



MHRA Strategy to 2030: What it means for MedTech

Medical technologies (MedTech) will play a central role in transforming healthcare across the UK, enabling earlier diagnosis, more personalised treatment, digital healthcare and improved patient outcomes. Our Strategy to 2030 sets out how we will strengthen patient safety while creating a more agile, innovation-friendly environment for MedTech developers, investors and health systems. It reflects our commitment to supporting public health, patient access and the UK's life sciences ambitions.

We will work closely with industry, the NHS, government, patients and international partners to ensure innovative technologies can be developed, assessed, adopted and monitored safely and efficiently across the UK.

Supporting innovation, access and safety across the MedTech lifecycle

Our priority

What it means for MedTech

Modernised MedTech regulation

We will continue our programme of regulatory reform, including reforms to pre-market legislation. Subject to parliamentary approval, new powers for regulatory assessments will provide flexibility and capacity in the regulatory system. These changes will provide clearer, efficient routes to market while maintaining high standards of patient safety.

Increased international reliance and recognition

As part of this reform, we will expand international reliance and recognition with trusted international regulators. Building on the wider US-UK pharmaceutical partnership, we will work with the US FDA to explore mutual recognition for medical devices. Following our 2026 consultation, we are also considering indefinite recognition in Great Britain of devices compliant with the EU Medical Device Regulation and In Vitro Diagnostic Medical Devices Regulation. Greater international alignment will reduce unnecessary burden, support UK competitiveness and help innovative technologies reach patients faster.

Faster access for innovative technologies

We will strengthen support for novel technologies, including AI-enabled devices, advanced diagnostics, robotics and innovative implantable technologies. Enhanced scientific and regulatory advice, regulatory sandboxes, the Innovation Accelerator and the Early Access Service for Devices will help companies bring promising technologies to patients more quickly.

A leading framework for AI in healthcare

By 2030, we aim to deliver a globally leading approach to regulating AI as a medical device. This includes continuous monitoring of real-world performance, staged authorisation, expanded Predetermined Change Control Plans, exploration of foundation model Master Files and a whole-system approach to safe deployment. We will establish an MHRA Centre for AI and Digital Health to strengthen expertise and support developers.

World-class safety and surveillance and simpler reporting

We will strengthen device monitoring and excellence in compliance through improved use of health data, AI-enabled analytics and targeted market surveillance. Upgraded registration and reporting systems will improve transparency and enable faster identification of safety issues. Subject to Parliamentary approval, unique device identifiers (UDIs) or an equivalent system will be required for most medical devices, providing greater traceability. Improvements to accessibility of the Yellow Card scheme will help patients and healthcare professionals report concerns and enable earlier identification of emerging risks.

Global collaboration and growth

We will play a leading role in international MedTech regulation through forums including the International Medical Device Regulators Forum (IMDRF) which we will chair in 2029, the Health AI Global Regulatory Network and by joining the Medical Device Single Audit Program (MDSAP).

