MedTech Europe feedback on the European Commissions proposal for a Directive on Liability rules for Artificial Intelligence (The Artificial Intelligence Liability Directive - AILD)

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Executive Summary

MedTech Europe is the European association of medical technology manufacturers, including digital health products that fall under the scope of our sectoral regulations, some of which would fall under the scope of the proposed Artificial Intelligence Liability Directive (AILD).

MedTech Europe supports the European Commission's objective to ensure that victims of damage caused with the involvement of AI have the same effective compensation as victims of damage caused by other technologies.

However, we also believe that it is important to find a balance between this objective and ensuring legal certainty in European civil justice systems as well as trying to avoid creating an innovation-stifling environment.

To avoid this, we would like to highlight the following areas of concern:

Regulating fault-based civil liability cases involving AI in a separate piece of legislation can create confusion

We question the need to create a separate Directive regulating key aspects of civil liability involving AI systems when the majority of its substantive, product safety provisions depend entirely on the final text of the AI Act, which is still very much under discussion.
At the same time many of its procedural mechanisms are the same as the newly presented proposal for a revision of the Product Liability Directive, even if one tackles fault-based claims and the other one claims based on strict liability.
As a consequence, the proposal tries to combine two very different regimes; product safety and product liability.
Considering this, we believe that the provisions of this Directive could have been included in either the AI Act or in the Product Liability Directive to avoid potential inconsistencies, confusion, and repeating discussions.

The proposal leads to a de-facto reversal of the burden of proof

The presumptions listed in Article 4 are so wide ranging that we question if a majority of cases would not in fact fall in its scope, creating a scenario in which defendants are left to prove a negative, a concept that is contrary to continental legal traditions.

This will ultimately deter innovation by increasing the costs of launching innovative AI systems in Europe due in part to a constant threat of unnecessary litigation.

The evidence disclosure requirements are excessive and one sided

The current proposal lacks proper and clear limits to the type and scope of information that a defendant will be required to disclose. This uncertainty can unfairly trigger one of the presumptions of Article 4.
Considering the innovative nature of AI systems, it is critical to ensure that IP and trade secrets are more clearly protected from overreaching evidence disclosure requests.
Additionally, the disclosure obligations are not reciprocal, which would likely be key in any cases involving personal damage.

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.

For more information, please contact: Aline Lautenberg, General Counsel and Director General Legal & Compliance