Chapter 6: Conformity Assessment

Section 26 - Conformity Assessment

Background

26.1 To place a medical device on the Great Britain market, manufacturers need to demonstrate that their medical device meets the requirements in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) by carrying out a conformity assessment. The type of assessment (and whether it can be undertaken by the manufacturer or must be undertaken by an Approved Body), depends on the classification of the medical device. You can read more about this here.

26.2 Approved Bodies conduct conformity assessments of certain IVDs and medical devices to ensure they comply with the requirements of the UK medical devices regulations. If the device meets applicable requirements, then the Approved Body issues a Certificate of Conformity that allows the manufacturer to market their medical device in Great Britain. The majority of IVDs reaching the UK market are not currently subject to conformity assessment by Approved Bodies.

26.3 Bringing new devices into scope of the UK medical devices regulations or changing their classification (see Chapter 1) could increase the volume of medical devices requiring a conformity assessment before they are placed on the market. Also, changing the classification of a type of medical device and/or IVD (Chapter 2) may impact the conformity assessment they are subject to. Note, for example, the IVD Chapter (see Chapter 9) sets out the option for IVDs to be classified differently, which may result in a higher proportion of IVDs being subject to scrutiny by Approved Bodies.

Possible Changes and Questions

26.4 The UK medical devices regulations set out the process that must be followed in applying for, or undertaking, a conformity assessment. The MHRA is interested in having greater transparency and consistency in conformity assessments. 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.

26.5 We are considering whether our existing conformity assessment procedures require clarification and strengthening to ensure this. We are also considering whether there are any routes which are rarely utilised and should be removed.

Clarity and adequacy of conformity assessment requirements

26.6 MHRA is considering what updates to existing regulations may be needed to strengthen and clarify the conformity assessment requirements for medical devices. Options are (but not limited to) to revise Approved Body conformity assessment procedures and requirements to:

a. **remove the option** for manufacturers of class III, IIb and IIa general medical devices to use production quality assurance
b. **require** implantable Class IIb device technical documentation to be reviewed on a 100% basis rather than on a representative basis
c. **require that** reusable surgical instruments must undergo conformity assessment by an Approved Body for aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing and the related instructions for use
d. **require** manufacturers lodging an application for conformity assessment with an Approved Body to not lodge an application in parallel with another Approved Body for the same conformity assessment procedure on the same product
e. **specify** a time limit for Approved Bodies to respond to an application for conformity assessment
f. **require** manufacturers to declare whether they have withdrawn an application with another Approved Body prior to the decision of the Approved Body they have applied to and provide information about any previous application for the same conformity assessment that has been refused by another Approved Body
g. **require** Approved Bodies to inform other Approved Bodies and the MHRA of any manufacturer that withdraws its application prior to the Approved Body's decision regarding the conformity assessment
h. **specify the required structure** of manufacturers' technical files for a medical device (as is currently set out in guidance in other jurisdictions).

26.7 Up-classifying medical devices is considered in Chapter 2 – Classification. Up-classifying IVDs and implantable medical devices (or certain types of these medical devices) will mean they are subject to higher scrutiny in pre-market conformity assessments. We are interested in whether, beyond this, any further changes are needed to the conformity assessment criteria and process applied to these medical devices in particular to ensure they are subject to an adequate level of scrutiny. This is explored further in the Implantable Devices and IVD sections (Chapter 9 and Chapter 11).

Q26.1 Do you think the conformity assessment requirements for medical devices should be clarified and strengthened for medical devices as set out in paragraph 26.6 above? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q26.2 Please outline any other clarifications or additions to requirements that you think should be introduced to strengthen the conformity assessment of medical devices under the UK medical device regulations. Please include your rationale and any expected impacts on you/other stakeholder groups (including any implementation considerations such as guidance that may be required).

Q26.3 The current timeframe for which manufacturers must retain technical documentation is 15 years for implantable devices, and 5 years for all

other medical devices. We are considering whether this is sufficient. An option is for this to be 15 years for implantable devices and 10 years for other medical devices. For how long should the manufacturer be required to keep technical documentation for a medical device they have manufactured?

a. **1-5 years after the last product has been manufactured**
b. **6-10 years after the last product has been manufactured**
c. **11-15 years after the last product has been manufactured**
d. **For the expected lifetime of the device, after the last product has been manufactured**
e. **Other (please specify)**

Scope of routes available

26.8 Anecdotally we are aware that the following conformity assessment routes for general medical devices are rarely utilised by manufacturers: batch verification, product quality assurance and type examinations. The MHRA considers that the UK medical devices regulations could be amended to exclude these as possible conformity assessment routes.

Q26.4 Do you think that certain conformity assessment routes, including those in paragraph 26.8 or others, should be removed from the UK medical devices regulations? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q26.5 If you have answered 'yes' to question 26.4, please outline which conformity assessment routes could be removed from the UK medical devices regulations.

Q26.6 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 26.1-26.5, including any impacts on you or other stakeholder groups.

Section 27 - Mechanism for transparency and scrutiny of conformity assessments of certain medical devices

Background

27.1 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) include limited requirements for Approved Bodies to supply to the MHRA any information about the medical devices for which they have granted Certificates of Conformity. Introducing further requirements could increase the information available for these medical devices to the MHRA, thus aiding MHRA investigations of unsafe medical devices.

Possible Changes and Questions

27.2 Approved Bodies are currently required to notify the MHRA of certificates they have granted to all medical devices. The UK medical devices regulations could require the Approved Body to provide certain documents as part of this notification. Such documents could include:

a. summary of safety and clinical performance (see Chapter 7, Section 45)
b. the assessment report by the Approved Body
c. the instructions for use.

27.3 The MHRA could apply additional scrutiny to the conformity assessment report for certain classes/types of medical devices, for example:

a. class III implantable medical devices,
b. class IIb active medical devices intended to administer and/or remove a medicinal product
c. class IIb implantable medical devices
d. highest risk IVDs i.e. Class D under the EU IVDR (2017/746) where it is the first certification for that type of medical device
e. artificial intelligence/machine learning based medical devices.

27.4 The Regulations could be amended to enable the MHRA to raise any concerns regarding the completed conformity assessment with the Approved Body who may be required to take further action. This would provide an extra layer of protection to public health by ensuring that high risk medical devices entering the market have been appropriately assessed and scrutinised.

Q27.1 Do you think Approved Bodies should be required to notify the MHRA of certificates they have granted for general medical devices with the accompanying documentation set out in paragraph 27.2? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q27.2 Do you think the MHRA should apply additional scrutiny to the conformity assessment report for certain classes/types of medical devices? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q27.3 If you have answered 'yes' to question 27.2 please outline which types/classes of medical devices this additional scrutiny should apply to.

Q27.4 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 27.1-27.3, including any impacts on you or other stakeholder groups.

Section 28 - Certificates of Conformity

Background

28.1 Approved Bodies issue Certificates of Conformity to manufacturers who have passed the conformity assessment procedure. The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) does not set out clear requirements for the conformity assessment certificate. Including these requirements in the Regulations could enhance uniformity across all Approved Bodies.

Possible Changes and Questions

28.2 The MHRA considers that the UK medical devices regulations could be amended to detail the minimum content of the certificates which must be provided for in English. For example, minimum content could include:

a. name, address and identification number of the Approved Body
b. name and address of the manufacturer and, if applicable, of the UK Responsible Person
c. unique number identifying the certificate
d. date of issue
e. date of expiry
f. if applicable, reference to any previous certificate
g. reference to the UK Medical Devices Regulations 2002 (as amended) and the relevant Schedule in accordance with which the conformity assessment has been carried out
h. examinations and tests performed, e.g. designated standards, test reports and audit report(s)
i. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered
j. if applicable, information about the surveillance by the Approved Body
k. conclusions of the Approved Body's conformity assessment with regard to the relevant Schedule, and
l. conditions for or limitations to the validity of the certificate.

Q28.1 Do you think the UK medical devices regulations should detail the minimum content of Certificates of Conformity? (‘Yes’ / ’No’ / ’Don’t Know/No Opinion’)

Q28.2 If you have answered ‘yes’ to question 28.1, please outline what should be included as part of the content of a Certificate of Conformity (you may reference bullet points a-l above).

28.3 The MHRA considers that the UK medical devices regulations could be amended to allow Approved Bodies to impose restrictions of a medical device to certain groups of patients or require manufacturers to undertake specific post-market clinical follow-up or post-market performance follow-up studies (see Chapter 8).

Q28.3 Do you think Approved Bodies should be allowed to impose restrictions/requirements on the use/follow-up of certain medical devices? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q28.4 If you have answered 'yes' to question 28.3, please outline what restrictions / requirements Approved Bodies could impose.

28.4 The MHRA considers that the UK medical devices regulations could be amended to include requirements for Approved Bodies to enter information regarding any conformity certificates they have issued into the MHRA registration system. This could include information regarding suspended, reinstated or withdrawn certificates and restrictions imposed on certificates. Such information shall be published and accessible to the public.

Q28.5 Do you think the UK medical devices regulations should require Approved Bodies to enter information about certificates into the MHRA registration system? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q28.6 If you have answered 'yes' to question 28.5, please outline what certificate information Approved Bodies should be required to enter into the MHRA registration system.

Q28.7 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 28.1-28.6, including any impacts on you or other stakeholder groups.

Section 29 - Voluntary change of Approved Body

Background

29.1 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) do not set out specific requirements for when a manufacturer changes Approved Body. Setting out these requirements could enable a smoother changeover that keeps the manufacturer under appropriate Approved Body oversight.

Possible Changes and Questions

29.2 In cases where a manufacturer terminates its contract with an Approved Body and enters into a contract with another Approved Body in respect of the conformity assessment of the same medical device, the MHRA considers that the UK medical device regulations could be amended to set out the minimum content that should be included in an agreement between the manufacturer, the incoming Approved Body and, where practicable the outgoing Approved Body.

Q29.1 Do you think the UK medical devices regulations should set out the minimum content that should be included in the agreement for a change of Approved Bodies? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q29.2 If you have answered 'yes' to question 29.1, please outline what this agreement should include.

Q29.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 29.1-29.2, including any impacts on you or other stakeholder groups.

Section 30 - Declaration of Conformity

Background

30.1 The Declaration of Conformity is a declaration from the medical device manufacturer that the medical device complies with the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations). It is signed by the manufacturer before the UKCA marking is applied to the medical device. All medical device manufacturers must draw up and sign a Declaration of Conformity whether or not the medical device has undergone conformity assessment from an Approved Body.

30.2 The UK medical devices regulations set out very limited minimum requirements for the Declaration of Conformity. Including such requirements will ensure uniformity across all Declaration of Conformity's drawn up.

Possible Changes and Questions

30.3 The MHRA considers that the UK medical devices regulations could set out the minimum requirements for the content of the Declaration of Conformity. For example, minimum content could include:

a. device name, registered trade name or registered trade mark
b. manufacturer, and, if applicable, its UK Responsible Person, and the address of their registered place of business
c. a statement that the Declaration of Conformity is issued under the sole responsibility of the manufacturer;
d. the Basic UDI-DI (see Chapter 4, Section 18)
e. product and trade name, product code, catalogue number;
f. risk class of the device;
g. references to any designated standards used and in relation to which conformity is declared;
h. where applicable, the name and identification number of the Approved Body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;
i. place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

Q30.1 Do you think that the UK medical devices regulations should set out the minimum content requirements for the Declaration of Conformity? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q30.2 If you have answered 'yes' to question 30.1, please outline what the requirements for the Declaration of Conformity should be (you may refer to bullet points a-i in paragraph 30.3).

Q30.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 30.1-30.2, including any impacts on you or other stakeholder groups.