HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

29th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 10 March 2026

UK Country Update


London


Edinburgh


Glasgow


Leeds


Belfast


Cardiff

Dr Rob Reid

Deputy Director, Innovative Devices

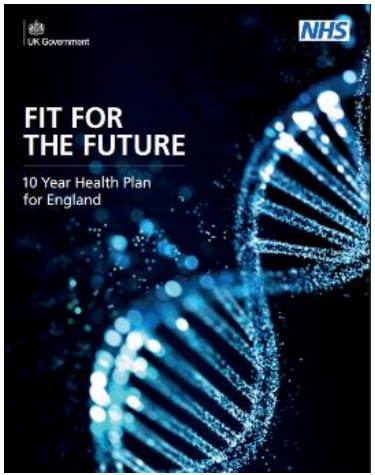
MHRA

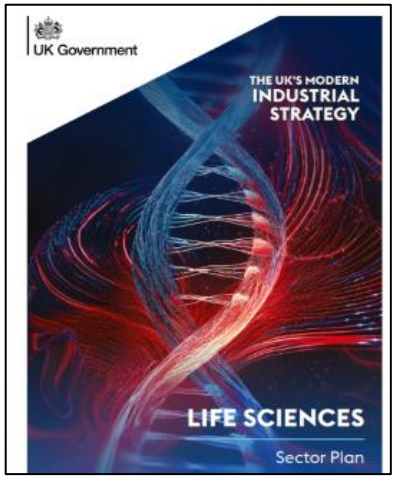
Innovation at scale for patients, the NHS and the economy

"The NHS is the best placed system in the world to harness the advances we are seeing in Artificial Intelligence and genomic science."

By 2030 "the UK will be one of the top 3 fastest places in Europe for patient access to medicines and MedTech."

Regulation at the pace of innovation





2025: A year of progress for innovative MedTech regulation

GOV.UK

Home > Health and social care > Medicines, medical devices > Medical devices regulation and safety

Guidance

Medical devices: post-market surveillance requirements

How to interpret post-market surveillance (PMS) requirements for medical devices in Great Britain.

June ‘25

UK Updates: International Reliance, IVDs, UDI, and Possible Indefinite Recognition of CE Marking

July ‘25

MHRA's AI Airlock Pilot Paves the Way for Rapid Integration of AI in Healthcare

October ‘25

Chief Officer – Digital and Technologies, Medicines and Healthcare products Regulatory Agency

United Kingdom

February ‘26

Standard

Statement of Policy Intent: Early Access to Innovative Medical Devices

Published 31 July 2025

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Introduction

The UK medical devices market is a dynamic and innovation-driven sector. To ensure that innovative technologies reach patients quickly and safely, the MHRA is taking key actions aligned with the Government's 10-year Health Plan for England and the Life Sciences Sector Plan. These strategies aim to drive health innovation, enable research and development, create an outstanding ecosystem for investment, and highlight the key importance of the MedTech sector in this.

September ‘25

National Commission into the Regulation of AI in Healthcare

The National Commission into the Regulation of AI in Healthcare is an expert, non-statutory advisory body established by the MHRA to review current regulations and provide recommendations for a new regulatory framework for AI in healthcare.

Open consultation

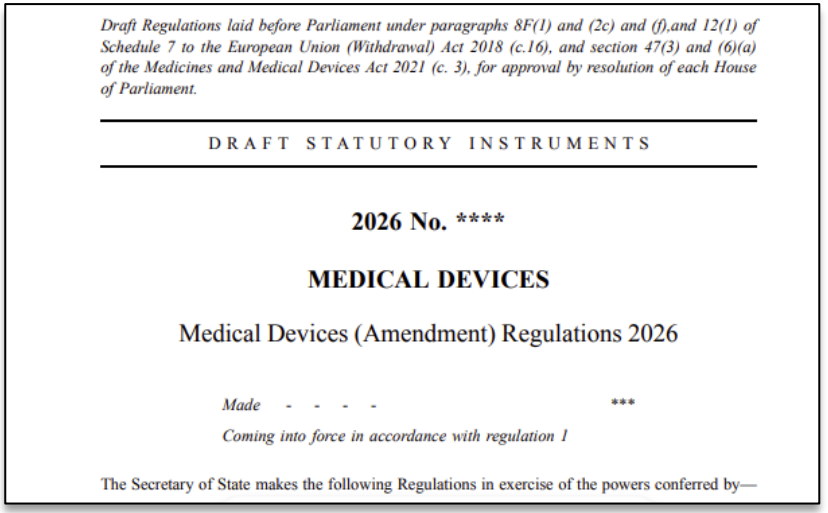
Medical devices regulations: targeted consultation on the indefinite recognition of CE marked devices

From: Medicines and Healthcare products Regulatory Agency

Published 16 February 2026

Pre-market regulatory updates

- Finalising drafting with government legal
- Intending to lay in Parliament Q3 2026
- Debates potentially Q4 2026 – depending on parliamentary timetables
- Expected to come into force in 2027
- Questionnaire live for 90 days alongside WTO



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—

Routes to market

UK CA

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 processes

International reliance – Australia, Canada, US

Live consultation: Indefinite recognition of CE

- Medical devices must be CE marked to be placed on the EU market
- Certain regulations in MDR 2002 (including the essential requirements) can be treated as being satisfied if a device has a CE mark
- CE marked medical devices are therefore recognised in GB until June 2028 or June 2030
- Approximately 90% of medical devices currently registered for the GB market are CE marked

Closes: 10 April 2026

Written responses can be posted to:

Medical Devices Consultation
MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU

Early Access Pathway

- Accelerate safe access to innovative technologies
- Support research and development and strengthening investment in the MedTech sector

The Early Access Service will provide:

- Conditional access for innovative devices addressing unmet clinical needs
- Maintain patient access to devices where clinical investigation has ended and the manufacturer is awaiting approval

Next steps:

- Working groups with relevant stakeholders to develop policy and design the pathway
- Invest in internal capability, systems and processes

National Commission for the regulation of AI in Healthcare

- Brings together global AI leaders, clinicians and regulators to advise the MHRA on the development of a new regulatory framework for AI in healthcare, **to be published in 2026**
- Chaired by Prof. Alastair Denniston and Deputy Chaired by Prof. Henrietta Hughes, the National Commission is also supported by four working groups with specialist expertise
- Informed by a Research and Engagement programme to ensure patients, clinicians, and industry can contribute in-depth insight through workshops and deliberative forums
- Responses to a Call for Evidence now being analysed and will help to shape the Commission's recommendations

National Commission into the Regulation of AI in Healthcare

The National Commission into the Regulation of AI in Healthcare is an expert, non-statutory advisory body established by the MHRA to review current regulations and provide recommendations for a new regulatory framework for AI in healthcare.

Five strategic questions we aim to address

How do we…

- Best **serve the patients and people** of our country?
- Play our role in **shaping growth opportunities?**
- **Balance demand with finite supply** for our services?
- Adapt to and shape the **changing regulatory paradigm?**
- Support **UK prosperity?**

Thank You!

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