

Council's position on the proposed Product Liability Directive may impact European medical technology innovation and competitiveness

Brussels – 14 June 2023 – MedTech Europe voices concern over the hasty position agreed on by representatives of Member States (COREPER) without further considering industry experts' concerns on the new Product Liability Directive (PLD).

While the well-intended nature of the revision was meant to bring about targeted changes to make consumer access to compensation easier, the new proposal has introduced fundamental changes that risk upheaving almost 40 years of functioning civil liability law. The unintended result could be decades of costly litigation and significant increases in insurance premiums that will put economic pressure on medical technology companies in the EU, impacting specifically the many Small and medium-sized enterprises (SMEs) that are at the heart of this industry.

The impact of such changes might be significant in the healthcare sector, as the interaction of a medical product with a consumer or patient often depends on a "learned intermediary", i.e. a healthcare professional. *"A sustainable horizontal liability framework in the EU needs to take into account the intricacies of such a sector, and the risk-benefit approach that is at the core of patient care"* says Oliver Bisazza, CEO of MedTech Europe.

The excessively fast pace with which the revision of core principles of civil liability law is advancing is also worrisome. We are concerned that sub-optimal final rules will have unwanted negative implications for future case law and will not instil confidence in, or incentivise, medical technology manufacturing in Europe. This also contradicts the commitments made at the European Council level to ensure that a competitiveness check is performed for every EU initiative.

Looking ahead, MedTech Europe is ready to work towards a balanced litigation system in Europe that has patients and consumers at heart. We look forward to an inclusive, open, and flexible approach – built in collaboration with Member States and European stakeholders - that ensures the safest and best-in-class medical technology reaches patients and consumers.

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. www.medtecheurope.org.

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