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Life Sciences

Brazil: Trends & Developments

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Trends and Developments

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Increased Demand for Alternative Business Models for Healthcare Service, Funding and Payment

Brazilian demographics are changing rapidly. According to the Brazilian Institute of Geography and Statistics, the elderly is the fastest-growing group. The institute also pointed out that life expectancy keeps increasing at a steady pace; indeed, life expectancy in Brazil has increased from 45.5 years in 1940 to 69.8 years in 2000 and finally jumped to 76.9 years in 2018. An ageing population brings about an increase in age-related diseases. As a result, this group boosts demand for doctor's appointments, therapies, exams and surgeries. This is challenging the current healthcare services model, its respective funding and payment structures; on the one hand, health services are still very hospital-centred; on the other hand, only a small percentage of the population has access to health insurance plans.

Looking at Brazil's hospital-centred culture, the country has roughly 6,700 hospitals, of which 70% are privately owned and 30% are public. Private hospitals offer, of course, supplementary care. Besides that, private hospitals may also participate in healthcare alongside the public health system in a complementary manner. In other words, private hospitals complement certain treatment needs whenever the public health system is insufficient to ensure adequate coverage in a certain area. Finally, it is also true that hospital costs tend to be higher than in simpler structures such as in emergency units, intensive care units, retail clinics and home care. These simpler structures have just very recently started operating and still do not have the same range as hospitals in the provision of health services.

The National Supplementary Health Agency (ANS) reported in January 2020 that the rate of the Brazilian population covered by private insurance plans (with and without dentistry coverage) was of 24.2%. This means that around one quarter of the Brazilian population uses private healthcare services, relying on private health insurance or plan, while the remaining three quarters relies solely on the public health system. In fact, many people have to queue up for months to obtain treatment.

There are three main reasons for insurance costs to increase (and the number of beneficiaries to be reduced). Firstly, the increased demand for services associated with the elderly; secondly, the incorporation of new technologies in the ANS's list of treatments subject to insurance plans' mandatory coverage; and thirdly, the increasing number of health-related lawsuits (*judicialização da saúde*) and court decisions imposing obligations on healthcare operators to cover items not previously included in the insurance policy.

A pressing issue for managing healthcare in Brazil is, therefore, the lack of structure to serve the entire population, the lack of sources of funding healthcare in general, and the lack of efficiency in hospitals, which are unable to cope with too many demands for all sorts of needs.

In this scenario, Brazil has recently seen a wave of new business models that aim to bridge the gap between access to health services and funding and payment for specific services. On the one hand, these relate to a greater number of emergency care and first-aid units and clinics, urgent care clinics, primary care units, drugstores services, retail and low-cost clinics, and diagnosis treatments. On the other hand, a number of new alternative forms of financing for these services, such as discount cards and self-carried plans, are beginning to develop.

This is a great market opportunity to tap into. Although there are regulatory challenges to overcome, it is expected that alternatives to hospitals will emerge in the near future and they will play a key role in the Brazilian health system, thus relieving overstretched hospitals and providing the population with better, cheaper and more accessible services.

Legality of "Discount Cards" by Outpatient and Low-cost Clinics

Back in 2017, the Federal Medical Council (in Portuguese, *Conselho Federal de Medicina*, CFM) issued regulation on outpatient and low-cost clinics. Not only did the regulation define certain requirements for these clinics to operate legally, such as mandatory registration with the respective class council, but the regulation also went beyond that and forbade these entities from offering the so-called "discount cards". The underlying idea is that this practice is unethical. In Brazil, it is illegal for doctors to advertise their services and fees openly, so the CFM thought "discount cards" were against the basic definitions of the medical profession.

The Consumer Defence and Protection Department claimed before the Brazilian antitrust authority (CADE) that the CFM and the Medical Council of the State of São Paulo had been threatening and applying disciplinary penalties to physicians

and clinics who accepted discount cards. Based on that, the CADE started investigations against these bodies, asserting that the ban in the CMF's regulation resulted in restricting the offer of alternative medical services to patients, to the detriment of the principles of free enterprise and competition.

As a result, on 5 April 2019, the CFM published a new rule, Resolution CFM No 2.226/2019, revoking Resolution CFM No 1.649/2002 Articles 4th and 5th, and Resolution CFM No 2.170/2017. The new rule also modifies Medical Ethics Code Article 72, with immediate effect. Therefore, as of 2019, the legality of the following practices were reaffirmed: firstly, physicians are authorised to participate, as owners, equity holders, managers or consultants in discount cards (but not in structures to finance healthcare services); secondly, physicians are authorised to associate with companies that advertise discounts on medical fees; and finally, outpatient clinics and medical companies in general are authorised to promote discount cards and similar products.

New Regime for Production and Importation of Low-risk Medical Devices

As of 2 May 2019, ANVISA's RDC rule No 270/2019 came into force. This rule established that class I medical devices which had been subject to a registration regime (*cadastramento*) became subject to a simpler regime called notification (*notificação*). In practical terms, starting in May 2019, class I medical devices no longer required ANVISA's technical analysis before companies can sell them. This change has drastically reduced the time manufacturers and distributors have to wait to sell these products legally.

Pressure to Offer Pharmaceutical Services

At present, just a small percentage of nearly 80,000 pharmacies in Brazil offer some kind of pharmaceutical service such as blood pressure measurement, glycaemic tests, ear-piercing, and vaccinations. Although offering several services to patients could help relieve the demand for health services, many regulatory obstacles hinder the increase of services pharmacies may offer; these include services such as remote lab tests, bio-impedance analyses, and other general check-ups.

In response to the pharmaceutical sector's demands, ANVISA launched a Pharmacies and Drugstores Direct Consultation for local health inspection bodies to respond to by 31 July 2019. It was basically a questionnaire that aimed to gather information about healthcare and pharmaceutical services currently carried out in drugstores. The questionnaire also focused on health-related activities requested to local health-inspection bodies.

On 1 August 2019, ANVISA also promoted a summit to obtain information, complaints and suggestions on the use of remote lab tests in health services. The objective was to guide the revision and potential amendment to ANVISA's RDC rule No 44 and ANVISA's RDC rule No 302 sets forth the technical regulations for the operation of clinical laboratories.

The market expects ANVISA to issue new regulations on pharmaceutical services to expand the offer of services soon.

Brazil in the Market of Cannabis-Derived Products

In December 2019, Brazil joined the group of countries which approved the prescription and use of medicinal cannabis. On 9 March 2020, ANVISA's RDC rule No 327/2019 came into force. This resolution regulates the manufacture, prescription, importation and sale of cannabis sativa-based products and sets forth the rules for monitoring and inspecting products containing this active ingredient for medicinal purposes.

The cultivation of cannabis remains forbidden (a separate resolution in that regard has been vetoed and archived). Thus, the active ingredient must be imported in bulk, phytopharmaceutical, or industrialised, in the form of vegetable derivates, exclusively for medicinal purposes.

Cannabis-derived products must be registered with the authorised entities under the applicable law. These products, however, will be subject to rules applicable to a new class of sanitary-inspected products that the resolution creates, which is "cannabis-based products" instead of "medicines". This new category is being created so that cannabis-based products and medicines are characterised differently, thus complying with different frameworks.

In addition to establishing the requirements companies must fulfil to manufacture or import cannabis-based products, the regulation contains further rules on labelling and quality control, distribution, and sale in pharmacies and drugstores.

Anvisa has also simplified the rules for patients to continue to import cannabis-derived products for personal use, to facilitate access while the new products are not readily available for sale.

Finally, the end of 2019 also brought novelty to the Brazilian capital markets. In October and November, two Brazilian-registered investment funds targeting corporate medical and recreational cannabis investments were launched. If the Brazilian sanitary authority continues to be progressive in its criteria and regulation, new business opportunities in this market will arise.

Telemedicine

On 6 February 2019, the Federal Medical Council (in Portuguese, *Conselho Federal de Medicina*, CFM) published Resolution No 2.227/2019, which regulates long-distance medical

appointments and procedures using technology. This resolution, however, which would have drastically changed the CFM's previous views on the matter, did not even come into force. Although that would have occurred 90 days after its publication, it was revoked less than one month after its publication.

On the day of its publication, the fuss around the resolution expanding the legality of telemedicine services in Brazil was substantial. The regional councils mostly criticised four aspects: firstly, the lack of opportunities to participate in the debate on the text of the rule; secondly, the distance it could potentially create between physicians and patients; thirdly, the resolution's lack of clarity; and finally, the short time to implement the measures necessary for compliance.

The CFM replied that the revocation of the Resolution resulted from the opposition by physicians and class representatives. Still in February 2019, the CFM opened a public consultation and indicated in a note issued on 9 July 2019 that it would accept suggestions to edit the text until 31 July 2019. Amazingly, it received 1,500 physicians' contributions between February and July so this deadline was extended to 29 February 2020. All this input will be reviewed by a work group which will eventually issue a report that will serve as a basis for a new rule.

More than one year after the telemedicine regulation imbroglio, no new deadline for approving the new standards for the legal practice of telemedicine has been indicated.

In any case, telemedicine in Brazil is here to stay and healthcare operators, hospitals and similar services currently offer many telemedicine services, in spite of the CFM's conservative views on the subject.

Adding technology to offer enhanced patient care while relieving overcrowded and overstretched hospitals and clinics seems to be a requirement for the country's current health care infrastructure. Without doubt, telemedicine's potential for offering specialised medical treatment to patients who live in distant locations is vast. Telemedicine also aims to solve the problem of great demand for health services in Brazil — which is bolstered by the migration of patients in search of treatment. In addition to direct benefits to patients who will make use of long-distance medical services, the new regulation will also open up a new market for IT and telecommunications services and solutions' providers.

As per the Medical Code of Ethics, telemedicine is allowed in urgent and emergency situations. The coronavirus circumstances allow for a broader use of telemedicine and will serve to test the system.

The new Brazilian Data Privacy Law and Life Sciences

In a scenario of constant modernisation of the health sector in Brazil, it is also important to rethink how to reconcile technological innovation with the rights of patients concerning privacy, such as the confidentiality of their information and the protection of their data.

Brazil recently enacted a national privacy law (*Lei Geral de Proteção de Dados*, LGPD) which follows a European trend for more restricted data protection regulation. As far as health and medical data is concerned, the LGPD lists these types of information as "sensitive data", along with information about race, ethnicity, religious or political beliefs or sexual life, which demands a higher level of protection and more restrictive rules for processing, not only due to privacy concerns, but also in order to avoid targeting or discrimination. Sensitive data in the health sector may include data processed by AI, wearables, and certain IoT applications, patient profiling, biometric data, genetic data (including for medical diagnosis), DNA testing and medical research, social care records, among others. Except in some defined scenarios in which the law authorises the processing of sensitive data without consent, companies must obtain specific consent from data owners, and properly delimitate the purposes for which data will be used in each and every case. The law also prohibits health and medical data, particularly, from being commercialised, except for the purposes of portability and with the owner's explicit consent.

There are a number of aspects of the LGPD which are particularly challenging for life sciences businesses, as sensitive personal data accounts for the majority of personal data processed in a life sciences context, and this type of personal data attracts additional protections.

Territorial Scope

The LGPD applies not only to Brazilian organisations but also to foreign entities or individuals offering goods or services to data subjects in Brazil or monitoring their behaviour to the extent that processing takes place in Brazil. Enforcing the LGPD against a business without a presence in Brazil will be a challenge for the authorities and specifically for the Data Protection Authority, not yet constituted.

What Constitutes Personal Data

Personal data is defined as any information relating to an identified or identifiable natural person. This can include pseudonymised data. Pseudonymised data is data which can only be attributed to an individual when combined with additional information that is kept separately (subject to technical and organisational measures which protect the individual from being re-identified, a unique ID for a trial participant would be an example). This is an important aspect to be considered

for life sciences businesses. It is only by completely anonymising personal data, in such a way that it cannot be re-identified from other available information, that data falls out of the scope of the LGPD.

Data Protection Principles
The data protection principles are at the core of the LGPD. Personal data must be processed fairly and lawfully, and individuals must be provided with information as to what is happening to their data throughout its processing journey, including information relating to any transfer to other controllers or processors.

Data has to be collected for specified, explicit and legitimate purposes and cannot be processed for additional purposes not compatible with the original purpose. Data has to be limited to what is necessary for the purposes for which it is processed and must be kept accurate and up to date. Data can only be kept as long as necessary and must also be kept appropriately secure against any unlawful processing, accidental loss, destruction or damage.

Most importantly, it is not enough to comply; entities and individuals must be able to demonstrate compliance due to the accountability principle set forth in the LGPD. In particular, a record of processing activities must be kept by the data controller or an appointed representative, as the case may be.

Basis for Processing
In order to comply with the principle that personal data shall be processed fairly and lawfully, the processing operations must be carried out under one of the lawful bases for processing set forth in Articles 7 or 11 of the LGPD. The data controller will have to opt for the most appropriate one.

The LGPD sets forth a number of lawful bases which may apply to data processing connected with life sciences organisations, but they are not altogether straightforward and data controllers will have to consider carefully which one to use. There is no guidance yet in Brazil, but the European Data Protection Board has already published an opinion that includes a discussion of appropriate lawful bases for the processing of personal data in clinical trials.

Consent
Life sciences organisations carrying out clinical trials or pharmacovigilance, for example, often process large amounts of sensitive data. Data can be processed lawfully on the basis that data subjects have given their consent to the processing operation. Consent must be "freely given, prior, specific, informed and an unambiguous indication of the data subjects' desires". Data subjects must be able to withdraw consent at any time. In the context of life sciences, consent may be difficult to obtain and may not be the most useful legal basis on which to rely. If, for example, a data subject withdraws consent to the processing of his or her data as part of a clinical trial, that could have a major impact on the study. Thus, healthcare providers should identify another lawful basis (such as the protection of life, health tutelage, etc).

Data Transfers
Clinical trials often involve the transfers of large amounts of personal data across borders, including to other countries, in situations where a number of laboratories or healthcare providers or even the clinical trial sponsor may be in different jurisdictions. Although the LGPD sets forth a number of situations in which data can be transferred, there is a general lack of guidance in international transfers, as there is no Data Protection Authority yet in place. In addition to the LGPD, it may also be necessary to consider local legal or regulatory obligations relevant to the processing of health data in the context of cross-border clinical trials.

These are some of the issues life sciences businesses may need to consider when working to be compliant under the LGPD. Additional guidance would be expected from the Data Protection Authority, once it is in place, from ANVISA and from the National Health Council (CNS) as regards the processing of personal data in the life sciences sector, especially in relation to the treatment of sensitive personal data.

Federal Statute Demands that Public Entities Execute "Regulatory Impact Analyses" and Forbids the "Abuse of Regulatory Power"
Initially enacted as a Provisional Measure by President Jair Bolsonaro, and later converted into a statute by the National Congress, Federal Law No 13,874/2019 (the Act of Economic Freedom) contains a series of provisions aiming at reducing red tape and eliminating constraints that hamper the development of economic activity.

In addition to a "Bill of Economic Rights" (Article 3º), Federal Law No 13,874/2019 sets forth that "the Public Administration, when enacting administrative regulations, shall avoid the abuse of regulatory power" – in order to create artificial market barriers in order to benefit, through regulation, a specific professional or economic group to the detriment of their competitors; draft normative statements that prevent entry from new national or foreign competitors; demand technical specifications that are unnecessary in order to achieve a permissible goal; draft normative statements that prevent or delay innovation and the adoption of new technologies, procedures or business models, except in scenarios entailing high risks; artificially create demand for a product, service or professional activity; introduce limits to the free incorporation of business entities or execution of eco-

nomic activities; and restrain the use and exercise of advertising activities connected to an economic sector, except as otherwise provided in federal statutes.

Further, Federal Law No 13,874/2019 provides that proposals for new administrative regulations, or amendments to existing regulations, "shall be preceded by a regulatory impact analysis, which will contain information and data on the possible effects of the intended rule, so as to allow the assessment of the reasonableness of its economic impact" (Article 5º). The Federal Government has yet to issue a decree establishing how such analyses are to be executed, as well as the hypotheses in which they can be waived. In any event, a similar requirement has already been imposed on the Federal Sanitary Surveillance Agency (ANVISA) and the Federal Health Agency (ANS) by Federal Law No 13,848/2019 – which established a new general framework for federal Agencies.

Taken together, the duty to promote "regulatory impact analyses" and the prohibition to "regulatory abuse" are expected to increase the quality of federal regulation, as well as allow private parties who are harmed by arbitrary or flawed administrative rules to obtain prompt relief before the judiciary.

Federal Ministry of Health Introduces "Risk-Sharing Agreements" so as to allow the Introduction of new Drugs and Technologies in the National Healthcare System

In June 2019, the Ministry of Health allowed the employment of *"risk-sharing agreements"* by the Federal Government. Administrative Order No 1,297/2019 defined *a* "risk-sharing agreement" as a contract between the Ministry of Health and a pharmaceutical company "due to uncertainties as to [I.] whether the introduction of a drug within the National Healthcare System would be cost/effective"; and as to [II.] "the expected demand, considering the amount of pills/doses and its budgetary impact". As such, it should necessarily contemplate:

- a reduction in the price of that drug;
- the description of the disease to be treated, as well as the eligibility criteria for patients who may benefit from the risk-sharing agreement;
- the expected health outcomes, as well as the clinical parameters that will be employed to assess whether the drug was effective or not;
- the maximum number of patients that, funded by the Ministry Health, will receive the new drug – with a clause indicating that, in the event that such number is exceeded, the pharmaceutical company will bear the cost of rendering the drug to additional patients;
- technical criteria for the discontinuation of treatment, for those patients that do not present the expected health outcomes within the expected timeframe;
- how often periodic assessments are to be executed, according to the best scientific evidence available.

As per Administrative Order No 1,297/2019, the introduction of risk-sharing agreements aims as "allowing the incorporation of [a new drug] to the National Healthcare System", at a lower price, while also "gathering additional evidence on the cost entailed by the drug" and "allowing a new assessment of its incorporation under the light of such additional evidence."

So far, the Ministry of Health has only authorised the execution of one pilot experiment involving the purchase of the drug *Spinraza* by federal authorities; the results of that pilot experiment will be employed in the drafting of a general rule on "risk-sharing agreements" for the incorporation of new health technologies to the National Healthcare System.

Veirano Advogados assists clients with all the strategic, regulatory and litigation aspects of the healthcare and life sciences business. Its life sciences and healthcare team is made up of 20 lawyers with extensive industry knowledge, located in the four offices of Veirano in São Paulo, Rio de Janeiro, Porto Alegre and Brasília. The firm's main clients include manufacturers and distributors of medicines, medical devices and cosmetics, hospitals and clinics. The life sciences and healthcare team offers expertise in corporate, licensing/distribution, regulatory, compliance and IP matters, and works regularly with other departments in the firm, such as capital markets and tax. Areas of focus include mergers and acquisitions, strategic alliances, validation of strategic projects for healthcare providers, healthcare product liability litigation, compliance, IP registration and litigation and administrative litigation before regulatory authorities.

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