Liability challenges in AI medical technologies
Liability challenges in AI medical technologies

AI in healthcare can bring enormous benefits to patients, healthcare professionals as well as improving patient safety, effectiveness of treatment and increasing of healthcare systems.

Given the specificities of AI, new legal questions may present themselves when assessing liability for harm caused by AI technology. The legal framework regulating liability of AI (medtech) products must allow claims by injured parties without hindering access to innovation for patients and healthcare systems.

The specific roles and responsibilities in the healthcare ecosystem must be considered (e.g. healthcare professionals, healthcare organisations and producer).

In Europe, despite the complexity of this ecosystem, risks of personal injury are comprehensively covered by a range of liability regimes, whether through national contract and tort law or the Product Liability Directive (PLD). Here we aim to outline:

• **Overview of the stakeholder liability system** for harm caused by medical technologies, whether AI-based technologies.

• **Selected use cases** to illustrate different scenarios of liability allocation in this value chain, which include AI-based medical technologies, both with professional and private users.

**SUMMARY**

These existing liability regimes are well equipped to respond to the specific characteristics of AI technology. Any new rules should not undermine the legal certainty that the current liability framework provides to injured persons and AI technology innovators. If changes to the current laws are considered, they must:

• Balance liability across the ecosystem, to avoid undue burdens on a specific stakeholder group;

• Promoting safe and effective AI-based medical technology

• Ensure the development of innovation and its integration into the healthcare systems.
The existing regulatory framework has established a strong and well-established liability system that ensures that the relevant stakeholders are held accountable for protecting patients in case of personal injury involving AI-based medical technologies.
### Autonomous AI systems – Monitoring and treatment of diabetes

**Potential risk for the patient**
- Possible direct physical harm due to injection of an incorrect dose of insulin

**Producer liability**
- Producer remains responsible in specific cases despite autonomy, excluding situations such as learning and development capability of the technology when placed on the market with appropriately designed and specific instructions: Errors resulting from false input data by the operator

**Liability of the operator (i.e. HCP/HCO)**
- Negligence could be argued where the user/operator further (after the placing on the market) trains the AI with “biased” data

### Robotics – AI applied to surgical robotics (surgeon assistance tools)

**Potential risk for the patient**
- Possibility of direct physical harm during the surgery

**Producer liability**
- Design and manufacturing defects
- Insufficient or faulty warnings or instructions

**Liability of healthcare professionals**
- Improper use of the robot violates the duty of care
- Inaccurate information provided to the patient by the HCP

**Liability of healthcare organisations**
- Breach of organisational and monitoring duties (e.g. HCP training, timely implementation of updates)

### Monitoring/ Wearables – Detection and monitoring

**Potential risk for the patient**
- Failure to provide necessary treatments
- Unnecessary treatments with harmful side effects

**Producer liability**
- Instruction, product design or manufacturing defects
- Lack of data management: ensure careful selection of training data and adequate AI training (both within manufacturing and, where necessary, in use)
- Product post-market monitoring obligations

**Liability of healthcare professionals**
- Breach of standard of care in case of diagnostic errors
- Omitted plausibility check

**Liability of healthcare organisations**
- Breach of organisational and monitoring duties (e.g. HCP training, timely implementation of updates)
- False/bias data input

**Responsibility of the patient**
- Failure to install necessary updates (contributory negligence of the patient in the event of harm may be invoked in individual cases)