compounding of medicines of the same presentation as those which already have marketing approval from ANVISA. The rule states that compounded medicines are an exception, and should only be marketed on a customised basis (that is, for each patient in need of a different dosage or pharmaceutical form of the industrialised drug).

However, in practice, many compounding pharmacies produce medicine with the same doses of manufactured products available on the market. In addition, it is common to find the drug association products with the same doses provided by the industry in presentations of individual drugs. ANVISA does not require proof of efficacy and safety of these products. Up to the present moment, there are no proposals to reform the regulation of this issue.

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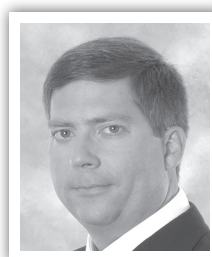
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**Areas of practice.** Life sciences; intellectual property; patent prosecution; counselling.

#### Recent transactions

- Actively participated in many projects focusing on patent strategy.
- Submitted successful arguments to the Patent and Trade mark Office to protect various scientific breakthroughs, such as mammal cloning technology and anti-retroviral drugs.
- Provided several technical and legal opinions for the life science industry, including patentability, non-infringement and freedom-to-operate analyses.
- Advised and defended leading pharmaceutical companies against the National Sanitary Surveillance Agency (ANVISA) in cases where consent to patent applications has been denied.



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- Ranked among the top most accredited attorneys for IP matters in Brazil according to several specialised publications.
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## Intellectual Property - Brazil

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