

Chapter 17 Questions for members of the general public

Section 76 - Introduction

76.1 We all come across medical devices in our everyday lives – from artificial hips to plasters, glasses to pregnancy tests, and COVID-19 test kits.

76.2 The Medicines and Healthcare products Regulatory Agency (MHRA) is exploring how future rules around medical devices in the UK can better protect public health, unlock innovation, and help our life sciences sector flourish.

76.3 The MHRA is inviting the public to share views to help shape our future rules around medical devices in the UK.

76.4 While we welcome your views on all questions in this consultation, this Chapter contains a shorter set of key questions that you may wish to complete if you have limited time.

76.5 These cover rules around:

- products with no medical purpose (but similar risks to medical devices) e.g. coloured contact lenses
- how medical devices are classed (based on risk)
- medical devices that are made in health institutions such as hospitals
- importers and distributors of medical devices
- how medical devices are identified and traced
- clinical information required for medical devices
- reporting about medical devices (including problems with them)
- medical devices implanted in people (e.g. pacemakers)
- possible new ways to getting a device approved for the UK market.

76.6 This consultation looks at how we might change the law around medical devices in the UK by updating the Medical Devices Regulations 2002 (as amended) (UK medical devices regulations). It does not cover any changes to guidance.

76.7 See the Introduction section for more information about how the Government envisages a UK-wide regime could operate in relation to Northern Ireland.

Section 77 - Background Information on Medical Device Regulation

77.1 The range of medical devices is vast. It includes most healthcare products, other than medicines, used to diagnose, prevent, monitor and treat disease, injury, or disability. Examples include glasses, COVID-19 test kits and plasters.

77.2 Two main types of medical devices for this consultation are:

- a. ***in vitro* diagnostic medical devices (IVDs)** – a medical device used for testing samples from the human body (for example, blood) outside the human body – for example a COVID-19 test kit; and
- b. **general medical devices** – other types of medical devices that are usually used in or on the human body – for example, a pacemaker.

77.3 Where we have used the term ‘medical device’ or ‘device’ we are referring to both of these types of medical devices.

77.4 With few exceptions, a medical device cannot be put on the Great Britain market unless it has a UKCA or a CE marking. Under the current rules a medical device on the Northern Ireland market needs a CE marking.

77.5 A CE marking shows that the medical device meets relevant EU rules. A UKCA marking shows the medical device meets the requirements of the UK medical devices regulations and, when used as intended, works properly and is acceptably safe.

77.6 For all but the lowest risk medical devices, such as certain types of bandage, an independent certification body must check that the requirements that must be followed to apply these markings are met. For UKCA markings on medical devices this body is known as a UK Approved Body. The MHRA designates and audits Approved Bodies to ensure that they perform well.

77.7 Manufacturers must be able to support claims about how their medical device will perform. In many cases this information will come from a clinical investigation (for general medical devices) or a performance study (for IVDs). Once a medical device is on the market, the manufacturer must continue to assess the safety and performance of that medical device - this is called ‘post-market surveillance’. They should also report certain incidents involving the medical device to the MHRA - this is called ‘vigilance’.

Section 78 - Scope and classification

Products without a medical purpose

78.1 There are some products on the market where a manufacturer claims only a non-medical purpose, but which are similar to medical devices in their functioning and risk level. For example, coloured contact lenses have similar risks to prescription contact lenses. Other examples include dermal fillers, hair removal lasers and equipment for liposuction.

78.2 These products may be subject to other regulatory requirements. However, they are not currently regulated under the UK medical devices regulations despite having similar risks to medical devices, which include infection and injury. We consider that these products could be regulated under the UK medical devices regulations to ensure they meet appropriate safety and performance requirements.

78.3 For opportunities to comment in more detail see Chapter 1 of the full consultation.

Q78.1 Do you think these products should be regulated under the UK medical devices regulations? (Yes/No/No Opinion/Don't Know)

Q78.2 If you have answered 'yes' to question 78.1, which products should be regulated under the UK medical devices regulations (please select all those which apply)

- a. Non-prescription contact lenses or other items intended to be introduced into the eye
- b. Products intended to be totally introduced into the human body through surgically invasive means e.g. buttock implant
- c. Products intended to be partially introduced into the human body through surgically invasive means e.g. microneedling products
- d. Substances intended to be used for facial or other dermal or mucous membrane filling by injection, excluding those for tattooing e.g. dermal fillers
- e. Equipment intended to be used to reduce, remove or destroy fat tissue, such as equipment for liposuction
- f. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body e.g. hair or tattoo removal lasers
- g. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the skull to modify activity in the brain e.g. transcranial (non-surgically invasive) stimulation
- h. Diagnostic tests for health and wellbeing e.g. genomic testing for diet/nutrient optimisation, genomic testing for skin care, lactate testing for fitness training
- i. Other (please specify)
- j. I don't know/no opinion

Q78.3 Please provide your reasoning for your answers to questions 78.1-78.2 or any general comments on key considerations for the regulation of products without a medical purpose.

Classification

78.4 The classification system for medical devices reflects the perceived risk associated with each device.

78.5 Currently, general medical devices are classified into four classes of increasing levels of risk:

- **Class I** – lowest risk e.g. medicine spoons, spectacle frames, standard plasters
- **Class IIa** – e.g. short-term corrective contact lenses, standard hearing aids,
- **Class IIb** – e.g. apnoea monitors, ventilators and surgical lasers
- **Class III** – highest risk e.g. pacemakers and breast implants

78.6 IVD medical devices are classified into four groups in order of increasing risk:

- **General** – lowest risk e.g. blood collection tubes and urine sample containers
- **Self-test** – intended to be used by lay users in the home environment – e.g. home pregnancy tests
- **List B** – e.g. IVDs used for the detection of Chlamydia; devices for evaluating Down's Syndrome risk; and devices for home blood glucose testing
- **List A** – highest risk e.g. IVDs used for the detection of HIV infection

78.7 Manufacturers must carry out a conformity assessment to demonstrate that their medical device meets the requirements set out in the UK medical devices regulations. The type of assessment required, and whether an Approved Body needs to be involved in it, depends on the device's classification. For example, a Class I medical device without a sterile or measuring function (e.g. a plaster) does not need to be assessed by an Approved Body. A Class IIa device (e.g. a hearing aid) would be assessed, but less extensively than a higher risk Class III device (e.g. a heart valve).

78.8 Since the classification rules were established for medical devices, there has been significant technological and medical progress. We are considering whether the classification rules could be amended to keep pace with this progress. This would ensure that the assessment that a device receives better aligns with the level of risk it presents. The MHRA believes there is a need for this, particularly with implantable devices such as surgical mesh, IVDs, and software as a medical device.

78.9 Examples of how we could amend the rules to change or more clearly set out the classes that certain devices fall into include:

- Move the following devices to the highest risk category (Class III):**
 - surgical meshes
 - total or partial joint replacements
- Introduce new rules for the classification of:**
 - **software as a medical device** which align with international best practice IMDRF [guidance](#) on software classification. These classification rules consider the state of the patient's healthcare condition and how the software is being used
 - **IVDs** – the current classification rules are a list-based approach and enable a high proportion of IVDs (~80%) to be placed onto the market without the involvement of an Approved Body. This is on the assumption that they present a low risk to individual or to public health. We propose to amend the classification rules moving away from a list-based approach to rules that better consider the risk that different types of IVD present to individual and public health. For example, we could amend IVD classification in line with international best practice [guidance](#) or the approach taken by the new EU Medical Devices Regulations (2017/745). This would likely see an increase in the proportion of IVDs that are in higher risk classes, increasing the level of scrutiny applied to IVDs.

78.10 For opportunities to comment in more detail on classification, and further examples of possible changes, see Chapter 2, on software as a medical device (Chapter 10) and IVDs (Chapter 9) of the full consultation.

Q78.4 Do you think the classification rules for general medical devices and IVDs should be amended as above? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q78.5 Please provide your reasoning for your answer to question 78.4 or any general comments on the classification of medical devices (including ideas for other ways classification may need to change).

Section 79 - Economic operators, registration of medical devices and Unique Device Identification

Health Institutions

79.1 Some health institutions (bodies that provide care for patients and promote public health e.g. an NHS hospital or a dental practice) manufacture or modify medical devices for use within that health institution. Currently, these do not need to meet the requirements for medical devices under the UK medical devices regulations. These devices are manufactured 'in house'.

79.2 The UK medical device regulations could be amended to introduce requirements that 'in house' manufactured devices must meet to ensure they are safe and performing as intended.

79.3 For example, health institutions could be required to:

- meet the relevant 'essential' requirements of the UK medical devices regulations. These include requirements for areas such as device labelling and instructions
- put a suitable Quality Management System into effect. This would ensure procedures are in place for the safe manufacturing, documenting, and monitoring of medical devices
- make certain documentation about devices available to the MHRA on request. This might include a requirement to justify why patient needs cannot be met by a device that is already on the market
- register these devices with the MHRA. Information provided about the device at device registration would be publicly accessible (subject to data protection legislation).

79.4 For more information see MHRA's gov.uk [guidance page](#) and for opportunities to comment in more detail see Chapter 3, Section 8 of the full consultation.

Q79.1 Do you think that health institutions should be required to meet certain requirements for 'in house' manufactured devices, such as those laid out above? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q79.2 If you have answered 'yes' to question 79.1, please choose which requirements should be met by health institutions (select all those which apply from the list below):

- a. meet the relevant essential requirements of the UK medical devices regulations
- b. draw up a publicly available declaration that devices meet the essential requirements of the UK medical devices regulations
- c. apply a suitable organisational infrastructure (a Quality Management System)
- d. justify why the target patient group's needs cannot be met with an equivalent device available on the market
- e. keep technical information available for the MHRA, review clinical use of the devices and take necessary corrective actions e.g. stop further use of the device in patients where there is an issue
- f. report certain types of incidents relating to 'in house devices' to the MHRA
- g. register devices produced or modified 'in house' with the MHRA
- h. other (please specify)
- i. I don't know/no opinion

Q79.3 Please provide your reasoning for your answers to questions 79.1 and 79.2, or any general comments on the rules that should apply to 'in house' manufacturing of medical devices.

Importers and Distributors

79.5 The UK medical devices regulations could set out requirements for medical device importers and distributors to have a greater role in ensuring the safe supply of medical devices to the UK market.

79.6 This could include ensuring the medical devices that they import or supply, are accompanied by the correct documents, correct storage and handling of medical devices, and checking medical device labelling/certificates to ensure that the device meets the requirements of the Regulations. Importers and distributors could also be required to cooperate with the MHRA during any of its investigations of a device and to register their details with the MHRA.

79.7 For opportunities to comment in more detail see Chapter 3, Section 13 of the full consultation.

Q79.4 Do you think that medical device importers/distributors should meet additional requirements such as those outlined above? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q79.5 Please provide your reasoning for your answer to question 79.4 or any general comments on rules applying to importers/distributors of medical devices in the UK

Unique Device Identification (UDI)

79.8 If all medical devices on the UK market had to be given a Unique Device Identifier (UDI) set, this could improve the MHRA's ability to trace and identify medical devices back to the medical device manufacturer. It could also assist healthcare professionals, economic operators and the wider public in reporting incidents related to medical devices, as the medical device in question could be more easily identified and traced.

79.9 The UK medical devices regulations could also include requirements for manufacturers, importers, distributors, and health institutions to store UDI of certain medical devices that they have supplied or purchased. It may be impractical to require the persons above to store the UDI of all medical devices including low risk medical devices such as bandages. So, this requirement could be limited to certain types/classes of medical devices.

79.10 For opportunities to comment in more detail see Chapter 4 of the full consultation.

Q79.6 Do you think manufacturer should be required to assign UDI numbers to medical devices before they enter the UK market? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q79.7 What types/classes of medical devices should be included in the requirement for UDI storage (select only one)?

- a. all implantable medical devices
- b. Class III implantable medical devices
- c. Class III and Class IIb implantable medical devices
- d. I don't know/no opinion
- e. Other (please specify)

Q79.8 Please provide your reasoning for your answers to questions 79.6-79.7 or any general comments on UDI requirements for medical devices.

Section 80 - Clinical investigations and performance studies

Clinical investigations of medical devices

80.1 Manufacturers must ensure that the design and manufacture of a device does not compromise the clinical condition of patients and users before they apply a UKCA marking to their product and place the device on the market. To do this a manufacturer must systemically collect, analyse, and assess the clinical data relevant to the medical device in order to verify the safety and performance of that device - this is known as a **clinical evaluation**.

80.2 Where there is not sufficient pre-existing evidence to demonstrate that the device conforms with the relevant safety and performance requirements, the manufacturer should carry out a **clinical investigation**.

80.3 Currently, manufacturers can use the clinical data arising from investigations of a similar “equivalent” device as evidence that their own device is safe and performs as intended. This is due to the similarities between the devices. Manufacturers often claim equivalence on the basis that only part of a device is similar to another device. For example, a manufacturer may claim a device it has produced is equivalent to a device with the same function, but this device may be made from different materials. This can result in ‘product creep’ where new devices on the market in practice become very different from their ‘equivalent’ devices. The UK medical devices regulations could introduce stricter requirements for claiming equivalence to prevent this from occurring.

For example:

- the device the manufacturer is claiming equivalence to, should be “entirely equivalent” to the manufacturer’s medical device (on a biological, physical, and clinical basis).
- where a manufacturer does claim equivalence to another medical device they must have a contract with the manufacturer of that medical device to allow them full access to the device’s necessary documentation
- manufacturers claiming equivalence must have post-market studies in place to collect their own data, once the device is on the market.
- manufacturers of certain devices such as implantable and Class III devices cannot claim equivalence to other devices except in specific circumstances.

80.4 For more information on clinical investigations see [here](#) and for opportunities to comment in more detail, see Chapter 7 of this consultation.

Q80.1 Do you think the UK medical devices regulations should include stricter requirements for claiming equivalence? (‘Yes’ / ‘No’ / ‘Don’t Know/No Opinion’)

Q80.2 If yes, should it be the requirements above or other?

Q80.3 Please provide your reasoning for your answers to question 80.1 and 80.2 and/or any general comments on rules that you think should apply to claiming equivalence to another medical device as set out above.

Summary of Safety and Clinical Performance (SSCP)

80.5 There is currently no requirement for manufacturers of medical devices to make clinical data publicly available for medical devices placed onto the UK market (with certain exceptions for Northern Ireland).

80.6 The MHRA could require manufacturers of medical devices to publish data on device safety and performance. This would allow intended users of the medical device to access this information. This information could be in the form of a ‘Summary of Safety and Clinical Performance (SSCP)’ which could include easy to

understand information on the medical device's safety, clinical data, and clinical performance.

80.7 For example, it could include a summary of the clinical evaluation and information on risks and any undesirable effects, warnings and precautions. We could require manufacturers (or their UK Responsible Person or Authorised Representative, if applicable) to upload the SSCP (or a link to it) provide to the MHRA registration system. This would allow members of the public, healthcare professionals and economic operators to view it.

80.8 For opportunities to comment in more detail see Chapter 7, section 47 of the full consultation.

Q80.4 Do you think the UK medical devices regulations should introduce the requirement for an SSCP for medical devices? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q80.5 What types/classes of medical devices should require a SSCP (select all that apply)?

- a. all implantable medical devices
- b. Highest risk (Class III) medical devices
- c. Highest risk IVDs
- d. Medium risk (Class IIb) medical devices
- e. Medium risk IVDs
- f. Other (please specify)

Q80.6 Please provide your reasoning for your answers to questions 80.4-80.5 and/or any general comments on introducing a requirement for medical devices to have SSCPs.

Section 81 - Approved Bodies and Conformity Assessment

81.1 This section does not contain questions on the above topic in light of its technical nature. To share your thoughts on this topic, see Chapters 5 and 6 of the full consultation.

Section 82 - Post market surveillance, vigilance, and market surveillance

Vigilance (reporting of incidents)

82.1 Currently, under the UK medical devices regulations, manufacturers must submit reports to the MHRA when certain incidents occur in the UK involving their medical device e.g. when a medical device may have caused harm.

82.2 In these situations, the manufacturer will investigate the incident to work out what the root cause of the incident was and how this could be put right, to reduce the risk. They may undertake a Field Safety Corrective Action (FSCA) to correct the issue e.g. recalling the device from the market. A Field Safety Notice (FSN) is the means by which the manufacturer tells customers what the problem is, the risks involved and what actions the customer needs to take. This advice could range from "stop using the medical device and return it to the manufacturer" to "please read and keep these new instructions on how to use your device safely".

82.3 There is currently no requirement for manufacturers to consult with patients and the public in these investigations.

82.4 For more information about vigilance see this MHRA [guidance page](#). For opportunities to comment in more detail see Chapter 8 of the full consultation.

Q82.1 Do you think manufacturers should be required to consult with patients when investigating device incidents? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q82.2 If you have answered 'yes' to question 82.1, how do you think manufacturers should consult with patients when investigating incidents (you may want to consider: how the manufacturer would find patients with lived experiences, methods of communication, how the manufacturer would demonstrate that they have taken into account patient views).

Q82.3 Please provide your reasoning for your answers to questions 82.1-82.2 or any general comments on patient and public engagement during incident investigation.

Section 83 - Specific products and topics

Implantable medical devices

83.1 Implantable medical devices include things like pacemakers and hip replacements. These types of devices bring with them some unique challenges – procedures to introduce them can be highly invasive. They are used for a longer duration than many other types of medical device and their removal brings additional risks.

83.2 The UK medical devices regulations could require manufacturers of implantable devices to provide patient implant information with the medical device. This could be provided in digital or physical card form. Health institutions could be required to make this information available to patients being supplied with implantable devices.

83.3 Implant information could include:

- information allowing the identification of the medical device - e.g. Unique Device Identifier (UDI)
- information/warnings on any potential negative interactions - e.g. with MRI scanners or certain environmental conditions
- information about the expected length of time the device will work for and any necessary follow-up - e.g. where the patient might require repeat scans to ensure the medical device is still working as it should
- any other information to ensure safe use of the medical device by the patient.

83.4 There could be a requirement to update the digital implant information where appropriate e.g. where new findings emerge.

83.5 Certain implantable devices could be excluded from this requirement to have accompanying implant information. For example, sutures, staples, dental fillings, dental braces, tooth crowns, screws (not including dental implants) plates, wires, pins, clips and connectors could be excluded. However, manufacturers and health institutions should consider providing patient implant information for these types of medical devices where there is a demonstratable risk of dangerous interaction e.g. clips made from magnetic material which may interact in an MRI scanner.

83.6 For more opportunities to comment in more detail see Chapter 11 of the full consultation.

Q83.1 Do you think that the UK medical devices regulations should include the requirements for manufacturers and health institutions to provide patients with implant information? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q83.2 If you have answered 'yes' to question 83.1, is there any other information which should be included within the implant information? If so, please outline below.

Q83.3 Please provide your reasoning for your answers to questions 83.1-83.2 or any general comments on patient implant information.

Routes to market

83.7 The MHRA is considering introducing different tailored pathways manufacturers can follow to obtain approval for putting a medical device on the market in the UK.

83.8 Some possibilities are:

- Manufacturers that have a certificate from an international programme that checks they have adequate processes in place to assure the quality of their medical devices (a [Medical Device Single Audit Programme](#) (MDSAP) certificate) could follow a tailored pathway to placing their device on the UK market.
- Manufacturers with approval to market their devices from another jurisdiction (e.g. approval to market their device elsewhere, such as from an EU Notified Body, the FDA or Health Canada) could have a tailored pathway to placing their device on the UK market.

83.9 For more opportunities to comment in more detail see Chapter 14 of the full consultation.

Q83.4 Do you think the MHRA should introduce a tailored pathway to market approval for:

- a. manufacturers whose quality management system has been certified under the international programme Medical Device Single Audit Programme (MDSAP)
- b. medical devices that have regulatory approvals from elsewhere, or
- c. innovative devices?

(Yes/No/Don't Know/No Opinion)

Q83.5 Please provide your reasoning for your answers to question 83.4 or any general comments on possible pathways to approval to bring a device to the UK market.