

## **MHRA consultation on the future regulation of medical devices in the United Kingdom - GMC response**

*24 November 2021*

- 1** We welcome the opportunity to respond to the Medicines and Healthcare products Regulatory Agency's (MHRA) consultation on proposed changes to the regulatory framework for medical devices in the United Kingdom
- 2** Most of the questions in the consultation fall outside our regulatory remit or areas of expertise. We have therefore restricted our comments to a specific number of areas. For this reason, as well as for ease of reading, we are responding to the consultation in the form of a submission.

### **The GMC's role and remit**

- 3** The General Medical Council (GMC) is an independent regulator that helps to protect patients and improve medical education and practice across the UK.
  - We decide which doctors are qualified to work here and we oversee UK medical education and training.
  - We set the professional standards that doctors need to follow, and work to make sure that they continue to meet these standards throughout their careers.
  - We take action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.
- 4** Every patient should receive a high standard of care. Our role is to help achieve that by working closely with doctors, their employers, and patients to make sure that the trust patients have in their doctors is fully justified. We expect doctors to be familiar with and follow our ethical guidance and be willing and able to justify any departure from it.
- 5** Our professional standards, as set out in published guidance, are consistent with laws across the UK and any specific legal duties that the law requires of doctors.

## General points

- 6 We strongly support the MHRA's aims to develop a future regime for medical devices, which enables improved patient and public safety, greater transparency and more responsive regulation. Doctors have an important role to play as they are involved in developing, conducting research into and making shared decisions with patients about medical device treatments.
- 7 We appreciate that the MHRA's proposals form an important part of the healthcare system's response to the Independent Medicines and Medical Devices Safety (IMMDS) Review.
- 8 It is important to note that the areas of the consultation we have commented on overlap with professional standards we set for doctors. We have referenced our guidance for doctors so this can be considered as part of the development of updated Medical Devices Regulations and any accompanying guidance. We have also suggested opportunities to strengthen the proposals where relevant.
- 9 Beyond this consultation response, we would be pleased to work with the MHRA to help ensure that future legal requirements in relation to medical devices, and our professional standards, are consistent and provide clarity about our shared expectations of doctors.

## Specific points

### Clinical investigations and performance studies

#### Proposed conditions that must be met for performing a clinical investigation and performance study

*Q33.14. Do you think the UK medical devices regulations should set out the requirements that must be met for performing a clinical investigation, including those outlined in paragraph 33.13?*

*Q33.15. Please outline any other requirements that should be met when performing a clinical evaluation.*

*Q34.22. Do you think the conditions for conducting a performance study should be set out in the UK medical devices regulations, including those outlined in paragraph 34.15?*

*Q34.23. Please outline any other conditions which should be met when conducting a performance study.*

- 10 It seems likely there would be significant patient safety benefits from introducing legal requirements for investigating and testing medical devices, similar to those for conducting clinical research. Setting out legal conditions around medical devices

should ensure that clinicians (and others) are consistently applying the same standards when considering patient safety issues, seeking ethics approval, and ensuring there is appropriate knowledge sharing and transparency about these investigations and studies.

- 11** We think there are opportunities to strengthen the proposed conditions set out at paragraphs 33.13i and 34.15l. These currently say that 'no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on his or her legally designated representatives, to participate [...] in a clinical investigation or performance study.
- 12** We agree that this principle is important, and it may be helpful to say what non-financial influences should be areas of concern. For instance, in our guidance on good practice we have spelt out that doctors offering services to patients and the public must not use promotional tactics in ways that could encourage people to make an ill-considered decision. We also say that doctors' marketing must be responsible. It must not minimise or trivialise the risks of interventions and must not exploit patients' vulnerability. Doctors must not claim that interventions are risk free (paragraphs 49 and 52, [Guidance for doctors who offer cosmetic interventions](#)). This approach may be helpful to consider here.
- 13** In our guidance we also address concerns about where a patient can't make a decision freely (paragraphs 69-75, [Decision making and consent](#)). In some cases, patients may feel pressure from others to have particular treatment or care. It may be helpful to consider whether this could be relevant to those taking part in a clinical investigation or performance study.

#### Rights of participants to withdraw from a clinical investigation or performance study

*Q33.16. Do you think the UK medical devices regulations should set out the rights of subjects/participants to withdraw from clinical investigations, as outlined in paragraph 33.14?*

*Q34.24 Do you think the rights of subjects to withdraw from a performance study should be included in the UK medical devices regulations, as set out in paragraph 34.16?*

- 14** We agree that the right for subjects/participants to withdraw should be set out in regulations. However, to ensure that subjects/participants can fully exercise this right, there must also be a duty on those leading the investigation or study to *inform* them that they have such a right.
- 15** It may be helpful to refer to our Research guidance, which emphasises that doctors must inform research participants of, and respect, their right to decline to take part in research and to withdraw at any time, with an assurance that this will not adversely affect the person's relationship with those providing care or the care they receive (paragraph 3, [Consent to research](#)).

## Informed consent

*Q35.1. Do you think the UK medical devices regulations should include requirements for obtaining informed consent from individuals participating in a clinical investigation or performance study?*

*Q35.2. If you have answered 'yes' to question 35.1, please outline what the requirements for obtaining informed consent should be.*

- 16** Our guidance, [Decision making and consent](#), sets out for doctors the principles of good practice in making decisions in partnership with patients. That guidance focuses on decision making in the context of investigations and treatment, but the principles apply more widely, including to decisions on taking part in research, including clinical investigations and performance studies.
- 17** In other words, doctors conducting clinical investigations or performance studies have an existing professional duty to obtain informed consent from participants/subjects. We are not clear whether there is a need to introduce a legal requirement as well. But it may be logical to do so, if the intention is to introduce a legal right to withdraw and an accompanying duty to inform subjects/participants of this right.
- 18** If the MHRA decides that it is beneficial to introduce such requirements it will be important to ensure these are aligned with existing professional standards.
- 19** Paragraph 35.1 provides a definition of 'informed consent' in relation to clinical investigations and performance studies:
- “‘Informed consent’ means a subject’s free and voluntary expression of his or her willingness to participate in a particular clinical investigation or performance study, after having been informed of all aspects of the clinical investigation or performance study that are *relevant to their participation* [...] [emphasis added]”.
- 20** While we appreciate that this is not intended to be an exhaustive description, when thinking about promoting good practice in relation to informed consent, we think it is helpful to make clear *who* decides what information is relevant to a person’s participation. In *Decision making and consent* we say that doctors must give patients the information they want or need to make a decision. Dialogue with the patient is central to good decision making as doctors can find out what is important to a patient, and identify the information they will need to make the decision ([paragraphs 8 and 10](#)). The MHRA may want to consider whether there is scope to align with existing professional standards around shared decision making and consent.

## Additional requirements for clinical investigations or performance studies involving minors

*Q36.1. Do you think additional requirements, including those outlined in paragraph 36.3, should be required for clinical investigations or performance studies on minors?*

*Q36.2. Please outline any other requirements which should be introduced for clinical investigations or performance studies on minors.*

- 21** We do not have a specific view on whether additional requirements in this area should be introduced. However, we appreciate that the legal position on the rights of children is a complex area and can evolve quickly through case law. It is therefore important that legal requirements relating to minors are clear in terms of the actions that clinicians would be expected to take to comply with the legal principles; and that any interaction with other law relating to children is explained.

#### Clinical investigations/Performance studies in emergency situations

*Q37.1 Do you think the conditions should be set out in which informed consent to participate in a clinical investigation or performance study may be obtained or given after the decision to include the subject in a clinical investigation or performance study due to an emergency situation?*

- 22** We understand that the specific clinical investigations and performance studies being considered here relate to medical devices that are intended to be used in emergency situations, and that the research could therefore only be carried out on patients who have presented with medical emergencies.
- 23** The principles on emergency treatment in *Decision making and consent* ([paragraphs 62-64](#)), and in *Consent to research*, where we address urgent research into procedures or treatments used in emergencies ([paragraphs 33-35](#)), may be helpful to consider.
- 24** As the clinical investigations and performance studies would be happening in very specific and potentially challenging circumstances, explicitly setting out the requirements around informed consent may provide useful clarity and reassurance to clinicians. It may be helpful for the MHRA to consider related principles already set out in the legal framework and [good practice guidance](#) published by the Health Research Authority for obtaining consent for involving someone in a clinical trial of a medicinal product in emergency situations.

#### **Implantable medical devices**

*Q66.8 Please select any/all of the options listed in paragraph 66.6 (d) you consider should be introduced*

*Q66.11 Do you think that the UK medical devices regulations should require manufacturers of implantable devices to provide implant information for recipient patients with the device when placing it on the market as set out in paragraph 66.6?*

*Q66.12 If you have answered 'yes' to question 66.11:*

*a. should manufacturers be required to provide implant cards/leaflets to healthcare settings/professionals?*

*b. what should be included on the implant card and patient information leaflet?*

*c. should manufacturers be required to make available implant information in both physical and digital formats, (for example, in the form of a card, leaflet or other appropriate format)?*

*[...]*

*e. should health institutions be required to make this information available to patients who have been implanted with the device?*

- 25** We note that paragraph 66.6d proposes requiring that high-risk implantable medical devices may only be supplied to medical device users by practitioners with specialist expertise and experience in the treatment of the condition requiring the device. We are unsure if 'medical device users' refer to patients who receive implants. If so, we support the aim of this proposed requirement. Our guidance is clear that doctors must recognise and work within the limits of their competence (Good medical practice, [paragraph 14](#)).
- 26** The consultation also proposes requiring manufacturers of implantable devices to provide patient implant information with the medical device when placing it on the market, in both digital and physical card or leaflet format. It suggests that health institutions and healthcare professionals could be required to make this information available to patients having implantable devices both during the process of seeking informed consent to a procedure for an implant, and at the point where a procedure introducing an implant has been completed.
- 27** We strongly support efforts to improve the information available to patients, doctors, and other healthcare professionals as this is vital to shared decision-making. We do not have a view on the specific content or format that implant information should take, but patient information should be provided in formats that can meet different information needs for example around literacy, language, visual impairments.
- 28** In relation to the proposed requirement to share implant information with patients, doctors have an existing professional duty to share information that patients want or need to make a decision. We say that patients need relevant information to be shared in a way they can understand and retain, so they can use it to make a decision (Decision making and consent, [paragraph 27](#)).

## **Unique Device Identification**

*Q19.19 Do you think healthcare professionals and/or health institutions should be required to store the UDIs of certain medical devices?*

**29** Paragraph 19.19 says that:

*'The UK medical devices regulations could be amended to require healthcare professionals and/or health institutions to store and keep by electronic means, the UDI of the medical devices which they have supplied and to which patient they have been supplied or with which they have been supplied. This requirement could apply to all implantable medical devices, or certain types of implantable medical devices.'*

**30** We do not have a specific view on whether doctors should be required to store this type of information. But we appreciate that this proposed requirement follows the IMMDS Review, which highlighted the vital importance of the healthcare system taking prompt and effective action where issues and concerns are emerging regarding the use of medical devices.

**31** If doctors are required to store and share details of relevant patients to whom a device has been supplied, it would be helpful to provide doctors with clear information about the circumstances in which the information might be disclosed, to whom and how it might then be used. Doctors will want to be reassured about how the regulations align with the standards we set for recording and sharing patient information. Our guidance, [Confidentiality: good practice in handling patient information](#), is underpinned by principles that patients are able to exercise their legal rights to be informed about how their information will be used. Patients should also be provided with information about disclosures of personal information that they wouldn't reasonably expect, in ways that they can understand.

**32** When developing more detailed proposals, we encourage the MHRA to consider how it can raise awareness with patients to help them understand how their information will be used, and the circumstances in which this might be disclosed.

### **Claims made about medical devices**

*Q10.1 Do you think that we should introduce the provisions set out in paragraph 10.4?*

**33** Paragraph 10.4 says:

*'The MHRA considers that the UK medical devices regulations could be amended to prohibit, insofar as they are not adequately prohibited in other legislation, the use of text, names, trademarks, disclaimers, pictures, images, videos and figurative or other signs that may mislead the user or the patient with regard to its intended purpose and the safety and performance of the medical device. The Regulations could provide that a person who makes a misleading claim on the device labelling, instructions for use, packaging or sales material / advertising (including online) would be responsible for this. [...]*

**34** We support the aim of this provision. Our guidance says that doctors must be honest and trustworthy in all their communication with patients and colleagues. This means

they must make clear the limits of their knowledge and make reasonable checks to make sure any information they give is accurate. When advertising their services, doctors must make sure the information they publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge (Good medical practice, [paragraphs 68 and 70](#)).

- 35** We hope these comments are helpful. We would be happy to explore or clarify any aspect of our response with you further.