Something is going on in product liability

On the Proposal for a Directive of the European Parliament and of the Council on liability for defective products

The proposal for a Directive on liability for defective products is currently being prepared. If finally adopted, this proposal will repeal the existing Directive 85/374/EEC and will significantly change the legal regime for claims under product liability law.

Purpose of the proposal and main features

The proposal aims to address a number of shortcomings identified by the Commission in the application of the rules that have been in place for the past decades. It seeks to ensure that product liability rules adapt to the nature and risks of products in the digital age and the circular economy.

The system will continue to be based on a strict liability regime, where the burden of proof lies on the claimant to prove the defectiveness of the product, the damage suffered and the causal link between the defect and the damage.

However, the proposal aims to make it easier for the claimant to prove the defect, the damage and the causal link. To this end, it will facilitate access to evidence and introduce presumptions in favour of the claimant.

Let's explore some of the key changes in the proposal.

A clearer concept of defective product

The test for determining whether a product is defective will remain substantively the same. A product is defective if it does not provide the safety which the public at large is entitled to expect, taking all circumstances into account.

However, in order to clarify the concept, the proposal extends the non-exhaustive list of circumstances to be considered when assessing defectiveness. These include, for example, (i) the presentation of the product (including its instructions for use); (ii) the reasonably foreseeable use and misuse of the product; (iii) product safety requirements; (iv) any intervention of by a regulatory authority or an economic operator responsible for the safety of the product. As in the previous regulation, the proposal provides that in no case shall a product be considered defective because a better product or an improved or upgraded version of the product is subsequently placed on the market.

In this way, the proposal aims to clarify the concept of a defective product. In the field of medicinal products and medical devices, this greater clarity may be beneficial in order to put an end to unsubstantiated claims relating to off-label use of a product or relating to a risk or adverse effect that is duly warned in the package leaflet or in the SmPC.

Measures to facilitate evidence

In order to make it easier for the claimant to prove the defect and the causal link in complex cases, the proposal presents a new system of access to evidence and presumptions of proof.

a) Disclosure of evidence by the defendant

An injured party who presents facts and evidence sufficient to support the plausibility of their claim for compensation may ask the court to order the defendant to disclose relevant evidence that is at its disposal, or produce it, which may be necessary to support the claim.

b) Presumptions of evidence

The product is presumed to be defective if the defendant refuses to disclose or produce evidence accepted by the court. The product is also presumed to be defective if the claimant proves that the product does not comply with the mandatory safety requirements set out in the applicable regulations; or if the claimant proves that the damage was caused by an obvious malfunction of the product during normal use.

The causal link between the defectiveness of the product and the damage is presumed if it is established that the product is defective and that the damage caused is of a kind typically consistent with the defect in question.

Finally, if a court considers that the claimant faces excessive difficulties , due to technical or scientific complexity, to prove the defectiveness of the product or the causal link, or both; the defectiveness of the product or the causal link, or both, shall be presumed if the injured party has proved the probability that the product is defective or that its defect is a likely cause of the damage, or both.

The defendant will be entitled to contest both the existence of excessive difficulties and the referred likelihood.

The defendant is also entitled to rebut any such presumption by providing evidence of the suitability of the product or the absence of a causal link between the alleged defect and the damage.

The defendant's defence

The defence in a product liability case is usually based primarily on proving that the product was not defective because it offered the safety that could reasonably be expected, taking all circumstances into account.

The assessment of defectiveness should involve an objective analysis and should relate not to the safety that a particular person is entitled to expect, but rather to the public at large. For this purpose, the intended purpose of the product, its objective characteristics and properties and the specific needs of the target group of users should be assessed. In the case of medicinal products and medical devices, it can be argued that a product offers the safety that can reasonably be expected if the benefits of the product outweigh its risks and it has been authorised (which proves that society is prepared to place such a product on the market despite its risks because of the benefits it offers).

A second possible argument is that the alleged damage was not caused by the alleged defect in the product.

Furthermore, the defendant will not be liable for damage caused by a defective product if it can prove that:

(i) in the case of a manufacturer or importer, it has neither placed the product on the market nor put it into service;

(ii) in the case of a distributor, it has not commercialised the product;

(iii) that the defect which caused the damage was probably not present when the product was placed on the market or put into service

or, in the case of a distributor, when it was commercialised, or that the defect occurred after that date;

(iv) that the defect is due to the fact that the product conforms to mandatory regulations issued by public authorities;

(v) that the objective scientific and technical state of the art at the time when the product was placed on the market or put into service, or during the period when the product was under the control of the manufacturer, did not allow the discovery of the defect;

(vi) in the case of the manufacturer of a component, that the defectiveness of the product is attributable to the design of the product in which the component is incorporated or to the instructions given by the manufacturer of the product to the manufacturer of the component; or

(vii) in the case of a person who modifies a product, that the defect which caused the damage relates to a part of the product not affected by the modification.

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