International
Comparative
Legal Guides

Drug & Medical Device Litigation 2021

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

Second Edition

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ICLG.com

Expert Analysis Chapter

Q&A Chapters

Spain

Xavier Moliner

Juan Martínez

Faus & Moliner Abogados

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 Parliament and Senate are the principal legislative bodies for enacting legislative initiatives regarding medicinal products, medical devices, supplements, over-the-counter ("**OTC**") products and cosmetics. The life sciences sector is also subject to EU regulations and directives.

The main regulatory authority regarding technical aspects and surveillance of medicinal products, medical devices, cosmetics and personal care products is the Spanish Agency on Medicines and Medical Devices ("**AEMPS**"). Regarding supplements, the competent regulatory agency is the Spanish Agency for Food Safety and Nutrition. In addition, regional authorities (Spain is divided into 17 autonomous regions) are also responsible for controlling advertisement, performing inspections of manufacturing and distribution premises and performing all necessary controls to ensure that the products comply with applicable regulations.

The Spanish Ministry of Health ("**MoH**") is the department of the central Spanish government responsible for, among other things, drafting and implementing rules on pricing and reimbursement of medicinal products that are financed through public funds in Spain. Healthcare authorities of the 17 regions also participate in the committee of the MoH, responsible for assessing applications relating to the price and reimbursement of medicines, as the public funds used to finance reimbursement of medicinal products come out of their budgets.

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 for defective products regime is established in Royal Legislative Decree 1/2007 of 16 November, which approves the consolidated text of the General Law on the Protection of Consumers and Users and other complementary regulations ("**RLD 1/2007**").

The general regime for product liability set forth in RLD 1/2007 is mainly of a strict nature. Under this regime, the "producer" of a defective product will be liable for any damage caused by death or by personal injuries, and/or any damage to, or destruction of, any item of property other than the defective product itself, provided that the item of property is of a type ordinarily intended for private use or consumption and was used by the injured person mainly for his own private use or consumption. It will be on the claimant to prove that the product was defective, the damage occurred and the causal link between the defective product and the damage suffered.

This strict liability system does not preclude other liability systems providing an injured party with greater protection, nor does it affect any other right to damages, including moral damages, that the injured party may have as a consequence of contractual liability, based on the lack of conformity of the goods or any other cause of non-performance or defective performance of the contract, or of any other non-contractual liability (general torts regimen) that may apply.

The authorisation of a medicinal product or the EU certification of a medical device do not exclude any potential claim by an injured party based either on the product liability regime, the general torts regime, or the contractual liability basis. However, the compliance of the requirements set forth in regulations/legislation for placing the product on the market may be used by defendants to reduce or exempt their liability.

The same goes for supplements, although these products are not subject to marketing authorisation but just to a notification of the product being placed on the market.

In addition, regarding medical devices, notified bodies might be also subject to general torts liability if they breach faulty or negligently their obligations conducting the conformity test.

It is also possible to file a complaint against the regulatory authority that authorised the defective product, based on the general regime on liability of the public administrations. This is possible when the damage is derived from facts or circumstances that could be prevented or avoided, according to the knowledge of science or techniques 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?

Breach of regulations of life sciences products may also motivate litigations between competitors.

Infringement of either regulations/laws that regulate the concurrent activity is considered unfair under Law 3/1991 on Unfair Competition. To prevail in the market of a competitive advantage acquired through the violation of the laws is also considered unfair under the same Law. Also, in case advertising of products breaches the Spanish General Law 34/1988 on Advertising, it will be deemed as unfair conduct under Law 3/1991.

Against 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 repetition (this may be exercised even if the conduct has not yet been put into practice);
(iii) a removal action for the effects produced by the unfair conduct;
(iv) an action to rectify misleading, incorrect or false information;
(v) a compensation action for damages caused by unfair conduct, if fraud or fault of the agent has intervened; and
(vi) an action of unjust enrichment, which will be only applicable when the unfair conduct damages a legal position protected by an exclusive right or another 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. FARMAINDUSTRIA is the national trade association of the Spanish-based pharmaceutical industry. It acts as the self-regulatory body for all pharmaceutical companies that have adopted its Code of Practice ("**Code of FARMAINDUSTRIA**"), which regulates the interaction of the pharmaceutical industry with healthcare professionals ("**HCPs**"), healthcare organisations ("**HCOs**"), and patient organisations ("**POs**") regarding medicinal products. FENIN is the national trade association of the medical devices industry. It acts as the self-regulatory body for all medical devices companies that have also adopted its Code of Practice ("**Code of FENIN**"), which regulates the interaction of the medical devices industry with HCPs, HCOs and POs regarding medical devices. ANEFP is the Spanish OTC industry association, which has also approved its own Code of Conduct on the promotion of OTC ("**Code of ANEFP**").

Additionally, AUTOCONTROL is the main association for self-regulation regarding advertising.

During the last few years, the number of complaints filed by companies before national courts in respect of competitor's advertising materials or promotional activities has decreased sharply. In contrast, the bodies responsible for ensuring compliance with the Code of FARMAINDUSTRIA were very active during said period, resulting in an increasing number of cases wherein companies had to adopt corrective measures. In some cases, settlement was accompanied by 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 a great impact on unfair conduct litigation and regulate certain interactions of the companies subject to them. Before going into national courts for claiming the cessation or rectification of certain unfair conduct, some companies consider going to self-regulation bodies to claim the cessation or rectification of such conduct.

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

The absence of necessary warnings or instructions for use, or the inaccuracy of such information, may give rise to an information defect. Therefore, when the product's information is not correct or is insufficient, such product may be deemed to be defective and may give rise to liability in the event that the product causes damages.

The information is considered to be appropriate when it allows the identification, assessment or reduction of the announced risk. The information is also considered to be appropriate when there is a balance between the information on the safety of the product in possession of the manufacturer, and the information made available to consumers.

Moreover, the producer shall be held liable for the absence of appropriate information only regarding reasonably foreseeable risks (i.e., in case the producer is aware of specific risks, or should be aware as required by a reasonable diligence). Within the framework of the regime for product liability established 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 the consumer's reasonable expectations". Further, within the scope of the consumer's legitimate expectations, only the information that was known by the producer or that, in accordance with the state of scientific and technical knowledge, should have been known by him at the moment of placing the product on the market, must be included.

As a general rule, the information and warnings that shall be considered in order to determine whether a product suffers from an information defect shall be the information provided directly to the user of the product.

However, regarding certain type of products in connection to which the intervention of an intermediary person is required, the courts may consider the information provided to such intermediary person so as to determine whether the information provided to the consumer, user or patient shall be understood to be sufficient and appropriate. This is the case for medicinal products.

Basic Law 41/2002 of 14 November, governing patient autonomy and rights and obligations as regards clinical information and documentation, establishes that it is the doctor's obligation to guarantee that the patient has all the necessary information to freely decide on the therapeutic strategy prescribed by the doctor. However, the information provided by the manufacturer to the doctor will be considered in order to assess the correctness and adequacy of the information provided to the patient.

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?

The requirements are different for the manufacture of medicines (including OTC medicines), medical devices, food supplements and cosmetic products.

Requirements set forth for the manufacture of medicines

Industrial manufacturing of medicinal products (both for human and veterinary use) in Spain requires prior authorisation from the AEMPS.

To obtain authorisation for the manufacturing of industrial medicinal products, applicants must provide the AEMPS with: (i) a description of a technical report on the medicinal products

that the applicant intends to manufacture, as well as a description of the premises where the quality control of the medicinal products will be performed; (ii) evidence that the applicant has sufficient and adequate premises, and the technical equipment required for the manufacturing of the medicinal products that the applicant intends to manufacture; and (iii) evidence that the applicant is advised by a duly qualified technical director (known as the "qualified person" under EU regulations) and responsible persons performing quality controls and manufacturing activities. If only small quantities or non-complex products are manufactured, the responsibilities for quality control may be assumed by a technical director.

Manufacturers are also required to observe the standards set forth in the guidelines issued by the European Medicines Agency on Good Manufacturing Practices.

Requirements set forth for the manufacture of medical devices

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

In order to be granted with such licence, the applicant will need to prove: (a) the availability of an organisational structure capable of guaranteeing the quality of the products and the execution of the appropriate procedures and controls; (b) the availability of adequate facilities, procedures, equipment and personnel according to the activities and products concerned; (c) the availability of a technical manager, with an adequate university degree to oversee the products to be produced; (d) the availability of a system file to store the documentation generated with each product manufactured or imported and to keep a record of all products; (e) the availability of a contact person for actions related to the Surveillance System; and (f) the availability of a procedure to apply appropriate restrictions on the use of the products and follow-up measures when needed, as well as any others that might be determined by the authorities.

All medical devices are required to hold the CE marking, proving compliance with the technical requirements and specifications applicable. Placing medical devices on the Spanish market requires the notified body to have verified and certified the manufacturer's procedures, their safety and quality (except for Class I medical devices).

Food supplements

The companies responsible for the production, processing, packaging, storage, distribution, import and marketing of 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 activities. The information that the operator of the company must provide will be the following: (a) its name or company name; (b) the relevant tax number (NIF, NIE or CIF); (c) the object of all its activities; and (d) the headquarters of the establishment or, in the case of companies that do not have any establishment, the registered office.

Cosmetics

Manufacturers of cometic products must submit a responsible statement to the AEMPS with the following content: (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 to which the responsible declaration refers, whether they are carried out materially by the holder or by subcontracted companies: bulk manufacturing; conditioning (packaging and labelling); control; storage; and importation; (d) information on the facilities or plants where the activities will be developed: name; address; and tax identification code; (e) categories and cosmetic forms that are the object of the activities; (f) expected start date of the activities covered by the declaration; and (g) a statement indicating that the manufacturer complies with the requirements and obligations inherent to the exercise of the manufacturing and importing activity, that the manufacturer has all the supportive documentation and commits to complying with the technical requirements set forth in the applicable regulations (regarding 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?

The EU has mutual recognition agreements regarding inspection of manufacturing facilities for medicines with Australia, Canada, Israel, Japan, New Zealand, Switzerland and the United States.

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

Violation or compliance with manufacturing requirements may have a direct impact, either on product liability litigation, contractual litigation, general torts litigation or unfair competition litigation.

From a product liability perspective

Under the product liability regime of RLD 1/2007, a product might be considered to be defective if it does not offer the security that might legitimately be expected, considering all the circumstances and, especially, its presentation, its reasonably foreseeable use and the moment it is put into circulation. In all cases, a product is defective if it does not offer the security normally offered by the other copies of the same series.

If, as a consequence of a violation of a manufacturing requirement, a product does not offer the security that might legitimately be expected, and causes damages, its producer may be subject to the strict liability regime foreseen in RLD 1/2007 for defective products.

However, the producer will not be liable if he proves that the defect was because the product was manufactured according to existing mandatory standards (ex. article 140.1 e) of RLD 1/2007).

From a contract litigation perspective

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

A breach of the obligations derived from a contract is subject to compensation for damages, which may include consequential damages and loss of profits.

From a general torts litigation perspective

Under the general torts regime, anyone who by action or omission causes damage to another, in case of fault or negligence, is obliged to repair the damage caused. This compensation may also include consequential damages and loss of profits.

From an unfair competition litigation perspective

See question 1.3 above.

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 approval requirement from local regulators regarding life sciences mergers/acquisitions.

However, Spanish Competition Law 15/2007 of 3 July and Royal Decree 261/2008 of 22 February set forth a prior notification system for any concentration meeting the legal thresholds referred to in said rules. 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 when, 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% of the national level or in a geographic market defined within it. This will not be applied in cases where the global turnover in Spain of the acquired company or of the assets acquired in the last accounting year does 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 affected markets, at the national level or in a geographic market defined within it.

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 of more than EUR 60 million.

In case any of the abovementioned 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 has been received.

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.

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.

General rules on advertising are set out in General Law 34/1988 on Advertising and Law 3/1991 on Unfair Competition. The provisions contained in EU directives on advertising of medicinal products and medical devices have been implemented in Spain through Royal Legislative Decree 1/2015 on guarantees and rational use of medicinal products and medical devices, Royal Decree 1416/1994 on advertising of medicinal products for human use, and Royal Decree 1591/2009 on medical devices.

Regarding medicinal products, the MoH issued an Instruction in 1995 (Circular 6/1995, amended by Circular 7/99) regarding the interpretation of Royal Decree 1416/1994.

In addition, the 17 Spanish autonomous regions are competent for the implementation of rules on 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 1/2015, approving the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices, is also noteworthy as it sets forth the sanctions for 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 Code of FARMAINDUSTRIA, which regulates the advertising of prescription-only medicinal products as well as interactions between pharmaceutical companies and HCPs, HCOs and POs. It has been recently updated by a new 2021 version, which came into force this year. This new 2021 version of the Code of FARMAINDUSTRIA introduces some new aspects regarding areas such as social media and the digital environment, relationships between companies and HCPs, POs, and the media.

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

(iii) AESEG – the Spanish generic medicinal products industry association – and the Code of ANEFP – the Spanish OTC medicinal products industry association – among others, have also adopted their own codes of conduct on the promotion of medicinal products.

(iv) The Code of ANEFP sets forth particular provisions on the advertising of self-care and other OTC products.

Responsibility for enforcing advertising rules (other than those resulting from industry codes of conduct) lies with the health authorities of the Spanish regions and courts. The industry codes of conduct are enforced by industry associations' self-regulatory bodies in agreement with AUTOCONTROL, a Spanish association that acts 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")?

Advertising of medicinal products and medical devices that have not obtained a marketing authorisation is not allowed.

In some specific cases, regulatory authorities, as well as the provisions of the Code of FARMAINDUSTRIA, accept the possibility of companies making information available to HCPs and HCOs prior to the approval of the medicinal products if it is merely scientific information, instead of advertising activity. However, it is advisable to take a rather restrictive approach regarding these activities, as any materials containing promotional statements will undoubtedly be considered advertising.

In this regard, objective and non-promotional scientific information on unauthorised medicinal products or unauthorised indications may be provided during congresses or meetings organised by a prestigious scientific society, provided certain conditions are respected.

Regulatory authorities and the provisions of the Code of FARMAINDUSTRIA accept that promotional materials on medicinal products authorised in countries other than Spain may be distributed during international congresses or meetings held in Spain, provided that the congress or meeting is attended by numerous professionals from other countries, that the materials are written in the language of the country where the product is approved or in English, and that the materials include a clear warning indicating (at least in Spanish) that the medicinal product is not marketed or authorised in Spain. Although the Code of FARMAINDUSTRIA does not set a minimum font size for this warning, this is something that must be checked by comparing the letters used in the warning to those used in the rest of the messages. Therefore, including this warning as a footnote using a small font size is not enough (see Ruling of the Jury of Advertising of AUTOCONTROL on the case "*Glaxosmithkline vs. Astrazeneca CD-PS 1/20 Symbicort®*", dated 7 July 2020).

Additionally, according to Royal Decree 1015/2009, which regulates the use of medicinal products in special situations, marketing authorisation holders must 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?

Litigations on advertising, promotion and sale of drugs and medical devices usually involve competitor companies rather than patients or consumers.

Most of these litigations are usually resolved before the Jury of Advertising of AUTOCONTROL in accordance with the agreements subscribed between industry associations' self-regulatory bodies and AUTOCONTROL. In addition, civil courts may also resolve disputes related to unfair competition and advertising in case any interested party exercises before them any of the legal actions foreseen in Law 3/1991 on Unfair Competition (see question 1.3). In this regard, see also questions 1.4 and 4.1.

5 Data Privacy

5.1 How do life sciences companies that distribute their products globally comply with GDPR 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**"), since this regulation is directly applicable in Spain. Such companies must also comply with Organic Law 3/2018 on the protection of personal data and guarantee of digital rights, as this norm implements GDPR requirements in Spanish law. Each company must be in a position to provide documentary proof that it complies at all times with its obligations in terms of data protection. The Spanish Data Protection Agency is the competent authority on data privacy in Spain, with specific powers of inspection and sanction. Fines in case of infringement are high: up to EUR 20 million or 4% of the company's worldwide turnover.

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 a rule, according to Organic Law 6/1985 on the Judiciary (article 236) and Law 1/2000 on Civil Procedure (article 212), access to documents produced in litigation in Spain is limited to the parties to the judicial procedure and their lawyers and attorneys. However, in this case, the court may adopt any measures that are necessary for the suppression of personal data from the documents to which the parties have access. Besides, access by the public to the text of the judgments is allowed, in any case after anonymisation of any personal data that they may contain.

As regards trade secrets, article 15 of Spanish Law 1/2019 on Trade Secrets, which implements Directive (EU) 2016/943 concerning the preservation of confidentiality of trade secrets in the course of legal proceedings into Spanish law, establishes that the parties, their lawyers, the personnel of the Administration of Justice, the witnesses, the 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 said procedure by reason of their position or the function they perform, may not use or reveal information that may constitute a trade secret. Likewise, the court may, *ex officio* or upon a reasoned request from one of the parties, adopt the specific measures necessary to preserve the confidentiality of the information that may constitute a trade secret and has been contributed to a procedure related to the violation of trade secrets (or to a procedure of another type) in which its consideration is necessary to resolve on the merits.

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

In the area of Digital Health, software, apps and similar that may be classified as medical devices must comply with regulations on medical devices. In Spain, such regulations are mainly Royal Decree 1591/2009, regulating medical devices and Royal Decree 1616/2009, regulating the active implantable medical devices. In the event that such devices collect health data of patients (i.e., a special category of personal data according to GDPR), such data processing must rely on any of the legal bases provided in article 9.2 GDPR and the patient must be provided with all the information indicated in article 13 GDPR. The data controller must be able to prove that said processing has been carried out in accordance with the legal basis informed to the patient. On the other hand, health data must be protected with appropriate technical and organisational measures to ensure a level of security appropriate to the risk.

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.

The performance of clinical trials with medicinal products in Spain is mainly regulated by Royal Legislative Decree 1/2015 and Royal Decree 1090/2015.

According to the special liability regime set forth in Royal Decree 1090/2015 for clinical trials, participants will be compensated against any personal damage caused as a result of their participation in the clinical trial, as well as the economic damages that derived from said personal damage, provided that this damage is not inherent either to:

(i) the pathology under study; or

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

It is a condition for conducting clinical trials in Spain that the sponsor hires a civil liability insurance covering those damages caused, either by the sponsor, the principal investigator, the investigator's team and the site where the clinical trial is conducted. The minimum guaranteed amount shall be EUR 250,000 per trial participant. A maximum insured capital per trial and per year of EUR 2.5 million may be established.

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)?

The clinical trial protocols shall describe the reasons, objectives, design, methodology, statistical considerations, and organisation of a clinical trial. The authorising of clinical trials in Spain by the AEMPS requires prior assessment of the protocol, which is done jointly by the AEMPS and 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 established in the protocol may be included to participate in a clinical trial.

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, compassionate use of unapproved medicinal products is specifically regulated in Royal Decree 1015/2009, which regulates the availability of medicines in special situations.

In accordance with the requirements established in said Royal Decree, the AEMPS may authorise the compassionate use of unapproved medicinal products if it is verified that the use of said products is needed to treat patients who suffer 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. The medicinal products in question must be subject to a marketing authorisation application or must be undergoing clinical trial.

In advance, the sponsor of the clinical trial or the applicant for the marketing authorisation must state their willingness to supply the unapproved medicinal products for compassionate use, as well as any other relevant information in this regard. Access to the use of unapproved medicinal products may be made through (i) an authorisation of individualised access, or (ii) the granting of temporary authorisation for use.

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

The only waivers of liability allowed for clinical trial are those expressly provided by Royal Decree 1090/2015.

As previously mentioned in question 6.1, Royal Decree 1090/2015 establishes the obligation to compensate any personal damage caused because of their participation in the clinical trial, as well as the economic damages that derived from said personal damage. There is a presumption (which 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 has occurred because of the trial.

Waivers of liability may only refer to the fact that the damage suffered by the subject of the trial is inherent either to (i) the pathology under study, 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 in this regard. However, under Spanish law, one of the conditions for conducting a clinical trial is the contracting, by the sponsor, of a civil liability insurance 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 shall be EUR 250,000 per trial subject. A maximum insured capital per trial and per year of EUR 2.5 million may be established.

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 establishes 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.

Under 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.

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 1/2015 and Royal Decree 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 is obliged to:

(i) comply its pharmacovigilance obligations;
(ii) observe the conditions under which the marketing authorisation was granted, in addition to the general obligations established in the legislation;
(iii) submit periodic safety reports established by regulation, in order to keep the safety file updated;
(iv) make the results of clinical trials public, regardless of the favourable outcome or not of their conclusions; and

(v) collaborate in the control programmes, guarantee 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 lot from the market.

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

(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, the quality guarantees are not fulfilled, or the required quality controls are not carried out;
(v) the data and information contained in the documentation are erroneous or do not comply with the applicable regulations on the matter;
(vi) the method of manufacture of the medicine or the control methods used by the manufacturer do not comply with those described in the authorisation;
(vii) for any other cause that poses a foreseeable risk to the health or safety of people or animals; or
(viii) in any other case in which the European Commission has so decided.

In case the existence of 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 1591/2009 on medical devices, which establishes that manufacturers, authorised representatives, importers and distributors must cooperate with the authorities in the adoption of such measures and execute any restriction measures on the placing on the market or the commercialisation of their products, as well as their withdrawal from the market, recovery of the users or any follow-up measure of the use of the products, as well as those that, where appropriate, may be determined by the health authorities, in case of suspicion or evidence of risk to health.

In this regard, manufacturers, authorised representatives, importers, and/or distributors must notify the AEMPS of:

(i) any malfunction or alteration of the characteristics or performance of the product, as well as any inadequacy of the labelling or of the instructions for use that led or may have led to the death or serious deterioration of the health status of a patient or user; and
(ii) any reason of a technical or sanitary nature linked to the characteristics or benefits of a product that, for the reasons mentioned in the previous point, has induced the manufacturer to take systematic action on products of the same type.

In this notification, they shall also inform about the corrective measures that may proceed. Before taking any action intended to communicate prevention measures, withdrawal, or other corrective actions, as well as any warning related to marketed products, they must notify their intention to the AEMPS. The AEMPS may determine the convenience of executing the proposed measures, and prevent or modify them for justified public health reasons.

Additionally, if a notified body observes that the manufacturer does not comply or has ceased to comply with the relevant requirements established by law, or that a certificate should not have been issued, it will suspend, subject to restrictions, or withdraw the issued certificate, bearing in mind the principle of proportionality, unless the manufacturer guarantees compliance with these requirements by applying effective corrective measures. In those cases, or in those cases in which the intervention of the competent authority may be required, the notified body will inform the AEMPS, who will inform the other Member States, the European Commission, and the autonomous regions of Spain about said events.

Furthermore, the AEMPS and the other competent health authorities, when they consider that a medical device may compromise the health and/or safety of patients, users or third parties, will proceed to adopt the appropriate precautionary measures. In such cases, the AEMPS will immediately notify the European Commission of the measures that have been adopted, indicating the reasons. Additionally, when the AEMPS considers that, with respect to a specific product or group of products, in order to guarantee the protection of people's health, safety or compliance with public health regulations, such products must withdraw from the market or that its placing on the market must be prohibited, restricted or subject to special conditions, it may adopt all the necessary and transitory measures that are justified, of which it will inform the European Commission and the other Member States indicating the reasons for its decision. For the same reasons, it may issue provisions on the conditions of use of the products or on special monitoring measures and include the necessary warnings to avoid health risks in the use of the products.

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 in the litigation the presumption that the product does not offer the security that can legitimately be expected from the product. However, said presumption could be contested by providing evidence on the safety of the product.

If the recall is due to a commercial decision of the company that commercialises the product, this presumption may not be applicable.

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 by EU authorities are immediately enforced by Spanish competent authorities. In the same way, product recalls adopted in other EU Member States will most likely be followed by a product recall in Spain.

On the other hand, actions taken in the United States do not directly imply the recall of a product in Spain. However, those actions may lead to the pertinent proceeding of investigation at national or EU level.

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 responsibilities, but not civil liability for damages based on the general regime for product liability set forth 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, adopting all the necessary measures to prevent the product placed on the market from continuing to generate damages is the first step that companies may adopt to protect themselves from future litigations and liabilities. This may include taking all necessary measures to ensure that the information is well disseminated and ensure the effectiveness of a complete and 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 the Code of Civil Procedure 1/2000 foresees the possibility of bringing collective legal proceedings and establishes that legally constituted associations of consumers and users shall have standing in court to defend the rights and interests of their members and of the association, as well as the general interests of consumers and users, without prejudice to the individual legal standing of the persons who suffered the damages.

When those damaged by a harmful event (e.g., by a defective product) is a group of consumers or users that are perfectly determined or may be easily determined, the standing to apply for the protection of these collective interests corresponds to (i) associations of consumers and users, (ii) legally constituted entities whose purpose is the defence or protection of such consumers and users, or (iii) the affected groups themselves.

In contrast, when those damaged by a harmful event is an undetermined number of consumers or users or a number difficult to determine, the standing to bring court proceedings in defence of these collective interests shall correspond exclusively to the associations of consumers and users, which form part of the Council of Consumers and Users. 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 also has legal standing to bring any action 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?

The most common is that product liability claims are brought by individual plaintiff lawsuits. Collective or class actions are not very common in Spain.

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 established 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 have 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 regime on liability for defective products is of a strict liability nature. It places on the claimant the burden of proving the existence of the product's defect, the damage, and the causal link between the defect and damage. To establish the causal link between the defect in the product and the damages suffered, the claimant must provide solid and substantial evidence that supports that link, and the damages must be an appropriate and sufficient result of the defect. Occasionally, the Spanish courts may also accept that the causal link can be proven by presumptions or circumstantial evidence.

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

There are no restrictions other than those related to conflicts of interest between clients. Breach of obligations on conflicts of interest may lead to civil liabilities and deontological and criminal sanctions.

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

Individuals, associations of public interests and foundations may have access to the public funding system (legal aid) if they do not have sufficient economical resources to be part of a litigation proceeding. This legal aid system is regulated in Law 1/1996 of 10 January on Legal Aid.

Litigants may also resort to third-party funding systems. There is no specific regulation on this matter apart from article 1255 of the Civil Code, which sets forth the following: "*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, if it is not contrary to the law, morals or public order, any agreement in this regard is valid.

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 between the same parties of a litigation process. Therefore, if a company is found liable in one case, that finding is not necessarily considered *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 if it caused the specific type of damage claimed 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?

Implementation of corrective measures may have a detrimental effect on litigation. They may generate on the Judge the impression that the company had not previously adopted all reasonable measures to avoid the damage caused.

On the other hand, implementation of improvement measures may have a positive effect on litigation if they create the impression that the company has implemented all necessary measures to reduce the causation of any damage.

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?

Plaintiff can submit any evidence that he considers necessary to evidence that a product is defective, including presenting the testimony of other users that have suffered the same adverse events.

Under Spanish Civil Law, there is no discovery obligation between the litigant parties, neither before court proceedings are commenced nor as part of the pre-trial procedures. The Spanish civil system is based on the principle of own production of evidence; i.e., each litigant party shall obtain and present its own evidence to support its claims in a court proceeding.

Exceptionally, and only applicable in those cases in which the applicant is unable to obtain by himself certain data necessary to file a claim, the applicant may request that the Judge, prior to filing the lawsuit, access certain sources of evidence specifically provided for, as preliminary proceedings, in the law. Among other preliminary proceedings provided in the law: (i) any interested party may request a copy of the medical records from the health centre or professional having the custody of said records; and (ii) the individual considering himself to be damaged by an event that could be covered by civil liability insurance may request for the exhibition of the insurance contracted.

Additionally, in the pre-trial hearing, any litigant may request the Judge to order the other party or third parties unrelated to the proceeding to exhibit any document related to the subject of the dispute. In said request, the applicant must: (i) prove that the document is not available to him and justify the impossibility of obtaining it; (ii) prove that the document refers to the purpose of the process (because it is documentary evidence relevant to the case) or to the effectiveness of other means of proof (because it gives, or not, effectiveness to other evidence presented); and (iii) provide a photocopy or simple copy of the document or indicate its content in the most exact terms.

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 be applicable in any phase of the process or judicial action, there are a number of countries, including Spain, that 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 person concerned may refuse to give evidence if he/she has a privilege or duty that obliges him/her to refuse to give the evidence. Additionally, the letter of request may also be denied if the Judge in Spain deems that compliance with this 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 658/2001, which approves the General Statute of Spanish Lawyers.

Professional privilege covers confidential communications between lawyers and their clients, and certain other documents and information exchanged in the context of such professional relationship.

The application of this confidential privilege to in-house counsel is more controversial, especially after the European Court of Justice Judgment of 14 September 2020 (*Akzo Nobel et al.*). In this case, the European Court of Justice pointed out that, in the context of inquiring measures in competition matters, attorney-client privilege may not apply to in-house counsel as their employment relationship questions their independence.

Additionally, professional privilege includes communications between lawyers and counterparties (unless disclosure is expressly authorised by other lawyers or parties).

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?

The confidentiality of companies' communications with external counsel is protected by the attorney-client privilege.

To make visible that a document/communication contains confidential information protected by attorney-client privilege, it is recommended to clearly mark that such document/communication is covered by privilege.

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

This depends on whether or not the foreign defendant is domiciled in an EU Member State or if the defendant is domiciled in a third country that has subscribed an international treaty with Spain regarding these matters.

Domiciled in an EU Member State

In such cases, the jurisdiction of Spanish courts will be established by the provision of Regulation (EU) Nº 1215/2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.

In this context, defendants not domiciled in Spain may be sued before the Spanish courts, 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 agree so, 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) N° 1215/2012).

Domiciled in a non-EU Member State

In the absence of an international treaty that regulates it, the jurisdiction of Spanish courts will be governed by the internal rules of Spain. In this regard, defendants not domiciled in Spain may be sued before the Spanish courts, among others:

(i) if the parties agree so, 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, when the harmful event has 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 United States may be recognised and enforced in Spain through an exequatur proceeding for the execution of the foreign resolution. By virtue of the recognition, the foreign resolution may produce the same or equivalent resolution in Spain as in the State of origin.

If the exequatur is filed in Spain, the one against which it is intended can oppose the recognition for any of 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 has been issued with a manifest infringement of the rights of defence of any of the parties. If the resolution had been issued in default of appearance, it is understood that there is a manifest infringement of the defence rights if the defendant was not provided with the document of summons or equivalent document on a regular basis and in sufficient time for him to be able to defend it;
(iii) the foreign resolution has ruled on a matter with respect to which the jurisdictional bodies are exclusively competent Spanish courts or, with respect to other matters, if the jurisdiction of the Judge of origin will not obey a reasonable connection. The existence of a reasonable connection with the dispute will be presumed when the foreign court has based its international judicial competence on criteria similar to those provided in Spanish legislation;
(iv) the resolution is incompatible with a resolution issued in Spain;
(v) the resolution is incompatible with a resolution issued previously in another State, when this last resolution meets the necessary conditions 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 abroad.

Foreign resolutions issued in procedures derived from collective actions are also subject to recognition and enforcement in Spain. For its enforceability in Spain to affected parties who have not expressly adhered to it, it is required that the foreign collective action has been communicated or published in Spain by means equivalent to those required by Spanish law and that said affected parties have had the same opportunities of participation or separation in the collective process than those domiciled in the State of origin. Additionally, in these cases, the foreign resolution will not be recognised when the jurisdiction of the court of origin was based on a forum equivalent to those provided for in Spanish legislation.

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

As Spain has different rules to the United States for determining liability and assessing damages, U.S. litigation may influence litigation in Spain, but its specific effect will depend on all the circumstances.

The likelihood of litigation evolving in Spain as a result of U.S. litigation shall be assessed on a case-by-case basis.

Xavier Moliner holds a law degree from the University of Barcelona and has been practising law since 1985. In 1997, he founded Faus & Moliner together with his partner Jordi Faus.
Xavier Moliner has written various articles on product liability, public procurement and data protection.
Faus & Moliner has been internationally acknowledged as one of the best law firms in Spain in pharmaceutical law by various publications. For more than 10 years, *Chambers and Partners* has considered Xavier Moliner as a professional with solid experience in the sector. In 2020, *Chambers and Partners* pointed out that Xavier Moliner "covers regulatory aspects and litigation proceedings" and that "he mainly acts for domestic and multinational pharmaceutical and medical device clients".
At Faus & Moliner, Xavier Moliner leads the teams in charge of advising on public procurement and product liability.

Faus & Moliner Abogados
Rambla Catalunya 135
08008 Barcelona
Spain

Tel: +34 93 292 2543
Email: xmoliner@faus-moliner.com
URL: www.faus-moliner.com

Juan Martínez graduated in law from the University of Granada and holds a Master's degree in legal practice with a specialisation in international business law from the Garrigues Studies Center. His law studies include stays in Freie Universität Berlin and the Pontifical Catholic University of Peru.
Juan Martínez has been part of the team of Faus & Moliner since 2017 and regularly advises national and international companies in litigation and arbitration procedures in various matters, specialising in conflicts related to contracts, unfair competition and product liability.

Faus & Moliner Abogados
Rambla Catalunya 135
08008 Barcelona
Spain

Tel: +34 93 292 2100
Email: jmartinez@faus-moliner.com
URL: www.faus-moliner.com

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