ITALY

Trends and Developments

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RASS – Studio Legale Rinaldi e Associati was established in Milan in 1995 and has offices in Rome, Bologna, Florence and Istanbul. The firm provides legal advice to foreign corporations interested in operating in Italy, to guide them in setting up and running their business, as well as to Italian companies aiming to expand their activities abroad. The following areas of practice are covered: litigation; national and international arbitration; insurance, reinsurance, and related legal and regulatory issues; specific expertise in insurance claims concerning product and dangerous activity liability, professional indemnity and medical malpractice; directors' and officers' liability; contractor liability; IP, IT and corporate law; and M&A. The product liability team, consisting of two partners and six lawyers, handles a broad range of matters for clients in the insurance, food & beverage and healthcare and life sciences sectors, including development and regulatory approval, marketing and distribution, product reimbursement, fraud, abuse, product liability and intellectual property litigation.

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Introduction

The present chapter examines the most recent case law on product liability, including artificial intelligence (AI) systems, and provides an overview of relevant regulatory updates at both the EU and national level.

The general rules governing liability for defective products are set out in Legislative Decree No 206/2005 (the so-called Consumer Code, which transposed the provisions of Directive (EEC) 85/374), which contains provisions on consumer protection and disciplines the relationship between consumers and professionals. However, further relevant provisions are included in the Italian Civil Code – ie, Articles 2043 and 2050, governing compensation for tortious acts and liability for the exercise of hazardous activities, respectively.

Regarding recent developments in EU legislation, the new Directive (EU) 2024/2853 (the *"Product Liability Directive"* or PLD) will be examined.

Recent Legislative Developments in Product Liability

On 8 December 2024, the PLD, published in the *Official Journal of the European Union* on 18 November 2024, entered into force.

The PLD repeals, effective from 9 December 2026, Directive (EEC) 85/374. Notwithstanding the above, according to Article 21, paragraph 1, of the PLD, Directive (EEC) 85/374 shall continue to apply with regard to products placed on the market or put into service before that date.

For the purposes of this analysis, it should be noted that the PLD clarifies that the liability for defective products set forth therein shall not affect *"any right which an injured person has under national rules concerning contractual liability or concerning non-contractual liability on grounds other than the defectiveness of a product as provided for in this Directive, including national rules implementing Union law"* or *"any right which an injured person has under any special liability system that existed in national law on 30 July 1985"*. This concept was already

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included in repealed Directive (EEC) 85/374, but it is emphasised more strongly by the PLD.

Likewise, the scope of the PLD has been significantly broadened, where the definition of *"product"* is significantly wider. In fact, the PLD provides that *"product"* means all movables, even if integrated into or interconnected with another movable or immovable, including electricity, digital manufacturing files, raw materials and software. AI software is expressly included.

The PLD aims to mitigate the information asymmetry that exists between consumers and manufacturers, especially with regard to AI systems. To this end, the PLD has introduced a series of provisions, including disclosure obligations and reversals of the burden of proof. These new provisions should give consumers a better chance of defending their rights in court.

Regarding the disclosure obligation, Article 9 of the PLD provides for several obligations upon defendants and claimants. The most important provision for consumer protection, clearly aimed at reducing the information asymmetry mentioned above, is the one set out in paragraph 1 of the aforementioned Article 9. According to this provision, upon request by a claimant *"who has presented facts and evidence sufficient to support the plausibility of the claim for compensation"*, the defendant is bound to disclose the documentation and technical information in their possession. Paragraph 2 imposes a similar obligation on the claimant, upon request by the opposing party, while paragraph 3 requires that the disclosure provided for under paragraphs 1 and 2 must be limited *"to what is necessary and proportionate"*, without providing any further clarification. Paragraph 5 states that, in the presence of trade secrets, the court may adopt confidentiality protection measures upon request or ex officio.

Generally, a court order of disclosure may cover not only documents but also technical information.

Given the technical complexity of the information that may be provided by professionals, paragraph 6 provides that such evidence must be presented *"in an easily accessible and easily understandable manner"*.

Under Italian general civil law, the most similar existing provision is Article 210 of the Code of Civil Procedure, concerning the court's order to exhibit documents in court.

The second remedy under Article 10 of the PLD consists of easing the burden of proof on the injured party by means of presumptions concerning the defectiveness of the product and the causal link between such defectiveness and the damage.

Paragraph 2 provides a presumption of defectiveness:

- if the defendant fails to disclose relevant evidence pursuant to Article 9, paragraph 1;
- if the claimant proves a breach of safety requirements under EU or national law; or
- if it is demonstrated that the damage was caused by an *"obvious malfunction"* during use.

Paragraph 3 presumes a causal link between defectiveness and damage if it is proven that:

- the product is defective; and
- the nature of the damage *"is of a kind typically consistent with the defect"*.

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Lastly, according to paragraph 4, the judge may presume the existence of defectiveness, the causal link or both, notwithstanding proper fulfilment of the disclosure by the manufacturer, if:

- the claimant *"faces excessive difficulties, in particular due to technical or scientific complexity, in proving the defectiveness of the product or the causal link between its defectiveness and the damage, or both"*; or
- the claimant demonstrates *"that it is likely that the product is defective or that there is a causal link between the defectiveness of the product and the damage, or both"*.

In any event, the defendant's right to submit contrary evidence is granted.

It is worth briefly considering civil liability for damages resulting from AI systems, with a glance at the Italian context. In this respect, recently, the European Commission withdrew its proposed AI Liability Directive.

Therefore, the only legislation applicable to AI remains the PLD (which covers AI systems) and Regulation (EU) 2024/1689 (the *"AI Act"*). There is no doubt the providers (within the meaning of the AI Act) are also to be regarded as manufacturers under the PLD.

In Italy, in March 2025, the Senate approved Draft Law S 1146 (the *"AI Draft Law"*), which governs AI across various sectors but does not deal with liability.

As a result, AI-related liability for damages continues to be governed by domestic general provisions – ie, Articles 2049, 2050 and 2051 of the Civil Code and the Consumer Code – while we await receipt of the PLD in the Italian legal system.

Recent Guidelines From the Italian Supreme Court on the Liability of Pharmaceutical Manufacturers

The Italian Supreme Court (the *"Court"*) recently ruled on the liability of pharmaceutical manufacturers. It should be noted that, over the years, the Court gave different, and sometimes ambiguous, interpretations in this area, particularly with regard to the applicable liability regime. Such diversity of interpretation will also emerge from the analysis of the judgments discussed herein.

Through Judgment No 8224 of 28 March 2025, the Court ruled on the appeal brought by a pharmaceutical company against a judgment of the Court of Appeal of Lecce. In 2021, the Court of Appeal of Lecce ruled that the Pharmaceutical Company had to pay compensation for damages caused by a flu vaccine. The Pharmaceutical Company challenged that ruling, alleging a misinterpretation of the legislation governing pharmaceutical product liability. According to the appellant, the Court of Appeal of Lecce had made an inadmissible *"patchwork"* by combining Consumer Code (containing general product liability and safety rules), Article 2043 of the Italian Civil Code (on compensation for unlawful acts) and Article 2050 of the same Code (on liability for the exercise of dangerous activities).

The Court upheld the appeal and remitted the case to the Court of Appeal of Lecce, setting out the following principle of law.

The rules governing liability for defective products under the Consumer Code, based on Directive (EEC) 85/374 – where the PLD does not apply, ratione temporis – do not preclude an injured party from seeking protection under other liability regimes provided by Articles 2043 and 2050 of the Italian Civil Code. However, once the applicable liability regime has been

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identified, no amalgamation of provisions from different regimes is permitted.

The Court decision also provides an interpretative overview of the three sets of rules governing the liability of the manufacturer of medicinal products, as follows.

Liability for defective products

Liability for defective products, governed by the Consumer Code, is presumed.

Under Article 120 of the Consumer Code, the injured party must only prove the damage, the defect and the causal link. With regard to the latter two elements, proof may be established through serious, precise and consistent circumstantial evidence.

Conversely, the manufacturer bears the burden of proving facts that would exclude its liability.

A central concept in this regime is that of a (non-) defective product, as defined in Article 117 of the Consumer Code. A product will not be considered defective if it cumulatively: (i) complies with the relevant regulatory standards; and (ii) corresponds to the legitimate expectations of consumers regarding its intended use.

With regard to point (ii), the manufacturer must provide adequate information about the product at the time it is placed on the market. Once this duty has been fulfilled, the principle of consumer self-responsibility applies. However, the mere provision of generic information regarding the dangerousness of the product does not exonerate the manufacturer from liability. In this regard, the Court recalls its previous decision (Judgment No 12225/2021), according to which the manufacturer's liability *"is not excluded merely by proof of having provided, by means of the product information leaflet (the so-called bugiardino), a general warning about the product's lack of safety; rather, such a warning must enable the consumer to make an informed assessment of the risks and benefits and to take all necessary precautions to prevent harm, thereby exposing themselves to the risk voluntarily and knowingly"*.

The Court further specifies that, in the case of vaccine administration, such information may also include, for example, interactions between the vaccine and other medicinal products. More generally, in order to provide the most complete information, the manufacturer must diligently gather all scientific data available up to the time the product is placed on the market. This obligation requires the acquisition of all available technical knowledge, even at significant cost.

Regarding the evidence excluding liability available to the manufacturer, it may validly be provided – insofar as it is relevant – in two cases (under Article 118 of the Consumer Code): (i) if the defect did not exist at the time the product was placed on the market; or (ii) if, according to the state of scientific and technical knowledge available at that time, the product could not have been considered defective.

Liability for the exercise of dangerous activities

Liability for the exercise of dangerous activities, set out in Article 2050 of the Italian Civil Code, is characterised by its almost strict (or quasi-objective) nature due to the high degree of inherent risk.

In this case, the manufacturer must remain constantly updated on the state of scientific knowledge; this obligation therefore extends beyond the time the product is placed on the market.

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Evidence excluding liability is validly provided only if the manufacturer demonstrates that it took all possible measures to prevent the damage, and yet the damage occurred as a result of a fortuitous event. It is not sufficient to prove mere compliance with technical standards or the generic fulfilment of the duty to provide information.

Liability for tortious acts

Liability for tortious acts, set out in Article 2043 of the Italian Civil Code, may also be invoked by the consumer.

In this case, the consumer has the burden of proving all the following elements: the fact, the causal link, the fraud (or negligence) and the damage.

It should be noted that the possibility for consumers to invoke any of the aforementioned liability regimes is also expressly recognised by the PLD – similarly to Directive (EEC) 85/374 – under Article 2, paragraph 4, letters (b) and (c).

However, the Court rejects the possibility of *"blending"* the different regimes of liability.

A ruling that takes an opposing view

A ruling that takes the opposite view, at least with regard to the liability regime applicable to the pharmaceutical manufacturers, is Court Order No 33984/2025 of 23 December 2024.

This case concerned an appeal brought by an individual alleging he was injured by the use of dental paste. His claim was rejected by the Court of Appeal. The appeal was upheld, and the case was remitted to the Court of Appeal. Two key points of the Court's decision are as follows.

- The manufacture of pharmaceuticals is a hazardous activity and falls within the scope of Article 2050 of the Civil Code – quasi-objective liability applies. There is an obligation to provide information that is as comprehensive and specific information as possible, constantly updated in light of the latest scientific knowledge. Specifically, in the subject case, the manufacturer should have warned consumers (in the package leaflet) of the foreseeable consequences of excessive use of the dental paste.
- The causal link between the defect and the damage is not interrupted by the careless but entirely foreseeable conduct of the injured party – especially if the manufacturer was aware of scientific studies highlighting the harmful effects of the product.

In conclusion, according to Court's recent case law, the issue of pharmaceutical manufacturers' liability requires a case-by-case assessment of the applicable legal framework.

Each case demands a reasonable balance between the manufacturer's duty to inform and the principle of consumer self-responsibility.

The EU Court of Justice Expands the Concept of Supplier Liability

Through the judgment of 19 December 2024 (case C-157/23 - Ford Italia S.p.A. v. ZP and Stracciari S.p.A.), the Court of Justice of the European Union (CJEU) has significantly broadened the supplier liability, following an unprecedented interpretation of Directive (EEC) 85/374. It should be specified that the CJEU's decision also applies to the PLD, which, for the purposes of this analysis, reproduces (in Article 4, paragraph 10, letter b)) the provisions of the repealed Directive (EEC) 85/374.

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By court order of 6 March 2023, the Court referred a preliminary ruling to the CJEU concerning the interpretation of Article 3, paragraph 1, of Directive (EEC) 85/374, which states with regard to the concept of producer: *"'producer' means the manufacturer of a finished product... and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer"*.

The Court focused, in particular, on the exact meaning of the expression *"by putting his name"*. The reference was made in the context of proceedings involving Ford Italia, which was sued (together with an authorised dealer) by a consumer alleging that they were harmed by a defect in the airbag of a Ford-branded vehicle.

Ford Italia is the company that distributes in Italy vehicles manufactured by Ford WAG, established in Germany. The Court asked the CJEU whether Ford Italia could be considered a manufacturer within the meaning of Article 3, paragraph 1 solely on the basis of sharing an identical name with that of the manufacturer.

The CJEU ruled that a company (like Ford Italia) that, due to a mere coincidence of name, has de facto presented itself as a manufacturer to consumers may be considered a manufacturer even in the absence of an active conduct consisting of putting their name, trade mark or other identifying sign on the product.

As explained in the decision, whether the supplier physically affixed its own name or trade mark, or whether there was simply an identical designation to that of the manufacturer, is irrelevant. Actually, the purpose of the rule is to protect consumers who have had a level of trust comparable to the reliance they would have had if the product had been sold directly by the manufacturer. In other words, the judgment highlights, from a different point of view, the element of the legitimate expectations of consumers, as mentioned in the preceding paragraph. Essentially, the CJEU aims to raise the level of consumer protection as much as possible.

Another innovative element that can be inferred from the ruling is that – contrary to what is provided by the Directives – mere communication to the injured party of the producer's identity is not sufficient to exempt a distributor who has de facto been perceived as the manufacturer from liability. In the proceedings, Ford Italia had indeed argued that it had indicated Ford WAG as the producer on the invoice.

Nonetheless, the judgment emphasises that *"in accordance with Article 5 of Directive (EEC) 85/374, since a person who presents him or herself as a producer and the manufacturer of the defective product are jointly and severally liable, the liability of that person invoked by the consumer is without prejudice to the provisions of national law concerning the rights of contribution or recourse"*.

The decision will have significant consequences, especially in the automotive and pharmaceutical sectors. It is likely that distributors operating as multinational groups will feel the impact of this ruling, as their local entities often have corporate names that coincide with that of the manufacturer.