UK to strengthen regulation of medical devices to protect patients

PUBLISHED JUN 25, 2022
BY GOV.UK

MHRA to reform medical devices regulation to improve patient health and encourage innovation

The UK is seizing the opportunities provided by leaving the EU to bring forward new legislation that goes further to improve people's health

To signify products have met these world-leading standards, they will carry the UKCA marking

New plans to strengthen the regulation of medical devices to improve patient safety and encourage innovation have been published.

Following the UK's exit from the European Union (EU), the Medicines and Healthcare products Regulatory Agency (MHRA) has a unique opportunity to improve how medical devices and in vitro diagnostic medical devices (IVDs) are regulated in the UK.

The package of reforms will apply to medical devices such as hearing aids, x-ray machines and insulin pumps; new technologies such as smartphone apps and Artificial Intelligence (AI); as well as certain cosmetic products like dermal fillers.

The new measures include:

Strengthening the MHRA's powers to act to keep patients safe - Giving the public and patients greater assurance on both the performance and safety of the highest-risk medical devices, such as those which need to be implanted.

Increasing the scope and extent of regulation to respond to public need - Enhancing systems that are already in place to better protect users of medical devices and certain cosmetic products, and providing greater assurance of their performance and safety.

Addressing health disparities and mitigating identified inequities throughout medical devices development and use - Mitigating against inequities in medical devices, ensuring they function as intended for diverse populations. The government has launched a review into the potential equity issues in the design and use of medical devices to tackle health inequalities and will update in due course.

Making the UK a focus for innovation, and the best place to develop and introduce innovative medical devices – Ensuring the new regulatory framework encourages responsible innovation so that patients in the UK are better able to access the most advanced medical devices to meet their needs.

Setting world-leading standards and building the new UKCA mark – Transforming a new stamp of certification, replacing the CE mark, into a trusted brand that signifies global safety, health and environment protection standards have been met for medical device products. This will in turn boost the MHRA’s global reputation and growing partnerships with other regulators

Health and Social Care Secretary Sajid Javid says:

Now we have left the EU, these new changes will allow innovation to thrive and ensure UK patients are among the first to benefit from technological breakthroughs.

We are now able to introduce some of the most robust safety measures in the world for medical devices to ensure patients are protected.

Dr June Raine, Chief Executive of the MHRA, says:

As a regulator, our priority is to protect patients and the public and make it easier and quicker for patients to access the medical devices and treatments they need.

We would like to thank everyone who has shared their views as part of this consultation, including patients, industry and the healthcare sector.

We all know the importance of medical devices in our day to day lives and your input has been invaluable in helping us to shape the future regulations and ensuring continued patient safety and access.

The regulations will keep pace with new and emerging technologies, for example software and artificial intelligence (AI) which are increasingly being used in areas such as screening and diagnosis, as well as the management of chronic conditions and developing new treatments. The new measures will ensure innovations such as these are subjected to the same robust standards as medical devices, protecting patient safety while encouraging innovation to ensure UK patients are among the first to access cutting-edge healthcare.

Today’s announcement follows a consultation on the future regulation of medical devices in which the MHRA asked for views on a broad range of regulatory issues – from requirements for running clinical investigations, to how devices are assessed before being placed on the market, through to importer and distributor obligations, and post-market safety monitoring to increase transparency and the role of patients.

This is an ambitious, transformational programme of reform and the MHRA will ensure that legislative changes to the system meet the needs of industry and the healthcare sector.

There will be continued work and engagement with industry and stakeholders whilst refining legislation and implementing changes.

The MHRA will gradually phase in the new requirements with transitional arrangements, to give industry enough time to adapt to the change.

Notes to editors

Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

The MHRA is an executive agency of the Department of Health and Social Care.

The government has introduced a Bill to make changes to the Protocol to establish a dual-regulatory regime in Northern Ireland. Once the Bill becomes law, this would mean that businesses could choose between meeting UK or EU standards - removing the barriers to goods made to UK standards from being sold in Northern Ireland and cutting the processes that drive up costs and disincentives businesses.

Under the current approach to the Northern Ireland Protocol, EU rules on medical devices and IVDs continue to apply in Northern Ireland. The EU Medical Devices Regulation (2017/745) (EU MDR) therefore took effect in Northern Ireland on 26 May 2021 and the in vitro Diagnostic Medical Devices Regulation (2017/746) (EU IVDR) took effect from 26 May 2022. The EU MDR and EU IVDR do not apply in Great Britain.

For further information on the government’s review into potential bias in medical devices, visit:

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