SPAIN

Law and Practice

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Faus Moliner

Contents

Faus Moliner is a modern boutique law firm specialising in legal matters typical of the pharmaceutical industry and affecting companies that operate in the life sciences sector. The firm was founded in 1997 and focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. Since its foundation, Faus Moliner has been widely recognised as a market leader in the area of pharmaceutical law in Spain. The product liability and civil and commercial litigation space is one of the leading areas of expertise for the firm. The team is well known for assisting industrial and insurance companies in complex high-stakes cases regarding medicinal products, medical devices and other products of the life science sector.

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1. Product Safety

1.1 Product Safety Legal Framework

Royal Legislative Decree 1/2007 (RLD 1/2007) is the main law setting out the legal regimen for product safety in Spain. It approves the consolidated text of the General Law on the Protection of Consumers and Users and other complementary regulations.

RDL 1/2007 establishes the main rules and obligations that, in general, must be respected by companies that make products available on the market to guarantee the protection of the health and safety of consumers and users.

Other laws and regulations set forth additional rules and obligations depending on the type of product and its impact on the health and safety of consumers. This is the case with the following laws and regulations:

- Royal Legislative Decree 1/2015, which approved the consolidated text of the law on guarantees and rational use of medicinal products and medical devices;
- Law 17/2011, regarding food safety and nutrition;
- Law 14/1986, on general public health;
- Royal Decree 1801/2003, on general product safety;
- Royal Decree 1345/2007, which regulates the authorisation, registry and dispensation conditions of medicinal products for human use prepared industrially;
- Royal Decree 192/2023, which regulates medical devices; and
- Royal Decree 85/2018, which regulates cosmetic products.

1.2 Regulatory Authorities for Product Safety

The General Directorate for Consumer Affairs of the Ministry of Consumer Affairs and the competent consumer authorities of the autonomous regions of Spain are the main authorities responsible for ensuring that the products made available to consumers and users meet the requirements established to provide a high level of health and safety at the same time as they respond to demands related to quality.

Other key sector-specific regulators are also in charge of ensuring that the specific products made available to consumers and users meet the requirements established to provide a high level of health and safety at the same time as they respond to demands related to quality. Such regulators include:

- the Spanish Agency for Medicinal Products and Medical Devices (AEMPS), which is the regulatory authority in charge of the technical requirements and surveillance of medicinal products, medical devices, cosmetics and personal care products; and
- the Spanish Agency for Food Safety and Nutrition (AESAN), which is in charge of the technical requirements and surveillance of food and nutritional products.

Regional authorities are also responsible for controlling advertising, performing inspections of manufacturing and distribution premises, and performing all necessary controls to ensure that products comply with the applicable regulations.

1.3 Obligations to Commence Corrective Action

According to the provisions of RLD 1/2007, any entity involved in placing a product at the disposal of consumers and users, within the limits

of its activity, must withdraw from the market, suspend marketing or recover from the consumer or user, through effective procedures, any product that does not meet the conditions and requirements of RLD 1/2007 or which, for any other reason, represents a foreseeable risk to personal health or safety on any other grounds.

In addition, the competent authorities may adopt all measures as are necessary and proportionate to eliminate the risk, including direct intervention regarding the product and direct compulsion of the entity involved. In these cases, all the expenses incurred will be charged to the involved entity whose conduct gave rise to such measures, irrespective of the sanctions that may be imposed, if any. The levying of such expenses and penalties may be carried out through the administrative enforcement procedure. Taking into account the nature and severity of the risks detected, public authorities may also inform affected consumers and users through the most appropriate means about the existing risks or irregularities, the affected product, the measures adopted and the appropriate precautions, in order to protect themselves from the risk and obtain their collaboration in the elimination of its causes.

1.4 Obligations to Notify Regulatory Authorities

The trigger for notification to authorities in respect of product safety issues may vary depending on the type of product at issue and the applicable regulations.

Medicinal Products

For instance, regarding medicinal products, applicable regulations establish that the holder of a marketing authorisation is obliged to:

- comply with its pharmacovigilance obligations;
- observe the conditions under which the marketing authorisation was granted, in addition to the general obligations established in the legislation;
- submit periodic safety reports established by regulation, in order to keep the safety file updated;
- make the results of clinical trials public, regardless of the favourable (or not) outcome of their conclusions; and
- 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 the authorities of all countries where it has been distributed, with the appropriate speed for each case and stating the reasons and any action undertaken to withdraw a batch from the market.

Without prejudice to their own responsibility, all authorities and health professionals, as well as pharmaceutical companies and distribution entities, are obliged to collaborate diligently in the dissemination of knowledge of the safety of the product. Likewise, health professionals, pharmaceutical companies and distribution entities are obliged to notify any anomalies of which they have knowledge to the health authorities.

Medical Devices

With regard to medical devices, manufacturers of devices made available on the Union market shall report to the relevant competent authorities, in accordance with provisions of Regulation (EU) 2017/745, the following:

(a) any serious incident involving devices made available on the Union market,

except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting; and

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

In addition, healthcare professionals and authorities who, in the course of their activity, become aware of a serious incident must also notify it to the AEMPS, through the electronic site enabled for this purpose, who will transfer it to the manufacturer of the affected product. Patients and users are also allowed to notify serious incidents to the AEMPS using the electronic procedure enabled for this purpose, without prejudice to the notification they may have made to the manufacturer, another economic agent or the healthcare professional.

Food and Nutritional Products

In accordance with Article 19 of Regulation No 178/2002, if a food business operator considers or has reasons to believe that any of the food that it has imported, produced, processed, manufactured or distributed does not meet the safety requirements, it shall immediately withdraw that food from the market when the food is no longer subject to its immediate control and shall inform the competent authorities thereof. In the event that the product may have reached consumers, the operator will effectively and accurately inform consumers of the reasons for its withdrawal. Moreover, if the competent authorities deem it necessary, the operator will recover the products that have already been supplied to consumers when other measures are not sufficient to achieve a high level of health protection.

1.5 Penalties for Breach of Product Safety Obligations

The intentional or negligent breach of product safety obligations may be subject to administrative and criminal sanctions. Furthermore, any person responsible for such a breach can be also liable for damages.

The most notorious criminal case in this regard was the rapeseed oil case, in which more than 30 industrialists were prosecuted during the late 1980s due to their participation in the commercialisation of a supposedly edible oil that was adulterated with rapeseed oil (for industrial use and forbidden for foodstuffs). The rapeseed oil contained a toxic chemical substance that caused the death of more than 300 people and left more than 25,000 affected. In 1992, the Supreme Court sentenced the industrialists responsible to significant convictions of imprisonment and to payment of the correspondent compensation to the affected persons. Because of the large compensation, some of the convicted industrialists became, and were declared, insolvent.

As a result, the affected persons started legal proceedings against the Spanish state to also declare its pecuniary responsibility due to the negligence of its officials in the process. The judicial battle ended in 1997 when the Supreme Court sentenced the state as a subsidiary liable party to pay compensation of more than 500 million pesetas to those affected.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

Liability Under RLD 1/2007

In Spain, the regime for general liability for defective products is established in RLD 1/2007, with Articles 128–146 setting the main rules on product liability. It is mainly a regime of non-absolute strict liability nature. Liability is deemed strict because the injured party is not required to prove fault or negligence on the part of the producer. However, it is not absolute, as the obligation to compensate arises only if the product alleged to have caused the damage is deemed *"defective"*.

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 their own private use or consumption. It is the responsibility of the claimant to prove that the product was defective, that damage occurred and that there was a causal link between the defective product and the damage suffered.

Under this regime of RLD 1/2007, a product is defective when it does not offer the safety that could legitimately be expected, considering all circumstances and, especially, its presentation, the reasonably foreseeable use of the product and the moment when the product was put into circulation. As established by the Spanish Supreme Court in its judgment 495/2018 of 14 September 2018, this concept of *"defective product"* is a normative concept that must be interpreted in accordance with the criteria established by law. In this regard, simple modification of a product (eg, to introduce enhanced information on warnings, risks, or side effects according to the latest available data) does not cause the product to be defective, since the defect definition makes it clear 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"*.

Therefore, within the framework of the regime for product liability outlined in RLD 1/2007, a defect is defined as *"the lack of safety that could legitimately be expected from the product"*, based on the criterion of *"legitimate safety expectations"*.

For the purposes of this regime, *"producer"* means:

- the manufacturer or the importer in the EU of a finished product, any raw material, or a component part of a finished product; and/or
- the *"apparent producer"* of the product – ie, any person who presents themselves as the producer of the product, by putting their name, trade mark or other distinguishing feature along with the product, whether on the container, wrapping or any other protective or presentational component.

The *"producers"* responsible for the same damage by application of this regime will be jointly and severally liable before the injured party. However, the one who responded to the injured party will have the right to file an action for recovery against the other responsible *"producers"*, according to their participation in the damage.

Where the *"producer"* of a product cannot be identified, each supplier of the product (ie, the distributor or the *"retail"* supplier) will be considered as its *"producer"*, unless they inform the injured party of the identity of the *"producer"* or

of the person who supplied them with the product within a term of three months before they are required to give such information. This has been clarified, among other matters, by the judgment of the Court of Justice of the European Union (CJEU) of 2 January 2009 (case C-358/08) and the judgments of the Spanish Supreme Court of 21 January 2020 and of 20 July 2020.

It must also be noted that the suppliers of a defective product will be treated as if they were its *"producer"* if they supplied the product while being aware that the defects exist. In such a case, the supplier is also able to file an action for recovery against the producer.

Other Forms of Liability

This strict liability system set forth in RLD 1/2007 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, to which the injured party may be entitled 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 that may apply.

2.2 Standing to Bring Product Liability Claims

Every injured party has standing to bring a product liability claim based on RLD 1/2007.

2.3 Time Limits for Product Liability Claims

The statute of limitations for bringing a claim for product liability under the regime of RLD 1/2007 is three years from the date when the damages were incurred by the injured party, provided that the identity of the party liable for the damages is known to the injured party.

The limitation period may be interrupted by the injured party by filing a claim before the courts, by means of an extrajudicial claim or through any act of acknowledgment by the liable party.

Nevertheless, the right to claim the recovery of damages as provided in the product liability regime of RDL 1/2007 expires ten years after the defective product was placed on the market. The only way to obviate this expiration date is to start legal proceedings.

2.4 Jurisdictional Requirements for Product Liability Claims

The requirements to invoke the jurisdiction of the courts of Spain for product liability claims will depend on whether the defendant is domiciled in an EU member state or in a third country (ie, a non-EU member state).

Domiciled in an EU Member State

If the defendant is domiciled in an EU member state, the provisions of Regulation (EU) 1215/2012, on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, will be applicable.

According to the rules set forth in this Regulation, Spanish courts have jurisdiction over any dispute when the defendant is domiciled in Spain, regardless of the claimant's domicile. Therefore, if the producer of the defective product is domiciled in Spain, a claim may be brought against them before the Spanish courts.

Defendants not domiciled in Spain may also be sued before the Spanish courts on product liability claims if the events leading to the product defect occurred in Spain, or if the damage occurred in Spain.

In this regard, see the judgment of the CJEU, case C-45/13, of 16 January 2014, or the judgment of the Spanish Supreme Court of 21 January 2019.

Domiciled in a Non-EU Member State

If the defendant is domiciled in a non-EU member state that has subscribed to an international treaty with Spain, the jurisdiction of the Spanish courts will be governed by the provisions of that treaty.

In the absence of an international treaty, the jurisdiction of the Spanish courts will be governed by the internal rules of jurisdiction of Spain. In this regard, a defendant not domiciled in Spain may be sued before the Spanish courts in the following situations, among others:

- if the parties agree to do so, or if the defendant appears before a Spanish court (this shall not apply where appearance was entered to contest the jurisdiction);
- regarding non-contractual obligations, when the harmful event has occurred in Spain; and
- in matters related to consumers if the consumer has its habitual residence in Spain.

2.5 Pre-Action Procedures and Requirements for Product Liability Claims

As of 3 April 2025, it is mandatory in Spain to attend a prior appropriate alternative dispute resolution (ADR) negotiation before initiating civil or commercial court proceedings (this includes any product liability claim). Appropriate ADR refers to *"any type of negotiation activity undertaken in good faith by the parties to a dispute with a view to finding an out-of-court solution to the dispute, either by themselves or through the intervention of a neutral third party"*.

Organic Law 1/2025 lists a number of systems to be considered as appropriate ADR methods, including, among others:

- mediation or conciliation;
- a confidential binding offer, acceptance of which is irrevocable;
- a neutral, non-binding and confidential opinion of an independent expert, to which the parties may voluntarily adhere;
- direct negotiation between the parties or with the intervention of their lawyers; and
- submission to a collaborative law process, consisting of a negotiation in which the lawyers involved will waive the right to represent their clients in court if they do not achieve a total or partial solution to the dispute.

2.6 Rules for Preservation of Evidence in Product Liability Claims

Before the initiation of any court proceeding, the one who intends to initiate it or any of the litigants during the course thereof may request the court to adopt, by means of an order, any useful measures to prevent the destruction of any evidence due to human conduct or natural events.

Among other things, the applicant for the adoption of any of these measures should prove that:

- the evidence to be insured is possible, pertinent and useful at the time of proposing its assurance/preservation;
- there are real reasons to fear that the use of said evidence may be impossible in the future if the preservation measures are not adopted; and
- the preservation measure proposed, or another measure that the court deems preferable for the same purpose, may be deemed conducive and carried out within a short time and without causing serious and dispropor-

tionate damage to the persons involved in the litigation or to any third parties.

2.7 Rules for Disclosure of Documents in Product Liability Cases

Under Spanish civil law, there is no general discovery obligation between the litigating 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 parties' own production of evidence (ie, each litigant shall obtain and present its own evidence to support its claims in court proceedings).

Exceptionally, and only in those cases in which they are unable to obtain by themselves certain data necessary to file a claim, the applicant may request that the judge provide access to certain sources of evidence specifically provided for, prior to filing the lawsuit by way of preliminary proceedings, in accordance with the Code of Civil Procedure 1/2000.

Among other preliminary proceedings provided in the law:

- any interested party may request a copy of the medical records from the health centre or professional with custody of said records; and
- an individual who considers themselves to have been damaged by an event that could be covered by civil liability insurance may request the exhibition of the insurance contract.

In addition, at the pre-trial 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 of the dispute. In said request, the applicant must:

- prove that the document is not available to them and prove the impossibility of obtaining it;
- prove that the document refers to the subject 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 does not give, effectiveness to other evidence presented); and
- provide a photocopy or simple copy of the document or indicate its content in the most exact terms.

2.8 Rules for Expert Evidence in Product Liability Cases

In this type of proceeding, the litigants are responsible for proposing the examination of expert evidence. The only restriction regarding its nature and scope is that it must be necessary to have scientific, artistic, technical or practical knowledge to ascertain any facts or circumstances that are relevant to the matter or to acquire certainty about them.

The parties are allowed to present their own evidence and bring their own technical specialists, and/or request the court to appoint any technical specialist in order to assess the evidence presented by the parties or ascertain any facts or circumstances that are relevant to the matter of the case.

Generally, in this kind of proceeding, the court may not ex officio propose the examination of expert evidence nor appoint technical specialists in order to assess the evidence presented by the parties. However, in exceptional cases, once the proceedings have been concluded and before judgment is rendered, the court may ex officio order the examination of new evidence (including expert evidence) on relevant facts if

the evidence already examined is found to be insufficient. In practice, this is very unusual.

2.9 Burden of Proof in Product Liability Cases

The product liability regime places the burden of proving the existence of the defect, the damage and the causal relationship between them upon the claimant. To establish such causal relationship, the claimant must provide solid and substantial evidence that supports such a link and proves that damages are an appropriate and sufficient result of the defect.

Proximate Causation

Nonetheless, occasionally, Spanish courts also accept that the causal relationship may be proven by means of presumption or circumstantial evidence.

In Spain, the principle of generic causation (ie, in order to prove the causal relationship, it would be enough to demonstrate that a product is capable of causing the alleged injury) is not applied. Spanish courts have ruled that the mere fact that a product can cause damage is not enough to determine the defective nature of that product; in order to prove that a product is defective, the claimant must prove that the damages suffered are effectively caused by the defective product. It is sufficient that the claimant proves the existence of a defect, but it is not strictly necessary that the claimant provides evidence of the specific defect of the product. It can, therefore, be concluded that the proximate causation principle operates in Spain.

Defective Batches/Series of Products

On 5 March 2015, the CJEU issued a ruling on joined cases C-503/13 and C-504/13, under which certain kinds of products can be considered defective under the proximate causation principle. In these particular cases, the CJEU concluded that Directive 85/374/CEE on damages caused by defective products shall be interpreted in a manner sensitive to the particular product in question. The security requirements that patients can expect from products such as pacemakers and cardioverter defibrillators are particularly high, considering their purpose and the vulnerability of the patients who use them. Under these circumstances, as they are products of the same model and production series, after a defect has been detected in a unit, the other units of the same model or batch can be classified as defective without it being necessary to prove the existence of the defect in each particular unit.

Proving Liability When Medical Research is Inconclusive

On 21 June 2017, the CJEU issued another decision (C-621/15) referring to the product liability of manufacturers whose products have a defect that poses a risk to the consumer. In these circumstances, the Court decided that European law does not preclude a national court from considering, when medical research does not establish or reject a relationship between the vaccine and the occurrence of a disease, that some facts alleged by the injured person constitute serious specific and consistent evidence enabling the court to conclude that there is a defect in the vaccine and that there is a causal link between that defect and the disease.

On the other hand, the Court also ruled that judges should ensure they do not reverse the burden of proof when applying this evidence regime. According to the Court, the Directive precludes rules based on presumptions in which medical research neither establishes nor rules out the existence of a link between the vaccine and the disease. The existence of a causal link

between the defect attributed to the vaccine and the damage suffered by the affected party will always be considered determined if certain predetermined factual evidence is presented.

In the five judgments issued between 2017 and 2019 by the National High Court (AN) regarding different liability claims filed in connection with human papillomavirus (HPV) vaccines, the Court confirmed that the burden of proving the defect, the damage and the causal relationship lies with the claimant and, in the absence of evidence from the claimant, the Court absolved the Ministry of Health and the pharmaceutical company of all wrongdoings attributed to them. The AN rejected the evidence proposed by the claimants, consisting of opinions that, according to the Court, did not undermine the studies and clinical trials that endorsed the efficacy of the product. With respect to the alleged lack of informed consent prior to its administration, the AN rejected the complaints because the claimants had not proven that the pathologies they were diagnosed with were a frequent adverse reaction, and therefore the obligation to inform did not include this risk since it was not known. Moreover, the AN considered that the causal relationship between the diagnosed diseases and the vaccines had not been proven, as the medical history did not point to the ailments and symptoms from which the claimants suffered being a consequence of the vaccine. Finally, the Court also rejected the liability of the pharmaceutical companies for defect of information in the summary of product characteristics and the leaflet on the basis that the claimants had not proven that their diseases were caused by the vaccine.

2.10 Courts in Which Product Liability Claims Are Brought

Product liability cases are usually brought before civil courts. In certain cases, product liability cases are also brought before administrative courts when, jointly with damages actions on product liability, the claimant brings actions against the public administration.

All these cases shall be resolved by judges.

The amount of compensation will depend on the damage suffered by the injured party. However, the producer's civil liability for damages caused by defective products is subject to the following rules:

- EUR500 will be deducted from the amount of compensation for material damage; and
- the global civil liability of a producer for death and personal injury caused by identical products that present the same defect will be limited to approximately EUR63 million.

2.11 Appeal Mechanisms for Product Liability Claims

In legal proceedings on product liability, it is possible to file an appeal before the Court of Appeal against the judgment issued by the Court of First Instance.

Against judgments on appeal rendered by the Court of Appeal, it is possible to file a cassation appeal before the Supreme Court. This cassation appeal may be funded infringement of a procedural or substantive provision, provided that there is an interest in the cassation proceedings. The appeal will be considered to have a cassation interest when the decision appealed against in cassation opposes the case law of the Supreme Court or resolves points and issues on which there is contradictory case law of the

Appeal Courts, or applies rules for which there is no case law of the Supreme Court. This cassation appeal cannot be grounded on the assessment of the evidence or the determination of facts, except on obvious and immediately verifiable errors of fact based on the proceedings themselves. When the appeal is based on an infringement of procedural rules, it is essential to prove that the infringement has been reported at all previous instances prior to the lodging of the appeal. If the procedural infringement has produced a defect that can be remedied, it must have been requested that it be remedied in the corresponding instances.

2.12 Defences to Product Liability Claims

The producer shall not be liable if they can prove that the product is not defective because it provides the safety that could legitimately be expected from it, taking all circumstances into account, including the time when the product was put into circulation, the presentation of the product and the use to which it could reasonably be expected that the product would be put.

The producer shall also not be liable if they can prove that:

- they did not put the product into circulation;
- it may be presumed that the defect did not exist when the product was put into circulation, given the circumstances of the case;
- the product had not been manufactured for sale or for any other form of distribution with an economic purpose, nor was it manufactured, imported, supplied or distributed within the context of a professional or entrepreneurial activity;
- the defect is due to the fact that the product was elaborated in accordance with existing mandatory rules; and/or
- the state of scientific and technical knowledge existing at the time the product was put into circulation did not allow for the discovery of the existence of the defect.

The producer of a part integrating a finished product shall not be liable if they prove that the defect is attributable to the design of the product into which the part was integrated, or to the instructions provided by the manufacturer of the finished product.

In addition, the doctrine points out that the apparent producer shall not be liable if they can prove that they were not the one who placed the sign, brand, logo or stamp that identifies them as the apparent producer into the defective product or its packaging.

In the case of medicinal products, foods or foodstuffs intended for human consumption, the producer shall not be able to invoke the state of scientific and technical knowledge defence referred to in the foregoing.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Compliance with regulatory requirements relating to the development, manufacture, licensing, marketing and supply of a product can be used as a defence if such requirements oblige the producer to develop, manufacture, license, market and/or supply the product in strict compliance with such regulatory requirements. If this is the case, the manufacturer could invoke the ground for exoneration mentioned in the fourth bullet point of **2.12 Defences to Product Liability Claims**.

In addition, compliance with regulatory requirements can be considered in the context of assessing whether a product meets legitimate

safety expectations and, therefore, when determining whether a product is defective or not. These cases should be evaluated on a case-by-case basis.

2.14 Rules for Payment of Costs in Product Liability Claims

At the end of the proceedings, the costs of the proceedings are imposed on the party who has had all its pleas rejected, unless the court considers that the case posed serious de facto or de jure doubts.

When the payment of costs is imposed on the party who has lost the case, that party shall pay all court fees and other incidental expenses, the fees of experts who have intervened in the proceedings, as well as the attorneys' fees of the successful party, up to an amount that shall not exceed one-third of the total claimed in the proceedings for each of the litigants who have obtained such an award. However, this limitation shall not apply if the court declares the recklessness of the losing party.

However, if the pleas were partially accepted or rejected, each party shall pay the costs generated on its behalf, and half of the common costs, except when there are reasons to impose the payment thereof upon one of the parties due to reckless litigation.

2.15 Available Funding in Product Liability Claims

Third-party funding is not forbidden in Spain. There is no specific provision that regulates this method, 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.

At the EU level, the European Parliament has launched the implementation of regulations on the private funding of litigious litigation. On 13 September 2022, the Parliament adopted a resolution with recommendations to the Commission on responsible private litigation funding. The Representative Actions Directive also contains provisions regarding third-party funding in relation to representative actions; however, this Directive has not yet been transposed in Spain.

Attorneys' professional fees shall be freely agreed upon between the client and the attorney in observance of the rules on ethics and free competition. Furthermore, lawyers are allowed to charge a success fee if they agree on such with their client. The form of payment of fees shall also be freely agreed upon, and may include payment of a percentage of the outcome of the claim. However, in any case, the client shall pay the minimum expenses that the lawyer may incur as a result of its designation.

Moreover, parties providing evidence that they lack sufficient economic resources to litigate may be beneficiaries of legal aid if they comply with the requirements established in Law 1/10 January 1996, on legal aid.

2.16 Existence of Class Actions, Representative Proceedings or Co-Ordinated Proceedings in Product Liability Claims

Article 11 of the Code of Civil Procedure 1/2000 foresees the possibility of bringing collective legal proceedings and sets out 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 asso-

ciation, as well as the general interests of consumers and users, without prejudice to the individual legal standing of the persons who have suffered the damages.

When those damaged by a harmful event (eg, by a defective product) are 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:

- associations of consumers and users;
- legally constituted entities whose purpose is the defence or protection of such consumers and users; or
- the affected groups themselves.

In contrast, when those damaged by a harmful event are an undetermined number of consumers or users, or if the number is 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 that 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 that 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.

Despite these procedural provisions, collective actions and representative proceedings for product liability claims are not very common in Spain. Such claims are usually brought by individual plaintiffs.

2.17 Summary of Significant Recent Product Liability Claims

Regarding product liability of medicinal products and medical devices, the following judgments of the Spanish Supreme Court deserve special mention.

The Judgments of 21 December 2020, and 21 and 28 January 2021

In these cases, the Supreme Court has resolved different appeals for the unification of doctrine and case law regarding whether a hospital that has used a product whose toxicity is discovered and alerted after it has been used shall be liable for the injuries caused to the patient, or if such liability must only fall upon the *"producer"* and the competent authorities that authorised the medicinal product, if applicable. The Supreme Court has clarified that, in such cases, liability must lie solely with the *"producer"* and, if applicable, with the authorities that authorised the product. The Supreme Court rejected any liability of the hospital as the competence for monitoring the adequacy of such products relied on the competent authorities (not the hospital). The Supreme Court also pointed out that the hospital cannot be held liable for the risk created by allowing the use of the product, since that risk derives from the defective manufacture of the product.

The Judgment of 1 March 2021

In this case, the Supreme Court ruled on the concepts of *"defective product"* and *"safety which may reasonably be expected"* with regard to a hip prosthesis that, after being commercialised, showed a revision rate higher than expected. Its manufacturer issued a safety notice recommending that users of the affected prosthesis follow a specific monitoring and control plan, and several months later voluntarily withdrew the product from the market.

The Supreme Court pointed out that a manufacturer may be held liable under the product liability regime of RLD 1/2007 not only for damages caused by products infringing safety and quality regulations but also for damages caused by products that, despite having undergone safety and quality controls, remain *"unsafe"*. The relevant time to determine whether a product is unsafe/defective is the time when the product is put into circulation. According to the Supreme Court, although the voluntary withdrawal of a product from the market does not necessarily mean that the product was defective at the time it was put into circulation, it may indeed constitute an indication that at that time the product did not comply with the safety standards that may reasonably be expected from it.

In the court proceeding, the manufacturer alleged that the prosthesis only had minor failures and that, in the majority of cases, it worked well in and accordance with its purpose. Furthermore, the manufacturer alleged that there was no proof that the damages were caused by the prosthesis itself and that the withdrawal of the product from the market had been entirely voluntary.

The Supreme Court did not accept these claims and considered that the fact that the prosthesis had an unexpectedly high rate of revisions must prevail. As per the Court, this high rate of revisions, which was neither identified nor disclosed by the manufacturer at the time the product was put into circulation (and, therefore, was not known by the medical community and the relevant notified bodies at that time), shows that the risks posed by the prosthesis were higher than expected. In these circumstances, the Supreme Court concluded that it falls on the manufacturer to prove why it was not possible to identify and disclose the true risks of the device (that ultimately caused the need to withdraw the product from the market) at the time the product was put into circulation.

The Judgment of 24 January 2022

In this judgment, the Supreme Court confirmed the doctrine set forth in the Judgment of 20 July 2020 regarding liability for damages in corporate groups.

The Supreme Court began by recalling that the general rule in Spain is to respect the concept of the separate legal personality of companies, meaning that:

- each company is only liable for the fulfilment of the obligations it assumed and those arising from its own actions; and
- belonging to a corporate group does not entail that a company may be held liable for acts carried out by other group companies.

Although the doctrine of veil piercing allows the plaintiff to sue a company other than that which performed the acts leading to the alleged damage, this is only possible on an exceptional basis. In order to apply such veil piercing, the plaintiff must prove that the company liable for the acts leading to the alleged damage was used abusively by another group company for the very purpose of impeding future claims. In these cases, the other group company may indeed be sued. In the remaining cases, suing a group company other than the one that performed the acts leading to the alleged damage will pose serious difficulties to the claimants.

The Supreme Court further stated that partially coinciding names between companies belonging to a corporate group is not a sufficient reason to sue a company for the acts carried out by another company of the same group.

The Judgment of 7 February 2024

In this case, the Spanish Supreme Court ruled on the extinction of liability time limit of ten years from the time the product is put on the market, during which an action based on the product liability regime of RDL 1/2007 can be brought. The Supreme Court pointed out, in this ruling, that when a product liability claim is brought against a distributor that does not comply with its identification duties, this period of extinction starts when the distributor (not the manufacturer) put the product on the market.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

On 24 December 2020, Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers, repealing Directive 2009/22/EC, entered into force.

This Representative Actions Directive has not yet been transposed in Spain. One of the developments of this 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. This may lead to significant modifications of the structure of the Spanish civil procedure regarding representative actions for the protection of the collective interests of consumers related to product safety infringement and product liability, among others.

Another trend in product liability and product safety policy is Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products, repealing Council Directive 85/374/EEC.

This new Directive on liability for defective products introduces certain measures that may have a relevant impact on product liability litigation. These include the following.

- A more precise, detailed and comprehensive definition of the parameters that outline the concept of defectiveness (which would continue to be based on the criteria of safety that a person is entitled to expect in accordance with the safety standards required under Union or national law) and a broader list of non-exhaustive circumstances to be considered when assessing defectiveness, including (i) the presentation and characteristics of the product, including its labelling, design, technical features, composition and packaging, and instructions for its assembly, installation, use and maintenance; (ii) the reasonably foreseeable use of the product; (iii) the effect on the product of any ability to continue to learn or acquire new features after it is placed on the market or put into service; (iv) the reasonably foreseeable effect that may be caused by other products that are expected to be used with the product (also by interconnection); (v) the precise time when the product was placed on the market; (vi) the relevant product safety requirements (including cybersecurity requirements); (vii) any recall of the product and/or any other interventions made by a regulatory authority or an economic operator responsible for the product in relation to its safety; (viii) the specific needs of the group of users for whom the product is intended; and (ix) in the case of a product whose very purpose is

precisely to prevent damage (as stated in the explanatory part of the Directive, for example a warning mechanism such as a smoke detector, the possible non-fulfilment of this purpose by the product. Finally, like the previous regulation, the new Directive establishes that in no case will a product be considered defective because a better product or an improved or updated version of it is subsequently placed on the market. With regard to this last element, it should be recalled that, in the field of medicinal products, the information provided in the summary of product characteristics and the package leaflet is regularly updated on the basis of the latest available data. Thus, a medicinal product that at the time it is marketed is not considered defective will not cease to offer the *"safety that can legitimately be expected"* simply because its summary of product characteristics and package leaflet are updated at a later date, including, for example, new warnings, risks or adverse effects (see the judgment of the Barcelona Provincial Court of 18 April 2008 in relation to Agreal® or the judgment of the Madrid Provincial Court in its judgment of 24 November 2011, in relation to Zyprexa®).

- 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.
- A new expanded list of responsible parties. In the case of defective products or components whose manufacturer is established outside the EU, the authorised representative of the manufacturer will also be liable alongside the importer; and, where there is no importer established in the EU or authorised representative, the logistics service provider will be liable. Any natural or legal person who substantially modifies a product outside the manufacturer's control and subsequently markets or puts it into service will also be considered the manufacturer of the product for the purposes of the new Directive. The distributor of the defective product (and the provider of an online platform that allows consumers to enter into distance contracts with traders) may also be liable when neither the manufacturer, the importer of the product or component, the authorised representative nor the responsible logistics operator is identified if: (i) the injured party requests the distributor (or the provider of the online platform) to identify the economic operator established in the EU responsible, or the distributor who supplied the product to them, and (ii) the distributor (or the provider of the online platform) does not identify the economic operator within one month of receiving such a request. In any case, where two or more economic operators are responsible for the same damage, they shall be jointly and severally liable to the injured party. However, the economic operator who is jointly and severally liable for compensation shall be entitled to recourse against the other economic operators responsible.
- The new rules on limitation and expiry periods. The limitation period for bringing product liability actions will continue to be three years. As a novelty, the new Directive establishes some modifications regarding the rules for its computation: the limitation period will start to run from the day on which the injured party becomes aware (or should reasonably have become aware) both of the damage and of the defective nature of the product, as well as of the identity of the economic operator who may be held liable. This limitation period may be interrupted in accordance with the applicable rules of national law. On the other hand, the ten-year expiration period remains in force. Once this period has elapsed sub-

sequent to the product being placed on the market, no claims for damages can be brought. However, this period is extended to 25 years for claims for damages that become apparent after these ten years have elapsed due to the latency of the injury caused.
- Another important novelty is that the new Directive removes the possibility for member states to set an overall monetary limit of liability per product of the same kind with the same type of defect. Member states will also have to ensure that the liability of economic operators under the new Directive cannot be excluded or limited, vis-à-vis the injured party, by a contractual provision or by national law.

3.2 Future Policy in Product Liability and Product Safety

The system of disclosure of evidence and presumptions provided by the New UE Product Liability Directive will lead to a major modification to the existing procedural rules in Spain on this matter.

As pointed out in **2.7 Rules for Disclosure of Documents in Product Liability Cases**, Spanish civil law is based on the principle of the parties' own production of evidence (ie, each litigant party must obtain and present its own evidence to support its claims in court proceedings), and no general discovery obligation exists between the litigant parties – neither before court proceedings start nor as part of the pre-trial procedures.

However, to facilitate the claimant's burden of proof in a complex product liability case, the New UE Product Liability Directive establishes the following measures on disclosure and presumptions.

Disclosure of Evidence by the Parties

A claimant who presents sufficient facts and evidence to support the plausibility of its claim may request that the courts order the defendant to disclose relevant evidence in their possession that the claimant considers necessary to support their claim. The defendant may also make this request in relation to evidence in the claimant's possession, where the defendant presents sufficient facts and evidence of the need to access this evidence in order to defend the claim.

The courts shall ensure that this disclosure of evidence between the parties is limited to what is necessary and proportionate, taking into account the legitimate interests of all persons concerned and, in particular, the protection of confidential information and trade secrets.

This measure represents a significant innovation in the Spanish procedural system, which is based on the principle that each party must provide the evidence at its disposal, and only in very exceptional cases is one party allowed to request that the other produces documents in its possession.

Presumptions of Evidence

The product shall be presumed to be defective if the defendant refuses to disclose or produce the evidence requested by the court.

A defect shall also be presumed when the claimant proves that:

- the product does not meet the mandatory safety requirements laid down in the applicable regulations; and
- the damage was caused by an obvious malfunction of the product during normal use.

In addition, a causal link between the defect and the damage shall be presumed to exist when it has been established that the product is defective and the damage caused is compatible with the defect in question.

Finally, the court may also presume a defect in the product, a causal link or both when, taking into account all the relevant circumstances of the case:

- the court considers that the claimant faces excessive difficulties, due to technical or scientific complexity, in proving a defect in the product, a causal link or both; or
- the claimant demonstrates that it is likely that the product is defective or that there is a causal link between the defect in the product and the damage, or both.

In any of these cases, the defendant shall have the right and the opportunity to rebut any of these presumptions by presenting evidence to the contrary.

In addition to the foregoing, the transposition of the Representative Actions Directive will also lead to a significant modification of the existing procedure on disclosure of evidence in relation to representative actions for the protection of the collective interests of consumers.