

Executive summary

We are updating our current regulatory regime for medical devices in the United Kingdom (UK). Powers in the Medicines and Medical Devices Act (2021) allow us to amend the Medical Devices Regulations 2002 which govern medical devices regulation in the UK. Amendments to create the new regime are scheduled to be in force at the beginning of July 2023 to align with the date from which we are due to stop accepting CE marked medical devices in Great Britain and will require the use of the UKCA marking.

The scope of this consultation has been informed by early engagement with a range of stakeholders and it sets a series of proposals which can help us make the UK the most attractive place to research, develop, produce, and supply safe and innovative medical devices.

Realising opportunities for safe and innovative devices – across the UK

Our purpose is clear: to protect and improve patient health by enabling the earliest access to, and high-quality supply of, safe, effective and innovative medical products through proportionate, data-driven assessment of risks and benefits. Over recent years patients and patient groups have emphasised the importance of patient safety, and the recent Independent Medicines and Medical Devices Safety Review, led by Baroness Cumberlege, reinforces that maintaining this focus is paramount.

The regulatory environment will also need to support the Government's ambition to be at the forefront of medical device innovation and adoption. In many areas, gaining and maintaining competitiveness in a global market will be best supported by alignment with internationally recognised best practice and standards.

Patient safety and innovation are not mutually exclusive, and we want to ensure that our regulations maximise both. With this bold new regulatory regime, we will propel our medical devices sector forward in several significant areas through:

- **creating new access pathways to support innovations**, which will ensure the UK remains an excellent place to launch new medical devices and avoid repeat assessments, granting early patient access to novel treatments whilst maintaining robust safety standards and capitalising further on our global reputation for R&D and the NHS;
- a unique, innovative, and ambitious framework for regulating **software and artificial intelligence as medical devices**. This leading regulatory model will address many challenges ahead of international peers, ensuring that we attract a world-class life sciences industry and innovators without compromising on safety;
- **reforming *in vitro* diagnostics (IVD) regulation** to update classification and include an extended patient risk review, recognising the central role that diagnostic devices have played in our response to the Covid-19 pandemic;
- **becoming a sustainability pioneer** through the safe re-use and re-manufacture of medical devices, offering a substantial opportunity to reduce single-use medical devices, help reach the Government's Net Zero target, support the Greener NHS Initiative, and improve supply chain resilience.

The new regulatory framework will be designed to boost patient safety and support the continued growth of the MedTech and diagnostics sector across the whole of the UK. It should be noted that the Government is seeking to find a new balance in the Northern Ireland Protocol whereby UK rules may apply as set out in its recent Command Paper “Northern Ireland protocol: the way forward.”

Timing of legislation

The Regulations will come into force on 1 July 2023 with appropriate transitional arrangements. We believe these timescales will deliver benefits at pace, whilst providing industry time to adapt to meet the requirements in future regulations.

In making changes to the regulatory framework for medical devices, the Medicines and Healthcare products Regulatory Agency (MHRA) will ensure that we use both regulations and guidance to establish a fluid and effective approach to the oversight of medical devices and technologies. In some cases, this is likely to involve greater use of guidance than under the existing regulatory framework to ensure that we can keep pace with dynamic innovation in medical technologies, whilst maintaining high standards of patient safety.