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# New MHRA post-market surveillance guidance published for medical devices

07 February 2025 Matthew Alderton

The MHRA has published new guidance for manufacturers of medical devices on post-market surveillance to help manufacturers understand and prepare for the **post-market surveillance (PMS) regulation**, which is due to come into force later this year on 16 June 2025.

The new legislation was introduced in 2014 to clarify and strengthen the post-market surveillance requirements for medical devices in use in Great Britain, including new surveillance, vigilance, and reporting requirements after devices are placed on the market. These changes are part of a wider regulatory reform introduce by the Government that aims to take a more risk-proportionate approach to safety and provide greater clarity for manufacturers.

The new requirements include enhanced data collection, shorter timelines for reporting serious incidents and summary reporting, and clearer obligations for risk mitigation and communication to protect patients and users. A helpful summary of the changes made by the new regulations and guidance has been provided.

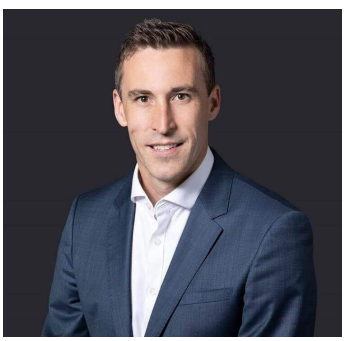
The MHRA has encouraged medical device manufacturers start using the guidance straight away so that they understand their obligations and are ready to comply with the regulations when they take effect. Manufacturers are also being encouraged to provide any feedback on the new guidance to the MHRA over the coming months.

The MHRA also published a revised roadmap for the wider regulatory reforms at the end of 2024. New guidance on digital mental health technologies, AI and IVDs are planned for the Spring.

The MHRA is also progressing plans to offer abridged approvals for certain medical devices already approved by the US FDA, Health Canada, TGA Australia and in Europe, which will be welcomed by medical device manufacturers which are eager to see a faster regulatory process for getting devices on the market in the UK.

Please contact Matthew Alderton if you have any questions about the new guidance or wider reform roadmap, or would like assistance in providing any feedback to the MHRA.

## Key contact

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