EU Policy and Regulatory updates

The regulatory landscape for computational modelling, artificial intelligence, and medical technologies continues to evolve rapidly across Europe and beyond. Over the past two months, several important developments have shaped the future of digital health and *in silico* innovation—from new guidance on the EU AI Act and progress on the revision of the Medical Device Regulations, to the adoption of international modelling guidelines and new biotechnology initiatives.

European Commission adopts FAQ on the interplay between the MDR, IVDR and the AI Act

In June 2026, the Medical Device Coordination Group (MDCG) published **MDCG 2025-6**, a new Frequently Asked Questions document clarifying the interaction between the Medical Devices Regulation (MDR), the In Vitro Diagnostic Medical Devices Regulation (IVDR), and the Artificial Intelligence Act (AI Act).

The guidance provides practical explanations on how the different regulatory frameworks complement one another, helping manufacturers understand their obligations when developing AI-enabled medical devices and in vitro diagnostic devices. It addresses topics such as scope, conformity assessment, notified body involvement, and the respective responsibilities under the different pieces of legislation.

This document represents an important step towards greater regulatory clarity as the AI Act begins to apply across the European Union.

Source: European Commission – MDCG Guidance

More Details here….

New harmonised standards published under the MDR and IVDR

The European Commission adopted new Implementing Decisions updating the list of harmonised standards supporting compliance with both the MDR and IVDR. The updated standards cover several important technical areas, including biological evaluation, electrical safety, labelling and other essential requirements. Manufacturers should review the newly harmonised standards to determine whether updates to their technical documentation or conformity assessment processes are required.

The publication of new harmonised standards continues the Commission's efforts to strengthen consistency and facilitate regulatory compliance across Europe.

Source: European Commission – Harmonised Standards

More Details here…

Stakeholder consultation on the revision of the MDR and IVDR closes

The European Commission's Call for Evidence supporting the targeted revision of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) remained a key policy development during May and June 2026. The consultation, which closed in early July, gathered feedback

from manufacturers, notified bodies, healthcare professionals, patients and other stakeholders on opportunities to simplify the regulatory framework while maintaining high standards of patient safety.
The revision aims to improve the efficiency and predictability of the regulatory system, reduce unnecessary administrative burden, and better support innovation within Europe's medical technology sector.
The Avicenna Alliance actively contributed to this consultation, advocating for a stronger recognition of *in silico* evidence and computational modelling and simulation within the European regulatory framework.

Source: European Commission – Better Regulation Portal (Call for Evidence on the revision of the MDR and IVDR) and European Commission Medical Devices webpages.

Council of the EU backs the first European Biotech Act package
On 16 June 2026, the Council of the European Union agreed its negotiating position on the European Biotech Act I, an important legislative initiative designed to strengthen Europe's biotechnology sector and accelerate the translation of scientific innovation into clinical and commercial applications.
The package includes targeted amendments to existing health legislation, notably updating the rules governing genetically modified micro-organisms (GMMs) and the processing of human organs. The objective is to simplify and modernise the regulatory framework while maintaining high standards of safety, transparency and public trust.
The proposed Directive complements the wider European Biotech Act I Regulation, which seeks to improve the competitiveness of the European biotechnology ecosystem by reducing regulatory barriers and facilitating innovation across the health sector. Once negotiations with the European Parliament begin, the legislation is expected to become a key pillar of the EU's broader life sciences and biotechnology strategy.

Source: Council of the European Union – *Council agrees mandate on measures to advance biotech innovation in the EU* (16 June 2026).

EUDAMED prepares for mandatory implementation
As the mandatory use of key EUDAMED modules became effective on **28 May 2026**, the European Commission continued to publish updates, technical documentation and guidance to support economic operators during the transition.

The mandatory modules now include:

- Actor Registration
- UDI/Device Registration
- Notified Bodies & Certificates
- Market Surveillance

Manufacturers and other economic operators are encouraged to ensure their registrations and data submissions are up to date as EUDAMED continues its gradual rollout.

Source: European Commission – EUDAMED Overview
More Details here…

EMA adopts ICH M15 Guideline on Model-Informed Drug Development
The European Medicines Agency (EMA) has adopted the ICH M15 Guideline on General Principles for Model-Informed Drug Development (MIDD) – Step 5, marking a significant milestone for the regulatory use of computational modelling and simulation in healthcare.
The guideline establishes a harmonised international framework for planning, evaluating, documenting and submitting model-informed evidence in support of regulatory decision-making. Rather than prescribing

specific modelling approaches, it provides a risk-based framework for assessing the credibility and suitability of computational models according to their intended context of use.

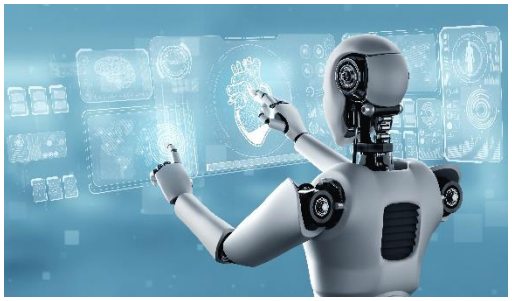
The guideline is intended to facilitate a multidisciplinary understanding of model-informed drug development (MIDD) and promote greater consistency across regulatory authorities worldwide. It applies to a broad range of modelling and simulation methods used throughout the drug development lifecycle and encourages early dialogue between developers and regulators.

Although the guideline focuses on medicinal products, it represents an important step forward for the broader *in silico* community. Its adoption reflects the growing confidence of regulators in computational evidence and reinforces the global trend towards integrating modelling and simulation into regulatory science—a development that is also highly relevant for medical devices and the Avicenna Alliance's mission. The guideline was published by EMA in February 2026 and will become legally effective in the European Union on 23 July 2026.

Source: European Medicines Agency (EMA) – *ICH M15 Guideline on General Principles for Model-Informed Drug Development (Step 5)*
More Details here…

European Commission reviews prohibited and high-risk AI practices under the AI Act

On 22 May 2026, the European Commission published its first annual report reviewing the lists of prohibited AI practices (Article 5) and high-risk AI systems (Annex III) under the EU AI Act.



While the Commission concluded that no immediate legislative changes are required, the report identifies several areas that warrant continued monitoring as AI technologies evolve. Of particular relevance to the healthcare sector are AI systems that process biometric data, infer sensitive characteristics, or perform emotion recognition and behavioural analysis. The report reiterates that AI systems used to infer emotions in workplaces or educational settings are prohibited under Article 5, except in narrowly defined circumstances, and confirms that applications involving biometric identification or categorisation remain subject to strict regulatory scrutiny.

The Commission also announced a targeted consultation on draft guidelines for classifying high-risk AI systems. The feedback received will inform future updates to the AI Act and help ensure that the regulatory framework remains fit for purpose as new healthcare AI applications emerge.

Source: European Commission – *Report on the review of prohibitions and high-risk AI* (22 May 2026).

UK progresses medical device regulatory reform with new AI and post-market surveillance proposals

Although outside the European Union, regulatory developments in the United Kingdom continue to be closely watched by the international medical device community.

During May and June 2026, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) advanced its programme to modernise the medical device regulatory framework. The consultation on the draft Medical Devices (Amendment) Regulations 2026 closed during this period, gathering stakeholder feedback on proposals that include strengthened requirements for AI-based Software as a Medical Device (SaMD), enhanced post-market surveillance obligations, revised pre-market requirements, and greater reliance on approvals from trusted international regulators.

The reforms aim to create a more agile and innovation-friendly regulatory system while maintaining high standards of patient safety. Particular attention is given to AI-enabled medical devices, reflecting the increasing role of machine learning and adaptive algorithms in healthcare.
The MHRA also published the findings of its broader Call for Evidence on the Regulation of AI in Healthcare, which will inform future regulatory policy for AI technologies used in clinical practice.

Sources:

- MHRA – *Regulation of AI in Healthcare: Call for Evidence outcome*.
- UK Government – *Pre-market Medical Devices Regulation: Stakeholder Impact Survey*.