IMDRF International Medical Device Regulators Forum

Medicines & Healthcare products Regulatory Agency

United Kingdom Country Update

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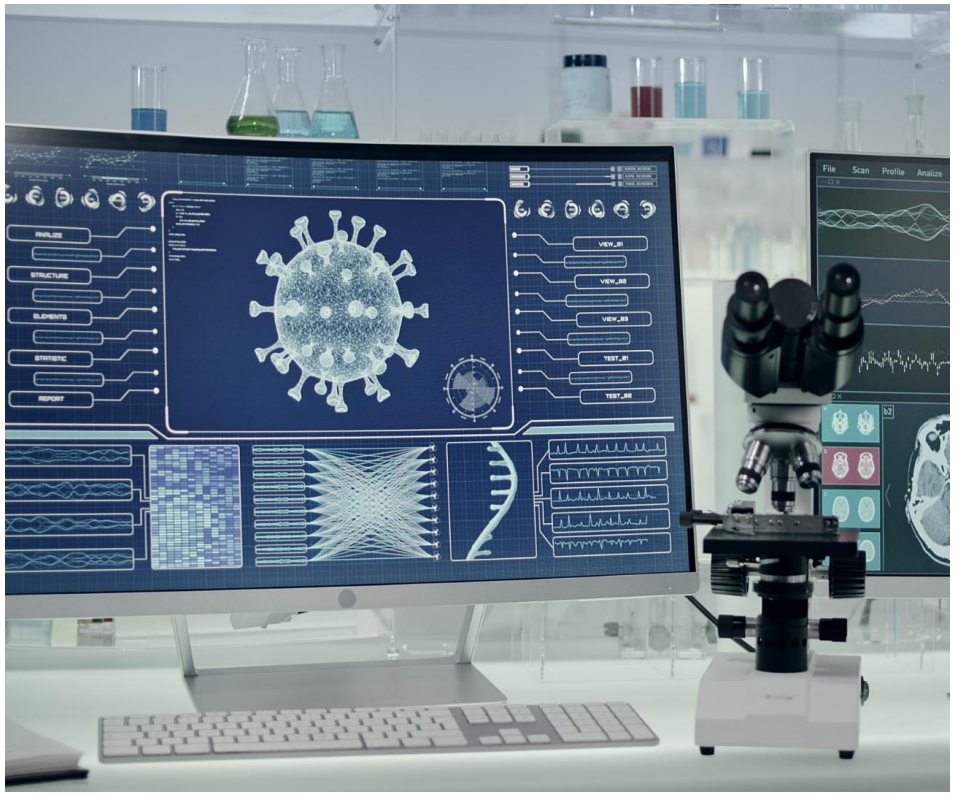
Overview

Safe, rapid access and a hub for innovation

- Policy context
- Medical Devices Regulatory Reform Roadmap
- Post-Market Surveillance legislation
- Pre-market Regulations legislation
- Driving innovation

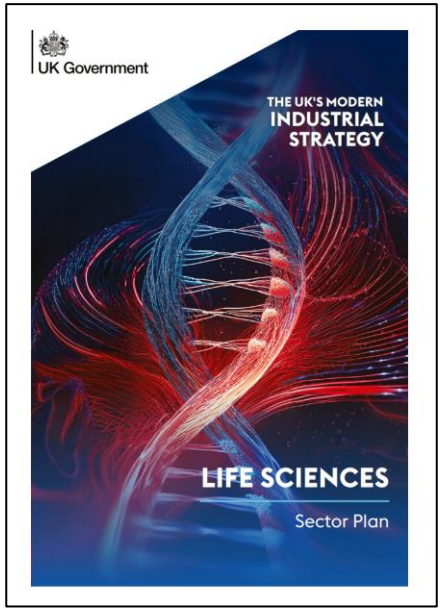


15 September 2025

A clear direction for the future

A regulatory framework for:

- Safe and rapid access to devices through:
  - Risk proportionate and predictable routes to market
  - New international reliance routes
  - UKCA focused on innovation e.g. AIaMD
  - Aligns with international standards to facilitate collaboration



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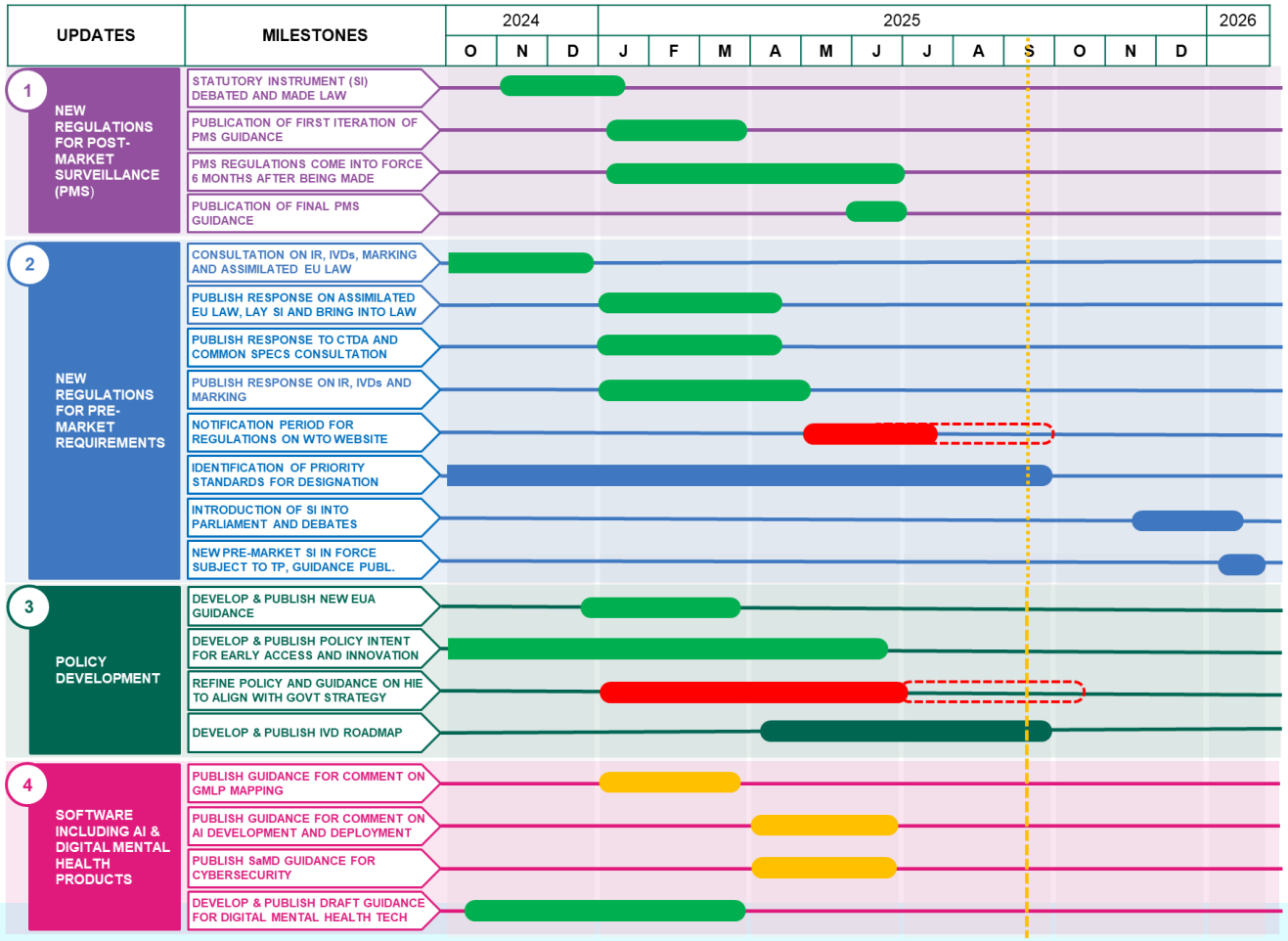
Medical Devices Regulatory Reform Roadmap



Delivered:

- PMS Regulations
- **Consultation on future routes to market**
- New Exceptional Use Authorisation guidance
- **Statement of policy intent for early access**

Pending:

- **Notification of Pre-market to WTO website**
- Priority designated standards
- Refined policy and guidance on HIE
- **Consultation on indefinite recognition**

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Post-market Regulations

STATUTORY INSTRUMENTS

2024 No. 1368

MEDICAL DEVICES

The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024

Made *16th December 2024*

Coming into force in accordance with regulation 1(2)

- Robust PMS requirements reflective of device risk classification
- Increased scrutiny and regulatory oversight
- Enhanced reporting obligations for manufacturers supporting early detection of safety issues
- Better harmonisation across industry and internationally
- Improved coordination and collaboration with other regulators
- In force since 16 June 2025
- Month on month increase in adverse incident reporting

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Pre-market Regulations

Our objectives are **patient safety, access to medical devices, supporting innovation and growth**

Risk based classification for medical device and IVDs

Enhanced requirements for implantables supporting safe innovation

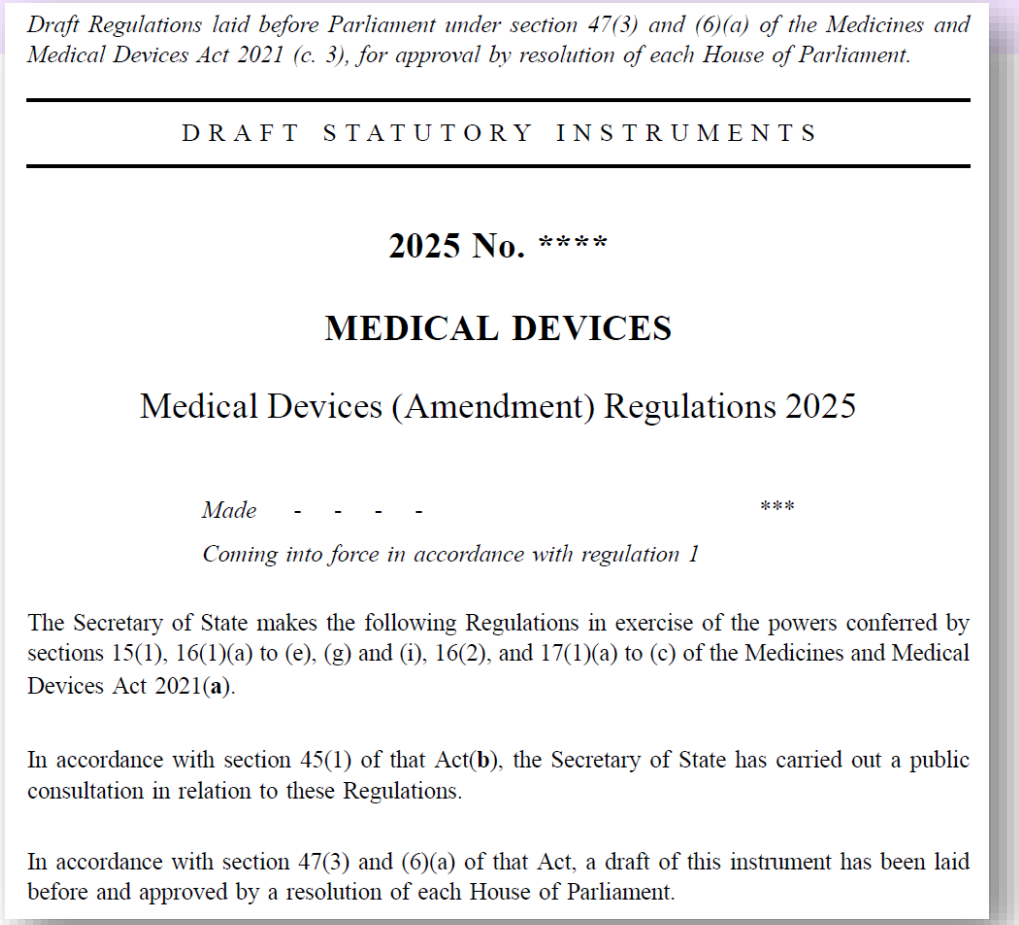
Pre-determined change control plans for software as a medical device

Improved traceability through mandated use of UDI

New routes to market including international reliance pathways

Pre-market Regulations progress

- Finalising drafting with government legal
- Routes to Market consultation now completed
- Short delay in notification to World Trade Organisation to around Oct 2025
- Plan to lay in Parliament end of 2025
- Debates in Q1 2026 – depending on parliamentary timetables
- Coming into force starting in 2026



Draft Regulations laid before Parliament under section 47(3) and (6)(a) of the Medicines and Medical Devices Act 2021 (c. 3), for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2025 No. **

MEDICAL DEVICES

Medical Devices (Amendment) Regulations 2025

Made - - - - ***

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 15(1), 16(1)(a) to (e), (g) and (i), 16(2), and 17(1)(a) to (c) of the Medicines and Medical Devices Act 2021(**a**).

In accordance with section 45(1) of that Act(**b**), the Secretary of State has carried out a public consultation in relation to these Regulations.

In accordance with section 47(3) and (6)(a) of that Act, a draft of this instrument has been laid before and approved by a resolution of each House of Parliament.

Supporting innovation

- **AI Airlock**
- UK CERSIs
- IDAP and innovation pathways
- **Early access to devices**
- Scientific and Regulatory Advice

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AI Airlock

A safe space to test medical device regulatory pathways with innovative AI products, to gain further understanding of targeted challenges and identify and influence regulatory consequences.

Airlock Objectives

Unlock

1.share pilot insights and learnings publicly, across the MHRA and **influence** the **Software Change Programme** Roadmap

2.to **transition future Airlock phases** into business operations including building team capacity and capability and a secured funding baseline

Expand

3. **Phase 2.0** – to work with a **new cohort** of applicants to investigate **further regulatory challenges** and recommendations for change

4. Partner Sandboxes to **increase scope and expertise** of the regulatory sandbox programme

Key partners

- DHSC
- NHS AI Team
- Team AB

Department of Health & Social Care

TEAM AB

Key outputs

- Influencing the Software Change Programme with outputs from the pilot.
- Pilot 2.0 - Evidence of further challenges in regulating AIaMD and Airlock recommendations for change
- Secured funding baseline and programme team

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Early Access to Devices

The statement of policy intent outlining initial plans to launch an Early Access service for innovative medical technologies.

Building on UCNA and IDAP pilot

The service builds on the UCNA tool piloted in IDAP and incorporating partners' feedback.

Expanding Access for Innovators

The service will support more innovators to meet demands in the NHS or to develop innovations incubated within the NHS.

Risk-Proportionate Regulation

The service emphasises risk-proportionate regulation and oversight as well as ongoing support to ensure patients receive safe medical devices.

Standard

Statement of Policy Intent: Early Access to Innovative Medical Devices

The MHRA's initial plans on an Early Access service, which will be developed further throughout 2025.

From: Medicines and Healthcare products Regulatory Agency

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Thank you!

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