Revision of the Product Liability Directive

MedTech Europe considerations for the interinstitutional negotiations

Executive Summary

The proposed revision of the Product Liability Directive (PLD) risks upsetting the careful and complex balance of interests the original Directive struck between fair and appropriate compensation for consumers, who have been harmed by a defective product, and ensuring innovation and fair competition in the EU single market.

Ensuring a balanced liability framework is critical in the health and medical technology sector, where patients can best receive first-line access to innovative medical technologies if manufacturers operate in an environment that provides legal certainty and enables innovation.

- We **strongly support the deletion of the reference to innovative medical devices in Recital 34** as proposed by the European Parliament, as the practical effect of singling out a specific sector will mean a presumption of complexity for all products in that sector.
- The European Parliament's amendment that shifts a test of "likelihood" that a product is defective to a mere **test of "possibility" is extremely concerning, effectively requiring companies to prove "impossibility" in order to succeed in a defence**. It undermines the foundations of European product liability principles and will lead to the automatic reversal of the burden of proof for "complex" products.
- The European Commission proposal skews evidence disclosure rights and obligations in favour of claimants. **MedTech Europe advocates for reciprocal obligations analogous to the established principle of "equality of arms"** and therefore supports the European Parliament's approach.
- The European Commission proposal inadequately protects confidential information and IP rights. **We welcome the European Parliament's stance against "phishing expeditions" in the Recitals and in Article 8 itself.**
- **More clarity and harmonisation are needed on "product safety requirements".** The European Parliament addresses these concerns and harmonises language for consistency.
- The inclusion of **"end-user expectations"** in determining when a product is defective **introduces a contradictory subjective component into what should explicitly be an objective test**. In the healthcare context this would also entirely leave out of account the vital role of "learned intermediaries" (healthcare professionals) in helping patients to properly evaluate the benefit/risk balance of different therapies (including medical technologies) for individual patients. The European Parliament's recognises this by having deleted the reference.
- An **"obvious malfunction" should not automatically denote a "defect"** as it could unjustly shift the burden of proof, ignoring the implications of misuse. The European Parliament adds a more balanced consideration of the manufacturer's intended use.
- **Expanding "damage" to include "medically recognised harm to psychological health" will bring ambiguous claims and unclear financial implications**. The European Parliament adds clarity regarding the type of psychological harm that would be taken into consideration via amendments to Recital 17, but clearer language is needed in Article 5a.

- The proposed **extension of the claim period for latent damage together with the unclear terminology around "manufacturer's control" will result in open-ended exposure to claims, and are likely to impact companies' ability to insure product liability risk**, which is mandatory in the medical technology sector. The insurability of this type of open-ended product liability risk for business has not been properly assessed. MedTech Europe warns of the erosion of a clear and finite limitation period in all proposals (including the re-starting of the risk period for updates and changes under the manufacturer's control"). We urge institutions to consider the European Commission's proposal of 15 years from the placing on the market of the original product to enable companies and their insurers to assess legal risk with a somewhat higher degree of certainty.

Introduction

The EU Product Liability Directive (PLD) is the corner stone of recourse for European consumers who have been harmed by defective products. It forms part of a balanced and legally certain civil justice system in Europe.

As it stands, the revision would significantly increase immediate pressure on [medical technology] companies to settle at an early stage of a dispute, potentially without ever testing the merits of the allegations against them. This will especially apply for product liability class-action claims under the Representative Actions Directive[1] including those backed by relatively unregulated third-party litigation funders, the number of which has been significantly growing in the past years in Europe. Such pressure for early settlement, driven by the significant costs and the company resource required to properly investigate the merits of claims, could result in a culture of litigation that encourages unmeritorious claims and also disincentivizes proper investigation and root cause analysis. This could be particularly harmful in the healthcare space with its highly complex ecosystem of actors, where patient safety and well-being through access to appropriate medical technologies is paramount.

Against this background, we urge the co-legislators to consider the points we raise in this document in their review of the proposed Directive.

MedTech Europe considerations

1. Designation of all innovative medical devices as inherently "complex" products.

The draft proposal introduces several mechanisms (i.e. rebuttable presumptions and unilateral disclosure of evidence) to reduce the burden on claimants and increase the burden on defendants. In this context, **the proposal specifically calls out "innovative medical devices" as an example for complex products in Recital 34.**

This call-out effectively designates all "innovative" medical devices as technically or scientifically complex products and carries a presumption that they therefore present claimants with excessive difficulty in proving either defectiveness or causation, necessitating a reversal of the burden of proof for either or both of these.

[1] Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC.

Designating all medical devices as "innovative" and thus complex ignores the diversity in the range of products of the over 500,000 medical technologies in use in the EU, ranging from implants to band aids, and from MRI machines to wheelchairs.

"Innovative" is also a concept that is not defined anywhere in the proposal. The medical technology sector is highly active in the area of research and development. The average global R&D investment rate (R&D spend as a percentage of sales) is estimated to be around 8% in the medical technology sector. Products typically have a lifecycle of only 18-24 months before an improved product becomes available. This leads to the medical technology industry being one of the highest patent-producing industries in Europe. In 2021, with 15,321 patent applications it was a close second only to the digital communication industry[2].

The call-out also ignores that complexity in the medical technology sphere does not necessarily derive from the products but from the highly individual nature of patients' health conditions, as well as the intervention of other actors like healthcare professionals ("learned intermediaries") and other actors, in the healthcare ecosystem.

In practice, courts could be guided by this recital, leaving medical technology providers to face excessive risk.

We therefore strongly support the position of the European Parliament deleting the reference to innovative medical devices from Recital 34, as it is objectively false that all innovative medical devices are complex products. Deleting this reference will not prevent judges from considering that certain medical devices are indeed complex.

2. Reversal of the burden of proof

Article 9.1 of the proposal states that a claimant shall be required to prove the defectiveness of the product, the damage suffered and the causal link between the defectiveness and the damage. Paragraphs 2, 3 and 4 introduce a large number of exceptions to this principle, by providing a number of cases where the defect or the link between it and the damage are to be presumed. In paragraph 4, the defectiveness or the causal link can be presumed in cases where the claimant faces "excessive difficulties" due to technical or scientific complexity, if they are able to prove that the product contributed to the damage and that it is "likely" that the product was defective or the defectiveness was a "likely" cause of the damage. These presumptions are rebuttable, putting the defendant in a position of having to prove negatives.

In the same paragraph, the European Parliament replaces the test of "likelihood" that a product is defective and/or contributed to the damage with a test of mere "possibility". It is extremely unclear how can a defendant legally prove, at that point in the process, that a product would under no circumstances be capable of being defective or contributing to a damage – a defendant would in effect have to prove the "impossibility" of such a defect in order to succeed in a defence.

[2] The European Medical Technology Industry in figures 2022: https://www.medtecheurope.org/wp-content/uploads/2022/09/the-european-medical-technology-industry-in-figures-2022.pdf.

We recommend avoiding concepts such as "possibility" and "likelihood" as this would undermine the bedrock of the European product liability regime to require a claimant to prove the existence of damage, of a defect in a product, and the link between the two, removing legal certainty for manufacturers placing products on the EU market. We warn in the strongest terms against adopting the unworkable threshold proposed by the European Parliament, which will lead to an automatic reversal of the burden of proof for any perceived "complex" product.

3. No reciprocity of claimant and defendant's rights

The proposal creates a significant shift in rights and obligations when it comes to **disclosure of evidence (Article 8),** which provides that national courts are empowered to order defendants to disclose "relevant evidence that is at its disposal" in some circumstances, while such evidence should be "necessary and proportionate[3]" to support the claim.

Disclosure obligations should be reciprocal, for instance the final text should clearly state that claimants could be ordered to disclose medical records or other relevant evidence (e.g. social media activity) that are at their disposal. Furthermore, national courts should be able to decline such disclosure requests where it considers them, for example, vexatious, unmeritorious or to be "fishing expeditions" (e.g. disclosure should only be ordered where this would assist the "fair administration of the claim").

We support the European Parliament approach which addresses this issue in a balanced manner, empowering national Courts to order the Claimant to disclose relevant evidence.

4. Erosion of IP rights and confidential information/trade secrets

Recital 32 and Article 8(3) of the proposal do not provide sufficient **protection of confidential information and trade secrets**. Rules relating to Intellectual Property (IP) rights are fundamental to the creation of an environment in which creativity and innovation can prosper.

Clarification that documents which are protected by European doctrines of legal privilege or other rules of professional and/or trade secrecy (e.g., IP) would not be disclosable under the revised PLD are needed. The European Parliament addresses the risk of "phishing expeditions" in the Recitals, which brings useful clarity.

5. Clarification of "product safety requirements"

Article 9.2, letter b) of the Proposal provides that "The defectiveness of the product shall be presumed, where (…) 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 paragraph needs to be read in conjunction with Article 6(1)(f) providing that defectiveness should also consider "product safety requirements".

[3] The interplay with the removal of the € 500 threshold for product liability litigation is important as well, for the purpose of the proportionality requirement. Disclosure of evidence carries a cost for the defendant, which may be much more extensive than the worth of the actual claim, in particular if it is a "small claim".

It is essential that the legislator not only uses the same concepts in both articles but clarifies what these requirements are. A feature of the Medical Devices Regulation (MDR) and the *In Vitro* Diagnostics Medical Devices Regulation (IVDR) relevant to litigation is the amount of information about incidents that will be available to the public (and lawyers). MDR/IVDR differentiate between non-compliance linked to safety and other non-compliance. In order to limit potential "fishing expeditions" it should be clarified that only patient safety incidents are relevant for litigation.

The European Parliament largely addresses these concerns by providing more clarity in Article 6. 1 f). The European Parliament further harmonises the language using "product safety requirements" in both articles, providing more certainty.

6. Deletion of "end-user expectations"

The proposal introduces an anomalous subjective element in what is supposedly an objective test based on public interest and expectations of safety to determine if a product is defective by including 'end-user expectations' in Article 6 h). This addition directly contradicts the explicit intention of the Directive stated in Recital 22 for an objective test as well as the first paragraph of Article 6, referencing a "level of safety which the public is entitled to expect".

Adding to that is that an end-user may be any of the following parties in the healthcare ecosystem: the patient, the hospital, or a healthcare professional. The latter is a so-called "learned intermediary" (LI) who is professionally responsible for communicating a quite complex individual benefit/risk assessment to patients at the appropriate level. Failure by a LI to properly evaluate and communicate the benefits and the risks outlined in the manufacturer's Instructions for Use (IFU) for an individual patient should not unnecessarily penalise the manufacturer. The inclusion of "end-user expectations" in the test for "defect" will likely neutralise the importance of the LI's role in the information chain to a patient.

The European Parliament removes this reference adding welcome clarity.

7. An obvious malfunction should not be considered a "defect"

The required causal connection between a product defect on the one hand and the damage on the other hand will in the future be presumed in favour of the injured party if the damage was caused by an "obvious malfunction of the product during normal use".

Article 9.2 c) of the proposal would appear to consider that any failure of, for example, an orthopaedic device (e.g. dislocation of a hip or knee joint) would presumably be an "obvious malfunction", leading to the reversal of the burden of proof. To date, courts have accepted this does not make those products defective within the meaning of the current PLD.

The European Parliament includes in the assessment of what constitutes an "obvious malfunction" a consideration to the use intended by the manufacturer, offering needed balance.

8. Psychological health

Article 4.6 (a) broadens the definition of damage to also include "medically recognised harm to psychological health". The lack of further clarification creates the risk of "worried well" claims (i.e. anxiety about developing future disease) and more broadly does not consider that a certain level of anxiety is always present when patients have to undergo any medical treatment. It also lacks clarity about the scope of material loss related to the psychological harm, e.g., cost of treatment, loss of income.

The implications of including "medically recognised harm to psychological health" need to be reconsidered with a view to the uncertainty on the calculation of monetary claims and the potential liability of economic actors that will need to be covered by insurance. Via amendments to Recital 17, the European Parliament provides some nuance as to what type of medically recognised damage to psychological health is to be included in the definition of damage, which should be included in Article 5a itself to ensure legal certainty.

9. Period of exposure to claims

Under the current PLD, consumers must bring a claim within 10 years of the date that the producer put the product in question into circulation. This limitation period provides important certainty to businesses about their claims risk and document retention processes. It is particularly important for insurance purposes as the calculation of insurance premiums also takes account of the period of exposure to potential legal claims.

The new proposal (Article 14(3)) extends this to 15 years in cases involving latent damage. The Council of the EU increases it to 20 years, while the European Parliament increases it to 30.

In addition, the introduction of the new concept of "manufacturer's control" in Article 10(2) in relation to related services and software updates/upgrades creates a potentially open-ended period of exposure to claims for manufacturers of any products featuring these.

This proposal removes legal certainty for manufacturers and other economic operators whilst the open-ended nature of the period during which they are exposed to claims will foreseeably burden them with significantly higher insurance costs to cover such open-ended exposure.

The impact of this on business, particularly on the insurability of product liability risk, has not been properly assessed. As the sectoral legislation for medical technology also imposes mandatory insurance or financial coverage for product liability risk this will represent a significant additional cost for business. In particular, small and medium-sized enterpises could effectively be priced out of the market by rising insurance costs to cover product liability risk.

Article 14(3): Any lengthening of the limitation period will negatively impact the insurability of medical technologies to be placed on the EU market and should thus not exceed the the European Commission proposal of 15 years.

Article 10(2): The European Parliament amends the proposal to limit the open-ended nature of the claims exposure for changes within the manufacturer's control to the "reasonably expected product lifetime". This may help economic operators and their insurers better quantify the potential claims exposure period.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions. MedTech Europe represents 35,000 companies out of which 92% are small and medium-sized enterprises (SMEs). Our mission is to make safe and secure medical technology available to more people in the EU.
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