Information for respondents

The purpose of this consultation is to obtain your views on how the regulatory regime for medical devices (including *in vitro* diagnostic medical devices (IVDs) in the UK should be amended.

This consultation invites views on aspects of the UK's future regulatory regime for medical devices. We ask that respondents consider how possible changes might affect the following factors when providing their answers:

- The safety and effectiveness of medical devices on the UK market
- The availability of medical devices on the UK market
- The likelihood of UK being seen as a favourable place in which to:
    - carry out research relating to medical devices,
    - develop medical devices, or
    - manufacture or supply medical devices.

We would also like respondents, where possible and as indicated in the questions, to provide information about how the proposed changes could be implemented. This includes suggested timescales and any guidance materials that would be needed for implementing the changes covered by this consultation.

Please note the focus of this consultation is on possible updates to the UK medical devices regulations – it does not encompass the MHRA's broader work to enhance how we regulate medical devices through refining our guidance. The MHRA will use the results of this consultation to inform the development of our future regulatory regime. We plan to publish secondary legislation to update the UK medical devices regulations and thus implement a new regulatory framework for devices in the UK.

How to engage with the consultation document

The potential scope of the new regulatory environment is wide ranging; this is a complicated, and at times technical, topic and by necessity many of the questions are very detailed. To help you navigate directly to the sections you would like to respond to, we have provided an overview of contents summarising the rationale for possible changes.

The document also contains a Glossary of key terms and an Appendix that sets out definitions included in the UK medical devices regulations.

There is no obligation to answer every question. For those with less time or those who have less technical knowledge but who wish to participate, we have developed a short set of overarching questions which can be completed alone or in combination with any other questions from the more technical set.

We are very grateful to stakeholders who have already engaged with us in the development of these proposals. We are committed to developing a framework that promotes public health by providing patients with safe access to critical and innovative medical technologies, and delivering on our ambitions for a thriving and world-leading medical devices sector.

This public consultation is a key part in shaping how we can deliver against those objectives and will run for a period of ten weeks, from 16 September to 11.45pm on 25 November 2021.

You can input your answers to the consultation questions via this link.

Scope

This consultation invites views on the future regulatory regime for medical devices in the UK. It should be noted that, as expanded upon above, the UK-wide scope of this consultation is consistent with the new balance for the Northern Ireland Protocol that the Government has set out in its Command Paper – Northern Ireland Protocol: The way forward.

This consultation does not include proposals on any new fees (such as fees payable by conformity assessment bodies for designation as Approved Bodies, fees for the approval of clinical evaluations or fees for registering medical devices), which will be subject to future consultation.