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Spain


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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 Spanish Congress and the Senate are the principal legislative bodies that enact legislation applicable to medicinal products, medical devices, supplements, over the counter ("**OTC**") products and cosmetics. In addition, the life sciences sector is also subject to EU regulations and directives.

The Spanish Agency for Medicines and Medical Devices (*Agencia Española de Medicamentos y Productos Sanitarios* or "**AEMPS**") is the main agency that regulates the technical aspects of and oversees medicinal products, medical devices, cosmetics and personal care products. In the case of supplements, the competent authority is the Spanish Agency for Food Safety and Nutrition (*Agencia Española de Seguridad Alimentaria y Nutrición* or "**AESAN**"). In addition, the regional authorities of the 17 Autonomous Regions within Spain are also responsible for overseeing advertisements and conducting inspections of manufacturing and distribution premises as well as all necessary controls to ensure that products comply with the applicable regulations.

The Spanish Ministry of Health ("**MoH**") is the department of the Government of Spain responsible for, among others, proposing and executing regulations and decisions on pricing and reimbursement of medicinal products that are financed with Spanish public funds. Considering that the reimbursement of medicinal products is financed by recourse to the funds of regional authorities, healthcare authorities of the 17 Autonomous Regions also participate in the committee of the MoH that assesses decisions on pricing and reimbursement of medicinal 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?

In Spain, the general liability regime for defective products is set out in Royal Legislative Decree no. 1/2007, of 16 November, approving the revised text of the General Law for the Protection of Consumers and Users and other complementary laws ("**RLD 1/2007**").

This general liability regime is mainly of a strict nature: the producer of a defective product is liable for any personal or property damages (including death, personal injuries and/or any damages to, or destruction of, any property), provided that the defective product is intended for private use or consumption and that the injured person uses it mainly for private use or consumption. The injured party seeking reparation of the damage will have to prove the defect, the damage and the causal relationship between the two.

This strict liability system does not preclude other liability systems that may provide greater protection to the injured party, nor does it affect the other rights for which the injured party may have to be compensated for damages, including the moral ones, as a consequence of contractual liability, based on the lack of conformity of goods or services or any other cause of breach or defective performance of contract, or of the non-contractual liability (general tort regime) that may apply.

The authorisation of a medicinal product or any certification of a medical device does not exclude any potential claim by the injured party based on the product liability regime (if the product is defective) or the general tort regime (if the damage has been caused by fault), but it may imply a presumption that there is no defect in the product or fault on the damage. Defendants may also claim or attempt to reduce or be exempted from liability by alleging compliance with the requirements set out in legislation and regulations governing the placing of such products on the market.

The same applies to supplements, despite not being subject to marketing authorisation, but merely to a notification of the product being placed on the market.

In addition, as regards medical devices, notified bodies (if they are private entities) may also be subject to general tort liability in case of wilful or negligent breach of obligations upon conducting the conformity test.

Moreover, based on the general liability regime of public administrations, a complaint may be filed against the regulatory authority that authorised the commercialisation of a defective medicinal product or medical devices, whenever the damage arises from facts or circumstances that could have been prevented or avoided, according to the state of scientific and technical knowledge existing at the time of the authorisation of the product.

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

Non-compliance with regulations applicable to life sciences products may also give rise to disputes between competitors.

Breach of regulations and laws regulating a given concurrent activity is considered unfair under Law no. 3/1991 on Unfair Competition, as is to prevail in each market with a competitive advantage that is acquired because of breach of law.

Pursuant to Law no. 3/1991, it is also unfair to advertise a product by breaching:

(a) the specific rules that may apply to advertising of such product; or

(b) the provisions of Law no. 34/1988 on General Advertising.

In case of acts of unfair competition, the following actions may be exercised:

(i) a declarative action of disloyalty;

(ii) an action for the cessation of the unfair conduct or for the prohibition of its future reiteration. The prohibition action may be exercised even if the conduct has not yet been put into practice;

(iii) an action to remove the effects produced by the unfair conduct;

(iv) an action to rectify misleading, incorrect or false information;

(v) an action to compensate damages caused by unfair conduct, if there has been fraud or negligence on the part of the agent; and

(vi) an action for unjust enrichment, which will only apply whenever the unfair conduct damages a legal position covered by an exclusive right or another legal position of similar economic content.

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?

There are different associations acting as self-regulatory bodies:

(i) FARMAINDUSTRIA is the national trade association of the Spanish-based pharmaceutical industry. It acts as the self-regulatory body of all pharmaceutical companies that have adopted its Code of Practice ("**FARMAINDUSTRIA Code**"), which regulates the interaction of the pharmaceutical industry with healthcare professionals ("**HCPs**"), healthcare organisations ("**HCOs**"), and patient organisations ("**POs**") as regards medicinal products.

(ii) FENIN is the national trade association of the medical devices industry. It acts as the self-regulatory body of all medical devices companies that have adopted its Code of Practice ("**FENIN Code**"), which regulates the interaction of the medical devices industry with HCPs, HCOs and POs as regards medical devices.

(iii) ANEFP is the Spanish OTC industry association. It also approved its own Code of Conduct on the promotion of OTC ("**ANEFP Code**").

(iv) AESEG is the Spanish generic pharmaceutical industry association. It also approved its own Code of Conduct on Interactions with the Healthcare Community ("**AESEG Code**").

(v) BIOSIM is the association of Spanish-based pharmaceutical companies with common interests in the research, development, production and/or marketing of biosimilar medicinal products. It also approved its own Code of Good Practices ("**BIOSIM Code**").

Moreover, AUTOCONTROL is the main self-regulatory association for advertising.

In recent years, the number of complaints filed by companies before national courts in respect of a competitor's advertising materials or promotional activities has decreased sharply. In contrast, the bodies overseeing compliance with the FARMAINDUSTRIA Code were very active during this period, which resulted in an increase in the number of cases in which companies were obliged to adopt corrective measures. In certain cases, settlement was complemented with a voluntary economic contribution made by companies to the fund created by FARMAINDUSTRIA to promote rational use of medicinal products.

These Codes of Practice have significant impact on litigation in cases of unfair conduct and regulate certain interactions between companies that are subject thereto. Prior to requesting the cessation or rectification of a given unfair conduct before national courts, companies sometimes resort to self-regulatory organisations.

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?

Lack or inaccuracy of necessary warnings in a product or its instructions for use, summary of product characteristics ("**SmPCs**") or prospect may give rise to information defects. Hence, whenever the information is incorrect or insufficient, it may be considered defective and give rise to liability in case of damages.

Information is considered appropriate if it allows for the identification, assessment or reduction of the declared risk, as well as whenever a balance exists between the safety information of the product available to the manufacturer and the one made available to consumers.

Producers are liable for the absence of appropriate information only regarding risks that are reasonably foreseeable (*i.e.*, if the producer is or should have been aware of specific risks with due diligence). In the context of the product liability regime set out in RLD 1/2007, a defect is defined as "*the lack of safety that could legitimately be expected from the product*", *i.e.*, based on the criterion of reasonable consumer expectations. Furthermore, within the scope of the reasonable consumer expectations, only information that was known by the producer or that, in accordance with the state of scientific and technical knowledge, should have been known at the moment of placing the product on the market, must be included. The mere modification of the information of a product, to introduce better warnings, risks or side effects according to the latest available data, does not cause the product to be defective, since the definition of defect expressly establishes that "*a product shall not be considered defective for the sole reason that such product is subsequently put into circulation in a more improved version*".

As a rule, the information and warnings provided directly to the users of a given product are to be considered when assessing whether a product suffers from information defects. However, in the case of products that require the intervention of an intermediary (such as those that require intervention by health professionals), courts may consider the information provided to the intermediary to determine whether the information provided to the consumer, user or patient is insufficient and inappropriate. Such is also the case for medicinal products.

Moreover, pursuant to Law no. 41/2002, of 14 November, governing patient autonomy and rights and obligations related to clinical information and documentation, the medical doctor shall ensure that the patient has all the necessary information to freely decide on the therapeutic strategy prescribed by the doctor.

In those cases, therefore, the information provided by the manufacturer to the doctor will be considered when assessing the correctness and adequacy of the information provided to the patient.

Despite this, however, RLD 1/2007 does not expressly foresee the referred "*learned intermediary rule*", pursuant to which the supply of information to the learned intermediary discharges

the duty owed by the manufacturer to the ultimate consumer to make appropriate product information available.

2 Manufacturing

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

Licensing requirements vary in the case of manufacture of medicines (including OTC medicines), medical devices, food supplements and cosmetic products.

Medicinal products

In Spain, industrial manufacturing of medicinal products (both for human and veterinary use) requires prior authorisation by the AEMPS.

For the purposes of obtaining this authorisation, applicants must submit the following documents to the AEMPS: (i) a description of a technical report on the medicinal products that the applicant intends to manufacture, as well as of the premises where the quality control of the medicinal products will be conducted; (ii) evidence that the applicant has sufficient and adequate premises as well as the technical equipment required to manufacture the envisaged medicinal products; and (iii) evidence that the applicant has a qualified technical director (known as the "qualified person" under EU regulations) and persons responsible for conducting quality controls and manufacturing activities. If only small quantities or non-complex products are manufactured, the technical director may also conduct quality control.

Manufacturers must also observe the standards set out in the guidelines issued by the European Medicines Agency on Good Manufacturing Practices.

Medical devices

Manufacturing of medical devices requires a prior licence granted by the AEMPS (in the case of custom-made devices, authorisation by the competent regional authorities may also be required).

For the purposes of obtaining this licence, the applicant must prove to have: (a) an organisational structure capable of guaranteeing the quality of the products and the execution of the appropriate procedures and controls; (b) adequate facilities, procedures, equipment and personnel according to the activities and products at stake; (c) a technical manager holding a relevant university degree to oversee the envisaged products; and (d) a system to file the documentation generated in respect of each product manufactured or imported and to keep record of all products, to ensure their traceability. Likewise, manufacturers shall make the notifications of events as provided in Section 2 of Chapter VII of Regulation (EU) 2017/745 through the procedures provided for this purpose in that regulation.

CE marking is mandatory for all medical devices to prove compliance with the applicable technical requirements and specifications. Prior to placing medical devices on the Spanish market, the notified body must have verified and certified the manufacturer's procedures as well as product safety and quality (except in the case of Class I medical devices).

Food supplements

Companies that produce, process, package, store, distribute, import and market food supplements must be registered in the General Sanitary Registry of Foodstuff and Food Companies.

Food companies must submit a communication prior to the start of their activity. The operator of the company must submit the following information: (a) name of the operator or company name; (b) corresponding taxpayer number (NIF or NIE); (c) description of the purpose of the company's activities; and (d) headquarters of the relevant establishment or, in the case of companies without any establishment, the registered office.

Cosmetics

Manufacturers of cosmetic products must submit a statement of responsibility to the AEMPS including the following information: (a) data of the owner of the activity: name or company name and address or registered office; NIF or NIE; and place for notification purposes; (b) details of a qualified contact person: name; and qualification; (c) activities covered by the statement of responsibility, whether materially performed by the applicant or subcontracted companies: bulk manufacturing; conditioning (packaging and labelling); control; storage; and import; (d) information on the facilities or plants where activities will be performed: name; address; and tax identification code; (e) categories and cosmetic forms covered by the relevant activities; (f) expected start date of the activities covered by the statement of responsibility; and (g) a statement indicating that the manufacturer complies with the requirements and obligations inherent to the exercise of the manufacturing and import activity, that the manufacturer holds all supportive documentation and undertakes to comply with the technical requirements set out in the applicable regulations (as regards personnel, facilities, equipment and operations).

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?

Local regulators in the EU have agreed to the setting up of a joint audit programme of GMP inspectorates to verify the implementation and equivalence of EEA GMP as established by European Directives into national laws. This is aimed at maintaining mutual confidence in the GMP inspection systems of each Member State by the other Member States, as established by the Compilation of Union Procedures on Inspections and Exchange of Information. The contents of the Compilation are constantly updated, developed and agreed, under the coordination of the EMA.

Additionally, the EU has signed mutual recognition agreements ("**MRAs**") regarding inspection conformity assessment of manufacturing facilities for medicines with Australia, Canada, Israel, Japan, New Zealand, Switzerland and the U.S. The EU has also reached trade and cooperation agreements with the UK on mutual recognition of GMP inspections and acceptance of official GMP documents by EU competent authorities, although these agreements do not exempt the importer/batch releaser for the EU from performing a batch recontrol.

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

Breach or compliance with manufacturing requirements may have a direct impact on litigation, whether it arises from product liability, contractual matters, general tort liability or unfair competition.

From a product liability perspective

Pursuant to the product liability regime set out in RLD 1/2007, a defective product shall mean a product which does not provide

the security which could be legitimately expected, considering all the circumstances, and in particular its presentation, the reasonably foreseeable use of the product and the timing of its implementation in circulation. In any case, a product is defective if it does not offer the security normally offered by the other copies of the same series.

If, because of infringement of a manufacturing requirement, a product does not provide the security which could be legitimately expected and causes damages, the producer may be subject to the strict liability regime set out in RLD 1/2007 for defective products.

However, the producer will not be liable if it is proven that the defect was due to the product being produced according to existing mandatory rules (*ex.* article 140(1)(e) of RLD 1/2007).

From the perspective of contractual litigation

Under the contractual liability regime, a violation of the manufacturing requirements may lead to a breach of contract if it entails any breach of contractual obligations, whether implicit or explicit, or non-conformity of the product.

Breach of contractual obligations is subject to compensation for damages, which may include consequential damages (including moral ones) and loss of profits.

From the perspective of general tort litigation

Breach of manufacturing requirements may also lead to liability under the general tort regime.

Under this regime, any person who causes damages to another person, whether by action or omission, in case of fault or negligence, must repair the damage caused. This compensation may also include consequential damages (including moral ones) and loss of profits.

From the perspective of unfair competition litigation

See answer to question 1.3.

3 Transactions

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

Spanish law does not provide any specific requirements of approval by local regulators for mergers/acquisitions in the sector of life sciences.

However, Spanish Competition Law no. 15/2007, of 3 July, and Royal Decree no. 261/2008, of 22 February, include a system of prior notification applicable to concentrations that surpass the legal thresholds set out therein. This notification system is enforceable provided that there is no obligation to notify the concentration to the European Commission under EU rules.

Spanish law provides two alternative notification thresholds: (i) the market share threshold; and (ii) the turnover threshold.

The market share threshold is reached whenever, as a result of the concentration, the market share of the company in connection with the relevant product or service is equal to or greater than 30% in either the national market or in the geographic market defined within. This does not apply whenever the global turnover in Spain of the acquired company or of the assets acquired in the last accounting year do not exceed EUR 10 million, provided that the participants do not have an individual or joint market share equal to or greater than 50% in any of the relevant markets, in the national market or in the geographic market defined within.

The turnover threshold is reached in cases where (a) the global turnover in Spain of the group of participants exceeds EUR 240 million in the last accounting year, and (b) at least two of the participants individually reached a turnover in Spain greater than EUR 60 million.

If any of the above-mentioned thresholds are met, the concentration must be notified to the Spanish Market and Competition Authority and will be subject to a general obligation to suspend execution of the operation until authorisation is obtained.

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?

Spanish law does not provide any specific restrictions on foreign ownership of life sciences companies or manufacturing facilities.

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 of medicinal products and medical devices in Spain is regulated by a combination of laws, guidelines of the regulatory authorities and codes of conduct adopted on a voluntary basis by the pharmaceutical industry.

Law no. 34/1988 on General Advertising and Law no. 3/1991 on Unfair Competition set out the general rules applicable to advertising. The provisions contained in the EU Directives on advertising of medicinal products and medical devices have been implemented in Spain by way of Royal Legislative Decree no. 1/2015 on guarantees and rational use of medicinal products and medical devices, Royal Decree no. 1416/1994 on advertising of medicinal products for human use, and Royal Decree no. 192/2023 on medical devices. However, as stated in the derogatory provision of Royal Decree no. 192/2023, stipulations on the advertising, promotion, incentives and sponsorship of scientific meetings established in the previous regulations (*i.e.*, Royal Decree no. 1616/2009) will remain in force until the development of their specific legislation.

Regarding medicinal products, the MoH issued an Instruction in 1995 (Circular no. 6/1995, amended by Circular no. 7/99) regarding the interpretation of Royal Decree no. 1416/1994.

All 17 Spanish Autonomous Regions are competent for the implementation of rules on the advertising of medicinal products and medical devices. Some Autonomous Regions have adopted guidelines reflecting the position of the regional authorities on the advertising of medicinal products (the most remarkable guidelines are those issued in the regions of Madrid and Catalunya). Furthermore, the MoH has issued guidelines on the advertising of OTC medicinal products (last updated version published in 2019). Royal Legislative Decree no. 1/2015, approving the revised text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices, is also noteworthy as it sets out the sanctions in case of breach of the rules on advertising of medicinal products and medical devices.

Spanish industry associations have also adopted codes of conduct that regulate, among other matters, interactions with HCPs, HCOs and POs, such as:

(i) The FARMAINDUSTRIA Code, which regulates the advertising of prescription-only medicinal products as well as interactions between pharmaceutical companies and HCPs, HCOs and POs. A new, updated 2021 version was recently issued and came into force this year. The 2021

version of the FARMAINDUSTRIA Code introduces new aspects as regards social media and the digital environment, relationships between companies and HCPs, POs and the media.

(ii) The FENIN Code, which also regulates the advertising of medical devices as well as interaction between pharmaceutical companies and HCPs, HCOs and POs.

(iii) AESEG and ANEFP, among others, have also adopted their own codes of conduct on the promotion of medicinal products. The ANEFP Code sets out specific provisions on the advertising of self-care and other OTC products.

Healthcare authorities and courts are responsible for enforcing advertising rules (other than those resulting from industry codes of conduct). The industry codes of conduct are enforced by the associations' self-regulatory bodies in agreement with AUTOCONTROL, a Spanish association acting as an independent tribunal for advertising self-regulation matters.

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 medicinal products is forbidden according to Royal Decree no. 1015/2009. Advertising medicinal products and medical devices without a marketing authorisation is also prohibited.

In certain specific cases, regulatory authorities, as well as the provisions of the FARMAINDUSTRIA Code, enable companies to make information available to HCPs and HCOs prior to the approval of the medicinal products, provided that it is merely scientific information, not advertising. However, a restrictive interpretation of this possibility is advisable, as any materials containing promotional statements will undoubtedly be considered advertising.

In this regard, objective, non-promotional scientific information on unauthorised medicinal products or unauthorised indications may be provided in congresses or meetings organised by scientific organisations, provided that certain conditions are met.

Regulatory authorities and the provisions of the FARMAINDUSTRIA Code allow promotional materials on medicinal products authorised in countries other than Spain to be distributed in international congresses or meetings held in Spain, provided that: numerous foreign professionals attend such events; materials are written in the language of the country where the product is approved (or in English); and they include a clear warning (at least in Spanish) indicating that the medicinal product is not marketed or authorised in Spain. Although the FARMAINDUSTRIA Code does not set a minimum font size for this warning, the lettering used in the warning must be compared to that of the remaining messages. By way of example, this warning cannot be included as a footnote in a small font size (see Ruling of the Jury of Advertising of AUTOCONTROL on the case "*Glaxosmithkline vs. Astrazeneca CD-PS 1/20 Symbicort®*", dated 7 July 2020).

In addition, according to Royal Decree no. 1015/2009, regarding the use of medicinal products in special situations, marketing authorisation holders may not distribute any type of information that may, directly or indirectly, stimulate the use of the medicinal product in conditions different from those resulting from its SmPC.

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?

Litigation on advertising, promotion and sale of drugs and medical devices usually involves competitor companies, and not patients or consumers.

Most of these cases of litigation are resolved before the Jury of Advertising of AUTOCONTROL in accordance with the agreements entered into by industry associations' self-regulatory bodies and AUTOCONTROL. Civil courts may also resolve disputes related to unfair competition and advertising if any interested parties initiate legal actions before these courts, as per Law no. 3/1991 on Unfair Competition (see question 1.3). In this regard, please also refer to the answers to questions 1.4 and 4.1.

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?

Life sciences companies operating in Spain must comply with Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation – "**GDPR**"), which is directly applicable in Spain. These companies must also comply with Organic Law no. 3/2018 on the protection of personal data and guarantee of digital rights, which adapts GDPR requirements to Spanish legislation. Each company must be able to provide documentary evidence that it complies with data protection obligations at all times. The Spanish Data Protection Agency is the competent authority overseeing compliance with data privacy provisions in Spain and is competent to conduct inspection and sanction procedures. Fines for non-compliance are high: up to EUR 20 million; or 4% of the company's worldwide turnover.

In addition, FARMAINDUSTRIA updated its Code of Practice in 2022, regulating the processing of personal data in the field of clinical trials and pharmacovigilance, which eased compliance with data protection obligations by adherent life sciences companies in these two particularly sensitive areas.

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?

As regards the confidentiality of documents produced in litigations, according to Organic Law no. 6/1985 of the Judicial Power (article 236) and Law no. 1/2000 on the Civil Procedure (article 212), access to documents produced in litigation is limited to the parties of the procedure, their lawyers and attorneys. The court may also adopt any measures that are necessary to redact personal data from documents that may be accessed by the parties. Moreover, the general public may access the text of the judgments once they are anonymised, and any personal data is redacted.

As regards trade secrets, article 15 of Spanish Law no. 1/2019 on Trade Secrets, which transposes Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure, states that the parties, their lawyers, the personnel of the Administration of Justice, witnesses, experts

and any other persons who intervene in a procedure related to the violation of a trade secret, or who have access to documents in this type of procedure due to their position or function, may not use or reveal information that may constitute a trade secret. Likewise, the court may, *ex officio* or upon reasoned request from one of the parties, adopt specific measures to preserve the confidentiality of information that may constitute a trade secret and has been disclosed in a procedure related to the violation of trade secrets (or of any other nature) in which this information is necessary to resolve on the merits.

Additionally, special rules apply to the confidentiality of documents produced in litigations related to damages arising from violations of competition law, intellectual property rights and unfair competition. In these cases, the court may adopt all necessary measures and actions to guarantee and preserve the confidentiality of any confidential information that is gathered from other parties to elucidate the relevant facts.

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

With regard to digital health, software and apps may, among others, be classified as medical devices, and hence must comply with regulations applicable to medical devices. In Spain, these regulations are mainly Royal Decree no. 1591/2009 on medical devices and Royal Decree no. 1616/2009 on active implantable medical devices, as well as Regulation (EU) 2017/745 on medical devices, which came into force in May 2021. If these devices collect health data of patients (*i.e.*, a special category of personal data according to GDPR), this data must be processed in accordance with article 9(2) GDPR and the patient must be provided with all the information listed in article 13 GDPR. The data controller must be able to prove that data has been processed in accordance with the legal information provided to the patient. On the other hand, health data must be protected with appropriate technical and organisational measures to ensure an appropriate level of security in relation to the risks.

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.

In Spain, clinical trials with medicinal products are specifically regulated by Royal Legislative Decree no. 1/2015 and Royal Decree no. 1090/2015.

According to the special liability regime set out in Royal Decree no. 1090/2015 for clinical trials, any personal damage to the participant during the trial and in the year following the end of treatment is presumed to have occurred as a result of the clinical trial, unless proven otherwise. In this regard, participants will be compensated for any personal damages caused as a result of participating in the clinical trial, and for economic damages deriving from personal damage, provided that this damage is not inherent either to:

(i) the pathology under analysis; or

(ii) the natural course of the disease of the participant as a result of the ineffectiveness of the treatment.

In Spain, any sponsor conducting clinical trials must contract civil liability insurance covering these damages as well as the sponsor, the principal investigator, the investigator's team and the site where the clinical trial is conducted. The minimum guaranteed amount is EUR 250,000 per trial participant. A cap of insured capital of EUR 2.5 million per yearly trial may be set.

However, any damages to the participants resulting from a "*low-intervention clinical trial*" do not need to be covered by a civil liability insurance contract if they are covered by the individual or group professional liability insurance of the site where the clinical trial is conducted.

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)?

Clinical trial protocols must describe the reasons, aims, design, methodology, statistical considerations and organisation of a clinical trial. In Spain, prior to authorising clinical trials, the AEMPS must previously assess the protocol, jointly with the ethics committee for research with medicinal products.

The clinical trial protocol approved by the competent authorities defines the profile and characteristics that clinical trial participants must meet. Only subjects that meet the profile and requirements set out in the protocol may be included to participate in a clinical trial.

Any damage caused by negligent failure of the participation test may be subject to compensation either in accordance with the special liability regime set out in Royal Decree no. 1090/2015 for clinical trials (please refer to the answer to question 6.1) or the general tort regime (please refer to the answer to question 2.3).

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

The compassionate use of unapproved medicinal products is specifically regulated in Royal Decree no. 1015/2009, which regulates the availability of medicines in special situations.

In accordance with the requirements set out in this Royal Decree, the AEMPS may authorise the compassionate use of unapproved medicinal products if it is proven that these products are needed to treat patients suffering from a chronic or seriously debilitating disease or one that is considered to be life-threatening and which cannot be treated satisfactorily with an authorised medicinal product. These medicinal products must be subject to a marketing authorisation application or must be undergoing clinical trial.

The sponsor of the clinical trial or the applicant for the marketing authorisation must state, in advance, its willingness to supply the unapproved medicinal products for compassionate use, as well as any other relevant information. Unapproved medicinal products may be accessed by way of (i) an authorisation of individualised access, or (ii) a temporary authorisation for use.

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

The only existing waivers of liability allowed for clinical trials are set out in Royal Decree no. 1090/2015.

As per our answer to question 6.1, Royal Decree no. 1090/2015 declares the obligation to compensate any personal damages resulting from participation in the clinical trial, as well as economic damages deriving from personal damages. It is

presumed (and may be rebutted) that any damage that affects the health of the trial subject during its performance and in the year following the end of the treatment occurred because of the trial.

Waivers of liability may only refer to the fact that the damage suffered by the participant is inherent either to (i) the pathology under analysis, or (ii) the natural course of the disease of the participant as a result of the ineffectiveness of the treatment.

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

There is no guidance that companies can follow to insulate or protect themselves from liability when proceeding with such programmes. However, as mentioned above, one of the conditions to conduct a clinical trial in Spain is to contract a civil liability insurance policy covering the civil liability of the sponsor, the principal investigator, the investigator's team, and the site against any claim brought by participants for damages suffered due to the clinical trial. The minimum guaranteed amount is EUR 250,000 per trial participant. A cap of insured capital of EUR 2.5 million per yearly trial may be set.

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.

Article 13 of RLD 1/2007 states that any entity involved in placing goods and services at the disposal of consumers and users must withdraw from the market, suspend marketing or recover from the consumer or user any goods or services that do not meet the necessary conditions or requirements, or which represent a foreseeable risk to personal health or safety on any other grounds.

According to article 51 of RLD 1/2007, the relevant public administration can order the precautionary or definitive withdrawal or recall of goods or services from the market on the grounds of health and safety.

The intentional or negligent supply of defective products can be a criminal offence under the Spanish Criminal Code, and the persons responsible for the crime can be liable for damages.

In the answer to the following question, we will explain the specific rules applicable to medicinal products and medical devices.

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?

Product recall schemes might differ between medicinal products and medical devices.

Regarding medicinal products

Product recall of medicinal products is mainly regulated in Royal Legislative Decree no. 1/2015 and Royal Decree no. 1345/2007, which regulate the authorisation procedure, registration and dispensing conditions of industrially manufactured medicines for human use.

Among other obligations, the holder of a marketing authorisation must:

(i) comply with pharmacovigilance obligations;
(ii) observe the conditions under which the marketing authorisation was granted, in addition to the general obligations set out in the law;
(iii) submit periodic safety reports set out by regulation, in order to keep the safety file updated;
(iv) make the results of clinical trials public, regardless of whether the outcome is favourable or not to their conclusions; and
(v) collaborate in the control programmes, ensure the suitability of the products on the market and report any possible withdrawal of batches from the market and notify the AEMPS, the Autonomous Regions and authorities of all countries where it has been distributed, with the appropriate speed for each case and stating the reasons of any action undertaken to withdraw a given lot from the market.

The AEMPS may decide to suspend, revoke or modify the authorisation of a medicinal product whenever:

(i) a medicinal product is considered to be harmful;
(ii) a medicinal product turns out to be therapeutically ineffective;
(iii) based on safety data, the medicinal product has an unfavourable benefit-risk ratio;
(iv) a medicinal product does not have the authorised quantitative or qualitative composition, quality guarantees are not fulfilled, or the required quality controls are not conducted;
(v) the data and information contained in the documentation are incorrect or do not comply with the applicable regulations;
(vi) the method of manufacture of the medicine or the control methods used by the manufacturer does not comply with those described in the authorisation;
(vii) the product poses a foreseeable risk to the health or safety of people or animals on any other grounds; or
(viii) the European Commission so decides.

Whenever an imminent and serious risk to health is reasonably suspected, the competent authorities, among others, may order:

(i) the withdrawal from the market and the prohibition of the medicinal products; and
(ii) the suspension of the preparation, prescription, dispensing and supply of drugs and medical devices under investigation.

Additionally, the distribution entities and, where appropriate, the pharmaceutical laboratories that directly distribute their products will be obliged to have an emergency plan that guarantees the effective application of any withdrawal from the market ordered by the competent health authorities.

Regarding medical devices

Product recall of medical devices is specifically regulated in Royal Decree no. 192/2023 and Regulation (EU) 2007/745. Under these provisions, the AEMPS and the other competent health authorities must take the necessary measures to comply with the procedure for devices presenting an unacceptable risk to health and safety established int article 95 of Regulation (EU) 2007/745. In accordance with this procedure:

(i) Where, having performed an evaluation pursuant to article 94 of the Regulation, the competent authorities find that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall without delay require the manufacturer of the devices concerned, its authorised representative and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements of this Regulation relating to the risk presented by the device and, in a manner that is proportionate to the nature of the risk, to restrict the making available of the device on the market, to subject the making available of the device to specific

requirements, to withdraw the device from the market, or to recall it, within a reasonable period that is clearly defined and communicated to the relevant economic operator.

(ii) The competent authorities shall, without delay, notify the European Commission, the other Member States and, where a certificate has been issued in accordance with article 56 of the Regulation for the device concerned, the notified body that issued that certificate, of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in article 100 of the Regulation.

(iii) The economic operators shall, without delay, ensure that all appropriate corrective action is taken throughout the EU in respect of all the devices concerned that they have made available on the market.

(iv) In addition, if the economic operator does not take adequate corrective action within the period previously mentioned, the competent authorities shall take all appropriate measures to prohibit or restrict the making available of the device on their national market, to withdraw the device from that market or to recall it. The competent authorities shall notify the European Commission, the other Member States and the notified body, without delay, of those measures, by means of the electronic system referred to in the Regulation. This notification shall include all available details, in particular the data necessary for the identification and tracing of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator

(v) Member States other than the Member State initiating the procedure shall, without delay, inform the European Commission and the other Member States, by means of the electronic system referred to in the Regulation, of any additional relevant information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall, without delay, inform the European Commission and the other Member States of their objections. This will lead to the initiation of the procedure for evaluating national measures at EU level established in article 96 of the Regulation.

Furthermore, the AEMPS and the other competent healthcare authorities are also competent to adopt appropriate precautionary measures whenever they consider that a medical device may compromise the health and/or safety of patients, users or third parties. These precautionary measures must be adopted in accordance with the procedure established in article 98 of Regulation (EU) 2007/745 for preventive health protection measures. In these cases, whenever the AEMPS considers that a specific product or group of products must be withdrawn from the market, prevented from being placed on the market, restricted or subject to special conditions so as to guarantee the protection of public health, safety or compliance with public health regulations, the AEMPS may adopt all necessary and interim measures and inform the European Commission and the other Member States, indicating the reasons for its decision.

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

The recall of a product by a competent authority may generate the presumption that the product does not offer the security that could legitimately be expected. However, this presumption could be rebutted with evidence regarding the safety of the product.

If the recall is due to a commercial decision of the company commercialising the product, this presumption may not be applicable unless there are other circumstances that may justify the lack of product safety.

In this regard, according to the European Court of Justice (in its judgment of 5 March 2015), in a case of voluntary recall by the manufacturer, a pacemaker was considered to be defective when a possible defect was found in a production series that advises on replacement, without the need to prove that each specific product had a defect that led to premature battery failure.

In another case of voluntary recall by the manufacturer, the Spanish Supreme Court, in its recent judgment of 1 March 2021, found that a hip prosthesis with an unexpected high rate of revision was defective, because the producer failed to prove that it was not possible to identify and disclose the proper rate of revision of the device when the product was put into circulation.

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?

Recall measures taken either by EU authorities or other EU Member States with an impact in Spain may be almost immediately enforced by Spanish competent authorities or followed by a product recall in Spain.

Although actions taken in the United States do not immediately imply the recall of a product in Spain, they may lead to the corresponding investigation proceedings at national or EU level.

Product recalls in the United States or Europe should have no impact on product liability litigations in Spain, if the products placed in the Spanish market are not affected by these recalls.

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

The implementation of internal investigations or risk assessment systems, including compliance programmes, may reduce or exclude criminal or administrative liability, but not civil liability for damages based on the general regime for product liability set out in RLD 1/2007.

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

If the product is likely to cause damages, companies should first adopt all the necessary measures to prevent the product placed on the market from continuing to generate damages, so as to prevent future litigation and liabilities. This may include taking all necessary measures to ensure both that the information is well disseminated, as well as the effectiveness of a complete, timely product recall.

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.

Article 11 of Law no. 1/2000 on the Civil Procedure permits

collective legal proceedings. It furthers states that legally established consumer and user associations may defend the rights and interests of their members and of the association in court, as well as the general interests of consumers and users, without prejudice to the individual legitimacy of the injured persons.

Whenever a group of consumers or users that are perfectly determined or may be easily determined are damaged by a harmful event (*e.g.*, by a defective product), the following persons may request the protection of collective interests: (i) associations of consumers and users; (ii) legally established entities whose purpose is to defend or protect these consumers and users; or (iii) the group of injured parties.

However, whenever a group of consumers or users that is undetermined or difficult to determine are damaged by a harmful event, only the associations of consumers and users that are part of the Consumers and Users Council may request the protection of collective interests. If the territorial scope of the conflict mainly affects one specific Autonomous Region, the specific legislation of the Autonomous Region shall apply.

The Attorney General's Office may also initiate actions in defence of the interests of consumers and users.

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

Product liability claims are usually initiated by individual plaintiffs. Collective or class actions are not very common in Spain in these types of cases.

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 general regime on liability for defective products is set out in articles 128 to 146 of RLD 1/2007. The actions available under RLD 1/2007 do not affect any other right to damages, including moral damages, that the injured party may be entitled to under contractual liability, based on the lack of conformity of the goods or services, non-performance or defective performance of the contract, or under any non-contractual liability.

The liability regime for defective products is strict. The injured party seeking to repair the damage will have to prove the defect, the damage and the causal relationship between the two. To establish the causal relationship between the defect in the product and the damages suffered, the claimant must provide solid, substantial evidence, and the damages must be an appropriate and sufficient result of the defect. Occasionally, the Spanish courts accept the use of presumptions or circumstantial evidence to prove a causal relationship.

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

Any lawyer is allowed to advertise his or her services, as far as he or she complies with the legislation on advertising, unfair competition provisions, the General Statute of the Lawyer, as well as the applicable Codes of Ethics.

Advertising by lawyers must always respect independence, freedom, dignity and integrity as essential principles and superior values of the profession, as well as professional secrecy.

In this regard, among others, lawyers are not allowed to offer professional services, by itself or through third parties, to direct or indirect victims of accidents or misfortunes, as well as catastrophes, public calamities or other events that have produced a high number of victims, whether or not criminal, at times or circumstances that condition the free choice of a lawyer, and in any case until 45 days after the event. This prohibition shall understand without effect if the provision of these professional services has been expressly requested by the victim.

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

Individuals, associations of public interest and foundations may have access to the public funding system (legal aid) if they have insufficient economical resources to litigate. This legal aid system is regulated in Law no. 1/1996, of 10 January, on Legal Aid.

Litigants may also resort to third-party funding systems. This matter is not specifically regulated in Spain, other than in article 1255 of the Civil Code, which states that: "*The contracting parties may establish any covenants, clauses and conditions deemed convenient, provided that they are not contrary to the laws, to the morals or to public policy.*" Therefore, provided that it is not contrary to the law, morals or public order, any agreement in this regard is valid.

At the EU level, the European Parliament has launched the implementation of regulations on the private funding of litigation. On 13 September 2022, the European Parliament adopted a resolution with recommendations to the European Commission on responsible private litigation funding. Directive 2020/1828 ("**Collective Redress Directive**") of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers also contains provisions regarding third-party funding of representative actions.

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?

The effects of *res judicata* produced by final judgments only apply to the parties of a litigation procedure. Therefore, if a company is found liable in a given case, this may not necessarily have the effects of *res judicata* in subsequent cases affecting other claimants.

Different claimants are also allowed to file different complaints claiming that a similar product is defective and caused a certain type of damage. In each separate proceeding, the judge will assess whether the specific product was defective and whether it caused the specific type of damage alleged by the claimant.

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?

Implementing improvement measures may have a positive effect on litigation if they induce the judge to believe that the company implemented all necessary measures to mitigate the damage caused. However, in some cases, implementing corrective measures may be detrimental to litigation if they induce the judge to believe that the company did not previously adopt all reasonable measures to avoid the damage caused.

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?

Under Spanish law, no general discovery obligations apply to litigating parties, whether in court or out-of-court.

The Spanish civil system is based on the principle that parties produce their own evidence (*i.e.*, each party in a litigation procedure must obtain and submit its own evidence to support its case in court). The plaintiff may produce any evidence that it considers necessary to prove that a given product is defective, including depositions of other users that suffered the same adverse events.

Exceptionally, and only in cases where the applicant is unable to obtain certain data that is necessary to file a claim, prior to filing the lawsuit, the applicant may request the judge to provide access to specific sources of evidence provided for in the law, such as:

(i) any interested party may request a copy of the medical records from the healthcare centre or professional holding these records; or

(ii) an individual who believes to have been damaged by an event that could be covered by civil liability insurance may request that the insurance contract be exhibited.

Additionally, at the preliminary hearing, any litigant may request the judge to order the other party, or third parties unrelated to the proceedings, to exhibit any document related to the subject matter. In this request, the applicant must: (i) prove that the document is not available to the applicant and impossible to obtain; (ii) prove that the document refers to the subject matter of the procedure (*i.e.*, it is documentary evidence relevant to the case) or to the effectiveness of other means of proof (*i.e.*, it grants or withdraws effectiveness to other evidence that has been submitted); and (iii) provide a photocopy or simple copy of the document or indicate its content in the most exact terms possible.

New legislative initiatives of the EU, such as Directive 2014/104/EU (governing actions for damages related to antitrust infringements) and the Collective Redress Directive (on representative actions for the protection of the collective interests of consumers), establish certain disclosure of evidence systems aimed to allow the plaintiff in these proceedings to have access to evidence (documentation, information and evidence that is in the control of the defendant or a third party) that is relevant to the action being brought (please refer to the answer to question 8.15 for the transposition of the Collective Redress Directive in Spain).

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 main rules for conducting depositions of company witnesses located in Spain for use in litigations pending abroad are (i) Regulation no. 1206/2001/CE if the request is formulated by a plaintiff or defendant located in the EU, or (ii) the Hague Convention of 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters if the request is formulated by a plaintiff or defendant located outside the EU.

In this regard, although the Hague Convention was intended to apply to any phase of the process or judicial action, various countries, including Spain, made a reservation to the Convention whereby they do not accept letters of request derived from discovery of common law countries (according to article 23 of the Convention).

In the context of the execution of a letter of request under the Hague Convention, the relevant person may refuse to give evidence if he or she has a privilege or duty to refuse to give the evidence. Additionally, a letter of request may also be denied if the judge in Spain deems that complying with the letter of request could cause damage to Spanish sovereignty or national security.

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?

In Spain, professional privilege is mainly regulated in the Organic Law of the Judicial Power and Royal Decree no. 135/2021 approving the General Statute of Spanish Lawyers.

Professional privilege covers:

(a) all the facts, communications, data, information, documents, reports or proposals that a lawyer or his or her team have become aware of, issued or received as part of their professional practice; and

(b) communications between lawyers outlining which content may not be revealed in court as evidence, or provided to clients via a copy, unless disclosure is expressly authorised by the lawyers of the other party. This prohibition, however, does not apply to letters, documents, and notes in which the lawyer acted with a representative mandate of its client and expressly stated it.

The application of confidential privilege to in-house counsel is more controversial, especially following the Judgment of the European Court of Justice of 14 September 2020 (Akzo Nobel *et al.*). In this case, the European Court of Justice stated that, in the context of inquiring measures in competition matters, attorney-client privilege should not apply to in-house counsel, because they are company employees, and their independence may be affected.

However, following the entry into force of the new General Statute of Spanish Lawyers in July 2021, it seems more possible to apply the professional privilege to in-house counsel provided that: (i) they acted as attorneys (not as mere representatives of the company); and (ii) they expressed to have professional privilege when communicating with the company.

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?

Communications of companies with external counsel are protected by the attorney-client privilege.

In order to make visible that a document/communication containing confidential information is protected by attorney-client privilege, it is recommended to state clearly that it is subject to attorney-client privilege.

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

It will depend on whether the foreign defendant is domiciled in an EU Member State or a third country that has subscribed to an international treaty with Spain regarding these matters.

Domiciled in an EU Member State

In these cases, the jurisdiction of Spanish courts follows from Regulation (EU) 1215/2012 on the jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.

In this context, defendants that are not domiciled in Spain may be sued before the Spanish courts in the following cases, among others:

(i) in matters relating to a contract, if Spain is the place of performance of the contract;
(ii) in matters relating to tort, delict or quasi-delict, if Spain is the place where the harmful event occurred or may occur;
(iii) in matters relating to consumers, if the consumer is domiciled in Spain; or
(iv) if the parties so agree, or if the defendant appears before a Spanish court (this shall not apply where appearance was entered to contest the jurisdiction or where another court has exclusive jurisdiction by virtue of Regulation (EU) 1215/2012).

Domiciled in a non-EU Member State

In the absence of an international treaty, the jurisdiction of Spanish courts will be governed by the domestic rules. Hence, defendants not domiciled in Spain may be sued before the Spanish courts in the following cases, among others:

(i) if the parties so agree, or if the defendant appears before a Spanish court (this shall not apply where appearance was entered to contest the jurisdiction);
(ii) regarding contractual obligations, when the obligation that is the object of the claim has been fulfilled or must be fulfilled in Spain;
(iii) regarding non-contractual obligations, whenever the harmful event occurred in Spanish territory; and
(iv) in matters related to consumers, if the consumer has its habitual residence in Spain.

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

Judicial decisions from the U.S. may be recognised and enforced in Spain through an exequatur proceeding. Through recognition, the foreign decision may produce the same effects in Spain as in the state of origin.

If the exequatur is filed in Spain, the defendant may oppose recognition on the following grounds, which may lead to the rejection of the exequatur:

(i) the judicial decision is contrary to public order;
(ii) the judicial decision was rendered in manifest breach of the rights of defence of either party. If the decision was rendered *in absentia*, it is understood that there is a manifest infringement of the rights of defence if the defendant was not served with a writ of summons or equivalent document in a regular fashion and in sufficient time to enable him or her to defend himself or herself;
(iii) the foreign judgment has been pronounced on a matter in which the Spanish courts have exclusive jurisdiction or, on the rest of the matters, if the jurisdiction of the judge of origin does not have a reasonable connection. The existence of a reasonable connection with the dispute shall be presumed when the foreign court has based its international jurisdiction on criteria similar to those provided for in Spanish law;
(iv) the resolution is incompatible with a judgment rendered in Spain;
(v) the resolution is incompatible with an earlier judgment given in another state, when the latter judgment fulfils the conditions necessary for its recognition in Spain; and
(vi) there is a pending litigation in Spain between the same parties and with the same object, initiated prior to the process in a foreign state.

U.S. resolutions rendered in class action procedures may also be recognised and enforced. For them to be enforceable in Spain for parties who have not expressly adhered to the class action, the foreign class action must have been communicated or published in Spain by means equivalent to those required under Spanish law, and the relevant parties must have had the same opportunities to participate or separate from the class action procedure than those domiciled in the state of origin. Additionally, in these cases, the foreign resolution will not be recognised whenever the jurisdiction of the court of origin was not based on a forum equivalent to those provided for under Spanish law.

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

U.S. litigation may not influence litigation in Spain because both countries have different rules to determine liability and damages. However, specific effects must be determined on a case-by-case basis. The likelihood of litigation evolving in Spain as a result of U.S. litigation must be assessed also on a case-by-case basis.

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.

As for the Collective Redress Directive, the Spanish Government's first preliminary draft law to transpose the Directive was published on 9 January 2023, which was followed by a period of public discussions. Once the final draft receives approval from the Council of Ministers, it will be debated and enacted by the Spanish Parliament. One of the developments of the Directive is to include a system of disclosure of evidence that allows qualified entities intending to bring a representative action to request that the defendant or a third party discloses certain pieces of evidence under its control that are relevant for the action to be brought.

As for the proposed Product Liability Directive ("**PLD**"), in September 2022, the European Commission of the EU published a proposal for a new Directive of the European Parliament and of the Council on liability for defective products. This proposal foresees certain measures that may have a relevant impact on the litigation of drugs and medical devices in Spain, such as:

a) a list of non-exhaustive circumstances to be considered when assessing defectiveness, including (i) the presentation of the product (including its instructions for use); (ii) the reasonably foreseeable use and misuse of the product; (iii) product safety requirements; and (iv) any intervention of by a regulatory authority or an economic operator responsible for the safety of the product. As in the current regulation, the proposal provides that in no case shall a product be considered defective because a better product or an improved or upgraded version of the product is subsequently placed on the market;
b) a new system of disclosure of evidence and presumptions, which aims to make it easier for the claimants to prove the defect and the causal link in complex cases; and
c) grounds that will allow the defendant to be exonerated from liability even if it is proven that the damage was caused by a product that is found to be defective. Among other grounds, the new proposal allows defendants to invoke that "*the objective state of scientific and technical knowledge*

at the time when the product was placed on the market, put into service or in the period in which the product was within the manufacturer's control was not such that the defectiveness could be discovered". The current provisions in Spain exclude this possibility with regard to medicinal products, but this should be modified if the proposal is finally enacted.

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