

Introduction

Our Aims

The Medicines and Healthcare products Regulatory Agency (MHRA) is inviting members of the public to provide their views on possible changes to the regulatory framework for medical devices in the United Kingdom (UK).

We want to develop a future regime for medical devices which enables:

- Improved patient and public safety;
- Greater transparency of regulatory decision making and medical device information;
- Close alignment with international best practice, and;
- More flexible, responsive and proportionate regulation of medical devices.

We welcome the views of patients, medical device researchers, developers, manufacturers and suppliers, clinicians, other healthcare professionals and the wider public to help shape our future approach to regulating medical devices in the UK.

As set out in MHRA's [Delivery Plan 2021-2023](#), we have a new focus on involving and engaging with patients, enabling patient access to new innovative medicines and devices, and speedier response to risks to patient safety and public health. We have recently concluded a [consultation](#) that invited views on our strategy for taking a more systematic approach to listening to and meaningfully involving patients and the public in our work. This current consultation will focus on how we can ensure that our new regime for medical devices prioritises patient safety.

Our Current Position

Medical devices and *in vitro* diagnostic medical devices on the UK market are regulated under the Medical Devices Regulations 2002 (as amended) (UK medical devices regulations). The UK medical devices regulations transpose three European Union (EU) medical devices Directives (the Medical Devices Directive (93/42/EEC), Active Implantable Medical Devices Directive (90/385/EEC) and *in vitro* Diagnostic Medical Devices Directive (98/79/EC)) into national law. The MHRA recognises that this regime is now out of step with other major international regulatory frameworks and is committed to improving the standards and scrutiny of medical devices that reach patients and members of the public.

The Medicines and Medical Devices Act 2021 (chapter 3) introduces powers to amend the UK medical devices regulations – bringing an opportunity to develop a more robust regime that prioritises patient safety. We plan to introduce this new regime at the beginning of July 2023. This will 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 (1 July 2023).

Under the current approach to the Northern Ireland Protocol, Northern Ireland follows certain EU rules, with the Medical Devices Regulation (2017/745) (EU MDR) having taken effect from 26 May 2021. The EU *in vitro* Diagnostic Medical Devices Regulation (2017/746) (EU IVDR) will apply in Northern Ireland from 26 May 2022. A number of the proposals set out for consideration in this consultation could bring greater alignment with requirements in these

EU regulations and other international regimes – rather than bringing in higher regulatory burdens for those in the medical devices industry than they face elsewhere.

It should be noted that the Government is seeking to find a new balance in the Northern Ireland Protocol in order to place it on a more sustainable footing. This includes proposals to establish a dual regulatory regime, which would include medical devices, in order to ensure that consumers in Northern Ireland do not face barriers in accessing goods from Great Britain. This would enable goods made to UK rules to circulate and be placed on the market in Northern Ireland. More information on these proposals can be found in the Command Paper – [Northern Ireland Protocol: The way forward](#).

This consultation sets out proposals being considered for our future UK-wide regime to regulate medical devices. It is envisaged that, in Northern Ireland, such a regime would run in parallel with any existing or future EU rules in accordance with the Northern Ireland Protocol. This approach is consistent with the Government's preferred approach to the movement of manufactured goods into Northern Ireland set out in the above paper entitled Northern Ireland Protocol: The way forward.