MedTech Europe
from diagnosis to cure

Liability challenges in AI medical technologies

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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 safety of patients must always be guaranteed – therefore liability rules must enable access to justice for injured parties.

Innovation, R&D investments and technological advancement require legal certainty from a liability perspective.

The established liability systems already ensure a fair distribution of risk among all parties involved.

New rules must ensure legal certainty and promote innovation and safety.

Liability & AI-based medical technologies: A substantial ecosystem aimed for protecting patients

Patients' liability claims in case of personal injury involving AI-based medical technologies

Liability of Notified Bodies

Notified Bodies have specific regulatory duties (MDR/IVDR) relating to ensuring that only safe medical technologies, including software medical devices, are placed on the market.

A claimant may rely on general tort law in connection with the regulatory provisions under MDR/IVDR and claim a violation of the Notified Body's regulatory obligations.

Producer liability

Medical technologies, whether embedded or stand-alone software medical devices (including AI), are subject to the general product liability rules of the EU member states. These laws are based on (1) a strict liability regime (without fault) under the national laws of the member states implementing the EU Product Liability Directive 85/374/EC ("PLD"), which at present is under revision, and (2) supplemental fault-based liability systems (negligence) under the national laws of torts of practically all EU member states. Both liability regimes apply in parallel.

Additional product safety legislation, such as the MDR/IVDR (and the upcoming AI Act) are important in view of the high threshold for medtech manufacturers to define not only warnings, but also precautions, contra-indications, measures to be taken and limitations of use regarding the technology, in both pre-, and post-market settings. For software, this also means IT security measures. For example, a producer can be held liable under product lability laws in case of a failure to provide adequate warnings, which could typically characterise a "defect" in the PLD sense.

Liability of healthcare professionals (e.g. physicians)

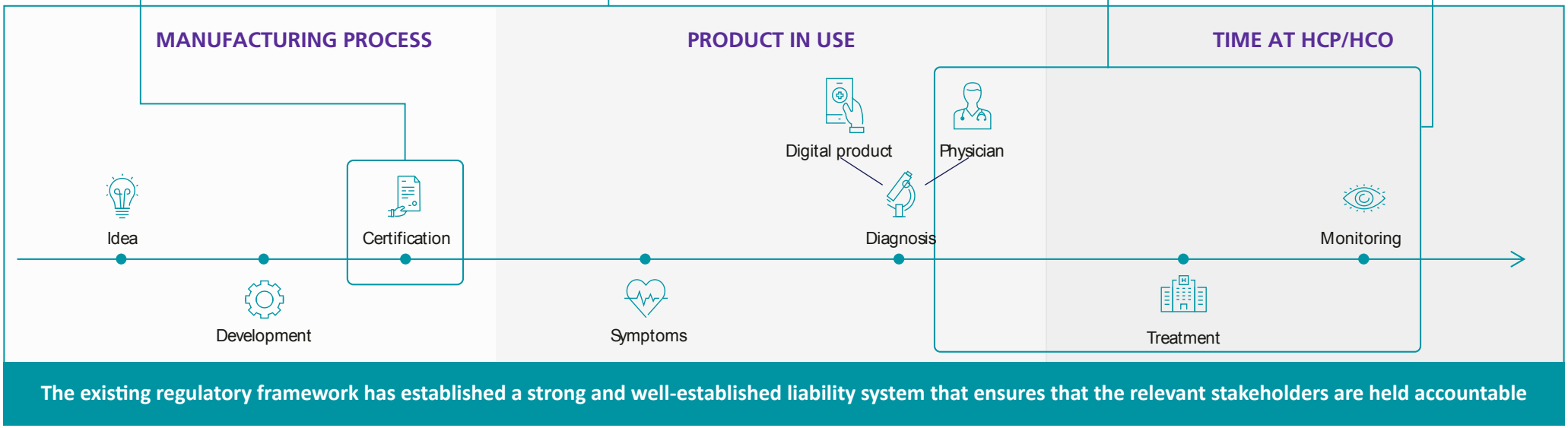
Medical malpractice would hold healthcare professionals (HCP) liable for harm deriving from failing to critically evaluate an AI recommendation. This may change as AI systems become the standard of care, because medical malpractice requires an injury caused by a HCP's deviation from the standard of care.

HCPs may also be liable for their decision to implement an improper AI system in their practice ("negligence").

Liability of healthcare organisations (e.g. hospital)

Healthcare organisations (HCO) may be liable for failing to provide appropriate training to HCPs, and/or ensure required updates, support and maintenance.

Potential liability for failing to adopt AI technologies that improve patients care.



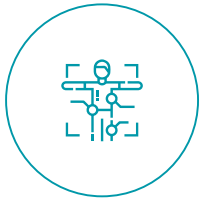
The existing regulatory framework has established a strong and well-established liability system that ensures that the relevant stakeholders are held accountable

Imaging – Radiology and medical imaging support

Potential risk for the patient

False negative or false positive findings

- 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

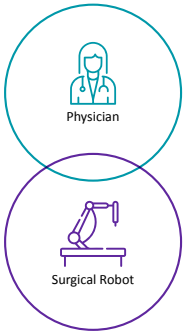
Liability of healthcare organisations

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

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

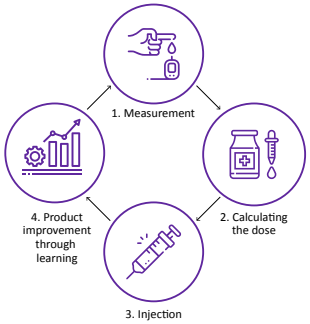
Liability of healthcare organisations

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

Autonomous AI systems – Monitoring and treatment of diabetes

Potential risk for the patient

Possible direct physical harm due to injection of an incorrect dose



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

Monitoring/ Wearables – Detection and monitoring

Potential risk for the patient

Smartwatch does not detect the patient’s myocardial, despite this being an intended function

No timely treatment

Producer liability

- Design and manufacturing defects
- Insufficient or faulty warnings or instructions (N.B.: Importance of the intended use/function of the technology)

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)