IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

UK Country Update


London


Edinburgh


Glasgow


Leeds


Belfast


Cardiff

Dr Rob Reid

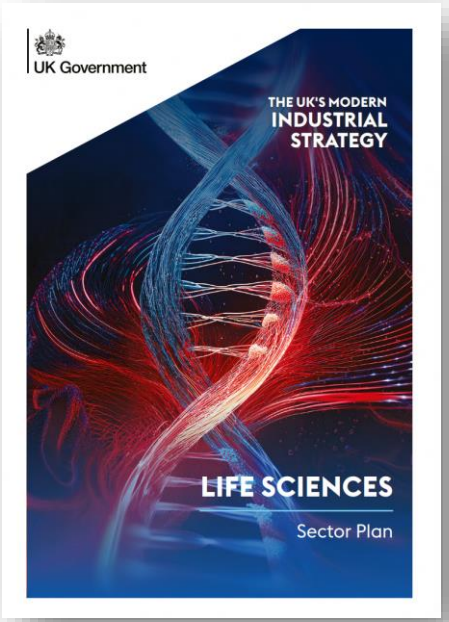
Deputy Director, Innovative Devices

MHRA

A clear strategic direction

Safe and rapid access to devices through:

- A modernized framework with risk proportionate and predictable routes to market
- International harmonization to support expanded reliance and recognition pathways
- A focus on driving innovation

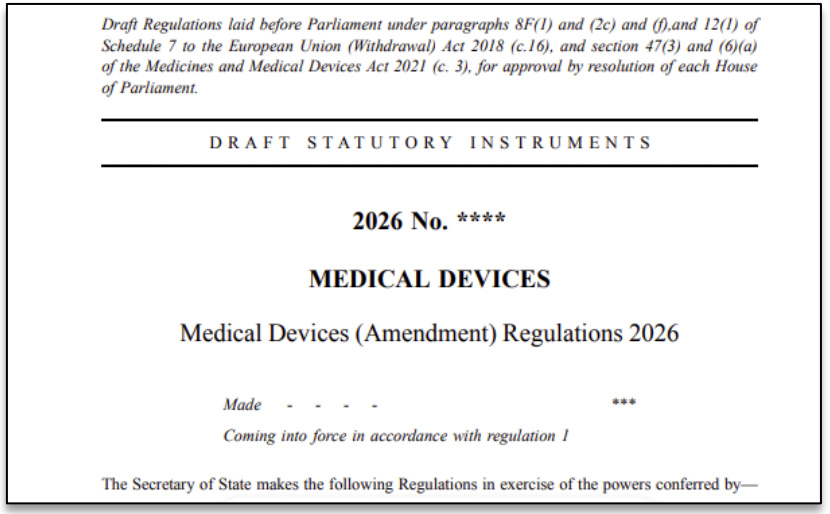


A modernized framework

A modernized framework with risk proportionate and predictable routes to market:

- Patient safety measures e.g. UDI, implant cards
- Modernized to reflect technology developments
- Internationally harmonized best practice
- Introduces international reliance pathways

- Notified to WTO May – July 2026
- Finalized legal text – Autumn 2026
- Parliamentary procedure – Winter 2026
- **SI in force (subject to transition periods) – Summer 2027**



Draft Regulations laid before Parliament under paragraphs 8F(1) and (2c) and (f),and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018 (c.16), and 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

2026 No. ****

MEDICAL DEVICES

Medical Devices (Amendment) Regulations 2026

Made - - - - ***

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by—

Future enhancements

Regulations must continue to evolve to reflect international best practice and technological developments

- Planning for **November 2026 consultation**:
  - Performance evaluation and clinical investigations
  - Streamlined Approved Body requirements
  - Medical device supply disruption / interruption
- Planning for **May 2027 consultation**:
  - Health institution exemption
- Planning for **later in 2027 consultation**:
  - Devices without an intended medical purpose
  - Sustainability and digital enablement

Harmonization, Reliance and Recognition

Harmonization

- IMDRF guidance implemented through pre-market SI and national guidance
- Bilateral partnerships towards enhanced alignment

Reliance

- Three risk-proportionate routes
- Three regulatory jurisdictions: Australia, Canada and US
- Laying in parliament in 2026
- Work to expand reliance beginning winter 2026

Recognition

- CE indefinite recognition consultation response imminent

Routes to GB market

UKCA

UK conformity assessment - UK MDR

EU recognition

30 June 2028

CE EU MDD, AIMDD

Long term approach subject to consultation

EU Recognition

30 June 2030

CE EU IVDD, IVDR, MDR

Subject to parliamentary process

International reliance – Australia, Canada, US

Driving innovation – Early Access Service

Provides

+ Conditional market access for innovative devices that address clearly defined unmet clinical needs from the NHS or that have the potential to significantly improve patient outcomes.

+ A bridging scheme to maintain patient access to devices where the clinical investigation has ended and the manufacturer is still awaiting regulatory approval.

Published Policy

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

Published 31 July 2025

Year 1 (2026)

- Establish team
- Initiate governance
- Finalise policy
- Set up systems
- **Identify first cohort of devices**

Year 2 (2027)

- Onboard first cohort
- Provide regulatory advice
- Assess applications
- **First conditional market access approvals**
- Identify second cohort

Driving innovation – Sandboxes

GOV·UK

Blog

MedRegs

Organisations: Medicines and Healthcare products Regulatory Agency

Advancing AI Regulation in Healthcare: Insights from AI Airlock Phase 2

Hannah Bowden, 9 June 2026 - AI Airlock

The rapid evolution of artificial intelligence (AI) is transforming healthcare, offering new opportunities to improve patient outcomes, enhance clinical decision-making, and increase system efficiency. At the same time, it presents complex regulatory challenges that existing frameworks were not specifically designed to address.

Press release

Pioneering AI health innovations regulatory sandbox launched

The London sandbox is a secure environment designed to safely test AI-enabled devices in a real-world environment so patients can benefit more quickly.

From: Medicines and Healthcare products Regulatory Agency
Published 10 June 2026

Press release

MHRA and Manchester NHS partner on health innovation sandbox

New partnership to create health innovation sandbox that will test promising new technologies and build evidence to accelerate the safe adoption of technologies, including AI, in the NHS.

From: Medicines and Healthcare products Regulatory Agency
Published: 2 September 2026

The AI Commission was established to help the UK health system harness the benefits of AI

Launched in September 2026, the National AI Commission provides independent, expert advice to inform the UK's approach to regulating AI in healthcare

The Commission aims to ensure that patients and the public benefit from safe and effective AI technologies, support the Government's ambition to make the NHS the world's most AI-enabled healthcare system, and foster a globally competitive regulatory environment.

Driving innovation – UK CERSIs

Centres of Excellence for Regulatory Science and Innovation CERSIs

Seven CERSIs ▪ established in 2025 ▪ one-year pilot ▪ different regulatory challenges ▪ a space for regulators, academia, industry and innovation partners to work collaboratively

Pharmacogenomics ▪ in vitro diagnostics ▪ in silico models ▪ AI as a medical device ▪ frameworks for AI in healthcare ▪ advanced therapy medicinal products ▪ AI and predictive models in CMC

CERSI-AI
Smarter Regulation for Better Innovation in AI & Digital Health

RADIANT

UK CERSI

CERSI-PGx

CERSI-AT
Centre of Excellence in Regulatory Science and Innovation for Advanced Therapies

CMAC

CLEARED Consortium

Thank You!

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