International
Comparative
Legal Guides

Drug & Medical Device Litigation 2021

A practical cross-border insight into drug & medical device litigation

Second Edition

Featuring contributions from:

Addleshaw Goddard LLP
AllBright Law Offices
Allen & Gledhill LLP
Beccar Varela
Bird & Bird LLP
Bull & Co Advokatfirma AS
Clayton Utz
Faus & Moliner Abogados
Harris Kyriakides LLC
Kellerhals Carrard
LexOrbis
Setterwalls Advokatbyrå
Sidley Austin LLP
Sorainen
Studio Legale Russo Valentini
Tompkins Wake
Veirano Advogados
Winston & Strawn LLP

ICLG.com

Expert Analysis Chapter

Q&A Chapters

Brazil


Rosangela Delgado Barreto


Renata Fialho de Oliveira


Amanda Celli Cascaes

Veirano Advogados

1 Regulatory Framework

1.1 Please list and describe the principal legislative and regulatory bodies that apply to and/or regulate pharmaceuticals, medical devices, supplements, over-the-counter products, and cosmetics.

The Unified Health System ("SUS") is ultimately under the Ministry of Health at a national level; its management, however, is decentralised to other entities of the federation (state, federal district and municipalities) according to Law No. 8,080/1990 (the Organic Health Law).

The National Health Regulatory Agency ("ANVISA"), created by Law No. 9,782/99, is a federal agency with broad authority to coordinate the National Health Regulatory System, including, among others, powers to issue general health regulations. ANVISA is the main regulatory body concerning products subject to health regulation such as pharmaceuticals, medical devices, supplements, over-the-counter products and cosmetics.

In view of the SUS's decentralisation, in the union, state, federal district and municipal spheres, entities of direct and indirect administration have authority to commission, license, regulate and inspect the production and circulation of goods subject to health regulation.

Medicines require marketing approval by ANVISA before being promoted or offered to the public for sale. Medical devices are subject either to notification or registration with ANVISA, according to their risk classification. Certification by the National Institute of Metrology, Quality and Technology may also be required for some products.

1.2 How do regulations/legislation impact liability for injuries suffered as a result of product use, or other liability arising out of the marketing and sale of the product? Does approval of a product by the regulators provide any protection from liability?

Product approval by regulators, when applicable, is a condition for the promotion and offer for sale of products subject to health regulation. Sanitary approval aims at ensuring that the product is safe for use, is of high quality and is effective for the recommended purpose. The sale of medicinal products without marketing authorisation or with incorrect information is a crime against public health pursuant to the Brazilian Penal Code. Also, it is a sanitary violation that may subject the violator to administrative penalties including warning, seizure, destruction and/or cancellation of registration and monetary penalties, in addition to civil liability.

In the context of the COVID-19 pandemic, Law No. 13,979/20, as amended from time to time, authorised – exceptionally and temporarily – the import of medicines, medical devices and inputs deemed essential for combatting COVID-19 without registration with ANVISA, provided that they are registered either with the United States Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA"), the Japanese Pharmaceuticals and Medical Devices Agency, or the Chinese National Medical Products Administration.

The general rule governing consumer relations in Brazil is the Consumer Defence Code ("CDC"), which foresees strict liability for damages. The exceptions are consumer or third-party exclusive fault, lack of product defect, lack of damage, or lack of causation between the product and the damage.

Specific regulations/legislation for drugs and medical devices are subsidiary to the CDC and suppliers must comply with all of these. Compliance with specific regulations/legislation or approval by the regulators does not exempt suppliers' liability in case of damage. It can be an element for the company to prove that its conduct was lawful, but it alone will not prevent liability.

1.3 What other general impact does the regulation of life sciences products have on litigation involving such products?

As it is an extremely regulated market, if there is a breach of regulatory rules, in addition to civil liability, regulatory penalties can be applied by regulatory bodies, class councils, and self-regulating bodies, and in some cases criminal liability as well.

1.4 Are there any self-regulatory bodies that govern drugs, medical devices, supplements, OTC products, or cosmetics in the jurisdiction? How do their codes of conduct or other guidelines affect litigation and liability?

The *Associação da Indústria Farmacêutica de Pesquisa* ("Interfarma") is an association for the pharmaceutical industry with which several of the most reputable pharmaceutical companies doing business in Brazil are associated. In 2007, Interfarma launched a Code of Conduct, which was reviewed and updated in 2016, providing for several penalties that may be applied by its Ethics Council. Since its creation, Interfarma's Ethics Council has reviewed several processes and applied penalties that vary from warnings to fines.

In litigation with patients/consumers, non-compliance with such Code of Conduct can be argued by plaintiffs, but is not common and will not, in itself, support a conviction, as it is not a source of law.

1.5 Are life sciences companies required to provide warnings of the risks of their products directly to the consumer, or to the prescribing physician (i.e., learned intermediary), and how do such requirements affect litigation concerning the product?

The packaging, label and medicine leaflets of approved products must contain all information relevant to the product, aiming at its appropriate use, and all mandatory information under ANVISA's regulation. The manufacturer is required to provide all information needed for the product's appropriate use, which includes a warning of the risks, directly to the consumer. The marketing and promotion of products subject to health regulation, especially medicines, are strictly regulated, and prescription-only medicine may not be advertised to the general public.

Under the CDC, the duty to inform (especially on risks) is one of the supplier's main obligations. This information must be written in Portuguese, in a clear and unequivocal manner. Failure to warn correctly (as to possible adverse effects, restrictions for use, etc.) will subject the supplier to (i) individual or collective claims for moral or pecuniary damages, and/or (ii) judicial or administrative proceedings by consumer protection authorities to impose sanctions and compliance, possibly including a product's withdrawal from the market.

2 Manufacturing

2.1 What are the local licensing requirements for life sciences manufacturers?

In addition to the general licensing required for companies to operate from a corporate, real estate and environmental perspective, life sciences manufacturers must further obtain health sanitary licences: a federal authorisation ("AFE") from ANVISA; a special authorisation for controlled drugs ("AE"), also from ANVISA, where applicable; and a local licence issued by the state or municipal public health authorities where the manufacturing facility is located. ANVISA is also the authority responsible for issuing good manufacturing practice ("GMP") certificates.

AFE requirements include, besides comprehensive data on the applicant, technical information, including fairness of manufacturing facilities, satisfactoriness of their quality system and capable personnel, among other requisites. Whenever the AE is needed, a list of all controlled pharmaceutical substances that will be produced is required, together with a copy of the guidelines on GMP.

2.2 What agreements do local regulators have with foreign regulators (e.g., with the U.S. Food and Drug Administration or the European Medicines Agency) that relate to the inspection and approval of manufacturing facilities?

There are currently no agreements between ANVISA and the FDA or EMA in place concerning the inspection and approval of manufacturing facilities. ANVISA, however, has acceded to becoming the 54th Participating Authority of the Pharmaceutical Inspection Co-operation Scheme ("PIC/S") as of January 1, 2021. ANVISA submitted a complete membership application in October 2014 and on November 27, 2020, the PIC/S Committee unanimously agreed by written procedure on the participation of ANVISA in PIC/S.

2.3 What is the impact of manufacturing requirements or violations thereof on liability and litigation?

The violation of manufacturing requirements is a sanitary violation that subjects the violator, in addition to the applicable civil and criminal responsibilities, to administrative penalties including warning, seizure, destruction, cancellation of registration, as well as monetary penalties.

From a consumer standpoint, non-compliance with manufacturing requirements affects litigation if the product has a defect (including an information defect) or causes damages to consumers or bystanders. If such non-compliance may represent a risk to consumers' health or safety, the company must inform authorities about such potential risk (see section 7 below) and, if the risk is confirmed, a recall will be imposed by the competent authority.

3 Transactions

3.1 Please identify and describe any approvals required from local regulators for life sciences mergers/acquisitions.

The acquisition of equity interest in life sciences companies does not require pre-merger governmental approval (other than antitrust clearance, when applicable); thus, change of control of the legal entity *per se* does not result in termination or revocation of licences attached to the facilities and product marketing authorisations.

In case of corporate reorganisations, AFEs and AEs may have to be updated or cancelled and new ones may be required, according to the type of transaction carried out (spin-off or merger). With respect to GMP, provided that the technical characteristics inspected at the time of issuance have not changed, GMP certificates will be updated to reflect the situation of the new owner.

The acquisition of individual assets (product or product portfolio) is characterised by the transfer of ownership/title of the applicable marketing authorisations and must be approved by ANVISA pursuant to the Resolution of the Board of Directors ("RDC") No. 102/2016.

3.2 What, if any, restrictions does the jurisdiction place on foreign ownership of life sciences companies or manufacturing facilities? How do such restrictions affect liability for injuries caused by use of a life sciences product?

Only companies organised pursuant to Brazilian law and domiciled in Brazil may apply for licences to operate and

commercialise medicines and medical devices in Brazil. There are no restrictions on foreign ownership of life sciences companies.

As for the liability for injuries caused by use of a life sciences product, the same rules apply. Nothing changes due to foreign ownership.

4 Advertising, Promotion and Sales

4.1 Please identify and describe the principal legislation and regulations, and any regulatory bodies, that govern the advertising, promotion and sale of drugs and medical devices, and other life sciences products.

The advertising and promotion of products subject to health regulation are regulated by Law No. 6,360 of 1976, the CDC, and the Brazilian Advertising Self-Regulation Code. Advertising of medicines is further subject to Law No. 9,294 of 1996 and ANVISA's RDC No. 96 of 2008. Interfarma's Code of Conduct and the Code of Ethics of the *Associação Brasileira da Indústria de Alta Tecnologia de Produtos para Saúde* also regulate interaction with health professionals regarding advertising and promotion of drugs and medical devices, respectively.

Among the several measures adopted by authorities with respect to the COVID-19 pandemic, the Brazilian Advertising Self-Regulation Council, CONAR, issued a Technical Note on July 1, 2020 with recommendations targeted especially at campaigns of sanitisers, hygiene and well-being to avoid false or misleading claims.

4.2 What restrictions are there on the promotion of drugs and medical devices for indications or uses that have not been approved by the governing regulatory authority ("off-label promotion")?

Off-label promotion is not authorised, since advertisement claims must be in accordance with data submitted to ANVISA.

4.3 What is the impact of the regulation of the advertising, promotion and sale of drugs and medical devices on litigation concerning life sciences products?

As regards the regulation of advertising, the promotion and sale of drugs and medical devices is usually stricter than for other products; suppliers are potentially more exposed to litigation based on failure to comply with the duty to inform, and on the applicable advertising/sale restrictions, if they are not duly observed.

5 Data Privacy

5.1 How do life sciences companies that distribute their products globally comply with GDPR standards?

The EU General Data Protection Regulation ("GDPR") is applicable to European establishments, regardless of the place of processing, and can therefore apply to the treatment of data and monitoring of behaviour of individuals situated in Brazil. Companies must adapt their practices for all data processing that falls under the GDPR (such as collecting, storing, using, disclosing, and destroying). In addition, the Brazilian General Personal Data Protection Law (Law No. 13,709/2018, or "LGPD") was recently enacted and came into force in September 2020 (with retroactive effects to August), which was inspired by and has generally the same principles as the GDPR. Although the sanctions provided for in the LGPD may only apply as of August 2021, companies must already adapt to complying with the provisions of the new law, which also means meeting the standards of the GDPR.

5.2 What rules govern the confidentiality of documents produced in litigation? What, if any, restrictions are there on a company's ability to maintain the confidentiality of documents and information produced in litigation?

Parties can request that a document or the entire case records remain confidential, with access limited to the parties and the judge. If the document/information is very sensitive, the company may ask to provide it only to the court-appointed expert, if applicable. Also, with the enactment of the LGPD, there may be an additional form of judicial secrecy for proceedings involving sensitive data, based on the LGPD's principles and systematic interpretation of its articles: even if there is no total or partial secrecy declared by the judge, the parties can request that their sensitive personal data not be disclosed to third parties.

5.3 What are the key regulatory considerations and developments in Digital Health and their impact, if any, on litigation?

Except for certain rules concerning minimum security requirements for electronic medical records, online scheduling of medical appointments and telemedicine, Brazil does not have detailed legislation on Digital Health. Telemedicine used to be allowed in very restricted circumstances. The COVID-19 pandemic has changed the scenario drastically in that telemedicine has become broadly permitted and practised. COVID-19-related regulation of telemedicine is emphatic in indicating that telemedicine is only temporarily allowed, i.e., while the state of emergency related to the pandemic persists and that, thereafter, the Federal Medical Council shall be responsible for formulating and issuing a definitive regulation.

The CDC already contained data protection rules before the enactment of the LGPD. According to case law, health data is deemed highly sensitive and consumers (patients or deceased) extremely vulnerable. The key elements for the avoidance of litigation on Digital Health are compliance with the duty to inform and to obtain the consumer's informed consent for data collection. In the LGPD, the hypotheses for processing sensitive data are restricted and, therefore, the most common avenue is to obtain consent from the patient.

6 Clinical Trials and Compassionate Use Programmes

6.1 Please identify and describe the regulatory standards, guidelines, or rules that govern how clinical testing is conducted in the jurisdiction, and their impact on litigation involving injuries associated with the use of the product.

Clinical testing is subject to ethical and sanitary regulations. Resolution No. 466/2012 issued by the National Health Council regulates the CEP-CONEP System (dual-instance ethics review). ANVISA's RDC No. 09/2015 regulates clinical trials of drugs

in alignment with those of the main international regulatory agencies, including submission of technical documentation and best clinical practices, and provides a term for ANVISA to evaluate dossiers for the clinical development of projects relating to medicines for clinical trials in Brazil. ANVISA RDC No. 10/2015 regulates clinical trials of medical devices. A bill of law concerning clinical trials is under discussion.

Brazilian regulation guarantees full medical assistance to subjects of trials during and after trial, and post-trial access to the best treatments, free of charge and with no time limit, as well as providing for joint and several liability of the researcher, sponsor, institutions and organisations.

The supplier must observe the duty to inform and collect patients' consent for product use, especially at trial stage. Consumers shall expressly consent to use a product that has not yet passed all tests or been approved by regulators. However, even with patients' consent, the supplier cannot: (i) violate the constitutional principle of human dignity; (ii) engage in conduct deemed abusive by the CDC, such as taking advantage of a patient's weakness or ignorance, in view of his/her age, health, knowledge or social condition, to force them to use products or services; or (iii) ask the patient to waive his/her right to compensation for damages.

6.2 Does the jurisdiction recognise liability for failure to test in certain patient populations (e.g., can a company be found negligent for failure to test in a particular patient population)?

Although ANVISA's guidelines for the preparation of reports on clinical trials for registration and post-registration purposes require an indication and description of the population of trial subjects, the regulation does not explicitly regulate responsibility for failure to test in a particular patient population.

6.3 Does the jurisdiction permit the compassionate use of unapproved drugs or medical devices, and what requirements or regulations govern compassionate use programmes?

Individuals may request ANVISA's authorisation to import pharmaceutical products for which marketing authorisations have not been granted for personal use.

New medicines, exclusively for experimental use, under medical control, are exempt from registration, and may be imported upon the authorisation of the Ministry of Health (Law No. 6,360/1976).

Under compassionate use programmes, patients may have access to medicines that are still in the clinical development phase.

6.4 Are waivers of liability typically utilised with physicians and/or patients and enforced?

Waivers given by clinical trial patients are subject to consumer protection limitations (see question 6.1 above) and to regulatory restrictions; for instance, a patient may never be required to waive the right to be compensated for damages, the consent form should not contain any disclaimer that would displace liability or imply that the patient waives his/her legal rights, etc.

With respect to physicians, there is room for discussion, as they are not end users of the product (which is the typical consumer definition). However, the same consumer limitations can apply if it is understood – on a case-by-case basis – that they are vulnerable in comparison with the manufacturer (e.g., technical vulnerability regarding the product).

For litigation purposes, suppliers' liability before patients is strict (regardless of fault), but physicians' liability is fault-based. Therefore, it is expected that patients will seek the manufacturer's liability, as there would be no discussion or production of evidence regarding fault.

6.5 Is there any regulatory or other guidance companies can follow to insulate or protect themselves from liability when proceeding with such programmes?

Trial subjects must sign an informed consent to join the trial. Insurance coverage, although not mandatory, is available in the market for purchase.

7 Product Recalls

7.1 Please identify and describe the regulatory framework for product recalls, the standards for recall, and the involvement of any regulatory body.

Recalls of products in general are governed by the CDC and Ordinance 618/2019 (enacted in July 2019).

Under the CDC, products are defective if they pose risks to consumer safety or health beyond those legitimately expected considering the inherent characteristics of the product. If the supplier (manufacturer or other supplier of the consumption chain) of a product already placed into the market subsequently learns of an unexpected risk to consumers' health or safety, it must immediately report it to SENACON (the consumer authority that handles recall proceedings) and to consumers.

Ordinance 618/2019 created a new obligation for suppliers in case of a potential recall: informing SENACON, within 24 hours of awareness, of the beginning of internal company investigations. The recall will be initiated (i) upon conclusion of the internal investigations (at the supplier's own initiative or SENACON's determination), or (ii) when the supplier is *certain* about the existence of the risk. Such communication must be made within two business days in both cases.

The standard for notifying SENACON is the existence of a potential risk or a confirmed risk to the safety or health of consumers identified after the introduction of the product into the market, regardless of whether it is a reasonable risk.

As to drugs and medical devices, their recall is also subject to specific regulatory rules. Pharmacovigilance and recalls are ruled by ANVISA's Resolution No. 4/2009, Normative Ruling No. 14/2009, and Resolution No. 55/2005. In situations of risk to consumers, the holder of marketing authorisations must notify ANVISA and provide ANVISA with details concerning the recall actions carried out.

7.2 What, if any, differences are there between drugs and medical devices or other life sciences products in the regulatory scheme for product recalls?

Although it follows specific procedures, provided for in different regulations, in broad terms, the regulatory scheme for drug and medical device product recalls is similar, in that (i) manufacturers have the duty to produce communications warning the population about possible risks associated with product use, and (ii) ANVISA has discretionary authority to require a product recall in situations where it identifies risks to the population.

RDC No. 55/2005 sets forth the rules concerning recalls of drugs, and RDC No. 23/2012 relates to recalls involving medical devices. Though there are no specific rules concerning recalls of cosmetics, based on Law No. 6,360/1976, ANVISA may also require the recall of cosmetics whenever there are risks associated with them.

7.3 How do product recalls affect litigation and government action concerning the product?

Non-performance of a recall, or failure to perform a recall according to the law, may subject the supplier to administrative sanctions, such as seizure or destruction of the product, registration cancellation, prohibition on production, cessation of the supply or temporary suspension of the company's activities, among others. In addition, those involved may be subject to criminal implications (crimes against consumer relations), punishable with detention of six months to two years, plus penalty.

A recall does not prevent consumers from suing, individually or collectively, for damages. If one of the liability exceptions is not present (e.g., lack of damage or causation), the supplier can be held liable for damages regardless of whether the recall was properly carried out.

As to government actions, the likely effect of a recall is that the supplier and product will be more closely monitored.

7.4 To what extent do recalls in the United States or Europe have an impact on recall decisions and/or litigation in the jurisdiction?

The Brazilian authorities often monitor recall proceedings abroad and can request that the supplier clarify why a given product is being recalled elsewhere and not in Brazil. Consumers may also learn about recalls abroad and request the Brazilian authorities to notify the company in Brazil.

7.5 What protections does the jurisdiction have for internal investigations or risk assessments?

According to Ordinance 618/2019, suppliers must notify SENACON about internal risk investigations. The proceeding is intended to be confidential, although this is not expressly stated in the Ordinance. Suppliers must inform SENACON of the investigation steps and final conclusions. The conclusion not to perform the recall may be contested by SENACON and, if the determination is not fulfilled by the supplier, it may result in administrative and/or criminal sanctions (as referred to above).

7.6 Are there steps companies should take when conducting a product recall to protect themselves from litigation and liability?

Suppliers must comply with the specific rules provided in the CDC, Ordinance 618/2019, and the applicable regulatory rule, especially regarding a media plan. Close contact with SENACON to discuss case specifics is recommended, considering the open rules of Ordinance 618/2019 on media plans.

As soon as possible, the supplier should work on a plan for tracking consumers (where possible) and replacing/reimbursing the product, by collecting the recalled products in order to remove the risk from the market and therefore mitigate the risk exposure due to damages that could be caused by such product.

8 Litigation and Dispute Resolution

8.1 Please describe any forms of aggregate litigation that are permitted (i.e., mass tort, class actions) and the standards for such aggregate litigation.

Aggregate litigation can be filed through public civil actions (provided for in Law No. 7,347/1985) or collective claims (provided for in the CDC) in case of diffuse rights (i.e., of an indivisible nature, held by undetermined people) or collective rights (i.e., held by certain people, arising from a common origin or from the same legal relationship). This is the case, for instance, in: the introduction into the market of thousands of products with the same defect; misleading or abusive advertising that affects the whole society; commercialisation of spoiled medicine on a large scale; or leakage of personal data (sensitive or not) from a group of consumers, etc.

Aggregate claims can be filed by the Public Attorney's Office (the most common plaintiff), consumer associations, public defenders and other entities with standing, and do not require concrete damage to have occurred to consumers. The verification of an abusive clause or an illegal practice may lead to such claims, including for collective moral damages.

8.2 Are personal injury/product liability claims brought as individual plaintiff lawsuits, as class actions or otherwise?

Personal injury/product liability claims are usually filed as individual claims (given the need to assess direct causation between the damage and the product), but a collective claim on the matter is also viable, albeit less common.

8.3 What are the standards for claims seeking to recover for injuries as a result of use of a life sciences product? (a) Does the jurisdiction permit product liability claims? (b) Are strict liability claims recognised?

Yes, product liability claims are provided in the CDC, which is one of the most popular laws in Brazil. Almost all claims based on the CDC are subject to strict liability (except for self-employed professionals). Therefore, generally there is no discussion about fault in such claims. Also, liability caused by violations of the LGPD are also subject to strict liability of data processing agents, inspired by the CDC provisions.

8.4 Are there any restrictions on lawyer solicitation of plaintiffs for litigation?

Yes. The Brazilian Bar Association Statute and its Code of Ethics and Discipline impose several marketing restrictions and prohibit client solicitation, as well as any inducement to litigation.

8.5 What forms of litigation funding are permitted/utilised? What, if any, regulation of litigation funding exists?

The Code of Civil Procedure allows plaintiffs to request: (i) free legal aid when they do not have the financial means to bear litigation costs; and (ii) to pay the court fees in instalments. Case law has allowed the payment of court fees at the end of the claim, despite the lack of a clear legal provision in that regard.

As collective claims are usually filed by the Public Attorney's Office or associations at no cost to the plaintiffs, funding is less important. Also, individual and collective claims can be filed at no cost through a public defender.

Legal funding is neither prohibited nor regulated in Brazil. Through private contracts, a party can acquire future litigation credits in exchange for funding such litigation. These private contracts are relatively recent and less common in consumer claims.

8.6 What is the preclusive effect on subsequent cases of a finding of liability in one case? If a company is found liable in one case, is that finding considered *res judicata* in subsequent cases?

There is no binding precedent in Brazil and divergent rulings can occur within the same appeals court, including the Superior Court of Justice. The exception being when the Federal Supreme Court declares a "binding precedent" in relation to a matter (usually involving tax or social security) or when the Superior Court of Justice rules on a certain subject under the specific procedure of "repetitive appeals", which decision will be replicated for all other cases dealing with the same theme. Other than that, adverse decisions will not be binding but may influence future rulings, especially if issued by the main appeals courts and by the Superior Courts.

8.7 What are the evidentiary requirements for admissibility of steps a company takes to improve their product or correct product deficiency (subsequent remedial measures)? How is evidence of such measures utilised in litigation?

Damages caused by a product must be indemnified, regardless of the subsequent measures taken by the company; the latter can demonstrate a company's good faith but will not exempt it from liability.

8.8 What are the evidentiary requirements for admissibility of adverse events allegedly experienced by product users other than the plaintiff? Are such events discoverable in civil litigation?

Plaintiffs can quote similar cases or consumer website complaints to reinforce their product defect allegation, but the supplier will always be able to produce technical evidence in the case at hand. In case of several reports of adverse events in a claim, the judge can order SENACON to investigate further.

8.9 Depositions: What are the rules for conducting depositions of company witnesses located in the jurisdiction for use in litigation pending outside the jurisdiction? For example, are there "blocking" statutes that would prevent the deposition from being conducted in or out of the jurisdiction? Can the company produce witnesses for deposition voluntarily, and what are the strategic considerations for asking an employee to appear for deposition? Are parties required to go through the Hague Convention to obtain testimony?

The purpose of hearing a company representative in Brazil is to obtain a confession. Plaintiffs or the court may request to hear a company representative, but the company itself may not request to hear its own representative. Because company representatives are not under oath, what they say in favour of the company will be valued at the judge's discretion, but what they say against the company will be deemed a confession.

Company witnesses can depose through letters rogatory, which can be forwarded to a different court of justice in Brazil or to another country to be used in litigation. The new Code of Civil Procedure allows deposition through videoconference, if authorised by the judge. With the COVID-19 pandemic, virtual hearings have become the rule in most cases, replacing in-person hearings. Hopefully this will contribute to demystifying depositions by videoconference and to avoiding the delay of letters rogatory by allowing the witness to be heard directly by the judge presiding the case. The deposition of a witness (not a representative) that is also an employee of the company can be questioned by the plaintiff, and the judge may decide to hear him/her only as an informant (not under oath).

For testimonies outside the jurisdiction, Brazil has signed the Hague Convention, which brings more speed and effectiveness to requests for legal cooperation by Brazilian citizens and companies to obtain evidence in various countries and *vice versa*. The Ministry of Justice is responsible for processing legal aid requests using the new Convention, and has been appointed to act as the central authority for this multilateral instrument.

8.10 How does the jurisdiction recognise and apply the attorney-client privilege in the context of litigation, and with respect to in-house counsel?

According to the Advocacy Statute, considering the fundamental rights and guarantees provided by the Federal Constitution, the communication between counsel and client, especially for the purposes of defence strategy guidance, is protected by inviolable secrecy. While the rules are the same for external and in-house counsel, recent case law on criminal matters has not always afforded in-house counsel the same level of protection as outside counsel. There is no discovery in Brazil.

8.11 Are there steps companies can take to best protect the confidentiality of communications with counsel in the jurisdiction and communications with counsel outside the jurisdiction for purposes of litigation?

Companies can use protected/encrypted software to: send documents and share information; control and reduce the number of people copied into messages and involved in the case; and sign non-disclosure agreements with service providers involved in the litigation (e.g., technical assistants).

8.12 What limitations does the jurisdiction recognise on suits against foreign defendants?

The same rules apply. The difference is that summoning a foreign defendant can be more difficult as it requires the issuance of letters rogatory. If the foreign company has a subsidiary in Brazil or another company from the same economic group, plaintiffs are more likely to sue the Brazilian company, provided it has standing. The enforcement phase of an individual claim against a foreign defendant can be challenging if the court award is not voluntarily fulfilled.

8.13 What is the impact of U.S. litigation on "follow-on" litigation in your jurisdiction?

U.S. litigation may impact Brazilian litigation if the same product or information defect affects the Brazilian market, especially where there has been extensive media coverage. However, U.S. litigation is not reproducible in Brazil due to the differences in the legal systems (e.g., there is no civil claims jury or punitive damages in Brazil). As previously mentioned, SENACON monitors recall proceedings abroad.

8.14 What is the likelihood of litigation evolving in your jurisdiction as a result of U.S. litigation?

There is a medium-level risk of this. Although liability standards may differ, litigation in the U.S. may influence the filing of new claims in Brazil.

Rosangela Delgado Barreto focuses her practice in the area of complex litigation, which includes product liability, commercial, contractual, general civil and regulatory litigation. She has significant expertise in the consumer products, automotive, transportation, publishing, marine, and hotel industries, counselling several top-tier Brazilian and international corporations.
Ms Delgado Barreto has advised a top global tobacco company for more than a decade in indemnity lawsuits filed by smokers and former smokers or their successors and in regulatory litigation, working on one of the highest-profile cases in Brazil, receiving the first-ever injunction granted worldwide to this client. She is actively managing pre-litigation investigations for the client in several regulatory matters.

Veirano Advogados
Av. Presidente Wilson, 231
25th floor – Centro
20030-021, Rio de Janeiro, RJ
Brazil

Tel: +55 21 3824 4747
Email: rosangela.delgado@veirano.com.br
URL: www.veirano.com.br

Renata Fialho de Oliveira represents pharmaceutical and medical device companies in transactional matters in relation to M&A and divestitures, joint ventures and strategic alliances, outsourcing projects, product development and licensing agreements. She also advises private equity and strategic investors in a wide variety of transactional matters in the healthcare industry. As a trusted advisor, she helps domestic and multinational life sciences companies, start-ups and investors to navigate the challenging Brazilian regulatory environment and develop practical and innovative approaches. Mrs Fialho de Oliveira is recognised for her expertise in life sciences and healthcare in *Who's Who Legal*, *Leaders League* and *Análise Advocacia 500*. Mrs Fialho de Oliveira co-leads the Healthcare practice at Veirano Advogados.

Veirano Advogados
Av. Brigadeiro Faria Lima, 3477
16th floor – Itaim Bibi
04538-133, São Paulo, SP
Brazil

Tel: +55 11 2313 5700
Email: renata.oliveira@veirano.com.br
URL: www.veirano.com.br

Amanda Celli Cascaes has a Master's degree in private law from the Federal University of Rio Grande do Sul (2018) and specialised in civil procedural law at the Pontifical Catholic University of Rio Grande do Sul (2015), having graduated from the same institution (2013). She is currently a Ph.D. candidate at the University of São Paulo, focused on consumer law and healthcare.
Ms Celli Cascaes' practice is focused on consulting and complex litigation before several courts, defence in liability and consumer law claims (including product liability cases), negotiation of agreements and drafting of contracts. She has extensive experience assisting domestic companies and multinationals with operations in the areas of food, medication, tobacco and technology.
She is a member of the Brazilian Institute for the Study of Competition, Consumer Affairs, and International Trade ("IBRAC") and author of the book "*Economic Analysis of Civil Liability: Equitable Reduction of Indemnity and Risk Activities*", published in 2019.

Veirano Advogados
Av. Brigadeiro Faria Lima, 3477
16th floor – Itaim Bibi
04538-133, São Paulo, SP
Brazil

Tel: +55 11 2313 5700
Email: amanda.cascaes@veirano.com.br
URL: www.veirano.com.br

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