

Product Liability rules and the Medical Technology Sector

MedTech Europe views on the revision of the Product Liability Directive

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Summary

The European Commission is finalising a revision of the Product Liability Directive (PLD). The priority in any PLD revision must be that it continues to uphold an established balance which (a) fosters safe innovation, (b) offers legal certainty and consistency with the existing legal frameworks (c) allows consumers to claim compensation if they suffer injury arising from defective products. Undermining this balance risks disrupting incentives to innovation, which is needed to provide state-of-the-art technologies that address the unmet needs of consumers and patients.

In addition to the requirements of the PLD, the medical technology sector is regulated through modern and extensive sector-specific safety legislation (i.e., Medical Device Regulation (MDR)¹, In Vitro Diagnostic Medical Devices regulation (IVDR)²) as well as horizontal legislation, including but not limited to the General Data Protection Regulation (GDPR). The combination of these complex pieces of legislation ensures the safety and performance of medical technologies, along with world-class data protection and product liability standards.

Given this context, MedTech Europe believes that the PLD in its current form is still fit for purpose. Where new emerging digital technologies and associated services make certain clarifications necessary, guidance could be published to address such developments.

Introduction

Medical technology is an innovative, fast-moving, and highly regulated sector. For the latest, state-of-the-art medical technology to benefit patients in the EU, the sector needs an enabling regulatory environment that supports research and incentivises innovation.

New rules regulating the safety and performance of medical technologies in the EU, the Medical Devices and In Vitro Medical Devices Regulations (MDR/IVDR), dating from 2017, are a key reference in terms of how to regulate technologies, addressing risk classification, refurbishment as well as liability coverage requirements; thereby ensuring the safety of products before they enter the market. MDR/IVDR are complemented by horizontal and market surveillance legislation, including the General Data Protection Regulation (GDPR), the

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

² Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Market Surveillance Regulation³, the proposed AI Act and the proposed General Product Safety Regulation (GPSR). Alongside these rules regulating safety and security before a product is placed on the market, the Product Liability Directive (PLD) plays an important role in providing consumer compensation in the case of a product being defective. The PLD thus is part of a comprehensive regulatory framework that creates an enabling environment for timely consumer access to innovative medical technologies that underlie extensive safety and security requirements.

MedTech Europe believes that the PLD is still broadly fit for purpose as it continues to provide consumers and patients with a high degree of protection while offering industry room and legal certainty for innovation. Instead of revising the structure and principles on which the PLD is based, we recommend that where required, guidance should be developed to clarify how the existing Directive applies to emerging technologies, including those using artificial intelligence (AI). Guidance allows for a faster and more specific response than introducing legislative changes, in particular where the field is still very much evolving, and avoids the risk of unsettling the core principles that the PLD has established.

This paper sets out MedTech Europe's rationale for its recommendation to preserve the PLD's status quo. Where the legislator does consider change, we make concrete recommendations from the medical technology industry point of view. In doing so, we focus on topics of particular concern, including "burden of proof", "the provision of information to an injured person", "software as a product", "extension of the scope for damages", "thresholds for compensation", "expiry periods for liability", "defences", "cybersecurity" and "liability for AI". MedTech Europe believes that in order to ensure the objectives for a liability framework set out by the European Commission to foster innovation, ensure product safety, and protect consumers and patients, these considerations will help paving the way for a balanced and future-proof liability framework.

Burden of proof

A key concern for the medical technology industry is the prospect of amending or reversing the burden of proof. The current PLD regime allows consumers who can prove that they have suffered harm as a result of a defect in a product to obtain compensation without the need to show fault on the part of the producer. Such burden of proof is the collateral of the strict liability regime. This is to ensure that companies are not exposed to unnecessary, frivolous, or even abusive litigation.

European jurisprudence has made it considerably easier for the injured person to demonstrate a causal link between the product defect and the damage. The only condition outlined by the European Court of Justice (ECJ) is that such alleviation does not undermine the Directive's provision that places the burden of proof on the injured person as well as that the free assessment of evidence by the courts must be preserved. One example is the ECJ's decision on the hepatitis B vaccine (C-621/15 W and Others v Sanofi Pasteur), where it ruled that the defect of a vaccine and the causal link between this defect and a disease can be demonstrated by serious, specific and consistent evidence, in the absence of scientific consensus about a causal relationship.

³ Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011.

A further alleviation, or even a reversal of the burden of proof, would constitute ground-breaking changes that fundamentally disrupt today's liability regime. This would have wide-ranging implications for Member States' civil liability systems. In such a scenario, producers, who already need to comply with extensive safety requirements before and after placing a product on the market, would have to demonstrate that their products are free from defect, even though they comply with all regulatory requirements, rather than the plaintiffs having to demonstrate the opposite.

In light of this, MedTech Europe proposes to maintain existing principles, where courts continue to have the flexibility to interpret and develop the law within the existing legal framework which permits an easing of the burden of proof without undermining this key principle. Any change to this principle would fundamentally transform the relationship between the injured party and producer in a manner that distorts the fair distribution of risks.

[The provision of information to injured persons](#)

The provision of information to injured persons is a key variable in the process of a liability claim. National procedural laws provide, among others, rules and principles relating to the taking of evidence and its evaluation. In addition, for medical technologies, injured parties have additional extensive rights to receive technical information from producers. The MDR/IVDR specifically provides that injured parties can access relevant documents in the event of a possible product liability case. Producers are also obliged to provide competent authorities with 'all information and documentation necessary to demonstrate the conformity of the device'⁴. Furthermore, authorities may provide potentially injured parties with access to this documentation⁵.

The MDR/IVDR also includes numerous information sharing obligations on the safety and performance of the device, throughout its entire lifecycle (i.e., ex ante), to all users (not only "injured"), by means of the documents accompanying each product such as, instructions for use as well as public registries (e.g., EUDAMED including data on incidents, clinical studies etc).

Beyond the scope of the MDR/IVDR, national procedural law can address specific cases where injured persons may find it difficult to prove the link between damage and defect due to limited access to technical information.

Given these national and sector-specific extensive rights for injured consumers and patients to obtain information from medical technology producers, MedTech Europe does not see the necessity to rewrite the rules on access to information under the PLD. If rewritten, it could risk introducing legal uncertainty for producers by creating regulatory misalignment between the existing regulations.

⁴ EU MDR, Art. 10 para. 14 subpara. 1

⁵ EU MDR, Art. 10 para. 14 subpara. 3

Software as a 'product'

The European Commission published in February 2020 a [report](#) which calls for a further clarification of the concept of product to better reflect the complexity of emerging technologies, such as digital products and software and products using artificial intelligence technology. MedTech Europe believes the current definition of a 'product' in the PLD is still relevant and appropriate even when applied to such innovative technologies. The Directive is technology-neutral and has been, amongst others, applied to cars, vaccines and blood, as well as to a range of medical technologies such as breast implants, pacemakers and artificial hip replacements, proving that it can successfully regulate various kinds and types of products.

Furthermore, for medical technologies, MDR/IVDR make no distinction between tangible products and intangible products. There are two main categories in which software is deployed in the medical technology field: embedded software which is part of a medical device (a product) and standalone software used for medical purposes. MedTech Europe believes that embedded software should be treated as part of a product, allowing any claim to be brought against a medical device producer via the PLD. As part of the product design process, the producer decides what software to use in its products and is responsible for the overall safety of the device.

Standalone software under the MDR/IVDR is subject to significantly stricter regulation than software used in a non-medical setting. In practice, software can only cause damage of the sort contemplated by the Directive (as opposed to, for example, data loss) where it acts through a physical product. In such cases, the patient's claim would not be that the software constituted a defective product, but that the product, in which it was installed, was defective as a result of the operation of its software.

Should the legislator consider specific refinements of the definition to make it more suitable for the digital age (e.g., movable products), MedTech Europe advises against overly broad definitions which would lead to lack of clarity and, in turn, risk undermining the effective application of the Directive.

In view of these considerations, MedTech Europe sees no need to change the definition of 'product' in the PLD with respect to medical technologies. MedTech Europe advises instead to rely on definitions of existing regulations applied via the use of guidance. This would promote a consistent and clear application of rules within the existing regulatory framework.

Damages: Extension of the scope (e.g. data protection breaches and environmental damage)

The precise scope of damages that can be compensated under the PLD is a matter both for the Directive itself and for national law. In many countries, consumers can recover for non-material damages (e.g., pain and suffering) if they are first able to prove that they suffered physical harm, which would often be the case in a claim under the Directive. Currently, the Directive only covers material damage of items primarily intended for private use and physical damage.

MedTech Europe believes that the current definition of damage under the Directive is sufficient and in line with the notion of safety⁶. More importantly, other types of damages are covered by other EU legislations. For example, damages relating to personal data are already covered by the General Data Protection Regulation (“GDPR”). Expanding the scope of the definition under the PLD could create application problems and make it unclear when one piece of legislation should be applied versus another for assessing damages.

In addition, expanding the scope of damages to include for example data loss that leads to privacy infringements or emotional damages, might not respect national legal rules and could raise challenges around proving and establishing a compensation for these damages which could create inappropriate risks of abuse⁷. Therefore, should such an extension be considered, in parallel there would need to be a re-visit of the position that the Directive forbids a producer from limiting the producer’s liability to an injured person by contract, at least for standalone claims for mental distress.

Thus, MedTech Europe recommends not to expand the scope of the definition of damages under the PLD, as it could create legal uncertainty and misalignment between existing regulations as well as national legal rules raising challenges about proving and establishing compensation and higher risk of abuse of liability rules.

[Thresholds for compensation](#)

Compensation for property damage below EUR 500 is not allowed under the PLD. This is designed to balance the need for businesses and citizens to have access to legal recourse while ensuring the courts are not overwhelmed with small claims.

If anything, the thresholds should be adjusted upwards for inflation, and alternatives to court-based litigation should be prioritised for smaller claims in the interests of the efficient administration of justice.

MedTech Europe believes this approach is still fit for purpose. Reducing or abolishing the threshold would add to the administrative burden and costs associated with legal cases and slow down the resolution of larger claims.

[Expiry Periods for Liability](#)

Under the PLD, an injured person has three years within which to seek compensation. The period starts from the date on which the person becomes aware of the damage, the defect, and the identity of the producer. Separately, the producer can no longer be held liable 10 years after the date the product was put on the

⁶ Under the Directive, an injured consumer would likely have a claim against the producer, on the basis that the product did not provide the level of safety which the public is entitled to expect. It is up to the courts to rule that, taking into account **all the circumstances**, the public is entitled to expect a specific level of “safety”.

⁷ Inherent in the risk of abuse is the subjectivity involved in assessing emotional damages, and the added cost and risk of abuse in seeking additional experts to become involved in assessing emotional damages to establish proof of their existence related to a claim for damages.

market. This is part of the balance that the Directive seeks to strike between the need to protect potential claimants' interests and providing legal certainty to industry.

Such expiry periods, already much longer than traditional warranties that are typically 2 years, are also in line with the notions of "lifetime" or "shelf-life" in industry specific regulations setting time limits for proactive obligations of manufacturers. They are also important for all stakeholders, as they provide certainty about the risk of claims for a product placed on the market and are essential for insurance purposes.

Therefore, MedTech Europe believes that the current liability period is justifiable and considers any extension to this period to be disproportionate given its impact on insurability and thus economic viability of placing an innovative medical technology on the market.

Defences

The PLD includes several defences which were carefully drafted considering consumer protection and innovation.

The 'development risk defence' (DRD) frees the producer from liability if, based on the state of scientific and technical knowledge at the time that the product was put on the market, it was not possible to foresee the defect. Member States may derogate from the "development risk defence". Additionally, a previous report carried out for the Commission by the Fondazione Rosselli⁸ concluded that DRD remained a significant factor in achieving the Directive's balance between the need to preserve incentives to innovation and consumers' interests. The MDR/IVDR requires that devices should be designed and manufactured taking into account the "state-of-the-art". This needs to be considered in the development life cycle, risk management, including information security, verification and validation and risks, which shall be "compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art".

The 'later defect defence' frees the producer from liability when it is probable that the defect did not exist when the product was placed on the market but came into being afterwards.

These two defences are essential to ensuring that manufacturers/producers are not at risk of being penalised for matters genuinely outside their control. They are of particular significance in fast-paced technology, such as the medical technology industry.

MedTech Europe believes these narrow defences remain fit for purpose and should be preserved as part of the overall package of rights and responsibilities contained in the Directive. They represent a reasonable conciliation which has performed well since the Directive was drafted and continue to be appropriate considering current and potential future risks, for example those associated with cybersecurity.

⁸ Please see [here](#).

Cybersecurity

New digital technology might provide both risks and solutions to the expanding threat landscape. It is important to recognise that cybersecurity is a shared responsibility among all stakeholders, including but not limited to medical technology manufacturers, healthcare providers, users, regulators, and vulnerability reporters.

European product safety legislation includes specific provisions related to security aspects and related standards. In addition, the upcoming Cyber Resilience Act will introduce common cybersecurity rules for manufacturers and vendors of tangible and intangible digital products and ancillary services. **Thus, MedTech Europe believes it is not necessary to address cybersecurity issues via the revision of the PLD.**

Liability for Artificial Intelligence

The European Commission identifies AI technologies as one type of products presenting certain complexities in product liability due to their potential for autonomous behaviour, opacity, and capacity for self-learning.

Generally, current AI-enabled products used in the medical technology sector are supervised by trained personnel and are not the last decision-making instance when it comes to the diagnosis, treatment, or management of a patients' health. AI systems in medical technology, for example, provide insights for therapeutic or diagnostic purposes, allowing treatment decisions to be made by healthcare professionals who are responsible for patient care.

Rather than addressing current and future AI systems by revising the PLD or developing a new liability framework for AI, it would be better to ensure that the proposed AI Act draws up dedicated ex ante rules for the making of these products safe. Where breaches occur, the responsible party would be held liable under the current framework.

In this context, MedTech Europe sees no need to create new liability rules specifically for medical technologies featuring AI systems. Seeking to rewrite the PLD to account for unknown AI technologies risks creating legal uncertainty for businesses and making it more difficult for consumers to obtain compensation for damages caused by products and services that use these technologies. In addition to existing safety rules, additional and specific safety requirements are already in the process of being developed by means of the AI Act.

Conclusion

The medical technology sector is highly regulated by both sector-specific and horizontal regulations. MDR/IVDR are designed to ensure product safety and performance while fostering innovation providing all necessary prerequisites for safe and secure medical technology to access the European market. The Product Liability Directive furthermore provides an established, technology-agnostic mechanism for seeking redress

where such medical technology products are defective. In view of this regulatory framework, MedTech Europe is of the opinion that a structural change of the liability framework will not fit with the current landscape, creating overlaps and legal uncertainty that will not only affect producers of medical technologies but also consumers and patients when seeking compensation in case of harm.

MedTech Europe believes the existing suite of regulations strikes a reasonable balance between our shared goals of consumer protection, access to medical innovation, and legal certainty for the thousands of small and large companies that make up Europe's medical technology sector. On the issues where reviews are being foreseen, MedTech Europe looks forward to working together with policymakers to make the current application of the PLD more up-to-date, standardised, aligned and clear by reinforcing the compatibility of interpretations with existing and upcoming regulations.

Recommendations

- **Retain the PLD in its current form**
- **Develop guidance where required to clarify how the Directive applies to emerging technologies**
Data protection, environmental damages and liability for AI should be addressed under respective existing and upcoming regulations (GDPR, AI Act and future environmental legislation)

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.

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