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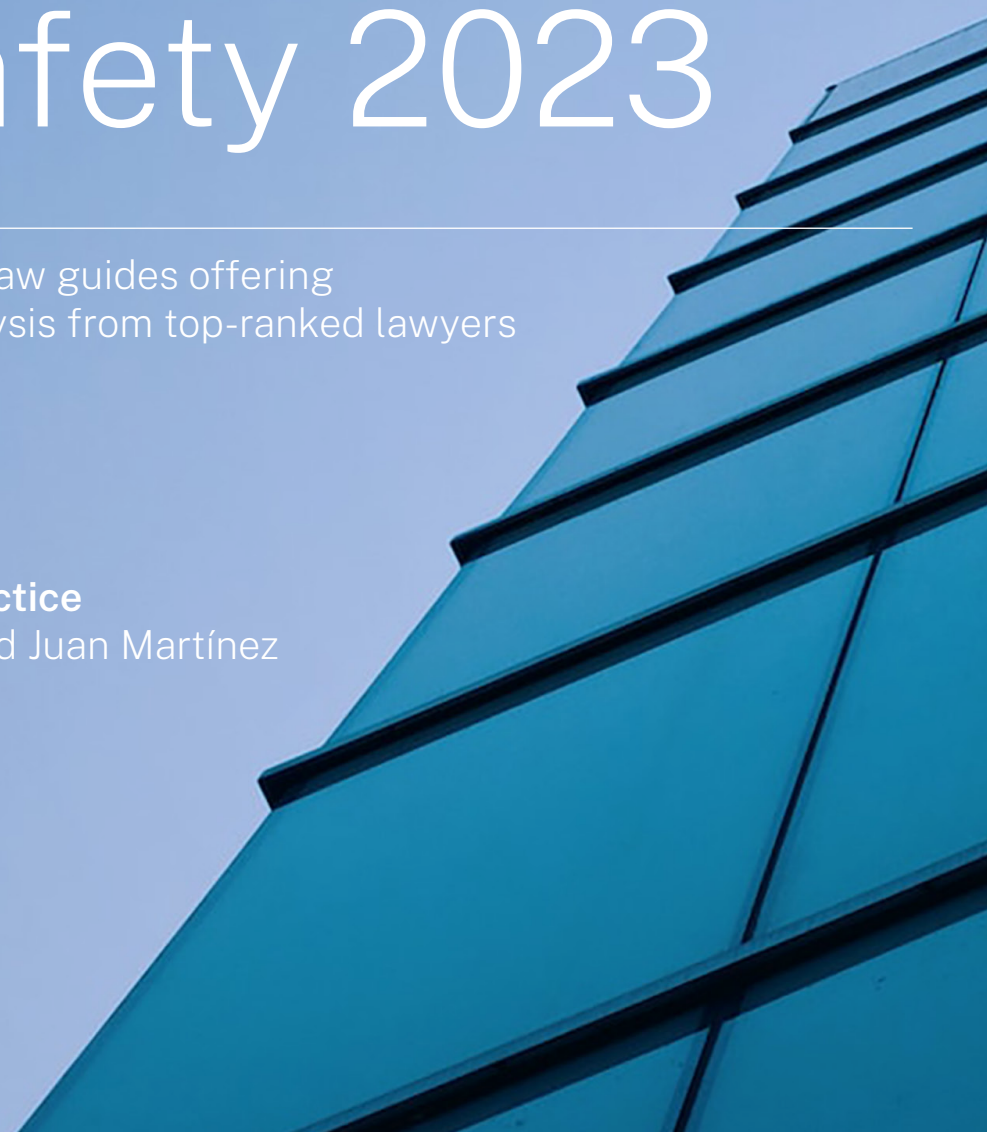

Spain: Law & Practice

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SPAIN

Law and Practice

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Faus Moliner is a modern boutique law firm, specialising in legal matters typical of the pharmaceutical industry and of other 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 1591/2009, 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 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 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 authoritiesmay 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 to 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, Royal Decree 1591/2009 establishes that manufacturers, authorised representatives, importers and/or distributors must notify the AEMPS of:

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

In addition, if a notified body observes that the manufacturer does not comply or has ceased to comply with the relevant requirements established by the legislation, 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 cases in which the intervention of the competent authority may be required, the notified body will inform the AEMPS, which will also apprise the other EU member states, the European Commission and the autonomous regions of Spain about said events.

Furthermore, if the AEMPS and other competent health authorities consider that a medical device may compromise the health and/or safety of patients, users or third parties, they will proceed to adopt appropriate precautionary measures. In such cases, the AEMPS will immediately communicate to the European Commission the measures that have been adopted, stating the reasons justifying them.

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 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 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 a "defective product" is a normative concept that must be interpreted in accordance with the criteria established by law.

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" – ie, based on the criterion of the "consumer's reasonable expectations".

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

- the manufacturer or the importer in the European Union of a finished product, any raw material, or a component part of the 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 this 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 or 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 stop 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

There are no mandatory steps that must be taken before a product liability proceeding can be commenced.

Nonetheless, prior to filing a lawsuit, it is common for the claimant to address an extrajudicial claim to the one who is intended to be sued, in order to try to resolve the dispute out of court.

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 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 the judge to 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 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 which, 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. These cases shall be resolved by a judge.

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 Provincial Court of Appeal against the judgment rendered at first instance by the Court of First Instance.

There are two appeal options against judgments on appeal rendered by the Provincial Court of Appeal:

- an extraordinary appeal for infringement of procedure; or
- a cassation appeal, provided that the amount at stake in the proceedings exceeds the sum of EUR600,000, or, provided that the decision on the appeal has reversal interest, because the judgment subject to appeal contradicts the Supreme Court's jurisprudence or decides on points and issues on which contradictory case law from the Provincial Courts of Appeal exists, or applies rules that have been in force for less than five years, as long as, in

the latter case, there is no jurisprudence from the Supreme Court concerning previous rules that have identical or similar content.

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 above.

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.

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 association, 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 Judgment of 20 July 2020

In this judgment, the Supreme Court dismissed the claim brought against the distributor in Spain of a hip replacement on the basis that the distributor identified the producer. The Spanish Supreme Court highlighted that the mere fact that the producer and the distributor have become part of the same corporate group does not imply, per se, that the distributor shall assume producer's liabilities in product liability claims. Companies belonging to the same corporate group are different companies with their own personality, unless they have been incorporated in order to wilfully obstruct the legitimate rights of third parties. The potential confusion between the producer and the distributor is already solved in the regulation on product liability, which obliges distributors to identify the producer. Therefore, a distributor may only be held liable for a producer's liabilities regarding defective products if the distributor does not identify the producer. If the distributor correctly identifies the producer, it shall not be held liable for any producer's liability.

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 which 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 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.

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, and repealing Directive 2009/22/EC, entered into force.

The Directive contains important modifications that had to be transposed no later than 25 December 2022, and the regulations resulting from such transposition must enter into force as of 25 June 2023. Therefore, important legislative initiatives must be carried out in the coming months to transpose the Directive. 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.

3.2 Future Policy in Product Liability and Product Safety

On 26 May 2021, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices became applicable. It contains significant modifications to the previous law regarding product safety, new technologies and medicinal products.

Among other things, the Regulation increases its scope of application to software programs, when they are specifically intended by their manufacturer for one or more of the medical purposes established in the definition of a medical device. In addition, Article 10 of the Regulation sets forth the obligation for manufacturers to implement measures to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, without prejudice to more protective measures under national law.

In addition, in September 2022, the European Commission of the European Union published a proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive), and a proposal for a new Directive of the European Parliament and of the Council on liability for defective products. These two proposals seek to establish new rules on product liability and civil liability arising from artificial intelligence.

3.3 Crisis Management/Situations/ Business Disruption and Product Liability and Product Safety Laws

The most significant measures to streamline and stimulate the development and approval of COVID-19 vaccines have been adopted by EU authorities.

In this regard, on 23 February 2021 the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency published a Reflection paper on the regulatory requirements for vaccines intended to provide protection against variant strains of SARS-CoV-2. This Reflection paper contains important considerations regarding the quality standards, non-clinical-data and clinical data that pharmaceutical companies may submit in the process of applying for the approval of vaccines intended to provide protection against variant strains of SARS-CoV-2.

Among other measures, due to the lack of medical respirators during the first months of the COVID-19 pandemic, the AEMPS author-

ised the use of different prototypes without CE marking by means of the authorisation of products in clinical research contemplated in Royal Decree 1591/2009, on medical devices, and Royal Decree 1616/2009, which regulates active implantable medical devices.

In addition, Royal Decree-Law 3/2022 was published on 2 March 2022, and establishes interesting provisions regarding the supply and procurement of authorised medicinal products (whether by Spanish or EU authorities) that meet a particular medical need in the fight against COVID-19 that has not yet been covered by another product. As explained in the preamble, this includes products that may reduce the risk of serious illness and death due to COVID-19, or those aimed at preventing this disease. This special regime does not apply to products that have not received a marketing authorisation (ie, medicines for compassionate use), but may apply to products that are subject to a conditional authorisation.

Among other provisions, Royal Decree-Law 3/2022 establishes that procurement agreements for these sorts of products entered into with public authorities may include liability clauses other than those set out in the general law. Therefore, special liability regimes may be provided for, as was the case with vaccines.

Apart from that, no specific modifications to the product liability and product safety regulations or special exemptions to respond to the crisis generated by the COVID-19 pandemic have been adopted by the Spanish government or the legislature in Spain.

As detailed in **2.1 Product Liability Causes of Action and Sources of Law**, under the product liability regime of RLD 1/2007, a product is defective when it does not offer the level of safety that could legitimately be expected, taking into account all circumstances and, especially, its presentation, the reasonably foreseeable use of the product and the moment when the product was put into circulation.

Therefore, when analysing the possible liability that may arise from a vaccine, medicinal product or medical device developed, manufactured and commercialised to address the COVID-19 pandemic, Spanish judges and courts must take into account the special circumstances in which such products were developed, approved and made available to the public.

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