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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 Italy, product liability is governed by Legislative Decree no. 206 of September 6, 2005, the so-called Consumer Code, which is the last of a series of legislative acts, the first of which dates back to 1988, whereby EU Directive no. 374 of 1985 was implemented.

The Consumer Code sets forth a strict, non-fault-based kind of liability. This liability can be claimed by the consumer for damages caused by a defective product, including personal damages, consisting of death or physical injuries, and damage caused to goods normally destined to private use.

This liability is alternative to contractual and tort liabilities, as already governed by the Civil Code.

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

In particular circumstances, in case of a large-scale violation of a constitutional protected right, the State may operate indemnity schemes. Indemnity cannot be regarded as a form of compensation, but rather as a kind of welfare measure. Thus, being entitled to an indemnity does not *per se* prevent the damaged consumer from raising claims seeking full compensation for the relevant damage.

By way of example, Law no. 210 of 1992 provides for a publicly financed monthly monetary indemnity for subjects suffering permanent injuries or illnesses as a result of transfusions of infected blood or blood derivatives, or as a result of the injection of defective vaccines.

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

Under the Consumer Code, the manufacturer is the first subject liable for damages caused by the defective product. The manufacturer is anyone:

- manufacturing the product in the EU;
- presenting itself as manufacturer by placing a name, a trademark or any other distinctive sign on the product, or reconditioning the product;
- representing the manufacturer whenever the former is not established in the EU, and importing the product whenever the manufacturer has no representative established in the EU; or
- included in the supply chain, insofar as its activity may affect the standards of safety of the product.

The distributor (i.e. any professional operator that is part of the supply chain of a product, provided that it does not impact the safety of the same product) may also be held liable, but only in a residual way, in the event that the manufacturer is not identified. Nonetheless, the distributor can escape such a liability by allowing the identification of the manufacturer.

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

Italian law provides for a series of duties for public bodies (e.g. Ministry of Economic Development, Ministry of Health, etc.) to ensure that products placed on the market are safe and to adopt all necessary measures to ensure public safety (including ordering product recalls or prohibiting their sale). In the case of failure to properly perform such monitoring activities, it could be argued that harmful events derived from unsafe products which the competent public bodies had a duty to control would entitle the damaged party to claim compensation from the State as well for not having complied with its "duty to protect". However, it is not possible to assimilate such a liability to the one generally known as "product liability", since reference should be made to other rules.

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?

Under the Consumer Code, the manufacturer has to manufacture and market safe products.

The manufacturer and/or distributor who is or should be aware, based on the information in their possession and in their capacity as professionals in the sector, that a product they placed on the market exposes consumers to risks that are incompatible with general safety requirements, must adopt corrective measures commensurate to the characteristics of, and to the risks posed by, the same product.

Corrective actions have to be evaluated, taking into account the risk that the product poses to consumers. The assessment of said risk is usually made on the basis of the following steps:

- identification of the defect, with details of its nature and cause, the total number of products affected and the number of persons who could be affected by the defect;
- an estimate of the level of risk, which depends on both the severity of the possible injury to those using the product and the probability of injury; and
- evaluation of the acceptability of the risk for consumers.

In case a serious level of risk emerges from the assessment of the above-mentioned elements, the corrective measure to adopt usually consists of the recall of the product. If necessary, lacking any initiative on the part of the manufacturer in this regard, the relevant authority may impose the recall itself.

Failure to undertake a recall or other corrective actions aimed at keeping a dangerous product off the market is punishable under Criminal Law. In addition, such a failure may represent evidence in favour of the consumer in case of litigation aimed at seeking compensation for damages caused by the dangerous product.

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

The manufacturer and/or distributor that fails to adopt measures aimed at remedying the risks deriving from a defective product placed on the market may incur criminal liability. Unless the conduct constitutes a more severe criminal offence (for instance, in the event the defect causes death), the manufacturer/distributor may be subject to arrest for a period of between six months and one year, or to pecuniary sanctions ranging from €1,500 to €50,000.

2 Causation

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

The consumer who claims to have been injured by the defective product has the burden of proving:

- the defect of the product;
- the damage allegedly suffered; and
- causation, in terms of existence of a causal relationship between the aforesaid defect and the damage claimed.

In line with a trend in the case-law of merits courts, it has emerged that the existence of the defect of a product could be inferred by the existence of damage and of the causal link between the use of the products and the damage itself; in other words, according to this trend, the mere fact that the use of the product would have led to the causation of damages would be enough to infer the existence of defects of that product. Thus, no specific evidence of the defect would be needed.

Nonetheless, such a trend appears to have been overturned following a decision of the Supreme Court, which can now be regarded as a benchmark in the matter. Specifically, in accordance with this decision, the existence of a defect of the product has to be proved. In other words, evidence has to be offered that the same product lacks the general safety conditions which are required and can be expected with regard to the common use for which the product has been manufactured and marketed (Court of Cassation, decision no. 6007 of March 15, 2007; more recently confirmed by the Court of Cassation, decision no. 3258 of February 19, 2016).

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 proof that the damaged party has to provide largely depends on the nature of the alleged defect.

In case the product itself is safe and only a single item, which the damaged party was exposed to, malfunctioned or was defected, the same damaged party has to prove the existence of the relevant defect (however, some authors state that said burden of proof could be satisfied by demonstrating that such single item differs from all other products of the same set).

In the event the injury derives from a defect which is common to all similar products (i.e. the product itself is unsafe or it has been wrongfully designed, or there is a lack of information provided by the manufacturer), it will be sufficient for the damaged party to prove that the entire category of products is defected, not having to demonstrate the existence of the defect of the single product he or she entered into contact with.

In cases where said proof is not easily reachable, presumptions may be considered sufficient by judges.

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?

Under the Consumer Code, in the event several subjects caused the damage together, each of them is jointly liable and obliged to provide compensation. Should only one of the subjects compensate the damage at issue, it would have the right to act against the others to recover the amount due by each of them. Said amount has to be determined taking into account the extension of risk, the seriousness of the wrongdoing and the relevant consequences attributable to each subject. Should this assessment not be possible, depending on the circumstances, all the subjects involved have to be considered equally liable.

If the damage is not caused by a common activity but by a single manufacturer to be identified, the relevant burden is on the plaintiff, and no form of market-share liability is applicable.

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?

Under the Consumer Code, the manufacturer has to provide the consumer with useful information to assess and prevent risks deriving from the use of the product as foreseeable given its scope, unless such risks are immediately obvious without any specific indication.

The content and extent of the information to be provided has to be determined with regard to the qualities and characteristics of the product. The ways the product is submitted to the attention of the public, including, for instance, packaging, warnings, handbooks, instructions and intermediaries, also have to be taken into account to this end.

Should the manufacturer fail to provide adequate information as above, preventing the consumer from understanding and consequently avoiding the risks arising from the use of the product, it may incur liability for defectiveness of the same product.

In general terms, in addition to publicly available information, only information provided to the consumer by the manufacturer is relevant in making an evaluation of the defectiveness of the product.

A slightly different situation occurs when the consumer can obtain the product only through an intermediary, who then has a personal duty to evaluate the suitability of the product. In this case, the intermediary, as a result of its professional skills and knowledge, may incur personal liability should it make an inappropriate evaluation or in turn fail to provide the consumer with adequate information in its possession. Despite the intermediary's liability, if a product turns out to be defective, the manufacturer will also be liable.

No principle of "learned intermediary" is applicable.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the Consumer Code, liability is excluded in case:

- the manufacturer did not place the product on the market. In general, a product is considered as marketed if it is delivered to the purchaser, to the user or to an assistant of one of them; which also includes samples or products to be viewed or tested only;
- the defect which caused the damage did not exist at the time the manufacturer placed the product on the market;
- the manufacturer did not manufacture the product for sale or distribution against payment of consideration, or did not manufacture or distribute it in the exercise of its business;
- the defect is due to the compliance of the product with a mandatory legal provision or with binding public measures; or
- the scientific and technical knowledge available when the manufacturer placed the product on the market did not allow the manufacturer to consider the product as defective.

In terms of exclusion of liability of the distributor, please refer to the answer to question 1.3 above.

Provided the above, liability is also excluded if the consumer caused the relevant damage. Specifically, compensation is excluded if the consumer, despite having been aware of the defect of the product and the related risks, voluntarily exposed himself or herself to them.

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?

Please refer to the answer to question 3.1 above.

According to some authors, however, the actual application of this exemption of liability should be limited in light of the provisions of product safety regulations imposing post-selling obligations on the manufacturer.

In any case, the burden to prove that there is no liability lies with the manufacturer.

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?

Please refer to the answer to question 3.1 above.

According to the majority of authors, liability can be escaped only when the mandatory legal provision or the binding measure imposes specific conditions or formalities on the manufacturer, and not when it sets forth minimum safety standards. As a matter of fact, compliance with such minimum safety standards would not amount to a valid defence.

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?

Different consumers, all allegedly damaged by the same kind of product, can each initiate separate proceedings and raise claims based on different legal grounds. No form of issue estoppel can prevent a different consumer from re-litigating issues related to liability for a certain product.

Provided the above, however, previous rulings over cases regarding liability for the same product, albeit not binding, may be regarded by judges as precedents to be followed when evaluating the relevant claims.

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 defendant allegedly liable for the damage claimed by the consumer can in turn raise a claim, in the same or in subsequent proceedings, against any third party that caused or contributed to the fault or defect of the product at issue.

Such a claim would be subject to its own statute of limitation period, in general:

- 10 years for contractual liability;
- five years for tort liability;
- three years for product liability (please refer to the answer to question 5.2 below); and
- one year for liability of the seller in case of the sale of a defective product to a professional. A professional is considered to be anyone purchasing goods within the exercise of its business.

Each of the above terms starts running from the day on which the relevant right can be exercised, i.e., in general terms, respectively when:

- the non-performed obligation became due or the breach of the relevant contractual obligation occurred;
- the harmful event occurred;
- the consumer became aware or should have become aware of the damage, the defect of the product and the identity of the liable subject (please refer to the answer to question 5.2 below); and
- the purchaser became aware or should have become aware of the defect of the sold goods.

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

Liability is excluded in cases where the damage has been caused by the consumer who claims to have been damaged by the defective product; specifically, compensation is excluded if the consumer, although having been aware of the defect of the product and the related risks, voluntarily exposed himself or herself to the same risks.

Furthermore, in cases where the consumer who has been damaged by the defective product contributed to the causation of the relevant damage, compensation is reduced proportionally with regard to the seriousness of the negligence attributable to the same consumer and the extent of the consequences arising therefrom.

4 Procedure

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

As a general rule, civil proceedings are held by a single judge or by a panel of judges in some specific cases.

Juries are not contemplated in civil proceedings.

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)?

Should the case require specific technical knowledge, the judge may appoint, also upon a party's request, one or more experts (*Consulente Tecnico di Ufficio* – "CTU") to act as the judge's assistants and provide technical expertise.

The CTU is selected from lists of experts filed in each court. Otherwise, the CTU's appointment has to be previously authorised by the President of the Court. The parties can oppose the appointment of the CTU on proper grounds, such as risk of impartiality or bias.

Each party can appoint its own retained expert to work together with the CTU (*Consulenti Tecnici di Parte* – "CTPs").

The CTU cannot make legal assessments, establish the existence and meaning of legal provisions or assess documentary evidence. His/her role is strictly limited to technical questions posed by the court.

The expertise proceeding is carried out in writing. The CTU shares a preliminary report with the CTPs; subsequently the CTU files a final report, including comments or remarks from the CTPs.

The content of the final report filed as above is not binding for the judge, who may disagree with its outcome and provide adequate grounds in support of his/her decision.

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?

A modification of the Consumer Code dating back to 2008 has introduced class actions as a mechanism to seek damage compensation for certain kinds of multiple claims, including claims arising from the same defective product.

A class action can be brought in relation to wrongful events which occurred after 15 August 2009.

The relevant procedure consists of a preliminary admissibility stage (certification), which may be followed by the merit stage for the assessment of liability and damage. Homogeneity of the rights claimed by the members of the group is an essential condition for admissibility.

Class actions are based on an opt-in system.

The decision of the court, ruling in panels, can provide for a direct condemnation or set forth the criteria to calculate the amount due to the members of the group or the minimum amount due to each of them. Assessment of individual damage can, in this second case, be remitted to a subsequent settlement or litigation.

Since class actions have been introduced in Italy, approximately 70 cases have been initiated, but only a very limited number of them have been certified. In fact, this procedural instrument appears to have not been very commonly used so far: an average of only 10 class actions per year has been brought. This is a very small result, considering that approximately four million new civil cases are initiated in Italy every year.

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

Class actions can be brought by any single consumer as a class representative, providing there is evidence that the claims raised are worthy of being litigated as class actions due to the existence of homogenous rights to protection within the potential group.

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

In Italy, there is no formal distinction between the trial and pre-trial phases.

In case of class actions, the certification phase (pre-trial phase) may last some months; including the appeal on certification, this phase can last up to a year.

On average, the complete first instance proceedings may last from one to five years. Timing may vary depending on different factors, such as the workflow of each court or the way the specific case develops, for instance whether or not evidence-gathering activities have to be carried out.

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 court can decide to evaluate preliminary issues first. They include preliminary procedural matters (e.g. lack of jurisdiction, lack of venue, lack of legal capacity to sue) or preliminary matters on the merits (e.g. time-barred claims).

In practice, however, judges tend to evaluate both preliminary and non-preliminary issues together at the end of the proceedings.

There is no jury in civil litigation.

4.7 What appeal options are available?

All parties have the right to appeal.

In general, in Italy there are three levels of courts:

- first-instance courts (justices of the peace and tribunals);
- second-instance courts (courts of appeal for judgments rendered by tribunals, and tribunals for judgments rendered by justices of the peace); and
- the Court of Cassation (Supreme Court).

Decisions issued in first instance proceedings can be appealed before courts of second instance, which can rule again on the merits of the case. Nonetheless, new claims and new challenges are not admissible; new evidentiary means or requests cannot be admitted unless they are deemed as essential for deciding the case or unless the party proves that they could have not been submitted during first instance proceedings for reasons not attributable to the same party.

All parties have the right to challenge the merit decision before the Supreme Court, which stands at the top of the court hierarchy. It is the court of last resort and its task is to ensure the consistent interpretation and application of the law. The Court's review is limited to issues regarding the interpretation and correct application of the law, without any further evaluation on the merits of the case.

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?

Please refer to the answer to question 4.2 above.

The parties may appoint their own experts, even if the judge fails to appoint a CTU, in order to draft written reports which shall be filed as exhibits in the proceedings. In general, there is no restriction on the nature or the extent of this kind of evidence.

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?

Pre-trial deposition or exchange of witness statements or expert reports is not allowed.

Pre-trial technical investigations can be initiated whenever there is the need to ascertain a factual situation which may be subject to modification or deterioration before evidence-gathering activities in subsequent proceedings are initiated. In general terms, these proceedings, which are court-ruled, are not widely used.

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

No discovery rule is applicable.

Pending the proceedings, during evidence-gathering activities, the judge may, upon a party's request, order the counterparty or any third party to exhibit documents. In case the counterparty or any third party as above refuses to do so and fails to provide a valid reason to support the refusal, the judge may infer from its conduct to rule over the case.

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

There are no pre-filing requirements to begin a formal, ordinary lawsuit for product liability. As a result of a recent reform of Italian procedural law, since 9 February 2015, for claims for payments of any amount between €1,100 and €50,000, before litigating in court parties to a dispute have to carry out negotiations in the presence of their attorneys at law to try to amicably settle their dispute (assisted negotiation). Assisted negotiation is not mandatory in the case of disputes that arise as per obligations set forth by agreements entered into by professionals and consumers.

In addition, Law no. 28 of 2010 provides for a "mediation procedure" for an out-of-court settlement, to be carried out before a mediation authority. Said mediation procedure is compulsory before trial in some specific matters (listed by Art. 5 of Law no. 28 of 2010), some of which (damages arising from medical and healthcare liability) may be relevant for product liability suits. In all other cases, the choice as to whether or not to initiate said mediation procedure is up to the parties.

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?

Jurisdiction over product liability cases is governed by EU Regulation no. 1215 of 2012, as well as Italian Law no. 218 of 1995, setting forth conflict of law provisions.

In general, on the basis of the above, Italian courts have jurisdiction over claims for compensation of damages due to an event which occurred or which may occur in Italy, irrespective of the fact that the claimant or the defendant is domiciled in Italy.

Italian courts also have jurisdiction over claims raised by a claimant who is not domiciled in Italy against any defendant who is domiciled in Italy.

5 Time Limits

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

The limitation period for product liability claims is three years, running from the day on which the consumer was allegedly damaged by the defective product, the day on which the consumer becomes aware or should have become aware of the damage or defect, or the day on which the consumer becomes aware of the identity of the liable party (please refer to the answer to question 3.5 above).

In any case, the right to be compensated for the defect of a product expires after 10 years from the day on which the manufacturer or importer within the EU placed the relevant product on the market.

However, the claimant may bring an ordinary tort action instead of a product liability action and exploit the relevant five-year term.

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?

Please refer to the answers to questions 3.5 and 5.1 above.

The limitation period does not vary based on the age or condition of the claimant. The court has no discretion in this regard.

The running of the limitation period can in any case be interrupted. In general, this occurs whenever proceedings are initiated to raise the relevant claim or such a claim is raised in pending proceedings. In case of interruption, the limitation period starts running again afresh as soon as a binding decision is issued as an outcome of aforesaid proceedings. In the field of product liability, as in several other fields under Italian law, the running of the limitation period can be interrupted also by way of a demand letter or letter of formal notice sent to the manufacturer by the allegedly damaged party denouncing the harmful event and asking for compensation.

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

No specific provision is set forth in relation to the effects of issues of concealment or fraud over limitation periods. Nonetheless, the aforesaid issues may impact the running of the same period. Indeed, as per the general rule set forth by the Consumer Code, the limitation period starts running from the day on which the consumer acknowledged or should have acknowledged, *inter alia*, the defect in question on the basis of ordinary diligence and overall circumstances; therefore, a concealment or fraud could postpone the beginning of the running of the limitation period (please also refer to the answers to questions 3.5 and 5.1 above).

Provided the above, in general, should such issues of concealment or fraud amount to criminal offences, the longer limitation period, generally of six years, provided by the criminal law to prosecute the offender, applies instead of the period indicated above.

6 Remedies

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

As a general remark, product liability claims can be raised to seek compensation for personal damage, causing death or physical injuries, as well as for damage to objects normally used for private purposes and destroyed or damaged by the defective product.

Having said that, both pecuniary and non-pecuniary damages suffered by the consumer (as above) are recoverable.

The Consumer Code does not provide for injunctive/declaratory relief for individual consumers, but only for consumer associations.

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

For some decades now, both case-law and authors have identified four categories of damages:

- material (pecuniary) damages, which consist of monetary damage due to pecuniary loss or loss of profits;
- non-material damages, i.e.:
  a) biological damages, affecting the psychological and/or physical integrity of a person, directly related to his or her health;
  b) moral damages, essentially consisting of pain and suffering, to be awarded only in cases provided for by law (mainly as a result of a criminal offence); and
  c) existential damages, as 'created' by case-law to allow for compensation of damages not included within the above category of moral damages and essentially consisting of any event that negatively affects someone's 'quality of life'.

By a stand-out ruling, the Joint Sections of the Court of Cassation maintained that non-pecuniary damages are compensable only in cases provided for by the law, i.e. whenever compensability is expressly acknowledged in a law provision and whenever, even lacking such a law provision, the damage entails the violation of a personal right which is constitutionally safeguarded (Court of Cassation, decision no. 26972 of 2008). In view of the above and on the basis of such ruling, existential damage is no longer compensable as an autonomous category of damage, but rather as a component of non-material damages. It is worth mentioning that decisions from Italian courts, even those issued by the Supreme Court, do not amount to binding precedents, even though they may have a persuasive effect. So far, the trend of lower level courts is to follow the above interpretation.

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?

In general terms, compensation is allowed only as restoration of damages actually suffered as a consequence of the defective product. Otherwise, in principle, no compensation is possible.

Having said that, once the damage has occurred, compensation may also cover costs for future medical monitoring, including costs related to investigations, tests and treatments, whether or not they were foreseeable as a result of the ascertained injury.

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

In general terms, Italian law does not provide for punitive damages in the field of product liability and, more in general, in the field of tort liability.

However, it should be highlighted that, by an unprecedented judgment (no. 16601 of July 5, 2017), dealing with a case of product liability, the Joined Sessions of the Court of Cassation clarified that such damages are not *per se* incompatible with the Italian legal order and with the function of tort liability under Italian law. Therefore, according to the court, punitive damages should be granted in case Italian judges are called to enforce a foreign decision rendered by a judge belonging to a legal order in which punitive damages are allowed. No similar cases have followed.

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?

No limit is set forth.

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?

No specific rule applies in the case of settlement of claims or proceedings. As far as class actions are concerned, in general, conciliation or settlement between class representatives and the defendant do not affect class members who are not party to the out-of-court agreement.

Regardless of product liability rules, some kinds of settlements involving minors have to be authorised by the judge.

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?

No specific regulation is set forth, nor is there any case-law to report in this regard.

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?

In its final decision the judge also awards costs of the proceedings. In general, it is the responsibility of the losing party to refund the winning party's court expenses and legal fees incurred during the proceedings. Nonetheless, depending on the circumstances, the judge may rule that each party bears its own costs. As a matter of fact, judges frequently deem that it is not appropriate for a company to recover costs against losing individuals.

Provided the above, in case they are awarded, recoverable fees are very rarely those actually paid by the winning parties. Fees are calculated to this end on the basis of parameters included in tariffs set forth by the Ministry of Justice; quite frequently, these parameters do not reflect the economic conditions applied by law firms.

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

In general, an indigent party can access legal aid by filing an application to the local Bar Association.

Legal aid is granted on the condition that the claim to be raised is not clearly groundless. Legal aid can be revoked at any time, also pending proceedings, should the judge ascertain that the income of the relevant party actually exceeds the threshold set forth by the law, that the requirements provided by the law are not actually met or that the same party acted or defended itself with malice or gross negligence.

Legal aid includes both costs and fees related to the proceedings. When legal aid is granted, some of the costs are paid by the State and others are waived.

Legal aid is not widespread, given strict limits of admissibility. Moreover, litigation in Italy is not particularly expensive.

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

Please see the answer to question 7.2 above.

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

Contingency or conditional fees have become admissible only in the last few years. Accordingly, parties can agree for legal fees to be calculated keeping the awarded sum as a parameter. Such agreements are only valid if they are in writing and particular limitations are provided.

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

Third party litigation funding is not regulated in Italy. In general, it is admissible, but at least so far it is not common at all.

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?

The court does not exercise control over the costs to be incurred by the parties and the claim filed to the court. The (allegedly) damaged party quantifies its claim, if possible, when starting the case. The costs of the proceedings may be influenced, sometimes significantly, depending on the development of the evidence-gathering phase, and in particular when it is necessary to obtain the opinion of a court-appointed expert. In order to prevent these costs from discouraging damaged parties to file their claims, Art. 120 of the Consumer Code allows the judge to initially place these costs on the defendant when the claim of the damaged party is plausible.

As for legal fees, the losing party is generally condemned to refund them to the winning counterparty (in application of the general "loser pays" principle). They are always quantified by the court with its final decision and are proportionate to the parameters set out by Law no. 247 of 2012 (said parameters depend on the value of the claim, the complexity of the case, the number of parties, etc.). This mechanism avoids the risk of the losing party being condemned to refund to the counterparty a disproportionate amount in relation to the value of the claim, even if, on the other side, the winning party may be only partially refunded (amounts set out by the parameters are often lower than the amounts effectively paid as legal fees).

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 the last few years Italian case-law on product liability has developed in line with previous trends as per: (i) the burden of proof – the Court of Cassation (no. 15851/15) confirmed that the damaged party is exonerated only from proving negligence/wilful misconduct by the damaging party, not from proving the "defect" – and (ii) the notion of "defective product", i.e. a product lacking safety in comparison with consumers' expectations – the Supreme Court (no. 3258/16) rejected a claim for compensation for damages allegedly caused by the explosion of a toxic house detergent, stating that the product itself could not be considered "defective", since it was manufactured and distributed in line with the safety standards required for this kind of product.

On this second profile, a decision of the Court of Justice of the European Union (March 5, 2015, Case nos. 503 and 504 of 2013) regarding medical devices to be implanted in humans for therapeutic purposes assessed that all medical devices placed on the market had to be considered defective – irrespective of whether or not anomalies in their functioning had actually been reported in the treated patients – since they did not provide the standard level of safety that patients may legitimately expect. Also, according to said decision, the quantification of damages suffered should include the costs of surgery required to remove the defect in the medical devices.

It is also worth mentioning that, in 2017, the same CJEU rendered a judgment (no. 621 of June 21, 2017) concerning the burden of proof for (medical) product liability claims, clarifying that the law cannot be interpreted as necessarily requiring definite medical evidence as to causation between the defect and the insurgence of an illness, it being sufficient to demonstrate probable cause (the case dealt with damages allegedly caused by vaccines).

With regards to updates on punitive damages, please see question 6.4 above.

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Daniele Vecchi, Partner of the Litigation Department, practises general commercial and civil litigation and is a specialist in product liability. He has extensive experience in defending companies in consumer and group actions involving tobacco products, food and pharmaceuticals.

Over the course of his career he has worked extensively with in-house counsels and lawyers in Italy and abroad, developing an international defence strategy with important expert witnesses.

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She has gained solid experience in litigation, with a specific focus on civil and international actions.

She specialises in Product Liability, and over the last 15 years, she has assisted and advised several companies, both domestic and foreign, providing full assistance in matters concerning consumers' claims and multi-claimant group actions.

She regularly contributes to international publications in her field of specialisation.

She was awarded "Product Liability Lawyer of the Year in Italy" by Corporate INTL Global Awards (from 2014 to 2018) and by Global Law Experts Practice Awards (2015 and 2014), and Lawyer of the Year in Consumer Law – Milan, Italy by Corporate LiveWire – Global Awards (2015).

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