

## **This publication was withdrawn on 18 July 2024**

The [Medicines and Medical Devices Act](#) became law in February 2021.

See [Medical devices regulations: compliance and enforcement](#) for information on:

- the Medicines and Healthcare products Regulatory Agency's enforcement duties
- how to report a non-compliant medical device

## Medicines and Medical Devices Bill: Enforcement and Civil Sanctions for Medical Devices

### Top Lines

- The Medicines & Healthcare products Regulatory Agency (MHRA) is the UK regulator for medical devices.
- The Bill will consolidate the MHRA's enforcement powers, providing greater transparency and clarity for industry on their legal obligations.
- It will also significantly improve the MHRA's ability to take proportionate and effective enforcement action when the regulations are breached.

### What does the Bill do?

- The Bill consolidates and streamlines the MHRA's existing enforcement powers.
- This will provide both the MHRA and industry greater transparency on the enforcement framework, supporting compliance with regulations and protecting patient safety.
- The Bill also clarifies existing rights to appeal against enforcement actions and introduces a new regime for civil sanctions. The MHRA will issue guidance in relation to the use of these sanctions and will consult appropriate stakeholders before doing so.

### What is the system we have now?

- The MHRA has various enforcement powers to ensure the safety, quality and performance of medical devices.
- These powers are currently found across several pieces of overlapping legislation, creating uncertainty for industry over its obligations and the enforcement framework.
- Enforcement actions include the issue of notices (requiring compliance to be achieved, supply to be suspended or a warning/recall to be conducted) and, where necessary, prosecution.

### Civil Sanctions

- The Bill introduces the ability for MHRA to pursue civil sanctions as an alternative to prosecution where there has been a breach of the regulations or a failure to comply with an enforcement notice.
- This will enhance the MHRA's ability to incentivise compliance with the medical device regulations which protect patient safety and ensure the quality and effectiveness of medical devices.
- For example, civil sanctions may be a more proportionate enforcement response than criminal prosecution in instances where a breach does not cause actual harm, but had the potential to cause harm.
- The Bill also provides an appeal process for civil sanctions.

### Enforcement action by MHRA

