

# Overview of contents

## **Chapter 1: Scope of the Regulations**

The Medical Devices Regulations 2002 currently set out definitions of a 'medical device' and an '*in vitro* diagnostic medical device' (IVD). Recognising an opportunity to improve the safety of certain products that are not currently regulated as medical devices, we are seeking views on whether to change the scope of the Regulations. Aligning with the Global Harmonization Task Force's and/or its successor organisation, the [International Medical Device Regulators Forum](#) (IMDRF), internationally recognised definitions could also remove trade barriers and thus further the availability of medical devices and improve favourability of the UK market.

Possible changes focus on **improving patient safety** and on **aligning with international best practice** and include:

- Expanding the IVD definition to include software and other products (**section 1**)
- Expanding the scope of regulation to products without an intended medical purpose but with similar functioning and risk profiles (e.g. cosmetic contact lenses) (**section 2**)
- Exclusion of products that contain viable biological substances (**section 3**) and exclusion of food (**section 4**).

## **Chapter 2: Classification**

General medical devices are classified into four classes of increasing levels of risk. We are considering whether the classification rules within the UK medical devices regulations could be updated to better align with international best practice, ensure that the scrutiny a medical device receives reflects changes in technology, and better account for how medical devices are used - including the level of invasiveness and potential toxicity.

Possible changes focus on **improving patient safety** and on **aligning with international best practice** and include:

- active implantable medical devices and their accessories could be classified as Class III
- *in vitro* fertilisation (IVF) and assisted reproduction technologies (ART) could be classified as Class III
- surgical meshes could be classified as Class III
- medical devices incorporating nanomaterial could be classified between Class IIa – III depending on potential internal exposure levels
- non-invasive medical devices which come into contact with mucous membrane (not only injured skin) could be classified between Class I – IIa depending on intended use (for all, see **section 5**).

## **Chapter 3: Economic Operators**

Current regulations include requirements for medical devices, ensuring they are safe and meet their intended purpose. The MHRA welcomes views on the need for more detailed requirements - honouring international best practice and technological developments to

make medical devices safer by strengthening the accountability of manufacturers, importers, and distributors.

Possible changes focus on **improving patient safety** and on **aligning with international best practice** and include:

- Clarifying requirements for devices using nanomaterials or to be safely interoperable, adjustable or disposable (**section 6**)
- Requiring manufacturers to hold liability insurance to ensure adequate compensation of those adversely impacted by a medical device (**section 7**)
- Introducing requirements for medical devices manufactured 'in house' by a health institution (**section 8**)
- Introducing requirements for persons selling medical devices at a distance via electronic means - e.g. via websites and app stores (**section 9**)
- Regulating the claims made about medical devices to ensure that any such claims accurately reflect their safety, performance and intended purpose (**section 10**)
- Specifying more detail of what should be included within a manufacturer's Quality Management System to ensure uniformity amongst all manufacturers (**section 11**)
- Introducing further requirements for UK Responsible Persons (**section 12**)
- Setting out requirements for medical device importers and distributors to improve device traceability and ensure the safe supply of medical devices (**section 13**)
- Introducing the need for appointing a Qualified Person responsible for supporting regulatory compliance (**section 14**)
- Clarifying the circumstances in which economic operators other than the manufacturer are required to take on the obligations of a manufacturer (**section 15**).

#### **Chapter 4: Registration and UDI**

The MHRA's ambition is to be world leading and patient-driven in enhancing the transparency and safety of medical devices from development through to use and disposal. The Medicines and Medical Devices (MMD) Act 2021 has expanded powers to disclose information about medical devices for the purpose of warning the public about safety concerns. Introducing new registration and identification requirements could enable the MHRA to make use of those powers effectively and in a targeted manner - and we are seeking your views on this matter.

Possible changes focus on **improving patient safety** and on **aligning with international best practice** and include:

- Improving the traceability of medical devices within the supply chain in the event of an issue occurring with a particular model or device type (**section 17**)
- Possible changes to medical device nomenclature use by manufacturers (**section 18**)
- Introducing a system of Unique Device Identifiers (UDI) which the MHRA could use to trace devices and patients and professionals could use to report incidents (**section 19**)
- Bringing together all the information about medical devices on the market in a single database to enhance transparency and market surveillance (**section 20**)
- Expanding and publishing medical device registration information (**section 21**).

## **Chapter 5: Approved Bodies**

An Approved Body is an organisation that has been designated by the MHRA to assess whether manufacturers and their medical devices meet regulatory requirements. The MHRA designates and monitors Approved Bodies on an ongoing basis as they need to have the facilities, resources and procedures to effectively assess medical devices and manufacturers. We are seeking views on how to improve the proper functioning of this vital part of the regulatory system.

Possible changes focus on **improving patient safety** and include:

- Setting out more detailed requirements for Approved Bodies to drive improvements in their operation (**section 23**)
- Increasing transparency of subsidiaries used by Approved Bodies (**section 24**)
- Placing additional requirements for the designation and monitoring of Approved Bodies to improve transparency of MHRA and Approved Body activity (**section 25**).

## **Chapter 6: Conformity Assessment**

The MHRA is interested in having greater transparency and consistency in conformity assessments (assessments of medical devices). We also want to ensure conformity assessments consistently, robustly, and effectively assess medical devices to assure their safety, quality and performance. This is especially important as we see increasingly complex software medical devices and more complex implantable medical devices reaching our market.

Possible changes focus on **improving patient safety** and include:

- Clarifying and strengthening conformity assessment procedures or removing rarely utilised routes (**section 26**)
- Applying additional scrutiny to the conformity assessment report for certain classes or types of medical devices (**section 27**)
- Specifying the minimum content of conformity assessment certificates and requiring Approved Bodies to submit details of any certificates issued, withdrawn, or suspended into the MHRA registration system (**section 28**)
- Setting out the minimum content that should be included in an agreement for any voluntary change of Approved Body (**section 29**)
- Expanding requirements for the content of the Declaration of Conformity (**section 30**).

## **Chapter 7: Clinical Investigation / Performance Studies**

Manufacturers must systematically collect, analyse, and assess the clinical data relevant to a medical device in order to verify the safety and performance of that device. Where there is not sufficient pre-existing evidence, the manufacturer should carry out a clinical investigation (or performance study for IVDs). We are consulting on new ways to ensure that medical device manufacturers conduct effective clinical investigations and performance studies in a consistent, comprehensive, and systematic way - protecting the health and welfare of any study participants.

Possible changes focus on **improving patient safety** and include:

- Tightening requirements for claiming equivalence to another medical device as well as requiring clinical investigations or pre-market studies for products without an intended medical purpose (**section 31**)
- Requiring documented evidence of scientific validity, and analytical and clinical performance data for IVDs (**section 32**)
- New requirements for clinical evidence for an IVD, including a requirement to update the clinical evidence throughout the lifecycle of an IVD, e.g. through monitoring of scientific and practice developments (**section 32**)
- Specifying a range of requirements for clinical investigations (**section 33**)
- Introducing requirements for IVD performance studies to ensure consistency, appropriate data collection and protect any study participants from harm (**section 34**)
- Ensuring that those conducting clinical investigations or performance studies effectively obtain informed consent from study participants (**section 35**)
- Adding requirements for clinical investigations or performance studies which are performed on vulnerable participants (**section 36**)
- Introducing requirements for conducting clinical investigations or performance studies in an emergency situation (**section 37**)
- Clarifying the application procedures by the sponsor and response from the MHRA and the associated timescales for greater fairness and transparency (**section 38**)
- Specifying how an application for a clinical investigation or performance study must be assessed by the MHRA (**section 39**)
- Detailing further how clinical investigations and performance studies should be conducted to ensure the safety and welfare of participants (**section 40**)
- Requiring sponsors to notify the MHRA where a clinical investigation or performance study is to be conducted to assess a device already UKCA marked (**section 41**)
- Setting out requirements that must be met when there is a modification to a clinical investigation or performance study (**section 42**)
- Specifying the corrective measures that MHRA could take in regard to a clinical investigation or performance study (**section 43**)
- Detailing what information that the sponsor must provide at the end of a clinical investigation or performance study, or in the event of a temporary halt or early termination (**section 44**)
- Improving the recording and reporting of adverse events that occur during clinical investigations or performance studies (**section 45**)
- Putting in place exemptions, that would apply in specific circumstances, to certain requirements of the UK medical devices regulations – for example, in relation to smaller early feasibility clinical investigations, and specifying circumstances in which the health institution exemption may not apply – for example in cases where a large number of patients are involved in a pivotal clinical investigation or performance study (**section 46**)
- Introducing a Summary of Safety and Clinical Performance (SSCP) which could include device information for the use of patients and clinicians (**section 47**).

## **Chapter 8: Post-market Surveillance, Vigilance, Market Surveillance**

After a medical device is placed on the market, manufacturers must continually monitor the performance of the medical device. This is called post-market surveillance. We are seeking views on expanding and clarifying requirements to improve patient safety by enhancing the ability of both the manufacturer and the MHRA to identify issues.

Possible changes focus on **improving patient safety** and include:

- Introducing post-market surveillance plans, which outline how information is to be collected and assessed (**section 48**)
- Clarifying requirements for reporting of serious incidents and field safety corrective actions (**section 49**)
- Ensuring that manufacturers report trends of all types of incident, whether serious or otherwise, to the MHRA (**section 50**)
- Defining minimum requirements for the content of field safety notices (FSNs) to ensure that all FSNs are drawn up to the same, high standard (**section 51**).

### **Chapter 9: *In vitro* Diagnostic Medical Devices**

This chapter outlines a range of changes.

Possible changes focus on **improving patient safety** and include:

- Increasing the level of scrutiny applied to IVD devices, by amending IVD classification, to drive greater patient safety (**section 53**)
- Requiring users of genetic tests to be provided with the appropriate information on the nature, significance and implications of their test (**section 54**)
- Placing Companion Diagnostics (CDx) in regulatory scope and defining specific classification and clinical evidence requirements for them (**section 55**)
- Removing the exemption from regulations for IVDs manufactured 'in house'.
- Making clearer that providers of testing services who supply IVDs to the UK market through distance sales are subject to the same requirements of the UK Medical Device Regulations as apply to economic operators in the traditional supply chain (**section 56**)

### **Chapter 10: Software as a Medical Device**

Software as a medical device (SaMD), including AI as a medical device (AIaMD) has grown in market share and complexity. Increasingly it has applications in health and social care that could not have been envisioned when existing regulations around medical devices were developed. Our proposal is that the UK medical devices regulations be amended in order to both protect patients and support responsible innovation in digital health.

Possible changes focus on **improving patient safety** and include:

- Defining 'software' as "a set of instructions that processes input data and creates output data" (**section 58**)
- Introducing requirements for persons selling SaMD at a distance via electronic means, e.g. via websites and app stores (**section 59**)
- Adopting the risk categorisation in the IMDRF Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations (**section 60**)
- Ensuring pre-market scrutiny to assure the safety, quality and performance of SaMD (**section 61 and 62**)
- Requiring a hyperlink to the Digital Yellow Card Scheme to allow swift SaMD-related reporting of incidents and require 'predetermined change control plans' (**section 63**)
- Introducing minimum requirements relating to cybersecurity (**section 64**)
- Defining specific requirements for AIaMD (**section 65**).

## **Chapter 11: Implantable Devices**

Implantable medical devices bring with them some unique challenges – procedures to introduce them and to stop using them can be highly invasive and they are used for a longer duration than many other types of medical devices, and their removal brings additional risks or may not be possible.

Possible changes focus on **improving patient safety** and **promoting innovation** and include:

- Expanding the scope of regulation to include temporarily implanted devices
- Up-classifying certain implantable devices
- Introducing more stringent pre- and post-market requirements, including reducing the reliance on equivalence in the assessment of implantable medical devices and introducing a requirement for implant information to be provided to patients
- Introducing more controlled access to implantable medical devices
- Increasing the level of information the MHRA captures and shares about implantable medical devices.

## **Chapter 12: Other Product-Specific Changes**

This chapter outlines a range of product-specific changes. Possible changes focus on **improving patient safety** and include:

- Introducing regulatory requirements for the re-manufacturing of single-use devices to ensure the device continues to operate safely and as intended (**section 67**)
- Clarifying that a ‘kit’ should be regulated in the same way as a system or procedure pack to avoid confusion about product combinations used for *in vitro* diagnostic examination (**section 68**)
- Requiring that replacement parts do not negatively affect the safety and performance of the medical device (**section 69**).
- Introducing more detailed requirements for custom-made devices including requirements for the technical documentation and post-market surveillance (**section 70**).

## **Chapter 13: Environmental sustainability and public health impacts**

The manufacture, use, and disposal of medical devices gives rise to a range of environmental impacts. We are interested in how our future regime for medical devices could help drive more environmentally sustainable manufacture, use and disposal to ultimately improve and safeguard public health (**section 71**).

## **Chapter 14: Routes to market**

The MHRA is considering introducing routes to the UK market which can be utilised by manufacturers with a Medical Device Single Audit Programme (MDSAP) certificate, or with an approval from certain other international regulators (**section 72**). Introducing alternative routes to market could have a number of benefits - for example in enhancing the supply of devices to the UK market and in emphasising the MHRA’s support for the global harmonisation of medical device regulation. Patient safety will remain a priority, and the

MHRA has carefully considered how these routes can be introduced with appropriate levels of scrutiny.

The MHRA is also considering introducing a “pathway for innovative MedTech” for devices that meet certain criteria e.g. innovative devices, devices used to treat rare conditions, or devices being manufactured by small and medium sized enterprises (SMEs) (**section 73**). This pathway would support manufacturers’ research and data gathering activities, alleviating some of the cost and capacity obstacles faced by SMEs in getting innovative products to market. The MHRA would grant approval for use of these devices in specific circumstances e.g. for use certain groups of patients.

### **Chapter 15: Transitional Arrangements**

Finally, this chapter explores options for arrangements to enable a smooth transition to any requirements introduced in a future medical devices system (**section 74**).