

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

