

THE PRODUCT
REGULATION AND
LIABILITY REVIEW

SEVENTH EDITION

Editors

Chilton Davis Varner and Madison Kitchens

THE LAWREVIEWS

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LIABILITY REVIEW

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CONTENTS

PREFACE.....	v
<i>Chilton Davis Varner and Madison Kitchens</i>	
Chapter 1	AUSTRALIA..... 1
<i>Colin Loveday and Sheena McKie</i>	
Chapter 2	AUSTRIA..... 14
<i>Eva Spiegel and Florian Horak</i>	
Chapter 3	CHINA..... 25
<i>Ariel Ye, Yue Dai, Xinyu Li and Tianren Li</i>	
Chapter 4	ENGLAND AND WALES..... 34
<i>Neil Beresford and Natasha Lioubimova</i>	
Chapter 5	FRANCE..... 46
<i>Christophe Hénin and Julie Vasseur</i>	
Chapter 6	INDIA..... 60
<i>Vivek Bajaj, Kaavya Raghavan and Sherien Kaul</i>	
Chapter 7	ITALY..... 72
<i>Daniele Vecchi and Michela Turra</i>	
Chapter 8	JAPAN..... 83
<i>Akihiro Hironaka, Kazuyuki Ichiba and Hidenori Sato</i>	
Chapter 9	PORTUGAL..... 94
<i>Joana Mota and Alexandre Pedral Sampaio</i>	
Chapter 10	PUERTO RICO..... 104
<i>Albéniz Couret-Fuentes and Elaine M Maldonado-Matías</i>	

Contents

Chapter 11	RUSSIA	115
	<i>Sergey Yuryev</i>	
Chapter 12	SINGAPORE.....	125
	<i>Lim Ren Jun and Clara Ng</i>	
Chapter 13	SPAIN.....	138
	<i>Alex Ferreres Comella and Cristina Ayo Ferrándiz</i>	
Chapter 14	SWITZERLAND	150
	<i>Frank Scherrer, Andrea Schütz and Marcel Boller</i>	
Chapter 15	UNITED STATES	160
	<i>Chilton Davis Varner and Madison Kitchens</i>	
Appendix 1	ABOUT THE AUTHORS.....	185
Appendix 2	CONTRIBUTORS' CONTACT DETAILS.....	197

PREFACE

In today's global economy, product manufacturers and distributors face a dizzying array of overlapping and sometimes contradictory laws and regulations around the world. A basic familiarity with international product liability is essential to doing business in this environment. An understanding of the international framework will provide thoughtful manufacturers and distributors with a strategic advantage in this increasingly competitive area. This treatise sets out a general overview of product liability in key jurisdictions around the world, giving manufacturers a place to start in assessing their potential liability and exposure.

Readers of this publication will see that each country's product liability laws reflect a delicate balance between protecting consumers and encouraging risk-taking and innovation. This balance is constantly shifting through new legislation, regulations, treaties, administrative oversight and court decisions. But the overall trajectory seems clear: as global wealth, technological innovation and consumer knowledge continue to increase, so will the cost of product liability actions.

This edition reflects a few of these trends from 2019. Notably, several jurisdictions proposed or enacted landmark legislation to strengthen rules governing long-existing industries or, in some cases, emerging technologies (such as autonomous vehicles, artificial intelligence, robotics and the Internet of things). In 2019, for example, China amended its Pharmaceutical Administration Law and thereby established a product traceability system to ensure drug quality. The revised law also provides an array of enhanced criminal penalties and civil liabilities, including novel remedies such as punitive damages. Additionally, countries like Singapore, India and Switzerland implemented expansive new measures – whether by judicial decision or legislative decree – to improve regulatory oversight over food safety. Several jurisdictions also experienced a proliferation of product liability class actions, including countries that only recently began experimenting with class adjudication. In July, Russia ushered in class action suits at a time when product liability and consumer protection cases have surged in the wake of amendments to Russia's Consumer Protection Law. This has led to the coinage of a new term in Russia – 'consumer extremism' – to describe frivolous suits designed to extract a quick settlement from sellers and manufacturers. Yet, other legal refinements impacting product manufacturers have not arrived as quickly as planned. In October, the European Commission delayed the widely anticipated launch of the European Database on Medical Devices (EUDAMED), an initiative designed to strengthen market surveillance and transparency for medical devices. While EUDAMED is not slated to take effect until May 2022, the deadline for medical device companies to recertify their products under the EU's new Medical Device Regulation remains May 2020.

Other significant legal developments in 2019 were spawned in courtrooms rather than legislative bodies. For instance, the US Supreme Court decided a pivotal pre-emption

case that clarified what evidence a drug manufacturer must adduce to demonstrate that the Food and Drug Administration would not have approved the plaintiffs' proposed warning. The Supreme Court also held that the determination of whether a manufacturer met this evidentiary burden constituted a question of law to be resolved by the judge, not a jury. Although the Court's ruling provides valuable guidance to manufacturers seeking to limit their exposure to failure-to-warn claims arising under state law, it also left many questions unanswered (and, thus, open to lower court interpretation in the years to come). Moreover, courts in various jurisdictions grappled with issues concerning the types of entities within the supply chain that should be held liable for alleged product defects. For instance, the Supreme Court of Spain confronted the question of when a mere supplier can be considered the 'producer' of a product for purposes of strict liability. And courts in various jurisdictions are divided on whether online retailers that sell products supplied by third-party vendors can be deemed liable for product defects even though the online retailer never took possession or title of the vendor's product. Although these changes and trends may be valuable in their own right, they also create a need for greater vigilance on the part of manufacturers, distributors and retailers to ensure compliance with increasingly complicated and evolving product liability regimes.

This edition covers 15 countries and territories, and includes a high-level overview of each jurisdiction's product liability framework, recent changes and developments, and a look forward at expected trends. Each chapter contains a brief introduction to the country's product liability framework, followed by four main sections: regulatory oversight (describing the country's regulatory authorities or administrative bodies that oversee some aspect of product liability); causes of action (identifying the specific causes of action under which manufacturers, distributors or sellers of a product may be held liable for injury caused by that product); litigation (providing a broad overview of all aspects of litigation in a given country, including the forum, burden of proof, potential defences to liability, personal jurisdiction, discovery, whether mass tort actions or class actions are available and what damages may be expected); and the year in review (describing recent, current and pending developments affecting various aspects of product liability, such as regulatory or policy changes, significant cases or settlements and any notable trends).

Whether the reader is a company executive or a private practitioner, we hope that this edition will prove useful in navigating the complex world of product liability and alerting you to important developments that may affect your business.

We wish to thank all of the contributors who have been so generous with their time and expertise. They have made this publication possible. We also wish to thank our colleague Luke Bosso, who has been invaluable in assisting us in our editorial duties.

Chilton Davis Varner and Madison Kitchens

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United States

March 2020

ITALY

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I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

In Italy, product liability is governed by Legislative Decree No. 206 of 6 September 2005, the Consumer Code, which implements both the EU Product Liability Directive (Directive 85/374/EEC) and the EU General Product Safety Directive (Directive 2001/95/EC).

With regard to the general rules on product safety and to the legal standards governing the manufacture, distribution and sale of products, the provisions of the Consumer Code only apply to those products that are not covered by other sector-specific legislation (e.g., toys, machinery, pharmaceuticals and food). The Consumer Code also complements the provisions of sector-specific legislation, where the latter does not cover certain matters such as, for instance, the powers of the relevant public authorities in charge of safety issues.

II REGULATORY OVERSIGHT

In Italy, the administrative body that is tasked with overseeing various aspects related to product liability is the Ministry of Economic Development, and specifically its directorate-general for market, competition, consumers, surveillance and technical legislation. Furthermore, Italian law provides for a series of duties for several authorities and public bodies to ensure that products placed on the market are safe and to adopt all necessary measures to guarantee public safety (including ordering product recalls or prohibiting their sale), depending on which kind of products are involved (e.g., the Ministry of Health for medical or pharmaceutical products).

The Ministry of Economic Development is also the main contact point for all safety issues related to products. If manufacturers or distributors discover that a product is not compliant with the due safety standards, they must notify the Ministry. Notifications must also be filed with the relevant authority or public body in charge of the matter, depending on the nature of the product in question.

Besides the Consumer Code, the main legal framework that manufacturers and distributors have to take into account to identify how to fulfil their obligations with regard to product safety are the guidelines adopted by the European Commission in relation to safety issues. In particular, Decision 2019/417EU provides guidance for the management of the EU rapid alert system for dangerous non-food consumer products (the RAPEX system) and

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for notification to the competent authorities. Said Decision also constitutes the fundamental framework that manufacturers and distributors have to refer to in assessing the level of risk posed by a product.

III CAUSES OF ACTION

In general terms, pursuant to the Consumer Code the manufacturer of a product is liable for damage that defects of said product might cause to the consumer. To this purpose, the 'product' is any movable good, even if incorporated in another movable or immovable good; the 'manufacturer' is whoever manufactured the finished product, or a component of the same, or the raw materials used in manufacturing the product. If the consumer cannot identify the manufacturer, he or she can claim the liability of the distributor. To this end, the 'distributor' is any professional operator that, as part of its business, supplies the product on the market as part of the supply chain of a product, provided that it does not impact the safety of the same product. However, the liability of the distributor has a residual nature. The distributor can escape liability if it allows the identification of the manufacturer of the product or of the supplier from which it purchased the product in the first place. Possible liability also extends to the importer of the product in the EU, should the manufacturer have no representative established in the EU.

Therefore, the consumer who suffered damages caused by a defective product may claim compensation of said damages from the manufacturer or the distributor of the product in question. The statute of limitation to bring said claim is three years from the date when the damaged party became or should have become aware of the damage, the defect of the product and the identity of the liable subject. In this regard, see Section IV.iii.

In most serious cases, the manufacturer and the distributor of a product that turned out to be defective and caused serious damage to consumers could also incur criminal liabilities (e.g., personal injuries or manslaughter). In the case of criminal proceedings, the civil claim for product liability could be raised within the same proceedings.

From an administrative perspective, the Ministry of Economic Development, as well as the authorities and public bodies in charge of the relevant monitoring activities, depending on the nature of the product, enjoy a series of powers aimed at guaranteeing that only safe products are available on the market. These powers include:

- a* controlling the products after they have been put on the market;
- b* requesting the transmission of information by concerned parties;
- c* taking samples of the products for monitoring purposes;
- d* prohibiting the placement of products on the market; and
- e* ordering the enactment of measures to render products safe.

Should it be assessed that an unsafe product has been marketed, the Ministry of Economic Development may order either that the product be immediately withdrawn from the distribution, adequately informing consumers, or the recall of the product from the consumers, depending on the seriousness of the case. The measures in question may be adopted with regard to the manufacturer and the distributor. Both of these subjects have a duty to promptly inform the Ministry of Economic Development if they are, or should be, aware, based on the information at their disposal and in their capacity as professional

operators, that the product they placed on the market or made available to consumers does not comply with due safety standards. Criminal charges can also be brought against the manufacturer or distributor that either:

- a* placed dangerous products on the market;
- b* violated a ban from government authorities not to market a certain product;
- c* did not make efforts to ensure that a certain product was safe or that consumers were warned about the possible connected dangers; or
- d* did not cooperate with the Ministry of Economic Development and the authorities or public bodies involved, in the performance of their surveillance. (See Section IV.ix.)

IV LITIGATION

i Forum

In the Italian legal order, product liability cases, like all other civil cases, are tried either before a justice of the peace or a court, depending on the value of the plaintiff's requests. More specifically, if the claim is lower than €5,000, the case shall be tried before a justice of the peace (said threshold will increase to €30,000 from 31 October 2021). If the claim is higher than the above-mentioned amount, the case shall be tried before a court.

In general terms, in the field of product liability, ordinary civil proceedings of first instance are held by a single judge. Class action proceedings of first instance are held before a court, ruling in a panel of judges. Appeal proceedings are held before a court of appeal and the decision is rendered by a panel of judges. If the first instance decision is rendered by a justice of the peace, the same may be challenged before a court, where the relevant proceedings are held by a single judge. Appeal decisions may, in turn, be challenged before the Court of Cassation – the Italian Supreme Court – where the proceedings are held by a panel of judges as well. In class action proceedings, orders of second instance ruling over admissibility cannot be further challenged before the Court of Cassation. Juries are not contemplated in civil proceedings.

ii Burden of proof

A consumer who claims to have been injured by a defective product has the burden of proving the defect of the product, the damage suffered and causation in terms of existence of a causal relationship between the defect and the damage claimed.

Several merit courts over the years have stated that the existence of the defect of a product could be inferred by the existence of the damage and of the causal link between the use of the product and the damage itself. In other words, in accordance with this case-law trend, the mere fact that the use of the product caused the damage would be enough to infer the existence of the defect of the product. Thus, no specific evidence of the defect would be needed.

Nonetheless, this case-law trend appeared to be overturned, following a benchmark decision of the Court of Cassation. In accordance with the rulings of the Supreme Court, the existence of a defect of the product must be proved. The plaintiff, therefore, must provide evidence that the product lacks the general safety conditions that 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 15 March 2007; this stance was more recently confirmed by Court of Cassation Decision No. 29828 of 11 November 2018).

In this regard, the proof that the damaged party must provide largely depends on the nature of the alleged defect. Assuming that the relevant product is generally safe and only a single item, to which the damaged party was exposed, malfunctioned or was defective, the damaged party must prove the existence of the defect (however, some argue that said burden of proof could be satisfied by demonstrating the single item differs from all other products of the same set). However, should the injury derive from a defect that is common to all similar products (i.e., the product itself is unsafe or has been wrongfully designed, or there is a lack in the information provided by the manufacturer), it will be sufficient for the damaged party to prove that the entire category of products is defective; they are not required to demonstrate the existence of the defect of the single product he or she entered in contact with.

If the proof of the defect is not easily attainable, presumptions may be considered sufficient by judges. In this regard the Court of Cassation found that once a 'secondary fact' is demonstrated, judges may indirectly infer from that fact the existence of the 'main fact', such as the existence of defect of the product. However, this is only if the secondary facts on which the presumption is built are clearly and specifically demonstrated (Court of Cassation Decision No. 29828 of 11 November 2018).

iii Defences

As a general principle, the manufacturer of a product is liable for damage caused by defects of the same product. For the purposes of product liability provisions, the definition of 'manufacturer' includes anyone manufacturing the product in the EU (either the finished product, or a component of the same, or its raw materials).

The distributor may also be held liable, if the manufacturer is not identified or identifiable. A distributor is any professional operator that is part of the supply chain of a product.

In the case of claims being brought against them by consumers, the manufacturer and the distributor should demonstrate facts that may exempt them from liability under the Consumer Code. Namely, liability is excluded if at least one of the following occurs:

- a* 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 (this also includes the delivery of samples or products to be viewed or tested only);
- b* the defect that caused the damage did not exist at the time the manufacturer placed the product on the market;
- c* 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;
- d* the defect is because of the compliance of the product with a mandatory legal provision or with binding public measures; and
- e* 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 addition, the distributor can escape liability by allowing the identification of the manufacturer. Further to that, Italian law does not provide for any special immunity for particular categories of defendants.

Without prejudice to the above, liability is also excluded if the damage was attributable to the consumer. 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, thereby accepting such risks. Furthermore, if the consumer who was damaged by the defective product contributed to the causation of the relevant damage, compensation is reduced proportionally having regard to the seriousness of the negligence attributable to the consumer and the extent of the relevant consequences.

As briefly highlighted above, the limitation period for product liability claims is of three years. This period starts running from either:

- a* the day when the consumer was allegedly damaged by the defective product;
- b* the day when the consumer became aware or should have become aware of the damage or defect; or
- c* the day when the consumer became aware of the identity of the liable party.

The running of the limitation period can be interrupted. In general, this occurs whenever proceedings are initiated to raise the relevant claim or at least a final demand letter is sent to the manufacturer or the distributor by the allegedly damaged party, denouncing the harmful event and asking for compensation. In the 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 any event, the right to be compensated for the defect of a product expires after 10 years from the day when the manufacturer or the importer within the EU placed the product on the market.

Without prejudice to the above, the consumer may consider bringing an action based on general tort liability as governed by the Italian Civil Code, instead of a product liability action. In this case, the limitation period is five years running from the date of the detrimental event. In litigation 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. If the claim concerns a product that is dangerous in itself, owing to its inner nature (e.g., gas cylinders, fireworks, pharmaceuticals), the consumer may ground his or her action on rules concerning liability for dangerous activities, which is a kind of strict liability. Nonetheless, it is worth considering that, based on the case law of the Court of Justice of the European Union and of the Italian courts, it is disputable whether the applicability of the rules on product liability derived from EU law to cases of damages caused by the use of a product excludes the possibility of applying another kind of strict liability regime to the same case, such as the rules on liability for dangerous activities mentioned above.

A particular situation occurs when the consumer can obtain the product only from an intermediary, which then has a personal duty to evaluate the suitability of the product and inform the consumer of the possible consequences of its use. In this case, the intermediary, in light of its professional skills and knowledge, may incur personal liability if it made an inappropriate evaluation or failed to provide the consumer with adequate information with regard to the products, thus preventing him or her from making an informed choice as to the type of product to use. However, the intermediary's liability would not per se exclude the manufacturer's liability should the relevant product turn out to be defective. This hypothesis is particularly relevant, for instance, in the medical field with regard to products such as prescription drugs or medical devices (prostheses, heart valves, etc.), which the consumer cannot have access to without a physician's intervention. In this hypothesis, according to the case law, the manufacturer of the product in question must make available to medical

professionals all relevant information concerning the product. The physician, in turn, is responsible for assessing which product is better suited for his or her patient's case and for informing the same of possible side effects of the product. In this scenario, should prejudicial effects derive to the patient as a consequence of the use of the product, the manufacturer may be exempt from liability, provided it had properly informed the physician of the possibility of such prejudicial effects. The ratio behind this reasoning is that the physician is in the best position, knowing the patient's medical history and the case to be treated, to weigh the risks and the benefits of the product and decide whether to use it. This reasoning does not apply if the product in question turns out to be defective, in which case the manufacturer may be held liable for damages consequently suffered (Court of Cassation Decision No. 20895 of 8 October 2007; Court of Cassation Decision No. 25148 of 11 October 2018). It may also not apply to the case of medical or pharmaceutical products to which consumers have free access, without the need of the intervention of a physician (Court of Cassation Decision No. 15734 of 2 July 2010).

iv Personal jurisdiction

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

In general terms, based on the provisions mentioned above, for Italian courts to have jurisdiction over claims for compensation of damages, including the case of damages caused by a defective product, the damages claimed must have been caused by an event that occurred in Italy, irrespective of the fact that the claimant or the defendant is domiciled or resident in Italy, and of where the product was manufactured, sold, or advertised. For instance, assuming that a product was manufactured in a foreign country and advertised only abroad or on the internet, if the damaging event occurred in Italy, Italian courts would have jurisdiction over claims for compensation of the damage.

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

v Expert witnesses

The parties to a proceeding can appoint their own retained experts to draft written reports to support their claims or defensive arguments. These reports are filed as exhibits in the case. In general, there is no restriction on the nature or the extent of the use of this kind of evidence. Also, the parties can ask the court to hear their own retained experts as witnesses.

Should the case require specific technical knowledge, the judge may appoint, also upon a party's request, one or more experts (a judicial technical consultant (CTU)) to act as the judge's assistants and provide technical expertise on the matter. The CTU cannot make legal assessments, establish the existence and meaning of legal provisions, assess documentary evidence or provide evidence of the facts at issue (in place of the parties). His or her role is strictly limited to the technical questions posed by the court.

The CTU is selected from lists of experts filed in each court. If the CTU is not chosen among the experts included in such lists, the appointment has to be previously authorised by the president of the court. Each party 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 (party-appointed experts (CTPs)).

The results of the expertise proceeding are put in writing. After his or her investigations, the CTU shares a preliminary report with the CTPs, which are then allowed to submit their remarks or comments; subsequently the CTU files a final report, including the CTPs' comments.

The content of the CTU's final report is not binding for the judge, who may disagree with its outcome in his or her final ruling, provided he or she has adequate grounds in support of this decision.

vi Discovery

US-style discovery procedure, by which each party can access its counterparty's entire internal documentation, has ever existed in Italy.

Recently, Law No. 31 of 2019 has reformed the existing provisions concerning class actions, introducing for the first time to the national legal system a procedural tool that is similar to US discovery (see Section IV.viii). Indeed, one of the main novelties introduced by this Law, which will become effective in October 2020, regards evidence-gathering. First of all, the court will be entitled to use statistical data and simple presumptions to ascertain the liability of the respondent. Furthermore, upon reasoned request by the petitioner, the court may order the resistant (only) to produce relevant evidence and documents within its possession. This order may also cover 'categories of evidence', identified by the common features of the evidence falling within their scopes (e.g., the time at which they were formed, the subject matter and contents of the evidence requested to be produced). If the resistant refuses or fails, without good reason, to comply with the relevant order to produce evidence, it may be sentenced to a fine of between €10,000 and €100,000.

In relation to ordinary proceedings, during evidence-gathering activities, the judge may, upon a party's request, order the counterparty or any third party to exhibit documents. If the counterparty or any third party refuses to do so and fails to provide a valid reason to support the refusal, the judge may infer from its conduct to rule on the case. Furthermore, the judge may also order the parties to the proceedings or third parties to subject themselves to inspections on their own persons or on goods in their possession, if such inspections are essential to assess the facts under dispute and may be put in place without serious detriment to the parties or third parties. Should one of the parties refuse to allow said inspections, the judge may infer from such conduct to rule on the case.

The Italian legal system does not provide for the possibility of US-style depositions. However, parties are allowed to file documents containing statements from third parties on facts that are relevant for the purposes of the proceedings, such as affidavits, or in any event to ask the judge to allow for third parties to be heard as witnesses during the proceedings.

The parties to the proceedings cannot be heard as witnesses; on the contrary, they can be heard through formal questioning. In this case, their statements have to be considered as evidence for the purposes of the judge's decision.

Last, Italian law allows for the possibility of international evidence-gathering procedures if evidence needs to be gathered in a foreign country.

vii Apportionment

Under the Consumer Code, if several subjects jointly caused the damage, each of them is considered liable to compensate such damage. The liability of each subject has to be determined by the judge, taking into account a series of factors: 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. Should only one of the liable subjects compensate the damage at issue, it would then have the right to raise claims against the other liable subjects to recover the amount due by each of them.

If the damage claimed is not caused by a common activity but by a single manufacturer, the burden to identify that single manufacturer lies with the plaintiff. No form of market-share liability is applicable.

In general terms, under Italian law, if a subject takes over the enterprise or company that has manufactured, distributed or marketed the defective product, the acquiring subject becomes liable for any damage that the acquired enterprise or company might have caused in the performance of its business, including any damage caused by a defective product manufactured by the same. However, attention should be paid to the content of the agreement for the acquisition of the company, by which the parties might stipulate that certain liabilities, up to the date of the acquisition, shall not pass over to the acquiring subject.

viii Mass tort actions

Since 2008, Italian law has provided for the possibility to resort to class actions as tools to seek damage compensation in relation to certain kinds of multiple claims, including claims for product liability arising from the defect of a certain product. Class actions can be brought in relation to wrongful events that occurred after 15 August 2009.

Class actions can be initiated by any single consumer as a class representative, providing there is evidence that the claim raised is worthy of being litigated as class actions owing to the existence of homogenous rights within the potential group. Homogeneity of rights under dispute is an essential condition for the admissibility of the class action.

In Italy, class actions are based on an opt-in system. The relevant procedure consists of a preliminary admissibility stage (certification), during which the homogeneity of the rights claimed by the members of the group is assessed. If the class action is considered admissible, the merit stage follows for the assessment of liability and damage.

The decision of the court, ruling in panel, 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. In this second case, the assessment of individual damage can be remitted to a subsequent settlement or litigation between the individual and the respondent.

Since the introduction of class actions in Italy, an average of 10 proceedings per year have been brought. This is a very small result, considering that approximately four million new civil cases are initiated in Italy every year. Moreover, out of those actions, only a limited number of them have been certified.

Very recently, Law No. 31 of 2019 has reformed the existing provisions concerning class actions. This reform, which will become effective starting from October 2020, has significantly modified the class action tool, with regard to both its scope of application and its functioning from a procedural perspective. The new set of provisions will apply to unlawful conduct that is carried out after the Law enters into force. Therefore, the class action would become a general remedy, which would be available not only to consumers, but to everyone claiming compensation for the violation of 'homogeneous individual rights'. Thus, professional operators (natural and legal persons) will be also entitled to promote a class action. Further to that, the main novelties introduced by the reform are the following: opting-in will also be permitted after the publication of the decision ruling on the case and the establishment of the liability of the resistant; by the decision ruling on the merits of the

case, the court appoints a common representative of the class members, in charge of preparing a distribution project for the class members, taking a position on each individual request; the unsuccessful respondent must pay the common representative and the plaintiff's attorney a 'reward fee', set as a percentage of the total amount due to the members as compensation. This last point is one of the most highly debated aspects of the reform; in fact, the business community is concerned that the reward fee may result in punitive damages and that the high amounts involved may render class action – as it is in the US – a relevant money-making business (see also Section IV.vi).

The Consumer Code also provides for the possibility of a representative action being brought by consumer associations, acting for the protection of the collective interests of consumers. By this action, consumer associations may request 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 conducts. The above-mentioned Law No. 31 of 2009 for the amendment of class action rules also provides for the reform of representative actions. According to this law, individuals will also be entitled to directly seek injunctive or declaratory relief (see Section IV.ix).

Before the introduction of class actions, Italian mass tort litigation was generally characterised by lawsuits jointly brought by single subjects who had suffered damage in connection to the same product, all acting as plaintiffs in the same proceedings or giving mandate to a single person to act on their behalf, as their representative in the proceedings. In our experience, following the introduction of class action, this practice has generally diminished. However, some lawyers tend to introduce 'strands' of lawsuits, in other words, bring a series of lawsuits having all the same objects, each one on behalf of a single consumer.

ix Damages

In general, product liability claims can be raised to seek compensation for personal damage (death or physical injuries), as well as for damage to objects normally used for private purposes and damaged by the defective product. In general terms, compensation is allowed only as restoration of damage actually suffered as a consequence of the defective product. Otherwise, in principle, no compensation is possible.

Both economic and non-economic damages suffered by the consumer as a consequence of the defective product are recoverable. For some decades now, both case law and authors have identified four categories of compensable damage:

- a* material (economic) damage, consisting of monetary damage due to pecuniary loss or loss of profits;
- b* non-economic damage, namely:
 - biological damage, affecting the physical or psychological integrity of a person, directly related to his or her health;
 - moral damage, 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
 - existential damage, a type of damage created by case law to allow for compensation of damage not included within the above category of moral damage 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 damage is compensable only in cases provided for by the law, in other words, whenever compensability is expressly acknowledged in a provision of law and whenever,

even lacking such a provision, the damage entails the violation of a personal right that 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 damage. In this regard, 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 on judges that have to rule on similar cases. So far, the trend of lower level courts has been to follow the above interpretation.

It is up to the judge to quantify compensable damage that should be awarded to the damaged party, based on the evidence submitted by the parties. As to the quantification of non-economic damage, the most recent practice of the courts has been to base their assessment on tables setting forth criteria for such quantification depending on several objective elements. Reference is made, in particular, to the tables drafted on a yearly basis by several Italian courts with regard to the compensation of non-economic damage derived from physical and psychological harm and of damage linked to the loss of a relative.

In general terms, Italian law does not allow for punitive damages to be awarded in the field of product liability and, more generally, in the field of tort liability. However, by an unprecedented judgment, dealing with a case of product liability, the Joined Sessions of the Court of Cassation clarified that punitive damages is not per se incompatible with the Italian legal order and with the nature and function of tort liability under Italian law (Law No. 16601 of 5 July 2017). In the relevant case, the Court found that punitive damages should be granted if 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 so far.

So far, the Consumer Code does not allow individual consumers to seek injunctive or declaratory relief; this possibility is granted only to consumer associations. This is one of the aspects being dealt with by Law No. 31 of 2019, for the reform of class action rules (see Section IV.viii). Pursuant to said Law, starting from October 2020, individuals will become entitled to directly seek injunctive or declaratory relief too.

From a criminal law perspective, should an unsafe product cause harm to its user, the manufacturer of the product in question might face criminal charges, depending on the facts of the case and the seriousness of the damage caused by the product (e.g., personal injury, manslaughter). In this case, criminal proceedings may begin and the consumer may also bring civil action in the criminal proceedings to seek compensation for the damage suffered.

Furthermore, Italian law provides for other more specific penalties if a manufacturer or distributor places dangerous products on the market and fails to adopt measures aimed at remedying the risks deriving from an unsafe product, as ordered by the Ministry of Economic Development or the authorities or public bodies involved. More specifically:

- a* unless the conduct constitutes a more severe criminal offence (e.g., if the defect causes death), 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 ranging from €10,000 to €50,000;
- b* unless the conduct constitutes a more severe criminal offence, the manufacturer or distributor that does not conform with an order issued by the competent authorities to act to make sure that a certain product is safe or that consumers are warned about the possible connected dangers may be punishable with pecuniary sanctions ranging from €10,000 to €25,000;

- c 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
- d if a more serious crime is also involved (e.g., injury or manslaughter), the relevant criminal provisions will also apply.

In any event, under Italian law, criminal liability cannot be imposed on corporations, but only to responsible individuals.

V YEAR IN REVIEW

In general terms, in Italy, product liability rules as set forth by the Consumer Code have not yet found an extensive application in judicial litigation, whereas general tort liability rules are more frequently resorted to.

In 2019, courts rendered decisions on cases of product liability, with regard to different kinds of products (i.e., cars, bicycles, drugs and paints). All the relevant actions were brought by individual consumers. Generally, insurance companies do not bring claims on behalf of consumers. It is common practice for businesses to stipulate insurance policies, also covering product liability.

The majority of the decisions issued in the past couple of years focused on the topics of the causal link between the defect of the product and the damage suffered by the consumer and the allocation of the relevant burden of the proof between the parties, as well as on the kind of evidence that the plaintiff should provide to demonstrate the existence of the causal link. The most relevant ruling in this regard is Decision No. 29828 of 11 November 2018 from the Court of Cassation, which concerned the use of ‘presumptions’ to demonstrate the existence of the claimed defect of the product. See Section IV.ii.

One of the most relevant cases initiated in Italy in the past few years on consumer law concerns the automotive sector and relates to the aftermath of the affair known as ‘Dieselgate’. After the recall of the vehicles involved on the part of the manufacturer, an Italian consumer association promoted two class actions in the name of the purchasers of said vehicles for breach of contract and unfair commercial practices. Both class actions were declared admissible. According to the press, more than 95,000 people exercised their right to opt in the actions and the aggregate value of the cases is reported as around €400 million, likely making these the biggest class actions in Europe.

Besides the above-mentioned case, the majority of product withdrawal or recalls in Italy concerned food products and beverages, toys and electrical appliances (especially low voltage devices).

As to recent Italian legislative developments in the field of consumer law and product liability, the most relevant ones concern Law No. 391 of 2019 for the reform of the class action, which will become effective starting from October 2020. See Sections IV.vi, IV.viii and IV.ix in this regard.

In 2018, the European Commission set up an expert group focused on product liability and new technologies. In this regard, the Commission announced that, owing to the work of this expert group, it will issue guidance on the Product Liability Directive and a report on the broader implications for liability and safety in relation to the employment of artificial intelligence, the Internet of things and robotics.

Based on our experience, businesses nowadays tend to pay an ever-increasing amount of attention to the topic of product and safety liability. A lot of them have developed internal policies of monitoring, control and audit to reduce related risks.

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