McCann FitzGerald

# Public consultation on EU Commission proposal for a new directive on liability for defective products

## Submissions of McCann FitzGerald LLP

**27 April 2023**

We refer to the Department of Enterprise Trade and Employment's request for submissions on the European Commission proposal for a new directive on liability for defective products, which was published by the Commission on 28 September 2022.

We are an Irish law firm which represents and acts for manufacturers and distributors of medicines, vaccines and medical devices among other clients.

We write on our own behalf only, as Irish and European Union lawyers, from our experience of the Directive 85/374 and other product liability law and litigation and we welcome the opportunity to provide submissions on the proposed directive. Our observations, which are limited to the provisions of Article 9, focus on medicines, vaccines and higher risk medical devices, but are applicable also to other products involving technical and scientific complexity.

Please contact us if you wish to discuss or clarify any of the matters which we address below.


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# Response

## Question 7: Article 9 states that Member States shall ensure that a claimant is required to prove the defectiveness of a product. What are your views on the conditions listed in subsection (2) regarding instances where the presumption of defectiveness exists.

### Summary

We submit that there are good reasons to delete (or at least amend) Article 9(2)(b), and not to proceed with Article 9(4).

### Background

Many claims for personal injuries compensation from the use of medicines, vaccines and medical devices (often involving software and other technology) are complex.

There may be a dispute about whether the product caused the alleged injury, or whether there were other causes, known or unknown. In other cases, the manufacturer may contend that the adverse reaction was an unavoidable consequence of the treatment or the use of the device, which the manufacturer had warned about, or which was well known to treating doctors. In some cases, the manufacturer will argue that it could not have foreseen the risk of injury when the product was made available on the market, given the state of scientific and technical knowledge. Scientists and clinicians usually give expert evidence about these matters at trial.

Article 9 includes presumptions which would reverse the onus to prove one or more key elements of a claim under the proposed directive, which otherwise would rest with the claimant. Two of the proposed changes, Article 9 (2)(b) and, Article 9(4), would be unfair to manufacturers.

## Article 9 (2) (b)

This provision provides that:

> The defectiveness of the product shall be presumed, where any of the following conditions are met:...
>
> (b) the claimant establishes that the product does not comply with mandatory safety requirements laid down in Union law or national law that are intended to protect against the risk of the damage that has occurred;

This presumption is unnecessary, given that among the circumstances relevant to defectiveness listed at Article 6 are product safety requirements. Thus, under Article 6, a court in assessing whether a product provided the safety which the public at large is entitled to expect would take into account prevailing safety requirements including compliance with mandatory safety requirements under EU or national law.

Furthermore, the proposed provision would mean that regardless of the effect of a breach, minimal or even trivial, there would be a presumption of defect. This would be disproportionate and unfair to manufacturers.

If the measure is included in the proposed directive, we suggest that, the presumption of defect under Article 9(2) (b) should arise only where the claimant shows that the product does not comply *in a relevant and material manner* with mandatory safety requirements laid down in Union law or national law that are intended to protect against the risk of the damage that has occurred. This would mean that only a significant, relevant breach would lead to the manufacturer having to carry the burden of disproving allegations of defectiveness made against it.

## Article 9 (4)

Article 9 (4) states:

> 4. Where a national court judges that the claimant faces excessive difficulties, due to technical and scientific complexity, to prove the defectiveness of the product or the causal link between its defectiveness and the damage, or both, the defectiveness of the product or causal link between its defectiveness and the damage, or both, shall be presumed where the claimant has demonstrated to, on the basis of sufficiently relevant evidence, that:
>
> (a) the product contributed to the damage: and

(b) it is likely that the product was defective or that its defectiveness is a likely cause of the damage, or both.

The defendant shall have the right to contest the existence of excessive difficulties or the likelihood referred to in the first subparagraph.

The relevant preamble in the proposed directive (34) explains that technical and scientific complexity which gives rise to excessive difficulties for consumers in proving defect, causation or both should be determined by national courts on a case-by case basis, taking into account various factors set out in the preamble. Article 9(4) provides that a defendant may challenge the claim of excessive difficulties.

## Unclearness of Article 9(4)

The proposed directive, including its preambles and its explanatory memorandum, is silent however about the intended meaning of the subsequent provisions required to give rise to the presumption of the defectiveness of the product or the causal link between its defectiveness and the damage, or both, namely, that a claimant must demonstrate, on the basis of "*sufficiently relevant evidence*", that the product "*contributed to*" the damage and that it is "*likely that the product was defective or that its defectiveness is a likely cause of the damage*", or both.

The level of proof of the matters necessary to create the presumption is stated to be "*sufficiently relevant evidence*". On a literal reading, the provisions appear in effect the same as what a claimant must prove to establish liability under the existing Directive 85/374, namely defectiveness and causation, as they appear to require the claimant to demonstrate that it is likely that the product's defectiveness caused, or contributed to, the damage. If that is the intention, it is not clear what the purpose of the resulting presumption is.

If, however, the level of proof required ("*sufficiently relevant evidence*") is intended to mean a lower standard than otherwise would be necessary to persuade a court on the basis of credible scientific and medical evidence that the product was defective or could cause the damage alleged, there would be a real risk of permitting doubtful or questionable theories in scientifically or technically complex cases to give rise to presumptions of defect or causation.

It may be suggested that the meaning of the provisions would be clarified by judgments of the Court of Justice of the European Union ("CJEU"). It could take many years however before these proposed provisions would be clarified, whilst in the meantime, national courts, claimants and industry would face uncertainty and protracted litigation.

## Change is unjustified

More fundamentally, we consider that the proposed presumptions in Article 9(4) are unjustified in light of the proposed directive's objective of maintaining a fair apportionment of risk between claimants and defendants.

Preamble 34 of the proposed directive justifies the proposed change on the ground that manufacturers have expert knowledge and are better informed than injured persons. In reality, any disparity in knowledge would be redressed in litigation, not least because Article 8 of the proposed directive itself requires a manufacturer to disclose relevant evidence at its disposal to a claimant when ordered by a national court to do so. A presumption of defectiveness will arise where a defendant fails to comply with that obligation. Also, claimants in most cases are advised and assisted by experts and lawyers. Regulatory information may be available to claimants. For medicines, vaccines and higher risk medical devices, much information about product safety is available on public websites maintained by regulators.

## Unfair consequences of the presumptions

Where the presumption(s) are found to apply, the onus would then be on the defendant to disprove defect and causation or both. The reversal of the onus of proof would put the defendant at risk of unjustified findings of liability where, for example, due to uncertainties in science the manufacturer was unable to prove that other known or unknown causes, not connected with the product, had caused the damage. This would unfairly expose defendants to significantly higher liability risks.

There would be difficulties and costs in implementing Article 9(4) too. A court would have to assess and decide those issues well in advance of trial, so that a defendant could prepare if the court held that the presumption(s) arose. This could be a lengthy and expensive mini-trial, given the difficulty of the issues.

## Conclusion

In most circumstances in civil litigation, the claimant must prove his or her allegations. A reversal of the burden of proof should be exceptional, and there are cogent reasons why the proposed presumptions under Articles 9(2)(b) and 9(4) are not justified and would be inconsistent with maintaining a fair apportionment of risk between claimants and defendants.

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