Chapter 11: Implantable Devices

Section 66 - Implantable Devices

Background

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

66.2 We want to ensure these medical devices receive adequate scrutiny before they reach the market, and sufficient post-market surveillance and responsiveness to any post-market issues. We want to see patients have a clear voice in how issues are responded to, and greater transparency around how these devices are approved and used.

66.3 Consideration of implantable devices with a non-medical purpose is addressed elsewhere in this consultation. Please see Chapter 1, Section 2 to share your views on the potential to bring implantable devices that do not have a medical purpose, such as some dermal fillers, within scope of medical device regulations.

Possible Changes and Questions

66.4 We are considering whether to update the regulation of these medical devices in order to:

a. **Expand the scope**
We are considering whether to expand the scope of implantable medical devices regulated under the UK medical devices regulations to include temporarily implanted devices to ensure these types of devices receive sufficient pre-market scrutiny and post-market surveillance, in line with regulated implantable medical devices.

Q66.1 Do you think there should be any changes to the scope of medical devices regulated as implantable devices? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q66.2 If you have answered 'yes' to question 66.1, please set out any implantable devices you consider should be brought into or removed from the scope of implantable devices regulated.

Q66.3 Please set out your reasoning in relation to questions 66.1 and 66.2, and any expected impacts (including implementation considerations). Please consider whether any further clarity is needed on what is out of scope of regulated implantable medical devices.

b. **Up-classifying certain implantable devices**
We are considering whether to up-classify certain implantable devices to ensure they receive pre- and post-market scrutiny commensurate with the level of risk they present. See the Classification Chapter 2 to share your views on the potential to change how implantable devices are classified under the UK medical devices regulations.

c. **Introduce more stringent pre-market requirements**
We are considering whether to introduce more stringent pre-market requirements for implantable devices. If some medical devices are up-classified, greater scrutiny of those medical devices before they are placed on the market will necessarily follow. We are interested in whether, beyond this, there should be greater/different requirements placed on implantable devices than corresponding non-implantable devices within the same risk category before they can be placed on the UK market. This could include more robust clinical investigations or technical document reviews. We would also like to consider if some implanted devices, such as screws and wedges should be subject to the same regulatory requirements as other implanted devices or not, based on the risk factors they may pose.

We are also considering if new implanted devices should have additional pre-market requirements placed on them as a pre-requisite to them being place on the market. This might include, for example, additional monitoring requirements and patient follow up through a specified initial launch period for the first 12 or 24 months, with all data collected to be reviewed to confirm if the device is performing as designed and that early side effects are as expected.

Please see Chapter 6 on conformity assessment to share your views on this aspect of potential change.

Q66.4 In relation to implantable devices, do pre-market evidence requirements need to change, particularly in respect to:

a. clinical investigations: should requirements for clinical investigations be more robust than those conducted for non-implantable devices? ('Yes' / 'No' / 'Don't Know/No Opinion')
b. technical documentation reviews: should requirements be more robust than those for non-implanted devices of the same risk category? ('Yes' / 'No' / 'Don't Know/No Opinion')
c. any exemptions required for certain implantable devices (e.g. screws, wedges)? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q66.5 Please explain your rationale for your responses to question 66.4, including how and why you think any changes are needed, including any expected impacts.

Q66.6 What are your views on adding additional conditions to the introduction of new implantable medical devices to the UK market?

Please consider: what controls should be in place? For how long? To what types of devices should controls apply?

d. **Introduce more controlled access to implantable medical devices**
We are considering introducing more controls over access to high-risk implantable devices. Options include limiting high risk implantable devices to:
    - being supplied only to medical device users in centres specialising in their use
    - being supplied to medical device users by practitioners with specialist expertise and experience in the treatment of the condition requiring the device
    - administered with proactive follow up with patients (for example, monitoring longer term patient outcomes or feedback post-implant).

Q66.7 Should there be more stringent controls over the use of implantable devices? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q66.8 Please select any/all of the options listed in paragraph 66.4 (d) you consider should be introduced:

- **being supplied only to medical device users in centres specialising in their use**
- **being supplied to medical device users by practitioners with specialist expertise and experience in the treatment of the condition requiring the device**
- **administered with proactive follow up with patients (for example, monitoring longer term patient outcomes or feedback post-implant)**

Q66.9 Are there any other controls over implantable devices you think should be introduced?

e. **Post market requirements**
We are considering whether changes are needed to the requirements that apply to an implantable medical device once on the market to ensure it is safe and performs well. These could include:
    - providing information to clinicians and patients about the requirements around the management and ongoing use of obsolete models of implantable medical devices
    - introducing a requirement for implant information to be provided (in the form of virtual or physical implant cards and/or leaflets) to recipients of implantable devices – both at the point of seeking informed consent to introducing the implant, and/or after a procedure introducing it has been completed (as expanded on below).

66.5 Under the UK medical devices regulations, while it needs to be in instructions for use, there is no legal requirement for patients to be provided with information regarding medical devices with which they have been implanted (e.g. artificial heart valves, bone plates) unless that device is a custom-made device – in which case information will be made available on request.

66.6 The UK medical devices regulations could be amended to require 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. Health institutions 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. The UK medical devices regulations could require health institutions to hold this information securely and to log this information onto patient records. It could require that the implant information include the following:

a. information allowing the identification of the medical device, including the medical device name, serial number, lot number, UDI, and medical device model, as well as the name, address and website of the manufacturer
b. any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference (interaction between a medical device and an instrument e.g. an MRI scanner, which negatively affects the medical device or the instrument) with reasonably foreseeable external influences, medical examinations or environmental conditions, including a caution that risk may emerge during use of an implantable device; any information about the expected lifetime of the medical device and any necessary follow-up e.g. where the patient might require repeat scans to ensure the medical device is still in place
c. any other information to ensure safe use of the medical device by the patient, including the overall qualitative and quantitative information on the materials and substances to which patients can be exposed.

There could be a requirement to update the digital implant information where appropriate.

66.7 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), wedges, plates, wires, pins, clips and connectors could be excluded. However, manufacturers and health institutions could still be required to consider providing patient implant information for these types of medical devices where there is a demonstratable risk of dangerous interaction e.g. ferromagnetic clips and interaction with MRI scanners.

Q66.10 Do you think that post-market requirements for implantable devices could be strengthened by:

a. clarifying or strengthening the requirements around use of obsolete models of implantable medical devices? (‘Yes’ / ’No’ / ’Don’t Know/No Opinion’)
b. introducing a requirement for implant information to be provided to recipients of implantable devices? (Yes/No/Don’t Know/No Opinion)

66.8 The following questions are more specifically about providing implant information in cards/leaflets.

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

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? ('Yes' / 'No' / 'Don't Know/No Opinion')**
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)? ('Yes' / 'No' / 'Don't Know/No Opinion')**
d. **Should the manufacturer be required to update the digital implant information where appropriate? ('Yes' / 'No' / 'Don't Know/No Opinion')**
e. **should health institutions be required to make this information available to patients who have been implanted with the device? ('Yes' / 'No' / 'Don't Know/No Opinion')**
f. **should health institutions be required to log the implant information onto the records of the patient implanted with the device? ('Yes' / 'No' / 'Don't Know/No Opinion')**

Q66.13 Are there any implants that should be excluded from the requirement to have accompanying implant information? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q66.14 If you have answered 'yes' to question 66.13, please outline what types of implant should be excluded and why. In your response, please set out any expected impact(s), with consideration of how these could be defined best for clarity of what is in scope of the exemption.

f. **Increasing the level of information we capture and share**

We are considering whether, beyond the core information set out for collection in relation to all medical devices at the point of medical device registration (set out in the Registration Chapter 4), there is further information we should collect and share about implantable medical devices in particular beyond the core information set out for collection in relation to all medical devices (set out in the Registration Chapter, 4). Please see Chapter 3, section 13, for an opportunity to comment on the timeframes technical documents relating to implantable devices must be retained by UK Responsible persons.

Q66.15 Is there further information we should collect and share about implantable medical devices in particular? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q66.16 Please set out your rationale for your answer to question 66.15. If yes, please include any detail of information you consider should be collected and shared.

g. **Reduce reliance on equivalence in the assessment of implantable devices.** Currently, equivalence to a previously approved medical device can reduce the level of evidence of a medical devices' conformance with relevant requirements a manufacturer must produce. We are interested in whether reliance on equivalence should be restricted or unavailable under future regulations for implantable medical devices. Please see Chapter 7: Clinical Investigation/Performance Studies to share your views on this.

Implementation considerations

Q66.17 What are the key implementation considerations for any changes you have outlined in response to previous questions in this chapter. Please consider: what types of implantable medical devices should these apply to (including any exemptions to them); impacts on inequalities such as access to devices and timeframes; where there should be a phased implementation; and how much guidance/support you think will need to be provided to facilitate transition.

Other

Q66.18 Are there any other key considerations you would like to raise regarding changes to the regulatory framework for implantable medical devices?

Q66.19 Please provide any relevant evidence to support your answers to questions 66.1-66.18 in this section, including any impacts on you or other stakeholder groups, and key implementation considerations for any changes that could be made.