Transforming the regulation of software and artificial intelligence as a medical device

These measures demonstrate the UK's commitment, following our exit from the European Union, to drive innovation in healthcare and improve patient outcomes.

The exciting and fast developing field of software and artificial intelligence (AI) as a medical device has an increasingly prominent role within health systems. Applications of AI to be regulated as medical devices can range from screening, to diagnosis, to treatment, and to management of chronic conditions. Regulatory measures will be updated to further protect patient safety and take account of these technological advances.

The MHRA has developed an extensive work programme to inform regulatory changes including key reforms across the software as a medical device lifecycle, from qualification to classification, to requirements that apply pre and post-market. This programme will consider challenges and opportunities posed by AI as a medical device, ensuring these devices are appropriately evidenced and address issues of human interpretability (lack of transparency of AI) and adaptivity (retraining of AI models).

These bold reforms will ensure that patients and public are protected and provide manufacturers with clear guidance to interpret requirements as well as the tools to demonstrate conformity. The changes will transform medical device regulation as it applies to software and AI, providing a regulatory system that is robust and dynamic for the future.

Minister for Innovation Lord Bethell said:

> While the UK remains a leading destination for cutting-edge healthcare, we are always searching for new and innovative ways we can improve the health and care system for NHS patients.
>
> Software and artificial intelligence in medical devices offer the potential to transform people's lives and these updated regulations will make a significant difference in the diagnosis and treatment of a variety of conditions.
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> I look forward to seeing the tangible impact these changes will have on improving patient safety and care for years to come.

MHRA Director of Devices Graeme Tunbridge said:

> Today's announcement of an exciting step change in the regulatory approach in this fast moving area underpins the MHRA's commitment to support responsible innovation that champions patient safety. Reforms will build on wider changes to medical device regulation already underway. We have also today launched our public consultation on proposed legislative changes in the Consultation on the future regulation of medical devices in the United Kingdom and we are encouraging everyone with an interest in these products and the way they are regulated to contribute their views.

> We will continue to evolve our regulations and guidance to respond to this fast-paced field and carry out further research into how best to manage the challenges posed by artificial intelligence as a medical device.

In addition to our overhaul of the regulations for AI and software as a medical device, today BEIS announced that the MHRA are recipients of a grant from the Regulatory Pioneers Fund.

The grant for £194,000 supports the MHRA's drive to become a global leader in regulating this field by carrying out further research into how adaptive AI algorithms in medical devices 'change' and how to regulate their decisions.

The MHRA is supported in bringing forward this programme of change thanks to support from NHSX, partners such as NICE, and input from academic and industry partners.