Summary

Product Liability in Medical Technologies

Why Europe should preserve the existing legal approach that protects consumers whilst supporting innovation

Medical technology is an innovative, fast-moving, and highly regulated field. Europe's medical technology sector is home to 27,000 companies, of which 95% are SMEs. Medical technologies save lives, improve health, and contribute to sustainable healthcare. Through innovative devices and diagnostics, the industry delivers value to patients, healthcare professionals, healthcare systems and society. Medical technology companies are also drivers of economic growth and job creation across Europe.

The safety and performance of medical technologies in the EU is regulated by a modern suite of medical technology-specific rules[1], as well as the General Data Protection Regulation (GDPR), the proposed AI Act, the proposed General Product Safety Regulation (GPSR) and others.

In addition, the Product Liability Directive (PLD) plays an important role in ensuring consumer compensation whilst supporting timely access to highly innovative medical technologies and providing legal certainty for industry. The European Commission has raised the prospect of making changes to the PLD.

MedTech Europe has examined the implications of changing the PLD and concluded that that **Directive is fit for purpose in its current form**.

Where needed, **guidance can be published to address emerging technologies**, while data, environmental and AI-specific issues are addressed separately.

A key rationale for reopening the Directive is its age: the legislation was drafted before recent advances in AI and connected healthcare devices were conceived. However, the PLD is technology-agnostic and has coped with several waves of innovation in its lifetime. It continues to provide a solid basis for liability protection, supplemented by specific guidance as required. Concerns related to data, the environment and AI, are covered by existing and forthcoming legislation.

MedTech Europe considers the current definition of a "product" in the Directive is still relevant and appropriate even when confronted with innovative technologies. The Directive has been applied to various products including cars, bicycles, mattresses, vaccines and blood, as well as to a range of medical technologies such as breast implants, pacemakers and artificial hip replacements. It is technology-neutral and remains fit for purpose. It should be noted that the flexibility to apply the Directive to particular products or facts has been

[1] EU Regulation 2017/745 on Medical Devices (MDR) and EU Regulation 2017/746 on In-Vitro Diagnostics (IVDR).

given to the Member State courts, guided by the judgments of the CJEU. The flexibility inherent in the concept of "defect" has allowed them to do this very successfully over the years, for a wide range of products and technologies.

The conclusion of the Commission's fifth report (COM/2018/246 final)[2] on the Application of the PLD echoes MedTech Europe's position. It found that that Directive broadly ensures liability for defective medtech products in a balanced way.

Undermining the status quo risks needlessly disrupting incentives to innovation which not only serve the European economy, but first and foremost provide valued technologies addressing the needs of consumers and patients and making healthcare better. It is in nobody's interest to unsettle this delicate equilibrium which is at the heart of the PLD regime.

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:246:FIN