

Inception Impact Assessment – Product Liability Directive

28 July 2021

Response to the Inception Impact Assessment

MedTech Europe, the European trade association for the medical technology industry including diagnostics, medical devices and digital health, welcomes the opportunity to provide comments on behalf of the medical technology industry to the European Commission on the [Inception Impact Assessment](#) regarding the revision of the Product Liability Framework¹.

As the European Commission concluded in its [Evaluation of the Product Liability Directive 85/374/ECC](#), the medical technology industry is also of the opinion, that in general, the Product Liability Directive (PLD) ensures adequately the liability for defective medical technology products. We believe that the PLD contributes to the reasonable balance between those who suffer injury and ensures fair competition. Therefore, MedTech Europe previously already commented that we support the status quo, i.e. the baseline scenario.

In our previous commentaries, we made the following points:

- We acknowledged that new and emerging technologies pose challenges and careful consideration should be given to the process of addressing those challenges². This should be done in a way which is consistent with other work being undertaken at EU level, such as adherence to the EC's Better Regulation's guidelines and principles, which seek to provide a simple, clear, stable and predictable regulatory regime for businesses as well as specific legislation, which for the medical technology industry is, *inter alia*, the MDR (Medical Device Regulation (EU) 2017/745), IVDR (In vitro Diagnostics Regulation (EU) 2017/746), and GDPR (General Data Protection Regulation 2016/679)³.
- New technologies in the medical technology sector, would fall under the concept of software medical devices⁴, whether this would include Artificial Intelligence (AI) or not. Such new medical technologies are included in the MDR/IVDR (i.e. ensuring the safety and the performance of a medical device and so also those with AI) and as such are subject to severe processes, evidence

¹ The document is available for download here: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence_en

² MedTech Europe position paper: https://www.medtecheurope.org/wp-content/uploads/2019/11/MEDTECH EUROPE_Nov19_AI-in-MedTech-Delivering-on-the-Promise-of-Better-Healthcare-in-Europe.pdf

³ The medical technology sector is already regulated through a system which has its foundations in the identification of risk profiles and the management of risk, and which also builds on the PLD's liability regime (Art 10.16)

⁴ In order to elaborate regarding the issue of software for medical technologies, it may be worth outlining the regulatory context for medical technologies. The MDR/IVDR do not define the term "software" (nor did MDD for that matter). The definition of software can however be found in the [recent MDCG Guidance](#) (2019-11) on Qualification and Classification of Software in MDR and IVDR, as well as in previous [MEDDEV guidance](#) (2.1/6). In this Guidance, it is clarified that a software must have a medical purpose on its own to be qualified as a medical device software ("MDSW"). Therefore, qualification and CE-marking of software as a medical device or IVD triggers considerably stricter legal requirements and liabilities than software, without a medical scope, as the manufacturer must thoroughly substantiate that the software is safe, performs as intended, and delivers a clinical benefit.

collections, risk/benefit assessment. MDR and IVDR also include specific liability provisions and defines responsibilities also for other economic operators in the supply chain. Therefore, any new liability rules that seek to compensate *ex-post* for damages suffered by patients due to a defective product should take in due consideration existing liability rules applicable for medical technology manufactures (i.e. manufacturing defects; design defects; warning defects) as well as to the economic operators. The latter, as per applicable legislation, have specific legal obligations, such as verification; reporting obligations as well as joint liability with manufacturers in certain cases to ensure a non-European manufacture cannot escape liability.

PLD covers all kinds of products including innovative ones and MedTech Europe does not think that further explicit reference to, for example *software* is necessary. The reason is that under our sectoral legislation there is always a medical device in some shape or form, most of the time a tangible hardware but it can also be a stand-alone software, and as such the medical device, whether tangible or not, would fall under the PLD, so patients always have a point of recourse.

- In most cases, AI in healthcare is not used for “final” autonomous decision making⁵ (as compared for example to autonomous cars or drones). Most new medical devices aim to “augment” or support the healthcare professional (HCP) in some way and not completely assume—specific tasks of the physicians. The HCPs should ultimately remain responsible for the diagnosis and treatment decisions, whatever technological support or products they decide to use⁶. The use of innovative technologies can help minimise the HCPs’ liability exposure. Accordingly, AI used in the afore-described manner does not increase but mitigates the risk of personal injury resulting from a faulty diagnosis or treatment.
- At Member State level, there is a range of mechanisms for patients, including out of court ones which have proven very effective to seek enforcement or redress for breaches of their personal rights⁷. Therefore, MedTech Europe believes that the PLD and other existing national options provide an adequate level of protection for patients.

Therefore, MedTech Europe is of the opinion that it is also important that any new proposal takes in due consideration existing liability rules applicable for medical technology manufacturers, hospitals, healthcare professionals and patients including alternative dispute resolution mechanisms and in case any material gaps are identified, then any “new” AI-related liability risks (including liability of healthcare professionals) need to be considered and build on existing rules. MedTech Europe is also concerned regarding the impact of some of the policy options suggested in the Inception Impact Assessment, as they would hinder patient access to medical technology innovations.

⁵ Jason Chung and Amanda Zink, ‘Hey Watson – Can I Sue You for Malpractice? Examining the Liability of Artificial Intelligence in Medicine’ (2018) 11 Asia Pacific Journal of Health Law & Ethics 51, p.68, accessible at: <https://eible-journal.org/index.php/APHLE/article/view/84>

⁶ Ibid.

⁷ European Commission, ‘Patients’ Rights in the European Union Mapping eXercise’, Final Report, p.38, 2016, accessible at: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_mapping_patientsrights_frep_en.pdf

However, we also agree, that even though the Directive continues to be fit for purpose, technology has and continues to develop at high speed. As a result, legal and regulatory frameworks can at times struggle to keep up. **Consequently, should the baseline scenario not be an option, MedTech Europe would support also developing policy option 2.1.a.**

MedTech Europe supports, in certain specific cases, the alleviation of the burden of proof and recognises that this is something that is already happening in some Member States. Such an alleviation of the burden of proof by allowing courts to infer that a product is defective or caused the damage under certain circumstances, e.g. when other products in the same production series have already been proven to be defective or when a product clearly malfunctions, is a concept that was already applied by courts to different products and different situations to properly balance public interest and expectations of safety as demonstrated by the [Boston Scientific case](#) (joined case C-503/13 and C-504/13).

On the other hand, MedTech Europe does not support the remaining policy options. In particular, the extension of the range of damages to non-material damages as MedTech Europe believes that the current definition of damage under the Directive is sufficient and in line with the notion of safety. Furthermore, 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 here would only 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/privacy loss, emotional damages, etc. might not respect national legal rules. On the contrary, it could raise challenges around proving and establishing an amount for these damages and would create inappropriate risks of abuse.⁸

In regard to the reversal of the burden of proof and placing it on the producer, MedTech Europe does not support this policy option either. The burden of proof for both causation and damage should, as a general rule, be on the victim (as is the case under current liability frameworks)⁹., further it would interfere with Member States procedural rules. However, as stated above, MedTech Europe agrees that where such a burden would be disproportionately high, lowering the burden of proof may be necessary.

In relation to the removal of the ‘development risk defence’ to ensure that producers continuously learn and adapt while in operation remain strictly liable for damage, MedTech Europe is of the opinion that the *defences* that form part of the Directive were drafted deliberately narrowly and form part of the balance between consumer protection and innovation that the legislator sought to achieve. This development risk defence foresees that a producer is not liable for a defective product if the state-of-the-art technical knowledge at the time of putting the product into circulation was not such as to enable him to be aware of the defect. A previous report carried out on behalf of the European Commission by the Fondazione Rosselli concluded that the development risk defence (DRD) remained a significant factor in achieving the

⁸ 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.

⁹ This is also the opinion included in the [report](#) published by the Expert Group on Liability and New Technologies – New Technologies Formation

Directive's balance between the need, on the one hand, to preserve incentives for innovation and on the other, the consumers' interests. Therefore, MedTech Europe is not in favour of removing the 'development risk defence'.

Another point MedTech Europe would like to bring to the attention of the European Commission is related to easing the conditions for making claims (time limits and EUR 500 minimum threshold for damage to property). In the past, some arguments have been made that a time period of 10 years is too short for certain products, in particular healthcare products. We believe that the periods for which producers are liable for the products they put into circulation provide legal certainty for the industry as well as other stakeholders (e.g. healthcare professionals). For industry, the 10-year "longstop" provides important certainty about their claims risk and is important for insurance purposes. Additionally, providing an expiry period of 10 years is five times as long as most warranties, which are typically around 2 years. Further, especially in the era of extremely fast technical development, we see rather reason for shortening it. Therefore, industry at minimum supports the status-quo on this point.

To conclude, and as already previously mentioned ([here](#)), to take full advantage of the impact and benefits of AI in the healthcare sector for patients, healthcare professionals and healthcare systems, the regulatory framework needs to remain flexible and follow the evolution of technological developments, allowing space for innovation both within large as well as smaller companies. Under the MDR and IVDR the medical technology industry already has a strict regulatory framework in place. The medical technology industry believes that a guidance that would provide an interpretation and describe novel approaches to meet the requirements, may promote innovation and competitiveness as well as enable developers to navigate the challenging European medical technology regulatory environment. We look forward to the impact assessment, which will follow after the inception impact assessment. and continue engaging with the EU institutions on this topic.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our purpose is to make innovative medical technology available to more people, while helping healthcare systems move towards a more sustainable path. 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.

For more information, please visit www.medtecheurope.org.

If you have any further questions, please reach out to:

Aline Lautenberg

General Counsel, MedTech Europe

a.lautenberg@medtecheurope.org