LEXOLOGY®
Getting The Deal Through

Life Sciences

in Brazil

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UPDATE AND TRENDS

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Brazil

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ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

How is healthcare in your jurisdiction organised?

Under the 1988 Federal Constitution, universal and equal access to health is a fundamental social right of every person and a duty of the state. Healthcare is organised around the Unified Health System (SUS). All entities of the federation (union, states, the federal district and municipalities) are bound to SUS, must cooperate and are joint and severally liable with respect to healthcare. Health actions and services have public character and the public power holds the right to regulate, supervise and control them.

Healthcare services, in all levels of complexity, are offered both by the state (directly, eg, in public hospitals or indirectly, through contracts with private parties) and by private institutions on their own. The participation in healthcare by the private enterprise is free and may take place alongside SUS, in a complementary manner or outside SUS, with supplementary character. Any time the private enterprise engages in healthcare in a complementary manner, philanthropic entities and non-profit organisations have priority.

The direction of SUS falls under the responsibility of the Ministry of Health at the national level, and at the state, federal district and municipal levels to the State Health Secretary, Federal District Health Secretary, and Municipal Health Secretary or equivalent. In each of the organisational levels of public administration, entities of their direct and indirect administration have authority to deliver, commission, license and regulate healthcare services.

The National Health Committee operates as the highest decision-making body of SUS. The National Supplementary Health Agency (ANS) regulates and monitors health plans and insurance operators. The National Sanitary Surveillance Agency coordinates the National Sanitary Surveillance System and has a very vast scope of authority, which includes, among others, regulation, issuance of licences, marketing authorisation and Good Manufacturing Practices Certificates, as well as authorisation for the import of medicinal products and medical devices.

Financing

How is the healthcare system financed in the outpatient and inpatient sectors?

Within SUS, both outpatient and inpatient services are offered free of charge, subsidised by the social security budget and reserves of all entities of the federation (union, state, federal district and municipalities).

Supplementary private care is financed either directly by end users or by private health insurance (roughly one-quarter of the Brazilian population rely on health insurance or plan). Health insurance carriers are subject ANS's regulations. ANS issues, from time to time, a list of proceedings, examinations and treatments with mandatory minimum coverage.

Brazil has, historically, a very hospital-centered healthcare culture. More recently, a wave of new business models emerged, targeting to bridge the gap between access to health services and the respective funding and payment. Such include emergency care and first-aid units and clinics, urgent care clinics, primary care units, pharmacy services, retail and low-cost clinics, and diagnosis treatments. Alternative forms of financing encompass discount cards and self-carried plans.

Basic structures

What are the basic structures of the provision of care to patients in statutory and private care?

Healthcare services, in all levels of complexity, are offered both by the state and by private institutions.

Healthcare actions and services carried out by SUS (directly, eg, in public hospitals or indirectly, through contracts with private parties) are regionalised and organised hierarchically, from less to more complex levels. Hospital and special ambulatory services, as well as others of higher complexity or technological density, shall be referred by the 'entry doors' to the Healthcare Attention Nets, which are primary care, urgent and emergency care, psychosocial care and specific healthcare for those who need special care as a result of labour hardship.

Private care is executed by independent licensed professionals and private entities. In carrying out supplementary healthcare initiatives, private parties must observe the ethical principles and rules issued by the direction of SUS.

HEALTHCARE SERVICES

Authorisation

What steps are necessary to authorise the provision of health services, and what law governs this?

The institutional provision of health services is highly regulated and licensing may result in a time-consuming endeavour.

In addition to general enrolments, healthcare providers must obtain sanitary licences, register with the National Healthcare Facility Enrolment, enrol with the applicable professional class councils and also indicate before such body the licensed healthcare professional who is technically responsible for the services. Certain businesses, such as dialysis, clinical laboratories, home care, intensive care and radiologic diagnostics must also observe specific sanitary requirements set forth in different resolutions issued by National Sanitary Surveillance Agency (ANVISA).

Considering the decentralisation directive of the Unified Health System (SUS), depending on the healthcare provider's location, a sanitary licence will be issued either by a municipal or state sanitary surveillance authority (usually, municipalities have more executory authority). Therefore, the specific legislation of the facility's location shall be scrutinised to certify the competent licensing body and exact licensing process and requirements.

The general legal framework relating to licensing health services includes:

- Law No. 8,080 of 1990;
- Law No. 9,782 of 1999;
- Ministry of Health Ordinance No. 1,565 of 1994; and
- Ministry of Health Ordinance No. 1646 of 2015.

Structure

Which types of legal entities can offer healthcare services?

The law does not restrict the offer of healthcare services to specific types of legal entities, as long as the legal entity is incorporated in Brazil and licensed for the specific activities according to the applicable rule. Only domestically incorporated legal entities may apply for licences and registrations required for the offer healthcare services in Brazil.

Services of foreign companies

What further steps are necessary for foreign companies to offer health services?

Only domestically incorporated legal entities may apply for licences and registrations required for the offer of healthcare services in Brazil. Foreign companies, thus, must either incorporate an operational Brazilian subsidiary and

go through the licensing process or acquire equity interest in a Brazilian company to be able to offer health services in Brazil. (Until quite recently, health services were activities restricted to purely domestic companies. Law No. 13,097 of 2015 modified article 23 of the Organic Health Law and it then became expressly authorised for Brazilian organised entities with foreign capital to instal, operate and exploit general hospitals, specialist hospitals, polyclinics, general clinics and specialised clinics.)

ADVERTISING

Legislation

Which legislation governs advertising of medicinal products to healthcare professionals?

The advertising and promotion of products subject to health regulation are governed by Law No. 6,360 of 1976, Law No. 8,078 of 1990 (Consumer Defence Code) and the Brazilian Advertising Self-Regulation Code issued by the Brazilian Advertisement Self-Regulating Council (CONAR). Advertising of medicinal products is further subject to Law No. 9,294 of 1996, National Sanitary Surveillance Agency's (ANVISA) RDC No. 96 of 2008 and RDC 60 of 2009, and Ordinance No. 344 of 1998 of the Ministry of Health. In addition, Interfarma's Code of Conduct contains rules concerning detailing (ie, a visit to healthcare professionals), events organised by pharmaceutical companies and promotional materials of medicinal products.

Main principles

What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

Healthcare professionals may receive free samples of medicinal products upon documented consent (only medicinal products registered with ANVISA may be distributed as free samples).

Only healthcare professionals may have access to advertisement of prescription only medicinal products and only healthcare professionals authorised to prescribe medication subject to special control may be advertised as such.

Visits of company representatives to healthcare professionals is permitted and its purpose shall be restricted to the promotion of products according to the usage approved by local regulatory authorities, limited to the drug information and characteristics registered at ANVISA. These visits must not interfere with patient care.

Advertising of medical devices

Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

The advertising of medical devices to healthcare professionals is not regulated as rigorously as advertising in the pharmaceuticals sector. Although the same general legal framework composed of Law No. 6,360 of 1976, the Consumer Defence Code, and the Brazilian Advertising Self-Regulation Code issued by CONAR apply to the advertising of medical devices, so far, no specific regulation targeting advertisement of medical devices has been issued.

The Code of Ethics published by the Brazilian Association of High Technology Medical Devices, which applies only to members of the association, contains directions concerning promotional activities by medical devices companies to health professionals.

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

Law No. 13,787 of 2018 created rules for the digitisation, use and electronic storage of medical records and shall be read together with Law No. 13,709 of 2018 (the Brazilian General Data Protection Law).

Early this year, the Brazilian Ministries of Health and Science, Technology, Innovation and Communication launched the Chamber of Health 4.0 programme, an environment for discussions between members of public and private institutions to develop the digital healthcare strategy for Brazil. This programme is part of the actions provided for in Brazil's Internet of Things (IoT) Scheme, launched by the government in 2019 aimed at connecting everyday devices to the internet. The idea is to implement and develop the internet of things in Brazil, based on free competition and data circulation, observing guidelines of information security, privacy and protection of personal data.

Bill No. 21 of 2020 was recently proposed to create a legal framework for the development and use of artificial intelligence (AI) in Brazil. The text, pending before the House of Representatives, sets forth principles, rights, duties and governance instruments for AI. If approved, the law will enhance legal certainty in testing, developing and use of AI in Brazil, which will help foster the digitalisation and provision of digital services in the health sector.

Provision of digital health services

Which law regulates the provision of digital health services, and to what extent can such services be provided?

Resolution No. 1,643 of 2002 issued by the Brazilian Federal Council of Medicine (CFM), regulates telemedicine services and requires that telemedicine services must have relevant and adequate technological infrastructure, and obey CFM technical standards relating to custody, handling, data transmission, confidentiality, privacy and guarantee of professional secrecy. CFM Resolution No. 1,643 of 2002 is quite laconic, and the interpretation adopted so far, in view of other provisions of the Medical Code of Ethics, has been predominantly conservative, in that telemedicine was deemed legal only as second medical opinion and provided that the patient was accompanied by a local doctor when enjoying telemedicine services, among other few exceptions. Broad telemedicine services became expressly authorised in the context of the covid-19 pandemic with the enactment of Law No. 13,989 of 2020. Therefore, while the state of public health national emergency declared by the Ministry of Health remains in place, telemedicine practices remain reassured. It is expected that the pandemic and experience with telemedicine in this period will also act as a catalyst for a broader use of telemedicine services after the covid-19 pandemic.

In 2018, the CFM issued Resolution No. 2,178 regulating the performance of mobile applications (APPs) for telemedicine and home care services. Among the requirements that APPs must comply with are the engagement of a medical technical director responsible for the APP, and registration of all professionals with the applicable Medicine Regional Council. Also, medical records must be kept in a readable and interchangeable format, allowing for the monitoring of treatments and portability rights of the patients in the event that the patient wishes to change for a new doctor.

National Sanitary Surveillance Agency (ANVISA)'s Resolutions No. 185 of 2001 and No. 40 of 2015 regulate the licensing requirements applicable for medical devices used for health and diagnostic devices. Among the types of medical devices that may be subject to marketing approval by ANVISA are software that, without considering the hardware, act as a health product. For example, image processing software for diagnostics, health diagnostic software

for glycaemic levels, radiotherapy planning software and even certain mobile applications may be deemed medical devices subject to ANVISA's surveillance. The definition of software acting as a medical device by ANVISA is vague, leaving regulatory gaps that make the framing of health software under ANVISA's authority unclear at times.

Authorities

Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

On 14 August 2018, a first specific legislation on data protection was enacted in Brazil, the General Data Protection Act, Federal Law No. 13,709 of 2018 (LGPD). The text follows the worldwide trend of strengthening personal data protection, guaranteeing a series of rights to data subjects, as well as imposing important obligations on processing agents, including the necessity to abide with the LGPD's principles and support any processing activity under a lawful basis.

Even though enacted in 2018, the date of entry into force of the LGPD remains undetermined. Currently, the official date for the LGPD to come into effect is 3 May 2021, with the effective date for the application of penalties arising from non-compliance with the LGPD on 1 August 2021. The current scenario is provisory and Congress may still determine the entry into force in August 2020.

The LGPD creates the Brazilian National Data Protection Authority (ANPD), which attributions are similar to those of the European Data Protection Board (EDPB). The ANPD is not yet operational, therefore, guidelines and case law on the subject are still to be developed. Also, there is no specific guidance, rules or authorities for data protection and privacy in the healthcare sector.

In spite of the uncertainties around the entry into force and actual operation of the ANPD, other bodies such as the Public Prosecutor's Office for the Federal District, the National Consumer Secretariat and the Brazilian Supreme Court have been recognising principles and obligations arising from the LGPD and enforcing them against processing agents.

While the LGPD entry in force is pending, the data protection legal framework in Brazil encompasses more than 40 legally binding norms that directly and indirectly deal with the protection of privacy and personal data in a sector-based system. This results in sometimes conflictive rules and does not provide an adequate level of legal certainty.

Requirements

What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

As a rule, any type of processing of personal data must be done in good faith and, in particular, respect the principles established in the LGPD. Generally, processing must be necessary, done for a legitimate, specific and non-discriminatory purpose, informed to the data subject in a clear, precise and easily accessible manner, and limited to the minimum necessary to achieve the established purpose.

Given the delicate nature of data concerning health, sexual life, genetic or biometric aspects of a natural person, these types of data are considered as sensitive personal data under the LGPD. Sensitive personal data should be processed with additional security layers, and can only be processed if framed under one of the following legal basis:

- data subject's or legal guardian's specific and explicit consent;
- when its essential for compliance with a statutory or regulatory obligation by the controller;

- when it is essential for the performance of public policies by the public administration;
- when it is essential for the conduction of studies by research bodies, guaranteeing, whenever possible, the anonymisation of personal data;
- when it is essential for the regular exercise of rights including in agreements and in lawsuits, administrative or arbitration proceedings;
- when it is essential for the protection of the life or of the physical safety of the data subject or of third parties;
- when it is essential for the protection of health, in a procedure carried out by health professionals or by sanitary entities; and
- when it is essential to ensure the prevention of fraud and the security of the data subject, in identification and authentication processes in electronic systems, provided that the fundamental rights and freedoms of the data subject that require personal data protection are not overridden.

The LGPD establishes that every controller must appoint a data protection officer (DPO). The law, however, does not specify the circumstances in which this appointment should occur, providing that the ANPD may further establish complementary rules about the definition and the duties of the DPO, including scenarios in which the appointment of such person may be waived, according to the nature and the size of the entity or the volume of data processing operations.

Currently, the LGPD enables the post holder to be a natural person, a committee or a legal entity, either based at the company or outside of it, at the processing agent's discretion. In view of his or her obligation to be a contact point for data subjects and for the ANPD, it is also a requirement that the DPO's contact information is always accessible to data subjects and to the ANPD and that the DPO is able to communicate in Portuguese.

Common infringements

What are the most common data protection and privacy infringements committed by healthcare providers?

Given that the Brazilian law on data protection and privacy is not yet in force, there are several undefined aspects of the LGPD that will require digital businesses processing personal data to interpret the law and take risks. The fine line between using personal data all the while ensuring personal data protection in innovative sectors such as AI, fintechs and health is the biggest challenge for organisations.

Considering that data protection and privacy standards are fairly new, processing agents are not familiar with their obligations under the LGPD and privacy policies are usually poorly drafted and insufficient in terms of information to the data subjects. We envisage that the lack of transparency in the type of data being processed and on the use of patient data for secondary purposes will be one of the top infringements committed by healthcare providers once the LGPD and the ANPD are in force and functioning.

Also, owing to the sensitive nature of the data processed by healthcare providers, authorities will most likely take a tighter grip on the sector to make sure patient data is safe and not processed in a discriminatory or unfair way.

COLLABORATION

Legislation

Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sectors?

The legislation governing collaboration of the pharmaceutical industry with healthcare professionals is the same for physicians in the outpatient and inpatient sectors. The most important pieces of regulation governing the collaboration of pharmaceutical industry with healthcare professionals are:

- National Sanitary Surveillance Agency (ANVISA)'s RDC 96 of 2008, which provides for rules regarding the promotion, publicity, information and other practices aimed at the advertising of medicinal products;
- ANVISA's RDC 60, of 26 November 2009, which provides rules regarding the production, provision and control of free samples;
- Interfarma Code of Conduct, which governs the conduct of pharmaceutical companies voluntarily associated to Research Pharmaceutical Industry Association ('Interfarma') and submitted to its self-regulation rules and procedures;
- the Medical Code of Ethics, issued by the Federal Council of Medicine;
- the Dentistry Code of Ethics, issued by the Federal Council of Dentistry;
- Codes of Ethics issued by class councils of other healthcare professionals categories; and
- Law 9,294, of 15 July 1996 (Law 9294) and its regulation by Decree 2018, of 1 October 1996 (Decree 2,018), which provide rules regarding the restrictions to the use and advertising of smoking products, alcoholic beverages, medicines, therapies and pesticides (including advertising that may only target health professionals).

Collaboration with healthcare professionals

What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

In general, promotional or advertisement activities involving medicinal products must not be deemed as an undue influence on the healthcare professional's autonomy to decide on the appropriate treatment for patients. Therefore, promotional activities directed at healthcare professionals shall not be conditioned to the prescription, sale or promotion of any type of medicinal product. Below are the most relevant rules and principles.

- Health professionals are forbidden to practice the medical profession with interaction or dependency of pharmacy, pharmaceutical, optical or other industry engaged in the manufacture, manipulation, promotion or commercialisation of medical prescription products. Health professionals must maintain their professional and scientific autonomy in relation to medical research sponsors.
- Health professionals are forbidden from obtaining any benefit originating from the prescription or commercialisation of medicines, the purchase of which derives from direct influence by virtue of their professional activity. Furthermore, pharmaceutical companies are not to grant, offer, promise or distribute gifts, benefits or advantages to prescribing or providing professionals, as well as to those who sell directly to consumers or to the general public.
- The offer of promotional aids of prescription drugs to health professionals is prohibited, as well as personal-use or office routine gifts.
- Health professionals may not participate in commercial advertising, whatever its nature, based on their profession.
- Any assistance or sponsorship for participation in scientific events shall not be conditioned to the prescription, provision or advertisement or promotion of any medication. There are also limitations regarding materials that may be distributed in events, covering of expenses, remuneration of attendants and lecturers, among other specific provisions.

Collaboration with patient organisations

What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

The Interfarma Code of Conduct sets forth the following main rules and principles concerning collaboration of the pharmaceutical industry with patient organisations.

- Pharmaceutical companies may interact with patient organisations, in a clear and transparent manner, to raise the population's awareness of health issues and provide relevant information regarding the prevention, treatment and diagnosis of diseases. The approval of projects created for this purpose shall not count on the participation of marketing and sales teams.

- Pharmaceutical companies may not influence the development of informative materials by patient organisations to obtain commercial advantage.
- Pharmaceutical companies shall not request, condition or demand exclusivity in turn for their support.
- All sponsorships, donations and other forms of support provided by pharmaceutical companies shall be properly recorded.
- Pharmaceutical companies are not to provide counselling in personal medical issues upon request from patient organisations; however, they may provide general information on their own products.
- Pharmaceuticals are permitted to hire patient organisations to provide services for education, motivational or informational purposes, provided that fair market value is observed.

Common infringements

What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

The following infringements are examples of matters reviewed and judged by the Interfarma Ethics Council:

- distribution of promotional aids in medical congress in breach of the Interfarma Code of Conduct;
- sponsoring of evening social gatherings for participants in events;
- uncontrolled distribution of printed materials regarding off-label products in medical congress;
- promotion of prescription medicines in medical congress with unrestricted access; and
- promotion of scientific event in a non-conforming manner and irregular advertising.

Collaboration on medical devices

Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

Collaboration of manufacturers of medical devices and healthcare professionals and patient organisations is not as heavily regulated as collaboration in the pharmaceuticals sectors.

In fact, according to the Brazilian Association of High Technology Medical Devices (ABIMED) Code of Conduct, which applies only to ABIMED members, manufacturers of medical devices are allowed to have a much more flexible

interaction with healthcare professionals, for both for promotional and nonpromotional purposes. However, rules limiting the payment or reimbursement of expenses for interactions with healthcare professional, prohibition of compensation for the time spent by healthcare professionals in promotional events, and taking undue advantages such as a commitment to refer certain products, also apply. Also, the codes of ethics issued by different healthcare professionals categories contain restrictions related thereto and set forth penalties, those, applicable to the healthcare professional.

COMPETITION LAW

Authority enforcement

Are infringements of competition law by healthcare providers pursued by national authorities?

All industry sectors are subject to Brazilian competition laws, including the healthcare industry. The main competition law in Brazil is Law No. 12,529 of 2011 (the Brazilian Competition Act) and CADE is the Brazilian competition agency with powers to enforce such law, including the investigation of anticompetitive conducts at the administrative sphere. The penalties imposed by CADE may include fines (0.1 per cent up to 20 per cent of gross revenues of the group), prohibition of participation in public bidding procedures, among others.

CADE has extensive case law and practice in the healthcare industry. Deals in the healthcare industry represent a large part of the transactions reviewed by CADE every year. CADE has published studies on the healthcare industry in recent years, including studies related to conducts (2015) and to mergers (2018) . CADE executed a cooperation agreement with the National Agency of Supplementary Health (ANS) in 2019 to facilitate technical cooperation in the monitoring of market concentration. As an example of CADE's enforcement, in March 2020, CADE opened an investigation into players in the healthcare industry for alleged abusive prices in the context of the covid-19 pandemic.

At the criminal level, the Public Prosecutors' Offices have powers to investigate individuals (not companies) for cartel behaviour. CADE and criminal authorities act independently, although they work together in some instances (eg, in negotiation of leniency agreements).

Private enforcement

Is follow-on private antitrust litigation against healthcare providers possible?

In addition to penalties that may be imposed by CADE at the administrative level, violators may be liable for civil damages caused by anticompetitive behaviour, notably cartel behaviour. This applies to healthcare providers who commit antitrust violations.

The Brazilian Competition Act sets out that injured parties may file lawsuits to obtain the cessation of violations and to request damages suffered from anticompetitive behaviour. In addition, because the right to free competition is considered as a collective right (Law No. 7,347/1985), Public Prosecutors' Office, private associations and others entities allowed by law may file collective civil lawsuits to protect the rights of third parties (eg, consumers). In 2018, CADE passed Resolution 21/2018 with rules aimed at facilitating access to materials of CADE's case records and thus incentivising private enforcement. Despite that, private antitrust litigation has not yet become very common in Brazil.

Anti-corruption and transparency

What are the main anti-corruption and transparency rules applicable to healthcare providers?

Brazil has undergone a severe change in terms of anticorruption enforcement since Lava Jato started in 2014, with

several high-profile corruption investigations and introduction of new legislation that made the Brazilian system more effective. A key factor to boosting the investigations was the introduction of new legislation related to anticorruption enforcement. The main anticorruption law applicable to companies in Brazil is Law No. 12,846 of 2013 (the Brazilian Anticorruption Act). The Brazilian Anticorruption Act entered into force on 29 January 2014 and was the first law in Brazil to introduce civil and administrative liability for corporations involved in acts of corruption. This law provides for strict liability of the legal entities in such cases. Other relevant laws used as a legal basis for enforcement action in the anticorruption arena include the Federal Bidding Law (Law No. 8666/93), the Improbity Act Law (Law No. 8429/92) and Law No. 13,964/2019 (the Anticrime Law).

Healthcare providers are subject to all laws mentioned above.

Criminal liability for acts of corruption is limited to individuals in Brazil (not companies). In such context, prosecutors may bring cases against individuals for acts of corruption (foreseen in the criminal code), money laundering and other criminal violations.

In addition to such laws, there are several other laws and regulations that may be applicable to corruption violations in specific situations or industries. In heavily regulated industries, such as healthcare industry, sector regulators have issued several regulations that address compliance and anticorruption elements. ANVISA issued Joint Resolution No. 2 of 2018 to regulate the exchange of information regarding bribery with the Ministry of Transparency. Similarly, ANS issued Resolution 443 of 2019 to provide corporate governance standards to all Brazilian health insurance plans.

PRICING AND REIMBURSEMENT

Price regulation

To what extent is the market price of a medicinal product or medical device governed by law or regulation?

The price of medicinal products is governed by Law 10,742 of 2003, as regulated by Decree 4,766 of 2003 and Decree 4,937 of 2003, and resolutions issued by the Drug Market Regulation Chamber (CMED). CMED is the competent body to adopt, implement and coordinate activities related to the economic regulation of the drug market. CMED establishes the criteria for the fixation and annual adjustment of prices of medication and determines the prices for sales by manufacturers, wholesalers, pharmacies and drugstores ('Factory Price' and 'Consumer Maximum Selling Price').

After obtaining a marketing authorisation for a medicinal product, manufacturers must request price approval by CMED prior to its commercialisation. The criteria for setting the initial price of new products or new presentations are set forth in Resolution CMED No. 2 of 2004, as amended.

Medical devices prices are not regulated. However, upon the application for marketing authorisation of certain medical devices (which are listed in a specific resolution issued by the National Sanitary Surveillance Agency (ANVISA)), petitioners must submit detailed information in the form of an Economic Information Report to ANVISA's Economic Advisory Centre on Regulation for purposes of transparency, health management and clarification of end users of medical devices.

Negotiations between manufacturers and providers

Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

Public healthcare providers are entitled to a mandatory minimum discount (CAP) calculated on top of the Factory Price (CMED Resolution No. 4 of 2006), resulting in the Maximum Price for Sale to the government. Currently, the CAP

discount is of 20.16 per cent.

Sales to the government, including to public healthcare providers, are, as a rule, subject to public procurement in Brazil, pursuant to Federal Law 8,666 of 1993. Private parties are invited to participate in public biddings in equal conditions and the public administration shall adjudicate the purchase to the best bid, following the specific procedure set forth in Law 8,666.

Law 8,666 provides for exceptions to the public bid rule in specific cases, such as when there are not enough competitors in the market or to deal with emergencies or public catastrophes (eg, immediate demand for certain health products deemed essential to deal with the covid-19 pandemic, in the terms of Law 13,979 of 2000), among others.

Reimbursement

In which circumstances will the national health insurance system reimburse the cost of medicines?

Pursuant to the Brazilian Federal Constitution, the government shall provide the population with universal access to healthcare, which includes the supply of medicine and treatment free of cost. Therefore, the Unified Health System (SUS) does not reimburse cost of medicines, but rather dispenses medicinal products directly to the population in public clinics, hospitals and other healthcare facilities. Ordinance GM/MS No. 3,047 of 2019 sets forth the list of medicinal products and supplies of the National Relation of Essential Medicinal Products (RENAME) for 2020, which are distributed within SUS. Drugs that are not dispensed by SUS directly to patients are frequently claimed before courts of law (this is referred to in Brazil as 'judicialisation of health').

Private healthcare and insurance plans operators play a supplementary role in healthcare. Healthcare and insurance plans are obliged to provide coverage (which may include reimbursement) for at least the procedures and medications set forth in the List of Procedures and Health Events issued by the National Agency of Supplementary Health (ANS). ANS's list shall be considered a minimum reference to be observed by health plan operators (additional coverage may be negotiated and paid for).

Price adjudication

If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

Not applicable.

Discount

Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

Manufacturers or distributors must observe the factory price and are not statutorily obliged to give discount to health insurance schemes. Statutory discounts are, however, applicable for sales to the government.

UPDATE AND TRENDS

Key developments of the past year

Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

Data Protection Law – entry into force

The General Data Protection Act, Federal Law No. 13,709 of 2018 entry into force will impact the processing of data concerning health, sexual life, genetic or biometric aspects of a natural person by health service providers in innovative medical services and devices such as artificial intelligence, wearables, internet of things applications, patient profiling, DNA testing and so forth, imposing higher levels of protection and more restrictive rules for processing patient data. In some cases, an explicit and informed consent by the data subject, with a clear definition on the purposes for which data will be used in each and every case, will be required, and a series of restrictions for international transfer of personal data will be imposed, directly impacting patient experience, commercial approaches to health data and the way cross-border clinical trials are carried out.

Additional guidance on the processing of sensitive personal data in a health context, especially relating to the collection and use of biometric data is expected from the National Data Protection Authority, once operational, from National Sanitary Surveillance Agency and from the National Health Council.

Telemedicine services and products

Telemedicine in Brazil is to stay and healthcare and IT providers have already been offering many telemedicine services and products, in spite of the Brazilian Federal Council of Medicine (CFM)'s conservative views on the subject, even before the covid-19 pandemic.

After a failed attempt to regulate telemedicine services with the publication of CFM Resolution No. 2.227/2019, which even did not come into force, the pandemic and emergency legislation have put an end to a legal embroglio around telemedicine, at least during the health crisis caused by covid-19. On 19 March 2020, the Federal Medical Council issued Resolution No. 1,756 recognising the legality of telemedicine beyond the restricted scope set forth in Resolution No. 1,643 of 2002 on an exceptional basis. After that, the Ministry of Health issued Ordinance 467 of 20 March 2020 regulating telemedicine on an interim basis, and on 15 April 2020 Law No. 13.989 was enacted, also authorising telemedicine on an exceptional basis during the covid-19 crisis.

In a country with continental magnitude such as Brazil, telemedicine will prove an extremely relevant tool to increase access to healthcare and education in remote areas. The coronavirus circumstances allowing for a broader use of telemedicine will serve to test the system and may be a catalyst for a relevant change in healthcare practice.

The advancement of technology and broader acceptance by patients represent fertile soil for telemedicine services and products to flourish and thrive. Players in the healthcare services business eagerly expect legal certainty with respect to telemedicine after the pandemic, with a much-awaited enactment of a general telemedicine law.