MHRA consultation on the future regulation of medical devices in the United Kingdom – November 2021

About us

As the professional representative organisations for eye care providers registered optometrists, contact lens opticians, dispensing opticians, and ancillary staff in the UK, we have three overarching objectives in respect of medical devices regulation:

a) patient safety which is paramount

b) patient access to the widest possible range of safe devices to meet individuals' needs

c) keeping costs of regulatory burdens to the minimum proportionate to risk and consistent with a) and b).

We would therefore argue for:

- the simplest regulatory system possible (commensurate with risk) which is easy for manufacturers, importers, and distributors to apply
- avoidance of any duplication in regulation e.g. that retail opticians are not inadvertently drawn into replicating regulatory requirements already fulfilled by manufacturers, importers or distributors and thus adding unnecessary costs to primary eye care for the NHS and patients.

Summary

We are responding only to specific overarching questions in this first round consultation. We look forward to being involved in future work the MHRA undertakes to ensure safe and proportionate regulation of medical devices, including relatively low risk devices such as spectacle frames and contact lenses in the United Kingdom.

Our response

On a scale of 1 – 5, how would you describe your level of expertise in the regulation of medical devices? *

Where 1 = nil to little expertise and 5 is high level of medical device expertise (relevant industry experience or training on the topic of medical device regulation)

- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ◉ 5
- ○ Prefer not to say

Please select the areas of the consultation that you are interested in responding to:

- [x] Chapter One: Scope of the Regulations
- [x] Chapter Two: Classification
- [x] Chapter Three: Economic Operators
- [x] Chapter Four: Registration and UDI
- [x] Chapter Five: Approved Bodies
- [x] Chapter Six: Conformity Assessment
- [x] Chapter Seven: Clinical Investigations / Performance Studies
- [x] Chapter Eight: Post-market Surveillance and Vigilance
- [ ] Chapter Nine: In vitro Diagnostic Medical Devices
- [x] Chapter Ten: Software as a Medical Device
- [ ] Chapter Eleven: Implantable Devices
- [x] Chapter Twelve: Other Product-Specific Changes
- [x] Chapter Thirteen: Environmental sustainability and public health impacts
- [x] Chapter Fourteen: Routes to Market
- [x] Chapter Fifteen: Transitional Arrangements
- [x] Chapter Sixteen: Feedback
- [ ] Chapter Seventeen: Questions for members of the general public

For more detail about these areas, please see Overview of Content (link in foot

Chapter 1: Scope of the Regulations

Q1.1 Do you think the scope of the UK medical devices regulations should be expanded to include the additions suggested above?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q1.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 1.1-1.2, including any impacts on you or other stakeholder groups.

Although fluorescein is correctly classified as a medicine for diagnostic purposes when injected into the body by a doctor, fluorescein-impregnated paper strips, when used by optometrists and contact lens opticians in the optical sector, are only used for staining in contact lens practice. In our view, this means they should continue to be classified as dual-purpose Class I medical devices.

In Europe, this is being achieved by dual classification depending on use and it is vital for primary eye care in the UK that some similar solution is achieved. Otherwise, the manufacture of paper strips will cease to be viable, which will have a detrimental effect on contact lens fitting and wear and increase risks to patients.

Q1.4 Should we make clear that 'intended purpose' is to be construed objectively and that key materials such as a manufacturer's technical documentation may be used as evidence of intended purpose?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q2.1 Do you think the scope of the UK medical devices regulations should be broadened to include devices without a medical purpose with similar risk profiles to medical devices?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q2.2 Please provide your reasoning for your response to question 2.1.

The scope of the UK medical devices regulations should be expanded to include non-prescription contact lenses as these have the same risk profile as prescription contact lenses. This is not, however, necessary for non-prescription ophthalmic lenses which are already adequately regulated as personal protective equipment. Bringing non-prescription contact lenses within scope will also ensure that these products are fitted by a registered optical professional so that patient safety protocols are followed and clinical advice about safe use reinforced. However, this is not necessary for non-prescription ophthalmic lenses which are already regulated as personal protective equipment.

Q2.3 If you have answered 'yes' to question 2.1:

a. please outline which products from the list at paragraph 2.3, and any others, you consider should be brought into scope of the UK medical devices regulations.

Non-prescription contact lenses or other items intended to be introduced into or onto the eye for cosmetic rather than medical purposes, including those which contain software e.g. coloured lenses, cosmetic iris implants.

b. please describe how these products should be assessed to ensure that they are safe and perform as intended.

We have no expertise in this area.

c. please outline how you think these products should be classified (for example, whether they should be classified in line with medical devices that have similar functions and risks).

They should be classified in line with medical devices that have similar functions and risks

Q2.4 Do you think that manufacturers of the products listed at paragraph 2.3 should be required to register them with the MHRA? (see Chapter 4, Section 21 for further information on registration requirements)

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q2.5 Please provide any other comments you wish to make about the possible regulation of products without a medical purpose as medical devices and your reasoning (including any available relevant evidence) to support your answers to questions 2.1-2.4. Please include any

impacts on, and implementation considerations for, you or other stakeholder groups.

We have expertise in the area of eye care. Please see our response to Q.2.2

Q3.1 Do you think that products which contain viable biological substances should be excluded from the scope of the UK medical devices regulations?

☐ Yes

☐ No

☐ I Don't Know

☒ No Opinion

Q3.2 Please provide your reasoning (including any available relevant evidence) to support your answer to question 3.1, including any impacts on you or other stakeholder groups.

We have no expertise in this area.

Q4.1 Do you think that food should be excluded from the scope of the UK medical devices regulations?

☐ Yes

☐ No

☐ I Don't Know

☒ No Opinion

Q4.2 Please provide your reasoning (including any available relevant evidence) to support your answer to question 4.1, including any impacts on you or other stakeholder groups.

We have no expertise in this area.

Chapter 2: Classification (page 32 on full document)

Q5.1 Do you think the classification rules for general medical devices in the UK medical devices regulations should be amended in any or all of the ways set out in paragraphs 5.8-5.10?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q5.2 If you have answered 'yes' to question 5.1, please specify which of the amendments should be made.

We agree that the "scrutiny a medical device receives should be commensurate with the level of risk that the device presents" and believe that the current Classifications are appropriate to risk in the cases of spectacles (Class I), contact lenses (Class IIa and solutions IIb).

Q5.3 Please outline any other amendments which should be made to the classification rules (including implementing rules and related definitions}.

Not applicable

Q5.4 Please provide your reasoning (including any relevant evidence} to support your answer to questions 5.1-5.2, including any impacts on you or other stakeholder groups.

Not applicable

Chapter 3: Economic Operators (page 35 on full document)

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

☐ I 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.

Instructions for Use (IFUs) should be permitted in electronic form (e-IFUs). This will enable more detailed and up to date information to be included (and subsequently updated). e-IFUs can be accessed on any electronic device, at any time, in multiple languages anywhere in the world. Paper-based IFUs are often discarded along with packaging immediately after purchase - leaving the patient without any on hand guidance or means of seeking guidance.

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.

It is essential that any requirements are proportionate to the risk of the specific device and s important for the MHRA to strike the right balance between essential safety requirements and over-regulation.

We do not believe that changes are necessary for Class 1 devices for example, for spectacles. Such a requirement would be disproportionate.

Equally, in respect of contact lenses (the Class II devices used in primary eye care), the essential requirements are already sufficient. Their purpose is self-evident and does not require labelling. Given that there is already limited space on labelling, every extraneous requirement would constrain this further especially for manufacturers who sell into multiple markets or who are not UK based. We would ask that the MHRA be mindful of this and limit labelling to the essential minimum for categories of device. However, we would support the requirement in para 6.4 (c) that device packaging or IFUs should make clear when a user should consult a healthcare professional. This s is what UK contact lens manufacturers already do.

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

☐ I 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.

We would not support blanket approach but rather one which is correlated with genuine risk.

For instance, spectacles are low-risk medical devices which would not require manufacturers' cover and the consequence of requiring them to do so would simply be to drive up cost for little, if any, tangible benefit for the patient. Eye care professionals already hold professional 'medical malpractice' insurance to protect patients and manufacturers insurance would simply duplicate this, adding to costs

Similarly contact lens fitting is a skilled clinical exercise requiring high levels of training, experience and expertise which is again covered by professional indemnities. There is no evidence that further insurance is required beyond current arrangements.

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

☐ I 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.

'Health institutions' is a catch-all and so should be defined and exclusions spelt out to avoid inappropriate inclusion or exclusion.

For example, if the term 'health institutions' were to include optical practices, these should be exempt from the medical devices obligations which apply to manufacturers. importers and distributors to avoid duplication and unnecessary costs – in line with Better Regulation principles.

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

☐ I Don't Know

☐ No Opinion

Q8.4 Do you think that 'in house' manufactured devices should be exempt from UKCA marking requirements?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

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

☐ I 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.

As 'health institutions' is a catch-all, it should be defined and exclusions spelt out. If the term 'health institutions' were to include optical practices, spectacle assembly where two existing devices (frames and lenses which are designed only to work in combination) are adapted to an individual's bespoke requirements – and subsequent adjustments and repairs should be excluded from any definition of inhouse manufacture.

On Q8.4, 'Yes' for mass produced devices but 'no' for bespoke 'custom made' products produced for a specific individual.

On Q8.5, Please see our answers to Qs 8.1-8.4

On Q8.6, please see our answers to Q 8.4.

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

☐ I Don't Know

☐ No Opinion

Q8.8 Do you think that health institutions should be required to register clinical investigations/ performance studies with the MHRA?

☐ Yes

☒ No

☐ I 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.

On Q8.7, No please see our answers to Q8.1- 8.4.

On Q8.11, No please see our answers to Q8.1- 8.4.

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?

No opinion

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

☐ I Don't Know

☐ No Opinion

Q9.2 Do you think that we should introduce the requirement set out in paragraph 9.6?

☒ Yes

☐ No

☐ I 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.

Contact lenses sold by distance selling should:

- only be sold in accordance with the contact lens specification issued by the original registered healthcare professional (contact lens optician, optometrist, medical practitioner)
- include instructions on how to access an e-IFU
- include instructions on handling, hygiene, duration of use, provisions for aftercare and when to contact a healthcare practitioner (see our response to Q.6.1)
- where equivalence to the device listed in the contact lens specification is claimed, it should be equivalent' to the original manufacturer's medical device (on a biological, physical, and clinical basis) - otherwise MHRA should prohibit substitution (as in the USA) except by a qualified optometrist, contact lens optician or medical practitioner, using their clinical knowledge and skills, and with the patient's informed consent, so that suppliers cannot play off one jurisdiction against another

- not be supplied by a supplier registered only in a separate country where supplies can effectively bypass the national law of the UK, undermining patient safety
- only be supplied by a supplier which makes its records available to MHRA only be supplied by a supplier listed on the MHRA website as meeting these requirements to enable patients to make informed choices about safety.

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.

It is important that medical devices sold online comply with all relevant UK legislation including medical devices regulations, but it would be helpful to have more information about how this will be enforced if the distance seller is based outside the UK. Further detail about how the MHRA's enforcement powers and capacity to ensure protection for patients in such cases would be helpful.

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

☒ Yes

☐ No

☐ I 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.

We agree the UK medical devices regulations should be amended as proposed 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 about the purpose, safety, or performance of medical devices. These obligations exist in other UK legislation and should explicitly cover medical devices. However, this would need to be assessed in a clear and objective manner to ensure fairness (to UK manufacturers) and consistency. Again, it is not clear how this will be enforced against distance sellers based outside UK.

Q11.1 Do you think that we should introduce the detailed requirements for Quality Management Systems outlined in paragraph 11.3?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

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.

Once again proportionality is key. Existing UK quality management systems (QMS) for the relatively low risk devices and solutions used in primary eye care already function effectively and protect patients well. Typically, UK manufacturers will have a QMS accredited to ISO 9001, having been externally assessed against the standard, though not necessarily by one of the approved bodies listed by the MHRA as there are currently only three of these.

In our view the MHRA proposals are overly detailed and onerous for these kinds of devices. It is hard to see any compelling reason for such requirements in respect of Class 1 devices and for Class II and III devices the MHRA should instead require manufacturers to comply with a QMS that follows the requirements of the National Standard i.e. BSENISO 13485 and is externally validated by a company registered with UKAS.

To introduce a list of requirements that will inevitably change over time at this end of the devices spectrum would be disproportionate and out of step with International Medical Regulators Forum (IMDRF) principles.

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

☐ I Don't Know

☐ No Opinion

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

☐ I Don't Know

☐ No Opinion

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

☐ I 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

☐ I Don't Know

☐ No Opinion

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)

We do not have expertise in implantable devices.

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)

It would be logical to mirror the retention period required of UK manufacturers, both for ease of document control and to achieve the same purposes.

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

☐ I Don't Know

☐ No Opinion

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

☐ I 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.

We share the views of the UK optical manufacturing bodies that making the responsible person (UKRP) legally responsible is an unnecessary burden which may discourage UK RPs, and hence lead to a barrier against providing devices into the UK market.
As far as contracts between manufacturers and UKRPs are concerned, it would be helpful to know the minimum requirements for a written agreement, as some applications are currently rejected on this basis. A changeover agreement would provide security to UK RPs in the case of any issues subsequently arising.

Q13.1 Do you think that importers and distributors should be required to meet the requirements outlined in paragraph 13.4?

☐ Yes

☐ No

☐ I Don't Know

☐ No Opinion

☒ Partial

If you have selected 'partial', please specify which options

It is right that importers and distributors should comply with the regulations. However, the proposed requirements are unduly onerous for custom-made, Class I, Class II and non-implantable devices. Low risk optical devices which should be exempt from UDI requirements.

It is important for the MHRA to ensure that Importer, distributor, and fulfilment service providers rules should inadvertently be extended to apply to optical retailers who are regulated by other healthcare and retail legislation. This would be unnecessary duplication without any benefits to patient safety and contrary to Better Regulation principles.

Q13.3 Do you think that fulfilment service providers should be regarded as importers under the UK medical devices regulations?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

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

☐ I 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.

As in our response to Q13.1, importers and distributors of Class I, Class II and non-implantable low risk optical devices should not be required to meet same level of obligations as for higher risk devices. Whilst, in principle, informing the MHRA of supply interruption seems a sensible approach, if adopted, it must be proportionate to the scale of risk of interrupted supply and the likely volumes involved.

Again, as in our response to Q13.1. importer, distributor, and fulfilment service provider rules should not apply to optical retailers who are regulated by other healthcare and retail legislation.

Re Q13.4, economic operators should not be required to inform the MHRA if they are aware of any issues that will interrupt supply/ cause a shortage of medical devices except in cases where this is likely to lead to serious harm of death. Again, proportionality is key and 'nice to have' requirements need to be set against the risks of burdens on business and costs to the NHS and consumer.

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

☐ I 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?

Further to our response to Q14.1, a blanket requirement for all manufacturers to have a Qualified Person available within their organisation with the qualifications and/ or experience outlined in paragraph 14.3, is not proportionate to risk. For Class 1 devices this requirement would be excessive.

For Class II and non-implantable low risk optical devices, manufacturers following a QMS to the BS13485 standard will already have demonstrated suitable qualifications for positions of regulatory oversight.

The MHRA should follow other international/ non-UK requirements in this regard to avoid placing conflicting/ excessive burdens on UK manufacturers.

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

☐ I 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.

If the proposal, which we do not support, were to go ahead, we agree that SMEs should be excluded. These businesses typically have fewer resources and less capacity than larger manufacturers and need a more flexible approach. Imposing such a requirement on SMEs – or other businesses which produce low risk devices - would not be proportionate, and by imposing an unnecessary regulatory cost burden, would inevitably reduce innovation and customer choice.

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

☐ I Don't Know

☐ No Opinion

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

☐ I Don't Know

☐ No Opinion

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

☐ I 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.

Further to Q15.1, an importer should only be required to take on the responsibilities of a manufacturer in the circumstances specified in paragraph 15.5. As with our responses to Q14.1 and 14.2, the approach should be risk based and proportionate and hence not apply to Class I products.

Further to Q15.2, we agree the MHRA should clarify when an economic operator would **not** be required to take on the responsibilities of a manufacturer. One obvious exemption would be optical retailers who are regulated by other healthcare and retail legislation.

Further to Q15.3, the approach must be proportionate, and risk based and the MHRA should avoid adding bureaucracy to an already well functioning system.

In respect of QMS audit certification and conformity assessments for Class I and Class II devices, the MHRA should accept certification from bodies that are not on its list of Approved Bodies (of which there are only three), as there is currently insufficient Approved Body capacity to meet demand. This is resulting in long waiting lists for assessments which is having a detrimental impacting on UK market entry, delaying products that would benefit patients, and adding costs to UK businesses.

Chapter 4: Registration and UDI (page 52 on full document)

Q17.1 Do you think the UK medical devices regulations should include the requirements set out in paragraph 17.1 for economic operators to ensure traceability of medical devices?

☐ Yes

☒ No

☐ I Don't Know

☐ No Opinion

Q17.3 If we were to introduce a requirement for economic operators to be able to track the supply of medical devices, and to keep the records pertaining to that for a specific time period (as set out under paragraphs 17.3 and 17.4 above), what time period should be specified?

If the MHRA were to introduce such a requirement for economic optical operators other than manufacturers, distributors, and fulfilment service providers - which we do not support – retention limits should not exceed shelf-life plus lifetime of the device.

Q17.4 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 17.1-17.3, including any impacts on you or other stakeholder groups.

Further to Q17.1, existing traceability systems have worked well for optical devices and public protection for many years, e.g. for contact lens and solutions batch recalls, and we do not feel that collecting this level of information for Class I, Class II and non-implantable devices low risk optical devices from operators other than manufacturers, distributors and fulfilment service providers, is either necessary or desirable in patient protection terms. It would simply add to costs on the eye care frontline without public benefit.

Whilst traceability is important for high-risk devices, and in particular implantable devices, the proposals are not appropriate or proportionate to lower risk Classes of device. Spectacle frames and ophthalmic lenses are low risk devices. They are also high volume, with around half the population wearing spectacles. Attempting to ensure traceability of every pair of spectacles would be a huge bureaucratic burden for manufacturers and distributors with no actual benefits. It would also overwhelm any registration system the MHRA chose to set up.

Regulatory bodies in the US and EU have already struggled to build systems that can cope with the vast numbers of permutations of product associated with optical devices.

At present, spectacles and contact lenses can be traced through labelling and barcodes on the product box or similar means, and this works very well in terms of patient protection in the cases of Class I and II products.

Introducing additional requirements, when the UK already has robust traceability systems in our sector, would not enhance patient safety but would have a significant adverse impact on businesses costs. The new regulations should carry across what is already successful and has been shown to work in the UK.

We strongly recommend that high volume, low risk devices such as spectacles and contact lenses (i.e. custom made, Class IIa, Class IIb and non-implantable products) remain exempt from UDI, UDI-DI, and UDI-PI requirements as now.

Q18.2 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 18.1-18.2, including any impacts on you or other stakeholder groups.

This is not an area where we have expertise although we would suspect that for optical manufacturers (and retailers) who operate internationally the GMDN, which is familiar and already widely used, would be the better option.

Q19.1 Do you think that the UK medical devices regulations should include a definition of the term 'Unique Device Identifier'?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q19.2 If you answered 'yes' to question 19.1, please outline what you think should be included in this definition.

The regulations should include a definition of the term 'Unique Device Identifier' to avoid confusion and align with EU MDR.

The definition should make clear how the UDI is allocated and to what classes of device. It would be sensible to follow the approach already developed by the EU for the EUMDR 2017, but the MHRA should take note of the fact that this has taken several years to develop and is still not fully in place.

However, a blanket requirement for all medical devices to have a UDI is not proportionate to risk.

We do not therefore support UDI or UDI-DI for low-risk Class I and II devices. Please see our responses to Q.17.1 and 17.4.

Q19.3 Do you think the UK medical devices regulations should require manufacturers to assign UDIs to medical devices before they are placed on the market?

☐ Yes

☒ No

☐ I Don't Know

☐ No Opinion

Q19.4 If you have answered 'yes' to question 19.3, please outline any particular requirements which should be introduced in regards to how UDIs should be applied to medical devices and any aspects which require clarification.

As we have explained in our responses to Q.17.1 and 17.4, the requirement for UDI should not apply to custom made, Class IIa, Class IIb and non-implantable optical devices.

With the vast array of medical devices covered by the legislation, it will be all but impossible to determine a system that is appropriate for all devices, and which would be efficient. We would strongly advise that where there are no current issues in device identification and traceability, as in primary eye care, UDI should not be considered as an option.

Where a UDI is required e.g. for high-risk devices, it makes sense for this to follow what is planned for the MDR. Adding two separate UDIs alongside all other required information would be highly impractical and confusing in many cases.

Q19.5 Should devices that are reusable bear a UDI carrier (e.g. barcode) that is permanent and readable after each process on the device itself?

☐ Yes

☐ No

☐ I Don't Know

☒ No Opinion

Q19.6 Please outline whether you think there should be any exceptions to this rule and please provide examples and reasoning.

An exception should be made for devices which are already easily traceable from currently available information (e.g. contact lenses where the device labelling/LOT number refers to a single device only. Moreover, for small low risk devices such as contact lenses it is difficult to add additional data items to the packaging.

Q19.7 Should the UK medical devices regulations include requirements for Basic UDI-DI to identify medical device models?

☐ Yes

☒ No

☐ I Don't Know

☐ No Opinion

Q19.8 Do you think manufacturers should be required to assign and apply UDIs to their medical devices before applying to Approved Bodies for conformity assessment?

☐ Yes

☐ No

☐ I Don't Know

☒ No Opinion

Q19.9 Do you think the UK medical devices regulations should stipulate that the UDI or Basic UDI-DI of a medical device should be provided in the circumstances set out in paragraph 19.12?

☐ Yes

☐ No

☐ I Don't Know

☒ No Opinion

Q19.11 Do you think that certain medical devices should be exempt from the UDI requirements?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q19.12 If you have answered 'yes' to question 19.11, please outline what medical devices should be exempt.

We consider, based on experience, that low-risk, high volume products, such as spectacles and prescription contact lenses, should be exempt from both UDI and UDI-DI. Practice Management Systems (PMS) in optical practices already provide good protection for patients, tracing and recalling faulty products immediately. There is no logical reason to change this approach. We would strongly advise therefore the continuing exclusion of Class I (spectacles) devices and contact lenses and solutions (Class II) from UDI.

Q19.13 Should manufacturers of custom-made devices be required to assign a unique serial number to the device?

☐ Yes

☒ No

☐ I Don't Know

☐ No Opinion

Q19.15 Do you think manufacturers should be required to keep an up-to-date list of all UDIs they have assigned to medical devices as part of the technical documentation?

☐ Yes

☐ No

☐ I Don't Know

☒ No Opinion

Q19.17 Do you think economic operators should be required to store the UDI numbers of certain medical devices?

☐ Yes

☐ No

☐ I Don't Know

☒ No Opinion

Q19.18 If you have answered 'yes' to question 19.17, please select which groups of medical devices should fall under this requirement:

☐ a. all implantable medical devices

☐ b. Class III implantable medical devices

☐ c. Class IIb implantable medical devices

☐ d. Other - please specify

☒ e. don't know/no opinion

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

☐ Yes

☐ No

☐ I Don't Know

☒ No Opinion

Q19.20 If you have answered 'yes' to question 19.19, please outline what types / risk classification of medical devices should fall under this requirement.

☐ a. all implantable medical devices

☐ b. Class III implantable medical devices

☐ c. Class IIb implantable medical devices

☐ d. Other - please specify

☒ e. don't know/no opinion

Q19.21 Do you think that the UK medical devices regulations should introduce new rules for the UDI system, to provide clarity?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q19.22 If you have answered 'yes' to question 19.21 please outline what rules the UK medical devices regulations should include in regard to the UDI system.

They should specify which classes of device are exempt from UDI requirements.

Q19.23 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 19.1-19.22, including any impacts on you or other stakeholder groups.

Please see our responses to Qs19.2, 19.4 and 19.12.

Q20.1 Do you think that we should introduce the proposal outlined in paragraph 20.1?

☐ Yes

☒ No

☐ I Don't Know

☐ No Opinion

Q20.2 Please provide your reasoning (including any available relevant evidence) to support your answer to question 20.1, including any impacts on or implementation considerations for you or other stakeholder groups.

While this might be necessary for high-risk devices, it would be unnecessary for lower risk devices such as Class 1, Class IIa, Class IIb and non-implantable optical devices. The volumes involved would simply overwhelm any database established, making it less useful for the safety purposes intended.

Q21.1 Do you think manufacturers should be required to provide the information in List One (at end of this Section) to the MHRA upon medical device registration?

☐ Yes

☒ No

☐ I Don't Know

☐ No Opinion

☐ Some

If you have selected 'some', please specify which aspects

Q21.2 Please specify any changes proposed and your rationale in relation to question 21.1.

This seems excessive for low-risk devices. There is no evidence we are aware of that the current guidance route is not effective.

Q21.3 Which of the following entities should be permitted to submit device registration information to MHRA (select all that apply):

☒ a. UKRPs and UK-based manufacturers (current requirement)

☒ b. non-UK based manufacturers

☒ c. authorised third party submitters

☐ d. other - please specify

It seems logical that (a), (b) and (c) above should all be permitted to submit data if they deem it appropriate to do so for the purposes of patient safety.

Q21.4 What mechanisms should be in place to submit data?

☐ a. web form

☐ b. machine-to-machine (e.g. HL7 etc)

☐ c. other - please specify

No opinion

Q21.5 Please outline the timeframes that you think should apply to this additional registration information.

No opinion

Q21.6 Should the information that the MHRA gathers at the point of medical device registration be made publicly available via a website or similar platform?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q21. 7 If you have answered 'yes' to question 21.6, please outline what information should be shared and provide your rationale and key considerations or limitations (please note sharing of information would be subject to UK GDPR requirements).

Any information which is relevant to patient safety, subject to UK data protection/GDPR requirements.

Q21.8 Do you think the UK medical devices regulations should include a requirement for manufacturers to register with the MHRA before applying to an Approved Body for conformity assessment and for the Approved Body to verify this registration?

☐ Yes

☒ No

☐ I Don't Know

☐ No Opinion

Q21.9 Should economic operators be given up to 30 days to update an MHRA registration record after a change has been made to a device's registration details?

☐ Yes

☐ No

☐ I Don't Know

☒ No Opinion

Q21.10 Please provide reasoning to support your answer to question 21.9.

We have no expertise in this area.

Q21.11 Do you think the UK medical devices regulations should include a requirement for economic operators to confirm all data submitted in their registration one year after submission and then every second year thereafter?

☐ Yes

☐ No

☐ I Don't Know

☒ No Opinion

Q21.12 How should economic operators be identified within the MHRA registration system?

☐ a. MHRA generated reference number (not internationally recognised)

☐ b. DUNs (internationally recognised external reference)

☐ c. GLN (internationally recognised external reference)

☐ d. other (please specify)

We have no expertise in this area.

Q23.1 Do you think the UK medical devices regulations should place more stringent requirements on Approved Bodies as set out in paragraph 23.3?

☐ Yes

☒ No

☐ I Don't Know

☐ No Opinion

Q23.2 Please outline any other requirements which should be introduced for Approved Bodies.

We have no evidence that UK Approved Bodies need more stringent requirements in respect Class IIa, Class IIb and non-implantable optical devices.

We understand from manufacturers that approved body auditing can sometimes lose perspective and stray from the essentials necessary for patients' safety. It would be helpful therefore to have a system whereby manufacturers can challenge the nature and relevance of questioning to reduce unnecessary costs. The MHRA should also be able to challenge approved bodies in the interests of manufacturers or patients who, in the end, will bear the costs or suffer from reduced choice

Q23.3 Do you think that Approved Bodies should be able to conduct fully remote or hybrid audits of their clients in specific circumstances, as outlined in paragraph 23.4?

☒ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q23.5 Please select the option you agree with: To become designated as an Approved Body the company/organisation:

☐ a. should be a distinct legal entity based in the UK (the company as a whole)

☐ b. should be a distinct legal entity based in the UK or have a branch in the UK

☒ c. other (please specify)

☐ d. don't know/no opinion

To become designated as an Approved Body the company/ organisation should meet appropriate UK standards and be fit for purpose.

Q25.1 Do you agree that the UK medical devices regulations should require Approved Bodies applying for designation to hold appropriate UKAS accreditation?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q25.2 Do you think the UK medical devices regulations should include the requirements set out in paragraph 25.4 for MHRA assessment of Approved Bodies?

X☐ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q25.3 Please outline any other requirements which should be introduced for MHRA assessment of Approved Bodies.

Further to Q25.1, or equivalent accreditation from a non-UK approved body that meets the same standards or higher. A form of mutual recognition between the assessments and certification by UK and EU approved bodies would be helpful to UK businesses.

Q25.4 Do you think that the MHRA should be able to perform remote audits of Approved Bodies or their subsidiaries in specific circumstances?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q25.6 Do you think the transitional arrangement above for 'roll over' of Medical Device & Active Implantable Medical Device Approved Body designation is suitable?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q25.7 Please explain your reasoning to question 25.6 and expand on what you consider would be suitable criteria for this 'roll over' if any.

To ease transition.

Q25.8 Do you think that the MHRA should be required to perform the tasks set out in paragraph 25.7 in the event of Approved Body designation withdrawal, restriction, or suspension?

X☐ Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q25.9 Do you think that the UK medical devices regulations should set out the circumstances in which certificates shall remain valid on an ongoing basis or for a defined time period in the event of designation withdrawal?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q25.11 Do you think the UK medical devices regulations should introduce requirements set out in paragraph 25.9 for Approved Bodies in relation to how they conduct their activities?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q25.13 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 25.1-25.12, including any impacts on you or other stakeholder groups.

To support manufacturers, ensure patient safety and provide transparency.

Chapter 6: Conformity Assessment

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

X No

☐ I 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).

Our response to Q26.1 is premised on the proposals in paragraph 26.6 not applying to Class I medical devices. Any proposed changes should be explicit in that they apply only to higher risk devices. The option for manufacturers of Class IIb and IIa general medical devices to use production quality assurance should remain.
In our view, the conformity assessment requirements for medical devices should be improved by the addition of a specified time limit for Approved Bodies to respond to an application for conformity assessment. This approach would provide greater certainty to manufacturers seeking to bring new devices to the market that would benefit patients.

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)

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

X No

☐ I Don't Know

☐ No Opinion

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.

We believe the flexibility of retention of batch verification, product quality assurance and type examinations as conformity assessment routes should be maintained, provided they deliver an equivalent level of assurance about patient safety. This would offer flexibility of routes to market and support competition amongst manufacturers which will in turn drive investment and innovation in medical devices for the benefit of patients.

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

X No

☐ I 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

☐ I Don't Know

X No Opinion

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.

Again, proportionality is key. The MHRA should only collect information that it needs, and this should be proportionate to risk.

Q28.1 Do you think the UK medical devices regulations should detail the minimum content of Certificates of Conformity?

X Yes

☐ No

☐ I 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).

Minimum content must be just that – it is crucial to guard against regulation which would impact on costs, business viability and safe choices for patients.

Q28.3 Do you think Approved Bodies should be allowed to impose restrictions/requirements on the use/follow-up of certain medical devices?

X Yes

☐ No

☐ I 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.

Restrictions of a medical device to certain groups of patients or requirements for specific post-market clinical follow-up or post-market performance follow-up studies for higher risk or break through devices as proposed in Paragraph 28.3. This would not normally be applicable to Class I and II devices.

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

X No

☐ I 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.

The MHRA should only collect information that it needs, and this should be proportionate to risk.

However there this is necessary, it is reasonable to require Approved Bodies to enter information regarding conformity certificates they have issued into the MHRA registration system, including information regarding suspended, re-instated or withdrawn certificates and restrictions imposed on certificates; and for such information to be published and accessible to the public, to improve transparency.

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.

This would improve transparency about high-risk devices.

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

☐ I Don't Know

X No Opinion

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

☐ I Don't Know

X No Opinion

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.
If minimum content is to be prescribed it must be just that – the minimum necessary for patient safety proportionate to risk. It is crucial to guard against regulation which would impact on costs and business viability without demonstrable benefit to patients. Otherwise, this will inhibit innovation and limit patient choice

Chapter 7: Clinical Investigation / Performance Studies (page 80 on full document)

Q31.1 Do you think that the specific requirements, outlined in paragraph 31.11, that relate to claiming equivalence should be introduced?

☐ Yes

X No

☐ I Don't Know

☐ No Opinion

Q31.2 Please provide any additional information (for example outline what requirements you think should be introduced around claiming equivalence or explain why you do not agree that additional requirements should be introduced).

Medical devices, such as contact lenses, are manufactured for a global market. It is important that MHRA regulations mirror robust regulations in established jurisdictions, for example the MDR in EU. This would ensure the MHRA does not add new and unnecessary complexity into the supply chain as this will simply increase costs without benefits for patients or local health systems.

Q31.3 Do you think that manufacturers of products without an intended medical purpose should be required to perform clinical investigations or other pre-market studies involving human subjects/ participants as set out in paragraph 31.12?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q32.1 Do you think that confirmation of conformity of an IVD with the UK medical devices regulations should be based on scientific validity, analytical and clinical performance data?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q32.2 Do you think that manufacturers should be required to produce a performance evaluation report as part of the technical documentation for the device?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q32.3 Do you think manufacturers should be required to specify and justify the level of clinical evidence necessary to demonstrate conformity with the UK medical devices regulations?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q32.4 Do you think the UK medical devices regulations should require manufacturers to rely on data from their own clinical performance studies unless they can justify reliance on other sources of clinical performance data?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q32.6 Do you think the UK medical devices regulations should require that the performance evaluation is updated throughout the lifetime of the IVD and used to update the technical documentation listed in paragraph 32.11?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q32.8 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 32.1-32.7, including any impacts on you or other stakeholder groups.

We have no expertise in this area.

Q33.1 Do you think that clinical investigations regulated under the UK medical devices regulations should be limited to those carried out for one of the purposes outlined in paragraph 33.5?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q33.2 Do you think that, if the sponsor is based outside the UK, they should be required to appoint a legal representative in the UK as outlined in paragraph 33.6?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q33.3 Do you think that the legal representative should be responsible for ensuring compliance with the sponsor's obligations and be the addressee for all communications with the sponsor?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q33.4 Do you think that any communication with that legal representative should be deemed to be communication with the sponsor?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q33.5 Do you think the UK medical devices regulations should set out the obligations of the sponsor, including those outlined in paragraph 33.7?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q33.7 Do you think the UK medical devices regulations should set out the minimum requirements for the clinical investigation report, including those outlined in paragraph 33.8?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q33.9 Do you think the UK medical devices regulations should require the sponsor to publish the clinical investigation report?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q33.10 Do you think the UK medical devices regulations should include the additional detailed requirements relating to the methods for a clinical investigation as outlined in paragraph 33.10?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q33.12 Do you think the UK medical devices regulations should set out the detailed requirements for the clinical investigation plan, including those outlined in paragraph 33.12?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

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?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

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?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q33.17 Do you think the qualification requirements for investigators of clinical investigations and personnel involved in clinical investigations, including those outlined in paragraph 33.15, should be introduced?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.1 Do you think we should require that, where appropriate, performance studies be performed in circumstances similar to the normal conditions of use of the medical device?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.2 Do you think the UK medical devices regulations should set out in detail the specific requirements for the performance studies in paragraph 34.5 above?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.4 Do you think the UK medical devices regulations should set out the obligations for the sponsor of a performance study, including those outlined in paragraph 34.7?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.6 Do you think sponsors should be required to implement a clinical performance study plan?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.7 Do you think detailed requirements for the clinical performance study plan should be set out in the UK medical devices regulations?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.9 Do you think this obligation should also extend to other types of performance studies (other than clinical performance studies)?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.10 Do you think the UK medical devices regulations should set detailed requirements for the purpose, methods, objectives and ethical considerations for a performance study including those outlined in paragraph 34.9?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.12 Do you think sponsors should be required to provide a clinical performance study report?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.13 Do you think the UK medical devices regulations should set out the minimum requirements for the clinical performance study report?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.15 Do you think this obligation should also extend to analytical performance studies?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.17 Do you think the UK medical devices regulations should require the clinical performance study report be published?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.18 Do you think the UK medical devices regulations should require ALL performance studies involving human samples to be subject to ethical review by an ethics committee?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.19 Do you think that performance studies involving companion diagnostics should be subject to the same requirements as all other performance studies?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.20 Do you think that performance studies involving companion diagnostics using only left-over samples should NOT be subject to the same requirements as all other performance studies?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.21 Do you think that performance studies involving companion diagnostics using only left-over samples should be notified to the MHRA?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

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?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

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?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.25 Do you think the UK medical devices regulations should set out requirements for the investigator and other personnel involved in the performance study, including those outlined in paragraph 34.17?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.27 Do you think that the UK medical devices regulations should require that, where appropriate, the facilities where the performance study is to be conducted should be suitable for the conduct of the study?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.28 Do you think that, where appropriate, the setting and users of the medical device in the clinical performance study should be similar to the intended setting and intended users of the medical device?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q34.29 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 34.1-34.28, including any impacts on you or other stakeholder groups.

We have no expertise in this area.

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?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q35.4 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 35.1-35.3, including any impacts on you or other stakeholder groups.

We do not have sufficient knowledge of the range of medical devices outside eye care to from an opinion.

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?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q36.3 Do you think additional requirements, including those outlined in paragraph 36.4, should be required for clinical investigations or performance studies on pregnant or breastfeeding women?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q36.5 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 36.1-36.4, including any impacts on you or other stakeholder groups.

We do not have sufficient knowledge of the range of medical devices outside eye care to from an opinion.

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?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q37.2 Please provide your reasoning (including any available relevant evidence) to support your answer to question 37.1, including any impacts on you or other stakeholder groups.

We have no expertise in this area.

Q37.3 Do you think that systems should be put in place for compensation as set out in paragraph 37.4?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q38.1 Do you think detailed requirements for the clinical investigation or performance study application form and the accompanying documentation required, including those outlined in paragraph 38.2 should be outlined?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q38.3 Do you think the UK medical devices regulations should outline the relevant timescales that the applicant and the MHRA should conform to when an application for a clinical investigation or performance study is submitted to the MHRA?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q39.1 Do you think the MHRA should be required to assess applications for performance studies?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q39.2 Do you think the detailed requirements for assessment of the application for clinical investigations or performance study should be outlined by the MHRA?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q40.1 Do you think the UK medical devices regulations should set out the requirements for the conduct of a clinical investigation or performance study, as outlined in paragraph 40.2?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q40.3 Do you think that the MHRA should be required to inspect, at an appropriate level, clinical investigation, or performance study site(s)?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q40.4 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 40.1-40.3, including any impacts on you or other stakeholder groups.

We have no expertise in this area.

Q41.1 Do you think the sponsor should be required to notify the MHRA of a clinical investigation or performance study within a specified time period prior to the start of that clinical investigation or performance study as outlined in paragraph 41.3?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q42.1 Do you think the UK medical devices regulations should set out the procedures for sponsors intending to introduce modifications to a clinical investigation or performance study, including the procedures outlined in paragraph 42.2?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q43.1 Do you think that the MHRA should be able to take the measures outlined in paragraph 43.2 in cases where it is considered that the requirements of the UK medical devices regulations in regards to a performance study have not been met?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q43.3 Do you think, except where immediate action is required, that the sponsor or the investigator or both should be asked for their opinion regarding the corrective measures outlined in paragraph 43.2 (suggested measures)?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q44.1 Do you think the procedures, including those outlined in paragraph 44.2 which must be undertaken and the timeframes which would apply at the end of a clinical investigation or performance study, or in the event of a temporary halt or early termination should be specified?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q45.1 Do you think sponsors of clinical investigations and performance studies should be required in legislation to fully record and provide information on adverse events, serious adverse events and medical device deficiencies including those set out in points (a} to (d} in paragraph 45.3?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q45.2 Do you think sponsors should be required to report, without delay, to the MHRA, the events set out in points (a} to (c} of paragraph 45.4?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q45.3 Do you think, where necessary, sponsors should be able to submit an initial report that is incomplete, followed up by a complete report?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q45.4 Do you think the UK medical devices regulations should require sponsors to report to the MHRA any event referred to in paragraph 45.4 that has occurred in a non-UK country in which a clinical investigation or performance study is performed under the same clinical investigation or performance study plan?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q45.5 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 45.1-45.4, including any impacts on you or other stakeholder groups.

We do not sufficient expertise in this area.

Q46.1 Do you think the UK medical devices regulations should allow for exemptions from some of the requirements of the Regulations for certain types of clinical investigations and performance studies as outlined in paragraph 46.4?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q46.3 Do you think that healthcare institutions should be required to notify certain types of clinical investigation/ performance studies to the MHRA for authorisation before proceeding?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q47.1 Do you think the UK medical devices regulations should introduce the requirement for an SSCP for medical devices?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q47.3 Do you think the UK medical devices regulations should set out the minimum content of the SSCP included in paragraph 47.5?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q47.5 Please select one of the following:

☐ a. the manufacturer should upload the full SSCP to the MHRA registration system

☐ b. the manufacturer should upload a link to the SSCP to the registration system

☐ c. the manufacturer should not be required to upload the SSCP to the registration system

☐ d. other - please specify

☒ e. don't know/no opinion

Q47.6 Do you think an Approved Body should validate the SSCP for a medical device?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q47.8 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 47.1-47.7, including any impacts on you or other stakeholder groups.

We do not sufficient expertise in this area.

Chapter 8: Post-market Surveillance and Vigilance (page 120 on full document)

Q48.1 Do you think manufacturers should be required to implement a post market surveillance system based on a post-market surveillance plan, which collates and utilises information from the range of sources listed in paragraph 48.4?

☐ Yes

X No

☐ I Don't Know

☐ No Opinion

Q48.2 Do you think the UK medical devices regulations should provide a detailed outline of what the post-market surveillance plan should address, including the examples given in paragraph 48.5?

☐ Yes

X No

☐ I Don't Know

☐ No Opinion

Q48.3 Please outline any other elements that a post-market surveillance plan should address.

Further to Q48.1, again this needs to be proportionate to the level of risk and the MHRA should be mindful of the balance between bureaucratic costs and genuine patient benefits.

The current system works well for low-risk Classes of devices, and the guidance approach is appropriate as not all devices necessitate the same levels of surveillance.

If made mandatory, the range of sources listed in paragraph 48.4 should be just that i.e. a range not all of which would be suitable or available for all devices.

Further to Q48.2, this should apply for high-risk devices only. The current arrangements already operate effectively for Class 1, Class IIa, Class IIb and non-

implantable optical devices and the sort of detail suggested would be better suited to guidance for low-risk devices which could be made mandatory for higher risk products.

Further to Q48.3, the evidence in eye care is that the existing regime has proven its effectiveness for Class I and Class II devices such as spectacles, contact lenses and contact lens solutions based on their low level of risk to patient safety. Legally requiring manufacturers of these devices to implement a post market surveillance system based on a post-market surveillance plan is unnecessary. The detail specified in the medical devices' regulations should reflect different risk levels and classes of device. The blanket approach proposed would be disproportionate if applied to all devices irrespective of risk, and contrary to Better Regulation principles.

Q48.4 Do you think the UK medical devices regulations should require IVD manufacturers to carry out post-market performance follow-up (PMPF) and to use PMPF findings to update the IVD's performance evaluation?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q48.5 Do you think the UK medical devices regulations should outline what should be included in the PMCF or PMPF plan, including the examples given in paragraph 48.8?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q48.7 Do you think that manufacturers should be exempt from the requirement to perform PMCF/PMPF for a medical device or IVD pursuant to a PMCF/PMPF plan if such manufacturers provide sufficient justification?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q48.8 Do you think the UK medical devices regulations should include requirements for manufacturers to summarise and present the information from their post-market surveillance activities in a postmarket surveillance report or a periodic safety update report as they are described in paragraph 48.9?

☐ Yes

X No

☐ I Don't Know

☐ No Opinion

Q48.9 If you have answered 'yes' to question 48.7, please outline which types or classes of medical devices should be subject to a post-market surveillance report and if there are any other elements which should be required for the post-market surveillance report.

A PMCF/PMPF for a medical device or IVD pursuant to a PMCF/PMPF plan should only be required where this is justified on grounds of risk.

Whilst it might seem reasonable, in principle, to ask manufacturers of lower risk medical devices to summarise their findings in a post market surveillance report and make this available to the MHRA, in practice, given the low rate both of serious and non-serious incidents, making this a legal requirement would be disproportionate and unnecessary. If this were to become a requirement for low-risk devices, we suggest there be threshold requirements which would trigger submission of a report to the MHRA rather than a catch-all approach.

Q48.12 Do you think manufacturers should upload post-market surveillance data to the MHRA devices register upon registration renewal?

☐ Yes

X No

☐ I Don't Know

☐ No Opinion

Q48.13 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 48.1-48.12, including any impacts on you or other stakeholder groups.

Requirements for both post market surveillance reports and publication should be proportionate to the risk of the device and thus only be required where the risk level of the device justifies this.

Q49.1 Do you think the UK medical devices regulations should include requirements for manufacturers to report incidents and FSCAs to the MHRA including points (a) and (b) as above?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q49.2 Do you agree with the proposed definitions for 'serious incident', 'serious deterioration' and 'serious public health threat'?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q49.4 Do you think the manufacturer should be required to report any serious incident in line with the time periods above?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q49.5 If you have answered 'no' to question 49.4, please outline what the timeframe for reporting serious incidents should be, or any other changes you would make to the criteria set out in paragraph 49.9.

There are so few serious incidents relating to devices in primary eye care that we do not have sufficient expertise to offer a view.

Q49.6 Do you think the UK medical devices regulations should specify further procedures for manufacturers regarding the reporting of serious incidents and field safety corrective actions (FSCAs) including (but not limited to} the points made in paragraph 49.10 above?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q49.8 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 49.1-49.7, including any impacts on you or other stakeholder groups.

Re Q49.6 and Q49.7 these are matters for manufacturers. There are so few serious incidents relating to devices in primary eye care that we do not have sufficient experience to offer a view.

Q50.1 Do you think the manufacturer should be required to report any statistically significant increase in the frequency or severity of incidents/erroneous results as set out in paragraph 50.3 above?

☐ Yes

X No

☐ I Don't Know

☐ No Opinion

Q50.2 Please provide your reasoning (including any available relevant evidence) to support your answers to question 50.1, including any impacts on you or other stakeholder groups.

This should apply only to high-risk devices and be on an exception basis as proposed. In the case of low-risk devices used in primary eye care, the incidence of device-related harm is so low that it is likely to be impossible to see trends, making

any such a requirement redundant for Class 1, Class IIa, Class IIb and non-implantable optical devices.

Q51.1 Do you think manufacturers should be required to issue field safety notices (FSNs) as part of their field safety corrective actions and to submit the content of the FSN to the MHRA for comment, except in cases of emergency?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q51.2 Do you think the UK medical devices regulations should set out the minimum requirements for the content of field safety notices issued by manufacturers?

☐ Yes

X No

☐ I Don't Know

☐ No Opinion

Q51.3 Do you think the MHRA should be required to notify the manufacturer or their UK Responsible Person of new risks it has identified through active monitoring of data in cases where these risks have already been subject to public disclosure?

☐ Yes

X No

Don't Know

No Opinion

Q51.4 If we were to mandate patient and public involvement and engagement in the medical device regulations, as part of manufacturers' vigilance obligations, what form should this take?

The mandating of patient and public involvement and engagement in the regulations, as part of manufacturers vigilance obligations, should depend on the type of device, how it is made available and the nature of the risk. The regulations should avoid a blanket approach and focus on higher risk products.

Q51.5 At what stages would you expect manufacturers to engage patients and the public? Multiple Choice:

☐ a. periodically once their medical device is on the market

☐ b. only when they or the MHRA becomes aware of a safety issue with the device

☒ c. other - please specify?

Option (c). It should depend on the type of device and level of risk.

Q51.6 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 51.1-51.5, including any impacts on you or other stakeholder groups.

Further to Q51.1, this seems reasonable but is unlikely to be relevant to Class 1, custom-made, Class IIa, Class IIb and non-implantable optical devices where a FSN has never yet been known.

Further to Q51.2, this should be device and case specific.

Further to Q51.5, in our experience, in the case of low-risk Class 1, Class IIa, Class IIb and non-implantable optical devices, this would only be when the manufacturer or the MHRA becomes aware of a safety issue with a device (which would be a vanishingly rare occurrence).

Chapter 9: In vitro Diagnostic Medical Devices (page 129 on full document)

This Chapter is not relevant to primary eye care.

Chapter 10: Software as a Medical Device (page 134 on full document)

Q58.1 Do you think that we should introduce the definition of software set out above?

☐ Yes

X No

☐ I Don't Know

☐ No Opinion

Q58.2 Do you think there are any other definitions that need to be added to, or changed in, the UK medical devices regulations to further clarify what requirements apply to placing SaMD on the UK market?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q58.3 If you have answered 'yes' to question 58.2, please outline what additions / modifications are required.

It would be helpful to clarify that software used to create a medical device does not fall within the scope of the regulations.

It would also be important that software – e.g. online tools – used as part of public health campaigns and raising awareness of risk factors are not inadvertently captured by regulations on the basis of a definition of software and medical assessment/diagnosis etc.

Q58.4 Please provide your reasoning to support your answers to questions 58.1-58.3, including any impacts on you or other stakeholder groups and any available relevant evidence.

The current definition paragraph 5.1 is "a set of instructions that processes input data and creates output data" of software in the context of diagnostics and medical examination is too broad.

For example, it is not clear whether this would capture public health awareness raising tools/ campaigns online which are designed to encourage people to question and act on medical or other symptoms for example – rather than diagnose per se. We assume the MHRA does not intend to bring such tools – which have clear explanations of their limitations and intended purpose – into medical device regulation.

Software packages will soon be able to create 3D printed devices for specific patients – e.g. Class 1 spectacles frames and ophthalmic lenses, or at the higher risk end surgical implants for a specific patient. It is important to be clear that the software that enables the manufacture of the device is not itself SaMD. In our view, the requirements for safety and conformity would be better placed on the device that will be used with/on/in the patient.

Q59.1 SaMD can be deployed in the UK by websites hosted in other jurisdictions. Is there any need for greater/ clearer requirements in such deployment?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q59.2 Do you think that the definition of placing on the market should be revised as set out above?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q59.3 Please provide your reasoning to support your answers to questions 59.1-59.2, including any impacts on you or other stakeholder groups and any available relevant evidence.

Given that this is an unknown area of risk and based on our past experience of risk to patients of contact lenses supplied from less/unregulated jurisdictions, we believe there is likely to be a need for clearer requirements when SaMD is deployed in the UK by websites hosted in other jurisdictions.

This would help create a level playing field. However, it would be helpful to have greater clarity from the MHRA of how this could be enforced across jurisdictions in a fast-moving development environment.

Q60.1 Do you think we should amend the classification rules in UK medical devices regulations to include the IMDRF SaMD classification rule (with supporting definitions and implementing rules) as set out in paragraph 60.2?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q60.2 Please set out your rationale and any impacts you expect this change would have.

So that the scrutiny applied to these medical devices is more commensurate with their level of risk and more closely harmonised with international practice in accordance with Better Regulation principles.

Q61.1 Do you think we should introduce an 'airlock classification rule' for SaMD with a risk profile that is not well understood?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q62.1 Do you consider additional essential requirements should be in place to assure the safety and performance of SaMD specifically?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q62.3 Do you consider regulations should set out SaMD essential requirements separate from those for other general medical device types?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q62.4 Please provide your reasoning (including any available relevant evidence) to support your answers to question 62.1-62.2, including any impacts on you or other stakeholder groups.

We do no expertise in this area.

Q63.1 Do you think the UK medical devices regulations should mandate a 'report adverse incident' link as set out above?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q63.3 Do you think that regulations should enable predetermined change control plans?

☐ Yes

☐ No

☐ I Don't Know

Q64.1 Do you consider existing UK medical devices regulations need to include cyber security and/or information security requirements?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q64.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 64.1-64.2, including any impacts on you or other stakeholder groups.

It is logical that UK medical devices regulations should include cyber security and/ or information security requirements to protect patient data and instil patient confidence that internet connected devices are as secure as reasonably practical.

Data protection requirements, and what to do in the event of any breaches, are already well served by legislation and guidance issued by the Information Commissioners Office (ICO).

Q65.1 Are there other statutory changes required to effectively regulate AIaMD over and above the changes detailed for SaMD above?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q65.3 Do you consider the use of IVDR-type performance evaluation methods (akin to scientific validity, analytical performance, and clinical performance) for diagnostic software but especially AI (even where no IVD data is used) to be appropriate?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q65.4 If yes, do you think the UK medical devices regulations should be amended to require this?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q65.5 Should the UK medical devices regulations mandate logging of outputs of further auditability requirements for all SaMD or just AIaMD for traceability purposes?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q65.6 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 65.1-65.5, including any impacts on you or other stakeholder groups, including how burdensome would further requirements along these lines be?

We have as yet no specific expertise in this area

Chapter 12: Other Product-Specific Changes (page 146 on full document)

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

☐ I Don't Know

X No Opinion

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

☐ I Don't Know

X No Opinion

Q67.5 Do you think that the MHRA should allow the re-manufacturing of Class I single-use medical devices?

☐ Yes

☐ No

☐ I Don't Know

X No Opinion

Q67.7 Do you think that the MHRA should continue to allow the reprocessing of single-use devices?

☐ Yes

☐ No

☐ I Don't Know

X 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.

We have no expertise in this area.

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

☐ I Don't Know

X 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

☐ I Don't Know

X No Opinion

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

☐ I Don't Know

X No Opinion

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.

Further to Q68.1-Q68.4, we have no experience of systems, kits or procedure packs in primary eye care.

However, given the problems that have arisen with the EU MDR 2017 about the classification of finished spectacles, it would be helpful to clarify that spectacles (which comprise two separate Class 1 medical devices: spectacle frames and ophthalmic lenses)

- are put together and adapted to create the final product
- the process of adapting the final device does not result in the creation of a new/third medical device, and
- the person who adapts the device does not fall within the definition of an assembler of a kit or system pack as described in paragraph 68.6.

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

X No

☐ I Don't Know

☐ No Opinion

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

X No

☐ I 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.

Further to Qs69.1and 69.2, these requirements would be disproportionate for the low risk devices used in primary eye care.

For instance, in the case of a Class 1 spectacle frame where a screw holding in place the arms of the frame may come lose and be lost, an optician would simply repair with another screw. Inclusion of such situations should not be within the scope of the regulations. Replacing a part or a component in a spectacle frame (e.g. a screw, nose pad or arm) would self-evidently not significantly change the performance or safety characteristics of the device.

Equally none of this would apply to contact lenses or solutions (Class II) by nature of the device.

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

X No

☐ I Don't Know

☐ No Opinion

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

X No

☐ I Don't Know

☐ No Opinion

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

X No

☐ I Don't Know

☐ No Opinion

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

We would be happy to provide further evidence/meet if the MHRA wishes to discuss further.

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?

X Yes

☐ No

☐ I 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.

Further to Q70.1, this would be disproportionate in our sector where custom made devices such as spectacle frames (Class 1) or contact lenses (Class 2) are low risk devices. The MDD and MDR already make clear provision for custom-made spectacles and contact lenses. It is essential that UK manufacturers continue to be allowed to offer custom-made spectacle frames and contact lenses to meet individual patient's needs, which they have done for years under existing regulations without any reported patient harm or safety risks.

Further to Q70.2, this would be disproportionate in our sector where custom made devices such as spectacle frames (Class 1) or contact lenses (Class 2) are low risk devices and where the feedback loops are immediate.

Further to Q70.3, this would be disproportionate in our sector where custom made devices such as spectacle frames (Class 1) and contact lenses (Class 2) are low risk devices and current systems have maintained patient safety effectively for many years.

On Q70.6, this will increasingly become the norm.

Chapter 13: Environmental sustainability and public health impacts (page 153 on full document)

Q71.1 To what extent are you or your organisation already implementing, or planning, activities to reduce the impact of medical devices on the environment? Please outline any key activities you have underway or planned.

As much as we can through information campaigns, the use of recycled materials in some spectacles and the development of yearly contact lenses. Contact lens manufacturers and optical retailers make available electronic Instructions for Use (e-IFUs) with each supply with the aim of eventually phasing out paper based IFUs, and manufacturers can already be accredited to ISO14001 in respect of their environment management systems (EMS). ISO14001 emphasises continual improvement.

Q71.2 Do you see a need for additional requirements to be placed on economic operators in order to encourage them to consider and/or mitigate the environmental impact of medical devices they place on the UK market?

☐ Yes

X No

☐ I Don't Know

☐ No Opinion

Q71.3 Please explain the rationale for your response to question 71.2 and any expected impacts.

Making eye care carbon neutral and sustainable (including devices and packaging) is already happening as fast as possible both as part of the UK environmental agenda and in response to changing consumer demands. There is therefore no case for placing additional requirements on economic operators to encourage them to consider or mitigate the environmental impact of medical devices they place on the UK market.

Moreover, we do not believe it is the MHRA's role to regulate the environmental sustainability of medical devices and some of the proposals e.g. in paragraph 71.5 would extend the remit of the MHRA beyond its scope of ensuring patient safety and into areas in which the MHRA has little or no expertise.

There is however scope for the MHRA itself to show leadership on sustainability by reviewing its own regulations to support and encouraging more environmentally sensitive behaviours such as permitting electronic prescriptions, labels and instructions for use.

Q71.4 What are your views on the options for change outlined in paragraph 71.5? Please state your rationale, key implementation considerations and the expected impact of these options.

We cannot see the case for including environmental and public health impact assessments, waste management requirements or minimisation of substance or particle release in devices regulations, as these are already covered by other legislation.

We do support the move to electronic labels and instructions for use wherever possible but, as noted in our response to Q 71.3, this is already happening and the pace of change will depend on continuing patient safety of these formats and consumer acceptability, not regulations.

Q71.5 What other changes or key considerations do you think are needed to ensure more sustainable medical devices?

None

Chapter 14: Routes to market

Q72.1 Do you think the MHRA should introduce an alternative route to market which utilises Medical Device Single Audit Programme (MDSAP) certificates?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q72.2 Please explain your answer to question 72.1 and, if applicable, please outline any further considerations/requirements that should be in place for accepting MDSAP certificates.

Maximising the range of routes to market for manufacturers will enable patients to access safe medical devices at the earliest possible opportunity and extend the range of options available to healthcare professionals to assist patients.

Q72.3 Do you think the MHRA should introduce an alternative route to market which utilises approvals from other countries (domestic assurance route)?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q72.4 Please explain your answer to question 72.3 and, if applicable, please outline any further considerations/requirements that should be in place for the domestic assurance route.

Please see our response to Q.72.2. This will also assist manufacturers which place devices on the NI/EU markets, as well as in GB, by reducing regulatory burdens.

However, this will rely on of the UK having sufficient Approved Bodies to cope with the workload. At present, the MHRA has only three Approved Bodies which is seriously insufficient and is the root cause of delays in assessments. This is both delaying accessibility to devices that would benefit patients and adding cost to UK businesses.

Ideally the UK should operate a system as close as possible to other international regulators and seek to ensure that UK medical devices are recognised in other jurisdictions on a parallel basis.

Q73.1 Do you think the MHRA should introduce a pre-market approvals route to place innovative medical devices into service for a specified time period and for specific use cases?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q73.2 Do you think the MHRA should have powers to conduct conformity assessments and issue approvals in certain scenarios, such as the one outlined in paragraph 73.3?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q73.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 72.1-73.2, including any impacts on you or other stakeholder groups and/or any other general comments on how this could be implemented, including potential timeframes and specified uses.

This would speed up access to devices in limited circumstances, e.g. for use on certain groups of patients and/or within specific healthcare institutions where there was an identified need.

Chapter 15: Transitional Arrangements (page 160 on full document)

Q74.1 Do you think that we should introduce the transitional arrangements proposed above in Option 1?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q74.2 Do you think that we should introduce the transitional arrangements suggested above in Option 2?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q74.3 Please give your reasoning for your answer to questions 74.1-74.2. If you have answered 'yes' to either question, please include what you consider the required arrangement(s) and any expected impacts of these on you or other stakeholder groups.

The new requirements should be phased in at different times depending on, for example, device type and the level of risk it presents (its classification) focusing on higher risk devices first. The MHRA should adopt this proportionate approach, recognising that industry requires time to make the necessary changes. The target date of July 2023 seems far too ambitious, and it would be better to plan a phased and smooth approach which can be delivered from the outset, in partnership with respondents to this consultation and other stakeholders.

Medical device manufacturers have already gone through the process of complying with or preparing to comply with the EU MDR, they have then had to

revert to the UK MDR regulations, and now potentially a third change is being proposed. Manufacturers and other economic operators have in some cases already incurred costs complying with a system that is not now being implemented, or which will shortly change. It is therefore essential that further changes have sensible transition periods not simply to allow manufacturers to understand and prepare for new regulations but also to avoid imposing yet more costs which are due to nothing other than changes to the system.

To assist a smooth transition, it would be helpful I for medical devices placed on the market before 1 July 2023 to remain on the market and. If already in the supply chain or in use, for there not be any requirement to recall them when either the CE certificate expires/or the certificate of conformity is no longer valid, given that they were compliant when placed on the market.

Many low-risk medical devices do not change substantially over time and would normally expect to remain on the market safely for several years. It would be counterproductive to recall devices for no obvious safety reason. It would provide no public health benefit but would put extra burdens on manufacturers. Transition periods should be geared to this principle.

As far as CE marked devices are concerned, additional assessment should not be necessary as these have already been assessed to be placed on the market. They will gradually transition as and when they are brought within the new requirements. Devices which are CE marked under the MDR will already meet high standards.

Q74.4 Do you agree with the transitional arrangements suggested in Option 5 above?

X Yes

☐ No

☐ I Don't Know

☐ No Opinion

Q74.5 Please give you reasoning for your answer to question 74.4.

Manufacturers require the ability to continue clinical investigations in process so as not to delay innovation coming to market for the public benefit. The proposed transitional arrangements, therefore, including the requirement to meet additional reporting requirements for clinical investigations that commence on or after 1 July 2023, are logical and meet this goal.

Q74.6 Please set out any other transitional arrangements or considerations you believe are required for putting in place a future regime for medical devices in the UK, why, and the expected impacts on you and other stakeholder groups.

As we said in our response to Q72.4, the UK needs more Approved Bodies. Without this, manufacturers cannot UKCA mark their devices.

We have seen that problems caused for EU MDR through the lack of notified bodies. The UK should learn from and not replicate this experience in the UK. Implementation should only proceed in line with the availability of Approved Bodies and should be phased according to access to Approved Bodies if sufficient are not in place.

As explained in our response to Q74.3 transitional arrangements should allow the continued use of CE certificates to place medical devices on the UK market throughout the transition period until the new UKCA marking requirements become mandatory. This should be until 2024 at the earliest so that there are sufficient Approved Bodies and one labelling change can be undertaken to meet both EU MDR and UKCA requirements thereby avoiding additional labelling costs for manufacturers and UK consumers.

At the same time, common specifications (or similar) for products without a medical purpose should be issued in plenty of time for these products to be brought into compliance. Again, lessons should be leant here from the experience of implementing the EU MDR.

Q74.7 How many years after 1 July 2023 should the MHRA accept UKCA certificates/ declarations of conformity issued before 1 July 2023? That is, what would be a suitable 'specified date' for Option 1 above?

☐ 30 June 2025

☐ 30 June 2026

☐ Other - please specify

Six years.

Q74.8 How many years after 1 July 2023 the date of implementation of the Regulations should the MHRA accept CE certificates issued before 1 July 2023? That is, what would be a suitable 'specified date' for Option 2 above?

☐ 30 June 2027

☒ 30 June 2028

☐ Other - please specify

Q74.9 For how long after expiry of the certificate/declaration of conformity or after the 'specified date' should devices covered by the transitional options 1 and 2 be permitted to be supplied to the UK market?

☐ They should not be permitted to be supplied after expiry or cut-off date

☐ 6 months

☐ 12 months

Q74.10 What additional checks, if any, would you consider to be necessary to allow CE marked products to remain on the Great Britain market after 1 July 2023?

We would not expect any additional checks to be necessary to allow CE marked products to remain on the Great Britain market after 1 July 2023, particularly if the UK regulatory and EU CE marked regulatory system reflect and complement each other.

Q74.11 Please provide your reasoning for your proposed dates above.

Further, 30 June 2028 would be a suitable end point (specified date) for the MHRA to continue to accept CE certificates issued before 1 July 2023. This would allow the current certificate to expire and transition at certificate expiry which is usually after five years. This would avoid a manufacturer being in the unfortunate position of

having a new device put on the market in early 2023 and then having to go through the whole process of conformity assessment again only three years later. For low-risk devices that change little over time less than six years would simply be too short a timeframe.

Moreover, the planned UKCA marking implementation date of 1 July 2023 is out of kilter with the grace period for MDD conformity certificates and certification under the EU MDR which ends on 25 May 2024. Where a manufacturer wishes to dual UKCA/ CE mark a device, this may make one labelling changes difficult. As these are time consuming and costly, this could potentially lead to a loss of some devices to the GB market for a period until EU MDR certificates are received and one labelling update can be completed. Therefore, an extension to the length of time a medical device can be placed on the market under a CE certificate is key. Recognising that many devices legitimately remain on the market for long periods without changing or updating, minimising the financial and bureaucratic impact for little or no gain is key.

Further to Q74.9, devices covered by the transitional options 1 and 2 should be permitted to be supplied to the UK market until they expire if they have a shelf life e.g. spectacle frames and contact lenses. Low risk medical devices in many spheres do not change substantially over time and would expect to remain on the market safely for several years. Transition periods should reflect this.

Further to Q74.10, we would not expect any additional checks to be necessary to allow CE marked products to remain on the Great Britain market after 1 July 2023, particularly if the UK regulatory and EU CE marked regulatory system reflect and complement each other.

Chapter 16 Feedback

Q75.1 How would you rate the level of ambition set out in this consultation? (multiple choice)

☐ Very Poor

☐ Poor

☒ Good

☐ Very good

☐ Excellent

72. 2 Do you consider the possible changes to UK medical devices regulations set out in this consultation document to be proportionate?

☐ Yes

X No

☐ I Don't Know

☐ No Opinion

Q75.3 Please set out your reasoning for your response to question 75.2.

We recognise that the driver for many proposals has been a number of high-profile incidents with high-risk devices. There is, however, a significant market in high volume, low-risk devices in the UK which contributes significantly to patient care and the UK economy, and the MHRA should ensure that these factors are given due weight in regulatory changes which should be proportionate to risk and set at the lowest possible level of imposition consistent with patient safety.

Q75.4

Against the parameters set out in the 'About us' section at the start of this response, the timescale allowed for this complex consultation was appropriate and appreciated. It allowed us to consult members and our supply chain manufacturers, importers and distributors - so thank you.

We also understand how complex these sorts of consultations are to structure, especially given the range of medical devices covered from sticking plasters to pacemakers but at times the three options multiple choice format was inhibiting. In many cases respondents may have been forced into answering 'no, when they might have liked to have responded yes 'in part' or 'with conditions'.

We also appreciate the efforts the MHRA has gone to make the consultation accessible and have found the Chapter format helpful.

However, further to our response to Q75.1, in many areas we found the consultation to be seems overambitious in the senses of

- seeking to do too much and all at once
- not sufficiently differentiating between low and high-risk devices and relative risks
- suggesting blanket approaches where a differentiated approach based on risk would have bene more appropriate
- combining essential requirements for patient safety with 'nice to have' gold-plating

All of which could cause significant extra work for manufacturers at a time when much of industry is struggling post Covid and seeking to cope with the effects of the UK's exit from the EU.

Most manufacturers had been working hard to prepare for the EU MDR 2017. Post the UK's exit from the EU, the ambition of manufacturers, importers and distributors is that the MHRA will take a realistic view about building on the preparations already undertaken with a view to creating a UK system which aligns as possible with the system of our international partners, to minimise the risk of double regulation and unnecessarily increased costs in the vital devices we use to assist eye care patients daily.

We hope our responses are helpful to the MHRA in achieving a proportionate regulatory regime for medical device safety in the UK.

We would be very happy to provide more detail on any of our responses or to meet with MHRA on a sector specific basis (eye care/healthcare) if that would be helpful, as policy is developed further.

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