Chapter 12: Other Product-Specific Changes

Section 67 - Re-manufacturing single-use devices

Background

67.1 Re-manufacturing of single-use devices refers to the practice whereby a company cleans, disinfects, and sterilises a single-use medical device, which is then tested against the re-manufacturer's specifications to ensure that the single-use device continues to operate safely and as intended. The re-manufacturing company must undergo a conformity assessment by an Approved Body and obtain a UKCA mark for the re-manufacturing process.

67.2 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) do not set out any requirements for the re-manufacturing of single-use devices. The MHRA has released guidance on the re-manufacturing of single-use devices (for purposes of this guidance 'CE marking' should read as 'UKCA marking' and 'Notified Body' should read as 'Approved Body').

67.3 Re-processing of single-use devices has a different meaning to re-manufacturing. Re-processing of single-use devices refers to the practice whereby a person, institution or organisation undertakes processes on a used medical device in order to allow the safe reuse of that device. The processes may include cleaning, disinfection, sterilisation, as well as testing and restoration of the technical and functional safety of the used medical device. The MHRA currently advises against the reprocessing of single-use devices as set out in its guidance. Please note that when we use the term "re-processing", we refer to the Great Britain interpretation of the term as set out in our guidance. We have not intended to draw parallels with the EU interpretation of the term as set out in the EU Medical Devices Regulations (2017/745).

67.4 The MHRA considers that re-manufacturing requirements could be set out in the UK medical devices regulations in order to provide additional clarity for re-manufacturers. . This would also ensure that there is a legal obligation on re-manufacturers to abide by the requirements.

Possible Changes and Questions

67.5 The MHRA considers that the UK medical devices regulations could be amended to introduce specific requirements for re-manufacturers of single-use devices, requirements could include:

a. that the re-manufacturer should meet all relevant criteria of the UK medical devices regulations and apply a UKCA marking to the product to attest conformity

b. that the re-manufacturer applies an appropriate Quality Management System
c. that an Approved Body must:
    - assess whether the re-manufactured single-use device meets all the relevant provisions of the UK medical devices regulations
    - confirm the validity and surety of all re-manufacturing processes and that they meet the relevant provisions of the UK medical devices regulations
    - ensure re-manufacturer compliance with the appropriate Quality Management System
d. that the re-manufacturer accepts all liabilities and obligations for the re-manufacturing of the single-use device
e. that the intended use of the re-manufactured medical device should not differ from the intended use of the original product (not including claims for single-use)
f. that the packaging and instructions for use clearly state that the single-use device is a re-manufactured version of the original and that the re-manufacturer can be clearly identified on the packaging and labelling
g. that the re-manufacturer has appropriate post-market surveillance and adverse event reporting procedures in place.

Q67.1 Do you think that the UK medical devices regulations should include the requirements for re-manufacturers of single-use medical devices set out in paragraph 67.5? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q67.2 Please outline any other requirements which should be introduced for the re-manufacturing of single-use devices.

67.6 The MHRA considers that the UK medical devices regulations could be amended to introduce requirements that would apply in cases where a person re-manufactures a single-use device on behalf of a healthcare institution. Requirements could include:

a. that the supply of the re-manufactured single-use devices should be through a closed loop contract between the re-manufacturer and the healthcare institution (e.g. hospital or clinic). At no time should a re-manufacturer or healthcare institution sell or provide a re-manufactured single-use device to any other third party
b. that a re-manufactured single-use device should only be used on an individual patient during a single procedure and, after that use, the single-use device should be returned to the contracted re-manufacturer.

Q67.3 Do you think the UK medical devices regulations should introduce the requirements set out in paragraph 67.6 for re-manufacturers of single-use devices on behalf of healthcare institutions? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q67.4 Please outline any other requirements which should be introduced for the re-manufacturing of single-use devices within healthcare institutions.

67.7 In line with MHRA's current guidance, the MHRA considers that the UK medical devices regulations could set out that Class I single-use medical devices should not be re-manufactured as there would be no assessment of UKCA marking compliance by an Approved Body (see Chapter 5 on Approved Bodies).

Q67.5 Do you think that the MHRA should allow the re-manufacturing of Class I single-use medical devices? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q67.6 If you have answered 'yes' to question 67.5 please outline what the requirements should be in place for the re-manufacturing of Class I single-use medical devices.

67.8 As outlined above, re-processing of single-use devices refers to the practice whereby a person, institution or organisation undertakes processes on a used medical device in order to allow the safe reuse of that device. Unlike a re-manufacturer, a re-processor is not expected to undertake a conformity assessment and place their own UKCA marking on the re-processed medical device prior to placing the device on the market or putting it into service. The MHRA has considered that its guidance on the re-processing of single use devices remains appropriate, but we are seeking views on whether this position should be reviewed.

Q67.7 Do you think that the MHRA should continue to allow the re-processing of single-use devices? ('Yes' / 'No' / 'Don't Know/No Opinion').

Q67.8 If you have answered 'yes' to question 67.7 please outline what requirements should be put in place for re-processing of single-use devices.

Q67.9 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 67.1-67.8, including any impacts on you or other stakeholder groups.

Section 68 - Systems, kits and procedure packs

Background

68.1 A procedure pack is a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose.

68.2 A system is a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose.

68.3 The MHRA considers a kit to be a set of components that are packaged together and intended to be used to perform a specific *in vitro* diagnostic examination.

68.4 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) include requirements for manufacturers who put together medical devices into systems or procedure packs for specific uses. However, these requirements may require further clarification, particularly where the system includes a combination of general medical devices, IVDs and/or other products.

Possible Changes and Questions

68.5 The MHRA considers that the UK medical devices regulations could clarify that a 'kit' should be regulated in the same way as a system or a procedure pack. This would help avoid confusion regarding the regulation of combinations of products (which include IVDs, general medical devices and other products) used for *in vitro* diagnostic examination.

Q68.1 Do you think that the UK medical devices regulations should include the term 'kit' when referring to medical devices and products which are assembled together? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q68.2 Should the definitions of systems, procedure packs and kits allow external software (e.g. a specific app identified in the labelling) to be considered as a component of the system, procedure pack or kit? ('Yes' / 'No' / 'Don't Know/No Opinion')

68.6 The UK medical devices regulations (regulation 14) sets out the requirements for individuals or companies placing systems and procedure packs on the market. In addition to these requirements, the MHRA considers that the UK medical devices regulations could require assemblers of systems, kits and procedure packs to implement procedures for:

a. selection and control of suppliers
b. risk management
c. handling of complaints
d. management of corrective and preventive actions with verification of their effectiveness.

The Regulations could require that these procedures should be outlined in the assembler statement / declaration.

Q68.3 Do you think that assemblers of systems, kits and procedure packs should be required to implement procedures for the factors listed in paragraph 68.6? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q68.4 Please outline any other requirements that you think we should introduce for system and procedure packs and the sterilisation of system and procedure packs.

Q68.5 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 68.1-68.4, including any impacts on you or other stakeholder groups.

Section 69 - Parts and components

Background

69.1 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) do not contain specific requirements for parts and components of a medical device. An example of a part or component could be the motor of an electric wheelchair, or the digital screen of a glucometer.

Possible Changes and Questions

69.2 The MHRA considers that the UK medical devices regulations could be amended to require that any individual or company (including health institutions), who places on the market or puts into service an item specifically intended to replace an identical or similar integral part or component of a medical device that is defective or worn, shall ensure that the item does not negatively affect the safety and performance of the medical device.

Q69.1 Do you think that the UK medical devices regulations should require that any individual or company who supplies an item specifically intended to replace an identical or similar integral part or component of a medical device that is defective or worn should ensure that the item does not negatively affect the safety and performance of the medical device? ('Yes' / 'No' / 'Don't Know/No Opinion')

69.3 The MHRA considers that the UK medical devices regulations could be updated to clarify that an item that is intended specifically to replace a part, component or function of a medical device and that significantly changes the performance or safety characteristics or the intended purpose of the medical device could be considered to be a medical device in its own right and therefore be required to meet the requirements of the UK medical devices regulations.

Q69.2 Do you think an item that is intended specifically to replace a part or component of a medical device and that significantly changes the performance or safety characteristics or the intended purpose of the medical device could be considered to be a medical device in its own right and therefore be required to meet the requirements of the UK medical devices regulations? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q69.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 69.1-69.2, including any impacts on you or other stakeholder groups.

Section 70 - Custom-made devices

Background

70.1 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) defines a 'custom-made device' as a medical device that is manufactured specifically in accordance with a written prescription (for example from a registered medical practitioner who gives, under their responsibility, specific characteristics as to its design) and is intended for the sole use of a particular patient.

70.2 Custom-made devices do not include mass-produced products which need to be adapted to meet the patient's specific requirements or of the medical practitioner or professional user.

70.3 Examples of a custom-made medical device include permanent dental crowns, orthopaedic bespoke footwear made from a cast and bespoke spectacle frame to fit a certain face shape.

70.4 The UK medical devices regulations set out requirements for custom-made devices. This includes requirements for the manufacturer to draw up a statement, which should be provided to the patient. The statement should contain the details of the healthcare professional prescribing the medical device and the intended patient. There are also requirements for the manufacturer to keep technical documentation, register with the MHRA, report adverse events and carry out post-market surveillance.

Possible Changes and Questions

70.5 The MHRA considers that the UK medical devices regulations could be amended to introduce more detailed requirements for the technical documentation that must be drawn up and kept by the manufacturer of a custom-made device. For example, manufacturers could be required to draw up a clinical evaluation report (see Chapter 7, Section 31) and keep information on how the relevant essential requirements of the Regulations were identified and actions taken to ensure the requirements have been met.

Q70.1 Do you think that the UK medical devices regulations should include more detailed requirements for the technical documentation that must be drawn up and kept by the manufacturer of a custom-made device, such as those outlined in paragraph 70.5? ('Yes' / 'No' / 'Don't Know/No Opinion')

70.6 The MHRA considers that the UK medical devices regulations could be amended to introduce more stringent requirements for the post-market surveillance of custom-made devices. For example, we could introduce requirements to establish periodic summary update reports for Class IIa, IIb and III custom-made devices or post-market surveillance reports for Class I custom-made devices (see Chapter 8, Section 48).

Q70.2 Do you think that the UK medical devices regulations should introduce more stringent requirements for the post-market surveillance of custom-made devices, such as those outlined in paragraph 70.6? ('Yes' / 'No' / 'Don't Know/No Opinion')

70.7 The MHRA considers that the UK medical devices regulations could require manufacturers of certain custom-made devices to implement a Quality Management System (QMS) which must be certified by an Approved Body.

Q70.3 Do you think that the UK medical devices regulations should require manufacturers of certain custom-made devices to implement a QMS which must be certified by an Approved Body? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q70.4 If you have answered 'yes' to question 70.3, please outline what types/classes of custom-made devices should fall under this requirement.

Q70.5 Please outline any further requirements which should be introduced for manufacturers of custom-made devices.

70.8 The MHRA considers that the UK medical devices regulations could be changed to clarify that the prescription written by a medical practitioner, who prescribes specific characteristics to the design of the custom-made medical device, can be an electronic prescription.

Q70.6 Do you agree that custom-made devices could be manufactured on the basis of an electronic prescription, as outlined in paragraph 70.8? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q70.7 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 70.1-70.6, including any impacts on you or other stakeholder groups.