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The International Comparative Legal Guide to:

Product Liability 2018

16th Edition

A practical cross-border insight into product liability work

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General Chapters:

Country Question and Answer Chapters:

EDITORIAL

Welcome to the sixteenth edition of *The International Comparative Legal Guide to: Product Liability*.

This guide provides corporate counsel and international practitioners with a comprehensive worldwide legal analysis of the laws and regulations of product liability.

It is divided into two main sections:

Seven general chapters. These chapters are designed to provide readers with an overview of key issues affecting product liability law, particularly from the perspective of a multi-jurisdictional transaction.

Country question and answer chapters. These provide a broad overview of common issues in product liability laws and regulations in 23 jurisdictions.

All chapters are written by leading product liability lawyers and industry specialists and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editors Adela Williams and Tom Fox of Arnold & Porter for their invaluable assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The *International Comparative Legal Guide* series is also available online at www.iclg.com.

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PREFACE

I'm delighted to have been asked to introduce the sixteenth edition of *The International Comparative Legal Guide to: Product Liability*.

The guide continues to be an ideal reference point with seven excellent general chapters covering significant developments in European, Asian and US law. This edition also has a special focus on product recalls, a practical guide around costs issues and considerations in the context of group actions in England & Wales and finally commentary on liability and insurance matters in the context of driverless cars.

As always, the bulk of the edition remains the enormously helpful country question and answer section, covering 23 jurisdictions, new to the guide this year being Albania and Kosovo.

I frequently have cause to make reference to the guide for matters concerning product liability all over the world and will continue to do so as the guide remains a thoroughly informative and comprehensive publication.

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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 on liability for defective products or services is established in Royal Legislative Decree ("RLD") 1/2007, of 16 November, approving the consolidated text of the General Law on the Protection of Consumers and Users and other complementary regulations. Such regime is found in articles 128 to 146, both inclusive, of RLD 1/2007.

Article 136 of RLD 1/2007 defines which types of products are subject to the regime on product liability, namely any movable asset, even when this is combined or incorporated into another movable or immovable asset, as well as gas and electricity. The concept of "any movable asset" is very broad and comprises practically all equipment and consumer goods.

The regime for product liability established in RLD 1/2007 is of a strict nature.

The actions available under RLD 1/2007 do not 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 services or any other cause of non-performance or defective performance of the contract, or of any non-contractual liability that may apply.

1.2 Does the state operate any schemes of compensation for particular products?

The regime on product liability established in RLD 1/2007 does not foresee any scheme of compensation for particular products.

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

The responsibility for the defect is borne by the manufacturer or by the importer who introduces the product into the European Union.

In the event that the manufacturer cannot be identified, the supplier of the product (the distributor or the "retail" supplier) shall be considered as such, unless he informs the injured party of the identity of the manufacturer or of the person who supplied the product to him, within a term of three months. This same rule applies in the case of imported products, in the event that the product does not indicate the name of the importer, even if it indicates the name of the manufacturer.

However, the supplier of the defective product shall be liable towards the injured party as if he were the manufacturer in the event that he supplied the product knowing that the defect existed. In such case, the supplier may enforce his right of recovery against the manufacturer.

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

Under the general regime on liability for defective products or services established in RLD 1/2007, the responsibility for the defective product is only borne by the manufacturer or by the importer who introduces the product into the European Union. Therefore, as the regulatory authority is neither a manufacturer nor an importer, 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. This is possible when the damage is derived from facts or circumstances that could be prevented or avoided, according to the knowledge of science or techniques at the time 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 the producers in case of medicinal products, foods or foodstuffs. Under the latter regime, the person liable shall not be able to invoke the state of scientific and technical knowledge defence, as it is expressly excluded under RLD 1/2007. However, the exoneration cause was introduced into the Law on Administrative Procedure in order to exonerate the public administration (regulatory authority) from responsibility, when the damage is derived from facts or circumstances that could not be 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.

On 17 May 2017, the National High Court (AN) issued two resolutions resolving a case of liability for damages caused by the administration of two vaccines, which were addressed against the Ministry of Health, Social Services and Equality (MOH) and against the pharmaceutical companies that had marketed the products.

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, did not act according to the scientific data and evidence available at that moment. The claimants did not provide any firm and 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 shall 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 which 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 insofar as the supply of the defective product can be considered as an intentional or negligent action. Such action is included as an offence in the Criminal Code and the damage caused is protected by such Criminal Code.

2 Causation

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

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

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 between the defect in the product and the damages suffered, the claimant must provide solid and substantial evidence that supports such link, and the damages must be 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.

In Spain, the principle of generic causation, i.e. that in order to prove the causal relationship it would be sufficient 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 is capable of causing damage is not sufficient to establish the defective nature of such product. In order to prove that a product is defective, the claimant must prove that the damages that he or she claims to have suffered are effectively caused by the defective product. It is sufficient that the claimant proves the existence of the 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 operates.

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 the 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 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 decease.

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 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 victim will always be considered to be established if certain predetermined factual evidence is presented.

In the Spanish cases issued by the AN mentioned in question 1.4 regarding liability for damage caused by the administration of two vaccines, the court confirmed that the burden of proving the defect, the damage and the causal relationship lies with the claimant and, in the absence of evidence from the claimant, it absolved the MOH and the pharmaceutical company of all the wrongdoings attributed to them.

The AN rejected the evidence proposed by the claimants consisting of opinions which, according to the Court, did not undermine the studies and clinical trials that endorsed the efficacy of the product.

With respect to the alleged lack of informed consent prior to its administration, the AN rejected the complaints because the claimants had not 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, since 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 his disease was 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?

In the event that it cannot be established which of several possible producers manufactured the defective product, all of the manufacturers shall be jointly and severally liable *vis-à-vis* the injured parties. The manufacturer who compensated the injured party shall have the right to claim recovery from the other manufacturers, depending on their involvement in causing the damages.

However, the manufacturer 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 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 suffer from: i) manufacturing defects; ii) design defects; and iii) information defects.

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

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

Moreover, the manufacturer or importer shall 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 special regime for product liability established in RLD 1/2007, a defect is defined as "the lack of safety that could legitimately be expected from the product, i.e. based on the criterion of the consumer's reasonable expectations". Further, within the scope of the consumer's legitimate expectations, only the information that was known to the manufacturer or that, in accordance with the state of scientific and technical knowledge, should have been known by him at the moment of placing the product on the market must be included.

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

However, 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 shall be taken into consideration in order to assess the set of information provided to the patient.

Lastly, we must point out that RLD 1/2007 does not expressly foresee the referred "learned intermediary rule", pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make appropriate product information available.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The manufacturer or importer shall not be liable if he can prove:

a) That he did not put the product into circulation.

b) That, given the circumstances of the case, it may be presumed that the defect did not exist when the product was put into circulation.

c) That the product had not been manufactured for sale or for any other form of distribution with an economic purpose, nor that was it manufactured, imported, supplied or distributed within the context of a professional or entrepreneurial activity.

d) That the defect is due to the fact that the product was elaborated in accordance with existing mandatory rules.

e) 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.

The manufacturer 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.

In the case of medicinal products, foods or foodstuffs intended for human consumption, the persons liable shall 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 existence 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 manufacturer has the burden of proving that the defect could not be 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 inexcusable obligation on the manufacturer to elaborate the product in strict compliance and observance of these requirements. If this is the case, the manufacturer could invoke the exoneration cause pointed out in point d) of question 3.1 above. It is not possible to provide a precise answer to this question, and every case should be evaluated on a case-by-case basis.

In case the damages caused by a company by means of its defective product were of criminal entity, that is, constituting an offence under the Spanish Criminal Code, such Code sets forth the possibility that legal entities are held criminally liable. Companies may be held criminally liable as a result of the behaviour of the following persons:

(a) their directors or legal representatives, if 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.

As a general rule, the company shall only be subject to criminal liability if the criminal behaviour of one of the above-mentioned persons was intentional and wilfully misconducted. Reckless behaviours may only result in the company being held criminally liable when involving crimes regarding "fraudulent insolvency", "natural resources and environment", "financing of terrorism" or "money laundering".

According to the Criminal Code and the rulings of the Spanish Supreme Court on this matter, for a legal person to be held criminally liable, the prosecution must prove that both the offence was committed and that the internal control tools deemed ideal and effective to prevent and try to prevent the criminal conduct in question at the company were either non-existent or ineffective.

To be exempted from liability, the accused company is responsible for demonstrating that the compliance system was in place and effective. In the opinion of the Spanish Supreme Court, if the prosecution is unable to demonstrate that the compliance system was non-existent or ineffective, the company cannot be held criminally liable.

In any case, the criminal liability of a legal person is a relatively new matter in Spain, on which the Spanish Supreme Court has not yet addressed this issue on a regular basis. To this end, we must carefully monitor future statements made by the Spanish Supreme Court, in addition to the interpretation, in general, of the Courts and the Public Prosecutor's Office in terms of the provisions of the Criminal Code.

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 and 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 capability of a product to cause a certain type of damage, provided that the claimant is really different. For example, in the event of personal damages 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 him/herself to file a claim against the car manufacturer for the compensation of 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.

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 manufacturer or importer 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, but his liability *vis-à-vis* the claimant will not be reduced hereby.

Nevertheless, the manufacturer or importer who paid compensation to the injured party shall be able to claim such part from the third party as corresponds to such third party's involvement in causing the damages 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 manufacturer or the importer may be reduced, or even excluded, if it is proven that the damages were caused partially

or entirely due to the actions or negligent behaviour of the injured party. However, the behaviour of the injured party must be valued on a case-by-case basis, and must hold direct relation with the defect.

For example, in the example 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.

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, the case shall be resolved by a judge.

4.2 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. In this type of proceeding, 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.

In exceptional cases, once the proceedings have been concluded and before judgment is rendered, the Court may *ex officio* order the examination of new evidence (among which expert evidence) on relevant facts, in the event that the evidence already examined should have been insufficient. In practice, this is very rare.

4.3 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 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 damages.

When those damaged by a harmful event (e.g. by a defective product) are a group of consumers or users, the components of 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 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. In the event that 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.

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

When those damaged are a group of consumers or users, then the claims can be brought by associations of consumers and users and/or the Attorney General's Office, in accordance with what is set out in the answer to question 4.3 above.

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

Even though it is difficult to provide a general answer, it is rather common that a period of 14 to 18 months goes by between the filing of the claim and the rendering of the judgment in first instance.

4.6 Can the court try preliminary issues, the result 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 that require prior resolution by the judge, are those that refer 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) *lis 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 only relate to matters of law.

4.7 What appeal options are available?

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

Against the judgment on appeal rendered by the Provincial Court, there are two appeal options: i) an extraordinary appeal for infringement of procedure; or ii) a cassation appeal, provided that the amount of the proceedings exceeds the sum of 600,000 Euros or the decision on the appeal has reversal interest, because the judgment subject to appeal contradicts the Supreme Court's jurisprudence, or decides on points and issues on which contradictory case law from the Provincial Courts exists or it applies rules that have been in force for less than five years, as long as, in the latter case, no jurisprudence from the Supreme Court exists concerning previous rules of identical or similar content.

4.8 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 must be necessary to have scientific, artistic, technical or practical knowledge to ascertain any facts or circumstances that are relevant to the matter or to acquire certainty about them.

4.9 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 the experts must be provided by the parties, together with the document initiating the proceedings or together with the response to the claim. In the event that this is not possible, the parties must announce their intention to provide such reports in the claim or in the response to the claim. In such case, the reports shall 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.

Expert reports, the necessity or usefulness of which results from the statement of defence or from the allegations and pleas set forth at the pre-trial hearing (i.e., expert report, the need for which becomes apparent at a later stage of the proceedings), shall 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 shall intervene in the trial in order to ratify, explain or clarify their reports, and in order to respond to any question regarding their reports.

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

After the filing of the claim and the response to the claim or, if appropriate, after the pre-trial hearing, documents and instruments related to the merits of the case presented by the claimant or the defendant shall only be admitted in the following cases:

i) If they are dated subsequent to the claim or the response to the claim or, if applicable, to the pre-trial hearing.

ii) If they are dated prior to the claim or response to the claim or, if applicable, to the pre-trial hearing, provided that the party which submits them justifies not having known of their existence before.

iii) If it was not possible to obtain them before due to reasons which are not attributable to the party, provided that the party duly designated the archive, official file or place where they are located, or the registry, registry book or files of which it seeks to obtain a certification.

When a document regarding facts related to the merits of the case is presented once the acts referred to in the previous section have concluded, the other parties may, during the proceedings or hearing, allege the inadmissibility of taking them into consideration.

No document shall be accepted after the trial, except for judgments, judicial or administrative resolutions, rendered or notified on a date subsequent to the moment of submission of conclusions, and provided that they may be conditional or determining for the decision.

4.11 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 that conflicts between consumers, users and companies may 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 or through the arbitration system governed by Law 60/2003, of 23 December, on Arbitration.

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

4.12 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?

Pursuant to Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012, on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (that recasted Council Regulation (EC) No 44/2001, of 22 December 2000), jurisdiction for product liability claims that derive from a contractual relationship between the claimant and the defendant corresponds to the Courts of the place of delivery of the defective product, unless otherwise agreed upon by the parties in the contract.

In the case of a contract with a consumer, the claim by the injured consumer against the manufacturer or importer may be brought before the Courts of the Member State in which the manufacturer or importer has its domicile, or before the Courts of the place of domicile of the consumer.

As to product liability claims that arise from non-contractual relationships, the same above-mentioned regulations establish that the Courts of the place where the harmful event occurred shall have jurisdiction.

If the claimant or defendant is not domiciled in the European Union, a case-by-case analysis will need to be carried out as the applicable bilateral or multilateral treaties will determine whether the person can be brought to Spanish jurisdiction or not.

5 Time Limits

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

The statute of limitations for proceedings for the recovery of damages caused by a defective product initiated under the regime of RLD 1/2007 is 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.

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?

In the event the claim is brought under the regime of RLD 1/2007 because of the defective nature of the product causing the damages, as defined in such regulation, the liability will always be of a strict nature, and the statute of limitations is three years. In the event 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.

In the event that the claim cannot be brought under such regulation, the claim shall 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 the statute of limitations of one year or three years applies, in cases of non-contractual liability we recommend initiating 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. However, the Court shall only reject the claim on this ground if the defendant raises the issue of limitation.

The prescription of the action 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 prescription 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. We also refer to our answer to question 5.2 above regarding the running 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 compensation in the form of an economic indemnity for the damages caused to him or her by the 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 damages, including death and material damages, provided that such damages have been caused to goods destined to private use or consumption and that they are mainly used by the injured party in such concept.

Damages to the defective product itself are not recoverable under RLD 1/2007. However, the injured party may claim compensation for such damages 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?

If the defect has not been proven, no damages have been caused yet, and, as a consequence, it is not possible to establish a causal relationship between the defect and the damages. Furthermore, it is not possible to obtain a judicial award that imposes the obligation to pay compensation for the costs of medical monitoring. In such a scenario, we consider that it would also be very complicated to obtain such compensation as a precautionary measure at the beginning of the proceedings, due to the difficulty of proving *fumus boni iuris*.

In this respect, the previously mentioned ruling of 5 March 2015 by the Court of Justice of the European Union establishes that the Directive 85/374/CEE, regarding damages caused by defective products, should be interpreted in the sense that the surgical operation for the replacement of a defective product implanted on 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 though the product has not malfunctioned yet.

However, in the particular case at stake, it is important to note that the manufacturer himself noticed the defect on the products and recommended doctors to replace them by means of surgical operations, so the defect of the products was acknowledged even though they had not malfunctioned yet.

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 manufacturer for damages – death and personal injuries – caused by identical products with the same defect shall be limited to the maximum amount of 63,106,270.96 Euros.

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 the parental authority, the minor shall be represented in the proceedings by his or her legal guardian, but the guardian will need a judicial authorisation in order to bring the 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 of Government authorities to be reimbursed 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; (b) their own legal costs of bringing the proceedings, from the losing party?

The costs of the proceedings shall be imposed on the party who has had all of 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 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.

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, and according to this Law, Spanish citizens, nationals of other Member States of the European Union and aliens who are in Spain may have access to legal aid for, amongst others, civil and commercial proceedings, if they provide evidence that they do not have sufficient 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:

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

ii) 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 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 for its Spanish acronym) in force at the moment of the application for legal aid, when 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, when 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, when the litigant forms part of any family unit with four or more members.

In the event that the litigant is a legal person, they shall be eligible for legal aid when they do not have sufficient means and the accounting result of the entity – annually calculated – is inferior to an amount equivalent to three times the IPREM.

The current annually calculated IPREM is of 7,455.14 Euros.

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

The amount of the attorney's professional fees shall be one 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 shall also be freely agreed upon, and may include payment of a percentage of the outcome of the claim. In any case, the client shall have to pay all expenses that may arise as a result of the assignment.

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

We are not aware of any regulation that prohibits third party funding of claims, and as a result, such third party funding is admissible. Such funding will be subject to the terms and conditions agreed upon by the parties, provided that they are not contrary to law, ethics or public order.

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, 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 provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction.

In our responses to the questions we have already included the newest trends and developments as regards product liability in Spain, with special regard to the ruling by the Court of Justice of the European Union regarding implantable medical devices.

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