

LIABILITY FOR DEFECTIVE PRODUCTS AND THE EPITOME OF COMPENSATION UNDER EU CONSUMER LAW: IS THE LEGAL FRAME ADEQUATELY SHAPED?

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ABSTRACT

The study approaches the problematics of the allocating of compensatory damages for physical damage and patrimonial damages caused to consumers by the use or interaction with a defective product, respectively of whether there is unjustified negligence or concurrent fault. Should the liable party invoke the risk of development, producers can be cleared of liability under certain conditions, notably, if they prove that the defective product has not been voluntarily put into circulation or that the defect was due to the compliance of the product with mandatory regulations issued by public authorities; nevertheless, the burden of proof pertaining to the exempt of liability lies on the producers' shoulders, including the cases in which the state of scientific or technical knowledge at the time the product was put into circulation could not facilitate the detecting of the defect in the testing stage. The epitome of compensation in defective products liability cases not only depend on the possibility of the claimant to establish the conditions for the existence of a duty of care (product security), but also depends on whether or not the misrepresentation has been incorporated into the contract, as depicted by the provisions of Directive (EU) 2019/770 on certain aspects concerning contracts for the supply of digital content and digital services and Directive (EU) 2019/771 on certain aspects concerning contracts for the sale of products.

Keywords: liability, defective products, compensation, contractual remedies, EU Consumer Law.

INTRODUCTORY REMARKS

The legal and practical challenges brought by the interpreting and the incidence of the provisions of the EU Product Liability Directive (Directive 85/374/EEC) in the field of damages caused to consumers by defective pharmaceutical products mainly relate to the notion of 'product', the time that the update is put into circulation, the notion of 'defect' (defective product), the burden of proof especially as to causation (which often proves to be the Goliath of the engaging of pharmaceutical manufactures' liability, namely the absence of scientific certitudes establishing the existence of a causality nexus between the consume of the pharmaceutical product and the negative physiological effect), as well as the intricacies relating to the calculation of time bars under positive European Consumer law. The recent efforts made at the EU level, in order to modernize and adapt the legal concepts of liability for defective products to the challenges brought by the increasing use of products with digital content (The European Consumer Organization Position Paper [BEUC], 2020), and incorporated AI structures (Koch, 2019; Lemann, 2019; Van Leeuwen, & Verbruggen, 2015). are emphasizing the importance of the key-concepts, such as the „risk – utility balance” and the invoking of the „risk of development”, in cases in which the state of scientific or technical knowledge (Chatzipanagiotis, 2020; Coppard, 2017; Corbin, 2019; Galasso, & Luo, 2018; Freeman, et al., 2020; Gómez, & García, (2020), at the time the product was put into circulation could not facilitate the detecting of the defect in the testing stage (Nigam, 2020).

The study also attempts to dissipate the opacity which surrounds the notion of „producer” (Hernández-Ramos, 2018), which, seditiously interpreted, within the meaning of the legal texts,

refers to the manufacturer of the product, that is established in the European Union, as well as to any person presenting itself as such a producer (Picod, & Picod, 2020; Piedelièvre, 2020; Sterrett, 2015; Santos et al., 2019;), by affixing its brand to the product, or even any distinctive sign, as well as, under certain circumstances, the legal person carrying out the service interventions on the product. It also encompasses the manufacturer's representative in the event that the latter is not established in the European Union and, in the absence of an identifiable manufacturer's representative, the importer will be considered as being liable similarly to the producer. According to the provisions of positive law, other professionals may be held liable as well, in the marketing chain, insofar as their activities may affect the safety characteristics of the product. Several remarks can already be made, in the perimeter of the paradigmatic concept of „producers' liability for defective products". Firstly, the definition of the category of producers, within the meaning of the provisions of Article 3 of Law no. 240/2004 on the liability of the producers for the damages generated by the defective products, with the subsequent modifications, under Romanian Consumer Law, recalls the definition given to the producer within the meaning of the legal regulations on liability for defective products, which was obviously inspired by the definition (Goicovici, 2018; Goicovici, 2018a) comprised in the EU Product Liability Directive (Directive 85/374/EEC), which should not be surprising insofar as the two texts in the national legislation draw their origin from the provisions of the mentioned directive (Bazin-Beust, 2020). Without being identical, however, the two definitions refer to the manufacturer, the importer or the person who affixes its brand, trademark or distinctive sign. Secondly, the first two categories of producers are clearly mutually exclusive: either the manufacturer is established in the European Union, and it is then the latter who is considered to be the liable producer; or it is established elsewhere, and it is then its representative, or failing that, the importer who is considered as a producer, in order to be held liable for the damages caused to consumers by defective products. Finally, the characteristic feature of the producer lies in the control the latter has over the design and the manufacturing process of the product, measured in the ability to affect the integrity of the product, and therefore its safety, at the moment at which a voluntary decision is made as to place the product on the market. In this sense, there is on the one hand the manufacturer who is held responsible, and those who are assimilated to the latter, for whom their mastery of the product is inherent to their quality, and on the other hand the other professionals of the distribution chain, but only if they possess such mastery on the manufacturing process (for instance, the manufacturing of the components) (Goicovici, 2020).

MATERIAL AND METHODS OF WORK

As referring to the methodology followed, which is based on doctrinal and empirical approaching to compensatory damages for physical damage and patrimonial damages caused to consumers by the use or interaction with a defective product, respectively of whether there is unjustified negligence or concurrent fault in recent jurisprudence, it should be pointed out that the study of the case law (in cases of the invoking of the risk of development, according to which producers can be cleared of liability under specific conditions, notably, if it has been established that the defective product has not been voluntarily put into circulation or that the defect was due to the compliance of the product with mandatory regulations issued by public authorities) is partly based directly on primary empirical sources (relevant case-law from the national Consumer Law entities), as well as on secondary theoretical sources (general textbooks, academic monographies and journal articles focusing directly or indirectly on the problematics of the using of strict liability, in circumstances under which the legal person carrying out the service interventions on the product, as well as the manufacturer's representative in the event that the latter is not established in the European Union and, in the absence of an identifiable manufacturer's representative, the importer will be considered as being liable similarly to the producer, as resulting from commenting caselaw between 2018-2020). The results of the contribution are assessing the importance of the possibility, for the claimant, to establish the conditions for the existence of a duty of care (product security), which also depends on whether or not the misrepresentation has been incorporated into the B2C contract or it becomes applicable the extra-

contractual liability. The tools used for analyzing data, which combined case study techniques, as well as extracting themes from unstructured data; in a qualitative research, our analysis was based on legal textual analysis. Specific methods included: (i) content analysis: categorizing and discussing the meaning of legal concepts applicable to extra-contractual liability; (ii) thematic analysis: coding and closely examining the jurisprudential data to identify broad themes and patterns; (iii) discourse analysis: studying regulations and meaning in relation to their legal context.

RESULTS AND DISCUSSIONS

The notion of „defective product” and conceptual reverberations in the field of liability for defective products.

„Defective product” describes the product for which the presentation, foreseeable use and date of purchase do not provide safety to consumers, causing damage to them (Annex of the Romanian Code of Consume, Pt. 30). The absence of information on the risks resulting from the normal and foreseeable use of the products, in the package leaflet, the technical book, the user manual, the information on the label / packaging of the product, represents a defect of the product for which it can be trained the liability of the producer / importer in the EU space, for the physical / patrimonial damage caused to the consumers of the defective product.

Three categories of defects attributable to manufacturers were jurisprudentially identified, encompassing the defective manufacturing, due to an unwanted syncope in the production chain (human errors, failures of production facilities / equipment, etc.), as well as the defective design (the manner in which the product was designed / conceived involves risks of consumption that far outweigh the benefits of consuming the product); nevertheless, the producer or the importer may be held liable also for defective compliance to the duty to disclose information or for informational deficiencies (absence of information on the risks resulting from the normal and foreseeable use of the products, in the package leaflet, the technical book, the user manual, the information on the product label / packaging). According to the provisions of Article 3 of Law no. 240/2004 on the liability of the producers for the damages generated by the defective products, with the subsequent modifications, under Romanian Consumer Law, the manufacturer is liable for the current and for the future damage, caused by the defect of the product.

From the content of art. 4 shows that the liability of the manufacturer is not limited in the situation where the damage is determined, cumulatively, by the defect of the product and by the action or omission of a third party. This provision is without prejudice to the right of the producer to bring legal proceedings against a third party, in accordance with the mentioned legal provisions.

Table 1. Pretorial categories of defects attributable to manufacturers.

Pretorial categories of defects attributable to manufacturers	
a) defective manufacturing	due to an unwanted syncope in the production chain (human errors, failures of production facilities / equipment, etc.);
b) defective design	the manner in which the product was designed / conceived involves risks of consumption that far outweigh the benefits of consuming the product;
c) defective compliance to the duty to disclose information	informational deficiencies (absence of information on the risks resulting from the normal and foreseeable use of the products, in the package leaflet, the technical book, the user manual, the information on the product label / packaging).

As previously underlined, in the perimeter of extra-contractual liability for defective products, the rule of joint and several civil liability operates on the basis of presumed culpable behavior; therefore, according to art. 10 of Law no. 240/2004, amended by Law no. 76/2012, if several persons are liable for the damage, they are jointly and severally liable. As specified in the content of art. 6, in order to engage the civil liability of the producer, the injured person must prove

the damage, the defect and the causal relationship between the defect and the damage. According to the provisions of art. 10 of Law no. 240/2004, amended by Law no. 76/2012, any contractual clauses of limitation or exoneration of liability of the producer are struck by absolute nullity.

In the situation where both the identity of the producer and the categories of persons assimilated to the manufacturer by the legal provisions, are known to the injured person, the question arises which one of them and in what order will be held liable for the damages caused by the defective products; salient questions remain as to establish whether a joint and several liability would be found between the manufacturer and the intermediary sellers, or the importers in EU. Art. 5 of Law no. 240/2004 does not specify whether these persons should belong to the same category (producers, manufacturers or intermediaries). By corroborating with art. 2 para. 1 lit. a, point 5, we interpret that there would be an order of liability, in the sense that the liability of distributors and importers will be engaged only if the manufacturer cannot be identified, this type liability being priorly applicable and only in the case of the subsidiary intermediaries, the latter can be held accountable for the prejudice registered by the consumers. The beneficiary of this type of liability may be any injured party whether or not the consumer is bound by the contract to the responsible person or whether it is the consumer or third-party consumer who acquired the product through a subsequent chain of distribution of will other than the sale-purchase contract (consumer loan, location), the latter being able to use the product occasionally not necessarily bound by a legal B2C contract (extra-contractual liability).

Time framework for evaluating the defective character: which are the most challenging aspects?

Article 7 (b) PLD entails that liability is imposed only for defects that existed at the time the product was put into circulation. As previously underlined, a product is put into circulation when it is taken out of the manufacturing process operated by the producer and enters a marketing process in the form in which it is offered to the consumers in order to be used or consumed (Table 2).

It should be underlined, nevertheless, that the mere existence of a product defect may be used to demonstrate a breach of the manufacturers or supplier's safety obligation by holding them liable. In addition, the analysis of the exonerating causes of liability shows that, from the moment of causing the damage, a relative presumption of culpable / negligent behavior is activated against the producer according to which the good put into circulation was defective, thus the victim being exempted from proving the defect of putting the product into circulation. However, the consumer will not be exempt from the burden of proof for the existence of the damage, defect and causation between defect and damage (in the generic sense) and the attributability to the manufacturer's conduct.

In the perimeter of the liability for defective products, the security of the product has been analysed in relation to the legitimate expectations of the user of the product, that is to say in relation not only to the use that will normally be made of it, but also to the legitimate expectation of the user. Second, it should be noted that Article 3 of Law 240/2004 offers a criterion for assessing security (essentially the legitimate expectations of the consumer), yet without giving a precise content to the notion of security. As a salient feature, the legitimate expectation, or normal or reasonably foreseeable use of the product may be held as a criterion for the establishing of the liability; admittedly, it is not the manufacturer that the legislation intends to protect, while offering the means to determine with precision the scope of the mentioned obligations.

The first level of analysis consists of evaluating products that are considered to be non-aporically safe, or more precisely considered to meet the general safety requirements. Under the provisions of Article 5 of Law 240/2004 on the liability for defective products, the mentioned category includes products that comply with the specific regulations applicable to the specific domain, aimed at protecting the health or safety of consumers; it is in this context that the link is expressly made between conformity and safety: compliance with the obligation of objective conformity implies the safety of the product, yet only in terms of liability for patrimonial losses, not for the physical injuries caused to consumers, which remain covered by the liability for the safety of the products. The cited legal provisions simply refer, in this perimeter of the

manufacturers' objective liability for unsafe products, to the product compliance with the specific regulations applicable to it having for object the protection of the health or safety of consumers; consequentially, it is reasonable to consider that only mandatory standards are concerned with the injunctive measures and compensation based on manufacturers' objective liability for unsafe products. The second level of the analysis consists of assessing the security of products which are relatively presumed to be safe for consume, that is to say which are non-peremptorily presumed to meet the mentioned safety obligations, which subsequently comply with non-compulsory national standards transposing European standards for which the European Commission has published the references in the Official Journal of the European Union (in application of Article 4 of Directive 2001/95/EC of the European Parliament and of the Council of December 3, 2001 on general product safety).

Table 2. Cases in which the producers were exonerated from liability for defective products (2018-2020 – Romanian Consumer Law).

Cases in which the producers were exonerated from liability for defective products	
	<i>Explicative assertions:</i>
a) The producer is not the one who has put that product into circulation;	- putting the product in circulation on the market is the action by which that product is available on the market, for the first time for distribution or use; - if the manufacturer entrusts the product to distributors, it means that it put the product into circulation; yet not considered put into circulation if the product was stolen or the producer did not voluntarily place it on the market; - putting the product into circulation for reasons not attributable to the producer; for example, the manufacturer can prove that the samples in the same series to which the product belongs defects have been checked by the competent authorities and have been found not to be defective.
b) the defect did not exist on the date on which it was put into circulation or subsequently appeared	- the product has not been manufactured for marketing or any other form of distribution for economic purposes of the manufacturer and was not manufactured or distributed within its professional activity;
c) the defect in the product is due to compliance with certain mandatory conditions imposed by regulations issued by the competent authorities;	- if public authorities have taken reckless measures and, in compliance with them, the producers put into circulation products with defects, the public authorities will be the ones held liable for the damages caused.
d) the level of scientific and technical knowledge at the time of putting the product into circulation did not allow him to detect the existence of the defect;	- objective criteria for the establishing of the risk of development vs. subjective criteria of conformity
e) the defect is due to the consumer's non-observance of the instructions for use provided in the technical documents accompanying the product	- culpable behavior or concurrent fault, demonstrated on the basis of expertise specialized techniques

It is worth recalling that the claims under the mechanism described in Directive 85/374/EEC must be brought within three years from the date on which the cause of action accrued (three years for claims under the provisions of Law 240/2004 on the liability for defective products for personal injuries, under Romanian Torts Law); it is important to notice that the limitation period runs from the date on which the consumer claimant became aware, or should reasonably have become aware,

of the existing of the damage and of the link of causation between the consume of the defective product and the prejudice generated by the former, which nevertheless is subject to the provision under which a claimant's rights under the provisions of Directive 85/374/EEC on the liability of the producers / importers for the damages caused by defective products are extinguished on the expiry of ten years from the date on which the producer released into circulation the actual lot of products which caused the damage, unless consumers have in the meantime instituted proceedings against the producer which suspended the course of the prescriptive time bars. While claim for personal injury due to negligence or breach of security duty of the producer (or of the designer of the products) are subject to a time limit of three years from the date on which the cause of prejudicial action or omission / omissive conduct accrued, the limitation period remains of three years from the date of accrual of the culpable conduct or the date on which the consumer claimant became aware of the accrual of the action / omission, whichever is later; in the field of contractual liability, the limitation period is similarly established on three years from the date of the accrual of the action / omission of the producer / importer of the product, as referring to the date on which the breach of contract occurred, yet not the actual date on which the damage is suffered by the consumer (which may be delayed in the case of indirect / residual damages).

Table 3. Prescriptive time bars in the perimeter of the objective liability for defective products.

Prescriptive time bars in the perimeter of the objective liability for defective products		
(a) liability for defective products causing personal injuries / patrimonial loss	three years from the date on which the cause of action accrued	the limitation period runs from the date on which the consumer claimant became aware, or should reasonably have become aware, of the existing of the damage and of the link of causation between the consume of the defective product and the prejudice generated
(b) personal injury due to negligence or breach of security duty of the producer (or of the designer of the products)	Time limit of three years from the date on which the cause of prejudicial action or omission / omissive conduct accrued)	Same provisions on time bars: compensatory rights are extinguished on the expiry of ten years from the date on which the producer released into circulation the actual lot of products which caused the damage
(c) contractual liability for breach of security duty / lack of conformity	three years from the date of the accrual of the action / omission of the producer / importer	Time bars referring to the date on which the breach of contract occurred, yet not the actual date on which the damage is suffered by the consumer, which may be delayed in the case of indirect / residual damages

CONCLUSIONS

In the perimeter of the liability for defective products, both in terms of national and EU regulations, the protection of the consumer primarily requires compensation for death and personal injury, as well as compensation for damage to property; while the latter are currently limited to products destined to the private use or consumption, the mechanism of compensation does not prejudice compensation for pain and suffering and other non-material damages payable, where appropriate, under the national law applicable to the case (Law 240/2004 on the liability for

defective products). Nevertheless, a uniform period of limitation for the bringing of action for compensation, in the interests both of the injured person and of the producer, is currently established to a period of 10 years from the date the lot of products has been released on the market, since it would not be reasonable to hold the producer liable for an unlimited period for the inherent defectiveness of the product; therefore, the adjustment of current legislation as to encompass new challenges brought by the use of products with digital content, including in terms of adjusting the time bars for the establishing of the producers's liability for defective design of the products, as well as for the flaws in the manufacturing process. The following conclusive assertions can be drawn based on the previous remarks:

(a) the risk of development may be invoked by the producers in order to be exonerated for the damages caused by the inherent defects of the products; the possibility offered to a producer to be exempt from liability if it proves that the state of scientific and technical knowledge at the time when the producer released the product into circulation was not such as to enable the existence of a defect to be discovered, without restricting unduly the protection of the consumer; as confronted with the challenges brought by the use of products with digital /AI content, it would be useful to maintain the use of this derogation in certain manufacturing areas, in order to raise, if possible, the level of protection in a uniform manner throughout the manufacturing chain;

(b) according to current regulations (article 3 of Directive 85/374/EEC), in hypotheses in which a defective product caused patrimonial losses or biological prejudices, should the producer of the product be unidentified, each supplier of the product from the distribution chain will be treated as its producer, in terms of liability issues, unless the latter informs the injured person, within a reasonable period of time, of the identity of the producer or of the person who supplied with the product components which have been proven to be defectively designed, the same remedy becoming applicable in the case of an imported product, if this product does not indicate the identity of the importer, while the identity of the distributor is known to the consumer;

(c) the dichotomy „product security – product conformity” continues to be maintained under the provisions of Directive (EU) 2019/770 on certain aspects concerning contracts for the supply of digital content and digital services and Directive (EU) 2019/771 on certain aspects concerning contracts for the sale of products; therefore, the professional seller will be liable to the consumer for any lack of conformity that exists at the time the products were delivered, especially if the delivered products do not comply with the description given by the seller, distributor or the professional trader and do not possess the qualities of the products that the seller has held out to the consumer as a sample or model. Similarly, should the products be unfit for any specific purpose for which the consumer required the product, as specified under explicit contractual terms, and which they made known to the seller at the time of conclusion of the contract and which the seller has accepted (bilateral acceptance of contractual terms referring to specific purposes and uses of the product), the producer will be hold liable, as well as in the cases in which the delivered products are not fit for the purposes for which products of the same type are normally used (taking into account the legitimate expectations of the consumer).

(d) the objective standard of conformity applies in cases in which the delivered products do not show the quality and performance that are typical in products of the same type and that the consumer can reasonably expect, given the nature of the products and considering any public statements on the specific technical characteristics of the products made by the seller, the producer or their representative, particularly in advertising or on labelling of the products, while taking into consideration the legal binding force of the producers's statements on the product characteristics.

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