Responses to the MHRA Consultation on the Future Regulation of Medical Devices in the UK

The following are the responses to the Medicines and Healthcare products Regulatory Agency's (MHRA) consultation on the future regulation of medical devices in the United Kingdom. These were submitted by: Dr Laura Downey, Dr Rachael Dickson, Dr Joseph Roberts, Professor Muireann Quigley, and Professor Jean McHale on 25th November 2021.

For the sake of brevity, as the consultation documents are extensive, we have included only the specific questions and responses here. To see the full consultation documents, which provide the necessary context to our answers please read the relevant chapters of the MHRA consultation available here.

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? (select answer)

Yes

Q1.2 Please set out what (if any) further amendments you would like to make to the scope of UK medical devices regulations. (Free text box 2500 characters)

N/A

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. (Free text box 2500 characters)

We broadly agree that the scope of the 2002 Regulations could be extended to include products that don't have an intended medical purpose but which have a similar risk profile, products intended for cleaning and disinfection of devices, products to support conception, for prediction/prognosis of disease etc. As we state later we support treating products with similar risk profiles to medical devices alike. However, we do not have expertise to offer an opinion on whether and what products currently regulated by the 2002 Regulations might be better regulated by other regulation.

The term "software" should be included in the definition of IVD to bring it in line with the position for general and implantable medical devices and to reflect the state of technology. In relation to extending the scope of the definition of IVD to include products which provide information concerning predisposition to a medical condition or disease, this would presumably include direct to consumer genetic screening (including companies such as 23andMe). This would reflect the position in the EU where the scope was extended by the In Vitro Diagnostics Regulations 2017/766 (IVDR). Whilst we broadly support this, one of the critical issues with such tests is lack of counselling services prior to using such products and when receiving potentially upsetting and life changing results. It is not clear if or how the Medical Device Regulations could account for this.

The example provided of the replacement of the word "handicap" with "disability" we would expect to have been made automatically. This is in line with international approaches to such matters; e.g. the United Nation Convention on the Rights of Persons with Disabilities.

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? (select answer)

Yes

Q1.5 Please set out the reasoning for your reply to questions 1.4, including your views on the materials that should be taken to evidence intended purpose, and any implementation considerations and expected impacts of any proposed changes. (Free text box 2500 characters)

In general, an objective test is desirable to avoid attempts to get around the regulations, or being captured by them, simply by claiming other intended purposes. Current MHRA guidance seems to reflect a partial objective interpretation of this clause already – with statements to the effect that claims on, for example, packaging that a device does not have a medical purpose will not exclude a device from the regulations where all other information clearly depicts a medical use. It is not clear if this objective test will extend to devices that might be put to medical purposes, but for which their advertised and "intended purpose" according to their instructions and other marketing materials falls short of this classification. This might occur, for example, in the cases of a large number of health and well-being apps.

This might not be such an issue if the scope is broadened to include/up-classify devices that do not have a medical purpose, but have a similar risk profile to medical devices. However, this may depend on whether there is a definitional change or whether specific devices/categories of device are named and included as within the scope of the regulations. Nevertheless, the position should be clarified one way or another.

Section 2: Products without a medical purpose

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? (select answer)

Yes

Q2.2 Please provide your reasoning for your response to question 2.1 (Free text box 2500 characters)

In line with our earlier comments, devices that do not have a medical purpose, but which have a similar risk profile to medical devices should be up-classified to improve safety requirements. It would bring into the scope of the Regulations devices that have risk profiles similar to medical devices and which interact with the body in similar ways to medical devices. Including them within the scope would enable the Regulations to treat like with like

and thus increase safety precautions for products with similar potential (adverse) consequences for patients and end-users.

Q2.3 If you answered yes to question 2.1:

a. Please outline which product 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. (tick boxes)

- 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
- Products intended to be totally introduced into the human body through surgically invasive means
- Products intended to be partially introduced into the human body through surgically invasive means
- Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by injection, excluding those for tattooing
- Equipment (including software) intended to be used to reduce remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty
- High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment
- Equipment intended for brain stimulation that applies electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain
- Diagnostic tests for health and wellbeing e.g. genomic testing for diet/nutrient optimisation, genomic testing for skin care, lactate testing for fitness training

b. Please describe how these products should be assessed to ensure that they are safe and perform as intended. (Free text box 2500 characters)

This is an issue which is explored later in the consultation document. They should be treated in the same way as clinical devices- please see later responses.

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) (Free text box 2500 characters)

We believe these products should be classified according to their risk profile in line with other medical devices. As stated in previous responses, this would treat like cases as like and improve safety.

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). (Select answer)

Yes

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. (Free text box 2500 characters).

The scope of the regulations should be expanded to include devices that don't have an intended medical purpose to reduce the prospect of risk to end-users. Such products pose considerable risk to end-users and in areas in relation to dermal fillers there have been calls for some years for tighter regulation both in this country and outside the jurisdiction. A move to include them in this new Regulation would be timely.

However, products that do not have a medical purpose and that are used for aesthetic rather than medical purposes should not have to show "clinical benefit" in the same way that products with a medical purpose do as they are not intended to provide clinical benefit. There is no requirement to show "clinical benefit" currently in the 2002 Regulations and neither are there questions on the inclusion of the need to show "clinical benefit" or definition of "clinical benefit" in the consultation despite it being mentioned in the sections on performance studies and clinical investigations. We note that question (Q31.4) asks whether a requirement for clinical investigations and for other pre-market studies for products with no medical purpose should be added to the regulations. Whilst such a requirement studies is very important and would facilitate consumer safety, the word "clinical" is not appropriate for this category of devices. We also note that there is no space provided to highlight this in text format after Q 31.4. A definition of "clinical benefit" and whether it could be required in the essential criteria should be clarified as if it is not included there may be issues of coherency in the operation of the regulations, and so that issues such as which products need to show clinical benefit can be addressed explicitly.

Section 3: Exclusion of products that contain viable biological substances

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

Don't Know/Opinion

Section 4: Exclusion of food

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

Don't Know/No Opinion

Q4.2 Please provide your reasoning (including any available relevant evidence) to support your answer to 4.1, including any impacts on you or other stakeholder groups. (Free text box 2500 characters)

The example given in the consultation of 'a cranberry-based product preventing cystitis' seems more like the kind of thing that is/ought to be covered by medicines rather than devices regulations. In the absence of examples where food substances are incorporated into devices/used as devices, then we lean towards agreeing that food should be excluded. But it is not clear what benefit explicitly excluding it in the Regulations (as opposed to saying in guidance that food is not generally considered as included). It is at least conceivable that technology might advance and explicitly excluding food now might fail to capture something which ought to be regulated in the future.

Chapter 2: Classification

Section 5: Classification of general medical devices

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? (Select answers)

Yes

Q5.2 If you have answered yes to question 5.1, please specify which of the amendments should be made. (Free text box 2500 characters)

We agree that the changes to the classification rules as set out are good and necessary.

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. (Free text box 2500 characters).

We broadly agree with the proposed changes as they would increase safety standards. They would also bring classification of these devices in line with their classification in the EU under the MDR/IVDR. Aligning risk classifications with the EU would also facilitate and support the trade and movement of medical devices, by removing a potential barrier to trade, between the UK, the EU and potentially more internationally. It would re-instate good and necessary provisions brought into law by the Medical Devices (Amendment etc)(EU Exit) Regulations 2019, but which we subsequently removed by the Medical Devices (Amendment etc)(EU Exit) Regulations 2019.

Chapter 3: Economic Operators

Section 6: Essential requirements for medical devices

Q6.1 Do you think the essential requirements of the UK medical devices regulations should be amended as set out in paragraph 6.4? (Select answer)

Yes

Q6.2 Please outline any other amendments which should be made to the essential requirements of the UK medical devices regulations. (Free text box 2500 characters).

We broadly agree that with the addition of essential requirements addressing the detail outlined, but we do not have the requisite expertise to comment further.

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. (Free text box 2500 characters).

We broadly agree that essential criteria need to be updated and that additional criteria need to be added to reflect international best practice and to keep abreast with the pace of technological development. We agree that explicit requirements are needed for electronic programmable systems which have been severely neglected in the regulations and the technology for which has vastly progressed since their drafting. The requirements should include: further detail to be provided about the uncertainties and potential long-term impacts of a device; when to consult a healthcare professional and how to report a serious incident; and list of ingredients/components that are known allergens, are all crucial for users and healthcare workers to make informed decisions about care and knowledge of risks. Indeed, it is not clear why they are not already requirements. Increasing information is also in line with aims to increase transparency. With regards to labelling, we support more detailed requirements to consider the end-user and what they might think about the 'intended use'.

Section 7: Manufacturer obligation measures for recompense

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?

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. (Free text box 2500 characters)

In principle having funds in place to compensate end- users and patients for adverse effects of devices is a reasonable and justifiable response to ensure that potential liabilities are covered. It would also bring the UK in line with the position in the EU as brought about by the MDR and IVDR and which would have been brought into place by the Medical Devices (Amendment etc)(EU Exit) Regulations 2019 before their amendment in 2020. However, we have some concerns about the impact of such a requirement.

It is not clear to what extent small medical device businesses/manufacturers would be affected by this requirement. In our responses to chapter 10 on SaMDs we note it is unclear whether non-profits, hobbyists, or patient-led collaborations (such as some open source software projects) are captured within the regulations and would thus be subject to this requirement to have funds to cover liabilities. If they are, such a requirement could have a

stifling effect on innovation coming from such quarters which should be taken into account both in relation to determining whether to include this requirement and/or in what form, and how or whether to include such contexts within the scope of the regulations in general.

Our secondary concern relates to the adequacy of the requirement. The Independent Medicines and Medical Devices Safety Review (IMMD) (aka the Cumberlege Review) recommended the introduction of an independent Redress Agency. Such an agency would conduct a non-adversarial process to determine where avoidable harm was caused through systemic failings rather than simply looking at individuals. It would provide financial and non-monetary support for individuals. Given the complexity and financial costs of legal processes (which are barriers to most people seeking redress/compensation through the courts), as well as the uncertainty and rarity of successful negligence claims (as demonstrated by the mesh scandal and subsequent actions), a National Redress Scheme could better provide support, acknowledgement, and financial recompense for those harmed by medical devices. Any requirement for medical device manufacturers to have sufficient funds to cover their liabilities would need to be supplemented by such measures if the needs of patients and end- users needs are to be adequately and fairly met.

Section 8: Health Institutions

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? (Select answer)

Yes

Q8.2 If you answered yes to question 8.1, please outline what you think should be included in this definition. (Free text box 2500 characters)

It should be made clear that the types of Healthcare Institutions to be included within the exemption are those that primarily deal with providing care through the provision of diagnosis, treatment, and in-person support. We are unclear and do not have the requisite expertise to comment further.

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

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

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

Q8.7 Do you think that health institutions should be required to register medical devices manufactured or modified 'in house' with the MHRA?

Yes

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

Yes

Q8.9 Do you think the provisions in paragraph 8.9 should be introduced for health institutions?

Yes

Q8.10 Do you think that medical devices manufactured on an industrial scale should be excluded from the health institution exemption and required to meet all relevant provisions of the UK medical devices regulations?

Yes

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. (Free text box 2500 characters)

If the aims of the in-house exemption are to account for the fact that healthcare institutions often need to create custom devices for a specific patient or patients as part of their care and to reduce the delay in getting that care to the patient(s), then we generally agree with its continued application. However, safety standards and transparency should not be compromised.

With this in mind in-house manufactured devices should be required to meet the essential criteria as set out in the Regulations and to meet the requirements set out in para 8.6, including having in place a suitable quality management system, and having a publicly available declaration that their devices meet the essential criteria. We agree in principle that adverse clinical incidents and other events impacting patient health connected with such devices should also be reported to the MHRA as part of increasing transparency, but would need more detail on what sort of “incidents” the regulator intends to be reported to comment further on this aspect.

Given the need to ensure effective and timely treatment, unless such devices are made available outside the healthcare institution or on an industrial scale, we do not think they should be required to have a UKCA. If the device is made available long term or is to be used in different institutions, it may be pertinent at that point to require a UKCA mark as the device enters wider circulation. Similarly, if a device is manufactured on a larger scale, the potential risk in that population and/or the potential for devices to be more widely circulated is greater. However, at what point a device might be considered manufactured on an “industrial scale” needs to be clarified and justified before being inserted into the Regulations.

It is essential that the in-house manufacture of medical devices provides good traceability to patients who receive said devices so that any issues relating to safety can be appropriately and adequately investigated. Publicly available information is needed to promote openness in the system and assure patients that regardless of where their device is manufactured the process of this manufacture is documented and available. With this in mind, we support amendments to require the registration of such devices with the MHRA, to register clinical investigations, and to enable the MHRA to request further information about the devices.

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?

Don't Know/No Opinion

Q8.14 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 8.12-8.13, including any impacts on you or other stakeholder groups. (Free text box 2500 characters)

Routine and specialist diagnostic services are not necessarily small scale, simply because they are concentrated in a particular laboratory or group of laboratories. And the example of the Supra-regional assay service given appears more akin to mass availability of testing/services (albeit on a smaller scale than other diagnostic services). The supra-regional assay service has multiple centres across the UK and is providing a mass service relating to a wide range of diagnostic tests, thus its work does not appear to be the kind of custom provision intended as the target of the health institution in-house exemption. We took the exemption to be related to one particular patient at a particular time or a specific group of patients. Thus, a stronger reasoning for why this service, and others like it, would need to be exempt is needed before Q8.12 can be answered in the affirmative or otherwise.

Section 9: Distance Sales

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

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

Yes

Q9.3 Please outline any other requirements that should be introduced for medical devices that are subject to distance sales. (Free text box 2500 characters)

We agree with the requirement as set out in para 9.6. In essence any entity which would be required to provide a copy of the Declaration of Conformity when it is NOT a distance sale should also be required to provide one when it is.

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. (Free text box 2500 characters)

Bringing medical devices offered by distance sales within the scope of the Medical Device Regulations would better reflect contemporary business practice given the ubiquity of the internet, and this would bring UK regulations in line with the position in the EU MDR/IVDR.

Our specific comments relate to SaMDs, on which we write more in chapter 10.

Targeting those supplying devices by distance sales rather than simply economic operators would mean that in the context of SaMDs, it would be the responsibility of app stores to ensure their advertised products bear a UKCA/UKNI mark and comply with the regulations. This may provide a practical means of policing the compliance of proliferating apps by ensuring that frequently used websites/app stores only advertise compliant devices to the UK market. Requiring that individuals, companies, or organisations offering medical devices by distance sales have a copy of the Declaration of Conformity of a medical device to present to the MHRA on request may also help to ensure some accountability and enforcement of the regulations. However, we note that this may also depend on, and thus is limited by, the ability of the MHRA to keep adequately up to date with websites and so that offer such devices.

In chapter 10 on SaMD it is asked whether clearer requirements are needed in the regulations for deployment of SaMD that is hosted on servers outside the UK. In addition to comments made in response to that particular question, we would add here that it should be made clear whether manufacturers based outside the UK, but offering devices via distance sales (which may nevertheless need shipping to the UK) will be captured in these amendments. If they are, then much will need to be done to raise awareness of the relevant regulations and manufacturers' obligations to those offering devices via distance sale, including the need to register and have a UK Responsible Person.

Section 10: Claims

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

Yes

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. (Free text box 2500 characters)

Ensuring that false or misleading claims are not permitted on medical device packaging, instructions and other marketing material is critical to ensure transparency and that end-users have accurate information about devices and can make informed choices. We note that provisions in the Consumer Protection from Unfair Trading Regulations 2008 cover misleading advertising and aggressive advertising. They include requirements that objective claims must be backed by evidence, marketers must not discourage medical treatment, marketing of diagnostic devices must not make claims that might lead to mistaken diagnosis,

and marketers must not make false claims that a product is able to cure an illness. With this in mind, clarity on what will be added to the medical device regulations and how they will interact with provisions in other legislation is needed.

Section 11: Quality Management Systems

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

Yes

Q11.3 Do you think that all manufacturers, including Class I and general IVD manufacturers, should be required to apply an appropriate Quality Management System?

Yes

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. (Free text box 2500 characters)

Whilst we broadly agree that manufacturers should be required to apply quality management systems, and that at a minimum they should be addressing the points suggested as a means of strengthening safety of devices and increasing transparency in the manufacturing process, we do not have the requisite expertise to comment further on this.

Section 12: UK Responsible Persons

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

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?

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

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

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

Other

Not all devices will have the same expected lifetime, Some may be quite short, some may be very long. In addition, for some patients, their devices may continue to function well beyond the original anticipated lifetime of the product. As such, it is probably reasonably to have a time-period which is for 'the expected lifetime of the device, after the last product has been manufactured' PLUS a buffer period.

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

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?

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. (Free text box 2500 characters).

We agree that the UK Responsible Person (UKRP) should be required to have an address in the UK at which they are physically located. This would go some way to ensuring the accessibility of UKRPs in carrying out their tasks and in the event that proceedings are brought against them.

With regards to the requirement that the UKRP be legally liable on the same basis as the manufacturer, it is unclear from the information provided how this would work. If the UKRP is, for instance, a direct employee of a large company, then to some extent they are the company when acting in this capacity. If, however, they are tasked with being the UKRP on some other contractual basis, it is unclear how they could be liable on that basis and to what ends. This is not to say that they shouldn't be held liable in their own right for failing to execute their obligations under the Regulations, but this would be liability relating to their own role not on the same basis as being the manufacturer.

Section 13: Obligations of importers and distributors

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

Yes

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

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

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. (Free text box 2500 characters)

We agree in principle with requirements aimed at improving the traceability and monitoring of medical devices and ensuring that, across the supply chain, medical devices are handled in ways that reduce the risk of damage. For this reason we support the proposed requirements listed in para 13.4. Since issues with supply of medical devices may also have an impact on public health, we also support the requirement to notify the MHRA of any known issues in the supply chain.

Section 14: Qualified Persons

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?

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? (Free text box 2500 characters).

We do not have the relevant expertise to comment in depth on this issue. However, given the myriad and often complex processes/routes to compliance, and given the currently unconsolidated, complex and unwieldy nature of the 2002 Regulations and subsequent amending regulations, we think that experience and expertise of navigating the legislation and regulatory process is a crucial factor. It is unlikely that simply having a qualification in one of the disparate disciplines listed in para 14.3 would be enough for a person to have the knowledge and skills to navigate and advise UKRPs or manufacturers on the regulatory system and its requirements.

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?

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. (Free text box 2500 characters).

In principle we agree that having access to a person/group who have experience and expertise to guide and advise on meeting the regulatory requirements is a positive thing. However, we

are concerned that requiring such a person be available in an organisation or be "at the disposal" of SMEs might be an impractical, financial barrier to many SMEs, non-profits, patient-led initiatives, or hobbyists (for whom inclusion within the ambit of the regulations is ambiguous and may need to be clarified as per our comments in Chapter 10 on SaMDs). This in turn may impact innovation and development.

We note, as per para 14.2, that the MHRA has historically provided advice to some manufacturers regarding the UK medical devices regulations. We wonder whether a formal, funded and supported service, within the MHRA would be better in these cases. As noted above, even having a qualification in a relevant discipline does not actually ensure adequate knowledge of the 'Qualified Person' of the detail of the Regulations, regulatory structures and processes, compliance, and so on. This is very specialised knowledge. We understand, of course, that the ability to provide this service would be contingent on an adequate level of resourcing of the MHRA for this service.

Should this become a requirement then it would need to be clarified in the Regulations/guidance what being 'permanently and continuously at their disposal' is to mean in practice.

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

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 *

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 *

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 *

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 stakeholders? (Free text box 2500 characters)

In order for economic operators to have certainty in relation to their legal responsibilities and liabilities, it is critical that we have clarity on the kinds of activities that would lead to them to assume the responsibilities of manufacturer, which are substantial. Given that changing the purpose of a medical device or making modifications that impact its performance may

implicate new/added risk, it seems pertinent that such actions require the economic operator to fulfil the obligations of a manufacturer and to follow the requisite requirements.

As not all modifications lead to such changes or implicate new or increased risk profiles it is also crucial to be clear on what actions will not attract such obligations. The translation of instructions/information or changes to packaging are reasonable examples of such actions.

Chapter 4: Registration and UDI

Section 16: General Background

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

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? (Free text box 2500 characters)

We do not have the requisite expertise to comment on the time period for tracking and record keeping. However, we support this as a general requirement and would recommend that records should be retained for a minimum of 20 years.

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. (Free text box 2500 characters)

Traceability at international level is increasingly seen as an important part of patient safety. This features in the EU Medical Devices Regulation with the use of the Unique Device Identifier. This can be regarded as an important part of ensuring safety and also maintaining public trust and confidence.

Section 19: Unique Device Identification

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

Yes

Q19.2 If you answered yes to question 19.1, please outline what you think should be included in this definition. (Free text box 2500 characters)

We agree that a definition of the term Unique Device Identifier should be included on the face of the Regulations. However, we do not have requisite expertise to comment on the nature of the definition.

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

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

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

Yes

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

Yes

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

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

Don’t Know/No Opinion

Q19.12 If you have answered yes to question 19.11, please outline what medical devices should be exempt. (Free text box 2500 characters)

More information would be required on the reasoning to potentially exempt these types of devices in order to give a fuller answer as to whether or not they should be exempt. However, as a general rule tight traceability seems desirable regardless of the device.

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

Yes

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

Q19.16 If you answered yes to question 19.15, how long should manufacturers be required to hold this information? When responding to this question, please indicate whether you think there should be different minimum periods of retention depending upon type of device/risk classification. (Free text box 2500 characters)

We agree that manufacturers should be required to retain information on the devices and UDIs they have assigned for a period of time. We do not have the requisite expertise to comment fully on the time period this should be for. However, for the purposes of ensuring the traceability of devices and for monitoring potential adverse events, the time period should take into account the risk classification and life-cycle of the devices in question.

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

Yes

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

Other - All implantable medical devices and higher risk devices (Class III and IIb) whether they are implantable or not.

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

Yes

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.

Other - All implantable medical devices and higher risk devices (Class III and IIb) whether they are implantable or not.

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

Yes

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. (Free text box 2500 characters)

We agree in principle that rules should clarify the UDI system, but we do not have the requisite expertise to comment further.

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 your or other stakeholders (Free text box 5000 characters)

We think it is imperative to improve the traceability and monitoring of medical devices in order to improve reactions to adverse events, identify where devices are, and who may have one in the event that a device recall or other corrective action is necessary. This latter aspect is particularly pertinent for implantable medical devices given that a lack of data on recipients of implants was a factor of concern during the PIP breast implant scandal. As implantable devices have direct interaction within the body over time (even for transitory and short- term implants), we think it is imperative to ensure a higher level of traceability through supply

chains to recipients and to have comprehensive data for monitoring and trend spotting. Ensuring robust data capture for medical devices in an accessible and comprehensive system is also a key recommendation in the Cumberlege Review. The current fragmented system meant that often information had either been unrecorded, or significant events/data had been recorded in an unlinked, inaccessible format (See the IMMD Review 2020 para 2.78-2.84). As such, as a minimum UDIs of all implantable devices should be stored, but we see no reason why devices in higher risk categories such as class III and class IIb should not also be covered regardless of whether they are implantable.

Section 20: Great Britain database on medical devices

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

Yes

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. (Free text box 2500 characters)

For many of the same reasons outlined in our answer to Q19.23 we support the creation of integrated databases that capture information on registration, vigilance, post-market surveillance, and market surveillance of medical devices. As outlined previously, one of the findings of the Cumberlege Review was that the fragmentation in the system led to inconsistent recording of information and that often information could not be linked through the system to provide proper learning on failings, patient outcomes or potential adverse incidents in relation to medical devices (and medicines). Having integrated databases can provide a centralised source for information that can be linked intelligibly and made available for monitoring to ensure that adverse incidents and failings are caught earlier and appropriate action taken, thus improving outcomes and safety for patients and end users.

In line with the Cumberlege Review we would also suggest that these integrated databases could go beyond the purposes listed in the consultation and also link to patient reported outcomes on experiences of perceived improvement. This data, if collected more consistently across the healthcare system, could provide much needed information on the therapeutic benefits (or lack thereof) for patients. It could also provide learning across the healthcare system.

Critical to the development of databases will be measures in place, including regulatory measures, to protect patient data. Any move to create these integrated databases should also have robust data protection at its core.

Section 21: Registration of Medical Devices

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

Yes

Q21.2 Please specify any changes proposed and your rationale in relation to question 21.1. (Free text box 2500 characters).

In addition to item 5 on the list, which asks manufacturers/UKRPs to identify other countries where the device is/has been on the market/made available, they should also be required to: (1) identify any countries where approvals/authorisation to place on the market have been denied and (2) the reasons given by the relevant body/authority for not approving the device.

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

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). (Free text box 2500 characters)

All information pertinent to the safety of a device, UDI and its supply chain should be made publicly available to allow end-users (including patients and healthcare workers) to see the potential risks associated with a device, the conditions for storing the device, and information that may be pertinent to identifying if/where it is traded elsewhere (for example other trading names). This will also aid them in caring for the device. Such information is crucial for safety and to allow members of the public to identify whether a device/product that has caused issues or adverse incidents is traded under other names thus increasing transparency and enabling better traceability. In general, there does not seem to be a reason why the information in list one should not be made public unless it is commercially sensitive.

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

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 devices registration details?

Yes

Q21.10 Please provide reasoning to support your answer to question 21.9. (Free text box 2500 characters)

We agree that economic operators should update the MHRA as soon as possible if information they are registered has changed. However we do not have the requisite expertise to recommend a specific timeframe within which such information must be submitted or the impact that this may have on medical device manufacturers/economic operators.

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

Q21.13 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 21.1-21.12, including any impacts on you or other stakeholder groups. (Free text box 2500 characters)

Increasing the information collected and registered about medical devices, especially that relating to risks of the devices, potential allergens and similar ingredients/components, and information pertinent to identifying, tracing, and monitoring devices is crucial to increase transparency and facilitate a more responsive system. In general, supporting an increase in transparency in medical devices means we are in favour of collecting and making available information about medical devices and manufacturers that is not otherwise commercially sensitive or infringes confidentiality. As part of this increase in transparency it is also critical that the information collected and stored is as up to date and accurate and as such that any changes to information are recorded as soon as possible and that there are reminders to those eligible to register information regularly enough to catch any overlooked inaccuracies.

Chapter 6: Conformity Assessment

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

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

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.

Notification to the MHRA will facilitate ultimate scrutiny, oversight and accountability. It will facilitate standards of quality and safety being maintained.

Section 28 - Certificates of Conformity

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

Yes

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 should be specified as this would facilitate consistency in approach to approvals and to scrutiny. The suggested criteria in the consultation document should be adopted.

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

Yes

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

The approach taken by Approved Bodies in relation to this would need to be very carefully monitored to ensure that there was consistency of approach. The MHRA should set very detailed guidance as to what categories of restrictions should be capable of being imposed which relate to the type of devices which were under consideration.

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

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 certificate itself, when it was awarded, to which organisation, the date.

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 information would facilitate traceability and oversight by the MHRA of the CE process which in turn would facilitate patient safety.

Section 30 - Declaration of Conformity

Q30.1 Do you think that the UK medical devices regulations should set out the minimum content requirements for the Declaration of Conformity?

Yes

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

We would support the inclusion of all criteria as set out here.

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.

These criteria are again important to facilitate consistency in approval processes, will facilitate ultimate oversight and accountability and help to ensure patient safety.

Chapter 7: Clinical Investigation/Performance Studies

Section 31: Clinical evaluation (general medical devices)

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

Yes

Q31.3 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. (Free text 2500 characters)

It is important for patient safety, transparency, and accountability that clinical performance data and clinical evaluation procedures can be precisely distilled. Preventing extraneous claims of equivalence by limiting the circumstances in which equivalence can be claimed will improve patient safety and contribute to end-user confidence in products. Further, the measures described will enable post-market surveillance to be more precise and any issues identified precisely.

Q31.4 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

Section 32: Performance Evaluations (IVDs)

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

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

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

Q32.4 Do you think that 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

Q32.5 If you have answered yes to question 32.4, please outline what factors you think this justification could include. (Free text 2500 characters)

The requirements relating to the clinical performance evaluation of medical devices has developed over time. Initially there was no direct definition in EU Directive 98/79/EC, but the concept of external evaluations emerged to denote performance studies that occurred outside the own premises of the manufacturer. Standard EN 13612 and the IVDD further developed this concept by permitting evidence in the form of data already available to the manufacturer, scientific literature, or data from external evaluation studies in other appropriate premises. Under the IVDR the requirement is that rules on performance studies should be in line with well-established international guidance in the field and a new international standard is under development ISO 20916. The level of documentation required for external studies is higher than those for internal studies and the guidance emphasises that the rules must be followed unless justification can be provided. However, objective criteria for this justification are not stipulated.

It would be advantageous for Great Britain to adhere to these standards as rigid objective criteria on the factors justifications could include may create undue barriers for devices being placed on the Great Britain market. Requiring justification, at all stages, for reliance on external evidence would promote best practice and demonstrate adherence to international standards without creating additional requirements for manufacturers. It is unclear from the proposed changes whether clinical performance evaluation studies carried out by the manufacturer in another jurisdiction, for example Europe, would be viewed.

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

Section 33: General requirements regarding clinical investigations (general medical devices)

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?

Don’t Know/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

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

Yes

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

Yes

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

Q33.6 Please outline any other requirements which should be introduced for the sponsor. (Free text 2500)

We broadly agree with the changes suggested in para 33.7, but query why it would be necessary for a publicly available summary of the study to be made available at the time of *submitting* a formal application to the MHRA. There might be good reasons why a manufacturer would not want to make information available until after an application has been approved. It would, however, be reasonable to require such a summary after approval.

It should also be noted that as currently drafted the text of the consultation refers to "clinical benefits" and "clinical safety"- however the proposals earlier in the consultation which we support also relate to devices which previously were excluded from "medical devices" regulations, which do not have an intended medical purpose. Thus the word "clinical" here would not be appropriate. However pre-market approval scientific investigations/pre-market studies would be important as a means of ensuring consumer safety.

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

Yes

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

Yes

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

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 para 33.12?

Yes

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 para 33.13?

Yes

Q33.15 Please outline any other requirements that should be met when performing a clinical evaluation. (FT 2500)

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

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

Yes

Q33.18 Please outline any other requirements which should be introduced for investigators of clinical investigations and the personnel involved in clinical investigations. (FT 2500)

Qualifications and/or appropriate experience would be a more appropriate requirement since it is conceivable that some investigators may have qualifications (not lack thereof) outside the usual disciplines/areas.

Section 34: General requirements regarding performance studies (IVDs)

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

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

Yes

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 para 34.7?

Yes

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

Yes

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

Yes

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

Yes

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 para 34.9?

Yes

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

Yes

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

Yes

Q34.14 If you have answered yes to Q34.13, please outline what the requirements for the clinical performance study report should be. (FT 2500)

We do not have the expertise to comment on the specifics of the reporting requirements for clinical performance studies. However, setting minimum standards is desirable, as this will ensure consistency in the format of reporting and stops the omission of information that might be important.

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

Don't Know/No Opinion

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

Yes

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

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

Don't Know/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?

Don't Know/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

Q34.22 Do you think the conditions for conducting a performance study should be set out in the UK medical devices regs, including those outlined in para 34.15?

Yes

Q34.24 Do you think the rights of subjects to withdraw from a performance study should be included in the medical devices regulations, as set out in paragraph 34.16?

Yes

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?

Don't Know/No Opinion

Q34.27 Do you think the UK medical devices regs 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

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

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. (FT 2500 – which is ridiculous to respond to 28 questions!!)

In relation to Q34.24 and the right to withdraw - the proposed changes are too narrowly defined and need more detail about what ought to happen to a device that has been implanted as part of a trial. We suggest that, in relation to these, a proportionate and tailored response would appropriate. This should include a requirement that sponsors include, in both their clinical performance study plan and application, a detailed outline of the withdrawal procedure and how, in relation to their specific device, the patient's right to withdraw will be respected.

Section 35: Informed consent

Q35.1 Do you think the UK medical devices regs should include requirements for obtaining informed consent from individuals participating in a clinical investigation or performance study?

Yes

Q35.2 If you have answered yes to question 35.1, please outline what the requirements for obtaining informed consent should be. (FT 2500)

Informed consent should be gained in a similar manner to that required in clinical trials for medicinal products. Participants should be given information about the trial procedure and their role in it, this document should outline their rights and provide points of contact to communicate with during and after the trial. Informed consent should be gained before a person is entered into a trial and reaffirmed periodically throughout the trial process, particularly if the trial is adjusted and their participation alters as a result. The Clinical Trials Regulations provide explicit requirements for gaining consent from incapacitated adults and minors. Section 251 of the NHS Act 2005 facilitates access to personal information without consent for defined medical purposes, such a measure may be appropriate in relation to medical devices.

Requirements for consent should also comply with existing English law more broadly. It should clearly state that consent must be freely and voluntarily given subject to no pressure. It should be informed of all relevant aspects and risks of the investigation which a reasonable person in the participants position would want to know, but also what that specific person would want to know (see Montgomery v Lanarkshire [2015]. Participants must have mental capacity under the Mental Capacity Act 2005. Specific provisions would need to be inserted in relation to any inclusion as participants of children to comply with the law concerning capacity.

Q35.3 Please outline any circumstances in which you think the requirements for obtaining informed consent might be waived? (e.g. observational studies where only fully de-identified data and/or left-over samples are used, or cluster randomised trials) (FT 2500)

Left over samples are a matter already separately regulated under the Human Tissue Act 2004.

Q35.4 Please provide your reasoning (including any available relevant evidence) to support your answers to 35.1-35.3, including any impacts on you or other stakeholder groups. (FT 2500)

The justification for this is stated above. Informed consent is a requirement in English law and to have the precise requirements stated clearly in the Regulation will ensure compliance with these legal principles and respect fundamental human rights, as well as facilitate trust, transparency, and patient safety

Section 36: Specific requirements for clinical investigations/performance studies

Q36.1 Do you think additional requirements, including those outlined in para 36.3, should be required for clinical investigations or performance studies on minors?

Yes

Q36.2 Please outline any other requirements which should be introduced for clinical investigations or performance studies on minors. (FT 2500)

The Regulations ought to clarify whether the proposed changes set out in para 36.3 all need to be met for the minor to participate or singly. We presume it is meant that they all should be met. In general we support this. However, note that there needs to be clarity on what 'direct benefit to the minor subject' means in item (d). It is at least conceivable that there may be circumstances in which this does not mean direct 'medical' benefit, but some other sort of benefit, such as in studies on low-risk devices where minors and their families might want to contribute to the overall research endeavour. It is not clear that they ought to be precluded simply in virtue of being a minor. Other additional safeguards could be required in such circumstances, for instance, review by specific ethics committees with expertise in studies on minors.

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

Yes

Q36.4 Please outline any other requirements which should be introduced for clinical investigations or performance studies on pregnant or breastfeeding women. (FT 2500)

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 included a provision, which was subsequently removed by paragraph 54 schedule 2 of the Medical Devices (Amendment etc.) (EU Exit) 2020, that 'no incentives or financial inducements are given to the subject except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation.' This should also be included in any updated medical devices regulations as some pregnant or breastfeeding women's decision to take part in a study, and assume a level of risk to their foetus or child, might be influenced by a financial incentive due to their personal circumstances.

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. (FT 2500)

In relation to specific informed consent procedures for minors, these are imperative in order to take account of the different developmental stages of minors at different ages. Minors should not automatically be deemed incapable of providing informed consent. Participant information should be provided to a minor prior to enrolment in a trial and the information adapted to their age and maturity levels. It should be specified that personnel experienced in working with minors should communicate this information to the minor participant. If a minor is capable of forming an opinion based on this information, their opinion should be respected. Importantly, consent should not be deemed to have been provided by their legal representative on their behalf if a negative opinion is expressed.

The conduct of a clinical investigation using minors must be necessary; that is, for a device that is used in the treatment of a condition that only occurs in minors or to validate data from earlier studies using persons able to give informed consent. In most cases, there must be an expected direct scientific benefit. However, as noted in our response to Q36.2,

there needs to be clarification on what 'direct benefit' should be taken to mean. And it is conceivable that there will be circumstance where there is not a direct benefit, but where participation would nonetheless be justifiable or beneficial (by some other measure). Appropriate extra safeguards should be in place in such circumstances.

Measures relating to minors should also include provisions that reflect the position of a minor who reaches the age of majority during the course of a trial/investigation. In such incidences, express consent should be reaffirmed for their continued participation in the study. The proposed additional requirements in para 36.3 are slightly diluted from those included in the The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 which were removed by paragraph 54 schedule 2 of the Medical Devices (Amendment etc.) (EU Exit) 2020, . The full breadth of the additional requirements provided in the 2019 Regulations should become part of any new regulations.

Section 37: Clinical investigations/Performance studies in emergency situations

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

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. (FT 2500)

It would need to be in compliance with the provisions of the Mental Capacity Act 2005.

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

Yes

Q37.4 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 37.1-37.3, including any impacts on you or other stakeholder groups.

We support the inclusion of such provisions as they indicate an improved consideration of patient safety within the regulations. It is important that the medical device regulations recognise that harms can occur at any stage of device use, not only after the device has been placed on the market. The measures outlined in paragraph 37.4 would close a gap in protection for those who assume additional risks by agreeing to participate in medical device trials. It also has the advantage of potentially reducing the burden on the courts as potential litigants could have issues resolved without necessarily having to go to trial. It could also speed up compensation payments.

Section 38: Application for clinical investigations/performance studies

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 para 38.2 should be outlined?

Yes

Q38.2 Please outline any other requirements which should be introduced for the application form and accompanying documentation. (FT 2500)

The application should also collect information on whether or not any applications for the study to be conducted in other countries have been approved or rejected. The reasons for this should also be required, especially if they have been rejected. This would ensure that the fullest information is available to the MHRA in making its decisions on the applications.

Q38.3 Do you think the UK medical devices regs 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

Q38.4 If you have answered yes to Q38.3, please outline what appropriate timescale should be. (FT 2500)

Specifying the timescales on both sides would ensure clarity in the decision-making processes and ensure that applications are dealt with in a timely manner. It is imperative that adequate resourcing of the MHRA is in place to facilitate this.

Section 39: Assessment of applications for clinical investigation/performance study by the MHRA

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

Yes

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

Section 40: Conduct of a clinical investigation/performance study

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 para 40.2?

Yes

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

Yes

Q40.4 Please provide your reasoning (including any available relevant evidence) to support your answers 40.1-40.3, including any impacts on you or other stakeholder groups. (FT 2500)

The inclusion of these requirements supports safety, transparency, and best practice within the sector and will go some way to ensuring compliance and identifying problems and issues at an early stage. Inspection of clinical investigation and/or performance study sites will enable early warnings to be issued and reduce the possibility of devices that could cause harm upon reaching the market. While it seems appropriate that devices which are self-tested or tested in a home setting are exempted from such inspections, it should be emphasised in the Regulations that self-testing and home testing should only be used for devices whose ordinary use would occur in these settings and would not be an option for other devices.

Section 41: Clinical investigations/Performance studies regarding devices bearing the UKCA mark

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 para 41.3?

Yes

Section 42: Modifications to clinical investigations/performance studies

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

Yes

Section 43: Corrective measures to be taken by the MHRA in relation to a clinical investigation/performance study

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

Yes

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 para 43.2 (suggested measures)?

Yes

Q43.4 If you have answered yes to question 43.3, please outline what you think should be specified time period for the sponsor or investigator to give their opinion. (FT 2500)

We support this as it gives a right to reply, chance for clarification, and opportunity to gather extra information. The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 regulation 117 (2), paragraph 54 schedule 2 of the Medical Devices (Amendment etc.) (EU Exit) 2020, stipulated 7 days unless immediate action was required in which case the Secretary of State could act without their opinion.

Section 44: Information from the sponsor at the end of a clinical investigation / performance study or in the event of a temporary halt or early termination

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

Section 45: Recording and reporting of adverse events that occur during clinical investigations / performance studies

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

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

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

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

Q45.5 Please provide your reasoning (inc any available relevant evidence) to support your answers to questions 45.1-45.4, inc any impacts on you or other stakeholders. (FT 2500)

With regards to Q45.3, this will enable timely reporting and prevent delays whilst fuller information on any incidents is being collected and collated.

With regards to Q45.4, medical device manufacture is a worldwide business and it is important for maintaining the safety of medical device users that the MHRA is alerted to any adverse incidents which occur in a non-UK country. Now that the UK no longer part of the EU and will not receive automatic alerts from Eudamed, procedures need to be in place so that the UK device users have a full picture with regards incidents relating to a particular device. Such procedures and sharing of data would contribute to decision-making and promoting best practice. It would also contribute to full transparency and accountability for device manufacturers.

Section 46: Types of clinical investigations / performance studies and exemptions / authorisations

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

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

Section 47: Summary of safety and clinical performance

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

Yes

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

Q47.4 Please outline any other content which should be included in the SSCP for a medical device. (FT 2500)

We agree that the minimum requirements should be specified. This would help to ensure consistency and to ensure that full information is given.

Q47.5 Please select one of the following:

The manufacturer should upload the full SSCP to the MHRA registration system

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

Yes

Chapter 8

Section 48: Post-market surveillance

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

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

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 IVDs performance evaluation?

Yes

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

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?

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 post-market surveillance report or a periodic safety update report as they are described in paragraph 48.9?

Yes

Q48.9 if you have answered yes to Q48.7, 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. (FT 2500)

We agree in principle that medical devices should be subject to a post-market surveillance report as outlined, however we do not have the requisite expertise to comment on which classes of medical devices should be covered or of other further elements that should be on such reports.

Q48.10 If you answered yes to Q48.7, please outline which types or classes of medical devices should be subject to a periodic safety update report and if there are any other elements that should be required for a periodic safety update report. (FT 2500)

We agree that some medical devices should be subject to more in-depth obligations relating to annual or biannual submission of a periodic safety update report, however we do not have the requisite expertise to comment on which classes of devices should be covered by the obligation or of further elements that should be included on such reports. Having said this, as a minimum we believe that Class III devices and all implantable medical devices should be covered by the obligation.

Q48.11 If you answered no to Q48.7, please outline any alternative requirements for how the manufacturer should summarise and present post-market surveillance data. (FT 2500)

We do not have the expertise to suggest any alternative requirements. However, we do note in relation to Q48.7, that what constitutes a 'sufficient justification' for an exemption would need to be specified in the Regulations and/or guidance.

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

Yes

Q48.13 Please provide your reasoning (including any available relevant evidence) to support your answers to Q48.1-48.12, including any impacts on you or other stakeholder groups. (FT 2500)

In line with our other responses, we believe that having to implement and follow a post-market surveillance plan and post-market performance follow up would facilitate better monitoring of devices, increase safety, and mitigate risks. Having to report the findings to the MHRA would also increase transparency and ensure that information critical to the safety, performance, and clinical benefit of devices over their lifecycles would be available for scrutiny and part of any integrated databases (suggested in section 20).

We do not have the requisite expertise to comment on whether requirements for how post-market surveillance and post-market performance plans should be conducted should be on the face of the legislation. Although we do note that encouraging scientific rigour in collecting and processing information relating to the safety and performance of devices is critical.

Section 49: Reporting of serious incidents and field safety corrective actions

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?

Yes

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

Yes

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

Yes

Q49.5 If you have answered no to Q49.4, please outline what the timeframe for reporting serious incidents should be, or any other changes you would make to the criteria set out in para 49.9. (FT 2500)

We agree that manufacturers should report serious incidents as soon as possible/immediately upon finding a causal relationship with their device. However, contradictory language is used as between the body of para 49.9 and the time periods specified in points a., b., and c. As such, it is not entirely clear from the wording of para 49.9 whether regulations would require that manufacturers notify the MHRA within the time period specified beginning from the point at which they have established the causal relationship between the incident and their device, or simply from the time they become aware of the incident. The former is the more reasonable requirement.

However, we note a concern regarding the wording of this in the consultation. As it is presented, manufacturers would only have to report the incidents once they have 'established a causal relationship' or that 'a causal relationship is reasonably possible'. This would seem to give too much latitude for manufacturers to claim that they did not report an incident because they had not yet established a causal relationship or that they did not think it was reasonably possibly. There should be a requirement to report where they are less certain in order for them to work with the MHRA to investigate this and to ensure problems and trends are uncovered as early as possible.

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?

Don't Know/No Opinion

Section 50: Trend reporting

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

Q50.2 Please provide your reasoning (including any available relevant evidence) to support your answers to Q50.1 including any impacts on you or other stakeholder groups.

In principle we agree that manufacturers should be required to report statistically significant increases in frequency and severity of incidents/erroneous results. This would greatly enhance the monitoring of devices and provide much needed information on whether devices actually provide benefits that justify their potential risks. It would also help to establish the accuracy of their risk assessment over time. We do not have the requisite expertise to comment further.

Section 51: Analysis of serious incidents and field safety corrective actions

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?

Yes

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

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

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? (FT 2500)

We agree that engaging patients in vigilance would be of benefit to monitoring medical devices. At a minimum there should be a well-publicised means for patients to contact manufacturers to report on specific devices - via an online form for example. Manufacturers could also engage in periodic focus groups with patients and end users with experience of living with the devices.

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

Other

Manufacturers should be required to engage with patients and the public in both of the circumstances listed above, but also when the device is in development. Engaging with potential end-users, and those with similar devices, whilst new devices are in development would aid in troubleshooting prior to devices being placed on the market.

Q51.6 Please provide your reasoning (including any available relevant evidence) to support your answers to Q51.1-51.5, including any impacts on you or other stakeholders. (FT 2500)

In principle we agree that involving and engaging patients is desirable. Indeed, engaging patients during the development process of some medical devices might benefit overall

design and performance according to patients' needs and experiences. In terms of vigilance, patients and end users will also be best placed to provide feedback on adverse experiences and side effects that may not otherwise come to light.

We do not have the requisite expertise to comment on the impact on some stakeholders, but do note that for many small and medium sized businesses or resource-strapped manufacturers, may find such requirements more burdensome than others. As such, flexibility in terms of the form such engagement might take may be desirable.

Chapter 10: Software as a medical device

Section 58: Scope and Definition

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

Yes

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?

Yes

Q58.3 If you have answered yes to Q58.2, please outline what additional additions/modifications are required. (FT 2500)

In relation to SaMDs, the term "manufacturer", and how it can/should apply to software developers, should be clarified. Currently the definition reflects an understanding of manufacturing as pertaining to physical goods and, as such, presupposes a central, easily identifiable entity or person as "manufacturer". Software development, especially open source software projects, do not necessarily conform to the structures of physical manufacturing and may have diffuse, global, and collaborative development models where responsibility for a product may not be claimed by or linked to any one entity/person.

Clarification is also needed regarding what it means to "place on the market" with regards to SaMDs. It is imperative that manufacturers and other entities know when/how or by what acts software/apps made available via download or streamed as distance sales can be said to be placed on the market. Further, the current definition as supplemented by Art 2(2) and 2(1) of Regulation (EC) No 765/2008 definition of "making available on the market" implies a commercial context, although no money needs to exchange hands. What is meant by a commercial activity/context needs to be made clearer in the regulations. It also needs to be made clear whether the scope of the regulations will extend to apps and open source software offered free of charge and which may be developed and made available by non-profits, amateur or "hobbyist" developers and/or as part of collaborative/patient led initiatives who may be acting outside a traditional commercial context.

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. (FT 2500)

The Medical Device Regulations (and the EU law which they implemented) were in essence designed to regulate tangible/physical goods and are informed by business and manufacturing models of the 1980s. Whilst software was added to the definition of "medical device" in 2008 none of the operational mechanisms or key definitions/terms were updated to reflect the realities of digital products or contemporary manufacture and software development. This can be seen in the current lack of provision for distance sales and in the difficulties and ambiguities in interpreting and applying key terms such as "manufacturer" and "place on the market" to the context of SaMD. Open source models of software development, in particular, are challenging in these respects.

The accessibility of software development has not only led to a proliferation in medical apps, it means that many developers may become "manufacturers" of medical devices without even being aware of this. There is also ambiguity as to when/whether software is "placed on the market" when it is done so by non-profits, for free, and/or as part of patient-led activities. In such cases there may be easily identifiable legal "manufacturer". These lacunae should be addressed.

Software developed within open source collaborations and available as uncompiled script also poses difficulties regarding whether or not they fall within the scope of the regulations. Having clarity on this may be particularly important if suggestions to require that manufacturers have enough funds to adequately compensate for harm caused by medical devices are also to be implemented.

A final point to raise relates to the part of the consultation which states that SaMD will mainly be dealt with through guidance, but no rationale is given for this. We appreciate that SaMD and AIaMD are particularly fast moving, and that setting too much in the regulations may lead to difficulties in the future. Indeed this is partially the cause of the current gaps and difficulties relating to SaMD and medical devices regulation. However, the guidance should supplement, or provide detail or clarification on, substantive provisions contained in the regulations. Such substantive provisions are necessary to ensure that manufacturers, economic operators, and other regulatees are aware of their obligations under law and are legally bound to comply with those obligations.

Section 59: Distance Sales

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?

Yes

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

Yes

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. (FT 2500)

Given the ability to download software from anywhere in the world, there is a need to clarify when and how SaMD is placed on the UK market. Inserting provisions regarding distance sales would bring the regulations in line with the EU MDR and IVDR. It would reinstate much needed provision which the Medical Devices (Amendment etc)(EU Exit) Regulations 2019 inserted into the 2002 Regulations, but which were subsequently removed by the Medical Devices (Amendment etc)(EU Exit) Regulations 2020.

It is not clear however, what acts or factors would help establish whether or when a SaMD offered via distance sales is "placed on the market". EU guidance published in 2016 on distance sales in general highlights that whether distance sales are offered for the EU market may be discerned from the languages websites use and the listed locations to which shipment is provided. However, as English is an international language and as software can be downloaded anywhere these factors are of limited utility in the SaMD context.

Further, in the case of some open source software or when software is made available as uncompiled script (that may be cut and paste rather than available as click for download), it is not clear whether or by what act this is made available/placed on the market. This should be taken account of in the regulations/guidance.

Section 60: Classification: Risk categorisation

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?

Yes

Q60.2 Please set out your rationale and any impacts you expect this change would have. (FT 2500)

We broadly agree that harmonising and raising risk classification of SaMDs could increase safety, but we do not have the requisite expertise to comment further on this.

Section 61: Classification: Airlock classification rule

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

Yes

Q61.2 Please provide your reasoning to support your answer to question 61.1 including any expected impacts on you or other stakeholder groups and any available relevant evidence. (FT 2500)

In principle this might be a good addition. However, this would seem to involve a large degree of discretion on the part of the regulator as to when such a measure is needed. It would have been helpful if the criteria for assessing when a device merits early access had also been available for consultation.

Section 62: Pre-market requirements

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

Yes

Q62.2 Please set out and explain your rationale for any additions and outline any expected impacts. (FT 2500)

The factors and considerations that need to be taken into account when assessing and designing for safety in software are distinct from general requirements for medical devices and they should be explicitly on the face of the regulations. However, we do not have relevant expertise to comment further on what additions or essential criteria should be included. We do note that having specific essential criteria for SaMD would bring the UK up to date with the EU MDR and IVDR which have specific essential criteria for software and which would have been incorporated in the Medical Devices (Amendment etc)(EU Exit) Regulations 2019 before they removed by in the Medical Devices (Amendment etc)(EU Exit) Regulations 2020.

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

Yes

Q62.4 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 62.1-62.3, including any impacts on you or other stakeholder groups. (FT 2500)

Given our answer earlier, that we are in broad agreement that essential requirements specific for SaMD are needed, it follows that we are also in agreement that they should be set out separately from those of other medical device types. We note, however, that many medical devices using software will raise overlapping concerns/issues with SaMDs and thus this should be taken into consideration in drafting any amendments.

Section 63: Post-market requirements

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

Yes

Q63.2 Please set out your rationale and any expected impact and any available relevant evidence to support your answer to question 63.1. (FT 2500)

In general as part of increasing safety, transparency, and facilitating trend reporting for SaMDs we agree that there should be a mandatory link to report adverse incidents.

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

Yes

Section 64: SaMD Cyber Security

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

Yes

Q64.2 If you have answered yes to Q64.1, what should this entail and why? What would be the expected impacts? (FT 2500)

We agree in principle with the inclusion of cyber security and information security requirements as necessary to increase the safety of devices, however we do not have expertise to comment further on what this would entail.

Q64.3 Please provide your reasoning (including any available relevant evidence) to support your answers to Q64.1-64.2, including any impacts on you or other stakeholders. (FT 2500)

We think that including cyber security and information security requirements are necessary to increase the safety of SaMD and software in general, but we do not have the requisite expertise to comment further.

Section 65: Artificial intelligence as a/in a medical devices (AIaMD)

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

Don’t Know/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

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

Yes

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

Yes

Q65.6 Please provide your reasoning (including any available relevant evidence) to support your answers to Q65.1-65.5, including any impacts on you or other stakeholder groups, including how burdensome would further requirements along these lines be? (FT 2500)

Regarding Q65.5, we support mandating logging for all SaMD.

Chapter 11: Implantable devices

Section 66: Implantable devices

Q66.1 Do you think there should be any changes to the scope of medical devices regulated as implantable devices?

Yes

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

a. clinical investigations: should requirements for clinical investigations be more robust than those conducted for non-implantable devices?

Yes

b. technical documentation reviews: should requirements be more robust than those for non-implanted devices of the same risk category?

Yes

c. any exemptions required for certain implantable devices (e.g. screws, wedges)?

Don't Know/No Opinion

Q66.5 Please explain your rationale for your responses to question 66.4, including how and why you think any changes are needed, including any expected impacts. (FT2500)

Implantable devices represent some of the most risky products subject to the Medical Device Regulations. As such, these should be subject to more robust requirements in terms of the evidence base for their safety (clinical investigations) and in their documentation to facilitate thorough auditing. However, we do not have the requisite expertise to comment further on this.

Q66.7 Should there be more stringent controls over the use of implantable devices?

Yes

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

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

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

a. Clarifying or strengthening the requirements around use of obsolete models of implantable medical devices?

Yes

b. Introducing a requirement for implant information to be provided to recipients of implantable devices?

Yes

Q66.11 Do you think that the UK medical devices regulations should require manufacturers of implantable devices to provide implant information for recipient patients with the device when placing it on the market as set out in paragraph 66.6?

Yes

Q66.12 If you have answered yes to question 66.11:

a. should manufacturers be required to provide implant cards/leaflets to healthcare settings/professionals?

Yes

b. what should be included on the implant card and patient information leaflet? (FT 2500)

Whilst we do not have the requisite expertise to comment extensively on what should be included on the implant card, we believe the following could be included: relevant safety information including risks; instructions for use and care if applicable; information on the device's longevity and lifecycle; potential side effects, and what to do/link to report an adverse incident.

c. should manufacturers be required to make available implant information in both physical and digital formats, (for example, in the form of a card, leaflet or other appropriate format)?

Yes

d. Should the manufacturer be required to update the digital implant information where appropriate?

Yes

e. should health institutions be required to make this information available to patients who have been implanted with the device?

Yes

f. should health institutions be required to log the implant information onto the records of the patient implanted with the device?

Yes

Q66.13 Are there any implants that should be excluded from the requirement to have accompanying implant information?

Don't Know/No Opinion

Q66.15 Is there further information we should collect and share about implantable medical devices in particular?

Don't Know/No Opinion

Q66.19 Please provide any relevant evidence to support your answers to Q 66.1-66.18 in this section, including any impacts on you or other stakeholder groups, and key implementation considerations for any changes that could be made. (FT 2500)

We are broadly in favour of increasing the information that is gathered and stored in relation to medical implants in order to increase transparency and monitor for potentially adverse outcomes, and thus increase capacity to react to adverse incidents. We are also broadly in favour of increasing transparency and access to information about medical implants for healthcare professionals, patients, and the public at large for similar reasons.

Chapter 12: Other product-specific changes

Section 67: Re-manufacturing single-use devices

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

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?

Don't Know/No Opinion

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

Don't Know/No Opinion

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

Don't Know/No Opinion

Section 68: Systems, kits and procedure packs

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

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?

Don't Know/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

Section 69: Parts and components

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

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

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. (FT 2500)

Whilst we do not have specific expertise on this, the individual components of medical devices should not adversely affect that safety of a device. Further, if a component changes the safety and performance profiles of a device, this is in essence the same as creating a new medical device with those risk/performance profiles and thus should be regulated as such. It would improve the safety of such devices and bring the UK law up to date with other jurisdictions on this matter, including the EU.

Section 70: Custom-made devices

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

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

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

Q70.4 If you have answered yes to question 70.3, please outline what types/classes of custom-made devices should fall under this requirement. (FT 2500)

We agree in principle that where the risk profile of a custom-made device is high then a QMS should be required, but we do not have sufficient expertise to comment on which classifications or the threshold risk level a device should cross before this requirement should be implemented.

Q70.6 Do you agree that custom-made devices could be manufactured on the basis of an electronic prescription, as outlined in paragraph 70.8?

Yes

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. (FT 2500)

We have broadly agreed that manufacturers of custom made devices should be subject to further requirements on the detail of technical documentation and that there should be more stringent requirements for post-market surveillance. Whilst we do not have the requisite expertise to comment fully on this, we believe that the requirements should be in line with the risk profile of such devices.

Chapter 14: Routes to Market

Section 72: MDSAP and Domestic Assurance

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

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.(FT 2500)

We do not have the expertise to comment in-depth on the MDSAP. Whether or not this should be introduced depends on the detail of how approvals work in each of the jurisdictions and with the international regulators. As noted in para 72.1, harmonisation is important.

However, there is also a need to ensure that manufacturers do not simply shop around for a jurisdiction with less stringent rules/regulations within the MDSAP countries (in terms of both approvals and QMS audits) and is then allowed access to the UK market based on this.

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

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. (FT 2500)

See our response to Q72.3. The concern is the same in relation to a domestic assurance route.

Section 73: Pathway for Innovative MedTech

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?

Yes

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?

Yes

Chapter 15: Transitional Arrangements

Section 74: Transitional Arrangements

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

Don't Know/No Opinion

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

Don't Know/No Opinion

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

Don't Know/No Opinion

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

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

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?

12 months