BIVDA
British In Vitro Diagnostics Association

Executive summary

The BIVDA response to the MHRA consultation on the future regulation of medical devices in the United Kingdom was submitted on 25th November 2021. Please find below this full response, along with the cover letter which was submitted to MHRA on 26th November 2021.

This response was generated using feedback provided by members. Although it was a full response on the majority of areas relevant to the IVD sector, emphasis was given on some prioritised sections within this consultation. Generally, BIVDA's response requested alignment to the EU IVDR.

We have summarised below the key messages that were provided within BIVDA's consultation response:

Economic operator requirements (Chapter 3)

BIVDA highlighted the importance of clear requirements and distinctions between economic operators, including definitions on these roles. We also highlighted that the UK industry utilised managed service providers for pathology products, something that is not particularly common within the EU, and this introduces further challenges when implementing new regulations. BIVDA are keen to ensure these organisations are not considered to be importers.

Clinical evidence (Chapter 7)

The requirements for performance studies should be detailed to ensure sponsors are aware of what exactly they have to meet. Manufacturers should be able to utilise existing clinical evidence for products already on the market where the requirements within the EU IVDR are met (i.e. continued access to that product's information, and sufficient evidence to show that it is an equivalent device). Clinical evidence should be proportionate to the risk of the device involved.

PMS and PMPF (Chapter 8)

Any post-market surveillance requirements should be aligned to the EU model, including using existing reporting templates where possible to ensure consistency for manufacturers that span multiple geographic regions. BIVDA also expressed that the additional requirements being proposed by MHRA were burdensome and not required.

Specific IVD questions (Chapter 9)

BIVDA focussed on the requirement for the classification system to be aligned to the EU IVDR model, but the classification for genetic tests and companion diagnostics should be amended to take a risk based approach rather than classifying them in the current way. The proposed amendments for products sold via distance sales were welcomed in BIVDA's response, and we have requested these be regulated in the same manner of other products being placed on the UK market.

Sustainability (Chapter 12)

New regulations relating to sustainability would be welcomed, however MHRA needs to ensure that there is no duplication between various pieces of legislation. UK Government is currently developing environmental legislation. Where there may be overlap, the regulations need to be explicit on applicability. BIVDA suggested that any requirements that are specific to medical devices or IVDs may be appropriate within the UK Medical Device Regulations, but more general regulations would be better suited to the relevant environmental legislation.

Mutual recognition and pre-market approval (Chapter 14)

BIVDA strongly encouraged the mutual recognition of products between the UK and the EU. Mutual recognition with other geographic areas (such as the US, Canada and Australia) would also be useful for placing devices on the UK market. Innovative products within the UK should have an innovative product pathway that can be utilised, but this should be open to all new innovations.

Transitional arrangements (Chapter 15)

In the event of not achieving mutual recognition, the timelines for implementing should be as long as possible. Lessons should be learnt from the EU and Australia who both had to delay implementation due to insufficient time.

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26th November 2021

Dear MHRA Colleagues,

BIVDA's response to the MHRA consultation on the future regulation of medical devices in the United Kingdom was submitted on 25th November 2021. Please consider this letter to be supplementary to that response.

BIVDA represents approximately 200 organisations within the IVD industry including start-up companies, SMEs, UK developers and manufacturers as well as subsidiaries of the global IVD corporations. We also represent some distributors and other economic operators. Our response was submitted on behalf of this membership and reflects the general views of companies within the IVD sector. Therefore, although we have provided responses to sections outside of the designated IVD chapter, the membership of BIVDA should be taken into consideration, and the responses should only be taken in context to IVDs. The responses do not span requirements for medical devices generally. There are a few key areas below which we are very eager to focus on where we feel the consultation format does not allow enough detail.

1. In light of the Covid-19 pandemic which has hugely affected the world over the past years, and the key role IVDs have played in providing necessarily diagnostics during this, it is crucial that lessons are learnt on how regulation should be managed during such unprecedented times. BIVDA would be keen for new legislation to include plans on how to manage any future pandemic or emergency responses. It has been clear that the method of implementing a new structure as these issues arise has not been particularly efficient, placing patient safety at a risk.

2. We need to ensure adequate planning and thought has gone into transition times to ensure existing products, particularly those in long term contracts with the NHS, are not at risk. This has been particularly relevant in relation to other geographic areas who have had to push back their initial timelines to accommodate delays.

3. In Great Britain, the role of managed service contracts to manage pathology purchasing has now become commonplace and this model as not common in the rest of Europe. Under EU regulation, any products supplied by a third party into a managed service would be deemed to be distributed by the prime contractor and require labelling changes (and other obligations) to reflect this. We feel this should

not be the case for UK regulation of IVDs as the product's manufacturer is clear and the prime contractor only places an order on behalf of the customer. The products are then supplied direct from the third party and are identifiable as such. We would be very happy to discuss this point separately to ensure there is clarity for drafting the appropriate piece in the legislation.

This consultation touches topics which are regulated by other pieces of UK legislation, including financial, data management, and environmental areas. BIVDA would like to emphasise that although changes in these areas are welcomed, confusion may arise in the event of duplication or differences in requirements between legislative documents. We would request that any requirements introduced which may be encompassed in other legislation have expectations clearly defined and take existing legislation into account.

BIVDA would also like to take this opportunity to reinforce the need for a consolidated piece of legislation for regulation of medical devices in the UK. To date, there have been numerous amendments to the existing UK Medical Device Regulations 2002, making it particularly difficult to navigate the regulatory landscape in the UK. This puts those involved in regulation at a disadvantage, as it is challenging to identify the requirements applicable to them.

We are grateful to be given the opportunity to comment on such important legislative changes, and BIVDA would like to reiterate that we are available to assist in future activity and dialogue into the changing regulatory landscape for IVDs in the UK. BIVDA remain at the disposal of MHRA should you require any clarification in relation to our consultation response.

Yours sincerely,

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Chapter 1: Scope of the Regulations

Section 1: Medical Device & IVD Scope

Q1.1: Do you think the scope of the UK medical devices regulations should be expanded to include the additions suggested in Paragraphs 1.6-1.9? [Yes / No / Don't Know/No Opinion]

Yes

Q1.2: Please set out what (if any) further amendments you would like to make to the scope of the UK medical devices regulations. [2500 character limit]

Addition of various definitions, including:

- *Clarified definition for manufacturer*
- *Amendment of definition for placing on the market*
- *[UKCA] marking of conformity*
- *Analytical performance*
- *Benefit-risk determination*
- *Calibrator*
- *Clinical benefit*
- *Clinical evidence*
- *Clinical performance*
- *Common specifications*
- *Compatibility*
- *Conformity assessment*
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- *Control material*
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- *Fully refurbished*
- *Generic device group*
- *Importer*
- *Informed consent*
- *Instructions for use*
- *Interoperability*
- *Interventional clinical performance study*
- *Investigator*

- *Kit*
- *Label*
- *Lay person*
- *Likelihood ratio*
- *Making available on the market*
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- *Single use device*
- *Sponsor*
- *Subject*
- *UK approved body*
- *UK Responsible Person*
- *User*
- *Withdrawal*

The definition of an IVD should also be amended to be:

"Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

a) concerning a physiological or pathological process or state
b) concerning congenital physical or mental impairments
c) concerning the predisposition to a medical condition or a disease
d) to determine the safety and compatibility with potential recipients
e) to predict treatment response or reactions
f) to define or monitoring therapeutic measures

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices"

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 relevant stakeholder groups. [2500 character limit]

The addition of software to the scope of IVDs would be welcomed. Such products have been becoming more prevalent on the UK market, and therefore they should be included within the scope of the regulations. This is also the case for products intended to predict a prognosis to a disease.

General definitions are particularly helpful for a number of terms to improve consistency across the industry. For example, where further guidance is likely to be required to clarify areas (such as the Blue Guide published by the EU to provide guidance on certain terms).

Q1.4: Should we make clear that 'intended purpose' is to be construed objectively and that key materials such as a manufacturer's technical documentation may be used as evidence of intended purpose? [Yes / No / Don't Know/No Opinion]

Yes

Q1.5: Please set out the reasoning for your reply to question 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. [2500 character limit]

A definition of intended purpose would be helpful. In particular: "the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements or as specified by the manufacturer in the performance evaluation".

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? [Yes / No / Don't Know/No Opinion]

No opinion

Q2.2: Please provide your reasoning for your response to question 2.1. [2500 character limit]

The majority of the products included below are medical devices. We do not agree that diagnostic tests for health and wellbeing should fall within the scope of the UK MDR.

Q2.3a: If you answered 'yes' to question 2.1, please outline which products from the list at Paragraph 2.3, and any others, you consider should be brought into the scope of the UK medical devices regulations [checklist; multiple answers allowed]:

- 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. infrared, 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 & wellbeing, e.g. genomic testing for diet/nutrition optimisation, genomic testing for skin care, lactate testing for fitness training

Q2.3b: Please describe how these products should be assessed to ensure that they are safe and perform as intended. [2500 character limit]

NA

Q2.3c: 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). [2500 character limit]

NA

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 2, Section 21 for further information on registration requirements)? [Yes / No / Don't Know/No Opinion]

No opinion

Q2.5: Please provide any other comments you wish to make about the possible regulation of products without a medical purpose as medical devices, and your reasoning (including any available relevant evidence) to support your answers to questions 2.1-2.4; please include any impacts on, and implementation considerations for, you or other stakeholder groups. [2500 character limit]

NA

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? [Yes / No / Don't Know/No Opinion]

Yes

Q6.2: Please outline any other amendments which should be made to the essential requirements of the UK medical devices regulations. [2500 character limit]

In summary, as the general safety and performance requirements detailed in the EU IVDR would surpass the 2500 character limit, we propose the GSPRs outlined in Annex 1 of the EU IVDR be implemented in the UK MDR.

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. [2500 character limit]

The GSPRs within the EU IVDR were updated to adequately represent the technological changes that have occurred since publication of the essential requirements in the EU IVDD. These changes are welcomed as it creates a higher quality of IVD within the market. They also introduce requirements for new technologies which were not foreseen in 1998.

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? [Yes / No / Don't Know/No Opinion]

Yes

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. [2500 character limit]

Since implementation of the UK MDR, there have been numerous legal cases regarding medical devices and their failures. Such failures will always occur as no product can be perfect, but it is the manufacturer's responsibility to ensure such failures happen as rarely as possible. In the case where a failure does occur, the individual who is harmed (directly or indirectly) should be entitled to fair compensation for that harm.

Such financial coverage should be proportionate to the risk class, type of device and the size of the enterprise. It is also appropriate to lay down rules concerning the facilitation by MHRA of information to persons who may have been injured by a defective device. This should also take into consideration existing UK legislation for such requirements.

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? [Yes / No / Don't Know/No Opinion]

Yes

Q8.2: If you answered yes to question 8.1, please outline what you think should be included in this definition. [2500 character limit]

An organisation, the primary purpose of which is the care or treatment of patients or the promotion of public health.

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

Yes

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

Yes

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

Yes

Q8.6: Please outline any other requirements which should be introduced for health institutions carrying out 'in house' manufacturing or modification of medical devices. [2500 character limit]

For IVDs, ISO 15189 'Medical laboratories — Requirements for quality and competence' should be added as a designated standard. High risk class products should also have documentation providing an understanding of the manufacturing facility, manufacturing process, design and performance data, and intended purpose. This documentation should be sufficiently detailed to demonstrate that the appropriate essential requirements have been met.

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

Yes

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

Yes

Q8.9: Do you think that the provisions in Paragraph 8.9 should be introduced for health institutions? [Yes / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

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. [2500 character limit]

Products being manufactured 'in-house' are still being used on patients, and so there should be an expectation that minimum safety and quality standards have been met in line with the essential requirements. It is for manufacturers of these products to ensure they are fit for purpose.

The rationale provided for IVDs generally to be registered with MHRA is to allow for an overarching view of the products on the UK market. This also allows for traceability in the event of safety issues within certain families of products. Both of these remain applicable for products manufactured 'in house'.

Products manufactured on an industrial scale imply they are being manufactured for a high volume of patients. Therefore, the full regulations should apply on these products.

A definition of 'industrial scale' would be beneficial.

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? [Yes / No / Don't Know/No Opinion]

Yes

Q8.13: If you have answered yes to question 8.12, please outline any circumstances in which the exemption should not apply (e.g. if the services are provided for commercial / profitable purposes or to private patients or providers outside its intrinsic health function)? [2500 character limit]

The exemption should apply if the institution is a specialist research and development laboratory that has been commissioned by another institution. This would usually be to manufacture a product for specific clinical or research purposes, which are not commercial objectives.

The manufacturing should be within the intrinsic health function of the institution.

The exemption should not apply where there is an alternative product available on the market.

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. [2500 character limit]

Products manufactured within a healthcare institution are being used on patients, and so verification and validation of these products should be maintained to demonstrate the products are fit for purpose.

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 / No / Don't Know/No Opinion]

Yes

Q9.2: The MHRA considers that the UK medical devices regulations could be amended to provide that, upon request from the MHRA, any individual, company or organisation offering a medical device by means of distance sales could be required to provide a copy of the Declaration of Conformity (a declaration that the device complies with the UK medical devices regulations) of the medical device concerned. Do you think that we should introduce this requirement [as set out above]? [Yes / No / Don't Know/No Opinion]

Yes

Q9.3: Please outline any other requirements that should be introduced for medical devices that are subject to distance sales. [2500 character limit]

A device offered by means of information society service to a natural or legal person established in the UK shall comply with the regulations.

Without prejudice to law regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services, directly or through intermediaries, to a natural or legal person established in the UK shall comply with the regulations.

Upon request by MHRA, any natural or legal person offering a device in accordance with the above or providing a service in accordance with the above shall make available a copy of the declaration of conformity of the device concerned.

MHRA may, on grounds of protection of public health, require a provider of information society services to cease its activity.

Such proposals must be made explicitly clear to prevent ambiguity. This would include providing a definition of distance sales, and specifying that managed service providers are not included or are not considered to be the distributor or importer in these situation.

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. [2500 character limit]

These products are being used within the UK market on UK patients, and so should fall within the scope. They should not be excluded because they are online or because the initial manufacturer of these products is based outside of the UK.

Section 10: Claims [made on medical device labels, packaging or sales materials – including on webpages and apps]

10.1: The MHRA considers that the UK medical devices regulations could be amended to prohibit, insofar as they are not adequately prohibited in other legislation, the use of text, names, trademarks, disclaimers, pictures, images, videos and figurative or other signs that may mislead the user or the patient with regard to its intended purpose and the safety and performance of the medical device. The Regulations could provide that a person who makes a misleading claim on the device labelling, instructions for use, packaging or sales material / advertising (including online) would be responsible for this. Where this person is an economic operator, they would also need to follow the relevant obligations under the UK medical devices regulations (see Section 13). Do you think that we should introduce the provisions set out [above]? [Yes / No / Don't Know/No Opinion]

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. [2500 character limit]

The claims made for a product are the basis for use of a medical device. If there is no scrutiny on whether these claims have evidence to justify them, manufacturers could potentially make false claims in the interest of commercial gain. Manufacturers should only be able to label or indicate their product can be used in the manner that it has evidence for. This also increases the reliability of medical devices in general.

Section 11: Quality Management Systems

Q11.1: The MHRA considers that the UK medical devices regulations could be amended to clarify that all manufacturers should have a Quality Management System in place which addresses at least [15 areas outlined in Paragraph 11.3]. Do you think that we should introduce the detailed requirements for Quality Management Systems outlined in Paragraph 11.3? [Yes / No / Don't Know/No Opinion / Some – please specify which in free-text field]

Yes

Q11.2: Please outline any other requirements which should be included in the manufacturers Quality Management System. [2500 character limit]

NA

Q11.3: Do you think that all manufacturers, including Class I and general IVD manufacturers, should be required to apply an appropriate Quality Management System? [Yes / No / Don't Know/No Opinion]

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. [2500 character limit]

A quality management system is required in order to ensure transparency through the lifespan of a medical device. It creates a system for order and clarity throughout and makes the process of managing the quality significantly easier. Without this, it is difficult for manufacturers to have an organised system.

A quality management system has been recommended for a while (ISO 13485 is a harmonised standard and a designated standard) but enforcing it through the legislation to make it mandatory is welcomed. However, caution may be required to ensure that if any future changes are required for a QMS, that the list is editable or expandable within the legislation.

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 / No / Don't Know/No Opinion]

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? [Yes / No / Don't Know/No Opinion]

Yes

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

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 / No / Don't Know/No Opinion]

Yes

Q12.5: What time-period should be specified for the retention of technical documentation relating to implantable devices by the UK Responsible Person? [11-15 years after the last product has been manufactured / 16-20 years after the last product has been manufactured / For the expected lifetime of the device, after the last product has been manufactured / Other]

NA

Q12.6: What time-period should be specified for the retention of technical documentation relating to non-implantable devices by the UK Responsible Person? [1-5 years after the last product has been

manufactured / 10 years after the last product has been manufactured / 11-15 years after the last product has been manufactured / For the expected lifetime of the device, after the last product has been manufactured / Other]

10 years after the last product has been manufactured

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

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? [Yes / No / Don't Know/No Opinion]

Yes

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. [2500 character limit]

The UKRP should have their place of business within the UK to ensure they are easily contactable and available in relation to UK documentation and acts of business.

Where the manufacturer is based outside of the UK, the UKRP takes on the legality of the manufacturer, including liability for defective devices. For the purposes of enforcement it is therefore appropriate to make the UKRP legally liable for defective devices in the event that a manufacturer established outside the UK has not complied with its general obligations. The UKRP should be jointly and severally liable with the importer and the manufacturer.

A legal contract should be required for traceability purposes, and to ensure tasks are appropriately designated. This is also the case for changing of UKRPs to ensure that each party is aware of the requirements on them in terms of contract ending and beginning, and expected responsibilities.

For non-implantable medical devices, UKRPs should hold documentation for 10 years after the date of its first manufacturer. This is a general time period for a lifespan of the device, where adverse events could happen at any point. Traceability and holding of this documentation are necessary. This is also the case where manufacturers have ceased activity – their products may still be on the market.

A Qualified Person should be available within the UKRP who possesses the requisite expertise in the field of in vitro diagnostic medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:

a) *a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by MHRA, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices*
b) *four years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.*

It would also be beneficial to add clarify responsibilities on UKRPs for transfer of documents, including confidentiality aspects and property rights.

Section 13: Obligations of Importers & Distributors

Q13.1: The MHRA considers that the UK medical device regulations could be amended to introduce a number of obligations on importers and distributors including [11 requirements outlined in Paragraph 13.4]. Do you think that importers and distributors should be required to meet the requirements outlined in Paragraph 13.4? [Yes / No / Don't Know/No Opinion / Partial – please specify which in free-text field]

Yes

Q13.2: Please outline any other requirements which should be introduced for importers and distributors. [2500 character limit]

Clear definitions for importers and distributors including the differences between each would be welcomed, as well as clarity on the provision of documentation between importers and UKRPs, including which organisation is responsible for what pieces of documentation. This may particularly be important when importers and UKRP are the same organisation.

Q13.3: The MHRA considers that fulfilment service providers could be regarded as importers under the UK medical devices regulations. Fulfilment service providers are companies /organisations carrying out the warehousing, packaging, addressing and dispatching of medical devices, excluding postal services. For example, medical devices sold online may be warehoused by a fulfilment service provider who will then address and dispatch the medical device when it is purchased. Do you think that fulfilment service providers should be regarded as importers under the UK medical devices regulations? [Yes / No / Don't Know/No Opinion]

Don't know

Q13.4: The MHRA considers that the UK medical devices regulations could be amended to require economic operators (including manufacturers, importers and distributors) to inform the MHRA if they are aware of any issues that will interrupt supply / cause a shortage of medical devices on the UK market. This could include, for example, shortages of critical components, operational issues at factories or supplier plants arising from floods or earthquakes, or quality issues requiring recall or rework. 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 [above]? [Yes / No / Don't Know/No Opinion]

No

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. [2500 character limit]

This is not a feasible requirement. In the case of natural emergencies, this could affect a high volume of companies at any one time. For example, the eruption of Eyjafjallajökull (Iceland) in 2010 or the blockage of the Suez Canal in 2021, both causing a global halt on supply. If every organisation were required to inform MHRA of this, MHRA would have been inundated with alerts. Enforcing this on all economic operators within the supply chain does not seem to be pragmatic.

In relation to smaller supply chain issues, particularly in the case of emergencies, companies' priority should be on the safety and wellbeing of their staff rather than alerting the national authority.

However, it may be more feasible for economic operators to notify MHRA of any supply issues that are within their control. For example, if they opted to use a new supplier who has a delay, but they choose to halt manufacturing rather than use the previous supplier.

Fulfilment service providers are unlikely to hold the information requested for importers to hold, and therefore it is unclear whether the suggestion of treating them as importers is realistic in practice. Such organisations may be an importer or a distributor depending on the circumstances of the specific product and manufacturer utilising them.

We would like to also put forward the position that managed service providers should not be considered importers or distributors, and instead should be end points (customers). This is a point BIVDA feels strongly on, so ongoing discussions between BIVDA and MHRA would be welcomed on this topic.

Section 14: Qualified Persons

Q14.1: The MHRA considers that the UK medical devices regulations could be amended to require that manufacturers have available within their organisation at least one Qualified Person with qualifications or regulatory experience that exceeds minimum standards that would be set out in the UK medical devices regulations in the field of medical devices / in vitro diagnostic medical devices. This could include, for example, a formal qualification in law, medicine, pharmacy, engineering or another relevant scientific discipline, or sufficient professional experience in regulatory affairs or in Quality Management Systems relating to medical devices. Do you think manufacturers should be required to have at least one Qualified Person available within their organisation as set out [above]? [Yes / No / Don't Know/No Opinion]

Yes

Q14.2: What qualifications and / or experience should the Qualified Person have in order to be eligible for this role? [2500 character limit]

a) *a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by MHRA, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices*
b) *four years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices*

Q14.3: Do you think that small and medium enterprises (SMEs) should be excluded from this requirement [as at Q14.1] and instead be required to have a Qualified Person permanently and continuously at their disposal? [Yes / No / Don't Know/No Opinion]

Yes

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. [2500 character limit]

It is very common currently for manufacturers to rely on consultants for their regulatory functioning, and when these individuals are only sporadically a part of the company, they may not be available in the event of a regulatory emergency. Having someone there are all times (or permanently and

continuously at their disposal) mitigates this and means that there will be someone to handle any regulatory emergencies as and when they occur.

It is not practical for all organisations to have regulatory affairs expert permanently within their organisation, and so the option to have them available is more feasible.

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 / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

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 stakeholder groups. [2500 character limit]

Clear explanations of when economic operators take on the legal obligations of the manufacturer allow for transparency within the supply chain. It would be expected that these would also be stipulated within the QMS of all parties to explicitly confirm the obligations on each.

Where an economic operator is taking on the responsibility of the manufacturer through modifications, they should have to validate and verify their changes to ensure it is still fit for purpose in line with the above requirements. This maintains safety of the device in question.

Chapter 4: Registration & Unique Device Identification (UDI)

Section 16: General Background

[Information only; no consultation questions.]

Section 17: Identification Within the Supply Chain

Q17.1: The MHRA is considering amending the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) to require that economic operators (manufacturers, importers, distributors etc.) share more information with the MHRA about the supply of medical devices, and to require economic operators to ensure the appropriate traceability of medical devices. The objective would be to improve the traceability of medical devices, which have been sold or are in the supply chain, in the event of an issue (i.e. a device recall) occurring with a particular model or device type. Do you think the UK medical devices regulations should include the requirements set out

[as above] for economic operators to ensure traceability of medical devices? [Yes / No / Don't Know/No Opinion]

Yes

Q17.2: Please outline any other traceability requirements which should be introduced for economic operators. [2500 character limit]

Economic operators shall keep a register of complaints, non-conforming devices and recalls and withdrawals, and provide the manufacturer, UKRP and distributors with any information requested by them, in order to allow them to investigate complaints.

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 in Paragraphs 17.3-17.4], what time period should be specified? [2500 character limit]

10 years after the last device has been placed on the market

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. [2500 character limit]

10 years is the period that we propose manufacturers and UK Responsible Persons are required to keep records for traceability purposes, therefore economic operators should be held to the same timeframe. This is a general time period for a lifespan of the device, where adverse events could happen at any point. Traceability and holding of this documentation are necessary. This is also the case where manufacturers have ceased activity – their products may still be on the market.

Section 18: Nomenclature

Q18.1: The MHRA considers that it has two options: it could continue to require the use of GMDN nomenclature for purposes of medical device identification, and the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) could be amended to reflect this. Or alternatively, the UK medical devices regulations could require manufacturers to use EMDN nomenclature for purposes of medical device identification. Please select which nomenclature, for purposes of medical device identification, should be required under the UK medical devices regulations. [GMDN / EMDN / Other]

GMDN

Q18.2: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 18.1-18.2, including any impacts on you or other stakeholder groups. [2500 character limit]

GMDN is an internationally recognised system, currently used by MHRA and the FDA. By continuing to use GMDN, this allows consistency for manufacturers and alignment to the US model in this aspect. GMDN holds thousands of codes relevant to in vitro diagnostic medical devices so it is very likely that the majority of IVDs will be covered within the existing codes, and where they are not, the GMDN Agency is assistive in adding new codes.

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 / No / Don't Know/No Opinion]

Yes

Q19.2: If you answered yes to question 19.1, please outline what you think should be included in this definition. [2500 character limit]

A series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

Q19.3: Do you think the UK medical devices regulations should require manufacturers to assign UDIs to medical devices before they are placed on the market? [Yes / No / Don't Know/No Opinion]

Yes

Q19.4: If you have answered yes to question 19.3, please outline any particular requirements which should be introduced in regards to how UDIs should be applied to medical devices and any aspects which require clarification. [2500 character limit]

Software

The UDI shall be assigned at the system level of the software. Only software which is commercially available on its own and software which constitutes a device in itself shall be subject to that requirement

The software identification shall be considered to be the manufacturing control mechanism and shall be displayed in the UDI-PI

A new UDI-DI shall be required whenever there is a modification that changes:

- *the original performance*
- *the safety or the intended use of the software*
- *interpretation of data*

Such changes include new or modified algorithms, database structures, operating platform, architecture, new user interfaces or new channels for interoperability

Minor software revisions shall require a new UDI-PI and not a new UDI-DI (minor software revisions are generally associated with bug fixes, usability enhancements that are not for safety purposes, security patches or operating efficiency; minor software revisions shall be identified by a manufacturer-specific form of identification)

- *where the software is delivered on a physical medium, each packaging level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the software and its packaging shall be identical to the UDI assigned to the system level software*
- *the UDI shall be provided on a readily accessible screen for the user in an easily-readable plain-text format such as an 'about' file, or included on the start-up screen*
- *software lacking a user interface such as middleware for image conversion, shall be capable of transmitting the UDI through an application programming interface*
- *only the human readable portion of the UDI shall be required in electronic displays of the software. The marking of UDI using AIDC shall not be required in the electronic displays such as 'about' menu, splash screen, etc.*

- *the human readable format of the UDI for the software shall include the application identifiers (AI) for the standard used by the issuing entities to assist the user in identifying the UDI and determining which standard is being used to create the UDI*

Q19.5: Should devices that are reusable bear a UDI carrier (e.g. barcode) that is permanent and readable after each process on the device itself? [Yes / No / Don't Know/No Opinion]

Yes

Q19.6: Please outline whether you think there should be any exceptions to this rule and please provide examples and reasoning. [2500 character limit]

The UDI carrier for reusable devices that require disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device.

Q19.7: Should the UK medical devices regulations include requirements for Basic UDI-DI to identify medical device models? [Yes / No / Don't Know/No Opinion]

Yes

Q19.8: Do you think manufacturers should be required to assign and apply UDIs to their medical devices before applying to Approved Bodies for conformity assessment? [Yes / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

Yes

Q19.10: Please outline any other circumstances in which the UDI or Basic UDI-DI should be provided for a medical device. [2500 character limit]

NA

Q19.11: The UK medical devices regulations could be amended to exempt certain medical devices from the requirement to assign a UDI. Such medical devices could include custom-made medical devices (see Chapter 12, Section 53) and investigational medical devices/medical devices for performance study (see Chapter 7, Section 44). Manufacturers could alternatively be required to assign a unique serial number to custom-made medical devices before they are placed on the UK market or put into service. This number should be retained by the manufacturer. Do you think that certain medical devices should be exempt from the UDI requirements? [Yes / No / Don't Know/No Opinion]

Yes

Q19.12: If you have answered yes to question 19.11, please outline what medical devices should be exempt. [2500 character limit]

Devices for performance evaluation

Q19.13: Should manufacturers of custom-made devices be required to assign a unique serial number to the device? [Yes / No / Don't Know/No Opinion]

No opinion

Q19.14: UDI-issuing entities operate systems for assignment of UDIs. There are currently four designated issuing entities for the EU system - GS1, HIBCC, ICCBBA, IFA. For a future UK system, the MHRA could designate one or more issuing entity. Manufacturers could be required to obtain a UDI from an MHRA-designated issuing entity and apply this to the medical device before placing the device on the UK market. Please outline which issuing entities should be designated by the MHRA. In your response please provide the following information: a. should the MHRA designate one or multiple UDI issuing entities? b. if there should be one issuing agency, which one (and why) c. if there should be multiple issuing agencies, which ones (and why)? [2500 character limit]

Multiple issuing entities. Using only one organisation creates a monopoly on the market and is likely to drive prices. This also puts the sector at risk if this single entity were to cease business, or an alternative was required.

Q19.15: Do you think manufacturers should be required to keep an up-to-date list of all UDIs they have assigned to medical devices as part of the technical documentation? [Yes / No / Don't Know/No Opinion]

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. [2500 character limit]

10 years after the last device has been placed on the market

Q19.17: Do you think economic operators should be required to store the UDI numbers of certain medical devices? [Yes / No / Don't Know/No Opinion]

No opinion

Q19.18: If you have answered yes to question 19.17, please select which groups of medical devices which should fall under this requirement [checklist; multiple answers allowed]:

- All implantable medical devices
- Class III implantable medical devices & Class IIb implantable medical devices
- Class III implantable medical devices
- *Don't Know / No Opinion*
- Other

Q19.19: Do you think healthcare professionals and/or health institutions should be required to store

No

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 [checklist; multiple answers allowed]:

- All implantable medical devices
- Class III implantable medical devices & Class IIb implantable medical devices

- Class III implantable medical devices
- *Don't Know / No Opinion*
- Other

Q19.21: The UK medical devices regulations could be amended to introduce rules for the UDI system to help clarify the requirements of the Regulations. Rules could, for example, set out circumstances in which a new UDI-DI would need to be assigned to a given device, e.g. a change in trade name of the manufacturer or change in sterility of the device. Do you think that the UK medical devices regulations should introduce new rules for the UDI system, to provide clarity? [Yes / No / Don't Know/No Opinion]

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. [2500 character limit]

A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability. In particular, any change of one of the following UDI database data elements shall require a new UDI-DI:

- *name or trade name*
- *device version or model*
- *labelled as single use*
- *packaged sterile*
- *need for sterilization before use*
- *quantity of devices provided in a package*
- *critical warnings or contra-indications*

Q19.23: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 19.1-19.22, including any impacts on you or other stakeholder groups. [5000 character limit]

UDI increases the traceability of IVDs within the market. This would be beneficial for device safety issues where devices need to be identified quickly, or where other issues are identified with products.

To clarify, the requirements relating to UDI set out within Annex VI of the EU IVDR should be implemented in the UK, with the exception to references to the UDI database (Eudamed).

Section 20: Great Britain Database on Medical Devices

Q20.1: We are considering capturing and processing information submitted to MHRA about medical devices (such as registration data, vigilance, post-market surveillance, and market surveillance regarding medical devices) in a series of integrated databases (electronic information systems). This would enable the MHRA to bring together all the information about medical devices on the market to ensure enhanced transparency and effective market surveillance activities. Do you think that we should introduce the proposal outlined [above]? [Yes / No / Don't Know/No Opinion]

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. [2500 character limit]

This would make the processing of IVDs submissions easier and allow for a more transparent approach to regulation. It also means that the information required by MHRA could be streamlined and

submitted using one system which makes the process much more efficient on inputters who currently utilise various different forms and systems.

Such a system should be modelled on the EU Eudamed system, and make the forms and processes as aligned to this as possible to further increase efficiency. Utilising different systems across major markets will be burdensome on manufacturers and increases the likelihood of human error.

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 Section 21] to the MHRA upon medical device registration? [Yes / No / Don't Know/No Opinion / Some – please specify which aspects]

Yes

Q21.2: Please specify any changes proposed and your rationale in relation to question 21.1. [2500 character limit]

Additions:

- *Name, address and contact details of qualified person (if implemented in requirements)*
- *Presence of tissues, cells or their derivatives of animal origin (Y/N)*
- *Presence of cells or substances of microbial origin (Y/N)*
- *In the case of devices designed and manufactured by another legal or natural person, the name, address and contact details of that legal or natural person*

Removals:

- *Presence of medicinal product*
- *PSUR*
- *Specification as to whether intended purpose of the device is not a medical purpose*
- *Clinical size*
- *Containing natural latex*
- *Sterilisation provider*
- *Info on label for carcinogenic, mutagenic or toxic to reproductive health, or endocrine disrupting properties*
- *Undertaking that the manufacturers have met requirement for measures in place for recompense*

Q21.3: Which of the following entities should be permitted to submit device registration information to MHRA [checklist; multiple answers allowed]:

- *UKRPs and UK-based manufacturers (current requirement)*
- Non-UK based manufacturers
- Authorised third-party submitters
- Other

Q21.4: What mechanisms should be in place to submit data [checklist; multiple answers allowed]:

- *Web form*
- *Machine-to-machine (e.g. HL7 etc.)*
- Other

Q21.5: Please outline the timeframes that you think should apply to this additional registration information. [2500 character limit]

Registration should occur prior to being placed on the market

Q21.6: Should the information that the MHRA gathers at the point of medical device registration be made publicly available via a website or similar platform? [Yes / No / Don't Know/No Opinion]

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). [2500 character limit]

- *Devices on the market, the relevant economic operators and certificates*
- *Summary of safety and performance*

Q21.8: Do you think the UK medical devices regulations should include a requirement for manufacturers to register with the MHRA before applying to an Approved Body for conformity assessment and for the Approved Body to verify this registration? [Yes / No / Don't Know/No Opinion]

No

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 / No / Don't Know/No Opinion]

Yes

Q21.10: Please provide reasoning to support your answer to question 21.9. [2500 character limit]

30 days is sufficient time for economic operators to have identified all of the relevant information required and submit their application. Clarification should be provided on whether this is calendar or working days.

Q21.11: Do you think the UK medical devices regulations should include a requirement for economic operators to confirm all data submitted in their registration one year after submission and then every second year thereafter? [Yes / No / Don't Know/No Opinion]

Yes

Q21.12: How should economic operators be identified within the MHRA registration system [checklist; single answer only]:

- MHRA generated reference number (not internationally recognised)
- DUNs (internationally recognised external reference)
- GLN (internationally recognised external reference)
- *Other*

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. [2500 character limit]

There is no preference between DUNs and GLN, but request that only a single system is used which is internationally recognised.

Chapter 5: Approved Bodies

Section 22: General Background

[Information only; no consultation questions.]

Section 23: Requirements of Approved Bodies

Q23.1: Do you think the UK medical devices regulations should place more stringent requirements on Approved Bodies as set out in Paragraph 23.3? [Yes / No / Don't Know/No Opinion]

Yes

Q23.2: Please outline any other requirements which should be introduced for Approved Bodies. [2500 character limit]

Confidentiality

The AB shall have documented procedures in place ensuring that its personnel, committees, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information which comes into its possession during the performance of the conformity assessment activities, except when disclosure is required by law.

The personnel of an AB shall observe professional secrecy in carrying out their tasks. Proprietary rights shall be protected. The AB shall have documented procedures in place in respect of the requirement.

Liability

The AB shall take out appropriate liability insurance for its conformity assessment activities.

The scope and overall financial value of the liability insurance shall correspond to the level and geographic scope of activities of the AB and be commensurate with the risk profile of the devices certified by the AB. The liability insurance shall cover cases where the AB may be obliged to withdraw, restrict or suspend certificates.

Financial requirements

The AB shall have at its disposal the financial resources required to conduct its conformity assessment activities within its scope of designation and related business operations. It shall document and provide evidence of its financial capacity and its long-term economic viability, taking into account, where relevant, any specific circumstances during an initial start-up phase.

The AB shall take into consideration guidance and best practice documents.

Q23.3: Do you think that Approved Bodies should be able to conduct fully remote or hybrid audits of their clients in specific circumstances, as outlined in Paragraph 23.4? [Yes / No / Don't Know/No Opinion]

Yes

Q23.4: If you answered yes to question 23.3 please outline any criteria you consider should apply to the use of remote and hybrid audits, and the expected impact of this change including any key implementation considerations that need to be considered. [2500 character limit]

Fully remote or hybrid audits should only be possible where all relevant information can be supplied electronically, and where the manufacturing facilities are not required to be inspected.

Q23.5: The MHRA considers that Approved Bodies should have a meaningful presence in the UK – for example with key roles physically based in the UK. Requiring a UK Approved Body to have a distinct legal presence in the UK would help to ensure that the legal liability rests with the UK entity as opposed to an overseas organisation, which would help to provide clearer lines of liability for both the manufacturer and from a patient safety perspective. There are a range of options for the legal status for an Approved Body including that the Approved Body is a distinct legal entity based in the UK e.g. a private limited company, or a UK establishment of an overseas company. To become designated as an Approved Body the company/organisation [checklist; single answer only]:

- Should be a distinct legal entity based in the UK (the company as a whole)
- *Should be a distinct legal entity based in the UK or have a branch in the UK*
- Don't Know / No Opinion
- Other

Q23.6: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 23.1-23.5, including any impacts on you or other stakeholder groups. [2500 character limit]

Considering there are currently three approved bodies with scope for IVDs in the UK, this is not sufficient for the whole IVD market to undergo conformity assessment in line with current requirements (assuming domestic assurance is not implemented) within the timeframes estimated by MHRA. Additional conformity assessment bodies are required to ensure there is sufficient market availability.

Section 24: Subsidiaries

Q24.1: The MHRA considers that the UK medical devices regulations could be amended to incorporate more visibility of Approved Bodies using subsidiaries, including a list of the location of each subsidiary. This could also include the requirement for Approved Bodies to:

a. Publish high level monitoring activities undertaken relating to subsidiaries

b. Publish a list of subsidiaries accompanying the designated scope of the Approved Body

Do you think that Approved Bodies using subsidiaries should meet the requirements set out above? [Yes / No / Don't Know/No Opinion]

Yes

Q24.2: Please outline any other requirements which should be placed on Approved Bodies using subsidiaries. [2500 character limit]

Where an AB subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the applicable requirements set out in the regulations and shall inform MHRA.

ABs shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

Conformity assessment activities may be subcontracted or carried out by a subsidiary provided that the legal or natural person that applied for conformity assessment has been informed accordingly.

ABs shall keep at the disposal of MHRA all relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them.

The AB shall have documented procedures in place ensuring that its subsidiaries respect the confidentiality of the information which comes into its possession during the performance of the conformity assessment activities, except when disclosure is required by law.

The top-level management of the AB shall ensure that the quality management system is fully understood, implemented and maintained throughout the AB organisation including subsidiaries involved in conformity assessment activities pursuant to the regulations.

Q24.3: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 24.1-24.2, including any impacts on you or other stakeholder groups. [2500 character limit]

Subsidiaries allow for approved bodies to hold a larger knowledge base that would routinely be possible within their own arsenal and creates the ability to conduct reviews for products which may only have a few experts. They should continue to be accepted within the regulatory framework for this reason, with the above mitigations in place.

Section 25: Approved Body Designation & Monitoring

Q25.1: Do you agree that the UK medical devices regulations should require Approved Bodies applying for designation to hold appropriate UKAS accreditation? [Yes / No / Don't Know/No Opinion]

Yes

Q25.2: The MHRA considers that the UK medical devices regulations could be amended to include new requirements for the MHRA assessment of Approved Bodies. This could include a requirement for MHRA to perform a complete re-assessment of an Approved Body sooner than 5 years after designation (current requirement) where there is sufficient justification e.g. where concerns are raised regarding that Approved Body. Do you think the UK medical devices regulations should include the requirements set out [above] for MHRA assessment of Approved Bodies? [Yes / No / Don't Know/No Opinion]

Yes

Q25.3: Please outline any other requirements which should be introduced for MHRA assessment of Approved Bodies. [2500 character limit]

The final assessment report from the designation procedure should be published.

Q25.4: Do you think that the MHRA should be able to perform remote audits of Approved Bodies or their subsidiaries in specific circumstances? [Yes / No / Don't Know/No Opinion]

Yes

Q25.5: If you answered yes to question 25.4, please outline any criteria you consider should apply to the use of remote audits, and the expected impact of this change including any key implementation considerations that need to be taken into account. [2500 character limit]

Fully remote or hybrid audits should only be possible where all relevant information can be supplied electronically.

Q25.6: The MHRA considers that the UK medical devices regulations could set out that Medical Device and Active Implantable Medical Device Approved Body designations issued prior to July 2023 could be 'rolled over' until expiry of the designation. In this event, Approved Bodies would be expected to be in compliance 6 months ahead of the implementation date in July 2023. The MHRA would conduct an assessment of the Approved Body to review their records, systems, procedures and processes to ensure readiness and compliance with the relevant new requirements ahead of the implementation date. Do you think the transitional arrangement above for roll over of Medical Device & Active Implantable Medical Device Approved Body designation is suitable? [Yes / No / Don't Know/No Opinion]

No opinion

Q25.7: Please explain your reasoning to question 25.6 and expand on what you consider would be suitable criteria for this roll over if any. [2500 character limit]

NA

Q25.8: Do you think that the MHRA should be required to perform the tasks set out in Paragraph 25.7 in the event of Approved Body designation withdrawal, restriction, or suspension? [Yes / No / Don't Know/No Opinion]

Yes

Q25.9: Do you think that the UK medical devices regulations should set out the circumstances in which certificates shall remain valid on an ongoing basis or for a defined time period in the event of designation withdrawal? [Yes / No / Don't Know/No Opinion]

Yes

Q25.10: If you have answered yes to question 25.9 please outline any circumstances in which certificates should remain valid on an ongoing basis or for a defined time period. [2500 character limit]

a) *MHRA has confirmed, within one month of the suspension or restriction, that there is no safety issue in relation to certificates affected by the suspension or restriction and MHRA has outlined a timeline and actions anticipated to remedy the suspension or restriction*
b) *MHRA has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the AB has the capability of continuing to monitor, and remain responsible for, existing certificates issued for the period of the suspension or restriction. In the event that MHRA determines that the AB does not have the capability to support existing certificates issued, the manufacturer shall provide, to MHRA, within three months of the suspension or restriction, a written confirmation that another qualified AB is temporarily assuming the functions of the AB to monitor and remain responsible for the certificates during the period of suspension or restriction*

Q25.11: Do you think the UK medical devices regulations should introduce requirements set out in Paragraph 25.9 for Approved Bodies in relation to how they conduct their activities? [Yes / No / Don't Know/No Opinion]

Yes

Q25.12: Please outline any other requirements which should be introduced in relation to how Approved Bodies conduct their activities. [2500 character limit]

NA

Q25.13: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 25.1-25.12, including any impacts on you or other stakeholder groups. [2500 character limit]

The current process within the UK when notified bodies cease business relies on manufacturers finding a new conformity assessment body despite the lack of approved being no fault of their own. This onus should be on the approved body which is ceasing business, and they should be required to let those manufacturers affected and MHRA know with plenty of time, and aid in finding them a suitable alternative approved body.

Chapter 6: Conformity Assessment

Section 26: Conformity Assessment

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

Yes

Q26.2: Please outline any other clarifications or additions to requirements that you think should be introduced to strengthen the conformity assessment of medical devices under the UK medical device regulations. Please include your rationale and any expected impacts on you/other stakeholder groups (including any implementation considerations such as guidance that may be required). [2500 character limit]

Conformity assessment of Annex II list A / Class D IVDs should include the involvement of a reference laboratory (if designated for that type of device) to verify the performance claimed by the manufacturer, and involvement of an expert panel.

Q26.3: The current timeframe for which manufacturers must retain technical documentation is 15 years for implantable devices, and 5 years for all other medical devices. We are considering whether this is sufficient. An option is for this to be 15 years for implantable devices and 10 years for other medical devices. For how long should the manufacturer be required to keep technical documentation for a medical device they have manufactured [checklist; single answer only]:

- 1-5 years after the last product has been manufactured
- *6-10 years after the last product has been manufactured*
- 11-15 years after the last product has been manufactured
- For the expected lifetime of the device, after the last product has been manufactured
- Other

Q26.4: Anecdotally we are aware that the following conformity assessment routes for general medical devices are rarely utilised by manufacturers: batch verification, product quality assurance and type examinations. The MHRA considers that the UK medical devices regulations could be amended to exclude these as possible conformity assessment routes. Do you think that certain conformity assessment routes, including those [above], should be removed from the UK medical devices regulations? [Yes / No / Don't Know/No Opinion]

No

Q26.5: If you have answered yes to question 26.4, please outline which conformity assessment routes could be removed from the UK medical devices regulations. [2500 character limit]

NA

Q26.6: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 26.1-26.5, including any impacts on you or other stakeholder groups. [2500 character limit]

There are different reasons manufacturers would choose different routes of conformity assessment, including cost, time, and their existing portfolio of devices. Giving manufacturers flexibility on this aspect is likely to support the UK market, and removing these options may mean manufacturers do not utilise the UK market at all.

Section 27: Mechanism for Transparency & 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 / No / Don't Know/No Opinion]

No opinion

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

Yes

Q27.3: If you have answered yes to question 27.2 please outline which types/classes of medical devices this additional scrutiny should apply to. [2500 character limit]

Annex II list A / Class D IVDs

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. [2500 character limit]

These are the highest risk class of IVDs, and so further scrutiny should be actioned to ensure such products are safe and effective on the UK market. MHRA should ensure they have appropriate resource and experience for this review.

Section 28: Certificates of Conformity

Q28.1: Do you think the UK medical devices regulations should detail the minimum content of Certificates of Conformity [as outlined at Paragraph 28.2]? [Yes / No / Don't Know/No Opinion]

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 [referencing bullet points A through I in Paragraph 28.2]. [2500 character limit]

a) *name, address and identification number of the approved body*
b) *name and address of the manufacturer and, if applicable, of the UKRP*
c) *unique number identifying the certificate*
d) *date of issue*

e) *date of expiry*
f) *if applicable, reference to any previous certificate*
g) *reference to the regulations and the relevant schedule in accordance with which the conformity assessment has been carried out*
h) *examinations and tests performed, e.g. designated standards, test reports and audit report(s)*
i) *if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered*
j) *if applicable, information about the surveillance by the approved body*
k) *conclusions of the 'approved body's conformity assessment with regard to the relevant schedule*
l) *conditions for or limitations to the validity of the certificate*

In addition:

m) *legally binding signature of the approved body in accordance with the applicable national law*

Q28.3: Do you think Approved Bodies should be allowed to impose restrictions/requirements on the use/follow-up of certain medical devices [as outlined in Chapter 8 of the consultation document]? [Yes / No / Don't Know/No Opinion]

No

Q28.4: If you have answered yes to question 28.3, please outline what restrictions / requirements Approved Bodies could impose. [2500 character limit]

NA

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

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. [2500 character limit]

- *notifications for conformity assessments and certificates*
- *withdrawal or refusals of applications for the certificates*
- *information regarding certificates*

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. [2500 character limit]

The rationale for medical devices being reported to MHRA is for transparency purposes, and for allowing easy identification if any issues arise. This same rationale can be used for certificates on the market.

As well as this, it would also allow for fraudulent or falsely UKCA marked medical devices to be identified if there is no certificate available to MHRA for that specific product.

Section 29: Voluntary Change of Approved Body

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

Yes

Q29.2: If you have answered yes to question 29.1, please outline what this agreement should include. [2500 character limit]

- *the date on which the certificates issued by the outgoing approved body become invalid*
- *the date until which the identification number of the outgoing approved body may be indicated in the information supplied by the manufacturer, including any promotional material*
- *the transfer of documents, including confidentiality aspects and property rights*
- *the date after which the conformity assessment tasks of the outgoing approved body is assigned to the incoming approved body*
- *the last serial number or lot number for which the outgoing approved body is responsible*

Q29.3: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 29.1-29.2, including any impacts on you or other stakeholder groups. [2500 character limit]

The above information allows for clear transparency over what requirements fall on which party in the event of a voluntary change of approved body. This is likely to prevent supply shortages due to any errors in these matters and maintain continuity.

Section 30: Declaration of Conformity

Q30.1: Do you think that the UK medical devices regulations should set out the minimum content requirements [as at Paragraph 30.3] for the Declaration of Conformity? [Yes / No / Don't Know/No Opinion]

Yes

Q30.2: If you have answered yes to question 30.1, please outline what the requirements for the Declaration of Conformity should be [referencing bullet points A through I in Paragraph 30.3]. [2500 character limit]

a) Name, registered trade name or registered trade mark
b) manufacturer information, if applicable, its UKRP, and the address of their registered place of business where they can be contacted and their location be established
c) A statement that the declaration of conformity is issued under the sole responsibility of the manufacturer
d) The Basic UDI-DI
e) Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI
f) Risk class of the device
g) References to any designated standards used and in relation to which conformity is declared

h) Where applicable, the name and identification number of the AB, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued

i) Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

Additional:

j) A statement that the device that is covered by the present declaration is in conformity with the regulations

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. [2500 character limit]

A specified list of minimum requirements for a declaration of conformity increases consistency across multiple manufacturers and makes the relevant information easier to identify.

Chapter 7: Clinical Investigations / Performance Studies

Section 32: Performance Evaluation (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 / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

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 [as outlined in Paragraphs 32.8-32.10]? [Yes / No / Don't Know/No Opinion]

Yes

Q32.4: Do you think the UK medical devices regulations should require manufacturers to rely on data from their own clinical performance studies unless they can justify reliance on other sources of clinical performance data? [Yes / No / Don't Know/No Opinion]

No

Q32.5: If you have answered yes to question 32.4, please outline what factors you think this justification could include. [2500 character limit]

Manufacturers should identify appropriate data to support the performance evaluation (e.g. literature review, general feedback).

Q32.6: Do you think the UK medical devices regulations should require that the performance evaluation is updated throughout the lifetime of the IVD and used to update the technical documentation listed in Paragraph 32.11? [Yes / No / Don't Know/No Opinion]

Yes

Q32.7: If you have answered yes to question 32.6, please outline how you think the performance evaluation should be updated by the manufacturer and if there is any other technical documentation which should be updated. [2500 character limit]

The performance evaluation and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from risk management, post market surveillance, post market performance follow up, and change control.

This should be conducted as part of regular technical documentation review, including within the quality management system.

Q32.8: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 32.1-32.7, including any impacts on you or other stakeholder groups. [2500 character limit]

The manufacturer shall specify and justify the level of the clinical evidence necessary to demonstrate conformity with the relevant essential requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

The above information will allow for any safety or design issues to be identified with the device and allow for continued monitoring of the devices use.

Manufacturers should have to justify use of clinical data which has not been sourced through their own products by the use of equivalence to other medical devices already on the market in the UK as long as they can demonstrate that the equivalent device is sufficiently similar to that of the device requiring clinical data.

Manufacturers should have access to the full clinical and technical data to the equivalent device, including continued access to any changes in this documentation.

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 / No / Don't Know/No Opinion]

Yes

Q34.2: Do you think the UK medical devices regulations should set out in detail the specific requirements for the performance studies in Paragraph 34.5? [Yes / No / Don't Know/No Opinion]

Yes

Q34.3: If you have answered yes to question 34.2, please outline what you think the specific requirements of the performance study should be. [2500 character limit]

The requirements for performance studies should be aligned to the requirements detailed in the EU IVDR (2017/746). Specifically, Articles 56-66, 68, 70, 71, 73, 76, Annex XIII and Annex XIV, adapted to be suitable to the UK Regulatory system (i.e. removal of references to EU and/or the EU legislative workings). This broadly includes, but is not limited to:

- *Meets the essential requirements*
- *Rights, safety, dignity and well-being of subjects is maintained*

- *Scientific and ethical review*
- *Requirements on when a performance study can be conducted*
- *Ability to withdraw from study*
- *Suitable facilities*
- *Informed consent requirements, the need for it to be clear and concise and freely given*
- *Information on the performance study to be provided to the participant (right, nature of study, alternatives, conditions being conducted, damage compensation)*
- *Requirements on incapacitated subjects, minors, pregnant or breastfeeding persons, in emergency situations*
- *Any additional national measures regarding persons performing mandatory military service, deprived of liberty, where they cannot take part due to judicial review, or persons in residential care institutions*

Q34.4: Do you think the UK medical devices regulations should set out the obligations for the sponsor of a performance study, including those outlined in Paragraph 34.7? [Yes / No / Don't Know/No Opinion]

Yes

Q34.5: Please outline any other obligations for the sponsor of a performance study which should be. [2500 character limit]

- *Person established in the UK where the sponsor is non-UK*
- *Damage compensation relating to damage from a performance study*
- *Applications for performance studies to MHRA, including details of what this application should include and clear timeframes – requirements should also include the process for review of such an application from MHRA*
- *Process for performance study involving an existing UKCA marked device*
- *Modifications, temporary halts, or early termination to performance studies, submission of this to MHRA and the process for review of such an application from MHRA*
- *Reporting and recording of adverse events occurring during a performance study*
- *Sponsor should ensure CTA approval has been sought specifically for companion diagnostics*

Q34.6: Do you think sponsors should be required to implement a clinical performance study plan [as outlined in Paragraph 34.8]? [Yes / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

Yes

Q34.8: If you have answered yes to question 34.7, please outline what you think the requirements for the clinical performance study plan should be. [2500 character limit]

- *Identification/contact details of the sponsor and/or contact person/legal representative in the UK*
- *investigator(s) information*
- *start date/duration*

- *identification/description of device, intended purpose, analyte(s) or marker(s), metrological traceability, specimens under investigation*
- *summary of study, design type, objectives/hypotheses of study, reference to the state of the art in diagnosis and/or medicine*
- *description of the expected risks/benefits of device and of study*
- *IFU of device/test protocol, required training/experience of the user, calibration procedures/means of control, indication of any other related product to be included/excluded and specifications on any comparator/comparative method used as reference*
- *description/justification for study design*
- *analytical performance*
- *parameters of clinical performance: the specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health and/or public health management decisions*
- *study population*
- *monitoring plan*
- *data management*
- *decision algorithms*
- *policy regarding amendments to/deviations from plan, with clear prohibition of waivers*
- *control of access, follow-up in relation to the device used in the study and return of unused/expired/malfunctioning devices*
- *statement of compliance with ethical principles for medical research in humans and GCP and applicable regulatory requirements*
- *informed consent process, patient information sheet and consent forms*
- *procedures for safety recording and reporting, procedures/timelines for reporting*
- *criteria/procedures for suspension/early termination*
- *criteria/procedures for follow up of subjects on completion, suspension/early termination, withdrawn their consent, or lost to follow up*
- *procedures for communication of test results outside the study, including to subjects*
- *policy as regards the establishment of the study report and publication of results in relation to legal requirements and the ethical principles*
- *list of the technical and functional features of the device indicating those that are covered by the study*
- *bibliography*

Q34.9: Do you think this obligation should also extend to other types of performance studies (other than clinical performance studies)? [Yes / No / Don't Know/No Opinion]

No

Q34.10: Do you think the UK medical devices regulations should set detailed requirements for the purpose, methods, objectives and ethical considerations for a performance study including those outlined in Paragraph 34.9? [Yes / No / Don't Know/No Opinion]

Yes

Q34.11: Please outline any other requirements for performance studies which should be introduced. [2500 character limit]

- *Identification/contact details of the sponsor and/or contact person/legal representative in the UK*
- *investigator(s) information*
- *start date/duration*
- *identification/description of device, intended purpose, analyte(s) or marker(s), metrological traceability, specimens under investigation*
- *summary of study, design type, objectives/hypotheses of study, reference to the state of the art in diagnosis and/or medicine*
- *description of the expected risks/benefits of device and of study*
- *IFU of device/test protocol, required training/experience of the user, calibration procedures/means of control, indication of any other related product to be included/excluded and specifications on any comparator/comparative method used as reference*
- *description/justification for study design*
- *analytical performance*
- *parameters of clinical performance: the specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health and/or public health management decisions*
- *study population*
- *monitoring plan*
- *data management*
- *decision algorithms*
- *policy regarding amendments to/deviations from plan, with clear prohibition of waivers*
- *control of access, follow-up in relation to the device used in the study and return of unused/expired/malfunctioning devices*
- *statement of compliance with ethical principles for medical research in humans and GCP and applicable regulatory requirements*
- *informed consent process, patient information sheet and consent forms*
- *procedures for safety recording and reporting, procedures/timelines for reporting*
- *criteria/procedures for suspension/early termination*
- *criteria/procedures for follow up of subjects on completion, suspension/early termination, withdrawn their consent, or lost to follow up*
- *procedures for communication of test results outside the study, including to subjects*
- *policy as regards the establishment of the study report and publication of results in relation to legal requirements and the ethical principles*
- *list of the technical and functional features of the device indicating those that are covered by the study*
- *bibliography*

Q34.12: The MHRA considers that the UK medical devices regulations could be amended to require sponsors to prepare and publish a clinical performance study report, containing documented information on the clinical performance study plan and results and conclusions of the clinical performance study, including negative findings. The UK medical devices regulations could clarify that this obligation also extends to other types of performance studies (such as analytical performance studies). Do you think sponsors should be required to provide a clinical performance study report? [Yes / No / Don't Know/No Opinion]

Yes

Q34.13: Do you think the UK medical devices regulations should set out the minimum requirements for the clinical performance study report? [Yes / No / Don't Know/No Opinion]

Yes

Q34.14: If you have answered yes to question 34.13, please outline what the requirements for the clinical performance study report should be. [2500 character limit]

A clinical performance study report, signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol plan, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.

Q34.15: Do you think this obligation should also extend to analytical performance studies? [Yes / No / Don't Know/No Opinion]

No

Q34.16: If you have answered yes to question 34.15, what types of performance study (other than clinical performance studies) do you think should be subject to a clinical performance study report? [2500 character limit]

NA

Q34.17: Do you think the UK medical devices regulations should require the clinical performance study report be published? [Yes / No / Don't Know/No Opinion]

No

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 [as outlined in Paragraphs 34.11-34.12]? [Yes / No / Don't Know/No Opinion]

No

Q34.19: Do you think that performance studies involving companion diagnostics should be subject to the same requirements as all other performance studies [as outlined in Paragraphs 34.13- 34.14]? [Yes / No / Don't Know/No Opinion]

Yes

Q34.20: Do you think that performance studies involving companion diagnostics using only left- over samples should NOT be subject to the same requirements as all other performance studies? [Yes / No / Don't Know/No Opinion]

No

Q34.21: Do you think that performance studies involving companion diagnostics using only left- over samples should be notified to the MHRA? [Yes / No / Don't Know/No Opinion]

Yes

Q34.22: Do you think the conditions for conducting a performance study should be set out in the UK medical devices regulations, including those outlined in Paragraph 34.15? [Yes / No / Don't Know/No Opinion]

Yes

Q34.23: Please outline any other conditions which should be met when conducting a performance study. [2500 character limit]

- *Person established in the UK where the sponsor is non-UK*
- *Damage compensation relating to damage from a performance study*
- *Applications for performance studies to MHRA, including details of what this application should include and clear timeframes – requirements should also include the process for review of such an application from MHRA*
- *Process for performance study involving an existing UKCA marked device*
- *Modifications, temporary halts, or early termination to performance studies, submission of this to MHRA and the process for review of such an application from MHRA*
- *Reporting and recording of adverse events occurring during a performance study*

Clarification provided on MHRA stance where UK samples are used in a study outside of the UK and whether these should be notified

Q34.24: Do you think the rights of subjects to withdraw from a performance study should be included in the UK medical devices regulations, as set out in Paragraph 34.16? [Yes / No / Don't Know/No Opinion]

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? [Yes / No / Don't Know/No Opinion]

Yes

Q34.26: If you have answered yes to question 34.25, please outline what you think the requirements should be. [2500 character limit]

The investigator shall be a person exercising a profession which is recognised in the MHRA, as qualifying for the role of investigator on account of having the necessary scientific knowledge and experience in patient care or laboratory medicine. Other personnel involved in conducting a performance study shall be suitably qualified, by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.

Q34.27: Do you think that the UK medical devices regulations should require that, where appropriate, the facilities where the performance study is to be conducted should be suitable for the conduct of the study [as outlined in Paragraphs 34.18-34.20]? [Yes / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

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. [2500 character limit]

Performance evaluations should be conducted in as similar as possible to how the device will be used in a 'normal' real-world setting. This requires the sponsor to ensure that the environment and clinical study population is appropriate.

The requirements for performance studies should be specified within the UK MDR to allow for consistency across different studies by different sponsors, but also to ensure that all in vitro diagnostic medical devices placed on the market in the UK (which utilise their own clinical evidence) can demonstrate the appropriate safety and efficacy required in relation to their intended purpose.

Companion diagnostic devices should have the same level of scrutiny in relation to performance evaluation but should also involve oversight from medicine assessors at the MHRA (or a suitable alternative authority for the regulation of medicinal components in the event of mutual recognition).

Where studies utilise left-over samples, these should be held to the same standard as other samples. They are still being taken from patients, and are still being used to demonstrate efficacy of a device which will ultimately go on to be used with real patient data.

Section 35: Informed Consent

Q35.1: Do you think the UK medical devices regulations should include requirements for obtaining informed consent from individuals participating in a clinical investigation or performance study? [Yes / No / Don't Know/No Opinion]

Yes

Q35.2: If you have answered yes to question 35.1, please outline what the requirements for obtaining informed consent should be. [2500 character limit]

This text box is not sufficient to detail desired requirements. We propose that the requirements of Article 59 of the EU IVDR are implemented into the UK MDR.

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). [2500 character limit]

In some situations, the requirement to conduct the performance evaluation outweighs the time that may be taken to generate consent. For example, with the Covid-19 pandemic. All medical devices used throughout this time were required at pace, and this may have been delayed if consent was included (or the process may have been faster if consent was excluded). Such situations should be clearly documented and justified, and it may be required for MHRA to grant approval for such situations.

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

NA

Section 36: Specific Requirements for Clinical Investigations / Performance Studies

Q36.1: Do you think additional requirements, including those outlined in Paragraph 36.3, should be required for clinical investigations or performance studies on minors? [Yes / No / Don't Know/No Opinion]

Yes

Q36.2: Please outline any other requirements which should be introduced for clinical investigations or performance studies on minors. [2500 character limit]

- *the minors have received the patient information in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children*
- *the explicit wish of a minor who is capable of forming an opinion and assessing the patient information to refuse participation in, or to withdraw from, the performance study at any time, is respected by the investigator*
- *no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the performance study*
- *performance studies on minors should only be conducted where there is a justified clinical need*

Q36.3: Do you think additional requirements, including those outlined in Paragraph 36.4, should be required for clinical investigations or performance studies on pregnant or breastfeeding women? [Yes / No / Don't Know/No Opinion]

Yes

Q36.4: Please outline any other requirements which should be introduced for clinical investigations or performance studies on pregnant or breastfeeding women. [2500 character limit]

- *no incentives or financial inducements are given to subjects, except for compensation for expenses and loss of earnings directly related to the participation in the performance study*

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. [2500 character limit]

Although minors cannot provide consent themselves, their maturity level should still be taken into account in relation to providing them with patient information, as well as considering their wishes in taking part in the study. It is possible that any study may have direct health effects on a patient, and such decisions should not only be taken on the consent of a guardian where the minor has directly expressed they do not wish to be involved.

Incentives or financial inducements may introduce bias to studies and is generally not accepted in other geographic areas for performance studies.

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 / No / Don't Know/No Opinion]

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. [2500 character limit]

In some situations, the requirement to conduct the performance evaluation outweighs the time that may be taken to generate consent. For example, with the Covid-19 pandemic. All medical devices used throughout this time were required at pace, and this may have been delayed if consent was included (or the process may have been faster if consent was excluded). Such situations should be clearly documented and justified, and it may be required for MHRA to grant approval for such situations.

Q37.3: Do you think that systems should be put in place for compensation as set out in Paragraph 37.4. [Yes / No / Don't Know/No Opinion]

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. [2500 character limit]

MHRA shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a performance study conducted in the UK are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.

The sponsor and the investigator shall inform MHRA of this.

Where medical devices unapproved are used on individuals, it is likely there will be some problems identified throughout the study. Such individuals who are victims of these should be duly compensated.

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 Paragraph 38.2 should be outlined? [Yes / No / Don't Know/No Opinion]

Yes

Q38.2: Please outline any other requirements which should be introduced for the application form and accompanying documentation. [2500 character limit]

- *Demonstration of the scientific validity and the analytical and clinical performance*
- *Clinical evidence and performance evaluation report*
- *Ethical considerations for clinical performance studies*
- *Methods for clinical performance studies*

Q38.3: Do you think the UK medical devices regulations should outline the relevant timescales that the applicant and the MHRA should conform to when an application for a clinical investigation or performance study is submitted to the MHRA? [Yes / No / Don't Know/No Opinion]

Yes

Q38.4: If you have answered yes to question 38.3, please outline what appropriate timescale should be. [2500 character limit]

Within 10 days of receiving the application, MHRA shall notify the sponsor as to whether the performance study falls within the scope of the regulation and as to whether the application dossier is complete.

Within one week of any change occurring in relation to the documentation, the sponsor shall update MHRA of that change to the documentation making it clearly identifiable.

Where MHRA finds that the performance study applied for does not fall within the scope of the regulations or that the application is not complete, it shall inform the sponsor thereof and shall set a time limit of maximum 10 days for the sponsor to comment or to complete the application. MHRA may extend this period by a maximum of 20 days where appropriate.

Where the sponsor has not provided comments nor completed the application within the 10 days, the application shall be deemed to have lapsed. Where the sponsor considers that the application falls under the scope of the regulations and/or is complete but MHRA does not agree, the application shall be considered to have been rejected. MHRA shall provide for an appeal procedure in respect of such refusal.

MHRA shall notify the sponsor within five days of receipt of the comments or of the requested additional information, whether the performance study is considered as falling within the scope of the regulations and the application is complete.

MHRA may also extend the periods above each by a further five days.

The date on which the sponsor is notified of being complete, shall be the validation date of the application.

MHRA shall notify the sponsor of the authorisation within 45 days of the validation date of the application. MHRA may extend this period by a further 20 days for the purpose of consulting with experts.

Q38.5: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 38.1-38.4, including any impacts on you or other stakeholder groups. [2500 character limit]

A clear process for the assessment of performance evaluation applications allows transparency and sets a clear timeline for the sponsor to determine when the performance evaluation study is likely to begin. This is particularly important in relation to study participation and identifying patients to be involved.

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 / No / Don't Know/No Opinion]

Yes

Q39.2: Do you think the detailed requirements for assessment of the application for clinical investigations or performance study should be outlined [as at Paragraph 39.3] by the MHRA? [Yes / No / Don't Know/No Opinion]

Yes

Q39.3: If you have answered yes to question 39.2, please outline what you think the requirements for assessment of the application for clinical investigation or performance study should be. [2500 character limit]

a) *the demonstration of compliance of the device(s) for performance study with the applicable essential requirements, apart from the aspects covered by the performance study, and whether, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, in case of performance studies, the evaluation of the analytical performance, and in case of interventional clinical performance studies, the evaluation of the analytical performance, clinical performance and scientific validity, taking into consideration the state of the art*
b) *whether the risk-minimisation solutions employed by the sponsor are described in designated standards and, in those cases where the sponsor does not use designated standards, whether the risk-minimisation solutions provide a level of protection that is equivalent to that provided by designated standards*
c) *whether the measures planned for the safe installation, putting into service and maintenance of the device for performance study are adequate*
d) *the reliability and robustness of the data generated in the performance study, taking account of statistical approaches, design of the performance study and methodological aspects, including sample size, comparator and endpoints*

Q39.4: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 39.1-39.3, including any impacts on you or other stakeholder groups. [2500 character limit]

Clear requirements on what will be assessed by MHRA allows sponsors to ensure their submission adequately addresses all points and will make the approval process more efficient for both parties (removing the back and forth that may come of missing or unclear information).

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 Paragraph 40.2? [Yes / No / Don't Know/No Opinion]

Yes

Q40.2: Please outline any other requirements which should be introduced for the conduct of a clinical investigation or performance study. [2500 character limit]

In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the performance study is in compliance with the requirements, the sponsor shall ensure adequate monitoring of the conduct of a performance study. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the performance study including the following:

a) *the objective and methodology of the performance study*
b) *the degree of deviation of the intervention from normal clinical practice*

All performance study information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified

while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.

Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves transmission over a network.

Q40.3: Do you think that the MHRA should be required to inspect, at an appropriate level, clinical investigation, or performance study site(s)? [Yes / No / Don't Know/No Opinion]

Yes

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

MHRA shall inspect, at an appropriate level, performance study site(s) to check that performance studies are conducted in accordance with the requirements of the regulations and with the approved investigation plan.

Section 41: Clinical Investigations / Performance Studies Regarding Devices Bearing the UKCA Marking

Q41.1: Do you think the sponsor should be required to notify the MHRA of a clinical investigation or performance study within a specified time period prior to the start of that clinical investigation or performance study as outlined in Paragraph 41.3? [Yes / No / Don't Know/No Opinion]

Yes

Q41.2: If you have answered yes to question 41.1, please outline what you think the specified time period should be. [2500 character limit]

At least 65 days prior to commencement of the study

Q41.3: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 41.1-41.2, including any impacts on you or other stakeholder groups. [2500 character limit]

The sponsor may start the performance study in the following circumstances:

a) *in the case of performance studies and where the specimen collection does not represent a major clinical risk to the subject of the study, unless otherwise stated by national law, immediately after the validation date of application, provided that a negative opinion has not been issued by an ethics committee in the UK concerned in respect of the performance study*
b) *in the case of performance studies, as soon as MHRA has notified the sponsor of its authorisation and provided that a negative opinion has not been issued by an ethics committee in the UK concerned in respect of the performance study. MHRA shall notify the sponsor of the authorisation within 45 days of the validation date. MHRA may extend this period by a further 20 days for the purpose of consulting with experts.*

The above timings should be applied, and therefore a full 65 days should be given to MHRA to allow for the above process to occur.

Section 42: Modifications to Clinical Investigations / Performance Studies

Q42.1: Do you think the UK medical devices regulations should set out the procedures for sponsors intending to introduce modifications to a clinical investigation or performance study, including the procedures outlined in Paragraph 42.2? [Yes / No / Don't Know/No Opinion]

Yes

Q42.2: Please outline any other procedures which should be introduce and/or what the timeframes for the procedures in Paragraph 42.2/suggested procedures should be. [2500 character limit]

The sponsor shall include an updated version of the relevant documentation as part of the notification. Changes to the relevant documentation shall be clearly identifiable.

The sponsor may implement the modifications at the earliest 38 days after the notification, unless:

a) *MHRA has notified the sponsor of its refusal or on considerations of public health, of subject and user safety or health, or of public policy*
b) *an ethics committee in the UK has issued a negative opinion in relation to the substantial modification to the performance study*

MHRA may extend the period by a further seven days, for the purpose of consulting with experts.

Q42.3: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 42.1-42.2, including any impacts on you or other stakeholder groups. [2500 character limit]

Any objection or no objection issued by MHRA is based on the evidence provided in relation to the performance study specifically. Any changes to this protocol may change this outcome and so should be notified.

MHRA should have clear timelines to be met for reviewing the amendment, and such timelines should be used to decide on when the sponsor would be expected to submit notice of the amendment.

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 Paragraph 43.2 in cases where it is considered that the requirements of the UK medical devices regulations in regards to a performance study have not been met? [Yes / No / Don't Know/No Opinion]

Yes

Q43.2: Please outline any other measures which should be introduced for either a clinical investigation or performance study. [2500 character limit]

NA

Q43.3: Do you think, except where immediate action is required, that the sponsor or the investigator or both should be asked for their opinion regarding the corrective measures outlined in Paragraph 43.2 (suggested measures)? [Yes / No / Don't Know/No Opinion]

Yes

Q43.4: If you have answered yes to question 43.3, please outline what you think should be the specified time period for the sponsor or investigator to give their opinion. [2500 character limit]

That opinion shall be delivered within seven days.

Q43.5: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 43.1-43.4, including any impacts on you or other stakeholder groups. [2500 character limit]

Certain information can be uncovered throughout the term of a clinical investigation, including potential safety or performance issues which could result in early termination. Where the sponsor does not end it, MHRA should have the authority to terminate it.

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 / No / Don't Know/No Opinion]

Yes

Q44.2: Please outline any other procedures which should be included and/or what the timeframe for notification should be for the procedures in Paragraph 44.2. [2500 character limit]

The end of a performance study shall be deemed to coincide with the last visit of the last subject unless another point in time for such end is set out in the performance study plan.

The performance study report should be made publicly available, at the latest when the device is registered with MHRA and before it is placed on the market. If the device is not registered within one year of the summary and the performance study report having been submitted, they shall become publicly accessible at that point in time.

The sponsor shall notify MHRA of the end of that performance study in the UK.

Q44.3: Please provide your views on what these timescales should be, and your reasoning (including any available relevant evidence) to support your answers to questions 44.1-44.2, including any impacts on you or other stakeholder groups. [2500 character limit]

If the sponsor has temporarily halted a performance study or has terminated a performance study early, it shall inform within 15 days MHRA of the temporary halt or early termination. In the event that the sponsor has temporarily halted or terminated early the performance study on safety grounds, it shall inform MHRA within 24 hours.

The sponsor shall notify MHRA of the end of that performance study in the UK. That notification shall be made within 15 days of the end of the performance study.

Irrespective of the outcome of the performance study, within one year of the end of the performance study or within three months of the early termination or temporary halt, the sponsor shall submit to MHRA a performance study report.

The performance study report should be made publicly available, at the latest when the device is registered with MHRA and before it is placed on the market. If the device is not registered within one year of the summary and the performance study report having been submitted, they shall become publicly accessible at that point in time.

Section 45: Recording & 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 / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

Yes

Q45.5: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 45.1-45.4, including any impacts on you or other stakeholder groups. [2500 character limit]

Such requirements are implemented for adverse incidents that occur outside of a performance study, and so should be relevant for any IVDs undergoing performance study. The ability to submit an initial report followed by a final report alerts MHRA as soon as possible while the sponsor conducts an investigation into the adverse incident.

Section 46: Types of Clinical Investigations / Performance Studies & 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 / No / Don't Know/No Opinion]

No opinion

Q46.2: If you have answered yes to question 46.1 please outline what types of clinical investigations and performance studies you think should be exempted. [2500 character limit]

NA

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 [as at Paragraph 46.5]? [Yes / No / Don't Know/No Opinion]

Yes

Q46.4: If you have answered yes to question 46.3 please outline what types of clinical investigations / performance studies should meet the requirements of the UK medical devices regulations. [2500 character limit]

Where products are within the scope of the UK MDR, any performance studies on these products should be notified to MHRA prior to commencement of the study

Q46.5: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 46.1-46.4, including any impacts on you or other stakeholder groups. [2500 character limit]

Certain IVDs will be manufactured in a healthcare institution for use on just their own patients. These products will need to be validated and so a minor performance studies may be conducted. Such studies should be notified to MHRA for a full picture of the medical devices entering the market, but do not need to conform to the full requirements of the UK MDR.

Section 47: Summary of Safety & Clinical Performance

Q47.1: Do you think the UK medical devices regulations should introduce the requirement for an SSCP for medical devices [as at Paragraphs 47.5-47.6]? [Yes / No / Don't Know/No Opinion]

Yes

Q47.2: If you have answered yes to question 47.1, please outline what classes/types of medical devices should require an SSCP. [2500 character limit]

Annex II List A and B / Class C and D

Q47.3: Do you think the UK medical devices regulations should set out the minimum content of the SSCP included in Paragraph 47.5? [Yes / No / Don't Know/No Opinion]

Yes

Q47.4: Please outline any other content which should be included in the SSCP for a medical device. [2500 character limit]

NA

Q47.5: As expanded on in Chapter 4, Section 20, the UK medical devices regulations could be amended to require manufacturers to upload the full SSCP or a link to the SSCP (hosted externally) to the MHRA registration system. Please select one of the following [checklist; single answer only]:

- *The manufacturer should upload the full SSCP to the MHRA registration system*
- The manufacturer should upload a link to the SSCP to the registration system
- The manufacturer should not be required to upload the SSCP to the registration system
- Don't Know / No Opinion
- Other

Q47.6: Do you think an Approved Body should validate the SSCP for a medical device [as at Paragraph 47.8]? [Yes / No / Don't Know/No Opinion]

Yes

Q47.7: If you have answered yes to question 47.6, please outline how this procedure should be carried out. [2500 character limit]

The approved body should review this documentation as part of the conformity assessment procedure to ensure the product meets the intended purpose and risk/benefit.

Q47.8: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 47.1-47.7, including any impacts on you or other stakeholder groups. [2500 character limit]

Annex II list A and B / Class C and D are the highest risk IVDs, and so should be subject to additional scrutiny on their clinical and safety performance.

Chapter 8: Post-Market Surveillance & Vigilance

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 / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

Yes

Q48.3: Please outline any other elements that a post-market surveillance plan should address. [2500 character limit]

The post-market surveillance plan shall address the collection and utilisation of available information, in particular:

- *information concerning serious incidents, including information from PSURs, and field safety corrective actions*
- *records referring to non-serious incidents and data on any undesirable side-effects*
- *information from trend reporting*
- *relevant specialist or technical literature, databases and/or registers*
- *information, including feedbacks and complaints, provided by users, distributors and importers*
- *publicly available information about similar medical devices.*

The post-market surveillance plan shall cover at least:

- *a proactive and systematic process to collect any information. The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market*
- *effective and appropriate methods and processes to assess the collected data*
- *suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management*
- *effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field*

- *methods and protocols to manage the events subject to the trend report, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period*
- *methods and protocols to communicate effectively with MHRA, approved bodies, economic operators and users*
- *reference to procedures to fulfil the manufacturers systematic procedures to identify and initiate appropriate measures including corrective actions*
- *effective tools to trace and identify devices for which corrective actions might be necessary*
- *a PMPF plan, or a justification as to why a PMPF is not applicable*

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 [as at Paragraphs 48.6-48.7]? [Yes / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

Yes

Q48.6: Please outline any other elements that a PMCF/PMPF plan should be required to address. [2500 character limit]

A definition of PMPF would be appreciated.

The PMPF plan shall specify the methods and procedures for proactively collecting and evaluating safety, performance and scientific data with the aim of:

- *confirming the safety and performance of the device throughout its expected lifetime*
- *identifying previously unknown risks or limits to performance and contra-indications*
- *identifying and analysing emergent risks on the basis of factual evidence*
- *ensuring the continued acceptability of the clinical evidence and of the benefit-risk ratio*
- *identifying possible systematic misuse*

The PMPF plan shall include at least:

- *the general methods and procedures of the PMPF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of performance or scientific data*
- *the specific methods and procedures of PMPF to be applied, such as ring trials and other quality assurance activities, epidemiological studies, evaluation of suitable patient or disease registers, genetic databanks or post-market clinical performance studies*
- *a rationale for the appropriateness of the methods and procedures*
- *a reference to the relevant parts of the performance evaluation report and to the risk management*
- *the specific objectives to be addressed by the PMPF*

- *an evaluation of the performance data relating to equivalent or similar devices, and the current state of the art*
- *reference to any relevant, designated standards when used by the manufacturer, and relevant guidance on PMPF*
- *a detailed and adequately justified time schedule for PMPF activities, such as analysis of PMPF data and reporting, to be undertaken by the manufacturer*

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? [Yes / No / Don't Know/No Opinion]

Yes

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 / No / Don't Know/No Opinion]

Yes

Q48.9: If you have answered yes to question 48.7, please outline which types or classes of medical devices should be subject to a post-market surveillance report and if there are any other elements which should be required for the post-market surveillance report. [2500 character limit]

All devices should be subject to a post-market surveillance report

Q48.10: If you answered have answered yes to question 48.7, 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. [2500 character limit]

Manufacturers of high risk IVDs (Annex II devices, class C or class D devices) shall prepare a periodic safety update report for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan, together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

- *the conclusions of the benefit-risk determination*
- *the main findings of the PMPF*
- *the volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.*

Manufacturers of Annex II, class C and D devices shall update the PSUR at least annually. That PSUR shall be part of the technical documentation.

Manufacturers of Annex II list A/class D devices shall submit PSUR to the approved body involved in the conformity assessment of such devices. The approved body shall review the report and provide an evaluation with details of any action taken. Such PSUR and the evaluation by the approved body shall be made available to MHRA.

For Annex II list B/class C devices, manufacturers shall make PSURs available to the approved body involved in the conformity assessment and, upon request, to MHRA.

Q48.11: If you answered have answered no to question 48.7, please outline any alternative requirements for how the manufacturer should summarise and present post-market surveillance data. [2500 character limit]

NA

Q48.12: Do you think manufacturers should upload post-market surveillance data to the MHRA devices register upon registration renewal [as at Paragraph 48.10]? [Yes / No / Don't Know/No Opinion]

No

Q48.13: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 48.1-48.12, including any impacts on you or other stakeholder groups. [2500 character limit]

As MHRA is responsible for regulation of medical devices and typically are involved where devices do not comply with the regulations, there is no need for MHRA to require any further PMS data which does not impact patient safety.

However, the existing system of providing adverse events in line with MEDDEV 2.12-1 rev 8 allows for a lack of oversight by MHRA, as they cannot be clear on whether they are receiving all expected adverse events from a manufacturer. The additional requirement on manufacturers of PSURs, internal PMS plans, and enforced requirements for adverse event reporting would improve the safety and efficacy of IVDs. Such items should be made available for MHRA review when required, but should not routinely be submitted to MHRA.

Although this is not specifically personal data, MHRA should only hold data where there is a justifiable reason and where they are taking action based on it. Where there is no use or need for this data, it should not be held. This is similar to the requirements of the Data Protection Act 2018.

Section 49: Reporting of Serious Incidents & 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 at Paragraph 49.5]? [Yes / No / Don't Know/No Opinion]

Yes

Q49.2: Do you agree with the proposed definitions for serious incident, serious deterioration and serious public health threat [as at Paragraphs 49.6-49.8]? [Yes / No / Don't Know/No Opinion]

Yes

Q49.3: If you have answered no to question 49.2, please outline what you would change about the proposed definitions? [2500 character limit]

NA

Q49.4: Do you think the manufacturer should be required to report any serious incident in line with the time periods [as at Paragraph 49.9]? [Yes / No / Don't Know/No Opinion]

Yes

Q49.5: If you have answered no to question 49.4, please outline what the timeframe for reporting serious incidents should be, or any other changes you would make to the criteria set out in Paragraph 49.9. [2500 character limit]

NA

Q49.6: Do you think the UK medical devices regulations should specify further procedures for manufacturers regarding the reporting of serious incidents and field safety corrective actions (FSCAs) including (but not limited to) the points made in Paragraph 49.10 above? [Yes / No / Don't Know/No Opinion]

Yes

Q49.7: Please outline any other requirements which should be introduced regarding reporting of serious incidents and field safety corrective actions should be. [2500 character limit]

The method of reporting to MHRA should be defined (ideally in guidance), aligning with the reporting form used within the EU.

Q49.8: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 49.1-49.7, including any impacts on you or other stakeholder groups. [2500 character limit]

Having multiple different reporting methods across geographic areas result in a higher likelihood of human error. This is also the case where requirements differ. Alignment for reporting should be as consistent as possible to reduce this error and make a more streamlined approach.

The timelines suggested within the consultation document are consistent with the reporting timelines and content for PMS submissions under the EU IVDR, meaning it will be a more streamlined system for manufacturers and other economic operators.

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 at Paragraph 50.3]? [Yes / No / Don't Know/No Opinion]

Yes

Q50.2: Please provide your reasoning (including any available relevant evidence) to support your answers to question 50.1, including any impacts on you or other stakeholder groups. [2500 character limit]

Not all incidents are reportable under vigilance obligations, so a requirement to report trends in other incidents create an obligation for manufacturers to monitor this for other related issues. It is also possible that individual events may not be a safety concern, but on a larger scale they become more serious. Therefore, trend reporting may be an important part of the vigilance system.

Section 51: Analysis of Serious Incidents & 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 / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

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 [see Paragraph 51.5]? [2500 character limit]

As there are wide variations between IVD products on the market, and most are not utilised directly by patients or the public, such requirements should take this into consideration and be realistic.

Manufacturers should take into account human factors where applicable to their products.

Q51.5: At what stages would you expect manufacturers to engage patients and the public [checklist; single answer only]:

- *Periodically once their medical device is on the market*
- Only when they or the MHRA become aware of a safety issue with the device
- Other

Q51.6: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 51.1-51.5, including any impacts on you or other stakeholder groups. [2500 character limit]

FSNs are crucial in allowing users to know of safety concerns with medical devices and mediate these safety concerns with any actions requested by the manufacturer. Where FSNs are inconsistent, this can make it difficult for users to easily identify the actions they are required to take. This is particularly true in larger healthcare institutions who may regularly receive FSNs for review.

Allowing MHRA to comment also increases this consistency and allows for specific terms to be removed which may be down-playing the risk of the issue.

Chapter 9: In Vitro Diagnostic Medical Devices

Section 52: General Background

[Information only; no consultation questions.]

Section 53: IVD Classification Rules

Q53.1: Should the classification rules for IVD products under the UK medical devices regulations be amended to align to the EU approach to IVD classification, as set out in the IVDR [see Paragraphs 53.1-53.3]? [Yes / No / Don't Know/No Opinion]

Yes

Q53.2: Should the classification rules for IVD products under the UK medical devices regulations be amended to align to the International Medical Devices Regulatory Forum (IMDRF) approach to IVD classification? [Yes / No / Don't Know/No Opinion]

No

Q53.3: Are the current IVD regulatory requirements for each class of IVD proportionate to their risk? [Yes / No / Don't Know/No Opinion]

No

Q53.4: Does the current approach to classification sufficiently cover the digital/software aspect of IVDs? [Yes / No / Don't Know/No Opinion]

No

Q53.5: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 53.1-53.4, including any impacts on you or other stakeholder groups. [2500 character limit]

The existing structure for IVD classification does not allow for any innovation within the industry. All new products are categorised as general IVD or self-test IVD where they are not included within the lists in Annex II. This means that high risk devices are not being subjected to the higher scrutiny that would be expected.

The EU IVDR introduces a new classification system which has a more adaptable classification rule set. Although there are some categories which still act on a list-based or generalised category approach (see genetic testing and companion diagnostic sections), they generally provide more flexibility for innovative IVDs and categorise based on the intended purpose of the product. This also prevents the issue of the same product having slightly different classifications across different geographic areas, particularly if the possibility of mutual recognition between GB and EU may occur. Some devices may be classified as IVD general under the current system, but be reclassified to IVD Class C in the EU, creating a bias.

Digital and software products are an area which are evolving rapidly, and so any classification of these products should continue to be done on an intended use bases rather than categorising outright.

Section 54: Genetic Testing

Q54.1: Should the UK introduce requirements around the information and data provided to individuals on the nature, significance, and implications of genetic tests [see Paragraph 54.2]? [Yes / No / Don't Know/No Opinion]

Yes

Q54.2: Should the UK medical device regulations be amended to align with the EU approach to the classification of genetic tests as set out in the IVDR? [Yes / No / Don't Know/No Opinion]

No

Q54.3: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 54.1-54.2, including any impacts on you or other stakeholder groups. [2500 character limit]

The EU IVDR classification system for genetic testing categorises them all as Class C regardless of what the intended purpose for the genetic test is. This is inconsistent with the other classification rules detailed which are predominantly based on the intended purpose and risk of the device. This means that tests for general genetic screening of mild disorders are in the same classification as genetic tests

for high-risk hereditary genetic diseases. This does not seem sufficient, and such products should be classified in relation to their intended use rather than as a general rule.

This also does not allow for any new innovative genetic tests to be classified based on risk and would stall the genetic testing supply chain if they were required to undergo more rigorous conformity assessment than is actually required.

Section 55: Companion Diagnostics

Q55.1: Should Companion Diagnostics be treated differently to other IVDs? [Yes / No / Don't Know/No Opinion]

Yes

Q55.2: How do we ensure the clinical evidence requirements for Companion Diagnostics are clear, appropriate, and proportionate to the risk? For example, should they differ for CDx that predict benefit / efficacy vs those that predict toxicity / harm? [2500 character limit]

The IVDR classification system for companion diagnostics (CDx) categorises them all as Class C regardless of what the intended purpose for the CDx is. This is inconsistent with the other classification rules detailed which are predominantly based on the intended purpose and risk of the device.

The current UK classification system categorises them all as general IVDs regardless of what the intended purpose for the CDx is.

This does not seem sufficient, and such products should be classified in relation to their intended use and risk profile rather than as a general rule.

Q55.3: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 55.1-55.2, including any impacts on you or other stakeholder groups. [2500 character limit]

Blanket classification does not allow for any new innovative CDx to be classified based on risk and would stall the CDx supply chain if they were required to undergo more rigorous conformity assessment than required, or risk patient safety where they were required to undergo a less rigorous conformity assessment than required.

Such products should be reviewed in parallel by the appropriate medicines regulator (MHRA) to ensure the basic principles of the human medicine legislation are met, and the device is sufficient for purpose.

Section 56: Distance Selling

Q56.1: Should it be made clearer that providers of testing services who supply IVDs to the UK market (through electronic or other distance sale methods), are subject to the same requirements of the UK Medical Device Regulations as apply to economic operators in the traditional supply chain? [Yes / No / Don't Know/No Opinion]

Yes

Q56.2: Should it be made clearer that those selling testing services, which include the provision of IVDs into the UK, be required to register their medical devices with the MHRA? [Yes / No / Don't Know/No Opinion]

Yes

Q56.3: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 56.1-56.2, including any impacts on you or other stakeholder groups. [2500 character limit]

A device offered by means of information society service to a natural or legal person established in the UK shall comply with the regulations.

Without prejudice to national law regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services, directly or through intermediaries, to a natural or legal person established in the UK shall comply with the regulations.

Upon request by MHRA, any natural or legal person offering a device in accordance with the above or providing a service in accordance with the above shall make available a copy of the declaration of conformity of the device concerned.

MHRA may, on grounds of protection of public health, require a provider of information society services to cease its activity.

Such proposals must be made explicitly clear to prevent ambiguity.

Chapter 10: Software as a Medical Device (SaMD)

Section 57: General Background

[Information only; no consultation questions.]

Section 65: Artificial Intelligence as a/in a Medical Device (AiaMD)

Q65.1: AiaMD is a subset of software as a medical device. Given this, MHRA views the changes noted above as also having benefits for the regulation of AiaMD. In addition, we are considering other changes to the Regulations specific to AiaMD. For example, we propose amending the Regulations to require performance evaluation methods for diagnostic AI which would take a comparable approach to performance evaluation methods used for in vitro diagnostic medical devices in terms of requiring demonstration similar to that of scientific validity along with analytical and clinical performance. This approach would build upon IMDRF's Software as a Medical Device (SaMD): Clinical Evaluation. Are there other statutory changes required to effectively regulate AiaMD over and above the changes detailed for SaMD above? [Yes / No / Don't Know/No Opinion]

No

Q65.2: If you have answered yes to question 65.1, please outline what additional changes are required. [2500 character limit]

NA

Q65.3: Do you consider the use of IVDR-type performance evaluation methods (akin to scientific validity, analytical performance, and clinical performance) for diagnostic software but especially AI (even where no IVD data is used) to be appropriate? [Yes / No / Don't Know/No Opinion]

Yes

Q65.4: If yes, do you think the UK medical devices regulations should be amended to require this? [Yes / No / Don't Know/No Opinion]

Yes

Q65.5: Should the UK medical devices regulations mandate logging of outputs of further auditability requirements for all SaMD or just AiaMD for traceability purposes? [Yes / No / Don't Know/No Opinion]

No opinion

Q65.6: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 65.1-65.5, including any impacts on you or other stakeholder groups, including how burdensome would further requirements along these lines be? [2500 character limit]

Where AiaMD are being utilised for diagnostic purposes, they would be used more in the context of IVDs than general medical devices and so should be regulated as such, including in the form of performance evaluation studies.

Any AI products should ensure they take into account variation within the general population (e.g. race, sex).

Chapter 12: Other Product-Specific Changes

Section 68: Systems, Kits, and Procedure Packs

Q68.1: The MHRA considers that the UK medical devices regulations could clarify that a 'kit' should be regulated in the same way as a system or a procedure pack. This would help avoid confusion regarding the regulation of combinations of products (which include IVDs, general medical devices and other products) used for in vitro diagnostic examination. Do you think that the UK medical devices regulations should include the term kit when referring to medical devices and products which are assembled together? [Yes / No / Don't Know/No Opinion]

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? [Yes / No / Don't Know/No Opinion]

Yes

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

Yes

Q68.4: Please outline any other requirements that you think we should introduce for system and procedure packs and the sterilisation of system and procedure packs. [2500 character limit]

Manufacturers of IVD kits should meet the full requirements of the UK MDR.

Q68.5: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 68.1-68.4, including any impacts on you or other stakeholder groups. [2500 character limit]

Manufacturers of IVD kits are still placing IVDs onto the market, so those IVDs should meet the regularly requirements that they would have to if they were independently placed on the market.

Section 69: Parts & 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 / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

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. [2500 character limit]

Products which replace the part should be a like for like replacement or part. Where this is not the case, the device should be validated and considered a new device in its own right.

Chapter 13: Environmental Sustainability & Public Health Impacts

Section 71: Environmental Sustainability & Public Health Impacts

Q71.1: To what extent are you or your organisation already implementing, or planning, activities to reduce the impact of medical devices on the environment? Please outline any key activities you have underway or planned. [2500 character limit]

At BIVDA we are supporting and empowering member companies to reach sustainable and environmental objectives. This includes a fully funded and resourced programme of extensive training, guidance, descriptive documents, templates, processes and case studies – all of which will enable companies to meet KPI's, the NHS Net Zero and meet social value elements against NHS England's Evergreen Framework. The BIVDA programme considers Sustainability as a concept and subject matter, not a competitive programme. Companies can use their sustainable credentials to be the company that embraces sustainability and is more attractive as they wish. Members are encouraged to consider Sustainability through all activities from design to waste, including socio-economic and ethnicity factors. We have delivered a programme of free training to members on Sustainability including Procurement Policy Notes PPH 06/20 and PPN 06/21 during 2021 and will deliver a Sustainability Programme Roadmap in Q1 2022 with defined objectives to achieve in order to meet the milestones in the Sustainability Roadmap published by NHS England.

Q71.2: Do you see a need for additional requirements to be placed on economic operators in order to encourage them to consider and/or mitigate the environmental impact of medical devices they place on the UK market? [Yes / No / Don't Know/No Opinion]

Yes

Q71.3: Please explain the rationale for your response to question 71.2 and any expected impacts. [2500 character limit]

The medical device industry in general could have a large impact on sustainability measures due to the volume of product produced each year.

Although agreed that additional requirements should be placed on economic operators to encourage consideration or mitigation of environmental effects of their products, such requirements are better placed within appropriate environmental legislation. It would also need to be clear where exemptions do and do not apply to IVDs specifically, including in any UK legislation adopting EU protocols (e.g. UK REACH). Suppliers should be encouraged to include, wherever possible, socio-economic and ethnic factors in the design and planning of their products

The scope in which electronic IFUs can be used could be broadened to cover a wider range of IVDs, however the option of other methods or IFU (i.e. paper) should be maintained for those individuals who may not have access. The UK has the opportunity to demonstrate how effective electronic IFUs can be in relation to environment impacts as well as patient access.

If there were to be any environmental considerations that would only apply to IVDs or medical devices, then it would be appropriate to place these within the UK MDR legislation.

Q71.4: What are your views on the options for change outlined in Paragraph 71.5? Please state your rationale, key implementation considerations and the expected impact of these options. [2500 character limit]

Such proposals would be welcomed as long as such measures were realistic and manageable for manufacturers. For example, there are some products where hazardous material is necessary as there is no viable or comparable alternative (such as Tritons being use as surfactants in many IVDs). Manufactures require the clarity to know what is required for their products, and how the legislative requirements detailing environmental changes link into other pieces of legislation on the topic.

Waste management, emissions, and plastic use (to name a few) are already being included within other pieces of legislation. It is currently unclear the scope that these will have on the IVD industry and whether there will be exemptions.

Q71.5: What other changes or key considerations do you think are needed to ensure more sustainable medical devices? [2500 character limit]

NA

Q71.6: What are the key implementation considerations for the options outlined in Paragraph 71.5 and any further potential changes you consider are required? [2500 character limit]

The environmental assessment of products should take into account the full product supply chain, and not just relate to the emissions, packaging or direct materials of the products.

Q71.7: Please set out which options could be introduced quickly (within 1-2 years) and which could be introduced within a longer timeframe? [2500 character limit]

Any requirements which are being adopted in the EU in this same time frame, so changes to REACH legislation currently being passed for certain products.

Optional electronic labelling or IFUs of products could be adopted by industry relatively quickly for those manufacturers who choose to do so.

Chapter 14: Routes to Market

Section 72: Medical Device Single Audit Programme (MDSAP) & 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? [Yes / No / Don't Know/No Opinion]

Yes

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. [2500 character limit]

The MDSAP programme allows for manufacturers to progress ISO 13485 audits at a faster rate than previously conducted by conducting them in the same time window. This means that products can be placed on specific markets quicker than could be historically done, allowing faster supply to patients who need them.

However, note that the MDSAP programme does not include audits for product certificates, so there is still an aspect of duplication unless mutual recognition of these certificates are introduced.

Although continuation of the MDSAP would be beneficial, this should not be the only option available to economic operators.

Q72.3: Do you think the MHRA should introduce an alternative route to market which utilises approvals from other countries (domestic assurance route)? [Yes / No / Don't Know/No Opinion]

Yes

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. [2500 character limit]

Many manufacturers are already complying to other regulatory systems for IVDs, with the largest being EU and USA. If manufacturers could utilise the conformity assessment from these markets to place product on the UK market, it would save cost and time in undergoing a full UKCA assessment. Other market approval processes would also be welcomed, including Australia and Canada.

Although cost should not be a priority in relation to patient safety, there is a risk that manufacturers may decide to not place product on the UK market because the UKCA route is too burdensome or costly on top of other regulatory pathways with larger markets (e.g. EU). The introduction of a domestic assurance route would make it much more inviting for manufacturers and may reduce the impact of devices being pulled from the UK market (which could result in a product shortage for patients).

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 / No / Don't Know/No Opinion]

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 / No / Don't Know/No Opinion]

Yes

Q73.3: Please provide your reasoning (including any available relevant evidence) to support your answers to questions 72.1-73.2, including any impacts on you or other stakeholder groups and/or any other general comments on how this could be implemented, including potential timeframes and specified uses. [2500 character limit]

The need for innovative products is ever greater as patients are living longer and rare diseases and disorders are coming to the forefront.

The ability to have a pathway for innovative products would be welcomed, as long as such a process is inclusive of all innovative products. This process should be for products with a clear identified patient need, and not be limited to the type or size of the organisation. It may also be useful to introduce an expedited pathway for products which are meeting an unmet clinical need.

It would be beneficial if a definition of an innovative product could be developed, and a clear pathway that MHRA would be expecting to conduct. Where products are marketed through the innovative pathway, it is assumed that such products will not meet the full requirements of the regulations (or there will be no benefit to the innovative pathway): clarity on whether these products would be expected to then ensure they meet the full requirements within a certain time frame, or at all, would be required. The requirements for products to utilise this pathway should be very clearly defined and adequately resourced.

Any innovative pathway could link to 'automatic' UKCA certification after a certain period of time and where conditions are met. However, it should be conducted on a risk-based approach.

Chapter 15: Transitional Arrangements

Section 74: Transitional Arrangements

[MHRA] are considering the following transitional arrangement possibilities, to work alone or in combination:

Option 1: for certification/declarations of conformity for medical devices certified before the future regime applies: medical devices and in vitro diagnostic medical devices lawfully placed on the market with a valid UKCA certificate/declaration of conformity before 1 July 2023 can remain on the market until the expiry date of that UKCA certificate/declaration of conformity or until a specified date (please see the question below on what this date should be), whichever is the earliest. After the expiry of the certificate/declaration or after the specified date, devices that were placed on the market in accordance with those certificates/declarations, could continue to be supplied for a further period, for example 1 additional year beyond the specified date.

Option 2: for certification/declarations of conformity for medical devices certified before the future regime applies: medical devices and in vitro diagnostic medical devices lawfully placed on the market with a valid CE certificate/declaration of conformity before 1 July 2023 can remain on the market until the expiry date of that CE certificate/declaration of conformity or until a specified date (please see the question below on what this date should be), subject to a light touch assessment that those devices meet the necessary regulatory standard. After the expiry of the certificate/declaration or after the specified date, devices that were placed on the market in accordance with those certificates/declarations, could continue to be supplied for a further period, for example 1 additional year beyond the specified date.

Option 3: device registration requirements could be phased in according to the risk classification of a device and UDI requirements could be introduced over time, including for devices already on the market (see the Registration and UDI Chapter 4 for more detail and an opportunity to comment on transition arrangements for registration requirements introduced in a future regime).

Option 4: Approved Body designations as expanded on in Chapter 5, the MHRA considers that the UK medical devices regulations could set out that Medical Device and Active Implantable Medical Device Approved Body designations issued prior to July 2023 could be 'rolled over' until expiry of the designation. Please see Chapter 5 Approved Bodies to comment on this possibility.

Option 5: Clinical Investigations which commence under the existing regulations before 1 July 2023 could continue to be conducted from 1 July 2023 providing any additional reporting requirements laid out in the new regulations for clinical investigations that commence on or after 1 July 2023 are met, such as around serious adverse events or device deficiencies. Please see Chapter 7 for additional information about clinical investigations and performance studies.

Q74.1: Do you think that we should introduce the transitional arrangements proposed above in Option 1? [Yes / No / Don't Know/No Opinion]

Yes

Q74.2: Do you think that we should introduce the transitional arrangements suggested above in Option 2? [Yes / No / Don't Know/No Opinion]

Yes

Q74.3: Please give your reasoning for your answer to questions 74.1-74.2. If you have answered yes to either question, please include what you consider the required arrangement(s) and any expected impacts of these on you or other stakeholder groups. [2500 character limit]

Option 1: This would be a welcomed approach, however a longer transition period would be required. Restricting this to one year is unrealistic and does not provide manufacturers long enough to comply with new regulations. This is demonstrated by the EU IVDR which allowed manufacturers a five year transition period, but there are a number of manufacturers who remain out of compliance due to no fault of their own (such as a restriction in EU Notified Body capacity).

Option 2: This proposal would be preferred where the CE mark can continue to be recognised and used to demonstrate conformance (please see section on Domestic Assurance). If this could not be gained, a longer transition period would be required. Restricting this to one year is unrealistic and does not provide manufacturers long enough to comply with new regulations. This demonstrated by the EU IVDR which allowed manufacturers a five year transition period, but there are a number of manufacturers who remain out of compliance due to no fault of their own (such as a restriction in EU Notified Body capacity).

Q74.4: Do you agree with the transitional arrangements suggested in Option 5 above? [Yes / No / Don't Know/No Opinion]

Yes

Q74.5: Please give you reasoning for your answer to question 74.4. [2500 character limit]

Where a performance evaluation study has begun under the previous regulatory requirements, it could compromise the study if they need to comply with additional requirements part way through. This could also bias the results if they are at all effected by the change.

Q74.6: Please set out any other transitional arrangements or considerations you believe are required for putting in place a future regime for medical devices in the UK, why, and the expected impacts on you and other stakeholder groups. [2500 character limit]

Both the EU and Australia have recently implemented new regulatory systems, and both took longer than the initial transitional plans estimated. Given this practice of over-ambitious deadlines, MHRA should be cautious of placing specific dates into legislation, and they should instead be staggered.

It may be more sensible for the initial transition period to be reflective of the infrastructure that is required, and the transition period for conforming to the new legislation based on the finish date of the infrastructure components. For example, the recent requirement for medical devices to be registered with MHRA: it would have been more helpful if the systems were fully functional (including resource) prior to enforcing the grace periods.

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 [checklist; single answer only]:

- 30 June 2025
- *30 June 2026*
- Other

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 [checklist; single answer only]:

- 30 June 2027
- 30 June 2028
- *Other*

Continuous – mutual recognition

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 [checklist; single answer only]:

- They should not be permitted to be supplied after expiry or cut-off date
- 6 months
- *12 months*

Q74.10: What additional checks, if any, would you consider to be necessary to allow CE marked products to remain on the Great Britain market after 1 July 2023? [2500 character limit]

Registration with MHRA, appointment of a UK Responsible Person, importers meeting the specified requirements for such organisations

Q74.11: Please provide your reasoning for your proposed dates above. [2500 character limit]

Restricting this to a short time period is unrealistic and does not provide manufacturers long enough to comply with new regulations. This demonstrated by the EU IVDR which allowed manufacturers a five year transition period, but there are a number of manufacturers who remain out of compliance due to no fault of their own (such as a restriction in EU Notified Body capacity).

There are contracts currently in place between suppliers and users of IVDs which may be in jeopardy in the event of a short time span, resulting in large costs on the industry to rectify. This could also result in a large resource requirement to customers who may be forced to find alternative products.

Chapter 16: Feedback

Section 75: Feedback

Q75.1: How would you rate the level of ambition set out in this consultation [checklist; single answer only]:

- Excellent
- Very Good
- *Good*
- Poor
- Very Poor

Q75.2: Do you consider the possible changes to UK medical devices regulations set out in this consultation document to be proportionate? [Yes / No / Don't Know/No Opinion]

Yes

Q75.3: Please set out your reasoning for your response to question 75.2. [2500 character limit]

These questions imply that the UK will tighten the scrutiny on IVDs within the UK market, however there are a number of places that they may fall short of the scrutiny placed on devices under the EU regulatory system.

Q75.4: Please provide any additional feedback comments. [2500 character limit]

Generally, the UK government does not provide consolidated text in relation to pieces of legislation with amendments. Given the complex nature of medical device regulation, and the sheer volume of amendments which have been added to the UK MDR 2002 in the past 20 years, a consolidated version of the legislation would be hugely beneficial to all stakeholders in the medical device industry.