Chapter 3: Economic Operators

Section 6 - Essential requirements for medical devices

Background

6.1 The Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) (UK medical devices regulations) include a list of essential requirements for medical devices. Manufacturers must ensure that their medical devices meet the essential requirements applicable to them and they must provide evidence of this.

6.2 These requirements ensure that the medical device is safe and that it meets its intended purpose. A number of specific requirements are covered - for example, requirements regarding the chemical, physical or biological properties of the medical device.

6.3 The MHRA considers that the essential requirements of the UK medical devices regulations are currently out of step with international best practice and technological developments and thus could be amended to enhance and safeguard public and patient safety.

Possible Changes and Questions

6.4 The MHRA considers that the UK medical devices regulations could be amended to provide further detail to the existing essential requirements and to add further essential requirements in line with technological progress and international best practice to deliver public and patient safety benefits. Examples of how the essential requirements could be amended include:

a. More explicit requirements for:
    i. electronic programmable systems
    ii. nanomaterials
    iii. medical devices with substances which are absorbed or locally dispersed
    iv. substances that are carcinogenic, mutagenic or endocrine-disrupting
    v. safe interoperability, adjustment, calibration and disposal of medical devices
b. More detail on what should be addressed in the manufacturer's risk management process
c. More detail on the information that should be provided with the medical device, including:
    - that it should reflect accurately what is known about the medical device, including uncertainties about the long-term impacts of use
    - when a user should consult a healthcare professional and how to report a serious incident to the manufacturer

- a requirement to list ingredients/component parts which are known allergen/sensitisers e.g. natural rubber latex, chlorhexidine etc.

d. more detailed requirements for the medical device label - e.g. a requirement for the 'intended purpose' of the medical device to consider what a person (not limited to the end user) would think the product is to be used for when looking at the instructions for use, labelling, advertising or other marketing material.

Q6.1 Do you think the essential requirements of the UK medical devices regulations should be amended as set out in paragraph 6.4? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q6.2 Please outline any other amendments which should be made to the essential requirements of the UK medical devices regulations.

Q6.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 6.1-6.2, including any impacts on you or other stakeholder groups.

Section 7 - Manufacturer obligation – measures for recompense

Background

7.1 To help ensure that those negatively impacted by an experience with a medical device are adequately compensated where appropriate, we are considering whether manufacturers could be required to have measures in place, that are proportionate to the risk class, type of device and the size of the company, to cover any legal liability arising from adverse incidents with medical devices that they place on or supply to the UK market. For example, we could require manufacturers to hold appropriate liability insurance.

Possible Changes and Questions

Q7.1 Do you think that the UK medical devices regulations should include a requirement for manufacturers to have measures in place (for example, sufficient financial coverage) for recompensing those impacted by adverse incidents with medical devices on the UK market? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q7.2 Please set out the reasoning for your answer to question 7.1, including any expected impacts of the change on you or other

stakeholder groups and key implementation considerations.

Section 8 - Health Institutions

Background

8.1 Health institutions (bodies that provide care for patients and promote public health – for example, an NHS hospital) which manufacture or modify general medical devices and *in vitro* diagnostic medical devices (including software as a medical device) for use within that health institution are not required to meet the provisions of The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations).

8.2 The UK medical devices regulations could be amended to introduce requirements for medical devices manufactured and modified 'in house' by a health institution. The objective would be to more comprehensively regulate these devices in order to safeguard the health and safety of patients and the public who may come into contact with devices that are manufactured 'in house'.

8.3 The MHRA considers that, in addition, the UK medical devices regulations could be amended to specifically exempt health institutions from meeting certain regulatory requirements and to clarify which requirements must be met. Further information is provided in the paragraphs below.

Possible Changes and Questions

8.4 The MHRA considers that the UK medical devices regulations could be amended to include a definition of a 'health institution' to provide clarification as to which entities the health institution exemption, described in paragraph 8.3, would apply to.

Q8.1 Do you think that the UK medical devices regulations should include a definition of the term 'health institution' to provide clarification as to which entities the health institution exemption would apply to? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q8.2 If you answered 'yes' to question 8.1, please outline what you think should be included in this definition.

8.5 The MHRA considers that the UK medical devices regulations could be amended to clarify that medical devices manufactured and modified 'in house' must meet the relevant essential requirements (see Section 6) of the UK medical devices regulations, but would not need to bear the UKCA marking.

Q8.3 Do you think that the UK medical devices regulations should require 'in house' manufactured devices to meet the relevant essential requirements of the UK medical devices regulations? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q8.4 Do you think that 'in house' manufactured devices should be exempt from UKCA marking requirements? ('Yes' / 'No' / 'Don't Know/No Opinion')

8.6 The MHRA considers that the UK medical devices regulations could be amended to require health institutions to meet certain requirements for 'in house' manufacturing. This could include obligations for the health institution to:

a. apply a suitable Quality Management System (see Section 11 for more detail)
b. justify why the target patient group's needs cannot be met with an equivalent medical device available on the market
c. draw up a publicly available declaration that their medical devices meet the relevant essential requirements of the UK medical devices regulations
d. keep technical information available for the MHRA, review clinical use of the medical devices and take necessary corrective actions
e. report certain types of incidents relating to medical devices manufactured 'in house' to the MHRA.

Q8.5 Do you think that health institutions should be required to meet the requirements set out in paragraph 8.6 when manufacturing or modifying medical devices 'in house'? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q8.6 Please outline any other requirements which should be introduced for health institutions carrying out 'in house' manufacturing or modification of medical devices.

8.7 The MHRA considers that the UK medical devices regulations could be amended to require health institutions to register medical devices manufactured or modified 'in house' with the MHRA. The public declaration (see paragraph 8.6, point c) could be requested by the MHRA during the registration process. If these provisions were to be introduced, the registrations made by health institutions would appear on the MHRA's Public Access Database for Medical Device Registration, with the aim of improving transparency.

Q8.7 Do you think that health institutions should be required to register medical devices manufactured or modified 'in house' with the MHRA? ('Yes' / 'No' / 'Don't Know/No Opinion')

8.8 The MHRA considers that the UK medical devices regulations could be amended to require health institutions to register clinical investigations / performance studies involving medical devices manufactured or modified 'in house' with the MHRA. For further questions on clinical investigations / performance studies conducted by health institutions please see Chapter 7, Section 46.

Q8.8 Do you think that health institutions should be required to register clinical investigations / performance studies with the MHRA? ('Yes' / 'No' / 'Don't Know/No Opinion')

8.9 The MHRA considers that the UK medical devices regulations could be amended to enable the MHRA to request that the relevant health institution provides further information about the devices it has manufactured or modified 'in house', including details about the manufacturing processes. Provisions could also be introduced to require the MHRA to restrict the use of such medical devices and to inspect the activities of relevant health institutions.

Q8.9 Do you think that the provisions in paragraph 8.9 should be introduced for health institutions? ('Yes' / 'No' / 'Don't Know/No Opinion')

8.10 The MHRA considers that the UK medical devices regulations could provide that the health institution exemption shall not apply to medical devices manufactured on an industrial scale and that such medical devices must meet all the relevant provisions of the UK medical devices regulations.

Q8.10 Do you think that medical devices manufactured on an 'industrial scale' should be excluded from the health institution exemption and required to meet all relevant provisions of the UK medical devices regulations? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q8.11 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 8.1-8.10, including any impacts on you or other stakeholder groups.

8.11 The MHRA considers that the UK medical devices regulations could provide that the health institution exemption shall apply to a health institution which provides routine or a specialist diagnostic service to other health institutions.

Q8.12 Should the 'in-house exemption' be applicable to health institutions which provide routine or specialist diagnostic services to other health institutions (e.g. the Supra regional assay service) or another body?

Q8.13 If you have answered 'yes' to question 8.12, please outline any circumstances in which the exemption should not apply (e.g. if the services are provided for commercial / profitable purposes or to private patients or providers outside its intrinsic health function)?

Q8.14 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 8.12-8.13, including any impacts on you or other stakeholder groups.

Section 9 - Distance sales

Background

9.1 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) do not include requirements for distance sales of medical devices.

9.2 By distance sales we are referring to medical devices that are sold at a distance via electronic means - e.g. via websites and app stores. This would apply, for example, to an individual buying a thermometer over the internet, or to a patient with diabetes purchasing an app which helps them to monitor their blood sugar levels.

9.3 The UK medical devices regulations could be amended to introduce requirements for persons providing distance sales services. The objective would be to safeguard the health and safety of patients and the public who may be using medical devices purchased / procured through these means.

9.4 Please note that there are additional questions related to distance sales in the IVD (Chapter 9) and software (Chapter 10) chapters of this consultation.

Possible Changes and Questions

9.5 The MHRA considers that the UK medical devices regulations could be amended to clarify that a medical device, or any diagnostic or therapeutic service involving a medical device (whether in return for payment or free of charge), must comply with the UK medical devices regulations if it is sold or provided at a distance through electronic means. This would be the responsibility of the person selling or offering the medical device or diagnostic or therapeutic service. Where the person supplying the device or service is an economic operator (e.g. a manufacturer or importer), they would also need to follow the relevant obligations under the UK medical devices regulations (see Section 13). The aim would be to enhance public and patient safety by ensuring that products sold or offered through electronic means meet all relevant regulatory requirements.

Q9.1 Do you think that we should introduce the requirements set out in paragraph 9.5 for medical devices or services sold or provided at a distance through electronic means? (‘Yes’ / ’No’ / ’Don’t Know/No Opinion’)

9.6 The MHRA considers that the UK medical devices regulations could be amended to provide that, upon request from the MHRA, any individual, company or organisation offering a medical device by means of distance sales could be required to provide a copy of the Declaration of Conformity (a declaration that the device complies with the UK medical devices regulations) of the medical device concerned.

Q9.2 Do you think that we should introduce the requirement set out in paragraph 9.6? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q9.3 Please outline any other requirements that should be introduced for medical devices that are subject to distance sales.

Q9.4 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 9.1-9.3, including any impacts on you or other stakeholder groups.

Section 10 - Claims

Background

10.1 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) do not include provisions on claims made about medical devices.

10.2 The following are examples of claims which can be made on medical device labels, packaging or sales materials (including on webpages and apps) in reference to a medical device:

- *"reduces symptoms of migraine in 95% of patients"*
- *"accurately predicts a person's risk of getting heart disease"*

10.3 The UK medical devices regulations could be amended to include requirements for claims made about medical devices to ensure that any such claims accurately reflect the safety, performance and intended purpose of the medical device. The objective would be to prevent misleading or unsubstantiated claims being made (whether made directly or implicitly) in order to safeguard the health and safety of patients and the public.

Possible Changes and Questions

10.4 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. Where this person is an economic operator, they would also need to follow the relevant obligations under the UK medical devices regulations (see Section 13).

Q10.1 Do you think that we should introduce the provisions set out in paragraph 10.4? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q10.2 Please provide your reasoning (including any available relevant evidence) to support your answer to question 10.1, including any impacts on you or other stakeholder groups.

Section 11 - Quality Management Systems

Background

11.1 A Quality Management System (QMS) is a system intended to ensure that the manufacturer has the appropriate infrastructure and procedures in place to consistently manufacture medical devices which meet the requirements of the Medical Devices Regulations 2002 (as amended) (UK medical devices regulations).

11.2 Currently, under the UK medical devices regulations, the manufacturer has an obligation to have a Quality Management System (QMS) in place. The UK medical devices regulations could be amended to include more detail of what should be included within a manufacturer's QMS to ensure uniformity of all manufacturer Quality Management Systems.

Possible Changes and Questions

11.3 The MHRA considers that the UK medical devices regulations could be amended to clarify that all manufacturers should have a Quality Management System in place which addresses at least the following aspects:

a. a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the medical devices covered by the system
b. identification of applicable essential requirements and exploration of options to address those requirements
c. responsibility of the management
d. resource management, including selection and control of suppliers and subcontractors
e. risk management
f. clinical evaluation, including post-market clinical follow-up (PMCF)
g. product realisation, including planning, design, development, production and service provision
h. verification of the UDI assignments
i. setting-up, implementation and maintenance of a post-market surveillance system
j. handling communication with competent authorities, Approved Bodies, other economic operators, customers and/or other stakeholders

k. processes for reporting of serious incidents and field safety corrective actions in the context of vigilance
l. management of corrective and preventive actions and verification of their effectiveness
m. processes for monitoring and measurement of output, data analysis and product improvement
n. requirements for management review
o. requirements for internal audit.

Q11.1 Do you think that we should introduce the detailed requirements for Quality Management Systems outlined in paragraph 11.3? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q11.2 Please outline any other requirements which should be included in the manufacturer's Quality Management System.

Q11.3 Do you think that all manufacturers, including Class I and general IVD manufacturers, should be required to apply an appropriate Quality Management System? ('Yes' / 'No' / 'Don't Know/No Opinion / 'Some' - please specify which aspects')

Q11.4 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 11.1-11.3, including any impacts on you or other stakeholder groups.

Section 12 - UK Responsible Persons

Background

12.1 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) introduce the concept of a UK Responsible Person (UKRP). To place a medical device on the UK market, manufacturers based outside the UK are required to appoint a single UKRP that is established in the UK (with some exceptions in relation to Northern Ireland). This ensures that there is a UK point of contact in place for medical devices on the UK market.

12.2 The UKRP acts on behalf of the non-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations (see those listed in guidance here). This includes registering the manufacturer's medical devices with the MHRA before the medical devices can be placed on the market (in line with grace periods set out in the UK medical devices regulations and summarised in the above guidance) and forwarding complaints about a medical device from the public or a healthcare professional to the manufacturer.

12.3 The UK medical devices regulations could be amended to place additional requirements on the UKRP to ensure that they can fulfil their existing obligations more effectively. The aim would be to enhance and safeguard public and patient safety. You can see more about transitional arrangements in Chapter 15 of this document.

Possible Changes and Questions

12.4 Currently, under the UK medical devices regulations, UKRPs must input an address to the registration system "at which service of any document relating in any way to the person's placing of the relevant medical device on the market will be effective". The MHRA is aware that, in some cases, persons located outside the UK have been able to act as UKRPs by uploading a "forwarding address" to the registration system. The MHRA advises in guidance that the UKRP should be "physically located" in the UK. However, we consider that amending our regulations to place an explicit legal obligation on the UKRP to provide a UK address at which they are physically located would reduce the instances of UKRPs that are physically located outside the UK attempting to register with the MHRA.

Q12.1 Do you think the UK Responsible Person should be explicitly required in the UK medical devices regulations to have an address in the UK at which they are "physically located"? ('Yes' / 'No' / 'Don't Know/No Opinion')

12.5 The UK medical devices regulations currently provide that a UK Responsible Person may be proceeded against as a person supplying or placing a device on the UK market. The MHRA considers that the Regulations could be amended to provide that the UKRP is legally liable (responsible or answerable in law) for defective medical devices **on the same basis as the manufacturer**. This would enhance public and patient safety by ensuring that there is a UK point of contact with liability for defective medical devices in cases where the manufacturer is based outside the UK.

Q12.2 Do you think the UK Responsible Person should be legally liable for defective medical devices on the same basis as the manufacturer as outlined in paragraph 12.5? ('Yes' / 'No' / 'Don't Know/No Opinion')

12.6 The UK medical devices regulations currently set out that the UK Responsible Person must provide the MHRA with written evidence that they have the manufacturer's authority to place a medical device on the market. The MHRA considers that the UK medical devices regulations could set out what is to be included as part of this written evidence. For example, it could require that it is in the form of a legal contract which should include:

a. a statement that the UKRP is exclusively acting for the manufacturer, and
b. the mandatory tasks that the UKRP is required to undertake on behalf of the manufacturer (the tasks of the UKRP currently set out in the UK medical devices regulations and in our guidance).

12.7 The MHRA also considers that the UK medical devices regulations could require the manufacturer to draw up a 'changeover agreement' in the event that they are changing their UKRP. This could be an agreement between the manufacturer, the incoming UKRP and the outgoing UKRP. The UK medical devices regulations could require the agreement to cover at least the following:

a. the date of termination of the legal contract of the outgoing UK Responsible Person and the commencement date of the legal contract of the incoming UK Responsible Person
b. the date until which the outgoing UK Responsible Person may be indicated in the information supplied by the manufacturer, including any promotional material
c. the transfer of documents, setting out the obligation of the outgoing UK Responsible Person, once their mandate has expired, to forward to the manufacturer or incoming UK Responsible Person any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device.

Q12.3 Do you think the UK medical devices regulations should include a requirement for manufacturers and UK Responsible Persons to draw up a legal contract as outlined in paragraph 12.6? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q12.4 Do you think that the UK medical devices regulations should include the requirement for manufacturers to draw up a changeover agreement when changing their UK Responsible Person as set out in paragraph 12.7? ('Yes' / 'No' / 'Don't Know/No Opinion')

12.8 Currently, UK Responsible Persons are required to keep available for inspection by the MHRA: a copy of the manufacturer's technical documentation, Declaration of Conformity, and if applicable a copy of the relevant certificate including any amendments or supplements for 15 years (for implantable medical devices) or 5 years (for other device classes).

12.9 The MHRA considers that the UK medical devices regulations could be amended to require the UKRP to keep, in relation to implantable and non-implantable devices, copies of these documents for an alternative time period (as set out in questions 12.5 and 12.6 below). The UK medical devices regulations could also require the UKRP to keep this documentation for the same time period in circumstances where the manufacturer has ceased activity - for example due to liquidation. This would aid the MHRA's investigations of a medical device in cases where the manufacturer is no longer in operation.

Q12.5 What time-period should be specified for the retention of technical documentation relating to implantable devices by the UK Responsible Person?

a. 11-15 years after the last product has been manufactured
b. 16-20 years after the last product has been manufactured
c. for the expected lifetime of the device, after the last product has been manufactured
d. Other (please specify)

Q12.6 What time-period should be specified for the retention of technical documentation relating to non-implantable devices by the UK Responsible Person?

a. 1-5 years after the last product has been manufactured

b. 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)

Q12.7 Do you think the UK medical devices regulations should introduce an obligation on UK Responsible Persons to retain documentation in cases where the manufacturer has ceased activity? ('Yes' / 'No' / 'Don't Know/No Opinion')

12.10 The MHRA considers that the UK medical devices regulations could be amended to require UKRPs to have permanently and continuously at their disposal, (available for contact at all times), at least one Qualified Person (see Section 14). This would be a person with a minimum level of qualifications or regulatory experience, who would be responsible for providing regulatory advice to the UKRP so that the UKRP is better equipped to meet the regulatory requirements of the UK medical devices regulations (see Section 14 for further information). The objective would be to ensure that the UKRP has access to appropriate expertise to assist them in fulfilling their obligations.

Q12.8 Do you think UK Responsible Persons should be required to have at least one Qualified Person that is permanently and continuously at their disposal as set out in paragraph 12.10? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q12.9 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 12.1-12.8, including any impacts on you or other stakeholder groups.

Section 13 - Obligations of importers and distributors

Background

13.1 The UK medical devices regulations provide that where an importer places a device on the Great Britain market, their registered place of business in Great Britain must have been provided to the MHRA by the relevant manufacturer or UK Responsible

Person (UKRP). The UK medical devices regulations do not currently set out any further requirements for importers.

13.2 The UK medical devices regulations do not currently define the term 'distributor' and do not place any specific obligations on distributors of medical devices.

13.3 The MHRA considers that the UK medical devices regulations could set out requirements for medical device importers and distributors to improve device traceability and ensure the safe supply of medical devices to the UK market.

Possible Changes and Questions

13.4 The MHRA considers that the UK medical device regulations could be amended to introduce a number of obligations on importers and distributors including requirements to:

a. keep documentation records for the medical device for a specified time period
b. ensure safe storage and transport of medical devices
c. ensure medical devices are appropriately labelled and have been assigned a UDI in accordance with Chapter 4, Section 19
d. inform the MHRA / manufacturer / UKRP (as applicable) of a medical device which does not meet the requirements of the UK medical devices regulations and remove that medical device from the market or refrain from placing that medical device on the market or distributing or supplying the medical device
e. inform the manufacturer of complaints about their medical device(s) e.g. from the public/private or healthcare professionals, NHS etc
f. cooperate with the MHRA during MHRA investigations of potentially unsafe medical devices
g. ensure that the end user does not receive a medical device which has passed its expiry date
h. inform the manufacturer or the manufacturer's UK Responsible Person that they intend to import the device (importers only)
i. provide information about themselves to the MHRA (please see Chapter 4, Section 21 on registration)
j. have an appropriate Quality Management System in place
k. provide their details on the medical device packaging or a document accompanying the medical device e.g. an invoice for the medical device or its instructions for use (importers only).

Q13.1 Do you think that importers and distributors should be required to meet the requirements outlined in paragraph 13.4? ('Yes' / 'No' / 'Don't Know/No Opinion'/ 'Partial' – please specify which options)

Q13.2 Please outline any other requirements which should be introduced for importers and distributors.

13.5 The MHRA considers that fulfilment service providers could be regarded as importers under the UK medical devices regulations. Fulfilment service providers are

companies / organisations carrying out the warehousing, packaging, addressing and dispatching of medical devices, excluding postal services. For example, medical devices sold online may be warehoused by a fulfilment service provider who will then address and dispatch the medical device when it is purchased.

Q13.3 Do you think that fulfilment service providers should be regarded as importers under the UK medical devices regulations? ('Yes' / 'No' / 'Don't Know/No Opinion')

13.6 The MHRA considers that the UK medical devices regulations could be amended to require economic operators (including manufacturers, importers and distributors) to inform the MHRA if they are aware of any issues that will interrupt supply / cause a shortage of medical devices on the UK market. This could include, for example, shortages of critical components, operational issues at factories or supplier plants arising from floods or earthquakes, or quality issues requiring recall or rework.

Q13.4 Do you think that economic operators should be required to inform the MHRA if they are aware of any issues that will interrupt supply / cause a shortage of medical devices on the UK market, as set out in paragraph 13.6? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q13.5 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 13.1-13.4, including any impacts on you or other stakeholder groups.

Section 14 - Qualified Persons

Background

14.1 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) do not include any requirements for manufacturers to appoint a Qualified Person. The Qualified Person would sit within the manufacturer's organisation and would be required to have a minimum level of relevant qualifications or experience. They would be responsible for supporting the manufacturer's regulatory compliance with requirements of the UK medical devices regulations, including requirements around the Quality Management System and the post-market surveillance system (monitoring the medical device once it's on the market – see Chapter 8)

14.2 The MHRA has historically provided advice to manufacturers that have limited understanding of their regulatory requirements under the UK medical devices regulations. The MHRA considers that introducing a requirement for manufacturers to have access to a Qualified Person would provide additional support to manufacturers over and above that provided by the MHRA.

Possible Changes and Questions

14.3 The MHRA considers that the UK medical devices regulations could be amended to require that manufacturers have available within their organisation at least one Qualified Person with qualifications or regulatory experience that exceeds minimum standards that would be set out in the UK medical devices regulations in the field of medical devices / *in vitro* diagnostic medical devices. This could include, for example, a formal qualification in law, medicine, pharmacy, engineering or another relevant scientific discipline, or sufficient professional experience in regulatory affairs or in Quality Management Systems relating to medical devices.

Q14.1 Do you think manufacturers should be required to have at least one Qualified Person available within their organisation as set out in paragraph 14.3? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q14.2 What qualifications and / or experience should the Qualified Person have in order to be eligible for this role?

14.4 The MHRA considers that small and medium enterprises (SMEs) could be excluded from this requirement and instead be required to have a Qualified Person "permanently and continuously at their disposal" (available for contact at all times).

Q14.3 Do you think that small and medium enterprises (SMEs) should be excluded from this requirement and instead be required to have a Qualified Person permanently and continuously at their disposal? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q14.4 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 14.1-14.3, including any impacts on you or other stakeholder groups.

Section 15 - Cases in which obligations of manufacturers apply to other economic operators

Background

15.1 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) do not clearly set out cases in which the obligations of manufacturers should or should not apply to importers, distributors or other economic operators.

15.2 For example, the following scenarios are not explicitly covered in the UK medical devices regulations:

- Whether an importer of a medical device who modifies that device so that it performs differently to what was intended by the original device manufacturer, should be considered the new manufacturer of that device.
- Whether an importer who modifies the packaging of a medical device (for example to make it fit on a shelf more easily) without affecting the medical device itself should be required to meet any obligations under the Regulations.

15.3 The UK medical devices regulations could be amended to set out more clearly, the circumstances in which economic operators other than the manufacturer, such as importers, are required to take on the obligations of a manufacturer, and to specify which requirements they should follow.

15.4 The objective of this would be to ensure that, where medical devices have been modified by a person who is not the manufacturer of that medical device, appropriate actions have been undertaken to safeguard the health and safety of patients and the public.

Possible Changes and Questions

15.5 The MHRA considers that the UK medical devices regulations could be amended to further clarify the circumstances in which an economic operator, such as an importer, would be required to take on the responsibilities of the manufacturer. This could include, for example, circumstances in which the economic operator:

a. changes the intended purpose of a medical device;
b. modifies a medical device in such a way that compliance with the applicable requirements of the UK medical devices regulations may be affected.

Q15.1 Do you think that the circumstances in which an economic operator other than the device manufacturer would be required to assume the responsibilities of the manufacturer should be clarified, as set out in paragraph 15.5? ('Yes' / 'No' / 'Don't Know/No Opinion')

15.6 The MHRA considers that the UK medical devices regulations could be amended to clarify the circumstances in which an economic operator would not be required to take on the responsibilities of a manufacturer. This could include, for example, cases where the economic operator:

a. translates the information accompanying a medical device into English
b. changes the medical device's outer packaging without affecting the condition of the medical device itself.

Q15.2 Do you think that the UK medical devices regulations should be amended to clarify the circumstances in which an economic operator would not be required to take on the responsibilities of a manufacturer, as set out in paragraph 15.6? ('Yes' / 'No' / 'Don't Know/No Opinion')

15.7 The MHRA considers that the UK medical devices regulations could outline the requirements that economic operators would need to meet in circumstances where:

- they have made a modification to a device, and
- they have not taken on the obligations of the manufacturer under the UK medical devices regulations

For example, relevant economic operators could be required to:

a. affix their name onto the packaging or in an accompanying document
b. inform the manufacturer and the MHRA of the modification
c. provide samples of the modified packaging or medical device information to the MHRA
d. implement an appropriate Quality Management System (see Section 11) which would need to be audited by an Approved Body (see Chapter 5).

Q15.3 Do you think that the UK medical devices regulations should outline the requirements that economic operators would need to meet in circumstances where they have made a modification, without taking on the obligations of the manufacturer, as set out in paragraph 15.7? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q15.4 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 15.1-15.3, including any impacts on you or other stakeholder groups.