One year of AI Act: MedTech Europe calls for coherent implementation to unlock the full potential of AI in healthcare

Brussels, 1 August 2025 – One year after the entry into force of the Artificial Intelligence (AI) Act, Europe's ambition to develop a forward-looking regulatory framework for AI is clear. Yet for the medical technology sector, the path ahead remains uncertain. As the deadline for full application of the AI Act approaches, MedTech Europe urges policymakers to ensure that the legislation is implemented in a way that complements existing sectoral legislation and enables continued innovation in healthcare.

AI is already driving life-saving advances in diagnostics, treatment, and disease management. But without clearer rules, medical technology manufacturers risk being caught between overlapping legal requirements, unclear definitions, and regulatory bottlenecks. The AI Act introduces new obligations for high-risk AI systems, including those embedded in medical technologies, which are already regulated under the Medical Devices Regulation (MDR) and *In Vitro* Diagnostic Medical Devices Regulation (IVDR). Applying two complex product frameworks in parallel – without adequate alignment – threatens to delay patient access to safe and effective technologies.

Crucially, the AI Act must not create unintended barriers to innovation and device safety. Clinical investigations and performance studies – which are required steps in the development of new medical technologies – should be explicitly exempted from AI Act obligations when conducted in line with existing medical devices legislation. Without this legal clarity, essential clinical evidence generation could be stalled, to the detriment of both innovation and patient care.

In this context, MedTech Europe calls on the European Commission to extend the date of application for AI systems covered by MDR and IVDR to 2 August 2029. This additional time would allow for essential guidance and harmonised standards to be finalised, the designation of relevant national enforcement authorities, and for the entirety of the healthcare ecosystem to prepare for implementation. In fact, a certain number of EU Member States will miss tomorrow's deadline (2 August 2025) to designate these authorities and establish the necessary sanction regimes, further reinforcing the need for an extended timeline. In parallel, we urge the Commission to confirm that existing Notified Bodies under MDR/IVDR can carry out AI conformity assessments, and to introduce AI-specific technology codes to streamline the process.

The European Union has a unique opportunity to lead in the responsible use of AI in healthcare. But to succeed, the regulatory framework must be coherent, predictable and fit for purpose, and must align effectively with existing sectoral legislation. MedTech Europe remains committed to supporting policymakers in delivering an AI framework that fosters Europe's innovation ecosystem and maintains high standards of device safety and performance.

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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 that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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