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Regulator Publishes Roadmap for Medical Devices Regulations

UK – February 2024

On 9 January 2024, the Medicines & Healthcare products Regulatory Agency (MHRA) published a document outlining its intended timelines for the new regulatory framework for medical devices in the UK (MHRA Update). The planned regulations, elements of which aim to enhance post-market surveillance from as early as 2024, will "prioritise patient safety, give patients access to the medical devices they need and ensure the UK remains an attractive market for medical technology innovators".

Why a New Regulatory Framework for Medical Devices?

New medical device regulations have been "on the horizon" in the UK for several years. The EU Medical Device Regulation (2017/745) (EU MDR) was due to come into force in the UK prior to the end of the Brexit transition period. As such, it would have carried over into domestic law under the grandfathering provisions that applied at the end of that period. However, the coming into force of EU MDR was postponed due to the COVID-19 pandemic. Because it ultimately came into force in May 2021 after the end of the Brexit transition period, EU MDR does not apply in the UK. It has been expected that new UK regulations would be introduced, broadly mirroring the EU MDR provisions, since that time.

The MHRA, the body responsible for regulating the UK medical devices market, has stressed that transformative technological and software advancements require innovative and tailored regulation, and intends these measures to deliver this.

Key Dates

Legislation has already been put in place, through amendments to the UK Medical Device Regulations 2002, extending the period during which CE-marked medical devices are permitted to be placed on the market in Great Britain. The relevant date is 30 June 2028 for general devices currently meeting the requirements of the EU Medical Devices Directive (93/42/EEC), or 30 June 2030 for in-vitro medical devices (IVD) meeting the requirements of the IVD Directive (98/79/EC), or in either case, if sooner, until the expiry of the relevant certificate. Devices (general or in-vitro) that comply with the new EU MDR can also continue to be placed on the GB market under a CE mark, until 30 June 2030.

The new UK regulations will be delivered through four statutory instruments.

The MHRA Update now confirms an expected timeline for post-market surveillance (PMS) requirements and core future obligations:

Early 2024	Stakeholder discussions on the future core regulations to give early sight of the detailed policy, developed from the policy positions in the response to the consultation on the future regulation of medical devices in the UK.
Late 2024	Introduction of PMS regulations intended to strengthen manufacturers' ability to act on issues they identify; publishing guidance on software as a medical device (SaMD); and continuing stakeholder discussions in respect of future core regulations.

Late 2024/ 2025	Intentions for the future core regulations include: • Bringing the essential requirements for medical devices placed on the GB market into greater alignment with the EU's, with particular emphasis on cyber security requirements for software as a service (including artificial intelligence). • Up-classifying and introducing improvements for implantable medical devices meaning "more stringent pre- and post-market requirements" and manufacturers being required to provide implant cards enabling patients to identify the device they have had implanted. • Requiring devices to have a unique device identifier. • Amending the classifications of certain devices, and in particular increasing the class of certain SaMD classifications and making in-vitro medical diagnostic device classifications consistent with International Medical Device Regulators Forum classifications. • Introducing a framework to enable easier international recognition as between comparable regulators and those with Medical Device Single Audit Program certificates. • Creating new requirements for exempt in-house manufactured devices, custom-made devices, for claims made by manufacturers, and for clinical investigations. • Clarifying requirements for conformity assessment bodies and different economic operators.

The roadmap indicates that the intention is for legislation to be laid in Parliament by mid-2025 and to be in force later in that year. It remains to be seen whether the upcoming election will affect the expected timetable.

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