

MedTech Europe statement on the political agreement on the revised EU Product Liability Directive

19 December 2023

Against the background of a political agreement achieved on the revision of the Product Liability Directive (PLD) on 14th December, MedTech Europe remains very concerned that the overall impact of the revised PLD on companies and consumers, and on the medical technology sector in particular, has not been properly considered.

The revised PLD lacks meaningful safeguards to ensure that a reversal of the burden of proof is only applied when very specific conditions are met. As a result, the newly introduced presumptions may lead to an increased volume of legal claims resulting in higher insurance costs, dampening innovation and putting at risk smaller companies. In addition, while certain improvements in the area of disclosure of evidence have brought the final text closer to a level playing field for claimants and defendants, the current wording still falls short with regard to ensuring the right to a fair trial for both sides.

We also continue to warn about the impact of Recital 34, that singles out medical devices as the example for a product that could be considered “complex”, which could lead courts to automatically presume defectiveness of and the causal link for all medical devices without duly considering their actual complexity. Co-legislators should consider the European Parliament’s position in the final text to ensure that innovative medical technology’s complexity is assessed fairly and to provide manufacturers with a level playing field for any type of innovation they develop that benefits patients and health systems in the EU.

Against this background, we urge co-legislators to duly consider the impact of this revision and ask to adopt an approach that works for patients and health technology providers alike.

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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