Product Liability 2020

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Getting The Deal Through

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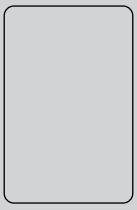

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Lexology Getting The Deal Through is delighted to publish the thirteenth edition of *Product Liability*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on China and the European Union.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Rod Freeman and Sarah-Jane Dobson of Cooley LLP, for their assistance with this volume.

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Italy

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CIVIL LITIGATION SYSTEM

The court system

1 | What is the structure of the civil court system?

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).

The justice of the peace has jurisdiction over legal actions up to the value of €5,000 and over proceedings related to damages caused by trafficking vessels or vehicles up to the value of €20,000. In acordance with a quite recent reform, starting from 31 October 2025, both these thresholds will be raised respectively to €30,000 and €50,000. In addition to this, the justice of the peace also has jurisdiction over some specific subject matters. Cases filed with the justice of the peace in which the amount claimed is less than €1,100 may be decided 'according to principles of equity'. In these cases, the justice of the peace may depart from the rules of law provided that the principles of the legal system are respected. Starting from 31 October 2025 the relevant threshold will be raised as well, to €2,500.

Tribunals have first-instance jurisdiction over all cases not expressly allocated to other courts, including class actions, and second-instance jurisdiction over decisions issued by the justices of the peace.

Courts of appeal have first-instance jurisdiction over some specific matters and second-instance jurisdiction over the challenge of decisions issued by tribunals.

Decisions issued by courts of appeal can be in turn challenged before the Court of Cassation, which is at the top of the Italian judicial 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, as the Court does not review any assessment of facts made in first and second instance proceedings.

In class action proceedings orders of second instance ruling over the admissibility of the class cannot be further challenged before the Court of Cassation.

Judges and juries

2 | What is the role of the judge in civil proceedings and what is the role of the jury?

Italy relies upon an adversarial judicial system.

Juries are not contemplated in civil proceedings in Italy. Ordinary civil proceedings of first instance are held by single judges; whereas class action proceedings of first instance are held before tribunals, ruling in a panel of judges. Appeal proceedings are held before courts of appeal, ruling in panels. The proceedings before the Court of Cassation are held by a panel of judges as well.

The judge is tasked with ruling on the parties' requests based on the evidence they submitted. The judge governs the functioning of the proceedings, setting out the dates for the hearings and the terms for the parties to perform judicial activities (eg, filing briefs, submitting evidence). He or she is not bound to apply the law identified by the parties.

Pleadings and timing

3 | What are the basic pleadings filed with the court to institute, prosecute and defend the product liability action and what is the sequence and timing for filing them?

In Italy product liability actions are governed by the same rules set forth by the Italian Code of Civil Procedure for ordinary proceedings.

A case begins with the plaintiff's writ of summons, which includes all the claims against the defendant. In the writ of summons the plaintiff must clearly state, inter alia, the kind of relief sought (namely, claim for compensation for damage), and the facts and points of law supporting the claim. The plaintiff shall serve its counterparty with the writ of summons.

The defendant's first pleading (statement of defence), whereby appearance is entered in the proceedings, must include any defence arguments and challenge to any fact and point of law indicated by the plaintiff to support the claims. This brief has to be filed within the mandatory term of 20 days before the first hearing in case the defendant intends to raise a counterclaim, join third parties in the proceedings or raise any 'strict' objection (ie, any objection, procedural or on the merits, that cannot be raised by the judge ex officio). Otherwise, the brief of appearance can be filed also at the first hearing.

At such a hearing, any of the litigants may request terms within which to file defensive briefs; namely, a first term of 30 days to specify or amend claims and defence arguments already submitted; a second term of additional 30 days to submit means or requests for evidence; and a third term of additional 20 days to oppose the counterparty's means or request of evidence.

The judge will then set a date for a hearing, where he or she will identify the items of evidence to gather. The judge may need to schedule one or more hearings to carry out and complete evidence-gathering activities.

When the judge, after – or even before – the conclusion of the evidence-gathering phase, deems the case ready to be decided, he or she schedules a hearing to let the parties specify their conclusions. Following this hearing, the parties are granted a term not longer than 60 days to file their final pleadings and a further term of 20 days to file their pleadings of reply. Alternatively, the judge can grant the parties only a term for filing their final pleadings and, instead of granting them a term for filing their pleadings of reply, schedule a hearing in which the parties can discuss the case orally. As a third option, the judge can let the parties discuss the case orally at the hearing for specification of the

conclusions or at a further hearing to be scheduled to this end. These, however, are not very common options.

Pre-filing requirements

4 | Are there any pre-filing requirements that must be satisfied before a formal lawsuit may be commenced by the product liability claimant?

There are no pre-filing requirements to begin a formal, ordinary lawsuit for product liability.

Since 9 February 2015, in the case of claims related to the payment of any amount between €1,100 and €50,000, before litigating in court, parties to a dispute have to attempt to carry out negotiations in the presence of their attorneys at law to try to amicably settle their dispute (assisted negotiation). Such a procedure is not mandatory if the dispute concerns agreements entered into by professionals and consumers.

Summary dispositions

5 | Are mechanisms available to the parties to seek resolution of a case before a full hearing on the merits?

Under Italian law, several alternative dispute resolution mechanisms are available to the parties before starting litigation in court. Reference is made in particular to assisted negotiation and mediation.

Since 9 February 2015, in the case of claims related to the payment of any amount between €1,100 and €50,000, before litigating in court, parties to a dispute have to attempt to carry out negotiations in the presence of their attorneys at law to try to amicably settle their dispute (assisted negotiation). Such a procedure is not mandatory if the dispute concerns agreements entered into by professionals and consumers.

Mediation is a procedure by which the parties charge a third and impartial subject (usually a professional mediator appointed by conciliatory bodies) with the task of trying to find an amicable solution to the dispute. In the field of product liability, it is not compulsory by law to make an attempt to reach an out-of-court settlement as a pre-filing requirement. However, the plaintiff can in any event try to use this procedure as a way to attempt to reach an amicable agreement with the adverse party, before starting litigation.

There are no mechanisms of summary dispositions available once proceedings are initiated.

Nonetheless, in appeal proceedings, at the first hearing before the court of second instance, an evaluation on the admissibility of the relevant writ of appeal has to be made, considering whether the relevant appeal is highly likely to be rejected (filtering evaluation). In the case of high likelihood of rejection of the appeal, the court of second instance declares the appeal inadmissible without specifically entering into the merits of the same, thus confirming the first instance decision.

Trials

6 | What is the basic trial structure?

Italian civil proceedings can be broadly divided into three phases:

- introductory phase: this is to assess the formal and procedural regularity of the proceedings, with regard to the parties (relevant legal standing and powers), the jurisdiction of the court seized and all the other procedural issues that may prevent the case from reaching the subsequent phase. The court examines the requests for evidence and grants the requests it deems appropriate;
- evidentiary phase: the evidence admitted by the court is gathered, witnesses are examined and experts appointed by the judge render their opinions; and
- decision phase: this includes the evaluation of the collected evidence and of the arguments submitted by the parties. This leads to the final decision.

There is no distinction between pretrial and trial phases, which is typical of the common law system. The same judge presides over all three phases of the proceedings, which are not formally divided. The judge sets the dates for the hearings, checks that there are no procedural flaws, rules on the requests of the parties, appoints experts, and conducts and oversees the evidence-gathering activities up to the final decision. Only the judge can question witnesses; however, he or she poses questions that have been previously submitted by the parties and that he or she has already approved.

Basically, proceedings are not public; access to court files is not permitted to third entities, not being party to the proceedings. Nonetheless, hearings held for discussion of the case are open to the public. Further, the decision is publicly available.

Group actions

7 | Are there class, group or other collective action mechanisms available to product liability claimants? Can such actions be brought by representative bodies?

Class action seeking damage compensation as a mechanism has been effective in the Italian legal system since 1 January 2010 in relation to wrongful events that have occurred since 15 August 2009. Since then, the relevant provisions have been subject to partial modifications. On 3 April 2019 the Italian Senate approved a bill of law for a reform of this procedural tool. Such reform has now been converted into Law No. 31 of 12 April 2019. The new rules should have come into force on 18 April 2020. However, by a recent legislative intervention, this term has been postponed to 19 November 2020.

Under the rules currently in force, class actions can be started by any single consumer as a class representative, as well as by associations or committees appointed by one or more consumers, in order to request compensation for damages or reimbursement in favour of consumers in the event of unlawful behaviour damaging a plurality of persons, including cases of product liability.

As of the date of writing, class actions consist of two phases: a first stage in which the admissibility of the class action is assessed and a second stage dedicated to determining liability and damage. An essential condition for admissibility is homogeneity of the rights claimed by the members of the group. Once the court, ruling in panel, declares the action admissible, the order attesting the admissibility of the class action is made publicly known, being the action based on an opt-in system.

In the case of a positive outcome of the class action, the decision of the court can either be a direct condemnation of the respondent, ordering him or her to compensate the damages in the amount liquidated by the same decision, or set the criteria to be used to calculate the amount to be paid to the class members, possibly establishing the minimum amount to be paid to each consumer. In this second case, the assessment of individual damages is then referred to a subsequent settlement or litigation.

Italian law also provides for the possibility of a representative action being brought by consumers' associations, not acting in the interest of individual consumers who appointed it to this aim, but for the protection of the collective interests of consumers. By this kind of action, consumers' association may seek injunctive or declaratory relief, by requesting the court to order the concerned business to refrain from conduct harming the interests of consumers and to adopt measures to remove the prejudicial effects of previous conduct. The above-mentioned reform approved by the Italian Senate includes a proposal for the reform of this kind of action as well.

Timing

8 How long does it typically take a product liability action to get to the trial stage and what is the duration of a trial?

The average length of ordinary first instance proceedings, whose rules also govern product liability actions, ranges from one to five years, depending mainly on the complexity of the evidence-gathering activity needed and on the workload of each individual court.

EVIDENTIARY ISSUES AND DAMAGES

Pretrial discovery and disclosure

9 What is the nature and extent of pretrial preservation and disclosure of documents and other evidence? Are there any avenues for pretrial discovery?

The law sets forth a duty to preserve documents for companies and professionals. The extent of such duty may vary depending on the nature of the documents concerned.

Formal US-style discovery, by which each party can access its counterparty's entire internal documentation, does not exist in Italy. Once the proceedings have started, any party can ask the judge to order the counterparty or any third party to file specific documents with the court. If the counterparty or any third party does not comply with this order without a valid reason for not doing so, the judge may infer from this conduct to rule on the case. In addition, the judge may order the parties to the proceedings or any third party to subject themselves to inspections on their own persons or on goods that are in their possession, if this is deemed as necessary to assess the facts under dispute and if such inspections can be put in place without serious detriment to the parties or third parties concerned. Again, should one of the parties or one of the third parties refuse to allow the inspections ordered by the judge, the latter may infer arguments from such conduct to rule on the case.

Very limited pretrial activities are allowed in order to procure evidence (witnesses, ascertainment over the status of goods, technical experts) prior to the beginning of proceedings. In general terms, this possibility is limited to the case there is a particular matter of urgency or the risk of not being able to procure the same evidence later on.

Evidence

10 How is evidence presented in the courtroom and how is the evidence cross-examined by the opposing party?

In the Italian civil law system, considerable weight is given to written evidence. The basic principle is that oral testimony is allowed in cases where documents are either unavailable or unreliable.

With regard to oral testimony, when submitting their requests for evidence, the parties must also include a list of people to be called to testify, along with the list of questions that could be submitted to them. The judge rules on the admissibility of both witnesses and questions. Witnesses can only testify as to factual circumstances and cannot express personal evaluations.

Witness statements are given verbally at the hearings, under oath. The parties are not entitled to question the witnesses directly and no formal cross-examination exists: it is only the judge who questions the witnesses, while the parties can suggest questions to the judge. Written witness statements in the form of depositions are admissible, albeit within strict limits depending on the nature of the matter, the agreement of the parties and the discretional evaluation of the judge.

The parties to the proceedings cannot be heard as witnesses. Upon request of the counterparty, however, each party, or its legal representative in the case of a legal person, can be summoned for a 'formal examination'. Formal examination is a kind of evidence, aimed at achieving a confession. Also, in this case, the party can be questioned only by the judge and on the questions previously approved. The party cannot be forced to appear, but if he or she fails to appear or refuses to answer, the judge can consider the facts to which the questions relate as admitted.

Moreover, the court can order the parties to appear in order to question them informally (free examination). During a free examination the party is not bound to answer, and the statements rendered are not considered as technical evidence.

Formal and free examinations are not used often, because the examination is not under oath and a possible lie would not be punished as perjury as the party is not – technically – a witness (principle of 'privilege against self-incrimination').

A party's 'oath' is a sworn statement affirming that one or more of the alleged facts are true. It is taken only upon the request of the opposite party, and the party requested to take the oath may also ask the other party to do the same. The oath, when taken, provides 'legal' evidence and conclusive proof of the facts. On the contrary, when the party requested to take the oath refuses to do so or fails to appear, the relevant facts are regarded as established. In practice, oaths are rarely used.

The court can rely only upon evidence provided by the parties and must refrain from personally investigating facts deemed relevant to the case. Nonetheless, the judge enjoys several ex officio powers with regard to evidence-gathering activities: he or she is entitled to appoint one or more experts, to ground his or her decision on facts or circumstances of general knowledge and to call as witnesses persons referred to by other witnesses during their testimony. The judge may ground his or her findings on certain particular items of evidence and disregard other items, provided that a logical and detailed explanation for this is given in the decision.

Expert evidence

11 May the court appoint experts? May the parties influence the appointment and may they present the evidence of experts they selected?

When the case requires specific technical knowledge, the judge may appoint, also upon a party's request, one or more experts (CTUs) to act as the judge's assistants and provide their technical opinions.

The CTU is selected among experts included in lists filed in court. Otherwise, should the expert to be appointed not be included in these lists, the authorisation of the court president is necessary. The parties can oppose the appointment of the CTU on proper grounds, such as risk of partiality and bias.

The CTU cannot make legal assessments, establish the existence of legal provisions, assess documentary evidence or provide evidence of the facts at issue in lieu of the parties. His or her role is strictly limited to answering to the technical questions posed by the court. Each party can appoint its own retained expert (CTP) to work together with the CTU.

The results of the CTU's expertise are put in writing. The CTU submits a preliminary draft report to the CTPs, who can reply in a given term with their observations and remarks. The process ends by the filing of a final report by the CTU, including comments on or remarks to the CTPs' notes. The CTU can be summoned to the hearing to explain the outcome of his or her activity or to reply to the questions raised by the lawyers and by the parties' experts.

It is the judge's duty to evaluate the findings of all experts. The judge may disagree with the conclusions reached by the CTU, as long as he or she provides adequate grounds for this disagreement in his or her decision.

Even if the court does not appoint a CTU, the parties may appoint retained experts, which can draft technical reports to be submitted to

the court as exhibits in the case. In addition, the parties can ask the court to hear their retained experts as witnesses.

Compensatory damages

12 What types of compensatory damages are available to product liability claimants and what limitations apply?

Any damage, including pecuniary and non-pecuniary damage, suffered by the injured party is recoverable. As a general remark, product liability claims can be raised to seek compensation for personal damage, as well as for damage to objects normally used for private purposes and damaged by defective products.

For decades, case law and scholars have made reference to four categories of compensable damage:

- economic damage, consisting of monetary damages (pecuniary loss incurred or loss of profits); and
- non-economic damage, namely:
  - biological damage: damage to the physical or psychological integrity of a person, directly related to his or her health;
  - moral damage: non-pecuniary damages (pain and suffering), which can be awarded only in the cases provided for by law (mainly in cases involving criminal offences); and
  - existential damage: this is a category of non-pecuniary damage 'created' by case law to compensate damage not covered by the moral damage category. The category can cover any event that negatively affects 'quality of life'.

By a stand out ruling of 2008, the Joint Sections of the Court of Cassation maintained that non-pecuniary damage is compensable only in the cases provided for by law, namely in two sets of cases: cases in which compensability is expressly acknowledged (eg, in cases in which the tort is characterised by elements that make it amount to a criminal offence); and cases in which, although compensability of such kind of damage is not expressly provided for by any legal provision, the tort seriously prejudiced a personal right that is directly protected by the Constitution (Judgment No. 26972 of 2018). As a consequence of such decision, damage defined as 'existential' is practically no longer compensable as an autonomous category of damage, but as a subcategory of the wider category of non-economic damage, so as to avoid duplications of compensable damages.

In Italy, decisions, even from the Supreme Court, do not constitute binding precedents and only have a persuasive effect on judges having to rule on similar cases. In recent years, however, the trend of both high and lower courts has been to follow the above interpretation. After almost a decade, the same principles have been reaffirmed by the Court of Cassation (Judgment No. 30997 of 2018), which clarified once again that non-pecuniary damages is a sole category of damages, including all prejudices to personal constitutional rights.

The damage may also be proved on the basis of mere presumptions, but the damaged person still has to allege the factual elements from which the existence and the extent of prejudice may be gathered.

It is up to the judge to quantify the compensable damages to be awarded to the damaged party, based on the evidence submitted to the court. As to the quantification of non-economic damage, the most recent court practice has been to base the assessment in this regard on tables setting forth criteria for such quantification depending on several objective elements (eg, the tables drafted on a yearly basis by several Italian courts).

Non-compensatory damages

13 Are punitive, exemplary, moral or other non-compensatory damages available to product liability claimants?

Italian law does not allow for punitive damage to be awarded in the field of product liability and in that of tort liability. Compensation is allowed only as restoration of damage actually suffered; in accordance with Italian traditional legal theories, any damage not aimed at fully compensating the injured party for distress actually suffered (ie, punitive or exemplary damages) is not permitted. Some scholars and some legal provisions, in specific areas, are to some extent in support of allowing not strictly compensatory damages.

In 2017 the Court of Cassation, without any will to introduce such institute into the Italian legal system, conceded a slight opening in favour of 'punitive damages' (Judgment No. 16601 of 2017). This opening was, however, limited to a very specific case, that is to say recognition in Italy of a foreign judgment ordering the losing party to pay 'punitive damages'. By its decision, the Court of Cassation clarified that punitive damage is not per se incompatible with the Italian legal order and with the nature and function of tort liability under the Italian law. The Court found that when the award of punitive damage is included in a foreign judgment issued in accordance with the foreign national law, and the Italian judge is called to enforce such judgment, the institute of punitive damage is not incompatible with national public policy (in light of an EU-oriented evolution of the notion of public policy).

For completeness, when the judge orders the losing party to the proceedings to do something, upon request of the adverse party, he or she can also provide for a penalty for any subsequent violation of such an order and for any delay in complying with the order. The judge evaluates at his or her discretion whether this penalty is appropriate given the peculiarity of the case. The judge determines the amount of the penalty on the basis of the value of the dispute, the nature of the obligation that is the subject matter of the order, the damage that may be suffered by the winning party if the aforesaid obligation is not performed, and any other relevant facts. This is in fact an additional penalty that may be inflicted on the party that fails to voluntary perform their obligations under the court order.

Other forms of relief

14 May a court issue interim and permanent injunctions in product liability cases? What other forms of non-monetary relief are available?

The Italian Code of Civil Procedure provides for different kinds of interim measures, which can also apply to product liability case. In general, parties may apply for an interim measure both ante causam (ie, before ordinary proceedings) and during the proceedings to ensure that their rights are not affected by the duration of the proceedings. For example, parties may apply to a court asking for a seizure over movable or immovable assets; for a measure of preventive investigation, which can be issued to ensure evidence-gathering when there is the risk that this evidence becomes unavailable in the future; or for any urgent measure that may be needed from time to time, based on a case-by-case analysis. The court releases the interim measure if the applicant proves that his or her claims will likely be admitted at the end of the proceedings and that there is the actual risk that the right he or she wants to safeguard might be irreparably undermined by the duration of the proceedings.

With regard to other forms of non-monetary relief, the Consumer Code provides for a specific action aimed at safeguarding the interests of the consumers (eg, inhibitory action). Consumers' associations are entitled to take action to protect the collective interests of consumers and users by applying to the court asking:

- to prohibit acts and conduct that are detrimental for the interests of consumers and users;
- to take appropriate measures to correct or eliminate the harmful effects of the infringements established; and
- to order the publication of the measure in one or more national or local newspapers where publicity for the measure may help to correct or eliminate the effects of the infringements established.

Moreover, with reference to agreements concluded between consumers and professionals, consumers' associations may apply to a court asking to prohibit the use of the general terms and conditions included therein, when these terms and conditions are considered to be detrimental for the interests of the consumers. Before applying to a court, consumers' associations may initiate a conciliation procedure to settle the dispute.

LITIGATION FUNDING, FEES AND COSTS

Legal aid

15 | Is public funding such as legal aid available? If so, may potential defendants make submissions or otherwise contest the grant of such aid?

An indigent party can access legal aid, provided that the claim is not clearly groundless. To obtain legal aid, the party must file an application to the local bar association. Thereafter, the court before which the proceedings are pending may revoke the legal aid if the income of the party is found to be above the threshold set forth by the law, or if it finds that the requirements provided by the law are lacking or that the party has acted or defended itself with malice or gross negligence. Legal aid includes lawyers' fees and any other costs linked to the case. When legal aid is granted, some of the costs are anticipated by the state and others are waived. Legal aid is, however, not widely resorted to, because of its limitation in admissibility and because – in general – litigation in Italy is not particularly expensive.

Third-party litigation funding

16 | Is third-party litigation funding permissible?

Generally, third-party litigation funding is permissible but not common.

Contingency fees

17 | Are contingency or conditional fee arrangements permissible?

Contingency or conditional fees have become admissible in the past few years. Accordingly, legal fees can be agreed as a percentage of the value of the claim filed to court. Such agreements must be made in writing. In any case, if the agreement sets out that the lawyer is paid with a portion or percentage of the award, this agreement is still prohibited.

'Loser pays' rule

18 | Can the successful party recover its legal fees and expenses from the unsuccessful party?

The court's final decision also awards costs. As a general rule, the losing party has to pay both the expenses and the fees incurred by the winning party; however, this does not mean that the winner will certainly recover all the relevant amounts. As a matter of fact, the court does not liquidate the effective costs incurred by the winning party, but determines them on the basis of certain criteria as established by the law. In accordance with these criteria, fees have to be calculated with regard, basically, to the value of the claims and the activities carried out by the lawyers in each and every phase of the proceedings (ie, study of the case, introductory, evidence-gathering and ruling phases; and the enforcement procedure).

The court may also (wholly or partly) set off the expenses between the parties under certain conditions, that is, when:

- it assesses that the costs to be reimbursed to the winning party are excessive or superfluous;
- all the parties are losing under some aspects of the final decision;
- there are serious and exceptional reasons to do so; and
- the case regards a new matter that has never been decided before by case law or the final decision departs from case law, establishing a principle that revises or overrules what had been established until then by the case law.

In any event, irrespective of the outcome of the proceedings, the court may order one of the parties that by its conduct breached its duty of loyalty and probity in the same proceedings to reimburse to the other party the costs borne as a consequence of the same proceedings.

As a matter of fact, courts frequently deem it not appropriate for a company to recover costs against losing individuals.

SOURCES OF LAW

Product liability statutes

19 | Is there a statute that governs product liability litigation?

EU Directive 85/374/EEC on product liability was implemented in Italy in 1988 by the Product Liability Act, as amended by Legislative Decree No. 25 of 2001 (PLA). The PLA was, to a certain extent, supplemented by Legislative Decree No. 115 of 1995, which implemented the European Directive 92/59/EEC (as amended by Legislative Decree No. 172 of 2004, which in turn implemented European Directive 2001/95/EC, which introduced general obligations on product safety), imposing an obligation on manufacturers and producers to withdraw unsafe products from the market. All the above Acts were subsequently incorporated into the Consumer Code, enacted in 2005 (Legislative Decree No. 206 of 2005).

In general terms, the provisions of these Acts were conceived as a response to the difficulties that consumers had been facing in seeking damage caused by a defective product by relying on the 'traditional theories of liability', namely in contract or in tort; the former, in fact, implies that the action has to be laid against the party that the consumer had signed a contract with (usually the seller), while the latter implies the fault of the manufacturer, that has to be proven by the consumer.

On the contrary, the EU Directive and the Consumer Code have set forth a new kind of liability, which is strict, not fault-based, and can be claimed directly against the manufacturer, regardless of the existence of a contract between the latter and the consumer or user.

The provisions of the Consumer Code only apply to those products that are not covered by other sector-specific legislation (eg, toys, food, machinery and pharmaceuticals). The Consumer Code also complements the provisions of sector-specific legislation, where the latter does not cover certain matters such as the powers of public authorities in charge of product safety issues.

Traditional theories of liability

20 | What other theories of liability are available to product liability claimants?

Further to the provisions of the Consumer Code, claimants may consider claiming compensation on the basis of tort or contract liability, or both. In particular, it is very common for the consumer to submit both a claim for product liability and, alternatively or subordinately, a claim for general tort liability, in relation to the same events.

Tort liability is based on the 'duty of care' concept. The main rule in this regard establishes that: 'Any person who wilfully or negligently commits an act causing another party to suffer unjust damage shall be required to pay compensation for such damage'. Additionally, the Italian legal system provides for a strict liability regime, based on a presumption of liability, on subjects who perform a 'dangerous activity', so that 'whoever has caused injuries to others while performing dangerous activities (defined as dangerous by their nature or because of the type of instruments used to perform them), is required to pay compensation, if he or she is unable to prove that all measures that would have been suitable to avoid any injury have been adopted'. The presumption of liability exempts the injured party from the burden of proving the fault of the allegedly liable party. Therefore, if the claim in question concerns a product that is dangerous in itself, owing to its inner nature (eg, gas cylinders, fireworks), the consumer may consider filing an action on rules concerning liability for dangerous activities. Nonetheless, based on the case law of the Court of Justice of the European Union and of the Italian courts, the applicability of the rules on product liability derived from EU law to cases of damage caused by the use of a product would exclude the possibility to apply another kind of strict liability regime to the same case, such as the above-mentioned rules on liability for dangerous activities.

Contractual liability, based on the breach of an obligation undertaken by one of the parties, relies on the general rule according to which, in the event of non-performance or imperfect performance of the contract (which includes the supply of a defective product), the seller and the lessor are liable to the buyer, leaseholder or user, unless they can prove that non-performance was owing to facts beyond their control. For contractual liability, compensation is limited to reasonably foreseeable damages at the time of entering into the contract.

Consumer legislation

21 | Is there a consumer protection statute that provides remedies, imposes duties or otherwise affects product liability litigants?

The Consumer Code entered into force in 2005, to consolidate all the different provisions concerning consumers already in force in Italy. It consists of 146 articles divided into six parts:

- Part I contains the 'general provisions' governing consumers' and users' rights. In particular, section 2 contains a list of consumers' rights (eg, the rights to protect health; to safety and quality of products and services; to adequate information and fair advertising; and to fairness, transparency and equity in contractual relationships);
- Part II deals with consumers' education and information in terms, for instance, of quality, price and risks, and advertising;
- Part III contains the provisions regulating contracts signed by consumers;
- Part IV concerns the quality and the safety of products, providing for, in particular, provisions on liability for defective products, legal guarantee of conformity and commercial guarantee for goods;
- Part V deals with consumers' associations and access to justice, including class actions. Consumers' associations are entitled to act in defence of consumers' health, safety and quality of goods and services, adequate information and fair advertising; and
- Part VI contains final provisions, including the provision establishing that consumers' rights cannot be waived and the consequent nullity of any agreement in this regard.

Criminal law

22 | Can criminal sanctions be imposed for the sale or distribution of defective products?

Pursuant to the Consumer Code, it is the manufacturers' duty to ensure that products placed on the market are safe. Furthermore, the Consumer Code grants the power to the relevant authorities to monitor the safety of products and to order or impose certain measures aimed at preventing any possible damage.

From a criminal law perspective, should an unsafe product cause harm to someone, the manufacturer of the product might face criminal charges, depending on the facts of the case and the seriousness of the damage caused by the product (eg, personal injury, manslaughter). In this case, criminal proceedings may begin and the damaged person may also bring civil action in the criminal proceedings to seek compensation.

Furthermore, Italian law provides for other more specific penalties if the manufacturer or the distributor places dangerous products on the market, violates a ban from the competent authorities not to market a certain product and fails to adopt measures aimed at remedying the risks deriving from an unsafe product. More specifically:

- unless the conduct constitutes a more severe criminal offence, the manufacturer or distributor that markets dangerous products, or violates a ban issued by a government authority to market a product, may be punishable with imprisonment up to one year and pecuniary sanctions from €10,000 to €50,000;
- unless the conduct constitutes a more severe criminal offence, the manufacturer or distributor that does not comply with an order issued by the competent authorities to make sure that a certain product is safe or that consumers are warned about possible dangers may be punishable with pecuniary sanctions from €10,000 to €25,000;
- the manufacturer or distributor that does not cooperate with the competent authorities in the performance of their monitoring and surveillance activities may be punishable with pecuniary sanctions ranging from €1,500 to €40,000; and
- if a more serious crime is also involved (eg, injury or manslaughter), the relevant criminal provisions will also apply.

Novel theories

23 | Are any novel theories available or emerging for product liability claimants?

There are no significant novel theories available. In general terms, theories on product liability litigation are still developing.

Product defect

24 | What breaches of duties or other theories can be used to establish product defect?

In accordance with the Consumer Code, a product is defective 'when it does not provide the safety a person can reasonably expect, taking into account all circumstances' or, in the case of manufacturing defects, when it does not provide the safety normally provided by other category specimens. In assessing this standard, various factors are considered, including the manner in which the product was distributed and marketed; its clear features; the instructions and warnings provided; the reasonably foreseeable use of the product; and the time the product was put on the market.

Consumers' safety expectations are evaluated on the basis of a series of objective parameters, including price, technical rules (mandatory standards that the manufacturer or producer must comply with), any trial, test and present state of technical and scientific knowledge available at the date of distribution of the product. Finally, the reasonable use of the product is evaluated not in abstract terms but rather in relation to the users to whom the product is destined (such as the foreseeable use of a toy for children).

Three types of defects are set forth under the Consumer Code: manufacturing defects (when the defect is the result of an error in production of an otherwise well-conceived product); design defects (when the

defect is inherent to the project of the product); and defects based on inadequate information (when the product is well conceived and manufactured, but it is dangerous as it has been placed on the market without adequate information to users or consumers).

Defect standard and burden of proof

25 | By what standards may a product be deemed defective and who bears the burden of proof? May that burden be shifted to the opposing party? What is the standard of proof?

The injured party bears the burden of the proof with regard to the defect of the product, the damage suffered and the existence of a causal link between the defect and damage.

A traditional trend of merit courts was to assume the existence of the defect by the damage caused; in other words, in accordance with this stance, the mere fact that the use of a product caused damage would be enough to infer the existence of a defect. However, this trend has been overturned further to a decision of the Supreme Court, which can be now regarded as a benchmark in the matter (Court of Cassation, Judgment No. 6007 of 15 March 2007). Indeed, assuming a more severe approach, the Supreme Court established that the general rules on burden of proof set out in the Civil Code have to be applied. Italian decisions, even if from the Supreme Court, do not consist of binding precedents and only have a persuasive effect. Nonetheless, so far, the trend of both high and lower courts is to follow the interpretation at issue. In addition, more recent case law of the Supreme Court confirms the requirement for the damaged party to prove that the damage suffered was caused by the 'defect' of the product (which has to be thus identified) and not merely by the product itself (see Court of Cassation, Judgments Nos. 29828 of 20 November 2018; 23477 of 28 September 2018).

However, if the proof of the defect is not easily attainable, presumptions may be resorted to in order to demonstrate the existence of them. In this regard, the Court of Cassation confirmed that the demonstration of a 'secondary fact', if based on clear and demonstrated facts, may be considered sufficient by judges to indirectly infer the existence of the 'main fact', such as the defect of the product (Court of Cassation, judgment No. 29828 of 20 November 2018).

A decision of a trial court (Court of Appeals of Brescia, judgment of 2 February 2014) in which the relevant case was sent back by the Supreme Court to be decided again on the merits (Court of Cassation, judgment No. 20985 of 8 October 2007) established that the injured party can meet its burden to prove the defect of the product by merely submitting evidence that the same product cannot be used safely, as could be legitimately expected. Thus, according to this decision, it is not necessary that the injured party indicates and detects the inherent vice owing to the project or the manufacturing of the product at issue (in this case, the defect regarded a breast implant, which emptied out just two years after it was inserted).

According to a relevant decision of the Court of Justice of the European Union in a case concerning medical devices, the detection of a potential defect of products belonging to the same group or series may legitimately lead to assume that a single item from this group or series is defective, without the need to conduct a specific assessment over the single item (judgment of 5 March 2015, Cases Nos. C-503/13 and C-504/13).

Possible respondents

26 | Who may be found liable for injuries and damages caused by defective products? Is it possible for respondents to limit or exclude their liability?

The principle is that manufacturers shall be liable for damage caused by their products. To this purpose, the definition of 'manufacturer', as described by the Consumer Code, includes anyone manufacturing the product (either the finished product, or a component of the same, or its raw materials).

Distributors may also be held liable, but only if manufacturers are not identified or identifiable. Distributors can be released from liability if they allow the identification of the manufacturers.

Causation

27 | What is the standard by which causation between defect and injury or damages must be established? Who bears the burden and may it be shifted to the opposing party?

With reference to the standard for establishing causation, the stance of the Supreme Court is to consider the threshold of probability in civil cases lower than that required in criminal cases; consequently, in civil cases, causal chain can be determined on the logic of 'more probable than not'. It follows that the relevant causal chain, for which wrongdoers shall be liable, is that related to consequences that are 'usually' produced by their actions, unless a new fact occurs in relation to which they have no duty or possibility to act (in compliance with the 'theory of causal regularity'). The law does not set forth any reversal of the burden of the proof, which lies on the plaintiff.

Post-sale duties

28 | What post-sale duties may be imposed on potentially responsible parties and how might liability be imposed upon their breach?

The Consumer Code requires the manufacturer and the distributor to place on the market a safe product. They also have a general duty to carry out 'post-market controls' (testing the product, monitoring consumers' claims, etc) and a number of post-sales duties aimed at preventing damage that a defective product might cause. These may include the withdrawal of the product from the market, the recall from consumers or users and provision of supplementary information aimed at making consumers aware of risks and instructing them on how to avoid damages. Manufacturers are also required to inform the competent authorities of any of their products' defects or risks and cooperate with them in all activities aimed at preventing damage.

In turn, the authorities have the power to instruct manufacturers to withdraw or recall any product they deem to be faulty and to supplement information in order to prevent damage.

LIMITATIONS AND DEFENCES

Limitation periods

29 | What are the applicable limitation periods?

For product liability claims, the statute of limitation period is three years from the day on which the injured party becomes or should have become aware of the damage, the defect and the identity of the liable party. In any event, the right to be compensated for the damage caused by a defective product expires after 10 years from the day on which the manufacturer or the importer within the EU of the product places it on the market.

If the action is based on the general tort rules, the statute of limitation period is five years from the day of the harmful event or, as clarified by case law, the day the harmful event becomes discernible. In contract liability actions, the relevant limitation period is 10 years, from the consumer's awareness of the breach of contract.

State-of-the-art and development risk defence

30 Is it a defence to a product liability action that the product defect was not discoverable within the limitations of science and technology at the time of distribution? If so, who bears the burden and what is the standard of proof?

Pursuant to the Consumer Code, liability is excluded if 'the scientific and technical knowledge available at the time the product was put on the market was not yet of such a kind as to allow the product to be considered faulty'. According to some authors, this exemption from liability would be tacitly revoked, or in any event tempered, by the rules governing product safety that impose post-selling obligations. The burden of proof in this regard is borne by the defendant.

Compliance with standards or requirements

31 Is it a defence that the product complied with mandatory (or voluntary) standards or requirements with respect to the alleged defect?

The fact that the product is in compliance with mandatory standards or requirements is a valid defence, as, pursuant to the Consumer Code, liability is excluded if the defect is owing to the compliance of the product with a mandatory law or a binding order.

According to commentators, this defence may be applied if the mandatory law or a binding order imposes specific conditions or formalities or features of the product on the manufacturer, but not if the mandatory law or a binding order sets forth minimum safety standards. In this case, compliance with these minimum safety standards does not amount to a valid defence.

Other defences

32 What other defences may be available to a product liability defendant?

Liability is excluded if:

- the manufacturer did not place the product on the market;
- the defect that caused the damage did not exist at the time the manufacturer placed the product on the market; or
- 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.

Moreover, another defence for the exclusion of liability that has, in our experience, proved to be fairly effective is the one based on the contribution given by the injured party to the causation of the claimed damage. The Consumer Code allows for exclusion from compensation if the damaged party, although aware of the defect and the related risks, voluntarily exposes him or herself to risk of damage, thereby accepting this risk. Furthermore, if the consumer contributed to the causation of the damage, compensation is proportionally reduced based on the seriousness of the negligence attributable to the consumer and the extent of the relevant consequences.

Appeals

33 What appeals are available to the unsuccessful party in the trial court?

Decisions issued in first instance proceedings for product liability can be appealed by ordinary means before courts of second instance.

Tribunals have first-instance jurisdiction over all cases not expressly allocated to other courts, including class actions, and second-instance jurisdiction over decisions issued by the justices of the peace. Courts of appeal have first-instance jurisdiction over some specific matters and second-instance jurisdiction over the challenge of decisions issued by tribunals. Decisions issued by courts of appeal can be in turn challenged before the Court of Cassation, which is at the top of the Italian judicial 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, as the Court does not review any assessment of facts made in first and second instance proceedings. In class action proceedings orders of second instance ruling over the admissibility of the class cannot be further challenged before the Court of Cassation.

Second instance courts can rule again on the merits of the case. As a general remark, new claims and new challenges are not admissible. New evidentiary means or requests cannot be admitted unless the party proves that they could not have been submitted during first-instance proceedings for reasons not attributable to the same.

Appeal decisions can in turn be challenged before the Supreme Court for limited reasons of law, but are not subject to further review on the merits and facts of the case.

SETTLEMENT AND ALTERNATIVE DISPUTE RESOLUTION

Settlement

34 What rules and procedures govern the settlement of product liability cases?

Under Italian law, no specific regulation is provided in relation to the settlement of product liability cases. Depending on the availability of the parties, disputes can be settled either before or during the proceedings. If proceedings are pending, the settlements can be reached by the parties out of court or under the court's guidance.

A dispute that is the subject matter of class action proceedings can also be settled out of court by the parties without the need to ask for the court's prior approval. However, the settlement agreement does not affect the rights of the consumers who did not expressly approve it.

Alternative dispute resolution

35 Is alternative dispute resolution required or advisable before or instead of proceeding with litigation? How commonly is ADR and arbitration used to resolve claims?

Several alternative dispute resolution (ADR) mechanisms are available and, in some instances, they are compulsory for the parties before starting litigation in court. For instance, in the case of claims related to the payment of any amount between €1,100 and €50,000, before litigating in court, parties to a dispute must attempt to carry out negotiations in the presence of their attorneys at law and try to amicably settle their dispute (assisted negotiation). Furthermore, pursuant to Law No. 28 of 2010, anyone who intends to bring an action in court relating to a dispute concerning property rights, insurance, banking and financial contracts, compensation for damages resulting from the circulation of vehicles and boats, and medical and healthcare liability, is obliged to initiate a mediation procedure in the attempt to solve the dispute out of court, before starting any judicial proceedings. Nothing prevents parties to any dispute from making such an attempt on voluntary basis, out of the hypothesis listed. Since 1 May 2020, recourse to mediation before bringing a legal action is compulsory for disputes concerning breach of contractual obligations attributable to covid-19 containment measures.

ADR is still not broadly used to solve domestic claims. Recourse to arbitration is often preferred to solve disputes that concerns parties from different jurisdictions for business-to-business claims and for claims of a high value, considering the costs involved. Court litigation in Italy is definitively less expensive.

JURISDICTION ANALYSIS

Status of product liability law and development

36 Can you characterise the maturity of product liability law in terms of its legal development and utilisation to redress perceived wrongs?

Although theories and case law on product liability are still developing, there does appear to be a good balance between the provisions governing product liability in terms of compensation of damages suffered by consumers and those aimed at preventing these damages, and in particular those enforcing post-sales duties and post-market controls.

However, statistically, the plaintiffs' lawyers still tend to largely rely on the rules concerning tort liability, rather than on specific product liability rules. Consequently, the number of cases concerning product liability decided every year, albeit seemingly increasing, remains limited. The familiarity of the judiciary with this area of the law still has room for improvement. Moreover, differences can be seen between lower and higher courts, and also in different territorial areas across the country.

Product liability litigation milestones and trends

37 Have there been any recent noteworthy events or cases that have particularly shaped product liability law? Has there been any change in the frequency or nature of product liability cases launched in the past 12 months?

Until the end of the 1960s, judges based manufacturers' liability on general tort rules. This solution was extremely detrimental to injured parties in that, in accordance with the applicable rules, the burden of proving the manufacturer's fault lay with the injured party. Case law underwent a crucial transformation in the *Saiwa* case, decided in 1964 by the Court of Cassation (judgment No. 1270 of 25 May 1964). In that case the judges rendered their decision on the basis of the criteria of strict liability, and the fault of the manufacturer was assumed as *culpa in re ipsa*; in other words, the manufacturer's fault was presumed simply based on the damaging nature of the product.

Further to the *Saiwa* case, judges began – although case law was far from uniform – to decide cases of product liability by presuming liability on the part of the manufacturer. In particular, from the 1980s onwards, case law began to refer to other rules to simplify the injured party's position, including article 2050 of the Italian Civil Code on dangerous activities, affirming that an activity could also be defined as 'dangerous' based on the nature and characteristics of the product that is the final result of the relevant activity. In this regard, case law on infected blood products and drugs should be mentioned.

In 1988 the Product Liability Act, as amended by Legislative Decree No. 25 of 2001 (PLA) was introduced, and then amended by Legislative Decree No. 25 of 2001. However, the PLA had limited application in Italy, as shown by the few rulings rendered specifically based on this regime. In fact, the first action based on the rules set forth by the PLA, known as the *Mountain Bike* case, was brought in 1991, concerning personal injuries owing to the sudden breakage of the column supporting the front gear shift of a mountain bike and the consequent detachment of the bicycle wheel. Another well-known decision was issued by the Court of Cassation, which excluded the liability of the manufacturer in relation to a swing. In ruling on the case, the Court held that: 'The manufacturer of a product that has caused damage shall be exempt from liability [...] when it is shown that the safety defect of the product was only manifested in relation to a method of use thereof that did not fall within the use that can be reasonably foreseen by the manufacturer'.

Two other significant decisions were issued in 2008 by the Joint Sections of the Supreme Court, ruling on causation and on statute of limitation. The Joint Sections have held that in civil litigation the existence of causation does not require a certainty beyond any reasonable doubt; rather, the criterion of 'more probable than not' applies. The Supreme Court also maintained that, when evaluating causation, judges must take into account whether the event could have been foreseen, in the sense that, in order to grant compensation of the damage, the harm resulting from an act or omission must be reasonably predictable on the basis of statistical or scientific criteria.

In this regard, it is also worth mentioning that the awareness of the risks or the relevant warnings turned out to be a winning defence argument in product liability litigation. With respect to warnings, some merit courts ruled on the relevant standard and clarified that the warning must be sufficiently explicit to enable the consumer to appreciate the particular hazard involved, especially where the hazard is likely to arise from normal use of the product. This interpretation was confirmed by the Court of Cassation. In a case for compensation of damage caused by the use of sun tanning lotion with no sunscreen protection, the Supreme Court stated that the product could not be considered as 'defective' only because of its potential riskiness, as the liability of the manufacturer of a defective product could only be ascertained if the damage had been caused by this product when used 'in accordance with its normal use', namely, in accordance with the instructions and warnings provided for by the manufacturer (judgment No. 25116 of 13 December 2010). This principle was subsequently followed by both higher and lower courts.

In recent years, Italian case law on product liability has developed in line with its consolidated trends. For instance, the Court of Cassation confirmed its previous rulings in relation to the applicable burden of proof and the notion of defective product. Regarding the burden of proof, the Court of Cassation reiterated that the damaged party is relieved from the proof of negligence or wilful misconduct by the damaging party but not from the proof of the 'defect' (judgments Nos. 29828 of 20 November 2018; 23477 of 28 September 2018; 3258 of 19 February 2016; and 15851 of 2015) and of the existence of a causal link between the defect and the alleged damage. With regard to the notion of defective product, the Court of Cassation 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', as it was manufactured and distributed in line with the safety standards required for this kind of product (judgment No. 3258 of 19 February 2016). Thus, in this case, the Court of Cassation found again that a product is defective only if it lacks safety in comparison with consumers' safety expectations.

Again, with regard to the notion of defective product, in 2015 the Court of Justice of the European Union issued a relevant decision (judgment of 5 March 2015, Cases Nos. C-503/13 and C-504/13). The case concerned the alleged defects of medical devices to be implanted in humans for therapeutic purposes. By this ruling, the Court assessed that all the medical devices that had been 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 – as they did not provide the standard level of safety that consumers or patients may legitimately expect; this decision is also significant for the quantification of damage suffered, which should include, according to the court, the surgical intervention required to remove the defect in the medical devices.

Climate for litigation

38 Describe the level of 'consumerism' in your country and consumers' knowledge of, and propensity to use, product liability litigation to redress perceived wrongs.

Despite the legislative instruments available to injured parties, disputes concerning product liability have not had wide, significant development.

Consumers' actions are generally carried out as individual claims (or, in some cases, as cumulative claims in a single action) because the class action mechanism is not well developed in Italy, and is not considered a particularly strong and efficient tool, also according to consumers' associations. The increasing attention of consumers' associations to the matter may, however, determine new trends in the future; also, the scenario may change following the reform of class action which has been recently implemented.

Efforts to expand product liability or ease claimants' burdens

39 Describe any developments regarding 'access to justice' that would make product liability more claimant-friendly.

Litigation based on product liability claims is still developing in Italy. A series of laws introduced in the past few years may have a role in speeding up such a development. These laws introduced a class action procedure in Italy – which has recently reformed – and the possibility for clients to enter into contingency fee agreements with their lawyers, which used to be inadmissible. Third-party funding (which is not prohibited but which at the same time is not regulated) may contribute as well.

Nonetheless, to date, statistics show that the above mechanisms are still timidly approached by plaintiffs and that general awareness on their availability and potential effects is not yet mature.

On the subject of class actions, since the introduction of this procedural tool in 2010, an average of 10 proceedings per year have been initiated and only a small percentage of them have actually been declared admissible. This is a small result, considering that approximately 4 million new civil cases are initiated in Italy every year. Moreover, in almost all these cases, the relevant claims were rejected on the merits.

On 3 April 2019, the Italian Senate definitively approved a bill of law for a reform of the rules concerning class actions and collective actions for injunctive relief. The new rules are not in force yet: they will become effective from 19 November 2020. Moreover, the new rules will only apply to damaging conduct put in place after the entry into force of the reform, whereas all conduct put in place before that date will remain subject to the rules previously applicable.

The reform deeply modifies the nature and functioning of class actions, with regard to both their scope of application and their procedural rules. Among other innovations, class actions have become a tool generally available not only to consumers, but also to any subject claiming compensation for damages caused by violations of their homogeneous individual rights. Thus, business-to-business disputes can also be litigated by a class action procedure. Furthermore, class members will be allowed to opt in to the proceedings also after the court's decision granting the request for compensation. The new rules also provide for economic advantages for lawyers assisting the plaintiffs in class action proceedings: in addition to the amounts due as compensation of the damage and to legal costs borne by the parties, the losing respondent will, in fact, have to pay the plaintiff's attorney an amount as a 'reward fee'.

The same law enacts a reform of representative actions seeking injunctive or declaratory relief as well. Under the new rules, individuals will also be entitled to directly seek this kind of relief, which is therefore no longer available only to consumers' associations.

UPDATE AND TRENDS

Emerging trends

40 Are there any emerging trends or hot topics in product liability litigation in your jurisdiction?

As to legislative developments in the field of consumer law, the most relevant one concerns the approval of a reform of the rules on class actions and collective actions for injunctive relief, which the Italian Senate passed on 3 April 2019. The reform will come into force after 19 months from its publication on the Official Journal of the Italian Republic, which occurred on 18 April 2019.

As far as legislative developments at EU level are concerned, on 21 November 2019 the European Commission issued a detailed report ('Liability for Artificial Intelligence and other emerging digital technologies') where it analyses the existing liability regimes in relation to digital technologies and describes how these regimes should be designed and, where necessary, changed. This report serves as guidance on Directive 85/374/EEC, concerning product liability, with specific regard to the implications for product liability and safety in relation to the employment of robotics, artificial intelligence and the internet of things.

Furthermore, works are underway for the adoption of the New Deal for Consumers, launched in April 2018 by the European Commission (ie, a package of new provisions with the purpose of improving the level of consumer protection in the EU). The main purpose of the initiative is to empower qualified entities to start actions on behalf of consumers, as well as to provide the competent authorities of the member states with stronger sanctioning powers in the field of consumer law and to attain a higher level of protection for consumers in online marketplaces. More specifically, the European legislature is working on the drafting and the approval of the Representative Action Directive, aimed at modernising and replacing Directive 2009/22/EC. On 22 June 2020, the European Parliament and Council negotiators agreed on a preliminary text for the Representative Action Directive, which now has to be examined by the European Parliament and the Council of Ministers of the EU for approval. The Representative Action Directive would introduce a harmonised model for representative action in all member states, in order to ensure that consumers are protected against mass harm and, at the same time, to ensure appropriate defences from abusive lawsuits. Besides general consumer law, the scope of the Representative Action Directive would include violations in matters including, but not limited to, data protection, telecommunications, the environment and health.

With regard to Italian case law, the majority of the decisions recently rendered by Italian courts focus on the topic of the causal link between the defect of the product and the damage suffered by the consumer, as well as on the allocation of the relevant burden of proof between the parties.

Coronavirus

41 What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

During the covid-19 pandemic, the Italian government issued some provisions to regulate the production and the distribution of medical devices aimed at reducing the spread of the pandemic. More specifically, to address the current sanitary emergency, the Italian government has introduced new rules to place on the market surgical masks and personal protective equipment (PPE) including working coveralls, shoe covers, gloves, glasses and visors. In accordance with article 15 of Law Decree No. 80 of 17 March 2020, the government provided for new, more flexible provisions for manufacturers until the end of the emergency (ie, 15 October 2020). Particularly, given the peculiarity of the circumstances, manufacturers that are willing to bring surgical masks or PPE onto the market are no longer required to obtain proof that their products are provided with the CE marking, which in general is a guarantee that a product is safe. Instead, they are allowed to autonomously certify that their products are safe, as they have been projected and are manufactured in compliance with applicable legislation. For this purpose,

manufacturers of surgical masks have to submit self-declarations in writing to the Italian National Institute of Health (ISS). Manufacturers are liable for the content of their declarations, which must be true and accurate. In the three days following their declarations, they have to provide the ISS with any information regarding their products (eg, the technical documentation) that may allow the ISS to evaluate whether the same products are safe or not under the applicable legislation. In turn, the ISS has several days to communicate to the manufacturers the outcome of its assessments. The same procedure is applicable for PPE, but in this case the National Institute for Insurance Against Industrial Injuries (INAIL) is the authority in charge. If manufacturers obtain the validation of the ISS or INAIL, they can place the products on the market. On the contrary, they have to interrupt the manufacturing process and are in any event forbidden to place their products on the market.

Lastly, with regard to the area of commercial litigation in general, owing to the high number of contractual disputes generated by the covid-19 pandemic, since 1 May 2020, before starting a litigation in court in relation to disputes concerning the breach of contractual obligations in which the covid-19 containment measures can be assessed as a cause for exoneration of liability, parties must initiate a mediation procedure aimed at reaching a settlement.

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