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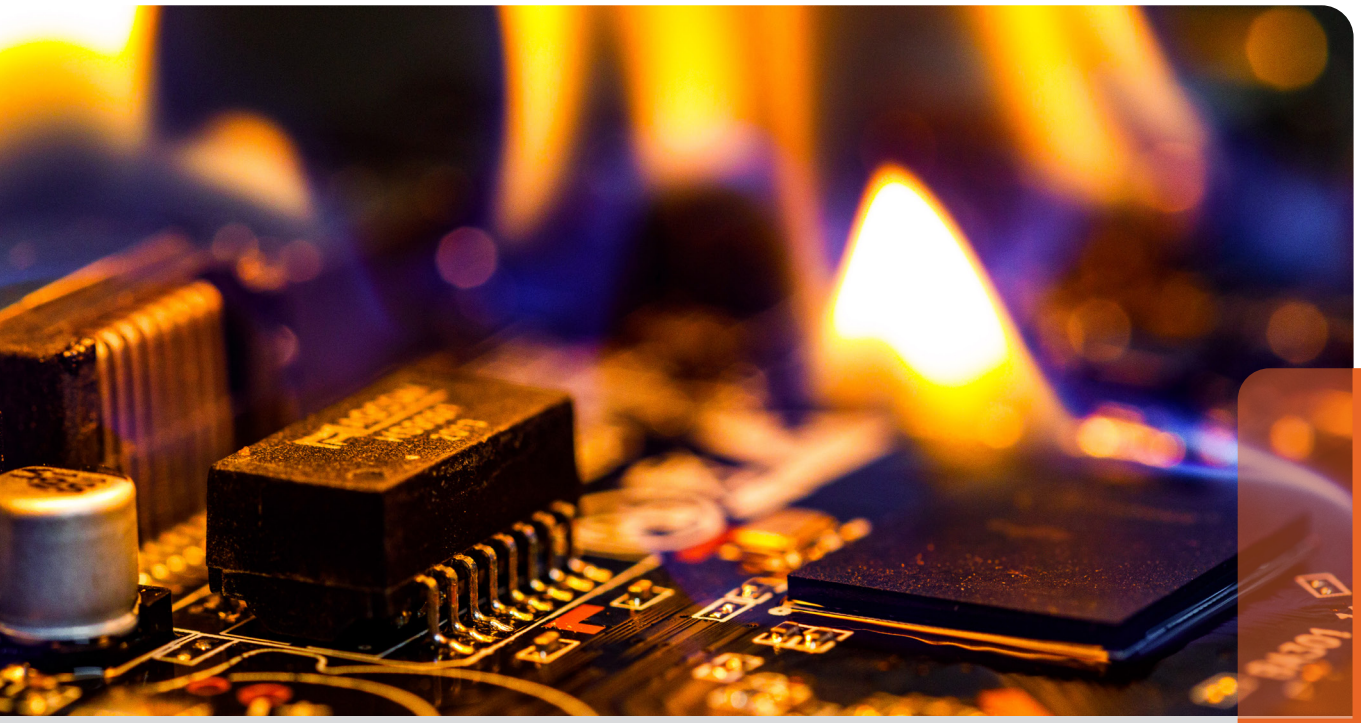

Product Liability

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

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

The general regime for product liability set forth in RLD 1/2007 is mainly of a strict nature (see question 1.3). Under this regime, the "producer" of a defective product will be liable for any damage caused through death or 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. The claimant is required 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 from 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 any other non-contractual liability that may apply.

1.2 Does the state operate any special liability regimes or compensation schemes for particular products, e.g. medicinal products or vaccines?

No. In Spain, the state does not operate any special scheme of compensation for particular products, but in several cases, the general regime on liability of the public administration may apply (see question 1.4).

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the 'retail' supplier, or all of these?

Under the RLD 1/2007 product liability regime, the responsibility for the fault/defect is borne by the "producer", who is strictly liable for the damage caused by the defective product (see question 1.1).

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).

Where the "producer" of a product cannot be identified, each supplier of this product (i.e., the distributor or the "retail" supplier) will be considered its "producer", unless he informs the injured party of the identity of the "producer" or of the person who supplied him with the product, within a term of three months before he is required to give such information. This has been clarified by, among others, 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 July 2020.

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.

Additionally, it must be noted that the supplier of a defective product will also respond as if he were its "producer" if he supplied the product while being aware that the defects existed. In such a case, the supplier is also able to file an action for recovery against the producer.

1.4 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

As mentioned above, under the regime on liability for defective products established in RLD 1/2007, the responsibility for the defective product is only borne by the "producer" (see question 1.3). As the regulatory authority is not a producer, it will not be responsible under this regime.

However, it is possible to file a complaint against the regulatory authority that authorised the defective product, based on the general regime on liability of the public administration. This is possible when the damage is derived from facts or circumstances that could have been prevented or avoided, according to the knowledge of science or techniques at the time it authorised or reviewed the authorisation of the product. Therefore, the state of scientific and technical knowledge works as a defence that may be used by the regulatory authority.

As we will see in question 3.1, this regime differs from the responsibility regime applied to "producers" in the case of medicinal products, foods, or foodstuffs. Under the latter regime, the producers are not permitted to invoke the "state of scientific and technical knowledge" defence, as it is expressly excluded under RLD 1/2007. However, this ground for exemption was introduced into the Law on Administrative Procedure to exonerate the public administration (regulatory authority) from responsibility when the damage is derived from facts or circumstances that could not have been prevented or avoided, according to the knowledge of science or techniques at the time it authorised (or reviewed the authorisation of) the product.

Therefore, when claiming damages against the regulatory authority, it is important to prove that, based on the state of scientific knowledge, the authority did not act according to the scientific data and evidence available at that moment.

Between 2017 and 2019, the National High Court ("AN") issued five judgments dismissing different damages claims, filed in connection with the authorisation and the administration of two human papillomavirus vaccines. These claims were addressed against the Ministry of Health ("MOH") and the pharmaceutical companies that produced and marketed such vaccines.

The AN rejected the complaints on the basis that the claimant did not prove that the competent authorities, based on the state of scientific knowledge, had not acted according to the scientific data and evidence available at that moment. The claimants did not provide any firm scientific evidence which would lead to the conclusion that such risk-benefit balance was unfavourable and that, therefore, the vaccines should not have been authorised.

1.5 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

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

In accordance with article 51 of RLD 1/2007, the corresponding public administration may order the precautionary or definitive withdrawal or recall of goods or services from the market on the grounds of health and safety.

1.6 Do criminal sanctions apply to the supply of defective products?

Criminal sanctions may apply if the supply of the defective product can be considered an intentional or negligent action specified as a criminal offence in the Spanish Criminal Code.

Criminal offences against public health are listed in the Spanish Criminal Code in articles 359 to 378.

According to the Spanish Criminal Code, natural persons as well as legal entities, such as companies, may be held criminally liable. However, companies can only be criminally liable for those criminal offences expressly provided in the Criminal Code for legal persons, and because of the behaviour of:

(a) their directors or legal representatives, whether they have been appointed to perform their duties or even if they do so without a formal appointment;
(b) other persons authorised to adopt decisions on behalf of the company, including middle management, general and individual proxies, and persons to whom control and organisation functions have been delegated (including the compliance officer); and
(c) those who are subject to the authority of the above-mentioned persons, including the employees of subsidiaries and persons with a commercial relationship with the company, such as self-employed individuals or subcontracted employees, provided that they are within the company's corporate domain, when the company has seriously breached its duty to control, monitor and supervise its activity.

As a rule, a company will only be subject to criminal liability if the criminal behaviour of one of the above-mentioned persons was intentional and constituted wilful misconduct. Reckless behaviours may only result in the company being held criminally liable when it is expressly foreseen in the Criminal Code.

According to the Criminal Code, there are internal control tools (compliance systems) to prevent criminal conduct from being caused, which can exempt legal entities from criminal liability or minimise such liability. For a legal entity to be held criminally liable, the prosecution must prove that the offence was committed, and that the internal control tools (compliance systems) required by the Criminal Code for the prevention of the criminal conduct were either non-existent or ineffective.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The injured party seeking compensation for damages has the burden of proving the defect, the damage and the causal relationship between the defect and the damage.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The regime on product liability places the burden to prove the existence of the defect, the damage and the causal relationship between such defect and damage upon the claimant. In order to establish the causal relationship, the claimant must provide solid and substantial evidence that supports such link, and demonstrates appropriately and sufficiently that damage was a 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.

In Spain, the principle of generic causation (i.e., that in order to prove the causal relationship, it would be enough to demonstrate that a product is capable of causing an alleged injury) is

not applied. The Spanish courts have established that the mere fact that a product can cause damage is not enough to establish the defective nature of such product. In order to prove that a product is defective, the claimant must prove that the damage suffered is 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. We can thus conclude that in Spain the "proximate causation" principle applies.

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 product can be considered defective under the proximate causation principle. In these particular cases, the Court concluded that Directive 85/374/CEE, regarding damage 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 it 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 from considering, when medical research neither establishes nor rejects a relationship between a 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 the proof. 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 be considered established if certain predetermined factual evidence is presented.

In the judgments issued by the AN (see question 1.4), regarding liability claims filed in connection to the human papillomavirus vaccines, the Court confirmed that the burden of proving the defect, the damage and the causal relationship lay with the claimant and, in the absence of evidence from the claimant, it absolved the MOH and the pharmaceutical company of all wrongdoing 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 demonstrated that the pathologies with which they were diagnosed 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.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

If it cannot be established which of several possible producers manufactured the defective product, all the manufacturers will be jointly and severally liable *vis-à-vis* the injured parties. The producer who compensated the injured party has the right to claim recovery from the other producers, depending on their involvement in causing the damage.

However, the manufacturer of a part that is integrated into a finished product will not be liable if he proves that the defect is attributable to the design of the product into which the part manufactured by him was integrated, or to the instructions provided by the manufacturer of the finished product.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

In accordance with Spanish doctrine and case law, there are three large groups of defects that products may have: (i) manufacturing defects; (ii) design defects; and (iii) information defects.

The absence of necessary warnings or instructions for use, or the inappropriateness of such information, may give rise to an information defect. Therefore, when the information that accompanies a product is inappropriate or insufficient, such product may be defective and may give rise to liability in the event that the product causes damage.

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

Moreover, the producer will only be held liable for the lack of information on reasonably foreseeable risks (i.e., risks that he is aware of, or should be aware of, through the exercise of reasonable diligence). Within the framework of the regime for product liability established in RLD 1/2007, a defect is defined as "the lack of safety that could legitimately be expected from the product, i.e.: based on the criterion of the consumer's reasonable expectations". In addition, the mere modification of the information of a product to introduce better warnings, risks, or side effects according to the latest available data, does not cause the product to be defective, since the definition of defect expressly establishes that "a product shall not be considered defective

for the sole reason that such product is subsequently put into circulation in a more improved version". Therefore, within the scope of the consumer's legitimate expectations, only the information that was known to the producer or that, in accordance with the state of scientific and technical knowledge, should have been known to him at the moment of placing the product on the market, must be included.

In principle, the information and warnings that should be considered in order to determine whether a product suffers from an information defect should be the information provided directly to the user of the product.

However, for certain types of product for which the intervention of an intermediary is required, the courts may take the information provided to the intermediary into consideration, in order to determine whether the information provided to the consumer is sufficient and appropriate.

Specifically in the case of medicinal products, Basic Law 41/2002 of 14 November, governing patient autonomy and rights and obligations as regards clinical information and documentation, establishes that it is the doctor's duty to guarantee that the patient has the necessary information to decide freely on the therapeutic strategy prescribed by the doctor. As a consequence, the information provided by the manufacturer to the doctor must be taken into consideration in order to assess the set of information provided to the patient.

Finally, it should be noted that RLD 1/2007 does not expressly foresee the "learned intermediary rule" referred to above, pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make appropriate product information available.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The producer will not be liable if they 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 presentation of the product, the reasonably expected use of the product, and the moment when the product was put into circulation.

In addition, even if the product is found to be defective, the producer will not be liable if they can prove that:

(a) they did not put the product into circulation;
(b) given the circumstances of the case, it may be presumed that the defect did not exist when the product was put into circulation;
(c) the product had not been manufactured for sale or for any other form of distribution with an economic purpose, and that it was not manufactured, imported, supplied or distributed within the context of a professional or entrepreneurial activity;
(d) the defect is due to the fact that the product was developed in accordance with existing mandatory rules; or
(e) 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 that is integrated into a finished product will not be liable if they can 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.

Additionally, the doctrine points out that the apparent producer will 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 onto the defective product or its packaging.

In the case of medicinal products, foods or foodstuffs intended for human consumption, the persons liable will not be able to invoke the "state of scientific and technical knowledge" defence set out in point (e) above.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The fact 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 defect may be used as a defence. However, as pointed out in the answer to question 3.1 above, such defence cannot be invoked in the case of medicinal products, foods or foodstuffs intended for human consumption.

The producer has the burden of proving that the defect could not have been discovered.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Compliance with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product can be used as a defence, if such requirements impose the obligation on the producer to develop, manufacture, license, market and/or supply the product in strict compliance with, and observance of, these requirements. If this is the case, the producer could invoke the ground for exoneration pointed out in point (d) of question 3.1 above.

Additionally, compliance with regulatory and/or statutory 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.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The effects of *res judicata* produced by final judgments, consisting in the permanence over time of the efficacy of the judgment as a mechanism for legal safety and certainty, have certain limits.

One of those limits is the subjective limit, which means that the effects of *res judicata* only apply between the litigating parties, and therefore it is possible to bring new claims on matters of fault, defect, or the capability of a product to cause a certain type of damage, provided that the claimant is different. For example, in the event of personal injury suffered by an individual during a traffic accident as a consequence of the malfunctioning of an airbag, it is possible for the injured person's insurance company to file a claim against the car manufacturer in order to recover the hospital expenses paid by such insurance company, and for the injured person themselves to file a claim against the car manufacturer for personal damages. Of course, such personal damages cannot include the hospital expenses paid directly by the insurance company. In this example, the claim by the insurance company would be brought under insurance law, and the claim by the injured person under the regime on product liability.

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

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings, is there a time limit on commencing such proceedings?

The producer against whom proceedings for product liability are brought may claim, in his defence, that the defect was due to the actions of a third party; however, his liability *vis-à-vis* the claimant will not be reduced thereby.

Nevertheless, the producer who paid compensation to the injured party is able to claim such compensation from the third party, as corresponds to such third party's involvement in causing the injury, in subsequent proceedings. Such proceedings against the third party must be brought within a period of one year, counted from the day the compensation was paid to the injured party.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

The liability of the producer may be reduced, or even excluded, if it is proven that the damage was caused partially or entirely due to the actions or negligent behaviour of the injured party. However, the behaviour of the injured party must be assessed on a case-by-case basis and must hold a direct relation to the defect.

For example, in the case of the malfunctioning of an airbag cited in our answer to question 3.4 above, the manufacturer of the airbag cannot defend itself by arguing that the accident was caused due to the reckless behaviour of the driver (injured party).

The behaviour of the injured party may have contributed to the accident, but not to the malfunctioning of the airbag.

3.7 Are there any examples in your jurisdiction of legislation providing exemptions from product liability in respect of products produced and/or deployed in the context of a public health emergency?

Spanish law has not provided any general exemption from product liability in respect of products produced and/or deployed in the context of a public health emergency.

However, with regard to authorised medicinal products which meet a particular medical need in the fight against COVID-19 that is not yet covered, Royal Decree-Law 3/2022 establishes that procurement agreements 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.

4 Procedure

4.1 In the case of court proceedings, is the trial by a judge or a jury?

In the case of court proceedings, cases are resolved by a judge.

4.2 What is the standard of proof applied by the court? Does the court have to be satisfied of a fact "on the balance of probabilities" (i.e. more likely than not), "beyond all reasonable doubt" or to a different or more flexible standard?

The courts will evaluate the probative force of each piece of evidence in accordance with the rules of sound criticism, taking into consideration the reason for the evidence, the circumstances of such evidence and, if applicable, the objections formulated and the results of the tests that have been carried out on such evidence.

In order to attribute liability to the defendant, the plaintiff must prove the existence of a causal relationship between the conduct of the defendants and the damage caused; proof that is incumbent upon the plaintiff regardless of the criterion used for the imputation of liability, which must be based on a certainty of proof that cannot be undermined by a possible application of the theory of risk, the objectivisation of liability or the reversal of the burden of proof.

4.3 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

In legal proceedings on product liability, the examination of expert evidence may only be proposed by the parties to the trial. As a rule, in these proceedings, the court may not *ex officio* propose the examination of expert evidence or appoint technical specialists in order to assess the evidence presented by the parties, but a party can request it.

In exceptional cases, once the proceedings have been concluded and before the 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 was insufficient. In practice, this is very unusual.

4.4 Is evidence introduced solely by the parties or may the court take evidence on its own initiative?

Judicial proceedings in Spain are governed by the principle of *ex parte* own production of evidence. This means that the Courts must rule on the dispute on the basis of the facts and evidence provided by the parties to the proceeding.

As mentioned question 4.3 above, in exceptional cases, once the proceedings have been concluded and before the judgment is rendered, the court may *ex officio* order the examination of new evidence on relevant facts, if the evidence already examined was insufficient. In practice, however, this is very unusual.

4.5 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure "opt-in" or "opt-out"? Who can bring such claims, e.g. individuals and/or groups? Are such claims commonly brought?

Article 11 of the Code of Civil Procedure 1/2000 foresees the possibility of bringing collective legal proceedings, and establishes that legally constituted associations of consumers and users will 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 will 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 will apply.

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

4.6 Can claims be brought by a representative body on behalf of a number of claimants, e.g. by a consumer association?

Yes; as previously stated in question 4.5, when those damaged are a group of consumers or users, then depending on the case, the claims can be brought by "associations" of consumers and users, legally constituted entities whose purpose is the defence or protection of such consumers and users, the affected groups of consumers and users, and/or even the Attorney General's Office.

4.7 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

In collective legal proceedings lodged by associations or entities formed for the protection of the rights and interests of consumers and users, or by groups of affected people, those who have been damaged, as consumers of the product or users of the service that gave rise to the proceedings, will be called to appear in order to assert their individual rights or interests. This call is made by the court, which announces the admission of the claim in the media with territorial coverage where the damage to these rights or interests occurred.

When proceedings involve certain damaged parties, or damaged parties that are easily determined, the claimant or claimants must have previously notified those concerned of their intention to lodge a claim. In this case, after the call, the consumer or user may act in the proceedings at any time but may only conduct the procedural acts which have not been precluded.

When the proceedings involve damage to an indeterminate number of persons or a number which is difficult to determine, the call will suspend the course of the proceedings for a limited time not exceeding two months, the duration of which is determined by the court in each case depending on the circumstances or complexity of the event, and the difficulties concerning the determination and localisation of those damaged. The proceedings then restart with the intervention of all the consumers who attended the call. As a rule, the individual appearance of consumers is not allowed subsequently, notwithstanding certain rights or interests that they may assert according to other provisions of the Code of Civil Procedure 1/2000.

4.8 How long does it normally take to get to trial?

Although it is difficult to provide a general answer, it is fairly common for a period of 14 to 18 months to go by between the filing of the claim and the rendering of the judgment at first instance.

4.9 Can the court try preliminary issues, the results of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The preliminary issues which, due to their very nature, represent an obstacle to the continuation of the trial and require prior resolution by the judge are those that relate to: (i) lack of jurisdiction or competence of the court before which the claim is brought; (ii) lack of capacity or representation of the litigants; (iii) *litis pendens* or *res judicata*; (iv) necessary passive joinder of defendants; (v) inappropriateness of the proceedings; or (vi) a legal defect in the way the claim has been filed.

These preliminary issues to be decided beforehand are only related to matters of law.

4.10 What appeal options are available?

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

In opposition to these appeal decisions rendered by the Provincial Court of Appeal, it will be possible to file a cassation appeal against the Supreme Court. These cassation appeals may be based on infringement of a procedural or substantive provision, provided that there is an interest in the cassation proceedings.

An 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 Provincial Appeal Courts, or applies rules on which there is no case law of the Supreme Court.

The assessment of the evidence and the determination of facts cannot be subject to appeal in cassation, except for 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 to be remedied in the corresponding instances.

4.11 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The proposal of the examination of expert evidence corresponds to the litigants, and the only restriction regarding its nature and scope is that it is 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.

4.12 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Witnesses are not required to present themselves for pre-trial deposition, and they only declare on the day of the trial.

The reports issued by experts must be provided by the parties together with their claim (i.e., the document that initiates the proceedings) or together with their response to the claim. If this is not possible, the parties can announce their intention

to provide such reports in the claim, or in the response to the claim. In such case, the reports must be provided to the court five days before the date set for the pre-trial hearing (*Audiencia Previa*), so that the court may provide a copy to the other party.

Additionally, any expert report whose necessity or usefulness lies in the statement of defence, or the allegations and pleas set forth at the pre-trial hearing, must be submitted by the parties for their transfer to the counterparties at least five days prior to the trial. If the parties so request, the experts who have prepared the reports may appear at the trial in order to ratify, explain or clarify their reports, and to respond to any questions regarding their reports.

4.13 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

Under Spanish civil law, there is no 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 the parties' own production of evidence, i.e., each litigant party must 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.

4.14 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation, e.g. mediation, arbitration?

RLD 1/2007 establishes the possibility for conflicts between consumers, users and companies to be resolved through the Consumer Arbitration System, with no special formalities and in a manner that is binding and enforceable on both parties, provided that the conflict does not concern intoxication, injury, death or the existence of reasonable evidence that an offence has been committed.

It is also possible to resolve conflicts in the field of product liability through the mediation system established in Law 5/2012 of 6 July, on mediation of civil and commercial matters through the arbitration system established in Law 60/2003, of 23 December, on arbitration.

Additionally, according to the Code of Civil Procedure 1/2000, the litigants are empowered to set out the matter at issue in the proceedings and may waive, acquiesce, or submit to arbitration or mediation, and reach agreements on the matter at issue.

The submission of the parties to any of the methods referred to is voluntary, and therefore alternative methods of dispute resolution are not required to be pursued before initiating any court proceedings.

4.15 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

As a rule, the Spanish courts have jurisdiction over any dispute when the defendant is domiciled in Spain. This is regardless of where the claimant is domiciled. Therefore, if the producer of the defective product is domiciled in Spain, a claim may be brought against him before the Spanish courts.

Additionally, in product liability disputes, defendants not domiciled in Spain may be sued before the Spanish courts if: (i) the events leading to the product defect occurred in Spain; or (ii) the damage occurred in Spain. In this regard, see the Judgment of the Court of Justice of the European Union, case C 45/13 of 16 January 2014, or the Judgment of the Spanish Supreme Court of 21 January 2019.

4.16 May hearings take place or witness evidence be given virtually via teleconferencing or other technical methods?

Judicial acts concerning hearings and/or the examination of witness evidence will generally be held in the presence of the Court. The procedural rules also allow for these to be carried out in a telematic manner.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

The statute of limitations to bring a compensation claim for damages caused by a defective product under the regime of RLD 1/2007 is three years, counted from the date the damage was incurred by the injured party, provided that the identity of the party liable for the damage is known to the injured party. This limitation period may be interrupted, as explained in question 5.2. In such case, the period of three years restarts, and a new statute of limitations period is to be counted from this date.

Nevertheless, the right to claim for recovery of damages as provided in the liability regime of RLD 1/2007 expires 10 years after the defective product is put on the market. The only way to stop this expiration date is to begin legal proceedings before it expires.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the court have a discretion to disapply time limits?

If the claim is brought under the regime of RLD 1/2007 because of the defective nature of the product causing the damage, as defined in such regulation, the liability will always be of a strict nature, and the statute of limitations is three years. In case of bodily injury, this statute of limitations starts to run from the moment when the final extent of the injury has been defined and established.

If the claim cannot be brought under such regulation, the claim will have to be brought under the general rules of civil law, the regime for liability of which is fault-based. In the event that the relation is non-contractual, the statute of limitations is one year.

In order to avoid a discussion on whether the product and the defects fall within the definition of RLD 1/2007 and, therefore, to avoid the debate on whether a statute of limitations of one year or three years applies, in cases of non-contractual liability some choose to initiate the proceedings within one year.

The age or the condition of the claimant does not affect the calculation of any time limit and the courts do not have any discretion to disapply them.

As noted above, legal proceedings brought under the product liability regime of RLD 1/2007 may be barred by limitation if they are initiated after a period of three years.

The limitation period for bringing proceedings 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.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The limitation period starts to run from the moment that the injured party has knowledge of the damage suffered and knows the identity of the person liable for such damage. We also refer to our answer to question 5.2 above regarding the beginning of the time limit in the event of bodily injury.

6 Remedies

6.1 What remedies are available, e.g. monetary compensation, injunctive/declaratory relief?

In accordance with RLD 1/2007, every injured party has the right to receive economic compensation for damage caused by a defective product.

6.2 What types of damage are recoverable, e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The regime on product liability established in RLD 1/2007 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.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

To recover the cost of medical monitoring, the claimant should be able to demonstrate that the cost incurred (the economic damage suffered) is a direct consequence of the product defect, even though the product has not yet malfunctioned and caused injury. Therefore, it must be demonstrated that medical monitoring is necessary to overcome or prevent the damage that the defective product will necessarily cause if there is no medical monitoring, and the existence of the product defect.

Additionally, it should be noted that in the previously mentioned Judgment of 5 March 2015, the Court of Justice of the European Union established that Directive 85/374/CEE, regarding damage caused by defective products, should be interpreted in the sense that the surgical operation for replacement of a defective product implanted in a patient constitutes "damage caused by death or personal injuries", for which the producer is liable, if such an operation is necessary to overcome the defect in the product in question, even if the product has not yet malfunctioned.

Furthermore, in the particular case at hand, it is important to note that if the producer himself warned of the defect on the product and recommended that doctors monitor and/or replace the defective products by means of surgical operations (in this case the defect of the products was acknowledged even though the products had not yet malfunctioned), the producer may be liable for any damage/cost incurred by the injured party as a consequence of the acknowledged defect.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Under Spanish law, no punitive damages – only compensatory damages – can be recovered. However, the courts have some discretionary powers in awarding such compensatory damages, and one may expect the conduct of the defendant to have some impact on the amount of damages awarded.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer, e.g. for a series of claims arising from one incident or accident?

The overall civil liability of one producer for damage – death and personal injury – caused by identical products with the same defect will be limited to a maximum amount of EUR 63,106,270.96.

6.6 Do special rules apply to the settlement of claims/proceedings, e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Minors do not have procedural capacity and must be represented in the proceedings by their parents with parental authority, which may be exercised jointly by both parents, or individually by one of the parents with the consent of the other. If for any reason the parents have been deprived of parental authority, the minor will be represented in the proceedings by his or her legal guardian, but the legal guardian will need judicial authorisation in order to bring or settle a claim.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the claimant in respect of the injury allegedly caused by the product? If so, who has responsibility for the repayment of such sums?

The possible right to be reimbursed by Government authorities in the terms set out in the question is not legally protected by the Spanish regime on product liability.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; and (b) their own legal costs of bringing the proceedings, from the losing party?

The costs of the proceedings will be 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 party who has lost the case, such party will 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 must 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 does not apply.

In the event that the pleas were partially accepted or rejected, each party must 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.

7.2 Is public funding, e.g. legal aid, available?

Law 1/1996, of 10 January, on Legal Aid, governs the regime of access to legal aid. According to this Law, Spanish citizens, nationals of other Member States of the European Union and aliens residing in Spain may have access to legal aid for (among other matters) civil and commercial proceedings, if they provide evidence that they do not have sufficient economic resources to litigate.

The following legal persons may also have access to legal aid, if they prove that they do not have sufficient resources to litigate:

(a) Associations of public interest, foreseen in article 32 of Organic Law 1/2002, of 22 March, that governs the Right to Association.

(b) Foundations recorded in the corresponding Public Register.

7.3 If so, are there any restrictions on the availability of public funding?

In order to have access to legal aid, when making the application for legal aid, the litigant must prove that he or she does not have sufficient economic means, and that he or she has access to gross economic resources and income – annually calculated for all concepts and per family unit – that do not exceed the following thresholds:

(a) Two times the Public Revenue Index ("IPREM" by its Spanish acronym) in force at the moment of the application for legal aid, where the litigant does not form part of any family unit.

(b) Two-and-a-half times the IPREM in force at the moment of the application for legal aid, where the litigant forms part of any family unit with less than four members.

(c) Three times the IPREM in force at the moment of the application for legal aid, where the litigant forms part of any family unit with four or more members.

In the event that the litigant is a legal person, it will be eligible for legal aid if it does not have sufficient means and the accounting result of the entity – annually calculated – is less than an amount equivalent to three times the IPREM.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

The amount of the attorney's professional fees is the amount which is freely agreed upon between the client and the attorney, in observance of the rules on ethics and on free competition. The form in which the fees are to be paid is also freely agreed upon and may include payment of a percentage of the outcome of the claim. In any case, the client will pay the minimum expenses that the attorney may incur as a result of his designation.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

In Spain, third party funding of claims is not illegal. There is no specific regulation on this matter apart from article 1255 of the Civil Code, which sets forth the following: "The contracting parties may establish any covenants, clauses and conditions deemed convenient, provided that they are not contrary to the laws, to the morals or to public policy." Therefore, if it is not contrary to the law, morals or public order, any agreement in this regard is valid.

At the European Union level, the Parliament has launched the implementation of regulations on the private funding of litigious litigation. On 13 September 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.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

No, in advance of the case proceeding to trial, the court does not exercise any kind of control over the costs to be incurred by the parties in order to check if they are proportionate or not.

8 Updates

8.1 Please outline the approach taken to date by the courts in your jurisdiction in relation to product liability for new technologies such as artificial intelligence, machine learning, and robotics, and identify the ways in which this approach differs (if at all) from the approach taken with other products.

There are no relevant cases to report for this edition, related to product liability in respect of new technologies and artificial intelligence.

8.2 If relevant for your jurisdiction, what impact do you anticipate as a result of the revised disclosure requirements under the proposed new EU Product Liability Directive?

The proposed new EU Product Liability Directive contains certain measures that may have a relevant impact on product liability litigation such as:

(a) The 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 can 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) The 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.

(c) The 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.

The new system of disclosure of evidence and presumptions will imply a big modification on the disclosure of evidence requirements existing in Spain.

8.3 Please identify any other significant new cases, trends and developments in Product Liability Law in your jurisdiction.

As for new cases, the Spanish Supreme Court has recently ruled (in a judgment on 7 February 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 product on the market.

With regard to new trends and developments in Product Liability Law for Spain, there are different legislative initiatives to report.

In addition to the proposed new EU Product Liability Directive, in 2022, the 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 (Proposal for AI Liability Directive). These two proposals seek to establish new rules on product liability and civil liability arising from artificial intelligence, which would impact the current the product liability framework, particularly given the advancements in new technologies.

Another new development will be the transposition of the Directive (EU) 2020/1828 ("Representative Actions Directive"). The Spanish Government's first preliminary draft law to transpose the Representative Actions Directive was published on 9 January 2023. This 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 disclose certain pieces of evidence under its control that are relevant for the action to be brought.

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The guide *Chambers and Partners 2024* highlights that "Xavier Moliner has standout experience in the defence of sensitive product liability claims brought against major life sciences companies. He also advises on procurement disputes".
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