iclg

Drug & Medical Device Litigation 2025

Sixth Edition

Contributing Editor:

Eric M. Friedman

Faegre Drinker Biddle & Reath LLP

glg Global Legal Group

Expert Analysis Chapter

Q&A Chapters

Chile


Ignacio Gillmore


Mónica Pérez


Camila Suárez


Bruno Caprile

Carey

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 Sanitary Code is the primary legislative framework for life sciences products. However, additional regulations may apply depending on the product type – the main ones are:

- For pharmaceuticals of human use, including both products subject to medical prescription ("Rx") and over the counter ("OTC") products, Supreme Decree ("S.D.") 3/2010 and S.D. 466/1984.
- For pharmaceuticals of veterinary use, S.D. 25/2005.
- For supplements, S.D. 977/1997.
- For cosmetics, S.D. 239/2003.
- For medical devices, S.D. 825/1999.

Please note that medical devices laws and regulations are being progressively implemented, with only 10 devices currently being required to comply with the mentioned regulations ("*regulated medical devices*"). Unless stated otherwise, answers shall be understood to refer to the aforementioned.

The main regulatory entities that are involved in the enforcement and/or overseeing of life sciences products regulations are: (i) the Public Health Institute ("ISP"), for human use pharmaceuticals, cosmetics, and medical devices; (ii) the Livestock and Agriculture Service ("SAG"), for pharmaceuticals of veterinary use; and (iii) the Regional Secretariat of Health ("SEREMI"), for supplements.

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?

The Sanitary Code sets a special statute for defective products, pursuant to which any damage caused using a defective sanitary product will imply civil and/or criminal liabilities for the holders of authorisations, manufacturers and/or importers, as applicable. Those responsible for the damage shall be jointly liable before the injured parties. However, those who compensate the injured have the right to seek recourse from other responsible parties based on their involvement in causing the damage.

The injured party seeking compensation for the damages will have to prove the defect, the damage and the causal link between them. The Sanitary Code expressly excludes the *development-risk defence*, and, therefore, the company may not evade liability by alleging that the damages caused by a defective sanitary product arise from facts or circumstances that were not foreseeable according to the state of scientific or technical knowledge existing at the time of its circulation or use.

Please note that approval of the product by the regulators does not preclude the possibility of pursuing the holder's liability regarding defective products. However, approval of the product and fulfilment of laws/regulations serve as a defence for the company in an administrative proceeding and litigation. Nevertheless, what will finally determine the existence of liability is the satisfaction or not of the standard of conduct expected in the particular case, and considering the Sanitary Code's exigent liability statute. In fact, manufacturers and importers of medical devices must have insurance, a guarantee or equivalent financial security to cover damages to health resulting from safety issues with the devices.

Finally, companies and their executives could also face criminal liability in cases of incurring the sanitary criminal offences listed in the Criminal Code (*e.g.*, manufacture and sale of knowingly deteriorated or adulterated medicines).

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

Any litigation regarding civil liability will consider the rules set forth by the Sanitary Code for defective sanitary products, notwithstanding the applicability of the general liability statute of the Civil Code. Additionally, life sciences regulations often play a key role in assessing the manufacturer's standard of diligence, as they outline the applicable obligations.

Furthermore, in case of regulatory infringements, administrative proceedings may also be conducted to determine the administrative liability of the manufacturer – or the relevant party – either prior to or in parallel with the civil procedure; and its findings may eventually be introduced to the civil procedure.

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?

Yes, there are various industry associations that issue self-regulatory bodies or codes that are binding to their members.

For instance, the Chamber of Pharmaceutical Innovation ("CIF") for pharmaceuticals and the Chilean Association of Medical Devices ("ADIMECH") have regulations and industry codes that are considered best practices. Moreover, the Self-Regulatory and Advertising Ethics Board ("CONAR") also enforces industry codes that encompass provisions relevant to life sciences companies within its scope.

In connection to litigation and liability, they are normally used to determine the standard of conduct of companies in cases where the law does not establish specific duties. However, courts are not bound by them and may set higher standards on a case-by-case basis.

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?

Yes, safety and proper usage warnings are usually required to be included in the labelling of life sciences products. For example, marketing authorisations ("MAs") for pharmaceuticals must include an authorised patient information leaflet to be inserted in its packaging, as well as a prescribing information leaflet, which will serve as the basis for promotional materials; notwithstanding the possibility that ISP may order that specific warnings be included in the product labelling. Likewise, cosmetics, medical devices and supplements must include instructions of use, along with other elements.

When these products are destined to consumers, they should also follow the normative requirements from Law No. 19,496 – the Consumer Rights Protection Act ("CRPA"), mainly regarding their advertising and serving as a complement to sectorial legislation.

These requirements may have an impact on litigation depending on whether and how they were fulfilled. Commonly, when they have not been satisfied, the authorities may impose a fine based on a regulation infringement. In the same way, Civil Courts may consider infractions to the law to determine negligence upon damage claims.

2 Manufacturing

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

Requirements to obtain a manufacturing authorisation may differ among life sciences products. In the case of pharmaceuticals and cosmetics, ISP may authorise a manufacturing facility upon compliance of the requirements set forth in S.D. 3/2010 and 239/2003, respectively, which include requirements on the facility, its areas (*e.g.*, manufacturing, packaging, etc.), GMP, sanitary requirements, etc.

Also, the manufacturing of medical devices does not require prior sanitary authorisation, notwithstanding the obligation of undergoing conformity verification and submitting the manufacturer's certification in order to obtain the corresponding MA (*e.g.*, ISO 9001/GMP).

In the case of supplements, SEREMI may authorise a manufacturing facility upon compliance of the requirements of S.D. 977/1997.

In all cases, additional authorisations may be required (*e.g.*, related to water systems, autoclaves, general sanitary requirements compliance, hazardous chemical substances, etc.).

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?

ISP maintains cooperation agreements with different foreign regulators for collaboration in broad aspects, which may include inspection and/or authorisation of manufacturing plants, GMP certification, among others. These agreements encompass regulators like the FDA, AEMPS, COFEPRIS, INVIMA, and countries within the Pacific Alliance. For further information, please see https://www.ispch.gob.cl/relaciones-internacionales.

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

Infringements should lead to the instruction of a sanctioning administrative procedure (*sumario sanitario*), risking fines, recalls, suspension or cancelling of authorisations, among other sanitary measures. At the same time, if there are any damages caused by these violations, liability arising thereof should be proven and determined according to the Sanitary Code and/or general liability provisions of the Civil Code.

3 Transactions

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

There are no sanitary-regulatory approvals required in connection with a merger/acquisition itself. However, to the extent that the transaction involves changes in the domain, corporate name, or other details related to authorisations or registries associated to life sciences products, it will be necessary to request and materialise these changes.

For instance, in the case of an assets acquisition including pharmaceutical MAs, ISP shall authorise the transfer of all MAs included in the transaction, as well as potential additional authorisations to be determined on a case-by-case basis.

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?

There are no restrictions on the nationality of owners, partners or shareholders of life sciences companies incorporated in Chile. This extends to manufacturing facilities, provided that the entity holding the manufacturing authorisation is properly represented or incorporated in Chile.

In any case, where consumers are affected by products with foreign manufacturers lacking legal representation in Chile, courts have interpreted the law to hold local intermediaries liable (*e.g.*, cases where the manufacturer and the importer or distributor are different legal entities, but part of the same corporate group).

Indeed, although article 46 of the CRPA sets forth the liability of the intermediary regardless of the manufacturer, this provision only refers to "services". Despite the aforementioned,

many courts have interpretated this article to include both services and sales.

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 Sanitary Code and S.D. 03/2010 regulate **pharmaceutical** advertising, defining it as any activity used to directly or indirectly inform the public about product characteristics, distribution, sale and use – which is only permitted for OTC products with express and prior ISP authorisation. Promotion ("information to the professional"), on the other hand, refers to any activity aimed exclusively at professionals that are legally authorised to prescribe and/or dispense pharmaceuticals, being subject to several requirements.

Regarding **medical devices**, it is understood that advertising and promotion are permitted by S.D. 825/1999 – although they are not expressly regulated.

Regarding **cosmetics**, advertising is permitted and regulated by S.D. 239/2003 – it is essential for advertising to comply with the nature and cosmetic purpose of the product.

As to the sale of such products, the common legal basis for commercialisation is generally given by the obligation of obtaining an MA – or, exceptionally, a provisional authorisation; additionally, pharmaceuticals can only be sold by authorised facilities (*e.g.*, pharmacies), as opposed to other life sciences products. Furthermore, in the case of cosmetics of low manufacturing risk and personal hygiene products, the MA obligation is replaced by a registration/inscription regime and they are not subject to sale restrictions.

In the case of **supplements**, advertising is regulated by S.D. 977/1997 and Ex. Res. 860/2017, and thereby subject to specific requirements, such as the prohibition of health claims. In connection to sales of supplements, they are not subject to MA nor sale restrictions; however, regulations with regard to such activities are enforced by SEREMI – either preventively, in the case of imports, and/or reactively, during commercialisation.

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 of **pharmaceuticals** is expressly permitted by article 212 of S.D. 03/2010, provided the information refers to unapproved indications or dosages, and that their off-label nature is clearly disclosed to the professional. The use of this information shall be under the sole responsibility of the professional.

As to **medical devices**, there are no legal/regulatory limitations in this regard. However, it is imperative to approach decisions regarding the promotion of medical devices with careful consideration and caution.

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?

Companies may be administratively fined or declared responsible for damages when the regulation of advertising, promotion and sales is infringed. Indeed, failure to comply with these legal duties is an infraction *per se* regardless of whether anyone suffers damages as a result. Hence, different authorities such as ISP and SEREMI, as the sectorial authorities, or the National Consumer Protection Agency ("SERNAC"), may pursue infringement liability in administrative or civil proceedings, as applicable. In some cases, the sanction could be directly imposed by the regulator (*e.g.*, ISP/SEREMI), while in other cases must be requested by the agency and imposed by a judge (*e.g.*, SERNAC).

Additionally, judges may determine civil liability as follows – in principle, if a company provides clear instructions for product usage and it is demonstrated that when following these instructions, the product does not harm the consumer, the company should not be held accountable for damages resulting from improper use.

5 Data Privacy

5.1 How do life sciences companies that distribute their products globally comply with data privacy standards such as GDPR and other similar standards?

The recent enactment of the new Data Protection Law ("NDPL") in December 2024 has aligned Chilean legislation with international standards such as GDPR, and will become effective on December 1, 2026. The NDPL expands legal bases for data processing beyond consent – incorporating legitimate interest and contractual necessity – regulates cross-border data transfers, enhances data protection rights, and creates a Personal Data Protection Agency to oversee compliance and enforcement, and is empowered to impose significant fines upon infringements, among other matters.

Notwithstanding the latter, companies with an international presence typically establish data privacy policies that conform to GDPR standards as the most stringent regulation, regardless of the local legislation.

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?

Administrative proceedings are mainly regulated by sectorial regulations and supplemented by Law No. 19,880, which specifically recognises the principle of transparency and publicity. Therefore, administrative acts and resolutions, their grounds and documents containing them, as well as the procedures they use in their preparation or issuance, are public. Nonetheless, Law No. 20,285 recognises certain exceptions – *e.g.*, cases where people's rights are affected by the disclosure in relation to their safety, health, private life or commercial or economic rights.

Civil procedures are also public. However, article 34 of the Civil Procedure Code establishes the right of the parties to ask for the confidentiality of part or the entirety of the procedure upon justified reasons. Most of these requests are denied, but in cases of defective pharmaceuticals that may involve sensitive information, courts may be more prone to grant them.

In the case of arbitration, the proceeding is entirely confidential except when the parties present an appeal before the Higher Courts, which are public.

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

Key regulatory developments in digital health include the regulation of online sales of pharmaceuticals within S.D. 466/1984, as well as advancements in telemedicine, such as the creation of the Department of Digital Health in 2019, the issuance of the National Program of Telehealth approved by Ex. Res. 342/2019, and the publication of S.D. 6/2022, Law No. 21,541/2023 on telemedicine (which includes the obligation to obtain a sanitary authorisation to offer such services, and accrediting technical platforms for data storage and processing, outlining provider liability for aspects such as regularity, safety and data security standards, among other matters), and General Technical Norm No. 237 of 2024, which provides technical guidelines to comply with the current legislation on this matter. Litigation in this regard has been scarce. However, some cases we can mention are: Supreme Court No. 14957-2020; Santiago Court of Appeal No. 24742-2018; and Coyhaique Court of Appeal No. 183-2020, which, predating current laws and regulations, tended to spark discussion on the applicability of conduct standards outlined in the Civil Code.

Additionally, it has been debated whether performing remote exams is part of the required standard of care of doctors in emergency situations where there is no specialist available.

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.

Scientific biomedical research in humans is mainly regulated by Law No. 20,120 and S.D. 114/2011, the Sanitary Code, Law No. 20,854, Ex. Res. 460/2015 (Guidelines on Good Clinical Practices), and Ex. Res 173/2024 (Guidelines on General Considerations Regarding Clinical Studies).

According to the same, clinical trials can only be conducted with prior authorisation of an Ethics Committee, and, if including the testing of a pharmaceutical or a regulated medical device, an additional authorisation from ISP, which will allow the import or manufacturing and use of the test product.

Regarding injuries or damages arising from clinical trials on pharmaceuticals or medical devices, the Sanitary Code establishes a stringent statute of civil liability where holders of the authorisation for the provisional use of the study product shall be liable for damages caused during the study, even if they result from facts or circumstances that could not have been foreseen or prevented according to the state of scientific or technical knowledge existing at the time the damages occurred. Likewise, once the damage is proven, it shall be presumed that it occurred in connection with the research, and the claim is subject to a 10-year statute of limitations from the manifestation of the damage.

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)?

There are no specific laws or regulations mandating the testing of a product in connection to specific populations. Furthermore, according to local regulations, the trial design and target population should be scientifically justified in the protocol and authorised by the corresponding Ethics Committee; therefore, this should not lead to liability hypothesis.

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

Yes. In Chile, compassionate use programmes are mainly regulated by article 99 of the Sanitary Code, S.D. 03/2010, S.D. 825/1999 and, recently, Ex. Res. 224/2024.

Indeed, article 99 of the Sanitary Code provides the main pathway for importing and distributing both products without MA, operating as a relatively open standard that is reviewed by ISP on a case-by-case basis, provided the product is intended for an urgent medicinal use derived from situations of inaccessibility or shortage that may affect people considered either collectively or individually.

Additionally, for pharmaceuticals, two regulatory pathways are specified, namely, (i) article 21 (a) of S.D. 03/2010, which allows the import, commercialisation and use of pharmaceuticals without MA in situations of collective shortage or inaccessibility, as well as urgent medicinal needs; and (ii) article 21 (b) of S.D. 03/2010, which allows the import, commercialisation, and use of pharmaceuticals with or without MA for urgent medicinal needs of individual patients ("import for personal use" or "named patient use").

In the case of devices, article 4 of S.D. 825/1999 provides a specific pathway regarding cases of national emergency or where the product is urgently required.

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

Waivers of liability are not permitted in the context of clinical trials, since the holder of the authorisation is liable for any damage caused by the trial, in accordance with the regime established by the Sanitary Code. This liability applies even if it results from circumstances that were unforeseeable or unavoidable according to the state of science or technology at the time of their occurrence; being also subject to the legal presumption of a causal link between the trial and the damage, once the latter has been proven.

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

Conducting clinical trials strictly abiding by the applicable laws and regulations, including the guidelines cited in the answer to question 6.1, is the first and main condition to protect sponsors and other involved entities from liability arising from the studies. Apart from the aforementioned, there are not any regulatory or other guidance available directly addressing this issue – notwithstanding the relevance of adopting different contractual safeguards, such as ensuring that relevant agreements properly address liability issues.

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.

Product recalls are generally regulated by the corresponding sectorial decrees, depending on the type of product in question, along with further administrative acts issued by the governing regulatory authority (see the answer to question 1.1). This regulatory body oversees the recall process and conducts investigations to determine appropriate sanitary measures and may initiate a sanctioning administrative procedure (*sumario sanitario*), if applicable.

Although recall standards may vary depending on the product, they are generally prompted by suspected or confirmed quality failures that could pose risks to patients or users.

As a reference, in the case of pharmaceuticals, recalls are regulated within S.D. 3/2010, complemented by Ex. Res. 3853/2020, Technical Guidelines No. 147/2013, and different instructive guidelines and forms, which set forth preestablished reports to be sent by the different entities involved at different stages of the recall, as well as different timelines and procedures as per the recall classification, based on the potential health risk that the product may represent, among other provisions.

Additionally, recall of products that are considered hazardous or without sectorial regulations in this regard (*e.g.*, non-regulated medical devices) are governed by the CRPA, and SERNAC will also be involved.

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?

It is necessary to note that the number of regulated devices is limited, by a comprehensive pharmaceuticals regulation that covers the full spectrum of products in the market, which leads to different control and information levels.

Along with the abovementioned, while both products fall under the jurisdiction of ISP, pharmaceutical recalls are more extensively regulated than those applicable to medical devices.

Specifically, as opposed to the regulations on pharmaceuticals recalls (see the answer to question 7.2), the recall process for devices is only mentioned by S.D. 825/1999, supplemented by the Guidelines of the National Technovigilance System and the Guidelines on Good Storage, Distribution, and Transport Practices for devices, which provide minimal guidance on recalls.

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

Usually, product recalls – either voluntarily conducted by the MAH or ordered by the authority – will trigger an investigation by the regulator. This could result, if applicable, in the adoption of different sanitary measures (*e.g.*, conducting special or additional analyses, manufacturing and/or distribution prohibitions, quarantines, suspension of authorisations, etc.), and/or in the instruction of a sanctioning administrative procedure (*sumario sanitario*), risking fines or the imposition of other sanctions. Additionally, civil litigation could be prompted by damages stemming from the cause of the recall.

Please note that voluntary recalls do not prevent administrative or civil liability from being established; however, they may be interpretated as a company commitment of compliance with regulations and an intention to prevent potential damages, which typically influences the imposition and grading of administrative fines or future compensation.

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?

Legally, foreign recalls do not impact recall decisions or litigation in Chile. However, considering that U.S. and Europe's regulators are international reference authorities, any recall decision affecting a product with active presence in Chile may trigger an investigation by ISP in order to determine whether the recall should also be applied locally.

Where a recall decision made abroad is based on reasons that are also applicable in Chile, but the company fails to execute the recall locally, a judge may take this circumstance as presumption of negligence in civil or administrative proceedings.

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

There is no legal recognition of internal investigations or risk assessments, therefore they do not have any special protection. However, internal investigations or risk assessments can be used by companies as a defence when they are being sued or fined by the relevant authorities.

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

Recall processes shall be conducted in strict compliance with the applicable regulations and the company should keep records of such compliance. This includes timely notification, timely recuperation of the product, product segregation and quarantine, proper handling and collaboration with the authority, etc.

Additionally, it is suggested that the company conduct an in-depth internal investigation, which could serve to either mitigate the claims made by the authorities or identify necessary improvements to assure the authorities that the issue has been rectified.

Finally, in the case that the company seeks to mitigate or eliminate any risk of being sued by consumers affected by the recall, the CRPA sets forth Collective Voluntary Procedures ("PVC"), which provide companies with an alternative, enabling them to obtain an expeditious, complete and transparent remedy for conduct that may affect the collective or diffuse interest of consumers. The remedy proposed by the company shall not imply a recognition of the facts constituting the possible infringement. In order for the settlement contained in the resolution issued by the service to have *erga omnes* effect, it must be approved by the Civil Court in the supplier's place of residence. The settlement shall have the effect of an out-of-court settlement with respect to all potentially affected consumers, except for those who have previously asserted their rights in court, entered individual settlements or transactions with the supplier, or reserved their actions affected. Nonetheless, consumers who do not agree with the settlement reached, in order not to be bound by it, must expressly reserve their individual actions before the court that approved the settlement.

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.

The Chilean legal system does not permit many forms of aggregate litigation. In fact, there is only one proceeding that expressly recognises class actions, which is set forth in the CRPA.

In such regard, consumer protection class actions have been understood by Chilean courts as a general procedure for addressing regulatory infringements that result in civil damages to consumers or violations of the CRPA itself in many regulated areas without prejudice to sectorial legislation, for the safeguarding of consumers.

Despite the aforementioned, the Civil Procedural Code recognises the general possibility of starting a proceeding with multiple parties, either as plaintiff or defendant, regarding any subject matter. This possibility can be useful when more than one person has suffered similar damages motivated by the same cause.

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

Personal injury/product liability claims can be brought either by an individual or multiple plaintiffs in a lawsuit, provided there is a damage that originates from the same cause.

However, this kind of liability can also be pursued by a class action, provided that the requirements of the CRPA – notably, the existence of a consumer relationship – are met.

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?

The Chilean jurisdiction allows product liability claims; based on the general civil liability standards and adjusted to the rules that the Sanitary Code sets forth in connection to defective sanitary products, allowing the claimant to pursue pecuniary damages (including both actual damage, and loss of profits) and non-pecuniary damages. Although strict liability is exceptional in Chilean legislation – recognised only in specific cases expressly established by law – there has been some debate as to whether the product liability framework under the Sanitary Code should be classified as strict liability or not.

Indeed, the Sanitary Code introduces some modifications to the liability rules of the Civil Code, which may lead people to believe that it is a stricter liability than the general regime. Notably, the Sanitary Code states that the victim must prove the defect, the damage and the causal link between them. In clinical trials, once the damage is established, a presumption arises that it occurred in connection with the research. Also, as indicated, the *development-risk defence* is excluded.

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

Article 14 of the Code of Ethics for Chilean Lawyers forbids solicitation, understood as any communication from a lawyer regarding one or more specific matters, directed to a specific recipient, either directly or through third parties, with the intent of securing the engagement of their professional services. However, the Code does recognise certain exceptions where solicitation is allowed.

Please have in mind that the Code of Ethics for Chilean Lawyers is only mandatory for lawyers who are members of the Chilean Bar Association, of which membership is voluntary. However, the Supreme Court has lately been applying this Code as generally enforceable.

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

Although there are some litigation funding institutions in Chile, no regulation exists with regard to this type of funding. Therefore, they must follow general regulations regarding ethics, criminal law, taxes, donations, among others.

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?

Liability in one case will normally not have an effect *per se* in other cases. In the Chilean jurisdiction *res judicata* analyses each case's specific circumstances, and, therefore, if a company is found liable in one case it will not imply that it is also liable in another. However, if the facts of the first case are similar enough to the following ones, the first ruling will probably be considered as a strong argument and evidence in further cases.

Nevertheless, the CRPA establishes a class action proceeding that may be used to pursue life sciences product liability and a ruling of which declaring that the responsibility of the defendant(s) shall have *erga omnes* effect, except for those cases where a consumer previously sued individually or in the cases that the consumer reserved their actions before the court.

If the lawsuit is dismissed, any active legitimate party may file a new action within the statute of limitations, presenting new circumstances to the same court, which will result in the suspension of the statute of limitations for the entire duration of the class action.

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?

There are not specific evidentiary requirements for admissibility of steps to solve or prevent product issues. Indeed, this kind of evidence should be incorporated according to the Civil Procedural Rules, which normally imply that it can be submitted before the court without any restriction. However, please note that documents that have been created by the same defendant are normally considered less relevant than the ones emanating directly from an authority or a third party and, consequently, it is common to introduce these measures through a witness deposition, auditors or experts reports, to assure the strength of the evidence at trial.

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?

This kind of evidence should be understood in the same way as is explained in the answer to question 8.7.

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?

Chilean law does not require going through the Hague Convention to obtain a testimony, and companies can produce their own witness deposition voluntarily in a tribunal hearing. In the case of employees, they can testify unless it is proven that they have a particular interest in the trial's result or that their deposition is conditioned to a further benefit. In Chile, records of depositions in a trial can be used with the same evidentiary value in another trial. However, the Chilean legal system does not recognise private depositions that are conducted outside of the courts.

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?

The Chilean jurisdiction equally respects attorney-client privilege in a litigation context and in-house counsel, establishing that they shall not be compelled to testify regarding facts that have been confidentially communicated to them in the course of their status, profession or occupation.

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?

Besides what was pointed out in the answer to question 8.10, the Civil Procedural Code establishes other ways to protect the confidentiality of communications with counsel, such as exceptions to compulsory exhibitions of documentary evidence – which may be ordered upon request of a party, provided they have a direct relation to the matter in dispute and the evidence is not considered secret or confidential information.

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

When a lawsuit is to be served out in a foreign country, the respective communication shall be addressed to the official who is to intervene, through the Supreme Court, which shall send it to the Ministry of Foreign Affairs so that it may, in turn, process it in the manner determined by the existing treaties or by the general rules adopted by the government. In addition, the communication shall specify the name of the person or persons that the interested party authorises to carry out the requested proceedings, or it shall indicate that it can be done by the person who presents it or by any other person.

Even though there is a special proceeding to present lawsuits against parties outside the Chilean jurisdiction, in practice, it is very problematic to do so due to the difficulties in collaboration between different jurisdictions. Generally, what is attempted is to sue the legal representative of the international company in Chile, and only if that is not possible, resort to a cross-border lawsuit.

In cases of constitutional protection actions seeking injunctive relief, Chilean law grants the courts broad powers to conduct the proceedings, including the authority to serve defendants by email or other more efficient means.

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

In principle, judicial rulings or litigation in the U.S. *per se* do not affect Chilean trials. However, relevant rulings may be introduced into local proceedings by one of the parties, as additional information for the court's consideration.

Moreover, it is worth noting that relevant class actions in the U.S. could encourage similar claims in Chile, usually led by Consumer Organisations; and the regulatory authority may decide to investigate and determine the administrative liability of a company based on relevant findings in the U.S. or other jurisdictions.

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

It certainly depends on the grounds which justify the U.S. litigation. If the factual circumstances from the U.S. are replicable in Chile and the defendant company has an agency in Chile, it is likely that it will be sued; however, if the case is the opposite, it should not happen. Nevertheless, even in the case that the facts were the same, the civil law tradition of the Chilean jurisdiction is quite different from the common law background of the U.S.; therefore, many claims that may be successful in the U.S. might not have the same result here.

8.15 For EU jurisdictions, please describe the status and anticipated impact of the Collective Redress Directive and Product Liability Directive on drug and medical device litigation in your jurisdiction.

This is not applicable to Chile.

Ignacio Gillmore is a partner at Carey and co-head of the firm's Life Sciences and Biotechnology and Public Law groups. His practice focuses on life sciences, biotechnology and public law, advising companies on intellectual property issues related to the pharmaceutical industry, cosmetics, medical devices, commercialisation and advertisement of these products, scientific research, clinical studies, regulation of medical professions, privacy, data protection, public and private procurement and biddings, licences, distribution and franchises. He also represents clients in administrative processes and in sanitary, administrative and judicial litigation derived from those operations. He has been recognised by international publications such as *Chambers and Partners*, *The Legal 500*, and *Latin Lawyer*, among others. In 2024 and 2021 he was awarded Lawyer of the Year in Life Sciences by *Best Lawyers*.
Ignacio graduated from Universidad de Chile's Law School.

Carey
Isidora Goyenechea No. 2800, 43rd floor, Las Condes
Santiago
Chile

Tel: +56 2 2928 2612
Email: igillmore@carey.cl
LinkedIn: www.linkedin.com/in/ignacio-gillmore-valenzuela-716286a1

Mónica Pérez is a partner at Carey and co-head of the firm's Litigation and Arbitration Group. Her practice focuses on civil and commercial litigation, domestic and international commercial arbitration, on matters including contracts, torts, corporations, consumer protection law, unfair competition, distribution agreements, international commerce, secured transactions, and environmental law, among others. Her practice also includes pre-litigious advice to national and international clients in the fields of mining, insurance, energy, automotive and retail, among others.
She has been recognised as a leading lawyer by *The Legal 500* and *Benchmark Litigation Latin America*.
Mónica is a member of the panel of young arbitrators of the Mediation and Arbitration Center of the Santiago Chamber of Commerce and member of the Chilean chapter of the Spanish Arbitration Club. She is also a member of the Chilean Bar Association and the Alabama State Bar Association (USA). She is a Professor of the postgraduate degree in Consumer Law at Universidad de Chile.

Carey
Isidora Goyenechea No. 2800, 43rd floor, Las Condes
Santiago
Chile

Tel: +56 2 2928 2203
Email: mperez@carey.cl
LinkedIn: www.linkedin.com/in/m%C3%B3nica-p%C3%A9rez-quintana

Camila Suárez is an associate at Carey, and her practice focuses on life sciences, biotechnology and public law; advising companies on issues related to the pharmaceutical, cosmetics and medical technology industry.
In 2018, she participated in the Linkage Program at Yale University in the USA.
Camila graduated from Universidad Diego Portales' Law School and holds a degree in Regulatory Aspects of Medicines, Cosmetics, Medical Devices and Disinfectants from Universidad de Chile.

Carey
Isidora Goyenechea No. 2800, 43rd floor, Las Condes
Santiago
Chile

Tel: +56 2 2928 2612
Email: csuarez@carey.cl
LinkedIn: www.linkedin.com/in/camila-su%C3%A1rez-alc%C3%A1ntara-8b6455157

Bruno Caprile is an associate at Carey and member of the Litigation and Arbitration, and Environmental Law and Litigation groups. His practice is mainly focused on civil, business and environmental litigation and arbitration before ordinary and special courts.
He is a teaching assistant of Civil Law and Roman Law at Universidad Católica de Chile.

Carey
Isidora Goyenechea No. 2800, 43rd floor, Las Condes
Santiago
Chile

Tel: +56 2 2928 2213
Email: bcaprile@carey.cl
LinkedIn: www.linkedin.com/in/bruno-caprile-jim%C3%A9nez-549924178

We are a full-service firm. Our various corporate, litigation and regulatory groups have highly specialised attorneys covering all practice areas of law.
Our clients include some of the world's largest multinationals, international organisations, and some of the most important local companies and institutions.
Our lawyers have graduated from the best law schools in Chile, and most of our mid-level and senior associates have graduate degrees from some of the world's most prominent universities.
We are an effective bridge between legal systems. Most of our partners and senior associates have worked in North America, Asia and Europe, as foreign or regular associates with leading international law firms, or as in-house counsel for major corporations or international institutions.

www.carey.cl

/Carey

iclg International Comparative Legal Guides

The **International Comparative Legal Guides** (ICLG) series brings key cross-border insights to legal practitioners worldwide, covering 58 practice areas.

Drug & Medical Device Litigation 2025 features one expert analysis chapter and 17 Q&A jurisdiction chapters covering key issues, including:

- Regulatory Framework
- Manufacturing
- Transactions
- Advertising, Promotion and Sales
- Data Privacy
- Clinical Trials and Compassionate Use Programmes
- Product Recalls
- Litigation and Dispute Resolution

The International Comparative Legal Guides are published by: glg Global Legal Group