MedTech Europe
from diagnosis to cure

AI, MedTech and Regulation: how these can be aligned?

Sailab

Benjamin Meany, Manager Digital, Software and AI Regulation

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Artificial Intelligence Act

*"The aim is to regulate the EU's **development, deployment, and use of AI** systems in a way that is safe, trustworthy, and ethical **while promoting innovation and competitiveness** in the EU's digital economy."*

Goals of the AI Act

Ensure that AI systems placed on the market are **safe and respect existing law** on fundamental rights

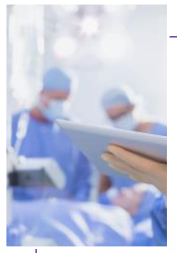
Ensure **legal certainty** to facilitate **investment and innovation** in AI;

Enhance governance of **effective enforcement of existing law on safety requirements** applicable to AI systems;

Facilitate the development of a **single market for safe and trustworthy AI** applications and **prevent market fragmentation**

AI Act: Scope of application

- AI Act is a **horizontal risk-based law**
- **Product legislation**: CE-marking mandatory
- **AI-enabled medical technologies** will be **high-risk**
- Currently regulated as **software in the MDR/IVDR**



Medical or *in vitro* diagnostic medical devices that are AI systems or use AI systems as safety components will be categorised as **high-risk AI systems** under the AI Act if they undergo third-party conformity assessment under the MDR/IVDR

The AI Act also applies to other AI systems, incorporated into **manufacturing processes** or company procedures (e.g., **HR/recruitment**)

Research-Use Only (RUO) products are exempt from the AI Act, as is **open-source software** developed with no commercial benefits

How is AI system defined?

Organisation for Economic Co-operation and Development (**OECD**)

N.B.: *Final definition far reduced in terms of scope – initial European Commission proposal risked including many general/traditional software as AI systems under the AI Act*

Article 3(1)

'AI system' means a ***machine-based system*** *designed to operate with* ***varying levels of autonomy*** *and that may* ***exhibit adaptiveness after deployment*** *and that, for explicit or implicit objectives,* ***infers, from the input it receives, how to generate outputs*** *such as* ***predictions, content, recommendations, or decisions that can influence physical or virtual environments***

MedTech Europe's reaction to the final AI Act and next steps

Challenges faced by the AI Act for the medical technology sector

Need for further alignment between **high-risk AI systems requirements under the AI Act** and related standards, and **MDR/IVDR requirements and related standards**

Support for the **single conformity assessment** and **technical documentation**
→ Notified Body designation concerns

A clear pathway for **clinical and performance evaluation** of medical technologies

Read MedTech Europe's perspective on the final AI Act

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AI Act faced numerous challenges upon release

1

No alignment between MDR/IVDR and AI Act

- ✓ *Much more alignment in the final text*
  → *Clarity is needed about how much following the MDR/IVDR means following the AI Act*

2

Duplications in regulatory assessment

- ✓ *AI Act assessment will be a part of the MDR/IVDR procedure*
- ○ *It should be clarified that a single set of technical documentation can be utilized*
- ○ *Concerns surrounding notified bodies*

3

Inconsistent definitions

- ✓ *Aligned AI definitions with the international definition (OECD)*
- ✓ *Risk definition is now in line with MDR/IVDR*
- ○ *Definition and interpretation of safety component still needs to be clarified*

4

MDR/IVDR testing process CE-marking is unclear for AI component

- ❑ *Issue is not resolved*
  → *Continue to advocate that this category follows MDR/IVDR logic*

AI Act: "Grandfather" Clause – AI-medical technologies already on the EU market

- ✓ Only AI-enabled medical technologies **marketed after the mid-2027 application date will be required to comply with the AI Act**, unless such technologies undergo "substantial modifications"
- ✓ What qualifies as a "**substantial modification**" will need to be clarified within forthcoming European Commission guidance and aligned with existing product legislation (such as MDR/IVDR) **to align with "significant change" under MDR/IVDR**

The AI Act will apply to AI-enabled medical technologies (AI-IVDs / AI-MDs) that are placed on the EU market after the date of application (mid-2027), and not to devices already on the EU market ("Grandfather" Clause")

However, in the event that an AI-enabled medical technology already on the market undergoes a "substantial modification" (significant change per the MDR/IVDR) it will need to apply the AI Act's requirements for high-risk AI systems in full (including third-party conformity assessment per the AI Act)

EU AI Act: High-level Summary and Implications

✓ **Single regulatory assessment**: MDR/IVDR + AI requirements → 1 CE Marking

✓ **Requirements partly overlap** but are **not identical to MDR/IVDR** and **additional AI obligations** apply

→ *How much does complying with the MDR/IVDR bring companies into compliance with the AI Act?*

"My device/IVD comprises AI….what do I have to know and do?"

➢ **Ensure compliance with AI Act requirements by 2027:** till then, MDR/IVDR compliance suffices

*(Note: Compliance with AI Act must be **completed** by 2027 – the work starts now)*

➢ **2027 onwards**: Single regulatory assessment covering both MDR/IVDR and AI Act requirements

➢ **Existing/legacy products:** AI Act requirements apply when re-certification is due

Measures in support innovation and SMEs

- Regulatory sandboxes, **run by notifying authorities and market surveillance authorities**, at national (member state) level
- Testing high-risk AI systems in **real-world conditions** and implementing acts to provide further details on the process
- **Support and exemptions for smaller businesses**
- Regulatory sandbox allows businesses to explore and **experiment with new and innovative products**, services or businesses under a regulator's supervision.
- It provides innovators **with incentives to test their innovations in a controlled environment**, allows regulators to understand the technology better, and fosters consumer choice in the long run.

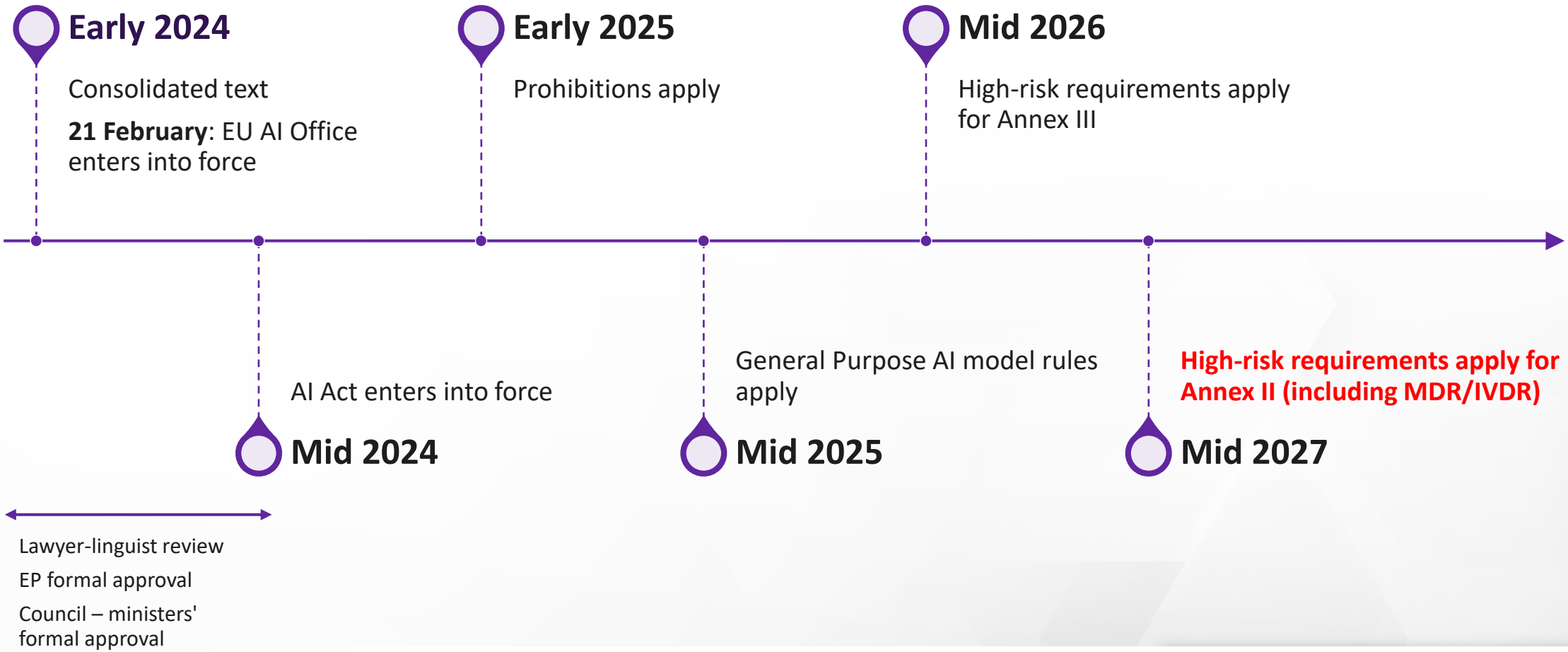
Ten AI Act requirements for high-risk AI systems (1/2)

Risk Management System	• Adoption of appropriate and targeted risk management measures to respond to identified risks
Data and Data Governance	• Use of quality training data, respect for appropriate data governance practices, assurance of accurate and unbiased data
Technical Documentation	• Inclusion of the minimal requirements of Annex VI
Traceability	• Availability of archives for the entire lifecycle of the AI system, with traceability and transparency
Human Oversight	• Incorporation of human-to-machine interface tools to minimise risks, allowing users to confidently understand, interpret and use the tools

Ten AI Act requirements for high-risk AI systems (2/2)

Accuracy, Robustness and Cybersecurity	• Assurance of constant accuracy, robustness and lifecycle cybersecurity, resilience against errors and appropriate measures to address potential bias
Quality Management System	• Establishment and documentation of a quality management system documenting regulatory conformity, the design, development, testing, risk management, post-market monitoring (surveillance) incident notification, communication, data management, registration, resource and responsibility management
EU Declaration of Conformity	• EU DoC declaring compliance with the Title III, Chapter II requirements of the AI Act, updated for 10-years,
CE Marking	• Clearly visible showing compliance with the relevant EU laws applicable to the device
Registration	• Before Placing on the Market or Putting into Service, registration in the relevant database (EUDAMED for MDs/IVDs)

AI Act provisional implementation timeline



Next steps to support industry preparation

Supporting industry preparation

MedTech Europe initial assessment of the AI Act	• To support members in **understanding the new AI Act**, and to get members up to speed
AI Act Task Force	• To **gather the relevant expertise, both regulatory and legal** • Assist members in **understanding and preparing to comply** with the AI Act
Regulatory compliance guide to support member compliance	• A key deliverable of the AI Act Task Force • Specific chapters *per* relevant subject as necessary (e.g., clinical evidence, post-market surveillance, etc.)
MDCG discussions and subsequent guidance	• The **MDCG New Technologies WG** will work on mapping the regulatory interplay between the AI Act and the MDR/IVDR as a **high priority** item

Questions & Answers

Thank you!

Benjamin Meany

b.meany@medtecheurope.org

+32 492 46 18 10

www.medtecheurope.org

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