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# The Legal 500 Country Comparative Guides

## Spain

# PRODUCT LIABILITY


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This country-specific Q&A provides an overview of product liability laws and regulations applicable in Spain.

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# SPAIN
# PRODUCT LIABILITY

## 1. What are the main causes of action upon which a product liability claim can be brought in your jurisdiction, for example, breach of a statutory regime, breach of contract and/or tort? Please explain whether, for each cause of action, liability for a defective product is fault-based or strict (i.e. if the product is defective, the producer (or another party in the supply chain) is liable even if they were not individually negligent).

In Spain, the general liability for defective products regime is established in Royal Legislative Decree 1/2007, of 16 November, which approves the consolidated text of the General Law on the Protection of Consumers and Users and other complementary regulations ("RDL 1/2007"). Articles 128 to 146 of RDL 1/2007, both inclusive, set the main rules on product liability in Spain.

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

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

## 2. What is a 'product' for the purpose of the relevant laws where a cause of action exists? Is 'product' defined in legislation and, if so, does the definition include tangible products only? Is there a distinction between products sold to, or intended to be used by consumers, and those sold for use by businesses?

For the purposes of this product liability regime set forth in RDL 1/2007, any movable property is a "product", even if it is attached to or incorporated into other movable or immovable property, as well as gas and electricity. This concept includes a software stored on a tangible medium or a software that is incorporated into a tangible good.

## 3. Who or what entities can bring a claim and for what type(s) of damage? Can a claim be brought on behalf of a deceased person whose death was caused by an allegedly defective product?

Every injured party has the right to bring a claim under this product liability regime for any damage caused by death or by personal injuries, and/or any damage to, or destruction of, any item of property other than the defective product itself, provided that the item of property is of a type ordinarily intended for private use or consumption and was used by the injured person mainly for his own private use or consumption. Claims can also be brought on behalf of a deceased person whose death was caused by an allegedly defective product.

## 4. What remedies are available against a defendant found liable for a defective product? Are there any restrictions on the types of loss or damage that can be

 

## claimed?

In accordance the product liability regime set forth in RLD 1/2007, every injured party has the right to receive economic compensation for damage caused by a defective product. As previously referred, the regime on product liability extends to personal/bodily injury, including death, 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 that it was used by the injured person mainly for his own private use or consumption. Damage to the defective product itself is not recoverable under RLD 1/2007. However, the injured party may claim compensation for such damage under general civil and commercial law. Moral damages may be recovered under general civil law.

## 5. When is a product defective? What must be shown in order to prove defect?

Under the product liability regime of RLD 1/2007 (ex. art. 137.1), 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 has been 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.

Regarding manufacturing defects, art. 137.2 of RLD 1/2007 establishes that, in any case, a product is defective if it does not offer the safety normally offered by the other units of the same series.

The mere modification of a product or its information (e.g.: to introduce better warnings, risks, or side effects according to the latest available data) does not cause the product to be defective, since the definition of defect (ex. art. 137.3 RLD 1/2007) expressly establishes that *"a product shall not be considered defective for the sole reason that such product is subsequently put into circulation in a more improved version"*.

## 6. Which party bears the burden of proof? Can it be reversed?

The regime on product liability places the burden of proving the existence of the defect, the damage and the causal relationship between such defect and damage upon the claimant.

To establish the causal relationship, the claimant must provide solid and substantial evidence that supports such link, and that those damages were an appropriate and sufficient result of the defect. However, occasionally, the Spanish courts also accept that the causal relationship may be proven by means of presumption or circumstantial evidence.

On 5 March 2015, the Court of Justice of the European Union 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 Court of Justice of the European Union concluded that the Directive 85/374/CEE regarding damages caused by defective products should be interpreted in the sense that, in the case of medical devices such as pacemakers and cardioverter defibrillators, considering their purpose and the vulnerability of patients who use them, the security requirements that patients can expect from such products are particularly high. Under these conditions, 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 being necessary to prove the existence of the defect in each of the units. On 21 June 2017, the Court of Justice of the European Union issued another case (C-621/15) referring to product liability of manufacturers in the event that their products have a defect which poses a risk to the consumer. The Court, in these circumstances, decided that European law does not preclude a national court to consider, when medical research does not establish nor 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 that when applying this evidence regime, they do not reverse the burden of proof. According to the Court, the directive precludes rules based on presumptions in which medical research neither establishes nor rules out 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 established if certain predetermined factual evidence is presented.

In five Judgements issued between 2017 and 2019 by the National High Court ("AN") regarding different liability claims filed in connection with human papillomavirus vaccines, the AN 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, it 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 claimants had not demonstrated that the pathologies they were diagnosed with were a frequent adverse reaction, and therefore the obligation to inform did not include such risk since it was not known. Moreover, the AN considered that the causal relationship between the diagnosed diseases and the vaccines had not been demonstrated, as the medical history did not associate the ailments and symptoms from which the claimants suffered with the vaccine. The liability of the pharmaceutical companies for defect of information in the Summary of Product Characteristics and the leaflet was also rejected because the claimants had not proved that their diseases were caused by the vaccine.

## 7. What factors might the court consider when assessing whether a product is defective? To what extent might the court account for a breach of regulatory duty, such as a breach of a product safety regulation?

The Court must consider all circumstances when assessing whether a product is defective, including its presentation, the reasonably foreseeable use of the product and the moment when the product was put into circulation. The breach of regulatory duty, such as a breach of a product safety regulation, will have a relevant impact when assessing whether a product is defective.

In addition, as previously mentioned, the mere modification of a product or its information (e.g.: to introduce better warnings, risks, or side effects according to the latest available data) does not cause the product to be defective, since the definition of defect (ex. art. 137.3 RLD 1/2007) expressly establishes that *"a product shall not be considered defective for the sole reason that such product is subsequently put into circulation in a more improved version"*.

## 8. Who can be held liable for damage caused by a defective product? If there is more than one entity liable, how is liability apportioned?

Under the product liability regime, liability lies with the "producer" of the defective product. For the purposes of this regime "producer" means: (i) 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 (ii) the "apparent producer" of the product (i.e.: any person who, by putting his name, trademark, or other distinguishing feature along with the product, whether on the container, wrapping or any other protective or presentational component, presents himself as its producer). Any "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 before 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.

If the "producer" of a product cannot be identified, each supplier of the product (i.e., the distributor or the "retail" supplier) will be considered as its "producer", unless he informs the injured party about the identity of the "producer" or the identity of the person who supplied him with the product. This identification must be done within three months from the moment the supplier is required to give such information. This has been clarified, among others, by the Judgment of the European Court of Justice of 2 January 2009 (case C-358/08) and the Judgments of the Spanish Supreme Court of 21 January 2020 and 20 of July 2020. Additionally, it must be noted that the supplier of a defective product will also respond as if he were the "producer" if he supplied the product being aware of the existence of the defects. In such a case, the supplier is also able to file an action for recovery against the producer.

Every persons liable for the same damage by application of the product liability regime shall be jointly and severally liable to the injured parties.

## 9. What defences are available?

The producer shall not be liable if he can prove that the product is not defective because it provides the safety which legitimately could 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.

In those cases where the product is found to be defective, neither shall be liable the producer if he can prove:

 

i. That he did not put the product into circulation.
ii. That, given the circumstances of the case, it may be presumed that the defect did not exist when the product was put into circulation.
iii. That the product had not been manufactured for sale or for any other form of distribution with an economic purpose, nor that it was manufactured, imported, supplied or distributed within the context of a professional or entrepreneurial activity.
iv. That the defect is due to the fact that the product was elaborated in accordance with existing mandatory rules.
v. That 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. However, this defense would not be applicable in Spain to medicinal products, foods or foodstuffs intended for human consumption.

The producer of a part that is integrated into a finished product shall not be liable if he proves 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.

Additionally, the doctrine points out that the apparent producer shall not be liable if he can prove that he was not the one who places the sign, brand, logo or stamp that identifies him as the apparent producer into the defective product or its packaging.

## 10. What is the relevant limitation period(s) for bringing a claim? Does a different limitation period apply to claims brought on behalf of deceased persons?

Under the regimen of RDL 1/2007, the statute of limitations to bringing a damages claim is of three years, counted from the date 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. This 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 damages as provided in the product liability regime of RDL 1/2007 expires 10 years after the defective product was put on the market. The only way to stop this expiration date is to start legal proceedings.

## 11. To what extent can liability be excluded, if at all?

Product liability of RDL 1/2007 cannot be excluded contractually. Any clause intended to exclude or reduce the liability system foreseen in RDL 1/2007 is ineffective against the injured party.

## 12. Are there any limitations on the territorial scope of claims brought under a strict liability statutory regime?

Yes. Product liability claims can be brought before Spanish Courts if defendant is domiciled in Spain, if the harmful event occurred in Spain and/or, in matters relating to consumers, if the consumer is domiciled in Spain.

In any case, the product liability regime set forth in RLD 1/2007 would be only applicable if according to the provisions of the Regulation (EC) no 864/2007 of the European Parliament and of the Council of 11 July 2007, on the law applicable to non-contractual obligations (Rome II), such claim is governed by the law of Spain.

## 13. What does a claimant need to prove to successfully bring a claim in negligence?

The general torts regime in Spain is regulated in article 1902 of the Civil Code, which establishes that whoever by action or omission causes damage to another, intervening fault or negligence, will be obliged to repair the damage caused.

Broadly speaking, in order to succeed in a claim for damages based in the general tort regime, the claimant must provide the court with solid evidence that proves:

i. the existence of an action or omission that generates a fault or negligent conduct attributable to the person or entity against whom the action is brought;
ii. the existence of a damage or injury caused by that fault or negligent action or omission; and
iii. the causal relationship between the damage and the fault or negligent action or omission.

These general notes have been shaped by the case law. In this regard, the case law has pointed out that, the regulatory diligence is not sufficient to avoid general torts liability if the facts of the case show that the guarantees adopted to avoid the foreseeable damages have been ineffective. As the Spanish Supreme Court establishes in its Judgement of 7 October 1988, the general tort liability does not consist in the omission of

 

inexcusable norms but in acting not adjusted to the due diligence required according to the circumstances of the specific case.

Among others, in the Judgement of 14 July 2006, the Supreme Court adds that the required diligence includes both the preventions and regulatory care as well as all those that prudence imposes to prevent the harmful event, in such a way that to determine the existence of a negligent conduct, it should not only be based on personal circumstances, time and place , but also to the traffic sector or physical and social environment where the conduct is projected, to determine if the agent acted with the appropriate care, attention and perseverance, and with the necessary reflection for the damage.

Additionally, the case law of the Spanish Supreme Court has also declared that although article 1902 of the Civil Code rests on a basic guilty principle, it is not allowed to ignore that the required diligence includes not only the preventions and regulatory care, but also all those that prudence imposes to avoid the harmful event. This may lead, in some cases, into the reversal of the burden of proof and to the presumption of a negligent conduct on the defendant, as well as the application, within prudent guidelines, of risk-based liability, although without establishing it as the sole basis of the obligation to compensate. In this regard see, among other, the Judgement of the Supreme Court of 13 of July of 1999.

In the Judgement of 29 October 2008, the Spanish Supreme Court also points out that when a damage is produced because of the normal or abnormal exercise of an activity from which a person or a company obtains an economic benefit, the burden of proof is reversed, in a way that it is not the injured party who has to prove the guilt of the person who causes the damage, rather, it is the economic agent who has to prove that he adopted all possible precautionary measures to avoid the damage. In those cases, it will be on the defendant the burden to rebottle this presumption. The defendant will bear the burden to prove its own diligence. It will imply to prove that it acted in accordance with the legal provisions, that were insufficient to prevent the damage, but also that reasonable and prudent measures were implemented to avoid such damage.

## 14. In what circumstances might a claimant bring a claim in negligence?

In claims of personal injuries caused by a defective product the most common is that claimants mainly base their claims on the strict liability regime for defective product established in the RDL 1/2007, as this regime does not require proof of negligence on the part of the tortfeasor.

However, claimants can add to this action a general tort action of the Civil Code, based on the intervention of fault or negligence, which will allow them to request compensation for other damages that are not compensable in accordance with RDL 1/2007, such as moral damages, the destruction of any property non-intended for private use, etc.

## 15. What remedies are available? Are punitive damages available?

The Spanish system does not contemplate punitive damages, only compensatory damages are available.

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

## 16. If there are multiple tortfeasors, how is liability apportioned? Can a claimant bring contribution proceedings?

The Civil Code does not foresee several liability as a rule in case of multiple tortfeasors. When there are several responsible subjects, it will be necessary to analyse whether the behaviour of each of the responsible subjects can be individualized or not.

If we are facing a case of concurrence of causes in which the responsibility can be distributed among the agents to whom said causes are attributable, each responsible subject will be liable for the damage caused. However, if it is not possible to carry out such individualization and the harmful event is a joint action, formed by the cooperation of various behaviours, all subjects will be jointly and severally liable for the harmful event.

## 17. Are there any defences available?

Defendants would be allowed to use any defence aiming to refute the liability requirements approached in question 13.

In this regard, defendants may invoke:

(i) That it has not been carried out any faulty or negligent conduct: in this case, the implementation of reasonable and prudent measures to avoid the causation of the damage will play a key role.

 

(ii) That the claimant has not suffered the damage claimed.

(iii) The lack of causal relationship between the damage claimed and the fault or negligent action or omission attributed by the claimant.

(iv) That the damage claimed is due to a force majeure event (i.e.: an extraneous event that was unforeseeable and insurmountable).

(v) That the damage claimed has been provoked by the intervention of a third party or by a faulty or negligently behaviour of the claimant. This may be invoke to either moderate or exclude the liability of the defendant in accordance with the impact of such intervention in the causation of the damage.

## 18. What is the relevant limitation period(s) for bringing a claim?

The statute of limitation to bring a claim based in the general torts regime of the Civil Code is one year.

This limitation period starts to run from the moment that the injured party has knowledge of the damages suffered and knows the identity of the person liable for such damages. In the case of injuries, the case law tends to interpret this rule in a favourable way to the injured party, starting to count the limitation period from the moment when the injured party received the medical discharge. In the case of continuing damages, the case law has held that the prescription does not begin until the production of the definitive result.

This limitation period can also be interrupted as previously explained in question 10.

## 19. To what extent can liability be excluded, if at all?

The main specialty of torts liability compared to contractual liability is the absence of a prior obligational relationship between the agent that causes damage and the injured party. The obligation to repair the damage derives not from the breach of a contractual obligation but from the existence of an unlawful act or omission (fault or negligent) that causes a damage to others. The case law regarding the exclusion of torts liability is very minor in our country. The doctrine is divided between the authors who consider that torts liability cannot be excluded as it is derived from the mandatory nature of article 1902 CC and those who do not see any legal inconvenience in excluding torts liability, based on the validity of the covenants of exoneration and limitation of liability. In our opinion, applying by analogy to tort liability the principle of validity of covenants of exoneration and limitation of contractual liability can pose many difficulties.

## 20. Do the laws governing contractual liability provide for any implied terms that could impose liability where the product that is the subject of the contract is defective or does not comply with the terms of sale?

Under Spanish Contract Law, anyone who during the performance of its contractual obligations incurred in fraud, negligence, or delay, or in any other way contravenes any terms of the contract, is subject to compensation for damages.

The negligent conduct consists in the omission of the diligence required by the nature of the obligation that corresponds to the circumstances of the person obliged, the time, and the place. If the obligation does not explicit the diligence to be used in its performance, the one required is the diligence of a prudent businessman.

Regarding B2B contracts, unless there is a clause to the contrary, the seller is obliged to respond for any vices or deficiencies detected in the object of the contract. With regard to B2C contracts, it is null and void and is considered ineffective any clause intended to exclude or limit: (i) the consumer or user´s right to compensation for damages caused by lack of conformity; or (ii) the agent liability in contract performance, for damages, death or injuries caused to the consumer or user due to an action or omission of the agent.

## 21. What remedies are available, and from whom?

The aggrieved party may choose between specific performance or termination of the contract, with compensation for damages and payment of interest in both cases. The aggrieved party may also request termination, even after having chosen performance, if performance proves impossible.

## 22. What damages are available to consumers and businesses in the event of a contractual breach? Are punitive damages available?

In contract law, compensations may include consequential damages, including moral damages, and

 

loss profits. Damages to be compensated would be measured exclusively depending on the prejudice suffered. The Spanish system does not allow to measure punitive damages.

## 23. To what extent can liability be excluded, if at all?

If the contract establishes a valid limitation clause of liability it will be fully effective between the parties subjected to the following exceptions:

i. The liability arising from fraud is enforceable in all obligations, any waiver to make it effective is always null and void (article 1102 of the Civil Code).
ii. The liability that comes from negligence is equally enforceable in the fulfilment of all kinds of obligations; but it may be moderated by the Courts according to the cases (article 1103 of the Civil Code).
iii. Any clause intended to exclude or reduce the liability system foreseen in RDL 1/2007 is ineffective against the injured party, but fully effective between B2B contracting parties, subject to the above-mentioned exceptions.

## 24. Are there any defences available?

Defendants would be allowed to use any defence aiming to refute the liability requirements approached in question 20.

In this regard, defendants may invoke:

i. That there is no breach of the contract, nor lack of conformity.
ii. Tat the claimant has not suffered the damage claimed.
iii. The lack of causal relationship between the breach of the contract and the damage claimed.
iv. That the damage claimed is due to a force majeure event (i.e.: an extraneous event that was unforeseeable and insurmountable).
v. That the damage claimed has been provoked by the intervention of a third party or by a faulty or negligently behaviour of the claimant. This may be invoked to either moderate or exclude the liability of the defendant in accordance with the impact of such intervention in the causation of the damage.

## 25. Please summarise the rules governing the disclosure of documents in product liability claims and outline the types of documents that are typically disclosed.

Under Spanish law, there is not a general discovery obligation between the litigant parties – neither before court proceedings start nor as part of the pre-trial procedures. The Spanish civil system is based on the principle of parties' own production of evidence, i.e., each litigant party shall obtain and present its own evidence to support its claims in court proceedings.

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

Additionally, 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: i) prove that the document is not available to him and justify the impossibility of obtaining it; ii) prove that the document refers to the purpose of the process (because it is documentary evidence relevant to the case) or to the effectiveness of other means of proof (because it gives, or does not give, effectiveness to other evidence presented); and iii) provide a photocopy or simple copy of the document or indicate its content in the most exact terms.

## 26. How are product liability claims usually funded? Is third party litigation funding permitted in your jurisdiction and, if so, is it regulated?

Product liability claims are typically funded in Spain by each litigant party.

Parties that do not have sufficient economic resources to litigate may be beneficiaries of the legal aid if they comply with certain requirements provided by the Law.

Litigants may also resort to third-party funding systems. This matter is not specifically regulated in Spain, other

 

than in article 1255 of the Civil Code, which states that: "The contracting parties may establish any covenants, clauses and conditions deemed convenient, provided that they are not contrary to the laws, to the morals or to public policy." Therefore, provided that it is not contrary to the law, morals or public order, any agreement in this regard is valid.

At the European Union level, the Parliament has launched the implementation of regulations on the private funding of litigious litigation. On September 13, 2022, the European Parliament adopted a resolution with recommendations to the Commission on responsible private litigation funding. The Directive 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 also contains provisions regarding third-party funding on representative actions.

## 27. Can a successful party recover its costs from a losing party? Can lawyers charge a percentage uplift on their costs?

Yes, at the end of the proceedings, the costs of the proceedings are imposed on the party who has had all his 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 losing party, such party shall pay all court fees and other incidental expenses, the fees of experts who have intervened in the proceedings, and, also, the fees of the attorneys of the party who has won the case, 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 award. If the court declares the recklessness of the litigant ordered to pay, such limitation shall not apply. In the event that 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 their payment upon one of the parties due to reckless litigation.

Lawyers are also allowed to charge success fees if they agree so with their client.

## 28. Can product liability claims be brought by way of a group or class action procedure? If so, please outline the mechanisms available and whether they provide for an 'opt-in' or 'opt-out' procedure. Which mechanism(s) is most commonly used for product liability claims?

Article 11 of the Code of Civil Procedure 1/2000 foresees the possibility to bring collective legal proceedings and establishes that legally constituted associations of consumers and users shall have standing in court to defend the rights and interests of their members and of the association, as well as the general interests of consumers and users, without prejudice to the individual legal standing of the persons who suffered the damage.

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

In contrast, when those damaged by a harmful event are an undetermined number of consumers or users or a number that 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 which form part of the Council of Consumers and Users. If the territorial scope of the conflict mainly affects one specific autonomous region, the specific legislation of the autonomous region shall apply.

The Attorney General's Office also has legal standing to bring any action in defence of the interests of consumers and users.

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

## 29. Please provide details of any new significant product liability cases in your jurisdiction in the last 12 months.

The Spanish Supreme Court has recently ruled (in Judgment of February 7, 2024) on the extinction of liability time-limit of 10 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 has 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 to run when this distributor (not the manufacturer) put the producto on

 

the market.

### 30. Are there any policy proposals and/or regulatory and legal developments that could impact the current product liability framework, particularly given the advancements in new technologies and increasing focus on the circular economy?

Yes. The Commission of the European Unión published (i) 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 (ii) a proposal for a new or a 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.

### 31. What trends are likely to impact upon product liability litigation in the future?

As for Directive (EU) 2020/1828 ("Representative Actions Directive"), the Spanish Government's first preliminary draft law to transpose the Representative Actions Directive was published on January 9th, 2023, which was followed by a period of public discussions. Once the final draft receives approval from the Council of Ministers, it will be debated and enacted by the Spanish Parliament. One of the developments of the Directive is to include a system of disclosure of evidence that allows qualified entities intending to bring a representative action to request that the defendant or a third party discloses certain pieces of evidence under its control that are relevant for the action to be brought.

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

a. a list of non-exhaustive circumstances to be considered when assessing defectiveness, including (i) the presentation of the product (including its instructions for use); (ii) the reasonably foreseeable use and misuse of the product; (iii) product safety requirements; and (iv) any intervention of by a regulatory authority or an economic operator responsible for the safety of the product. As in the current regulation, the proposal provides that in no case shall a product be considered defective because a better product or an improved or upgraded version of the product is subsequently placed on the market;
b. a new system of disclosure of evidence and presumptions, which aims to make it easier for the claimants to prove the defect and the causal link in complex cases; and
c. grounds that will allow the defendant to be exonerated from liability even if it is proven that the damage was caused by a product that is found to be defective. Among other grounds, the new proposal allows defendants to invoke that "*the objective state of scientific and technical knowledge at the time when the product was placed on the market, put into service or in the period in which the product was within the manufacturer's control was not such that the defectiveness could be discovered*". The current provisions in Spain exclude this possibility with regard to medicinal products.

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