Key messages on the proposal for a Regulation laying down harmonised rules on artificial intelligence

MedTech Europe views on the Artificial Intelligence Act

KEY MESSAGES

MedTech Europe
from diagnosis to cure

Executive Summary

MedTech Europe, representing the voice of the medical technology industry, welcomes the opportunity to share its key messages on the European Commission's proposed Artificial Intelligence Act (AI Act). While respecting existing laws on fundamental rights and Union values, the AI Act aims to ensure legal certainty to facilitate investment and innovation in AI, enhancing governance and safety requirements applicable to AI systems for trustworthy AI applications and preventing market fragmentation. Safe, high-quality and trustworthy AI in medical technologies can improve healthcare and patient outcomes. The medical technology industry welcomes AI regulation which supports accessibility of AI in medical technologies, and which provides a clear and innovation-friendly legal framework.

AI-enabled medical technologies (AIeMT) have been accessing the EU market safely for years, accelerated by the introduction of the Medical Devices Regulation and the *In Vitro* Diagnostic Medical Devices Regulation (MDR/IVDR). According to the AI Act proposal, medical or *in vitro* diagnostic medical devices that are themselves an AI system or which use an AI system as a safety component, would be subject to both the MDR/IVDR and the AI Act. To this end, the AI Act will determine how and if new AI-enabled medical technologies will be placed on the market and reach hospitals and patients. MedTech Europe is concerned that by bringing in another regulatory layer, the AI Act risks undermining a delicate and well-balanced regulatory environment, which guarantees high product safety standards, and stimulates innovation in the European medical technologies sector.

In order for the MDR/IVDR and the AI Act to work seamlessly together in practice, and thus enable the European medical technology industry to provide innovative solutions for patients and healthcare professionals and support the functioning of healthcare systems, the following key issues need to be addressed:

- **Safe, high-quality and trustworthy AI:** Patients' access to AI-enabled medical technologies depends on their trust in AI and their willingness to embrace it in healthcare, which must be built on tailored safety, transparency and explainability requirements for medical technologies.
- **Harmonisation and legal certainty:** Creating a level playing field for all actors involved is crucial to improve health systems throughout Europe. Therefore, ensuring legal certainty and regulatory alignment is essential to overcome fragmentation between horizontal and sectoral regulations, such as the AI Act and the MDR/IVDR.
- **Innovation**: As healthcare is one of the most fast-paced sectors in developing new practices and approaches, AI in medical technology can bring an additional layer of agility and adaptability. It is paramount that the legal framework is seen as an opportunity to drive innovation by making rules more transparent and effective to strive for better patient outcomes.

Patient Access and safety

The access and willingness of stakeholders in the healthcare ecosystem to embrace AI-enabled medical technologies (AIeMT) highly depends on trust and a well-balanced regulatory framework. **The MDR/IVDR provides a robust basis to build this trust, as they are designed to provide better patient outcomes through safe and innovative medical technologies**. The MDR/IVDR provides tailored safety, transparency and explainability requirements aligned with existing EU legislation on privacy and cybersecurity, such as the General Data Protection Regulation (GDPR) and the Directive on security of network and information systems (NIS Directive), through specific sectoral guidance, and the Product Liability Directive. However, the AI Act has created new concerns over the safety of AIeMT due to the new requirements on, for example **human oversight, which must not become undue human interference**. Medical technology manufacturers must be able to balance these new requirements against benefit-risk ratio requirements established in the MDR/IVDR which could be impacted as a result of excessive human oversight or intervention and cause malfunction to some devices.

Harmonisation and legal certainty

Misalignment and duplication of provisions between the AI Act and the MDR/IVDR and other legislation, such as GDPR needs to be avoided to prevent legal uncertainty. Under the proposal, there are concerns over:

- The **diverging classification systems between a high-risk AI system under the AI Act** and the device risk classification under the MDR/IVDR, as well as compliance with new requirements created by the AI Act.
- The **misaligned approach to governance and market surveillance** which may limit the uniform application and implementation of the AI Act and may cause fragmentation within the Single Market.

Innovation

The MDR/IVDR are designed to support the development of a trustworthy environment for AIeMT. Adding a new regulatory layer without clear and comprehensive alignment risks undermining this environment. **A sound horizontal regulation of AI can represent an opportunity to drive innovation, making rules clearer and more effective by:**

- Considering the legislative initiatives under the EU Data Strategy, such as the Data Act and the European Health Data Space Regulation (EHDS), due to the need for quality data to enable cutting-edge and robust AI innovation while reducing risks of malfunctioning and unintended bias in AI systems.
- Accounting for the changes in the existing intellectual property rights, data protection or confidentiality regimes by the Data Governance Act, Data Act and the European Health Data Space to allow AI systems to be supported by protected datasets.
- Clarifying the definition of AI under the AI Act to such an extent so as to avoid including non-AI systems within the scope. Such horizontal legislation must be clear for all stakeholders to prevent legislating in structural inconsistencies and weaknesses that might create long-lasting damage to European industrial innovation.

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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