This publication was withdrawn on 18 July 2024

The Medicines and Medical Devices Act became law in February 2021.

MMD-Bill@dhsc.gov.uk

Medicines and Medical Devices Bill: Medical Devices Information Sharing and Device Register

Top Lines

- The UK's Medical Devices Regulator (MHRA) regularly shares information about the safety of devices with UK bodies and EU counterparts. This allows them to warn of potential risks to the public, and make evidence-based decisions about whether to remove products from the market.
- The Bill will introduce a power allowing the MHRA to share information on medical devices with key partners across the NHS, wider healthcare system and the public, in response to concerns around patient safety.
- The Bill also provides a power to create registers of medical devices available on the UK market. This will support the MHRA's critical post-market monitoring work for medical devices.

What does the Bill do?

- The Bill will support the effective use of information on medical devices to protect patient safety.
- It will allow the MHRA to share information it holds about medical devices with the NHS, academia and, where warranted by safety concerns, the public.
- It also provides a power to create a register of devices and their manufacturers to support the role of the MHRA's post-market vigilance work.

What is the system we have now?

- To effectively carry out its critical regulatory and market surveillance functions the MHRA collates lots of information about the safety and effectiveness of medical devices.
- The current law surrounding information-sharing for medical devices is ambiguous and can limit the MHRA's ability to proactively share information as needed to protect UK patient safety.
- This limits their ability to work collaboratively across the system in response to patient

Information-sharing to protect patient safety

- By enabling the MHRA to share information with key partners such as the CQC, NHS hospitals and the public in response to safety concerns, the Bill will allow MHRA to use information they hold to support their oversight of medical device safety.
- The types of information that might be shared could include medical device incident data that has been reported to the MHRA.
- For example, if a healthcare professional reports an incident with a medical device to the MHRA and wants to know if another healthcare professional or institution has experienced similar issues with that device, this power would allow the MHRA to share relevant information as warranted by concerns for patient safety.
- The Bill sets clear parameters for sharing information, in particular that the MHRA cannot disclose information if it would breach data protection legislation and commercially sensitive information can only be disclosed where it is considered necessary and proportionate.

Medical Device Register

- Currently, the MHRA only registers some categories of medical devices placed on the UK market.
- The Bill provides a power to create a more comprehensive register of medical devices in the future, collecting appropriate levels of information about the medical devices available on the UK market.
- The register would support the MHRA's critical market surveillance and oversight functions to ensure the ongoing safety of medical devices once they reach the market.