



Medicines & Healthcare products  
Regulatory Agency

# **Government response to consultation on the future regulation of medical devices in the United Kingdom**

26 June 2022



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## **Ministerial Foreword**

The past few years have been a time of great change for medical devices. The UK's decision to leave the EU has presented a great opportunity to build our own regulatory regime, whereas the Covid-19 pandemic has seen huge advances in the life sciences and diagnostics.

We are well placed to succeed in this mission. We have a dynamic and pioneering MedTech sector, along with the MHRA's established track record of innovation-friendly regulation, who are renowned as one of the world's most effective regulators.

We will be launching the UK's inaugural MedTech strategy soon; and the plans in this consultation show the steps we are taking to deliver improved patient and public safety, greater transparency, and more proportionate regulation of medical devices.

I am also determined to eradicate bias, however inadvertent, when it comes to medical devices, and I have appointed Dame Margaret Whitehead to establish the extent of this issue and recommend what action can be taken.

I am grateful to everyone who has shared their views as part of this consultation, including patients, industry and the healthcare sector. Your input has been invaluable in helping us to shape the future of medical devices in the UK, and I am delighted that our plans for a step-wise, prioritised transition to these new regulations have been overwhelmingly supported.

We have a plan to build on the breakthroughs of the past few years, supporting this country's pioneers while keeping us all safe. Now, we must put it into action.

**Sajid Javid**

**Secretary of State for Health and Social Care**



# Executive Summary

Following our exit from the European Union (EU), we have a unique opportunity to improve how medical devices and *in vitro* diagnostic medical devices (IVDs) are regulated in the United Kingdom (UK). Powers in the Medicines and Medical Devices Act (2021) allow us to amend the Medical Devices Regulations 2002 which govern medical devices in Great Britain.

The Medicines and Healthcare products Regulatory Agency's (MHRA) purpose is clear: to protect patients and the public and facilitate access for UK patients to the latest advances the MedTech sector can offer. A strong regulatory foundation, MHRA's global reputation, strong international partnerships and globally recognised successes during the pandemic all provide a strong platform to build on. This regulatory framework will serve as the cornerstone to realising these opportunities.

Having analysed the many engaged responses to our consultation, our world-leading medical device regulatory framework will be built on five pillars:

- **Strengthening MHRA power to act** to keep patients safe
- **Making the UK a focus for innovation**, the best place to develop and introduce innovative medical devices
- **Addressing health inequalities** and mitigating biases throughout medical device product lifecycles
- Proportionate regulation which supports businesses through **access routes that build on synergies with both EU and wider global standards**
- **Setting world leading standards** – Building the UKCA mark as a global exemplar

A considered implementation plan for such an ambitious programme of reform is critical to its success. Our plan balances prioritisation and pace with the need to ensure there is time for the sector to adapt. It seeks to ensure patients and the healthcare system can continue to access the essential medical devices they need through the transition to the UK Conformity Assessed (UKCA) marking.

The Med Tech sector is fast-paced, and our regulatory framework needs to be agile enough to respond. This response sets out measures we consulted on which we will now move to implementation, as well as some where we will need to consult further. Along with our key partners, we will continue to work to develop our approach, keeping patient safety at the heart of the framework and building on the standing of the Medicines and Healthcare products Regulatory Agency as a leading global regulator.

# Introduction

Between September and November 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) consulted on proposed changes to the regulatory framework for medical devices in the United Kingdom (UK).

The aim was to seek views on developing a future legislation for medical devices which delivers:

- improved patient and public safety
- greater transparency of regulatory decision making and medical device information
- close alignment with international best practice, and
- more flexible, responsive and proportionate regulation of medical devices

The consultation sought the views of patients, medical device researchers, developers, manufacturers and suppliers, clinicians, other healthcare professionals and the wider public to help shape our future approach to regulating medical devices in the UK. It contained 15 technical chapters, one chapter on general feedback (Chapter 16) and one chapter on a range of topics aimed at lay persons and those with limited time (Chapter 17 - which we refer to in this document as the 'abridged consultation' chapter). During the consultation period, two webinars were held about the consultation – one aimed at industry, and one aimed at the wider public. The government response covers Chapter 17 of the consultation, and responses to it, within the main chapters where relevant (rather than having a dedicated chapter on responses to Chapter 17 as a whole).

## The response

We received 891 consultation responses: 413 from individuals and 451 from organisations. Due to the large scale of the consultation, respondents were invited to select and respond to their areas of interest and most respondents therefore did not answer every question. The response rates to some questions do not add up to 100% because of rounding.

We encouraged responses from a wide range of people. Respondents were not required to provide their demographic data. Data from those who chose to provide it is as follows:

- 263 healthcare professionals
- 200 manufacturers of medical devices
- 84 members of the public / patients
- 56 healthcare institutions
- 24 trade associations
- 63 small/medium enterprises (small)
- 55 small/medium enterprises (medium)
- 54 small/medium enterprises (micro)

## Highlights of the government response

In this far-reaching public consultation, the MHRA has received strong support for proposals that will enable the MHRA to **improve patient safety** and safeguard public health by enabling access to a high-quality supply of safe and effective medical devices through appropriate regulatory oversight. The MHRA will therefore proceed with preparing regulations reclassifying products such as certain implantable devices, extending the scope of regulations to capture certain non-medical products with similar risk profiles to medical devices (e.g., dermal fillers, coloured contact lenses)

and to strengthen and increase post-market surveillance requirements ensure better incident monitoring reporting and surveillance.

Strong support was also heard for improved traceability of medical devices, including the use of Unique Device Identification (UDI).

The consultation also outlined changes with potential to improve support for **innovation in medical devices, and access to medical devices**. These included improving regulation of novel and growing areas such as software (including artificial intelligence (AI)) as a medical device to offer alternative and safe routes to market for game changing innovation.

The MHRA received strong support to introduce routes to market which avoid duplication and minimise burden on industry, promoting international collaboration with like-minded regulators while maintaining regulatory oversight. Responses showed significant support for the introduction of a pre-approvals route for innovative devices but also support for the Agency broadening its role to host a conformity assessment function internally for certain scenarios and product groups.

In November 2021, the Secretary of State for Health and Social Care announced the **Equity in Medical Devices Independent Review**, chaired by Dame Margaret Whitehead, which seeks to establish the extent and impact of potential ethnic and other biases in the design and use of medical devices. The MHRA recognises the role of regulatory standards for equitable outcomes and will provide extended guidance on how manufacturers of medical devices, including software and AI medical devices, can demonstrate and ensure the safety and efficacy of their products across diverse populations.

The government will also be introducing alternative routes to market, including domestic assurance, to enhance the supply of devices while retaining appropriate levels of scrutiny to ensure patient safety remains a priority. The changes the MHRA will be taking forward will also ensure the UK aligns with **international best practice** where those standards are superior than current standards and they will introduce greater transparency of regulatory decision making through updating the requirements that apply to Approved Bodies and increasing the consistency of conformity assessments for example.

Respondents recognised the scale of what was proposed and expressed support for a stepwise **transition to the new framework**, enabling smooth implementation for patients, the healthcare sector and industry. In Chapter 15 of this response, we set out transitional arrangements which respond to this feedback. Whilst we still plan for the new regulations to come into force in 2023, there are significant measures enabling products which already have conformity markings, either UKCA or CE, to remain on the market after the regulations come into force for a period of 3 to 5 years, depending on the device and the rules under which the existing conformity mark was given.

Outside the scope of this consultation, the MHRA has also announced a work programme for the regulation (wider guidance, policy, and standards) of **health-related software and AI** that will deliver ambitious change, providing protection for patients and public and making the UK the home of responsible innovation in this sector.

This document sets out what the MHRA has heard, the government's response to the consultation, and the MHRA's next steps for the implementation of a transformed regulatory framework for medical devices in the UK.

# Assessment of the requirements under the Medicine and Medical Devices Act 2021

The Secretary of State's overarching objective when making regulations under section 15 of the Medicines and Medical Devices Act 2021 (MMD Act) must be safeguarding public health. The Secretary of State must have regard to the following when considering whether the regulations would contribute to the 'overarching objective':

- the safety of medical devices
- the availability of medical devices, and
- the likelihood of the UK being seen as a favourable place in which to carry out research relating to medical devices, develop medical devices, and manufacture or supply medical devices.

Where regulations may have an impact on the safety of medical devices, the Secretary of State may only make the regulations if he considers that the benefits of doing so outweigh the risks.

The MHRA have prioritised these considerations in our proposed changes to the medical device regulatory framework.

The regulatory framework for medical devices intends to improve and **safeguard public health**, better assuring the safety and quality of devices placed on our market by:

- Regulating medical devices more stringently, ensuring medical devices receive adequate scrutiny before they reach the market and sufficient post-market surveillance and responsiveness to any post-market issues. The Independent Medicines and Medical Devices Safety Review highlighted the need for improved regulation of implantable devices and our future regulatory framework intends to deliver on this.
- Increasing device traceability.
- Introducing a range of more stringent pre- and post-market requirements for medical devices, including for clinical evaluations and performance studies, which intends to drive up patient safety standards.

The regulations aim to **improve the safety of medical devices** while also meeting fast-moving developments and enabling innovation by:

- Modernising the scope and classification rules of medical devices and in vitro diagnostic medical devices to deliver meaningful improvements in the safety of medical devices and certain other products with a non-medical purpose. This will also align with international best practice, ensuring that the UK is seen as a favourable place to do business.
- Strengthening the accountability of manufacturers, importers and distributors engaged in the supply of medical devices to drive up safety standards.
- Supporting the identification of potential equity issues in medical devices arising from patient characteristics such as ethnicity and sex and improving standards to tackle these disparities, increasing the safety and availability of effective medical devices for all.

The updates to the regulations intend **to support the availability of medical devices across the UK**, whilst providing the necessary regulatory oversight to ensure that patients receive treatment with devices of the highest quality and safety standards. The MHRA aims to deliver on this ambition through:

- Introducing alternative routes to market to support increased availability of innovative devices and streamlining access to our market while creating a regulatory system that is safe, innovative, patient-centred, and fit for the future.
- Creating a novel pathway to market for software as a medical device, addressing challenges ahead of our international peers to ensure that the UK is a favourable place for innovation without compromising on safety.

The regulations aim to modernise our rules to better align with international best practice and keep pace with technological advances. This will ensure that the **UK remains a favourable place to do business** for the benefit of patients and carers through proportionate regulation, through:

- Introducing new routes to market which aim to promote international trade and collaboration, increasing availability of medical devices to the UK market and supporting the MHRA's ambition for global harmonisation for medical devices regulation, with patient safety at the heart.
- Supporting a thriving MedTech industry through appropriate transitional arrangements.
- Aligning with international best practice where this is to the benefit of UK patients and diverging only where advantageous to do so, ensuring the most appropriate regulations are in place to prioritise patient safety while reinforcing our reputation as a favourable place to develop and supply medical devices.
- Creating a regulatory framework that is fit for the future for the regulation of software and artificial intelligence as medical devices and leading the way for sustainability, enabling digital and environmental pioneers to actualise lasting value for the health system and society at large.

Throughout this government response, the MHRA aims to have demonstrated how we have listened and responded to themes concerning patient safety, availability of medical devices, and the favourability of the UK as a place to research, develop, manufacture and supply medical devices. The MHRA aims to create a new balanced framework for medical devices regulation that ambitiously yet pragmatically supports the UK's MedTech industry and delivers on the overarching objective of safeguarding public health.

# 1 – Scope of the Regulations

The MHRA consulted on amending the scope of the UK medical device regulations. Proposals would bring into scope medical devices and *in vitro* diagnostic medical devices (IVDs) captured within the Global Harmonization Task Force's (and/or its successor organisation, the International Medical Device Regulators Forum (IMDRF)) internationally recognised definitions, and account for advances in medicine, engineering or technology. The changes the MHRA consulted upon would also result in some products, previously either unregulated or regulated under different legislation, being brought into scope and others currently regulated as medical devices being removed from scope.

**The proposals will improve patient safety by providing greater assurance about the performance and safety of devices, including those with a similar patient risk profile to medical devices but which have no intended medical purpose. Through stronger international alignment, the proposed changes will also provide developers with a more closely aligned set of definitions to work to when considering routes to market for their products.**

## Section 1 - Medical device and IVD scope

### 1.1 Proposals

The MHRA consulted on expanding the **scope** of the UK medical devices regulations to include certain products within the definition of a 'medical device'.

The MHRA also consulted on expanding the scope of the UK medical devices regulations to amend the definition of an '*in vitro* diagnostic medical device' (IVD).

In addition, the MHRA proposed that the definition of 'medical devices' in the regulations could also be revised so that it refers to 'disability' rather than 'handicap'.

The MHRA consulted on amending the UK medical devices regulations to clarify that '**intended purpose**' for all medical devices (including active implantable medical devices) and IVDs should be construed objectively, from the standpoint of an objective observer, with reference to both the data supplied by the manufacturer on the labelling, the instructions for use and/or the promotional materials and also other key materials such as a manufacturer's technical documentation (including clinical evaluation for a medical device).

### 1.2 Feedback

The consultation invited views on whether the **definitions** set out in the UK medical devices regulations should be expanded on to include the additions suggested in the consultation text. Of the 464 responses to this question:

- 83% were in favour of expanding the definitions
- 11% were not in favour
- 7% did not know or had no opinion

Respondents were asked to set out what (if any) further amendments should be made to the scope of the UK medical devices regulations. Key themes from free-text responses can be summarised as follows:

- the regulations should provide that dermal fillers must only be administered by healthcare professionals
- dermal fillers should be available on a prescription-only basis
- certain brand name products associated with cosmetic procedures should be brought into scope of the UK medical devices regulations
- further clarity is needed around the regulation of ‘borderline’ products that could potentially fall under more than one regulatory framework to ensure consistent regulation – disinfectant products were cited as an example here

The consultation invited views on whether it should be made 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. There were 460 responses, of which:

- 83% were supportive of this approach
- 6% were unsupportive
- 10% did not know or had no opinion

Other information provided by respondents in the free text comments on what (if any) further amendments should be made to the scope of the UK medical devices regulations, can be summarised as follows:

- an objective and data-driven approach should be taken
- clarification is needed surrounding the term ‘objective observer’
- genetic tests should have a clear statement of intended use and avoid having broad or vague statements to escape more stringent requirements
- rules should be tightened around disclaimers to ensure they do not result in the evasion of responsibility
- respondents were also in favour of removing the current distinction between active implantable medical devices and general devices, noting that the intended use should be defined based on the same sources of information for each

### 1.3 The government response

The MHRA has carefully considered all responses to the questions raised in this section and have set out our response below.

The MHRA is responsible for the regulation of medical devices and, as outlined below, intends to bring into scope of the UK medical devices regulations, products for which a manufacturer claims only an aesthetic or another non-medical purpose, but which are similar to medical devices in terms of their functioning and risk profile. This suite of products will include **dermal fillers**, which will consequently be subject to more stringent regulation.

The MHRA would like to clarify that the MHRA does not have a role in **regulating healthcare practitioners**, which falls within the remit of the Department of Health and Social Care (DHSC). We recognise the importance of the points raised by many respondents around restricting the administration of dermal fillers to practitioners – however this is outside the bounds of this consultation.

The DHSC has recently announced its intention to strengthen the regulation of cosmetic procedures, specifically through proposals to introduce a licensing regime for non-surgical cosmetic procedures such as injectable Botulinum toxin (for example, Botox®) and fillers: [Government to crack down on unregulated cosmetic procedures - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/news/government-to-crack-down-on-unregulated-cosmetic-procedures). The MHRA has shared the consultation feedback with the relevant DHSC team for consideration as part of this work.

Regarding the points made around regulating dermal fillers as **prescription only medicines**, the MHRA would like to clarify that, generally, this requirement only applies to medicinal products. The 'prescription only' concept does not, as a rule, apply to medical devices. There are a few exceptions to this – for example, specific pieces of UK legislation place restrictions on the sale or supply of specific medical devices (for example, the Opticians Act 1989), however these do not apply to dermal fillers. As not all dermal fillers are classified as a medicinal product, the MHRA is not able to regulate them as a prescription only medicine (unless they do not have a medical purpose but contain a medicinal substance such as an anaesthetic), but rather as medical devices or, in some cases at the current time, general products. MHRA is unable to regulate these as prescription only medicines and will not be able to do so once they are brought into scope of the UK medical devices regulations.

It should be noted that one of the products that was referenced in some responses is a medicine and is regulated as such and is therefore already subject to a high level of scrutiny. Products meeting the definitions that will be set out in the regulations will be brought into scope of the UK medical device regulations.

Regarding the points raised on the **regulation of 'borderline' products** that could potentially fall under more than one regulatory framework, the MHRA provides guidance on this topic and will ensure that it is updated to reflect any changes made to the regulations. The MHRA can advise on borderline cases if manufacturers are unclear about which regulatory pathway applies to their products.

Considering the broad support for the proposals, the MHRA intends to proceed with amending the UK medical devices regulations to **amend the definitions of medical devices and IVDs** as set out in the consultation. We will also clarify that '**intended purpose**' is to be construed objectively with reference to the materials listed in the 'Intended purpose' section above. The MHRA will also remove the distinction currently made in the regulations between active implantable medical devices and other medical devices. Definitions of any new terms will be provided.

## **Section 2 - Products without an intended medical purpose**

### **2.1 Proposals and feedback**

The consultation invited views on whether the UK medical devices regulations should be broadened to include devices without a medical purpose with similar risk profiles to medical devices, as outlined in the consultation and set out in the list below. Of the 300 responses:

- 87% were in favour, with the majority supporting inclusion of all product types listed
- 7% were unsupportive of this approach
- 6% did not know or had no opinion

There was also strong support for this proposal among the 57 respondents to the abridged consultation (Chapter 17), with:

- 95% favouring the approach outlined in the consultation
- 2% not in favour of the approach
- 4% did not know or had no opinion

Those who answered 'yes' to the previous question (in response to Chapter 17) were asked to select the products they considered should be regulated under the UK medical devices regulations from the list below. The percentage rates of the 57 respondents that selected each option are as follows:

- a. non-prescription contact lenses or other items intended to be introduced into the eye **(89%)**
- b. products intended to be totally introduced into the human body through surgically invasive means e.g., buttock implant **(93%)**
- c. products intended to be partially introduced into the human body through surgically invasive means e.g., microneedling products **(88%)**
- d. substances intended to be used for facial or other dermal or mucous membrane filling by injection, excluding those for tattooing e.g., dermal fillers **(88%)**
- e. equipment intended to be used to reduce, remove or destroy fat tissue, such as equipment for liposuction **(88%)**
- f. high intensity electromagnetic radiation (e.g., infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body e.g., hair or tattoo removal lasers **(81%)**
- g. equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the skull to modify activity in the brain e.g., transcranial (non-surgically invasive) stimulation **(91%)**
- h. diagnostic tests for health and wellbeing e.g., genomic testing for diet/nutrient optimisation, genomic testing for skin care, lactate testing for fitness training **(72%)**
- i. other (please specify) **(5%)**
- j. don't know/no opinion **(4%)**

Respondents to the abridged consultation (Chapter 17) were asked to provide reasoning for their previous answers or any general comments on key considerations for the regulation of products without a medical purpose. The key themes from the 31 responses received can be summarised as follows:

- many respondents reaffirmed their agreement with the approach set out in the consultation
- some noted that the approach would deliver safety benefits
- there was suggestion that we should align with the EU Medical Devices Regulation (2017/745) (EU MDR)

The consultation invited views on whether manufacturers of these products should be required to register them with the MHRA. Of the 286 respondents to the detailed consultation (Chapter 1):

- 89% were in favour of this approach
- 3% were unsupportive
- 8% did not know or had no opinion

The following points were made in the corresponding free text responses:

- cosmetic products, such as dermal fillers, should only be administered/used by healthcare practitioners and should be available on a prescription-only basis
- regulations should be drafted in such a way as to allow some flexibility and future proofing for certain products such as micro-needling and polydioxanone (PDO) threads
- the requirements for such products should harmonise with global standards where possible
- a risk-based approach should be taken
- common specifications should be introduced
- clinical investigation requirements need to be tailored for non-medical purpose products – they are unlikely to be able to demonstrate clinical benefit if manufactured purely for cosmetic purposes

## 2.2 The government response

The government's response to comments about the regulation of practitioners administering dermal fillers is set out above, as is our response to the suggestion that dermal fillers should be available on a prescription-only basis.

Further to the proposals outlined in Chapter 7 of the consultation on clinical investigation and performance studies, we intend to require manufacturers of high-risk devices, including Class III medical devices, to publish data on device safety and performance following UK Conformity Assessed (UKCA) marking, for intended users of the medical device in the form of a 'summary of safety and clinical performance' (SSCP). This will include information on the medical device's safety, clinical data, and clinical performance. As part of the SSCP, manufacturers will need to define and set out the suggested profile and training for users, which would then be checked by their Approved Body.

It is considered that this approach, which would enable professional bodies to more effectively monitor these types of devices to determine conformance to their guidelines, will lead to increased transparency. Once all dermal fillers are in scope of the UK medical devices regulations, it is expected that they would become Class III medical devices under existing classification rules for implantable devices (and will not be made into a lower risk class by any of the consultation proposals set out in Chapter 2), and therefore an SSCP will be required for these products.

After careful consideration of the views expressed by consultees and in light of the high degree of support expressed, it remains the government's intention to proceed with the proposal to expand the scope of the UK medical devices regulations to include the list of product types outlined in a-g of section 2.3 of the consultation text. It is not intended to expand the scope to diagnostic tests without a medical purpose at this time but we will keep this under consideration.

In addition, in light of the positive consultation response, the government intends to require manufacturers of the products covered by this section will register them with the MHRA.

The government notes the points raised around the need for common specifications, clear guidance and clarity on clinical investigation requirements. The MHRA will develop clear definitions and guidance to accompany the regulatory changes and address the issues raised by respondents.

### **Section 3 - Exclusion of products that contain viable biological substances**

#### **3.1 Proposals**

The consultation invited views as to whether products which contain or consist of viable biological substances (for example, microorganisms) should be explicitly excluded from the scope of the UK medical devices regulations. The UK medical devices regulations do not explicitly include or exclude medical devices incorporating these products from scope, which has led to confusion.

#### **3.2 Feedback**

There were 150 responses in this section, of which:

- 43% were in favour of the approach set out in the consultation
- 23% were unsupportive
- 34% did not know or had no opinion

Respondents also provided a range of comments, which can be summarised as follows:

- there was confusion as to how these products would be regulated if not covered by the UK medical devices regulations
- a number of respondents misunderstood "viable biological substances" to mean, for example, ancillary bioactive coatings or proteins. We would like to clarify that "viable biological substances" here refers to cells that can live, grow and/or reproduce, such as live bacteria

- some respondents sought clarification on how Advanced Therapy Medicinal Products (ATMP) / medical device combination products would be regulated
- there is a need for a precise definition and explanation of what we mean to exclude, to ensure that any exclusions are specific and appropriate (for example, so that we do not rule out bioactive coatings, proteins etc. where these are ancillary components)

### 3.3 The government response

It is noted that there was a degree of misunderstanding as to what products we intend to exclude. As above, to clarify, the term '**viable biological substances**' refers to live cells in particular, and not to all products derived from a biological or organic source.

As noted above, the government intends to amend the UK medical devices regulations so that they are explicit about the exclusion of these other types of viable cell, not just human or animal cells, which will mean that the position is made clearer for manufacturers. There is no intention to set up an exclusion that would target and remove products derived from a biological or organic source which are already appropriately regulated as medical devices.

The MHRA would also like to clarify that, in cases where medicinal claims are made, viable biological substances are currently regulated as medicinal products, so are already subject to a highly scrutinised regulatory route and will continue to receive a high degree of scrutiny.

We will give further consideration to the need for clear definitions and guidance to avoid confusion in future and so that manufacturers can be clear about what is in and out of scope.

We note the points raised about the **regulation of ATMP / medical device combinations**. We would like to clarify that, where the ATMP function is primary, the product is already regulated as a medicinal product. We recognise that there is a need to clarify the position in cases where the medical device function is primary and will give this matter further consideration.

## Section 4 - Exclusion of food

### 4.1 Proposals

The consultation proposed that food could be explicitly excluded from the scope of the UK medical devices regulations in order to provide clarity and prevent inappropriate regulation.

### 4.2 Feedback

Of the 128 responses in this section:

- 71% were in support of excluding food from the scope of the UK medical devices regulations
- 10% were unsupportive
- 19% did not know or had no opinion

The key points that were raised in accompanying free-text responses can be summarised as follows:

- agreement that food products should be regulated separately (and not as a medical device)
- there is a need to include a definition of 'food' in the UK medical devices regulations
- foods for which specific medical claims are made, such as products that contain probiotics, should be in scope of the UK medical devices regulations
- food products that are used for a special medical purpose, such as high nutrition feeding formula, should be regulated as a medical device

- further consideration should be given to how devices which incorporate food substances are regulated

### 4.3 The government response

The MHRA does not currently regulate food. In light of the strong support received, we intend to explicitly exclude food from the scope of the UK medical devices regulations to clarify this.

In doing this, we recognise that it will be important that the regulations clearly define 'food'.

Regarding **probiotic products** - for clarity, the MHRA intends to explicitly exclude viable biological substances from the regulations, and this will include probiotics. It should be noted that, in cases where medicinal claims are made, probiotic products are and will be regulated as medicinal products and are therefore already subject to a highly scrutinised regulatory route.

**Food for special medical purposes (FSMP)**, such as high nutrition feeding formula, falls within the remit of the DHSC as the lead government department responsible for nutrition policy. FSMPs are governed by the overarching Food for Specific Groups legislation ([Regulation No 609/2013](#)) and specifically [Commission Delegated Regulation 2016/128](#) which regulates the specific compositional and information requirements for FSMPs. More detailed information on the relevant legislation and on notification procedures can be found at: Nutrition legislation information sheet - GOV.UK ([www.gov.uk](http://www.gov.uk)).

FSMPs are therefore already outside the scope of the UK medical devices regulations and we consider that bringing them into scope could lead to duplication and inappropriate regulation. These products also have a mode of action which excludes them from the definition of a medical device.

Regarding the points raised around **medical devices that incorporate food substances**, we would like to clarify that if a medical device has a food-derived component it is already regulated as a medical device.

## 2 – Classification

Since the classification rules were established for medical devices, there has been significant technological progress. The existing classification rules are, in some respects, out of step with best international practice, particularly for implantable medical devices such as surgical mesh and software as a medical device.

**The changes we intend to introduce take advantage of the significant opportunity we have to amend the classification rules for general medical devices. They will help ensure medical device classification better reflects changes in technology and better accounts for how medical devices are used in a modern world, including the level of invasiveness and potential toxicity of certain devices. The changes will update the classification rules within the UK medical devices regulations to better align with best international practice and ensure that the scrutiny a medical device receives is commensurate with the level of risk that the device presents.**

### Section 5 - Classification of general medical devices

#### 5.1 Possible changes

The consultation invited views and comments on possible changes to classification rules for general medical devices in the UK medical devices regulations, with examples provided in the consultation text.

The abridged consultation in Chapter 17 also invited views on possible changes to classification rules for general medical devices in the UK medical devices regulations, with examples.

#### 5.2 Feedback

Overall, a large proportion of those commenting on this section of the consultation were in favour of the possible classification changes outlined in the consultation. Of the 470 responses in this section:

- 70% were in favour of amending the classification rules for general medical devices in the UK regulations in any or all of the ways set out in the consultation
- 13% were not supportive
- 17% did not know or had no opinion

A small number commented on which of the proposed amendments they were in favour of. Overall, 126 respondents commented in favour of all proposed changes. Many highlighted the importance of alignment with EU Medical Devices Regulation (2017/745) (EU MDR). A small number expressed support for particular changes, including those concerning re-classification of:

- active implantable devices and accessories
- *in vitro* fertilisation (IVF) and assisted reproductive technologies (ART)
- surgical mesh
- joint replacements
- spinal implants
- nanomaterials
- changes impacting devices inserted into the mucous membrane
- delivering a drug by inhalation
- applied to the skin or a body orifice
- involving closed loop systems/automatic defibrillators

A small number expressed concerns about specific changes among those set out in the consultation, including:

- the regulatory burden and costs that changes to classification of active implantable devices and their accessories would bring
- some respondents noted that the proposed changes would render all types of device involved in IVF/ART procedures Class III medical devices, thereby increasing costs and reducing access to those procedures
- some respondents considered that making surgical mesh Class III may be disproportionate

When asked to outline any other amendments which should be made to the classification rules, the following themes were raised:

- a small number felt that there should be a classification rule explicitly on dermal fillers - however, no clear rationale was expressed for changing how dermal fillers in scope of classification rules are currently classified
- a number of respondents commented on the need for clear guidance to help manufacturers determine the correct classification, and some commented that the classification of borderline devices should be met with more flexibility

The abridged consultation (Chapter 17) invited views from respondents on whether the classification rules for general medical devices and *in vitro* diagnostic medical devices (IVDs) should be amended as outlined in the consultation text. Of the 59 responses received:

- 85% were in favour of amending the classification rules as outlined in the consultation text
- 8% were not in favour of these amendments
- 7% did not know or had no opinion

When respondents were asked in Chapter 17 to provide their reasoning for their answer to the previous question or any general comments on the classification of medical devices (including ideas for other ways classification may need to change), 23 responses were received, and the following themes were raised:

- UK regulations should be aligned with the EU
- device classification should be risk based

### **5.3 The government response**

Having considered the views of respondents, and including the concerns outlined above, the government remains in favour of progressing all classification changes set out in the consultation, subject to the following:

- the amendments it is considering around the classification of IVF/ART related devices would apply specifically to substance-based devices used *in vitro* in direct contact with human embryos before implantation or administration into the body, and not to every tool used in IVF/ART. We consider that up-classification is warranted for these limited devices involved in IVF/ART to ensure that the classification risk is commensurate with the risk that such a device presents, but not for all devices involved in these procedures, the majority of which are classified appropriately by existing classification rules, and
- the amendment to the classification of medical devices incorporating nanomaterials (being classified between Class IIa – III depending on potential internal exposure levels) should

apply not only to those incorporating nanomaterials, but also to those generating nanomaterials.

We acknowledge concerns raised by respondents about up-classifying surgical mesh but consider that this change is warranted to ensure the classification of these products is commensurate with the risk they present and to better protect patient safety. The government also acknowledges interest in clear guidance around classification rules and any changes to these - and will ensure that suitable guidance on classification rule changes is made available.

The government remains of the view that these changes will enable classification to be more commensurate with the risk of a medical device, ultimately helping to support the safety of medical devices, while supporting global harmonisation regarding how medical devices are classified. For the government's position on the classification of IVDs and of software as a medical device, see Chapters 9 and 10 respectively.

## 3 – Economic Operators

There are a number of areas relating to economic operators for which the UK medical devices regulations are out of step with international best practice. This chapter of the consultation sought to address these areas, covering:

- **essential requirements that could be amended to enhance and safeguard public and patient safety**
- **manufacturer requirements relating to recompense to cover any legal liability arising from adverse incidents**
- **‘in-house’ manufacture of medical devices by health institutions - to more comprehensively regulate such devices to safeguard the health and safety of UK patients**
- **distance sales - to more closely regulate the sale of devices or services via electronic means and provide greater protection for UK consumers**
- **claims made about devices - to prevent misleading or unsubstantiated claims being made and safeguard the safety of patients and the public**
- **more detailed requirements about the Quality Management Systems manufacturers must have in place, improving consistency in this area**
- **clarification of UK Responsible Person requirements to ensure they can fulfil their obligations more effectively, to enhance patient and public safety**
- **importer and distributor obligations, to improve device traceability and ensure the safe supply of devices to the UK market**
- **a requirement for manufacturers and UK Responsible Persons to have access to a Qualified Person, to support manufacturers’ regulatory compliance**
- **the circumstances in which economic operators other than the manufacturer, such as importers, are required to take on the obligations of a manufacturer, and to specify which requirements they should follow**

### Section 6 - Essential requirements for medical devices

#### 6.1 Proposals

The MHRA consulted on amending the UK medical devices regulations to add further detail to the existing **essential requirements** that apply to medical devices, and to add further essential requirements in line with technological progress and international best practice to deliver public and patient safety benefits. The consultation provided examples of how the essential requirements could be amended.

#### 6.2 Feedback

Out of 260 responses:

- 78% were in favour of amending the essential requirements of the UK medical devices regulations in line with the approach outlined in the consultation
- 15% did not support this approach
- 7% did not know or had no opinion

In response to the follow-up question inviting views on other amendments that should be made to the essential requirements, 157 respondents provided comments and raised the following common themes:

- post-market clinical studies should be required for high-risk devices
- a desire to align with international frameworks, including the EU Medical Devices Regulation (2017/745) (EU MDR), the EU *in vitro* Diagnostic Medical Devices Regulation (2017/746) (EU IVDR), International Organization for Standardization (ISO) standards ISO 14971 and ISO 14155, and the International Medical Device Regulators Forum's (IMDRF's) Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
- explicit requirements for human factors, usability testing, electronic programmable devices and cyber security
- information on labelling around the disposal or recycling of medical devices
- disclosure or transparency of risks and benefits of the device and its materials so patients can make informed decisions, with regard to allergens, human tissue, animal tissue and wear debris
- ability to track the device using a Unique Device Identification (UDI)

Respondents were also asked to provide reasoning (including any available relevant evidence) to support their answers to the questions on essential requirements, with the key themes from 185 responses summarised as follows:

- significant support for aligning with EU MDR/IVDR, with some referencing a desire to align with the General Safety and Performance Requirements (GSPRs) in particular
- requirements need to keep pace with rapid technological change
- be mindful that there is limited space on a label to include additional information
- the approach should align with medicinal products in terms of having allergen and sensitiser lists.

### **6.3 The government response**

After carefully reviewing the feedback received, it is the government's intention to amend the essential requirements for medical devices, accommodating technological progress and, where in the interests of the UK, aligning with other regulators in delivering international best practice.

As noted above, a significant number of responses requested close alignment with the GSPRs set out in the EU MDR and IVDR, to avoid confusion and potentially duplicative or divergent requirements and to facilitate the ongoing supply of devices to the UK market. In light of this, our intention is to broadly reflect the GSPRs in the UK regulations, tailored to the domestic context.

As set out in the consultation, the intention is to include a requirement to list ingredients or component parts which are known allergen or sensitisers (for example, natural rubber latex and chlorhexidine).

This approach is aimed at delivering public and patient safety benefits, as set out in the consultation and summarised above. The MHRA will take consultation feedback into consideration in the delivery of this work.

## **Section 7 - Manufacturer obligations – measures for recompense**

### **7.1 Proposals**

The MHRA consulted on potentially introducing a requirement for manufacturers to have measures in place (for example, sufficient financial coverage), proportionate to the risk class, type of device and the size of the company, to cover any legal liability arising from adverse incidents with medical devices that they place on or supply to the UK market. This, for example, could include a requirement for manufacturers to hold appropriate liability insurance.

## 7.2 Feedback

Of the 219 responses for this section:

- 65% supported this approach
- 16% were unsupportive
- 18% did not know or had no opinion

Respondents were asked to set out their reasoning for their response to the above question. Common themes from the 161 responses included:

- concern that the costs of obtaining liability insurance may be prohibitive, particularly for small and medium-sized enterprises (SMEs), and that setting overly prescriptive requirements could impact on the attractiveness of the UK market, which could in turn stifle innovation and cause supply issues
- concern about possible impacts on health institutions
- that the MHRA should take a risk-based approach
- that most reputable businesses already have adequate insurance in place to provide recompense
- that the government should establish and require manufactures to contribute to a compensation fund that could be used to compensate medical device users in the event of adverse incidents
- that recompense measures should be linked to defective devices, and not to clinical or user error
- a desire to align requirements with the EU MDR and IVDR

## 7.3 The government response

Having considered the wide range of views expressed by respondents, it is noted that the majority were in support of the approach outlined in the consultation. The government therefore intends to introduce a requirement for manufacturers to have measures in place (for example, sufficient financial coverage) for providing recompense to those impacted by adverse incidents with medical devices on the UK market.

The government considers this approach to be necessary as it will help ensure that those negatively impacted by an experience with a medical device are adequately and appropriately compensated. It is not intended to establish a centralised compensation fund at this time, as requested by some consultation respondents, as it is considered that introducing provisions to ensure manufacturers have sufficient financial coverage in place to respond in the event of an adverse incident would provide for patient recompense via alternative means.

The government has also noted the important points raised in the consultation feedback regarding the need for flexibility in terms of how this requirement is met and will provide guidance on this matter to accompany the regulatory changes. The MHRA will consider potential impacts on SMEs as the regulations and guidance are developed. However, as set out in the consultation, the intention here is that requirements will be commensurate with the type of device, risk class and size of company.

## Section 8 - Health Institutions

### 8.1 Proposals and feedback

The MHRA consulted on introducing a range of measures that would apply to medical devices that are manufactured or modified within a health institution (for example, an NHS hospital) for use within that health institution.

The consultation asked whether the regulations should include a **definition of the term 'health institution'**. Out of 182 respondents:

- 89% were in favour of including a definition
- 7% were not in favour
- 5% did not know or had no opinion

The consultation next invited views as to how health institutions should be defined. Feedback from the 148 respondents can be summarised as follows:

- a desire to align with definitions used in the EU MDR/IVDR
- calls from different respondents for the definition to either include or exclude private institutions
- a request for clarification or guidance on the definition of a health institution, and whether it includes entities such as dentists, research institutes, universities, and pharmacies
- a request that, in defining health institutions, we consider situations in which there is collaboration between health trusts

The MHRA consulted on amending the UK medical devices regulations to clarify that medical devices manufactured and modified 'in house' must meet the relevant **essential requirements**. There were 183 responses, of which:

- 84% supported this approach
- 5% did not support this approach
- 11% did not know or had no opinion

Response rates to the corresponding question in the abridged consultation (Chapter 17) were in alignment:

- 85% of respondents supported this approach
- 5% did not support of this approach
- 9% did not know or had no opinion

Those in support of introducing these requirements (in response to Chapter 17) were asked to select which of the requirements from the list below they considered should be met by health institutions. The percentage rates of the 51 respondents that selected each option are as follows:

- meet the relevant essential requirements of the UK medical devices regulations (**80%**)
- draw up a publicly available declaration that devices meet the essential requirements of the UK medical devices regulations (**61%**)
- apply a suitable organisational infrastructure (a Quality Management System) (**76%**)
- justify why the target patient group's needs cannot be met with an equivalent device available on the market (**65%**)
- keep technical information available for the MHRA, review clinical use of the devices and take necessary corrective actions, for example, stop further use of the device in patients where there is an issue (**75%**)
- report certain types of incidents relating to 'in house devices' to the MHRA (**84%**)

- register devices produced or modified 'in house' with the MHRA **(67%)**
- other (please specify) **(0%)**
- don't know/no opinion **(6%)**

The consultation invited Chapter 17 respondents to comment on the rules that should apply to devices that are manufactured and used 'in house'. Feedback can be summarised as follows:

- patient safety is paramount
- devices manufactured and used within health institutions should be compliant with the regulations
- there is a risk that having an exemption could create regulatory loopholes
- respondents noted concern that over-regulation of such devices could cause supply issues and stifle innovation

In addition, the consultation asked (in Chapter 3) whether 'in house' manufactured devices should be exempt from UK Conformity Assessed (UKCA) marking requirements. There were 182 responses, of which:

- 49% considered that there should be an exemption
- 34% did not support an exemption
- 17% did not know or had no opinion

There was a difference in responses by demographic group, with 47 responses from individuals (36% supported an exemption and 51% did not support an exemption and 133 responses from organisations (53% supported an exemption and 29% did not). This indicates a greater level of support from organisations than from individuals for the UKCA marking exemption, though the disparity in the overall volumes of responses from these two groups should be noted.

The MHRA consulted on introducing provisions that would mean health institutions would need to meet certain requirements for 'in house' manufacturing, including obligations as outlined in the consultation text. Of the 184 responses to this proposal:

- 76% were in support
- 8% were not in support
- 12% did not know or had no opinion

Respondents were asked to outline any other requirements that should be introduced for health institutions carrying out 'in house' manufacturing or modification of medical devices. The consultation received feedback from 123 respondents, including:

- health institutions should be required to have a certified Quality Management System (QMS), with consideration for a simplified requirement
- the exemption should apply to software, artificial intelligence and machine learning
- there should be document retention requirements
- we should include requirements for clinical evaluation
- we should include Qualified Person requirements
- health institutions should be subject to audits, with both internal and MHRA-led audits suggested

The MHRA consulted on amending the UK medical devices regulations to require health institutions to register medical devices manufactured or modified 'in house' with the MHRA. Of 183 responses:

- 73% supported this approach

- 14% did not support this approach
- 14% did not know or had no opinion

We also consulted on requiring health institutions to register with the MHRA, clinical investigations and performance studies involving medical devices manufactured or modified 'in house'. Of the 181 responses:

- 77% supported this approach
- 9% were not in support
- 14% did not know or had no opinion

In addition, the consultation sought views on whether the MHRA should be able to request that the relevant health institution provides further information about the devices it has manufactured or modified 'in house', including details about the manufacturing processes. The consultation also asked whether the regulations should require the MHRA to restrict the use of such devices that have been manufactured or modified 'in house' and to inspect the activities of relevant health institutions. There were 179 responses to the question on these proposals, of which:

- 83% supported this approach
- 6% did not support it
- 12% did not know or had no opinion

The consultation asked whether the regulations should clarify that the health institution exemption shall not apply to medical devices manufactured on an 'industrial scale' and that such medical devices must meet all the relevant provisions of the UK medical devices regulations. There were 181 responses, of which:

- 76% supported this approach
- 10% were unsupportive
- 14% did not know or had no opinion

Respondents were asked to outline their reasoning to support their answers to the preceding questions on health institutions. The following points were raised:

- there is a need to define what is meant by 'industrial scale'
- there should not be a health institution exemption
- the requirements align with the EU MDR/IVDR
- there should be a requirement for the health institution to inform the original equipment manufacturer (OEM) of any modifications made to the OEM's devices
- when modifying commercially available devices, health institutions should be required to assume manufacturer responsibilities

The consultation invited views on whether the regulations should provide that the health institution exemption applies to a health institution which provides routine or a specialist diagnostic service to other health institutions (for example, the Supra-Regional Assay Service). There were 175 responses, of which:

- 38% were in favour of this approach
- 29% were unsupportive
- 33% did not know or had no opinion

The consultation asked consultees to outline any circumstances in which the exemption should not apply (for example, if the services are provided for commercial or profitable purposes, or to private patients or providers outside its intrinsic health function) and to provide reasoning for their responses. Responses to this question indicated broad agreement that the exemption should not apply in cases where services are provided for commercial or profitable purposes.

## 8.2 The government response

The government intends to include a **definition of the term ‘health institution’** in the UK medical devices regulations. A wide range of views were put forward and, overall, respondents broadly welcomed the intention to provide clarity here. Our intention is to include a definition of ‘health institution’ within the regulations and to provide further detail in supplementary guidance, taking account of points raised in the consultation. In light of the consultation feedback, we intend to take as a starting point, the definitions set out in the EU MDR and IVDR, which define a health institution as an organisation, the primary purpose of which is the care or treatment of patients or the promotion of public health.

A common theme raised in response to the free text questions in this section was that **there should not be any exemption for health institutions**. The intention is that health institutions will be required to meet many of regulatory requirements that apply to commercial manufacturers – and the changes that are intended to be introduced will, in certain circumstances, place more extensive requirements and greater scrutiny upon health institutions than are currently in place. The key differences will be an exemption for health institutions from UKCA marking requirements, an exemption from the requirement for Approved Bodies to be involved in the conformity assessment process and an exemption from the requirement to have a *certified* QMS, though a QMS will still be required. It is considered that there is a strong case for taking this approach so that health institutions can continue to serve patients with rare conditions, whose needs may not otherwise be met by an equivalent device available on the market from a commercial medical device manufacturer.

The government intends to require that **‘in house’ manufactured or modified devices meet the relevant essential requirements of the UK medical devices regulations**. This will ensure that devices manufactured in these circumstances will be fit for purpose and as safe for use as any commercially produced device. Noting the comments about potentially creating supply issues and stifling innovation, the government does not accept that this is suitable rationale for allowing such devices to be manufactured and used on patients without meeting the same essential requirements a similar commercially produced device would be required to adhere to.

The largest portion of respondents were in favour of exempting ‘in house’ manufactured medical devices from full UKCA marking requirements. It is intended to introduce this provision as the devices in question will be put directly into service and will not be placed on the market. An **exemption from UKCA marking requirements** would be intended to reduce the burden on health institutions, which in turn would encourage and enable them to produce their own innovative devices for patients. As outlined above, it is considered that this will deliver clear benefits to patients, particularly those with rare conditions whose clinical needs may not otherwise be met by commercial medical device manufacturers.

The government intends to require health institutions to meet the requirements that were set out in the consultation. This will include **QMS requirements, technical document retention requirements and provisions on adverse incident reporting**. It is considered that this approach will increase transparency and accountability and will deliver patient safety benefits.

Given the positive consultation response on this topic, the government intends to introduce a requirement for health institutions to **register medical devices** that have been manufactured or

modified 'in house'. The MHRA will provide further guidance on these requirements to accompany the regulatory changes.

Having considered the views of respondents, it is noted that the majority of respondents supported the proposal to require health institutions to **register clinical investigations and performance studies** with the MHRA. The government intends to proceed with this proposal as outlined in the public consultation.

The government notes that the majority of respondents supported the proposal to amend the UK medical devices regulations to **enable the MHRA to request that the relevant health institution provides further information** about the devices it has manufactured or modified 'in house', including details about the manufacturing processes. It is the government's intention to introduce this provision.

The majority of respondents were supportive of proposals to enable the MHRA **to restrict** the use of devices manufactured or modified 'in house'. Under the existing legal framework, the MHRA will continue to be able to **inspect the activities** of relevant health institutions for compliance with the Medical Devices Regulations 2002 and take enforcement action to restrict the availability of devices. We consider that this allows the MHRA to take a pragmatic and flexible approach as part of its market surveillance and compliance activities.

The majority of respondents supported the exclusion from the health institution exemption of **medical devices manufactured on an 'industrial scale'**. We therefore intend to introduce this provision. A number of respondents sought clarity on the definition of 'industrial scale'. The MHRA will give this matter further consideration and will consider the need for supplementary guidance.

The consultation asked whether the 'in-house exemption' should apply to **health institutions which provide routine or specialist diagnostic services to other health institutions**. It should be noted that, to qualify for the exemption, the device will need to meet a patient group's specific need that cannot be met (or cannot be met at the appropriate level of performance) by an alternative device on the market. While the largest portion of responses expressed support for this proposal, there were similar levels of opposition to it. The intention is to proceed with this approach - our proposed regulatory changes will provide clearer expectations and allow greater oversight of such service provision, including on when the exemption will not apply. We have also taken account of the efficiency benefits that this approach is likely to provide to the NHS. In line with consultation feedback, our intention is that **the exemption will not apply in cases where services are provided for commercial or profitable purposes**.

## **Section 9 - Distance sales**

### **9.1 Proposals and feedback**

The MHRA consulted on amending the UK medical devices regulations to clarify that a medical device, or any diagnostic or therapeutic service involving a medical device (whether in return for payment or free of charge), must comply with the regulations if it is **sold or provided at a distance through electronic means**. It was noted that this would be the responsibility of the person selling or offering the medical device or diagnostic or therapeutic service and that, where the person supplying the device or service is an economic operator (for example, a manufacturer or importer), they would also need to follow the relevant obligations under the UK medical devices regulations. There were 188 responses, of which:

- 88% were supportive of this proposal
- 6% were not supportive
- 6% did not know or had no opinion

The consultation invited views on proposals 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 of the medical device concerned. There were 187 responses, of which:

- 88% supported this approach
- 5% were not supportive
- 6% did not know or had no opinion

The consultation invited comments on any other requirements that consultees considered should be introduced for medical devices that are subject to distance sales and asked that they provide any rationale for their views. Key themes raised in the free text responses can be summarised as follows:

- relevant websites and instructions for use should state that UKCA marking requirements have been met
- importer contact details should be provided for vigilance purposes
- rules on distance sales should only apply to products destined for UK consumers

## **9.2 The government response**

Having considered the views of respondents the government is minded to explore in more detail the scope to proceed with the above proposals and will have further cross-government discussions to ensure that our approach aligns, where appropriate, with similar measures in place for other products placed on the UK market.

## **Section 10 - Claims**

### **10.1 Proposals and feedback**

The MHRA consulted on proposals to amend the UK medical devices regulations 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 MHRA also noted that the regulations could be amended to provide that a person who makes a misleading claim on the device labelling, instructions for use, packaging or sales material / advertising (including online) is responsible for this. Out of 203 responses:

- 91% of respondents were in favour of these proposals
- 5% were not supportive
- 4% did not know or had no opinion

The consultation invited consultees to set out their reasoning to support their response. Key points can be summarised as follows:

- strong support that claims relating to a medical device should be accurate
- many called for alignment with EU regulations and other jurisdictions
- further comments called for legal liability and the term 'misleading' to be clarified fully in guidance

### **10.2 The government response**

Having considered the views of respondents, it is noted that there is significant support for introducing requirements for **claims** made about medical devices to ensure that any such claims

accurately reflect the safety, performance and intended purpose of the medical device. In light of this, the government intends to proceed with the proposals as outlined in the consultation text.

As outlined in the consultation and recognised by respondents, a key feature of this proposal is that it is intended to enhance patient safety and provide greater transparency for users of medical devices. The intention is to provide in the legislation, examples of instances where a claim would be misleading, and to supplement the regulatory changes with guidance, which will provide further detail as to what constitutes a 'misleading' claim, as requested by respondents.

## **Section 11 - Quality Management Systems**

### **11.1 Proposals and feedback**

The MHRA consulted on proposals to amend the UK medical devices regulations to clarify that all manufacturers should have a **Quality Management System (QMS)** in place, which addresses the requirements outlined in the consultation text, at a minimum. Out of 259 responses:

- 80% thought that the detailed requirements for QMS should be introduced as outlined in the consultation
- 9% were unsupportive of the proposals
- 2% did not know or had no opinion
- 9% selected 'other'

Respondents that selected the 'other' option provided further comments in relation to the proposed detailed requirements for QMS. These included a call to adopt International Organization for Standardization (ISO) standard 13485, suggestion that we should align with QMS requirements used within the EU or other international jurisdictions and a need to minimise burdens on SME innovators.

Respondents were asked to outline any other requirements which should be included in a manufacturer's QMS. Of the 139 responses received, some took the opportunity to reiterate general support for international alignment, particularly with EU MDR/IVDR requirements, to highlight a preference for following ISO 13485 and to request that QMS requirements should be proportionate to the risk class of a medical device.

The consultation asked consultees for views on whether all manufacturers, including Class I and general IVD manufacturers, should be required to apply an appropriate QMS. There were 259 responses, of which:

- 90% supported this proposal
- 5% were not supportive
- 5% did not know or had no opinion

Respondents were then asked to provide their reasoning (including any available evidence) to support their answers to the questions on QMS. Several themes were raised in the 200 free text responses, and key themes can be summarised below:

- respondents noted a preference to align the QMS requirements as closely as possible to ISO 13485 as most manufacturers and jurisdictions use this standard
- recognition that QMS supports good practice around risk management, which is crucial for the safety of medical devices and which should be proportionate to the risk of the device
- external audit is also beneficial to ensure processes are followed
- regulatory guidance is needed to clarify what is meant by an 'appropriate' QMS

## 11.2 The government response

After careful consideration of responses, it remains our intention to proceed with the proposal to introduce the **detailed requirements for QMS** that address the aspects outlined in the consultation. In addition, the government recognises that there is a desire to have QMS requirements that are proportionate to the risk class of the medical device.

The government intends to require all medical device manufacturers, including manufacturers of Class I devices, custom-made devices and general *in vitro* diagnostic medical devices (IVDs) to apply an appropriate QMS. This requirement will also apply to health institutions. A significant proportion of respondents supported the approach set out in the consultation and we consider that consistency and clarity in this area will deliver patient safety benefits. The MHRA will provide further guidance on QMS requirements

## Section 12 - UK Responsible Persons

### 12.1 Proposals and feedback

The consultation included several questions on requirements that should apply to **UK Responsible Persons** (UKRPs). Within this section, the consultation sought views on whether the regulations should include an explicit requirement for UKRPs to be physically located in the UK. Out of 241 responses:

- 71% supported this proposal
- 19% were not supportive
- 10% did not know or had no opinion

The consultation asked whether the UKRP should be legally liable for defective medical devices on the same basis as the manufacturer. There were 239 responses, of which:

- 46% supported this approach
- 40% were not supportive
- 13% did not know or had no opinion

The MHRA consulted on setting more detailed requirements regarding the written evidence that a UKRP must provide the MHRA to verify that they have the manufacturer's authority to place a medical device on the market. Here, the MHRA proposed that the written evidence could be in the form of a legal contract. There were 236 responses, of which:

- 82% were in favour of introducing this proposal
- 9% were not in favour
- 9% did not know or had no opinion

The consultation invited views on whether the UK medical devices regulations should include a requirement for manufacturers to draw up a changeover agreement when changing their UKRP. This would be an agreement between the manufacturer, the incoming UKRP and the outgoing UKRP. There were 237 responses of which:

- 78% were in favour of the proposal
- 9% were not in favour
- 13% did not know or had no opinion

The MHRA consulted on amending the technical document retention timescales that apply to UKRPs and set out a range of possible options, as outlined below. There were 213 responses regarding UKRP document retention requirements for **implantable devices**, which can be summarised as follows:

- 11-15 years after the last product has been manufactured (**28%**)
- 16-20 years after the last product has been manufactured (**8%**)
- for the expected lifetime of the device, after the last product has been manufactured (**42%**)
- other (please specify) (**23%**) - suggestions included:
  - 15 years after placing on market
  - retain forever
  - this should not be a requirement for UKRPs
  - expected lifetime of device with additional number of years as a buffer
  - lifetime of patients
  - there should be a central repository for these documents

Regarding the specified period for the retention of technical documentation relating to **non-implantable devices**, 224 respondents answered as follows:

- 1-5 years after the last product has been manufactured (**13%**)
- 10 years after the last product has been manufactured (**24%**)
- 11-15 years after the last product has been manufactured (**9%**)
- for the expected lifetime of the device, after the last product has been manufactured (**33%**)
- other (please specify) (**21%**) - suggestions included:
  - retain forever
  - this should not be a requirement for UKRPs
  - expected lifetime of device with additional number of years as a buffer
  - lifetime of patients
  - there should be a central repository for these documents

The consultation invited views on whether the UK medical devices regulations should introduce an obligation on UK Responsible Persons to retain documentation in cases where the manufacturer has ceased activity. There were 233 responses, of which:

- 69% supported the introduction of this obligation
- 20% were not supportive
- 11% did not know or had no opinion

The MHRA asked consultees for views on whether UK Responsible Persons should be required to have at least one Qualified Person that is permanently and continuously at their disposal (available for contact at all times). There were 235 responses, of which

- 63% thought that this requirement should be introduced
- 29% were not supportive
- 9% did not know or had no opinion

## 12.2 The government response

The government notes that the majority of respondents supported the proposal that the regulations should include an explicit requirement for the **UK Responsible Person to have an address in the UK** at which they are physically located and therefore we intend to proceed with the proposal. As described in the consultation, we are aware that, in some cases, persons located outside the UK have been able to act as UKRPs by uploading a “forwarding address” to the registration system. We believe that proceeding with the above proposal will help address this issue by clarifying in the regulations that this practice is not permitted and will ensure that the MHRA has a UK-based point of contact for all medical devices placed on the market.

Having taken account of consultation feedback, the government intends to proceed with the proposal to clarify that the **UKRP is legally liable** (responsible or answerable in law) for defective

medical devices on the same basis as the manufacturer, subject to further consideration on how this would operate in practice.

After careful consideration of responses, it remains the government's intention to proceed with the proposal to include in the UK medical devices regulations a requirement for manufacturers and UKRPs to draw up a **legal contract**, subject to further consideration on how this would operate in practice.

After careful consideration of responses, it remains the government's intention to proceed with the proposal to include in the UK medical devices regulations a requirement for manufacturers to draw up a **changeover agreement** when changing their UKRP subject to further consideration on how this would operate in practice.

For **implantable** medical devices, having considered the differing views of respondents, the government intends to introduce a requirement for UKRPs to **retain or have access to technical documentation** relating to such devices for the expected lifetime of a device after the product has last been manufactured or 15 years (whichever is longer). These timings received significant support from consultees and this approach will help ensure that sufficient support is available in the event of adverse incidents occurring in these long-lived devices.

For **non-implantable** medical devices, having considered the differing views of respondents, we intend to introduce a requirement for UKRPs to **retain technical documentation** relating to such devices for the expected lifetime of a device after the product has last been manufactured or 10 years (whichever is longer). As above, these timings were supported by consultees, and this approach will help ensure that sufficient support is available in the event of adverse incidents occurring in devices that have long in-service lives.

The government intends to amend the UK medical devices regulations so that they require the UKRP to **retain this documentation** for the same time periods, as outlined above for implantable and non-implantable devices, in circumstances where the manufacturer has **ceased activity** - for example due to liquidation. We consider that this approach will aid the MHRA's investigations of a medical device in cases where the manufacturer is no longer in operation.

The government intends to introduce a requirement for UKRPs to have a **Qualified Person** permanently and continuously at their disposal, subject to the outcome of further consideration on how this would operate in practice.

## **Section 13 - Obligations of importers and distributors**

### **13.1 Proposals and feedback**

The consultation invited views on a number of obligations that could be introduced for importers and distributors of medical devices, to support better accountability, transparency and safety. Further detail on these requirements is set out in the consultation document.

In relation to the proposals to introduce **obligations on importers and distributors** of medical devices, 213 responses were received, of which:

- 69% supported the requirements listed in the consultation
- 3% were not supportive
- 23% specified 'other'
- 3% did not know or had no opinion

A wide range of views were expressed by respondents that selected 'other', with many signalling that they agreed or broadly agreed with the proposed requirements. The remainder of responses disagreed with one or more of the proposed requirements. The rationale for this feedback included

a view that some requirements should only apply to high-risk devices, and that the requirements may be onerous for importers and distributors to adopt. In addition, some respondents expressed concern regarding the ability of importers and distributors to ensure that the end user does not receive a time expired device, suggesting that this requirement should only apply to stock that is within the control of the importer or distributor.

The consultation also invited views on the introduction of importer and distributor requirements in the abridged consultation (Chapter 17). Here 53 responses were received, of which:

- 92% supported the introduction of requirements set out in the consultation
- 6% were not supportive
- 2% did not know or had no opinion.

In terms of rationale, respondents reasoned that any requirements for importers and distributors should mirror those that apply to manufacturers and that this approach would generate safety benefits. Other respondents expressed concern about bureaucracy and possible supply issues and the capacity of importers and distributors to perform these functions. There were also calls to align requirements with those in the EU MDR/IVDR.

Respondents to Chapter 3 were asked to outline any other requirements which should be introduced for importers and distributors. There were 115 free text responses, of which 41% did not specify any further requirements or gave an unrelated response. Clear definitions of roles and responsibilities for importers and distributors were requested by 17% of respondents, and a further 7% called for alignment with the EU regulations generally, while 4% suggested that the proposed QMS requirements should utilise ISO standard 13845.

We asked whether the UK regulations should clarify that fulfilment service providers should be regarded as importers under the UK regulations. There were 218 responses, of which:

- 44% were in favour of this approach
- 28% were not in favour
- 28% did not know or had no opinion

The consultation invited views on whether economic operators (including manufacturers, importers and distributors) should be required to inform the MHRA if they become aware of any issues that will interrupt supply or 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. There were 218 responses, of which:

- 50% were in favour
- 35% were not in favour
- 15% did not know or had no opinion

Respondents were asked to provide their reasoning (including any available relevant evidence) to support their answers to the previous questions on obligations for importers and distributors, including any impacts on them or other stakeholder groups. There were several themes identified in the responses, as summarised below:

- regarding the requirement to notify the MHRA of issues that could cause interruption to supply of devices within the UK, some respondents noted that clear definitions would be needed, including for 'critical product' and 'supply shortage', while others suggested that only critical and/or unique device shortages should be reported

- there was a mixed response on the MHRA's role in monitoring supply, with some consultees in support of this and others asserting that the MHRA should not have a role here
- some respondents suggested that only critical and / or unique device shortages should be reported
- there was also some suggestion that document retention timescales should be proportionate to the device risk class

Mixed views were expressed regarding the requirements that should apply to fulfilment service providers (FSPs). Here a number of respondents raised concerns about possible duplication of importer requirements, for example leading to dual importer labelling and registration with the MHRA. Some respondents suggested that the obligations should be based on the role of the FSP within the supply chain (meaning, importer obligations should apply in the event that the FSP is importing a device and distributor requirements should apply if the FSP is distributing a device).

### 13.2 The government response

The consultation set out a number of **obligations on importers and distributors** that could be introduced. After careful consideration of all responses, the government intends to proceed with the proposal to introduce obligations on importers and distributors, as outlined in the consultation. We will give further consideration to the concerns raised regarding the ability of importers and distributors to ensure that the end user does not receive a time expired device. We consider that this approach will improve device traceability, helping to ensure the safe supply of medical devices to the UK market. Some respondents indicated that additional guidance may be necessary to clarify the roles and responsibilities of importers and distributors, and the government intends to produce supplementary guidance on the regulatory requirements.

Regarding the **regulation of fulfilment service providers**, as noted above, some consultees highlighted important concerns regarding the proposal to treat all FSPs as importers citing, for example, risks of setting duplicative labelling and registration requirements. Having taken this feedback into consideration, the government intends to adjust its position and to clarify in the regulations that FSPs will fall within the scope of the definitions and need to meet the requirements of 'importers' or 'distributors' depending on their role in the supply chain. We consider that this approach will help mitigate the risks of duplication, while improving device traceability, supporting compliance activity and ensuring the safe supply of medical devices to the UK market.

After careful consideration of consultation responses, the government intends to proceed with the proposal to require economic operators to inform the MHRA if they are aware of any issues that will **interrupt supply or cause a shortage** of medical devices on the UK market. The MHRA will take account of consultation feedback regarding the need to set clear requirements and intend to publish supplementary guidance, alongside the regulatory changes, that will address these points.

## Section 14 - Qualified Persons

### 14.1 Proposals and feedback

The consultation invited views on whether the UK medical devices regulations should 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 (which would be set out in the 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. There were 240 respondents, of which:

- 83% were in favour of introducing such a requirement

- 13% were not in favour
- 4% did not know or had no opinion

When asked what qualifications and/or experience the Qualified Person should have in order to be eligible for this role, 148 respondents provided a range of views. There was strong support for reflecting in the UK regulations, the 'Person Responsible for Regulatory Compliance' requirements set out in the EU MDR and IVDR.

The consultation asked whether small and medium-sized enterprises (SMEs) should be excluded from the above proposed requirements and instead be required to have a Qualified Person 'permanently and continuously at their disposal'. There were 236 responses, of which:

- 69% were in favour of such an exemption
- 15% were not in favour
- 16% did not know or had no opinion

159 respondents provided reasoning to support their answers to the questions on Qualified Persons, including any impacts on themselves or other stakeholder groups. The following themes were raised:

- requirements should align with the EU MDR/IVDR
- consideration of alternative terminology is needed to avoid confusion with Qualified Person requirements for medicines
- the regulations should allow the Qualified Person to be based outside the UK to avoid duplication with EU MDR/IVDR requirements (as many manufacturers will have already appointed a Person Responsible for Regulatory Compliance in the EU to meet MDR requirements)
- costs / burdens may be prohibitive for SMEs
- the proposed requirements will improve safety
- need to consider capacity issues and the number of Qualified Persons that will be available to manufacturers
- clarity is needed regarding the meaning of 'permanently and continuously at their disposal' and 'small and medium-sized enterprise'

## 14.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposal 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.

The government will take into consideration the need for international alignment as these proposals are further developed and will also consider the points raised by respondents around capacity and terminology. The government intends to further clarify in guidance, the requirements that will apply to Qualified Persons.

It is the government's intention to require that **SMEs have a Qualified Person permanently and continuously at their disposal** as this will ensure that all manufacturers will have appropriate regulatory support available to them. The government considers this to be a suitable compromise for SMEs and will avoid the need for them to directly appoint a Qualified Person to their workforce. In response to consultation feedback, we will provide further guidance on this requirement to accompany the regulatory changes.

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

### 15.1 Proposals and feedback

The MHRA consulted on clarifying the circumstances in which an economic operator, other than the device manufacturer, would be required to assume the responsibilities of the manufacturer. There were 214 responses, of which:

- 93% thought these circumstances should be clarified
- 3% did not support this approach
- 5% did not know or had no opinion

The consultation invited views on whether 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. Out of 213 respondents:

- 84% supported this approach
- 9% were not supportive
- 7% did not know or had no opinion

The consultation asked whether the UK medical devices regulations should outline the requirements that economic operators would need to meet in circumstances where they have made a modification to a device, without taking on the obligations of the manufacturer, as set out in the consultation. 213 responses were received, of which:

- 88% were in favour of this proposal
- 6% were not in favour
- 6% did not know or had no opinion

The consultation asked respondents to set out any reasoning for their responses to the above questions. Here, 138 responses were received, which can be summarised as follows:

- further clarity is needed on the above requirements and potential impacts on health institutions
- some respondents suggested that there is a need to align with the EU MDR/IVDR
- some respondents suggested that modifications could be addressed through contractual arrangements between the manufacturer and 'modifier' and covered in manufacturer's QMS
- cases in which the economic operator translates accompanying information into English could potentially have safety implications if not undertaken by a person with relevant qualifications or expertise

### 15.2 The government response

After careful consideration of responses, it is the government's intention to proceed with the proposal to amend the UK medical devices regulations to **clarify the circumstances** in which an economic operator other than the device manufacturer would and would not be required to **take on the responsibilities of the manufacturer**. This will bring greater clarity to this area, where there is currently some ambiguity.

The government also intends to proceed with the proposal to amend the UK medical devices regulations to outline the requirements that economic operators would need to meet in circumstances where they have made a **modification to a device, and they have not taken on**

**the obligations of the manufacturer.** We have noted the consultation feedback proposing that this could be addressed via contractual arrangements between the manufacturer and 'modifier' but the government does not consider this would adequately address this issue.

## 4 – Registration and UDI

**The MHRA wants to see greater transparency in its regulation of medical devices in the UK and more traceability of medical devices across the UK. We propose to enhance transparency of information about medical devices by increasing the amount of information we capture and share about devices at the point of device registration. We also plan to introduce requirements that will help identify medical devices placed on the UK market, helping to identify and address issues with devices where they arise. These changes have the potential to help better protect peoples' health and better inform all stakeholders, including patients and clinicians, about the medical devices in use in the UK.**

### **Section 16 – General background**

Section 16 of the consultation summarised MHRA's ambition to be world leading in the transparency of its regulation of medical devices. It noted that historically MHRA has been limited in the information it can capture and share on medical devices and that the Medicines and Medical Devices Act 2021 contains provisions for sharing information about medical devices. **This section did not contain any proposals or questions.**

### **Section 17 - Identification within the supply chain**

#### **17.1 Proposals and feedback**

The consultation outlined that the UK medical devices regulations could include a requirement for distributors and importers to cooperate with manufacturers, UK Responsible Persons (UKRPs), and public and private sector health institutions to achieve an appropriate level of traceability for medical devices. It highlighted that, for example, the regulations could be amended to require economic operators to be able to identify, record and retain the following records for a specified period of time and make these available to the MHRA upon request:

- a. any economic operator to whom they have directly supplied a medical device
- b. any economic operator who has directly supplied them with a medical device
- c. any public or private sector health institution or healthcare professional to whom they have directly supplied a medical device
- d. any lay person/user/patient directly supplied with the medical device

The consultation invited views on whether the regulations should be amended to require economic operators (manufacturers, importers, distributors etc.) to 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. 186 responses were received, of which:

- 75% supported the inclusion of the requirements
- 20% did not support the inclusion of the requirements
- 5% did not know or had no opinion

We next asked consultees to outline other traceability requirements that they considered should be introduced. There were 132 responses. Of these, some respondents signalled support for the proposals set out in the consultation (38% of responses), with a small number indicating that they were not in favour of requiring economic operators to be able to identify and record lay person/user/patient directly supplied with the medical device. Two respondents noted that they were not in favour of any of the proposed changes set out in the consultation. No additional traceability requirements were suggested beyond those set out in the consultation. A number of

respondents suggested that the requirements around the traceability of a device should align with EU MDR/IVDR (around 14%), be proportionate to device class (around 11%) and some suggested alignment with the approach of GS1 (Global Standards 1 – an international standards organisation).

Consultees were invited to specify the time period for which economic operators should be able to track the supply of medical devices and to keep the records pertaining to this, should such a requirement be introduced. There was no clear consensus among the 195 respondents who provided comments. A wide range of retention periods were suggested, with feedback including that retention periods should:

- be proportionate to device class/risk and take account of whether a device is implantable
- align with existing document retention regulations
- align to EU MDR/IVDR
- be until a device 'expires' (the lifetime of a medical device)
- be for the lifetime of a medical device **or** 10 years - whichever is longer.

When invited to provide reasoning for the responses given in this section, we received feedback from 58 respondents. Most sought alignment with EU MDR/IVDR and/or international regulation requirements more broadly, and a simple system which doesn't duplicate other systems and is not overly bureaucratic. Commonly, respondents raised the importance of traceability for patient safety over the lifetime of a device. Few said that traceability requirements should depend on device risk class, with more traceability requirements placed on higher risk medical devices. Many felt the possible requirement that economic operators be able to identify and record any lay person or user or patient directly supplied with the medical device, is not workable and could raise UK General Data Protection Regulation (UK GDPR) issues and would amount to a patient record.

## **17.2 The government response**

The government intends to bring in requirements for distributors and importers to cooperate with manufacturers, UKRPs, and public and private sector healthcare professionals and institutions, to achieve an appropriate level of traceability for medical devices.

It also intends to bring in requirements for economic operators to identify and record the following information:

- a. any economic operator to whom they have directly supplied a medical device
- b. any economic operator who has directly supplied them with a medical device
- c. any public or private sector health institution or healthcare professional to which they have directly supplied a medical device

The government considers these traceability requirements are important and should apply regardless of medical device type.

The government recognises that a number of responses raised concerns about the workability of requiring information to be provided about persons directly supplied with a device and does not plan to introduce this requirement at this time but will give this more detailed consideration.

## **Section 18 - Nomenclature**

### **18.1 Proposals and feedback**

When asked to select which nomenclature should be required under the UK medical devices regulations for the purposes of medical device identification, the majority of respondents considered Global Medical Device Nomenclature (GMDN) to be the best option for medical device nomenclature for the UK system. 340 responses were received, of which:

- 63% were in favour of using GMDN
- 31% were in favour of using European Medical Device Nomenclature (EMDN)
- 3% were in favour of both GMDN and EMDN
- 3% said 'other'

Comments from those who answered 'other' included:

- only use EMDN if interfacing with European Database on Medical Devices (EUDAMED)
- preference for one of the options set out (GMDN, EMDN, both), or no preference
- EMDN is free to access
- a new globally harmonised nomenclature should be developed
- GMDN preference as it is widely used internationally, and technically well established
- interest in harmonisation or mapping to identification numbers utilised elsewhere
- noting the cost of GMDN, and burden of moving to a different system
- regardless of which system is selected, much of industry need to work with both EMDN and GMDN across different markets

## 18.2 The government response

Having considered the views of respondents, the government intends to proceed with the proposal to require that manufacturers provide the MHRA with the relevant GMDN nomenclature for their medical device (including *in vitro* diagnostic medical devices) as part of device registration.

This nomenclature can be accessed free of charge, is already captured in MHRA's medical device registration system, and GMDN is the most widely used nomenclature system worldwide.

The government acknowledges points raised by some respondents that EMDN is also available free of charge and allows alignment with the EU market, as well as views expressed that there is a need for a globally harmonised nomenclature system for medical devices. There is currently no global consensus on device nomenclature, so international agencies, such as the World Health Organisation, are working on standardisation of medical device nomenclature, including GMDN and EMDN. This means that some alignment will be possible in the future. However, it is the government's view that maintaining the status quo of using GMDN nomenclature is the preferred option as it allows for harmonisation with other major jurisdictions (although not the EU), is the current system used in the UK and avoids additional costs of moving to a new system.

## Section 19 – Unique Device Identification

### 19.1 Proposals and feedback

The MHRA invited views on whether the UK medical devices regulations should **define 'Unique Device Identification' (UDI)**. 274 respondents were received, of which:

- 91% were in favour
- 3% were against defining UDI
- 7% did not know or had no opinion

A number of respondents outlined what they considered should be included in this definition. Out of 201 free text responses, 31% were in favour of definitions used by the EU and 38% sought a modified version of the definition proposed in the consultation. There was also interest in a number of responses in alignment with UDI definitions adopted by the International Medical Device Regulators Forum (IMDRF) and the US. In a number of responses, it was suggested that the UDI definition should include definitions of 'UDI device identifier' (UDI-DI) and 'UDI production identifier'

(UDI-PI) and should clarify the differences between UDI-DI, UDI-PI, Basic-UDI-DI and in some cases Unit of Use DI.

When asked whether the regulations should require manufacturers to **assign UDIs** to medical devices **before they are placed on the market**, 167 responses were received, of which:

- 83% were in favour of this requirement
- 7% were against the requirement
- 8% did not know or had no opinion

We invited those who answered 'yes' to this question in Chapter 4 of the consultation to further outline any particular requirements which should be introduced in regard to how UDIs should be applied to medical devices and any aspects which require clarification. Common to many of the 167 free text responses was interest in aligning requirements with the EU MDR/IVDR. A preference for alignment to the IMDRF UDI recommendations was also referenced in a number of responses. There was interest in having clear guidance, in particular for certain devices such as contact lenses, procedure packs and software devices. A number of respondents suggested that there should be a transition period for the introduction of UDI requirements. Additionally, a small number of responses indicated interest in limiting or reducing the UDI requirements that apply to lower risk devices.

We also invited views on UDI requirements in the abridged consultation (Chapter 17). We asked whether manufacturers should be required to assign UDI numbers to medical devices before they enter the UK market. Out of 53 respondents:

- 91% supported the introduction of requiring manufacturers to assign UDIs to medical devices before they are placed on the market
- 2% were not in support
- 8% did not know or had no opinion

In the abridged consultation chapter respondents to the above question were asked to provide their reasoning for their answers on UDI or any general comments on UDI requirements for medical devices. Out of the 14 responses:

- 86% were in favour of having UDI requirements for medical devices in the UK
- 14% did not know or had no opinion

In chapter 4 we also asked consultees whether we should require reusable medical devices to bear a UDI carrier (for example, a barcode) that is permanent and readable after each process on the device itself. 201 responses were received, of which:

- 70% of respondents were in favour of the requirement
- 9% were not in favour of this
- 26% did not know or had no opinion

In relation to the previous question, respondents were asked whether there should be any exemptions to this rule, and to provide examples and reasoning. Most commonly, respondents raised that there should be exemptions where it is not practical or possible to affix a UDI due, for example, to size limitations of a device. A number also suggested that direct marking requirements should not apply to software as a medical device. There was interest in having alignment of exemptions with EU and United States UDI systems, and with the IMDRF. Some respondents suggested exemptions for certain types of devices, such as custom-made devices, investigational devices, compassionate use devices, and disposable devices, for example, contact lenses. Some set out certain circumstances where they considered exemptions should apply - such as if a device

is manufactured and used within the same health institution or if a device is manufactured prior to the UDI rules becoming effective.

In relation to whether the UK medical devices regulations should include requirements for Basic UDI device identifiers (UDI-DI) to identify medical device models, 266 responses were received, of which:

- 65% were in favour of such a requirement
- 18% were not in favour
- 12% did not know or had no opinion

Those in favour of this requirement expanded on their reasoning and the most common reasons given for this were that UDI requirements will improve vigilance, traceability and overall patient safety. Some expressed interest in harmonising with the EU, US and IMDRF. Other points raised related to the burden and cost this would place on industry, which could result in higher costs of devices and a need to consider exemptions to the requirements (for example, only applying the requirement to higher risk classes).

When asked if manufacturers should be required to **assign and apply UDIs to their medical devices before applying to Approved Bodies** for conformity assessment, 264 responses were received, of which:

- 56% were in favour of this proposal
- 26% were not in favour of this proposal
- 18% did not know or had no opinion

The consultation set out that the UK medical devices regulations could be amended to include requirements for the use of UDI and/or Basic UDI-DI in certain circumstances, including the following:

- on the Certificate of Conformity for the medical device (Basic UDI-DI) – responsibility of the Approved Body (Linked to Conformity Assessment - Chapter 6)
- on the Declaration of Conformity for the medical device (Basic UDI-DI) – responsibility of the manufacturer (Linked to Conformity Assessment - Chapter 6)
- in the patient implant information provided for an implantable medical device (UDI-DI) – responsibility of the manufacturer (Linked to Conformity Assessment - Chapter 6)
- when registering medical devices with the MHRA (Basic UDI-DI and UDI-DI) – responsibility of the manufacturer or UK Responsible Person
- when reporting serious incidents, for example, death of a patient which could have been caused by the medical device to the MHRA (UDI-DI) – responsibility of the economic operator making the report (Linked to Post-market surveillance and vigilance - Chapter 8)
- when issuing field safety corrective actions (FSCAs), for example, advising the recall of a device due to a safety issue to the MHRA (UDI-DI) – responsibility of the manufacturer (Linked to post-market surveillance and vigilance - Chapter 8)

In relation to whether the UK medical devices regulations should stipulate that the UDI or Basic UDI-DI of a medical device should be provided in the circumstances outlined above, 264 responses were received, of which:

- 78% were in favour of the proposal
- 12% were against the proposal
- 10% did not know or had no opinion

When asked to outline any **other circumstances** in which the UDI or Basic UDI should be provided for a medical device, 125 free text responses were received. Several respondents indicated that the circumstances should be aligned to the requirements in the EU MDR/IVDR. Examples of circumstances highlighted in which the UDI or Basic UDI should be provided, that were not covered by the list consulted on, included but were not limited to: customer complaints, within service manuals and records, within technical documentation, on implant cards, the summary of safety and clinical performance, certificates of free sale, shipping notices and Medical Device Alerts issued by the MHRA (it should be noted that these have been superseded by National Patient Safety Alerts).

When asked whether certain medical devices should be **exempt from the UDI requirements**, 262 responses were received, of which:

- 57% supported the proposal
- 21% did not support the proposal
- 22% did not know or had no opinion

Those who indicated in responses that certain medical devices should be exempt from UDI requirements were invited to outline which medical devices should be exempted. 119 responses raised a range of possible exemptions, including custom-made devices, investigational devices or devices for a performance study, software as a medical device, software that is app or web-based, dental crowns, low-risk devices (such as those in Class I), small devices, procedure packs, in-house manufactured devices, and prosthetic devices where it is not possible to barcode without affecting the purpose of the device. Additionally, a small number of answers raised interest in aligning with international requirements.

When asked whether manufacturers of custom-made devices should be required to assign a unique serial number to the device, 257 responses were received, of which:

- 52% were in favour of the proposal
- 19% were against this proposal
- 30% did not know or had no opinion

The consultation also asked which **issuing entities** should be designated by the MHRA. Respondents were asked to provide information on whether the MHRA should designate one or multiple UDI issuing entities, if there should be one issuing agency, which one and why, and if there should be multiple issuing agencies, which ones and why. There were 183 responses. Of these, the majority (66%) of respondents favoured multiple issuing entities and many of these suggested consistency with the European system (meaning, utilising the following issuing entities: Global Standards 1 (GS1), Health Industry Business Communications Council (HIBCC), International Council for Commonality in Blood Banking Automation (ICCBBA) and Informationsstelle für Arzneispezialitäten (IFA) GmbH. A further 19% of respondents favoured GS1 only, 3% respondents favoured GS1 and HIBCC, 6% gave an alternative answer and 7% did not know or had no opinion.

The consultation also asked whether 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. Of 261 respondents:

- 80% were in favour of such a requirement
- 10% were not in favour
- 10% did not know or had no opinion

Respondents who answered in favour to the previous question were asked how long manufacturers should be required to hold this information, and to indicate whether they considered that there should be different minimum periods of retention depending upon type of device or risk classification. There was no clear consensus among the 209 responses on how long a manufacturer 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. The most common responses were in support of a retention period longer than the lifetime of the device, followed by support for retention periods being determined according to risk class, then alignment with EU MDR/IVDR requirements, and then between 6 and 10 years.

The consultation invited views on whether economic operators should be required to store the UDI numbers of certain medical devices. Of the 255 responses received:

- 68% were in favour
- 11% were not in favour
- 22% did not know or had no opinion

Respondents who answered in favour of the previous question were asked to select which groups of medical devices should fall under this requirement. The 48 respondents answered as follows:

- all implantable medical devices **(77%)**
- Class III implantable medical devices & Class IIb implantable medical devices **(6%)**
- Class III implantable medical devices **(2%)**
- don't know/no opinion **(15%)**
- other **(0%)**

The consultation also asked whether healthcare professionals and/or health institutions should be required to store and keep, by electronic means, the UDIs of certain medical devices. 256 responses were received, of which:

- 70% were in favour of this requirement
- 9% were not in favour
- 20% did not know or had no opinion

Respondents who answered in favour of the previous question were asked to select which groups of medical devices should fall under this requirement. Of the 54 respondents:

- 78% selected 'all implantable medical devices'
- 7% selected 'Class III implantable medical devices & Class IIb implantable medical devices'
- 4% selected 'Class III implantable medical devices'
- 7% did not know or had no opinion

The abridged consultation chapter aimed at the general public (Chapter 17), also invited views on what types/classes of medical devices should be included in the requirement for UDI storage. The 51 participants responded as follows:

- all implantable medical devices **(66%)**
- class III implantable medical devices **(4%)**
- class III and Class IIb implantable medical devices **(12%)**
- don't know/no opinion **(10%)**
- other **(8%)**

Of the four respondents who selected 'other', responses included:

- all classes of medical devices but with the same exemptions as for EU and US: custom-made medical devices and investigational medical devices/medical devices
- option a and b, and including Class III non-implantable medical devices only
- implantable devices, infusion pumps, electrocardiogram machines (ECGs)

When asked whether the UK medical devices regulations should introduce new **rules for the UDI system** in order to provide clarity, 259 responses were received, of which:

- 61% were in favour of this position
- 21% were not in favour of this position
- 18% did not know or had no opinion

Respondents who answered in favour of the previous question were asked to outline what rules the UK medical devices regulations should include in regard to the UDI system. Out of the 134 free text responses, those in favour of introducing new rules for the UDI, commonly highlighted the need for clarity about what triggers a change in UDI and showed interest in aligning with EU regulations on UDI. There was also some interest in alignment with IMDRF. Others commented on the scope of what the rules should cover - such as general requirements, labelling, retention and storage, what changes result in a new UDI being assigned, rules for specific types of device (for example, where several units are packaged together, kits and system and procedure packs) and designation of issuing entities. Some of those who were unsupportive or did not know whether new rules should be included, echoed other comments such as the need for alignment with international approaches, particularly on 'triggers' for UDIs (to reduce the burden on the market and consequent impacts on device availability), and further responses suggested that rules should be set out in guidance rather than legislation to maintain greater flexibility.

Respondents were asked to provide their reasoning (including any available relevant evidence) to support their answers to all previous questions on UDI, including any impacts on themselves or other stakeholder groups. The following common themes were raised by 126 respondents:

- 43 called for alignment with international requirements, of which, 28 called for alignment with EU/IMDRF specifically, and the remaining suggested alignment to other international jurisdictions such as the US
- 23 expressed support for the proposed changes to UDI as they would enhance traceability, patient safety, accessibility of information and support recalls
- Several respondents expressed concerns around the regulatory burden on manufacturers, other economic operators, and clinical teams
- 7 comments related to UDI 'triggers', suggesting similar requirements as other jurisdictions to minimise the impact on manufacturers and global UDI systems

Respondents to the abridged consultation (Chapter 17) were also asked to provide reasoning for their answers to questions on UDI or any general comments on UDI requirements for medical devices. The following common themes were raised by 19 respondents:

- UDI requirements should be harmonised with IMDRF, EU and other jurisdictions
- support was noted for UDI for certain medical devices for enhanced traceability and patient safety

## 19.2 The government response

We note that there was very strong support overall for the introduction of a **globally harmonised device identification and coding system** which allows unambiguous identification of a specific device on the UK market. The government also acknowledges and has considered concerns raised about the introduction of UDI requirements - such as the additional burden this would bring

to the medical devices industry. However, it is the government's view that bringing in requirements for assigning and applying UDI to medical devices placed on the UK market will enhance our ability to trace medical devices and take appropriate action if issues arise with a device.

It is our intention to proceed with **defining 'UDI'** within the UK medical devices regulations. The government has carefully considered the responses on what should be included in this definition and intends to utilise a definition that allows alignment with other jurisdictions such as the EU.

After consideration of the responses on the **assignment of UDIs**, it is the government's intention to proceed with the following proposals:

- to require manufacturers to assign UDIs to medical devices before they are placed on the market
- to require reusable medical devices to bear a UDI carrier (for example, a barcode) that is permanent and readable after each process on the device itself.
- to include requirements for Basic UDI device identifiers (UDI-DI) to identify medical device models

We also intend to issue clear guidance that helps the market understand the distinction between Basic UDI-DI and other forms of identifiers (e.g. unit of use DI), so that the rationale for, and value of, collecting this information is clearer.

After consideration of the responses received in relation to the **assignment of UDIs before applying to Approved Bodies** for conformity assessment, it is the government's view that this requirement should not be introduced for manufacturers of all medical devices, as the traceability benefits would not be proportional to the increased work required to implement this requirement for manufacturers. However, it is our intention to introduce an amended requirement for manufacturers of class III medical devices and some class IIb implantable medical devices only to assign a Basic UDI-DI to these devices before applying to an approved body for conformity assessment, as the traceability benefits this brings are justified for these higher risk devices.

Based on the responses received, the government also intends to proceed with **requiring the UDI or Basic UDI-DI** of a medical device to be provided in the circumstances outlined in paragraph 19.12 of the consultation.

Additionally, in relation to **other circumstances in which a UDI or Basic-UDI should be provided**, the government has considered the views raised by respondents in favour of including reflecting the circumstances that are included in the EU MDR and IVDR and considers the inclusion of those circumstances to be beneficial to the traceability of medical devices in the UK. It is our intention to also require the UDI or Basic-UDI to be provided in circumstances that are aligned with those stipulated in the EU MDR and IVDR.

The government will consider further whether there are valid **exemptions to UDI requirements** and whether there is a need for further guidance on how UDI requirements apply to certain product groups.

We intend to designate GS1, HIBCC, ICCBBA and IFA as **UDI issuing entities**, as a clear majority of respondents supported this option, and it presents an opportunity to align with other jurisdictions.

The government considers that 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 and be subject to the retention periods as outlined in chapter on Conformity Assessment (Chapter 6).

After careful consideration of the responses received, it is our intention to proceed with the proposal to require economic operators and healthcare professionals and/or health institutions to

**store the UDI numbers of implantable medical devices**, noting that the majority of respondents were supportive of this requirement.

After careful consideration of responses on proposals to introduce new **rules for the UDI system**, we intend to provide clarity in the UK medical devices regulations on the triggers that would result in a requirement to apply a new UDI-DI.

## **Section 20 – Great Britain database on medical devices**

### **20.1 Proposals and feedback**

The consultation outlined that the MHRA is considering the potential to capture and process information submitted to the MHRA about medical devices (such as device registration, vigilance and post-market surveillance, clinical investigations and performance studies) 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.

When asked whether this proposal should be introduced, out of 224 respondents:

- 78% supported the proposal
- 12% were unsupportive
- 9% did not know or had no opinion

Respondents were asked to provide their reasoning (including any available relevant evidence) to support their answer to the previous question, including any impacts on or implementation considerations for themselves or other stakeholder groups. The following common themes were raised by 198 respondents:

- responses showed overwhelming support for the development of an integrated system. Reasons given in favour included that it would be useful, would improve information gathered and allow better coordination, enhanced transparency and have a positive impact on patient safety
- many felt the approach taken to this proposal should be similar to EUDAMED
- those not in support reasoned that the approach would be burdensome for industry to implement, and that the MHRA should use EUDAMED rather than developing its own system

### **20.2 The government response**

The government is focused on establishing a more comprehensive **registration database** for medical devices, which will include UDI information. We remain focused on exploring whether and how best this database can operate as part a series of integrated databases for capturing and processing information submitted to the MHRA about medical devices (such as data on registration, vigilance, post-market surveillance, and market surveillance regarding medical devices).

## **Section 21 – Registration of medical devices**

### **21.1 Proposals and feedback**

The consultation invited views on whether manufacturers should be required to provide the information in 'List One', as set out in the consultation text, to the MHRA upon medical device registration. 269 responses were received, of which:

- 55% were in support of the proposal

- 17% did not support the proposal
- 10% did not know or had no opinion
- 18% selected 'other'

When asked to specify any changes proposed to the list of registration requirements and accompanying rationale, 148 free text responses were received. As set out below, respondents were invited to share the reasoning for their answer to this question. For those who were unsupportive of some or all of the proposed list of registration requirements, reasoning included that they felt the information already requested at point of device registration is sufficient, that the information listed is already available from other sources, that the requirement for certain information at device registration should only apply to high-risk classes of devices and/or concern about the burden on industry the requirement would bring. In addition, a number indicated that they would prefer alignment with the EU. There was no clear rationale given in favour of proposed additions to registration information required.

Respondents were asked to select which of the following entities should be permitted to submit device registration information to the MHRA (selecting all that apply). We received 213 responses as follows:

- UK Responsible Persons and UK-based manufacturers (current requirement) (**90%**)
- non-UK based manufacturers (**65%**)
- authorised third-party submitters (**52%**)
- all (**3%**)
- distributors (**0.5%**)

When asked what **mechanisms should be in place to submit data**, out of 247 responses there was strong interest in both web forms (from **93%** of respondents) and machine to machine upload (from **53%** of respondents). There was also interest in bulk uploads being made available.

Respondents were asked to outline the **transition timeframes** that they considered should apply to this additional required information. Opinions were varied amongst the 175 free text responses. The majority made reference a specific timeframe ranging from 1 month to 5 years. The highest proportion of respondents suggested a timeframe proportionate to the risk class of the device (29%), followed by 2 years (11%), 1 year (8%), 3 years (7%), and that the timeframe should align with the EU MDR/IVDR (3%).

We invited views on whether the information that the MHRA gathers at the point of medical device registration should be made **publicly available**, via a website of similar platform. 268 responses were received, of which:

- 65% were in support of this proposal
- 21% were not in support of this proposal
- 15% did not know or had no opinion

Those who answered in support of the previous question were asked to further outline what information should be shared and the rationale and key considerations or limitations, with 115 respondents raising the following themes:

- agree with proposal (**57%**)
- suggestion that only limited data should be displayed - mainly concerns around commercially sensitive data and UK GDPR (**55%**)
- suggest aligning with EUDAMED (**10%**)
- have concerns, disagree with the proposal, don't want to publish information or are unsure of the benefit (**5%**)

- gave no response (7%)

When asked whether manufacturers should be required to **register with the MHRA before applying to an Approved Body for conformity assessment**, and for the Approved Body to verify this registration, 265 responses were received, of which:

- 40% were in favour of this proposal
- 42% were against this proposal
- 18% said they did not know or had no opinion

We invited consultees to provide reasoning for their response to the above question. Some raised objections to the proposal, including that requiring registration ahead of pre-market approval from an Approved Body would be burdensome, with potential commercial implications (such as the need to release marketing plans before approval), and, concerns that a product may change between pre-approval registration and final approval, leading to unnecessary effort to register at this point in the process.

In relation to whether economic operators should be given up to 30 days' **timeframe to update an MHRA registration record** after a change has been made to a device's registration details, 260 responses were received, of which:

- 74% were in favour of such a requirement
- 12% were against it
- 14% did not know or had no opinion

Respondents were asked to provide their reasoning to support their answer to the above question on the timeframe for updating registration records. The majority of the 158 respondents expressed agreement with the proposed '30 days' timeframe, with significant support also for favouring a 'longer timescale' and that 'those timescales should be proportionate to class'. Themes that emerged from the responses included concerns over getting the required information/documents from represented organisations and conformity assessment bodies, burden on industry and a desire for flexibility and extensions to deadlines.

In relation to whether 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 (biennially), 261 responses were received, of which:

- 56% supported this proposal
- 28% did not agree with this proposal
- 17% did not know or had no opinion

When invited to expand on their reasoning for their responses to questions in this section of the consultation, objections respondents raised to having annual/biennial confirmation of registered data included that annual/biennial review for accuracy is not necessary if there is also a requirement to update registrations with any changes.

We invited views on how **economic operators should be identified** within the MHRA system. 212 responses were received, and responses were fairly evenly split, as follows:

- 32% in support of Data Universal Numbering System (DUNS)
- 28% in support of Global Location Number (GLN)
- 29% in support of a MHRA generated number

We invited consultees to provide reasoning for their responses to questions in this section. Limited rationale was provided, including:

- general greater registration information to improve device traceability and safety
- concern for the additional burden/proportionality of additional registration requirements
- interest in alignment with EU requirements.

## 21.2 The government response

The government intends to extend the **data required at the point of device registration** as set out in the consultation, with the following amendments.

In light of consultation feedback, the intention is not to introduce requirements for the following information to be submitted when registering a medical device with MHRA:

- periodic safety update report or post-market surveillance report with each registration renewal – and instead require this to be provided to the Secretary of State on request
- information about other countries in which the device is made available/placed on market- as it is considered a disproportionate burden on industry to collect and keep such information updated, and
- sterilisation provider - as this information is subject to change and would create a disproportionate burden to maintain

MHRA is of the view the following information should form part of information collected at the point of medical device registration, notwithstanding concerns raised with this:

- an undertaking that manufacturers have met the requirement to have measures in place for recompense for negative impacts of a medical device – we consider it important that this information is confirmed at the point of device registration
- the reference number of the clinical investigation / performance study conducted in relation to the medical device – we intend to introduce this requirement to improve the ability to cross reference data held by the MHRA

The following minor variations have been made to the information MHRA plans to collect at point of medical device registration following feedback received:

- the 'status of the medical device' will be revised to 'status of availability' (for example, 'on the market', 'pre-market', 'withdrawn from market')
- specification as to whether the intended purpose of the product is 'other than a medical purpose' - we will ensure this is 'if applicable' MRI safety status information – this will only apply if relevant to the device

The government will also consider further whether to require additional information regarding whether tissues or cells of human and/or animal origin, or their derivatives, are present.

The government intends to extend the list of those **who can submit device registration information** to give manufacturers greater flexibility in how / who can submit data, which will reduce burden on manufacturers in meeting registration requirements.

In terms of the mechanisms that could be put in place for submitting device registration information, respondents signalled significant support for web form and machine to machine mechanisms. The government will further consider these mechanisms. The MHRA is minded to ensure medical device registration information can be submitted via both web forms and machine-to-machine mechanisms. It does not consider that **mechanisms for submitting data** need to be prescribed in regulations but will continue to ensure that there is clear guidance on the mechanisms for providing device registration information.

The government intends to provide a **phased introduction of new registration requirements**, commensurate with the risk classification of a device. This will be similar to the phased approach taken to introducing new medical device registration requirements during 2021, where compliance timeframes were set in accordance with device classes.

The government intends to make all registration data **publicly available** to enable more informed choices around the use of medical devices, excluding personal information and commercially sensitive information, and in compliance with UK GDPR.

After consideration of the responses received, the government intends to consider further whether to introduce 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. We are interested in the traceability benefits this could bring.

As supported by the majority of respondents, the government intends to proceed with its proposal for economic operators to be given up to a 30-day **timeframe to update an MHRA registration record after a change has been made to registration details**. The government recognises that respondents gave limited rationale for their proposed timeframes, but some references were made to the need to consider the burden on manufacturers and take an approach proportionate to risk of a device, as well as calls for alignment with the EU MDR. Taking this feedback into account, we consider that allowing 30 days to update information will ensure that the MHRA has timely, accurate information to share with the public and utilise as appropriate if an issue with a device arises.

The government also intends to introduce **a requirement for economic operators to confirm all data submitted in their device registration** one year after submission and then every second year thereafter. The government acknowledges that there was not strong support for this provision from respondents, and objections raised included that the introduction of a 30-day requirement to update the MHRA of any changes would be sufficient. However, it is the government's view that ensuring the accuracy of medical device registration information is a crucial aspect of regulation and that the benefits of having in place assurances of the accuracy outweigh any concerns about additional burden to industry that an annual/biennial update would pose.

The government intends to require the **identification of certain economic operators** (such as manufacturers (including assemblers or sterilisers of system of procedure packs), UK Responsible Persons, importers and distributors of a medical device to register with the MHRA. We intend that when registering, these economic operators will need to be issued with a unique MHRA-generated number. In addition, if it is already held, an economic operator will be able to voluntarily provide another internationally recognised external reference (for example, DUNS, GLN, SRN).

## 5 – Approved Bodies

The MHRA is responsible for the designation of Approved Bodies in the UK and the consultation proposals included a range of enhanced requirements for Approved Bodies, to improve transparency and ensure that Approved Bodies work to a consistent standard across the whole of the UK. This will increase patient safety through better alignment and increased scrutiny of medical devices placed on the UK market.

### Section 23 – Requirements of Approved Bodies

#### 23.1 Proposals and feedback

When asked whether the UK medical devices regulations should place more stringent **requirements on Approved Bodies**, as outlined in the consultation, 201 responses were received, of which:

- 73% supported the proposal
- 15% did not support the proposal
- 11% did not know or had no opinion

When asked to outline any other requirements for Approved Bodies, 109 responses were received. A number of common themes were raised, which can be summarised as follows:

- there should be requirements to ensure that Approved Bodies have the necessary technical competence
- requirements for Approved Bodies should be aligned with EU regulations
- impartiality and independence requirements should be clarified in regulations and/or guidance
- Approved Bodies should be able to provide advice relating to the correct implementation of the regulatory requirements and maintaining compliance with these
- no additional requirements should be introduced

When asked whether Approved Bodies should be able to conduct fully remote or hybrid audits of their clients in specific circumstances, out of 201 responses:

- 87% were in favour
- 7% were not in favour
- 6% did not know or had no opinion

The consultation proposed that fully remote audits could be used in specific circumstances – for example, where there are restrictions on international travel or safety concerns due to a pandemic or civil unrest. Hybrid audits, where some elements are completed onsite and others remotely, could potentially be allowed more generally.

When asked to outline any criteria that 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, 84 respondents provided information, including:

- fully remote audits should only be allowed in exceptional circumstances, and should never become the norm
- Approved Bodies should be able to apply remote or hybrid audits on a case-by-case basis using a risk-based approach with appropriate justification
- a remote/hybrid approach is more efficient, and cost and time effective

- remote audits should only be allowed where information can be provided electronically, and inspection of a manufacturing site is not required
- remote audits have worked well during the pandemic and should become the norm

The MHRA sought views on options for the legal status for an Approved Body. Responses were as follows:

- a distinct legal entity based in the UK (the company as a whole) (**26%**)
- a distinct legal entity based in the UK or with a branch in the UK (**52%**)
- other (**12%**)
- don't know/ no opinion (**10%**)

Of the respondents that selected 'other', 4 respondents provided information, including:

- an Approved Body should not be required to be based in the UK (**3%**)
- any EU Notified Body or UK Approved Body should qualify (**3%**)
- any CE-Approved Body should qualify (**3%**)
- disagreed with all options (**3%**)

When asked to provide reasoning to support their answers on requirements for Approved Bodies, 90 respondents provided input. Common themes can be summarised as follows:

- in order to act in the best interests of UK medical device manufacturers it would be beneficial to have legal entities that have a vested interest in the UK
- requirements on Approved Bodies should not be too restrictive to ensure that a sufficient number of Approved Bodies are available for the medical devices industry
- every aspect should be driven by quality and traceability with appropriate accountability within the UK
- these changes are in the interest of enhanced patient safety and transparency around Approved Bodies
- the Approved Body should be a distinct legal entity based in the UK, but may be a division of a larger, international organisation as is common with major international certification bodies

## 23.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposal to **place additional requirements on Approved Bodies**. The requirements the government is looking to introduce are as outlined in the consultation text. There was strong support for introducing more stringent requirements on Approved Bodies, and in particular for these requirements to align with other jurisdictions.

The government is concerned about the ability of Approved Bodies to conduct on-site audits amid special circumstances, such as a global pandemic. It is the government's view that allowing fully remote or hybrid audits in disruptive circumstances that otherwise make it difficult for Approved Bodies to conduct on-site audits, will enhance the functioning of the UK medical devices regulatory system.

In light of comments from respondents and recent experiences, the government intends to allow Approved Bodies to conduct **fully remote or hybrid audits of their clients in specific circumstances**. The government notes the consultation feedback that the circumstances in which hybrid or full remote audits are permitted to be undertaken should be genuinely disruptive / justified.

We consulted on whether Approved Bodies should have a **distinct legal presence in the UK** and a range of options for the legal status for an Approved Body were proposed. After careful consideration of responses, the government notes that the largest portion of respondents were in support of the option that would require an Approved Body to be a distinct legal entity based in the UK or to have a branch in the UK. However, 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. It is the government's intention to proceed with the proposal to amend the UK medical devices regulations to require an Approved Body to be a distinct legal entity based in the UK. Guidance will be published to clarify the processes and procedures in this area.

## **Section 24 - Subsidiaries**

### **24.1 Proposals and feedback**

We sought views on whether Approved Bodies with subsidiaries should meet the following requirements:

- a) publish high-level monitoring activities undertaken relating to subsidiaries
- b) publish a list of subsidiaries accompanying the designated scope of the Approved Body

Out of 132 responses:

- 80% were in favour of this approach
- 6% were not in favour
- 14% did not know or had no opinion

We invited consultees to outline any other requirements which should be placed on Approved Bodies using subsidiaries. The common themes from the 53 responses can be summarised as follows:

- ensure Approved Bodies maintain alignment in expectations, interpretations, and support with their subsidiaries
- publishing a list of subsidiaries used by the Approved Body will ensure transparency to the public and clients of the Approved Body
- Approved Bodies should be fully accountable for the activities of subsidiaries

When asked to provide reasoning to support their answers to the questions on subsidiaries, 59 responses were received, and the following themes were identified:

- support for the proposals as the benefits are increased transparency and improved oversight
- requirements on Approved Bodies and their subsidiaries should align with EU MDR/IVDR as much as possible
- subsidiaries are as important as Approved Bodies, and they should be publicly known and accountable

### **24.2 The government response**

After careful consideration of responses, it remains the government's intention to proceed with the proposal to amend the UK medical devices regulations to provide more visibility of **Approved Bodies using subsidiaries**, which will include the requirement for Approved Bodies to publish high-level monitoring activities undertaken relating to subsidiaries and to publish a list of subsidiaries accompanying the designated scope of the Approved Body.

## Section 25 – Approved Bodies designation and monitoring

### 25.1 Proposals and feedback

We asked whether the UK medical devices regulations should require **Approved Bodies applying for designation** to hold appropriate UK Accreditation Service (UKAS) accreditation. 180 responses were received, of which:

- 66% supported the proposed requirement
- 18% were not in favour
- 15% did not know or had no opinion

When these answers were separated between individual respondents and organisations, **individuals** answered the previous question as follows:

- 84% of respondents supported the proposed requirement
- 7% were not in support
- 8% did not know or had no opinion

While a lower proportion of **organisations** were in favour:

- 59% of respondents supported the proposed requirement
- 24% were not in support
- 17% did not know or had no opinion

When asked if the UK medical devices regulations should be amended to include new requirements for **MHRA assessment of Approved Bodies**, out of 180 responses:

- 82% were in favour of this proposal
- 7% were not in favour
- 11% did not know or had no opinion

As set out in the consultation, 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, for example, where concerns are raised regarding that Approved Body.

We invited consultees to outline any other requirements which should be introduced for MHRA assessment of Approved Bodies. 70 responses were received and can be summarised as follows:

- the regulations should retain the option for MHRA to undertake re-assessment if considered warranted in certain circumstances
- there is a need to increase the capacity of Approved Bodies in the UK
- align with requirements of EU MDR/IVDR
- unannounced audits should be introduced

We asked whether the MHRA should be able to perform **remote audits** of Approved Bodies or their subsidiaries in specific circumstances. 181 responses were received, of which:

- 86% were in support
- 6% were not in favour
- 8% did not know or had no opinion

We asked those who answered in support of this question to further outline any criteria that they 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 considered. 91 respondents provided feedback which is summarised as follows:

- remote audits should be for exceptional circumstances, and onsite audits should be the norm
- remote audits should be applied to Approved Bodies with a strong audit history
- remote audits should be considered for more circumstances, as it would have a positive environmental impact by reducing the need for travel
- there should be detailed criteria as to when remote or hybrid audits are allowed

We sought views on possible transitional arrangements, for roll over of Approved Body designations issued prior to July 2023 until expiry of the designation, with certain conditions outlined in the consultation. Of 178 responses:

- 49% supported the proposals
- 21% were unsupportive
- 30% did not know or had no opinion

When these answers were separated between individual respondents and organisations, **individuals** answered the previous question as follows:

- 59% were supportive
- 17% were unsupportive
- 19% did not know or had no opinion

While a lower proportion of **organisations** were in favour:

- 41% were supportive
- 24% were unsupportive
- 35% did not know or had no opinion

Respondents were asked to provide their reasoning for their previous answer and to expand on what they considered would be suitable criteria for this 'roll over' if any. 69 responses were received, and the common themes were:

- allowing Approval Bodies to roll-over designation would allow Approval Body capacity to be better managed
- the approach would minimise administrative burden during the transition phase
- most respondents agreed with a 6-month roll-over period (as set out in the consultation), and some respondents thought this could be extended to 12 or 24 months

Respondents were asked whether the MHRA should be required to perform the tasks set out below in the event of Approved Body designation withdrawal, restriction, or suspension and assess the impact on the certificates issued by the Approved Body:

- require the Approved Body to suspend or withdraw, within a reasonable period of time determined by the MHRA, any certificates which were unduly issued to ensure the safety of medical devices on the market
- ensure the certificates are marked as suspended or withdrawn on the MHRA registration system

Out of 180 respondents:

- 83% were in favour of this approach
- 4% were not in favour

- 13% did not know or had no opinion

Respondents were asked whether 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. Out of 178 responses:

- 84% were supportive of this approach
- 4% were unsupportive
- 12% did not know or had no opinion

We invited consultees to outline any circumstances in which certificates should remain valid on an ongoing basis or for a defined time period. The common themes for the 94 responses can be summarised as follows:

- in the event that an Approved Body ceases to exist or be approved, there should be fail safes in place to protect manufacturers and the supply of devices
- certificates should remain valid for essential devices with no UKCA marked alternatives
- certificates should remain valid where the 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 has outlined a timeline and actions anticipated to remedy the suspension or restriction

When asked whether the UK medical devices regulations should introduce requirements for Approved Bodies in relation to how they conduct their activities (which could include points a-d outlined below):

- a) make their fees available on request to any interested party
- b) where they cease their activities unexpectedly, inform the MHRA and the manufacturers concerned as soon as possible
- c) where they plan to cease their activities, inform the MHRA and the manufacturers concerned one year before ceasing their activities
- d) where they have ceased their activities (planned or unexpected) take any reasonable actions to find a suitable Approved Body to take on their clients

176 responses were received, of which:

- 84% were in support of the requirements below
- 7% did not support the requirements
- 10% did not know or had no opinion

Consultees were asked to outline any other requirements which they considered should be introduced in relation to how Approved Bodies conduct their activities. Common themes raised by the 76 respondents can be summarised as follows:

- Approved Body fees and costs should be transparent and readily available
- there should be consistency across all Approved Bodies
- set timelines for assessments with suitable clock stop periods to respond to questions would be seen as a benefit and would allow greater predictability on when products can be made available

When asked to provide reasoning (including any available relevant evidence) to support their answers to all questions on Approved Body designation and monitoring, including any impacts

them or other stakeholder groups, 83 responses were received. Key themes can be summarised as follows:

- these seem essential to ensure the public's confidence in the safety of approved medical devices
- the capacity for reviewing medical devices is finite
- need to ensure the continuation of supply of medical devices in the UK
- need to support consistency and transparency in the approach taken by Approved Bodies
- implementation of the requirements must be made with clarity and efficiency

## 25.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposal to require Approved Bodies applying for designation to hold appropriate **UKAS accreditation**. The processes and procedures to deliver this will be laid out in guidance.

The government also intends to proceed with the proposal to amend the UK medical devices regulations to include new requirements for **MHRA assessment of Approved Bodies**. This could include, for example, 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.

We intend to also take forward the proposal to amend the UK medical devices regulations to provide that **MHRA's audit of an Approved Body or their subsidiaries** may be conducted partially or fully remotely in specific circumstances. Based on the consultation feedback, we intend to provide that such circumstances may include situations where there are no significant concerns about the performance of an Approved Body and where at least one on-site audit has already taken place.

A **transitional arrangement** for the roll-over of designation was proposed in the consultation, specifically that: Approved Body designations issued prior to formal implementation date should be 'rolled over' until the expiry of the designation. We will proceed with this proposal. The MHRA may also assess the Approved Body to review their records, systems, procedures and processes to ensure readiness and compliance in time for the implementation date of any new requirements that will apply to these Approved Bodies with rolled over designations.

It is the government's intention to proceed with the proposal to amend the UK medical devices regulations to provide that, in the event of **Approved Body designation withdrawal, restriction, or suspension**, the MHRA should be required to perform the tasks set out below:

- assess the impact on the certificates issued by the Approved Body
- require the Approved Body to suspend or withdraw, within a reasonable period of time determined by the MHRA, any certificates which were unduly issued to ensure the safety of medical devices on the market
- ensure the certificates are marked as suspended or withdrawn on the MHRA registration system

In relation to whether 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, it is the government's intention to proceed with the proposal as outlined in the consultation.

The consultation outlined that the UK medical devices regulations could be amended to adopt the following requirements for Approved Bodies in relation to how they conduct their activities.

- a. make their fees available on request to any interested party
- b. where they cease their activities unexpectedly, inform the MHRA and the manufacturers concerned as soon as possible
- c. where they plan to cease their activities, inform the MHRA and the manufacturers concerned one year before ceasing their activities
- d. where they have ceased their activities (planned or unexpected) take any reasonable actions to find a suitable Approved Body to take on their clients

It is the government's intention to proceed with adopting the requirements outlined in points b, c and d. The government (alongside many respondents) is concerned about the commercial effect of requiring an Approved Body to make their **fees available on request** to any interested party. Based on responses received on this issue, the government intends to amend the requirement outlined in (a) to require that an Approved Body make their fees available on request by the Secretary of State.

## 6 – Conformity Assessments

The UK medical devices regulations set out the process that must be followed in applying for, or undertaking, a conformity assessment. The MHRA is interested in having greater transparency and consistency in conformity assessments, with the aim of ensuring that conformity assessments are carried out consistently and robustly, effectively assessing medical devices to assure their safety, quality and performance.

**The purpose of the consultation in this area was to assess existing conformity assessment procedures to determine whether they require clarification or strengthening in order to ensure that the quality, safety and performance objectives laid out above are met. In the case of rarely utilised conformity assessment routes, the consultation sought to determine whether these should be removed.**

### Section 26 – Conformity Assessment

#### 26.1 Proposals and feedback

When asked whether the conformity assessment requirements for medical devices should be clarified and strengthened for medical devices as set out in the consultation text, 244 responses were received, of which:

- 72% supported the proposal
- 18% did not support the proposal
- 11% did not know or had no opinion

Respondents made additional suggestions for requirements that could be introduced to strengthen the conformity assessment process, which are summarised below:

- aligning with international practices would bring economic and operational benefit to manufacturers by streamlining the conformity assessment process across markets
- details relating to the structure of a technical file should be covered in guidance
- devices with a risk category of IIa or above should require 100% of technical documentation to be assessed

When asked how long they felt the manufacturer should be required to keep technical documentation for a medical device they have manufactured, respondents answered as follows:

- a. 1-5 years after the last product has been manufactured (**6%**)
- b. 6-10 years after the last product has been manufactured (**19%**)
- c. 11-15 years after the last product has been manufactured (**14%**)
- d. for the expected lifetime of the device, after the last product has been manufactured (**33%**)
- e. other (**28%**)

Responses for 'other' included:

- the expected lifetime of the patient using the device
- align with the EU MDR and IVDR
- the required time should be longer for implantable devices
- product lifetime plus a number of specified years. Suggestions included 5, 10 and 25 years

When asked whether certain conformity assessment routes, including batch verification, product quality assurance and type examinations, should be removed from the UK medical devices regulations, 229 responses were received, of which:

- 27% of respondents were in support of the proposal
- 36% were not in support of the proposal
- 37% did not know or had no opinion

Respondents were invited to provide reasoning for their answers to questions in this section. Key points can be summarised as follows:

- rarely utilised conformity assessment routes place strain on Approved Bodies
- small and medium-sized enterprises (SME) manufacturers benefit from having a range of routes available to them
- various conformity assessment routes provide manufacturers with flexibility even if rarely used
- additional conformity assessment options cause some confusion and clearer guidance is required
- a number of respondents were unaware that batch verification, product quality assurance and type examinations were options for conformity assessment under the current regulations or had not heard of these options at all

## 26.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposals to:

- remove the option to use batch verification (except for Class D *in vitro* diagnostic medical devices (IVDs)) and type examination for all medical devices. However, for production quality assurance, this route will only be removed for class III, IIb devices and IVDs.
- improve the scrutiny placed on implantable medical devices. The future regulations will require that Class IIb implantable devices (except for sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors) will be subject to 100% review of their technical documentation as opposed to a representative review by Approved Bodies.
- require that reusable surgical instruments undergo review by an Approved Body with respect to aspects relating to the reusability of the device such as sterilisation and functional testing
- prohibit manufacturers from lodging parallel conformity assessment applications with more than one Approved Body for the same assessment
- set out a requirement in regulations that Approved Bodies must specify within their internal procedures a time limit to respond to a conformity assessment application
- require manufacturers to declare whether they have withdrawn an application with another Approved Body prior to the decision of the Approved Body they have applied to and provide information about any previous application for the same conformity assessment that has been refused by another Approved Body
- require Approved Bodies to inform other Approved Bodies and the MHRA of any manufacturer that withdraws its application prior to the Approved Body's decision regarding the conformity assessment
- specify the required structure of a manufacturers' technical file for a medical device

Following careful consideration of responses, the government's intention is to proceed with the proposal to increase the **document retention timescales for implantable devices** to the

expected lifetime of the device or at least 15 years, after the last product has been manufactured (for when the expected lifetime of the device is less than 15 years). Similarly, for non-implantable devices, the timescale for document retention will be increased to the expected lifetime of the device or at least 10 years, after the last product has been manufactured (for when the expected lifetime of the device is less than 10 years).

Having considered the views of respondents, the government notes that batch verification, product quality assurance and type examinations are rarely used and place additional burden on Approved Bodies, which can slow the assessment process overall. Given this, the government intends to proceed with the proposal to amend the UK medical devices regulations to exclude these as possible conformity assessment routes. The government acknowledges concerns raised by some respondents that this may disproportionately impact SMEs. However, we consider that the amendments listed earlier in this chapter will facilitate more effective conformity assessment through a clear route. See Chapter 14 on alternative routes to market for further details on supported market access.

## **Section 27 – Mechanism for transparency and scrutiny of conformity assessments of certain medical devices**

### **27.1 Proposals and feedback**

The consultation sought views on whether Approved Bodies should be required to notify the MHRA of certificates they have granted for medical devices with the accompanying documentation, as set out in the consultation text. 193 responses were received, of which:

- 58% were in favour of the proposed requirement
- 25% felt were unsupportive
- 18% did not know or had no opinion

The consultation invited views on whether the MHRA should apply additional scrutiny to the conformity assessment report for certain classes/types of medical devices. Out of 194 responses:

- 51% supported the proposal
- 37% did not support the proposal
- 13% did not know or had no opinion

Free-text responses detailing which types or classes of medical device this additional scrutiny should be placed on can be summarised as follows:

- class IIb implantable medical devices and above
- combination products
- software as a medical device
- all implantable devices
- a risk-based approach should be taken based on intended use

Other information provided in comments from respondents relating to the questions in Section 27 can be summarised as follows:

- MHRA should not have increased involvement in Approved Bodies' work
- MHRA should not have increased involvement in Approved Bodies' work unless there is a defined benefit to patients
- Approved Bodies should provide MHRA with certificates and accompanying documentation for general medical devices
- higher risk devices should have greater scrutiny on their conformance to the UK medical devices regulations

## **27.2 The government response**

After careful consideration of the responses, the government acknowledges the support to require Approved Bodies to notify the MHRA of certificates they have granted and to require the MHRA to apply additional scrutiny to the conformity assessment reports for certain classes as outlined in the consultation. It remains the government's intention to proceed with both proposals. However, we are considering further whether this requirement will be added to the upcoming regulations or whether it will be instead form part of a future regulatory update.

## **Section 28 – Certificates of Conformity**

### **28.1 Proposals and feedback**

The consultation invited views on whether the UK medical devices regulations should detail the minimum content of certificates of conformity, which must be provided for in English. 214 responses were received, of which:

- 87% supported the proposal
- 5% did not support the proposal
- 7% did not know or had no opinion

In the follow-up free text question, many respondents signalled their support for requiring that certificates include the data proposed in the consultation text.

The consultation invited views on whether Approved Bodies should be allowed to impose restrictions/requirements on the use/follow-up of certain medical devices as set out on the consultation. 204 responses were received, of which:

- 67% supported the proposal
- 22% did not support the proposal
- 18% did not know or had no opinion

When asked what restrictions / requirements Approved Bodies could impose, we received feedback from 103 respondents. This can be summarised as follows:

- restrictions or requirements should be limited to high-risk devices
- the risk category of the device should determine the level of Approved Body involvement
- conditional approvals or the requirements for specific post-market clinical/performance follow-up studies should be imposed but informed by clinical evidence during the conformity assessment
- allowing Approved Bodies to impose restrictions may discourage innovation and hinder supply of new products on the UK market

The consultation sought views on whether the UK medical devices regulations should require Approved Bodies to enter information about certificates into the MHRA registration system. Of the 205 responses:

- 72% supported the proposal
- 14% did not support the proposal
- 14% did not know or had no opinion.

Additional comments provided in relation to the certificate information that Approved Bodies should be required to submit can be summarised as follows:

- increasing the level of information that Approved Bodies are required to enter into the MHRA system will put strain on Approved Body resources
- requiring Approved Bodies to enter information into the MHRA database may duplicate data and workload

## 28.2 The government response

After careful consideration of responses and in light of the high level of support from consultees, it remains the government's intention to proceed with the proposal to **detail the minimum content of Certificates of Conformity** within the regulations.

The government acknowledges both the support and the concerns expressed by respondents regarding the proposal to **allow Approved Bodies to impose restrictions or requirements** on the use or follow-up of certain medical devices. After careful consideration of the responses, it remains the government's intention to proceed with the proposal, which will deliver improved patient safety and better regulatory oversight.

The government has noted the support for the proposal to introduce **requirements for Approved Bodies to enter information about conformity certificates into the MHRA registration system**. However, an appropriate IT system needs to be available to deliver this, which is not yet in place and the provision is therefore suspended for future consideration. In the meantime, Approved Bodies will be required to provide the MHRA with the information about certificates of conformity via an alternative route until the registration system is in place.

## Section 29 – Voluntary change of Approved Body

### 29.1 Proposals and feedback

The consultation sought views on whether, in cases where a manufacturer terminates its contract with an Approved Body and enters into a contract with another Approved Body, in respect of the conformity assessment for the same medical device, the UK medical devices regulations should set out the minimum content that should be included in the agreement for a change of Approved Bodies. Of the 163 responses:

- 71% supported this proposal
- 9% did not support the proposal
- 21% did not know or had no opinion.

Respondents were invited to comment on what should be included in an agreement for a change of Approved Bodies. Feedback can be summarised as follows:

- the agreement requirements should align with the EU to allow for ease of transition
- only specific documents should be included
- this requirement would improve transparency within the conformity assessment process
- the only information required should be notifying the MHRA, as a requirement to provide further information would place additional strain on manufacturers and Approved Bodies
- having a clear agreement will ensure the transition process is smooth for manufacturers

### 29.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposal. We are mindful of the comments made in relation to resource and capacity impacts but consider that setting out the minimum requirements in the regulations will ultimately help manufacturers and Approved Bodies plan for and execute such **transfers between Approved Bodies** and will standardise the approach to these transfers.

## Section 30 – Declaration of Conformity

### 30.1 Proposals and feedback

The consultation sought views on whether the UK medical devices regulations should set out the minimum content requirements for the Declaration of Conformity as listed in the consultation text.

Of 231 respondents:

- 91% supported this proposal
- 6% did not support the proposal
- 3% did not know or had no opinion

Respondents were invited to provide additional comments in relation to declarations of conformity, which can be summarised as follows:

- aligning with EU requirements will reduce operational burden on manufacturers
- setting out a consistent approach is useful for SMEs when producing documentation
- including all of the information listed in the consultation is useful for detailed and accurate record keeping

### 30.2 The government response

After careful consideration of responses and in light of the high level of support, it remains the government's intention to proceed with the proposal to set out the **minimum content requirements for the Declaration of Conformity** as listed in the consultation text in order to facilitate a more consistent approach and remove ambiguity.

## 7 – Clinical Investigation and Performance Studies

The consultation considered whether the UK medical devices regulations should include more detailed requirements for conducting and documenting a clinical evaluation. The objective of this would be to ensure that medical device manufacturers conduct effective, consistent and systematic clinical evaluations of their medical devices, taking into account all relevant clinical data, in order to demonstrate that a medical device is safe and performs as intended.

This would help ensure that medical devices are not placed on the UK market unless there is sufficient evidence of their safety and performance.

### Section 31 – Clinical evaluation (general medical devices)

#### 31.1 Proposals and feedback

Currently, manufacturers can use the clinical data arising from investigations of a similar 'equivalent' device as evidence that their own device is safe and performs as intended (due to the similarities between the devices). This can result in 'product creep' where new devices on the market in practice become very different from their 'equivalent' devices.

The MHRA consulted on proposals to introduce stricter requirements for claiming equivalence. These included requirements for an equivalent medical device to be 'entirely equivalent' to the manufacturer's medical device and for appropriate contractual arrangements to be in place with the manufacturer of the predicate device. Of 218 respondents:

- 61% supported the proposals outlined in the consultation relating to claiming equivalence
- 35% were not in support of these proposals
- 4% did not know or had no opinion

Those who supported this proposal reasoned that industry, patients and other stakeholders need regulatory certainty and that requirements around entire equivalence would lead to improved patient and public safety.

Suggestions for additional requirements that could be introduced around claiming equivalence included:

- the contractual arrangements referred to above should cover adverse event data
- recalls of predicate devices should be extended to the chain of 'equivalent' devices
- it was also noted that the approach may cause issues for registering or listing legacy devices

Comments from those that did not support the proposal were mainly based on the concern that more stringent requirements for claiming equivalence could stifle innovation and would be burdensome on industry and resources. Some respondents considered that requirements around claiming equivalence should be balanced against the class and risk of the device. Others caveated their support and commented that we should align with the EU's position on equivalence, rather than requiring that devices must be "entirely equivalent".

We also invited views on equivalence from respondents to the abridged consultation (Chapter 17). Of the 56 respondents to this question:

- 80% were in favour of introducing stricter requirements for claiming equivalence

- 13% were not in favour
- 7% did not know or had no opinion

The abridged consultation also invited views from those who answered ‘yes’ to the previous question to indicate their preferred requirements for claiming equivalence. Out of 44 responses selected options as follows:

- the device the manufacturer is claiming equivalence to, should be “entirely equivalent” to the manufacturer’s medical device (on a biological, physical, and clinical basis) **(39%)**
- where a manufacturer does claim equivalence to another medical device, they must have a contract with the manufacturer of that medical device to allow them full access to the device’s necessary documentation **(9%)**
- manufacturers claiming equivalence must have post-market studies in place to collect their own data, once the device is on the market **(27%)**
- manufacturers of certain devices such as implantable and Class III devices cannot claim equivalence to other devices except in specific circumstances **(14%)**
- other **(11%)**

When asked to provide rationale for the answers on clinical evaluations in Chapter 17, some respondents suggested that requirements should align with EU and US approaches, while others noted that equivalent devices should either be the same as or similar to the predicate device. Other comments identified a need to consider equivalence of manufacturing techniques, while some noted a preference for a risk-based approach, with higher risk devices subject to more stringent requirements.

We invited views on whether manufacturers of **products without an intended medical purpose** should be required to perform clinical investigations or other pre-market studies involving human subjects/participants and that such products should be regulated under the UK medical devices regulations, unless reliance on existing clinical data from an entirely equivalent medical device is duly justified. Of 213 respondents:

- 61% supported the proposal
- 17% did not support the proposal
- 23% did not know or had no opinion

### 31.2 The government response

After careful consideration of consultation responses, the government intends to introduce requirements on entire equivalence on a **biological, technical and clinical basis** (please note that we have amended the wording from “physical” basis in the consultation document to “technical” basis in order to align with the recognised international terminology). This approach would take us beyond the equivalence requirements in the EU MDR. There was support for this among consultation respondents and we consider that this approach will lead to improvements in patient and public safety. The government recognises that there was also support among consultees for alignment with EU requirements. However, we consider that the proposed approach will help mitigate the risks of ‘product creep’ where new devices on the market in practice become very different from their ‘equivalent’ devices. In addition to making legislative changes in this area, the MHRA will provide clear and detailed guidance on this topic.

The government also intends to proceed with the proposal to introduce clinical investigation requirements for **products with similar functions and risk profiles to medical devices that do not have an intended medical purpose**. We will provide supplementary guidance on these

requirements and will work with the Health Research Authority and the Devolved Administrations regarding any requirements for ethical review.

## **Section 32 – Performance evaluations (IVDs)**

### **32.1 Proposals and feedback**

We sought views on whether confirmation of conformity of an *in vitro* diagnostic device (IVD) within the UK medical devices regulations should be based on scientific validity, analytical and clinical performance data. Of 140 respondents:

- 86% supported the proposal
- 1% did not support the proposal
- 13% did not know or had no opinion

The consultation invited views on whether manufacturers should be required to produce a performance evaluation report as part of the technical documentation for the device. Of 139 respondents:

- 86% supported the proposal
- 1% did not support the proposal
- 13% did not know or had no opinion

We asked consultees whether manufacturers should be required to specify and justify the level of clinical evidence necessary to demonstrate conformity with the UK medical devices regulations. Of 137 respondents:

- 81% supported the proposal
- 4% were unsupportive
- 15% did not know or had no opinion

We invited views on whether 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. Of 138 respondents:

- 74% supported the proposal
- 14% did not support the proposal
- 12% did not know or had no opinion

Those in favour of introducing the above proposals suggested that the following factors could be included in the justification:

- proof of safety and functionality
- the device could be substantially rather than entirely equivalent to the predicate device
- published peer-reviewed literature / study data
- reliance on other sources (in addition to small scale studies) could get products to market more quickly
- clinical evidence could be derived from real world evidence
- clinical evidence could be derived from registries

Other respondents commented that alignment with the EU IVDR and with relevant standards would be beneficial.

We asked consultees whether the UK medical devices regulations should require that the performance evaluation is updated throughout the lifetime of the IVD, and that performance evaluation data should be used to update the summary of safety and clinical performance (SSCP) and the post-market performance follow-up report (PMPF). Of 137 respondents:

- 82% were in favour of the proposal
- 5% of did not support the proposal
- 13% did not know or had no opinion

When asked how the evaluation should be updated by the manufacturer and whether any other technical documentation should be updated, respondents made the following suggestions:

- requirements should be proportionate to device risk class (for example, more frequent updates for higher risk devices)
- updates should be made on a continuous basis, for example, when a manufacturer has new information on risks associated with a device or when the use case changes or when the design or function changes
- the documents should be updated to a regular schedule - for example, annually, biannually, every 5 years and product lifecycle should be considered
- manufacturers should inform users of issues with false results and the Yellow Card scheme could support this

Other comments provided on this topic included:

- there is a need to take account of Approved Body capacity in terms of validation of technical documents
- there is a need to avoid additional burdens, particularly for small and medium-sized enterprises (SMEs) and for well-established devices, and the requirements should be proportionate

## 32.2 The government response

Taking into account the high degree of support, it remains the government's intention to introduce the proposals outlined in this section of the consultation. The government also intends to provide guidance regarding what the **justification for reliance on other sources of clinical performance data** should include. In developing the guidance, the MHRA will reflect on the points raised in the consultation, including the need for international alignment, the role of designated standards in demonstrating compliance, and the clinical performance data sources that can be used to support the justification.

Reflecting on consultation feedback, the government considers that the requirement should be that the **SSCP and PMPF** are updated on at least an annual basis. There would be nothing to preclude a manufacturer from updating these documents more frequently, for example, on a continuous basis or in response to changes in device design or function. This approach aligns with international practice. We consider that it is best practice for the manufacturer to regularly review available evidence on state of the art to ensure that they are keeping abreast of any new developments.

This approach is intended to support international alignment and consistency for manufacturers. The government is mindful of the need to avoid unnecessary manufacturer burden (particularly for SMEs) but considers that setting requirements for an **annual review** should not be overly onerous and is necessary for safety reasons. As noted above, this approach does not prevent manufacturers from updating more frequently where necessary and we would encourage this.

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

### 33.1 Proposals and feedback

#### Requirements for clinical investigations

The consultation invited views on whether clinical investigations regulated under the UK medical devices regulations should be limited to those carried out for one of the purposes outlined in the consultation. 175 responses were received, of which:

- 75% were in support of the proposal
- 10% did not support the proposal
- 15% did not know or had no opinion

In regard to the proposal that in situations where the sponsor of a clinical investigation or performance study is based outside the UK, they should be **required to appoint a legal representative in the UK**, 177 responses were received, of which:

- 63% were in support of the proposal
- 16% did not support the proposal
- 21% did not know or had no opinion

The consultation invited views on whether the legal representative should be responsible for ensuring compliance with the clinical investigation sponsor's obligations and be the addressee for all communications with the sponsor. Of the 175 responses received:

- 62% were in support of the proposal
- 16% were not in favour of the proposal
- 22% did not know or had no opinion

On the proposal that any communication with that legal representative should be deemed to be communication with the clinical investigation sponsor, 174 responses were received, of which:

- 63% supported the proposal
- 16% were not in favour of the proposal
- 21% did not know or had no opinion

The consultation invited views on whether the UK medical devices regulations should set out the **sponsor obligations** for a clinical investigation. 174 responses were received, of which:

- 76% were in support of the proposed approach
- 9% were not in favour of this approach
- 15% did not know or had no opinion

Suggestions of other requirements that respondents considered should be introduced for the sponsor of a clinical investigation included:

- requirement for the sponsor to publish the study summary
- requirements around the reporting of serious adverse incidents
- requirement to appoint an independent monitor
- requirement to appoint a UK Responsible Person

Some respondents raised concerns over additional burdens that may be associated with these requirements.

The consultation invited views on whether the UK medical devices regulations should set out the minimum requirements for the **clinical investigation report**, as set out in the consultation. Of the 177 responses:

- 87% were in favour of the proposal
- 6% were not in favour
- 7% did not know or had no opinion

Respondents made the following suggestions for other requirements which they considered should be introduced regarding the clinical investigation report:

- refer in the regulations to specific standards (for example, International Organization for Standardization (ISO) standard 14155, and ISO 20916) to ensure consistency
- an accessible report or summary, suitable for lay persons, should be published
- clarify timelines on notification of end of trial and submission of reports
- the report should include patient-related outcomes
- a template of the clinical investigation report should be provided in guidelines

Other respondents commented that alignment with the EU MDR/IVDR would be beneficial.

The consultation sought views on whether the UK medical devices regulations should require the sponsor to publish the clinical investigation report. 174 responses were received, of which:

- 61% were in support of this proposal
- 25% were not in support of the proposal
- 14% did not know or had no opinion

The consultation sought views on whether the UK medical devices regulations could be amended to further clarify and supplement the existing **requirements relating to the methods for a clinical investigation**. 175 responses were received, of which:

- 79% were in support of this proposal
- 12% were not in support
- 9% did not know or had no opinion

Respondents also outlined other requirements, relating to the methods for a clinical investigation, that they considered could be introduced - including:

- clinical investigation sites and investigator training should be strengthened and recorded
- we should require the recording of patient outcomes
- we should require long term follow-ups
- MHRA should provide a template for reports, with focus on endpoints and outcomes

Many respondents commented that alignment with the EU MDR and ISO 14155 would be beneficial and that there is a strong need for specific guidance to support the regulations. Others noted that more clarity is required on what is meant by 'clinical benefit'.

The consultation invited views on whether the UK regulations should set out more detailed requirements for **the clinical investigation plan**, as outlined in the consultation. 176 responses were received, of which:

- 79% were in favour of the proposal

- 10% were not in favour of the proposal
- 11% did not know or had no opinion

Respondents also made the following comments in relation to requirements for the clinical investigation plan:

- there is a need to align with the EU MDR
- standards are sufficient and there is no need to add further requirements to the regulations
- it is not necessary to include financial arrangements in the clinical investigation plan

The MHRA consulted on proposals to expand the **conditions that must be met when performing a clinical investigation** and set out a number of possible requirements in the consultation. 174 responses were received, of which:

- 79% were in support of the proposal
- 10% did not support the proposal
- 11% did not know or had no opinion

The MHRA asked respondents to outline any other requirements that should be met when performing a clinical evaluation. Key points can be summarised as follows:

- requirements should align with the EU MDR and ISO 14155; or potentially with medicines clinical trials
- clinical Investigations should represent diverse populations, racial bias should be reduced where possible and we should consider using gender neutral terms, for example, refer to breastfeeding 'people' rather than 'women'
- the proposed requirements may be overly stringent
- the requirement for a UK-based legal representative was challenged

The consultation invited views on whether the UK medical devices regulations should set out the **rights of subjects/participants to withdraw from clinical investigations** at any time without any resulting detriment and without having to provide any justification. 172 responses were received, of which:

- 83% were in favour of the proposal
- 5% were not in favour of the proposal
- 12% did not know or had no opinion

When asked for views on the introduction of **qualification requirements for investigators of clinical investigations and personnel** involved in clinical investigations as set out in the consultation, 173 responses were received, of which:

- 79% were in favour of the proposal
- 6% were not in favour of the proposal
- 15% did not know or had no opinion

Some respondents supported the consultation proposals and felt that no additional requirements beyond those proposed were needed for investigators of and personnel involved in clinical investigations, and many respondents proposed that aligning with EU MDR and IVDR would be beneficial.

Respondents suggested that the following requirements should be introduced for investigators of and personnel involved in clinical investigations:

- follow relevant standards

- follow Good Clinical Practice Guidelines
- be inclusive - for example, include nurses, clinical scientists and other health care professionals

There was disparity in views regarding the need for qualifications, with some respondents advocating that relevant experience was equally or more important than academic qualifications. Others considered that it would be important for the investigator and other personnel to hold relevant qualifications.

### 33.2 The government response

After careful consideration of responses to the proposals outlined in this section, it remains the government's intention to proceed with all areas, for the reasons set out below.

Based on the consultation response we intend to set out in the regulations, the **purposes for which clinical investigations** shall be designed, authorised, conducted, recorded and reported in line with the consultation proposals – namely:

- a. a. to establish and verify that, under normal conditions of use the medical device achieves the performance intended by its manufacturer
- b. b. to establish and verify the clinical benefits of a medical device as specified by its manufacturer
- c. c. to establish and verify the clinical safety of the medical device and to determine any undesirable side-effects, under normal conditions of use of the medical device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the medical device.

We consider that this approach will provide clarity and consistency for manufacturers and sponsors.

Based on the consultation response we intend to **require non-UK-based sponsors of clinical investigations and performance studies to appoint a UK-based legal representative**. This will ensure that the MHRA has a UK-based point of contact in relation to all clinical investigations, which will lead to more streamlined and efficient communications and will facilitate MHRA oversight.

The government considers that the **sponsor obligations** set out in the consultation are necessary to facilitate enforcement activities and therefore improve public and patient safety, and the proposals were supported by the majority of respondents. The MHRA will support manufacturers in transitioning to these changes, including through the provision of detailed guidance, covering aspects such as publication requirements and timings.

It remains the government's intention to proceed with the proposal to set out the minimum requirements for the **clinical investigation report**, as detailed in the consultation. Reflecting on the consultation feedback, we will require that the clinical investigation report shall be accompanied by a publicly accessible lay person summary. The MHRA will clarify in the regulations, the time frame for publication. We will take international frameworks and standards into consideration as we take forward this work. Further guidance and templates will also be developed for the clinical investigation report. We will work with the Health Research Authority and the Devolved Administrations in developing this guidance.

The government intends to take forward the proposal to introduce additional detailed **requirements for conducting clinical investigations** relating to methods for a clinical investigation, as outlined in the consultation. The MHRA will take international frameworks and

standards into account as we take forward this work. We will also develop guidance to set out further detail on the regulatory requirements, taking account of the consultation feedback.

It remains the government's intention to proceed with the proposal for setting out the detailed requirements for the **clinical investigation plan**, including those outlined in the consultation.

The government intends to set out in the UK medical devices regulations, the **requirements that must be met for performing a clinical investigation**, including those outlined in the consultation. We consider the points raised around bias and diversity to be very important and will address them within the regulations and supplementary guidance. We will work with the Health Research Authority and the Devolved Administrations in developing this guidance. In addition, the MHRA will continue to support the review led by Dame Margaret Whitehead into identified inequities for medical devices announced on 4 February 2022: [Government launches landmark reviews to tackle health disparities - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/news/government-launches-landmark-reviews-to-tackle-health-disparities).

Based on the consultation response it remains the government's intention to set out in the regulations, the **rights of participants to withdraw from a clinical investigation**, as outlined in the consultation, so that this is clear for subjects/participants and sponsors.

It remains the government's intention to proceed with the proposal to set out in the regulations, **requirements for investigators of clinical investigations and personnel** involved in clinical investigations, with supplementary guidance to provide additional detail. Reflecting on consultation feedback, our intention is to take a comprehensive approach here with regards to the relevant skills and qualifications that will be applicable.

## **Section 34 – General requirements regarding performance studies (IVDs)**

### **34.1 Proposals and feedback**

The MHRA consulted on introducing a requirement that, where appropriate, **performance studies shall be performed in circumstances similar to the normal conditions of use of the medical device**. 133 responses were received, of which:

- 83% were in favour of the proposal
- 5% were not in favour of the proposal
- 12% did not know or had no opinion

The consultation sought views on whether the UK medical devices regulations should set out in detail, the **specific requirements for any performance study**, as outlined in the consultation document. 131 responses were received, of which:

- 73% supported the proposal
- 5% were not in favour
- 22% did not know or had no opinion

Many respondents considered that aligning with the EU IVDR and ISO 20916 / 14155 standards would be beneficial. Others noted that these requirements should be set out in guidance rather than in legislation.

Respondents made the following suggestions for the specific requirements of a performance study:

- align with Clinical Trials of Investigational Medicinal Products (CTIMPs)
- such studies should be subject to ethical review and approval
- there is a need to define 'invasive sampling'
- follow Good Clinical Practice (GCP) guidance, for example, on transparency and informed consent

- there should be an exemption for research only IVDs

The consultation proposed that the UK medical devices regulations could be amended to set out the obligations applicable to sponsors of performance studies, including a requirement to provide a publicly accessible summary of the study at the time of registration and on completion of the summary. Of 130 respondents:

- 78% were in favour of introducing the proposal
- 7% did not support the proposal
- 15% did not know or had no opinion.

A number of respondents considered that aligning with the EU IVDR and relevant standards would be beneficial. Others felt that these obligations should be set out in guidance rather than in legislation.

When invited to outline any other obligations that should apply to the sponsor of a performance study, respondents made the following comments:

- the study summary should not need to be made publicly available at all or at the point of registration
- there is a need to clarify how the study summary should be made publicly available and the types of study this obligation would apply to

On the proposal that sponsors should be required to implement a **clinical performance study plan**, 128 responses were received, of which:

- 78% were in favour of the proposal
- 7% were not in favour of the proposal
- 15% did not know or had no opinion

On whether detailed requirements for the clinical performance study plan should be set out in the UK medical devices regulations, 128 responses were received, of which:

- 74% were in favour of the proposal
- 11% were not in favour of the proposal
- 15% did not know or had no opinion

When invited to suggest possible requirements that could be put in place for the clinical performance study plan, respondents commented that:

- there should be a requirement to take account of patient feedback
- there should be different requirements for archived and left-over samples

A number of responses proposed that we align with the EU IVDR and ISO standards 20916 / 14155, and some noted that these proposals would be duplicative of existing practice (for example, ISO and United Kingdom Accreditation Service (UKAS)). Others considered that these obligations should be set out in guidance rather than in legislation.

The consultation invited views on whether these obligations should also extend to other types of performance study (other than clinical performance studies). 128 responses were received, of which:

- 40% were in support of the proposal
- 28% were not in support of the proposal
- 32% were not sure or had no opinion

The consultation invited views on whether the UK medical devices regulations should set detailed requirements for performance studies, including purpose, methods, objectives and ethical considerations for a performance study. Of 129 respondents:

- 74% were in favour of the proposal
- 10% were not in favour of the proposal
- 16% did not know or had no opinion.

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU IVDR and relevant ISO standards. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through the regulations.

On the proposal that sponsors should be required to provide a **clinical performance study report**, 128 responses were received, of which:

- 76% were in support of the proposal
- 9% were unsupportive of the proposal
- 15% did not know or had no opinion

The consultation invited views on whether the UK medical devices regulations should set out the **minimum requirements for the clinical performance study report**, as outlined in the consultation. Of 127 responses:

- 72% supported the proposal
- 13% did not support the proposal
- 15% did not know or had no opinion

Respondents made the following suggestions for requirements that could be put in place for the clinical performance study report:

- there should be a requirement to include a lay person summary
- requirements should be aligned with requirements for the clinical investigation report
- clarify how and where the report would be published and whether it would need to be peer reviewed
- suggestion that we should follow relevant reporting guidelines, for example, Standards for Reporting of Diagnostic Accuracy Studies (STARD) guidelines
- there is a need to be mindful of commercial sensitivities
- there is a need to consider handling of bias

A number of respondents felt that the UK Regulations should align with international frameworks, such as the EU IVDR and relevant ISO standards. Some respondents also suggested that the detailed requirements could be covered by guidance rather than regulations.

The consultation invited views on whether minimum requirements for the clinical performance study report should also extend to **analytical performance studies**. Of 126 responses:

- 48% supported the proposal
- 23% were not supportive
- 29% did not know or had no opinion

A number of respondents felt that the UK Regulations should align with international frameworks, such as the EU IVDR and relevant ISO standards. Some respondents also suggested that clear definitions on the scope and requirements of different types of study are required.

Suggestions for other types of performance study (other than clinical performance studies) that should be subject to a clinical performance study report were as follows:

- carry-over
- sample stability
- analytical performance studies

On the proposal that the UK medical devices regulations should require the **clinical performance study report to be published**, 124 responses were received, of which:

- 56% were in favour of the proposal
- 25% were not in support of the proposal
- 19% did not know or had no opinion

Regarding the proposal that all performance studies involving human samples should be subject to **ethical review** by an ethics committee, 130 responses were received, of which:

- 49% were in favour of introducing this requirement
- 35% were not in favour of introducing this requirement
- 16% did not know or had no opinion

On the proposal to introduce a requirement that **performance studies involving companion diagnostics** should be subject to the same requirements as all other performance studies, 128 responses were received, of which:

- 70% were in support of the proposal
- 27% did not support the proposal
- 2% did not know or had no opinion

In regard to the proposal that performance studies involving **companion diagnostics using only left-over samples** should not be subject to the same requirements as all other performance studies, 129 responses were received, of which:

- 39% were in favour of the proposal
- 24% were not in favour
- 37% did not know or had no opinion

The consultation invited views on the proposed introduction of the requirement that performance studies involving companion diagnostics using only left-over samples should be **notified to the MHRA**. Of 129 responses:

- 47% were in favour of the proposal
- 19% were not in favour
- 34% did not know or had no opinion

On the proposal that the **conditions for conducting a performance study** should be set out in the UK medical devices regulations, 130 responses were received, of which:

- 76% supported the proposal
- 12% were not in support of the proposal
- 12% did not know or had no opinion

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU IVDR and relevant ISO standards. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through legislation.

Some respondents also suggested that GCP guidance should be used when conducting a performance study, and that there are existing frameworks that could also be utilised (for example, those provided by the Health Research Authority (HRA)).

In regard to setting out in the regulations, the **rights of subjects to withdraw from a performance study** at any time without any resulting detriment and without having to provide any justification, 130 responses were received, of which:

- 84% supported the proposal
- 3% were not in support of the proposal
- 13% did not know or had no opinion

The consultation invited views on whether the regulations should include requirements around the **requisite skills and qualifications for the investigator of and other personnel involved in the performance study**, as set out in the consultation. Of the 129 responses:

- 71% were in support of the proposal
- 6% were not in support of the proposal
- 23% did not know or had no opinion

Many respondents suggested that aligning with international approaches such as the EU IVDR and the use of relevant standards would be beneficial.

Other suggestions and comments included:

- guidelines on GCP should be followed
- there is a need to take an inclusive approach in terms of requisite skills and qualifications, so as to avoid excluding nurses, clinical scientists and other health care practitioners
- a need to avoid being overly prescriptive, which may risk excluding academics and SMEs, for example
- conversely some respondents felt that key personnel should be doctors or surgeons
- there is a need to define what is meant by 'suitably qualified' in relation to the requisite education, training or experience in the relevant medical field and in clinical research methodology (as set out in the consultation)

As with the corresponding questions on clinical investigations, there was a degree of disparity among respondents regarding the balance of relevant experience and formal qualifications. Some respondents considered relevant experience to be of greater value than academic qualifications, whereas others were of the view that qualification requirements should be set.

The consultation invited views on the proposal 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. Of 126 responses:

- 82% were in support of the proposal
- 13% were not in support of the proposal
- 5% did not know or had no opinion

The consultation proposed 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. Of the 126 responses received:

- 80% supported the proposal
- 6% were not in support of the proposal
- 14% did not know or had no opinion

Consultees were asked to provide any reasoning and supporting evidence for the answers given in this section. Respondents were broadly supportive, noting that performance studies should reflect real world use conditions and user populations as this approach would generate more accurate data.

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU IVDR and relevant ISO standards. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through regulations.

### 34.2 The government response

Having considered the views of respondents, the government intends to proceed with the proposals laid out in this section of the consultation, to provide clarity and ensure that **performance studies** are carried out in a consistent way.

The government intends to proceed with the proposal to set out in detail, the **specific requirements for any performance study**. We note the points raised around the need for guidance and intend to publish detailed guidance to accompany the regulatory requirements. This will cover concepts referred to in the legislation, such as 'invasive sampling'.

Having considered the views of respondents, it remains the government's intention to proceed with the proposal to set out set out the **obligations of the sponsor** of a performance study, as outlined in the consultation. The government will provide supplementary guidance on the detailed requirements, in line with consultation feedback.

Having taken account of consultation feedback, the government intends to proceed with the proposal that sponsors should be required to implement a **clinical performance study plan**. We also intend to set out in legislation, the detailed requirements for the clinical performance study plan.

In addition, we intend to proceed with the proposal for **extending the requirement for a clinical performance study plan to other types of performance studies** (other than clinical performance studies). Although there was not an overall majority, the largest portion of respondents supported the proposal to extend the obligation and we consider this will create a more robust, consistent approach to conducting these studies.

Having considered the views of respondents, it remains the government's intention to proceed with the proposal that detailed **requirements for the purpose, methods, objectives and ethical considerations for a performance study** should be outlined in the regulations. In developing the regulations, the government will take account of international approaches. We recognise the importance of standards in this area – however we consider that setting out requirements in legislation will place them on a more robust footing and provide clarification for manufacturers and sponsors.

The government intends to take forward the proposal that sponsors should be required to provide a **clinical performance study report**. In developing the regulations, the government will take account of international approaches. As above, we recognise the importance of standards in promoting best practice but consider it necessary to set out requirements in legislation to facilitate a clear and consistent approach. Further consideration will be given to how we approach the handling of bias, including through guidance.

It also remains the government's intention to proceed with the proposal to require **analytical performance studies to have performance study reports**. Although there was not an overall majority, the highest portion of those who responded were in favour of extending the obligation and

the government considers that this approach will create a more robust, consistent approach to conducting these studies.

After careful consideration, the government intends to proceed with the proposal for requiring **all performance studies involving human samples to be subject to ethical review** by an ethics committee. Although there was not an overall majority, almost half of the respondents were in support of extending the obligation and the government considers that this approach will create a more robust, consistent approach to conducting these studies. We will work with the Health Research Authority and Devolved Administrations as we take forward this work.

Based on the consultation response, it remains the government's intention to introduce the consultation proposals to require that **performance studies involving companion diagnostics** are subject to the same requirements as all other performance studies. This approach was supported by the majority of respondents, and we consider that it will create a more robust, consistent approach to conducting these studies.

It also remains the government's intention to introduce the proposal that performance studies involving companion diagnostics using only left-over samples should **not** be subject to the same requirements as the types of performance studies outlined in Section 34.5 of the consultation. However, performance studies involving companion diagnostics using only left-over samples should be subject to the same requirements as all other performance studies using left-over samples.

The government also intends to introduce the proposal that **performance studies involving companion diagnostics using only left-over samples** should be notified to the MHRA. Although there was not an overall majority, almost half of the respondents were in favour of the proposal and, as above, the government considers that it will create a more robust, consistent approach to conducting these studies.

Having considered the views of respondents, it remains the government's intention to proceed with the proposal that the **conditions for conducting a performance study**, as outlined in the consultation, should be set out in the regulations. In developing the regulations, the government will take account of international approaches, including the IVDR.

Based on the consultation response, the government intends to set out in the regulations, provisions concerning the **rights of subjects/participants to withdraw from a performance study**. We consider that this would provide clarity to both sponsors and study subjects/participants so that they are aware of and able to exercise their rights. We will work with the Health Research Authority and the Devolved Administrations as we take forward this work.

Having considered the views of respondents, the government intends to proceed with the proposal to set out **requirements for the investigator and other personnel** involved in the performance study. We will set out the details of the requirements in supplementary guidance, taking account of the need to take an inclusive approach.

Based on the consultation response, we intend to introduce the proposals, as outlined in the consultation, for the **settings, facilities and users for conducting performance studies**. In developing the regulations, the government will take account of international approaches and the role of standards in promoting best practice.

## Section 35 – Informed consent

### 35.1 Proposals and feedback

The consultation invited views on the proposed introduction of **requirements for obtaining informed consent** from individuals participating in a clinical investigation or performance study. Of the 173 responses received:

- 85% supported the proposal
- 8% were not in support of the proposal
- 7% did not know or had no opinion

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU MDR and IVDR, the U.S. Food and Drug Administration (FDA), and relevant ISO standards. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through regulations. In addition, some respondents felt that informed consent should fall within the remit of ethics committees.

Respondents also outlined additional considerations for obtaining informed consent, including:

- the approach should align with applicable medicines / clinical trials regulations
- the approach should align with the CTIMPs
- the approach should follow GCP and the Declaration of Helsinki
- the MHRA should work with the Health Research Authority on this matter
- the approach should consider the NHS Act 2005 s251
- involve patients and the public
- use plain English for consent forms
- risks and benefits should be explained
- de-identified surplus samples should be exempt from informed consent requirements
- the person obtaining consent should be required to sign relevant forms and paperwork in addition to the subject or participant

Respondents were asked to outline any circumstances under which they considered that the **requirements for informed consent should be waived**. Some respondents felt that informed consent requirements must never be waived. Others considered that informed consent is covered by other frameworks that the UK should align with and that there is no need for additional requirements to be set. Further comments considered that the UK regulations should align with international frameworks, such as the EU MDR and IVDR.

Other comments included:

- waive informed consent requirements for observational studies
- waive informed consent requirements for de-identified data and / or left-over samples
- waive informed consent requirements for life or death / emergency situations
- follow the Declaration of Helsinki
- there is a risk that de-identified samples can later be re-identified

Respondents were asked to provide any reasoning and supporting evidence for the answers given in response to Section 35 of the consultation.

A number of comments were similar to points raised above in response to previous questions, including the need for international alignment, advocacy of the use of standards and calls for guidance rather than regulation in this area.

Some respondents commented on their personal experiences of injuries caused by surgical mesh implants, noting that they had not been properly consented to their procedures - highlighting the need for clear and robust regulation in this area, rather than reliance on guidance.

## 35.2 The government response

Having considered the views of respondents, it remains the government's intention to proceed with the introduction of **requirements for obtaining informed consent** from individuals participating in a clinical investigation or performance study.

In the consultation feedback, a number of respondents highlighted existing standards, legislation and guidance documents that outline best practice on obtaining informed consent. The government is mindful of the need to align with best practice and avoid duplication. However, we consider that, given the importance of this issue and the points raised by consultees, there is a need to set out clear requirements in legislation that align with and complement existing frameworks. This will provide clarity and consistency for both public and private sector entities. We will work closely with the Health Research Authority and the Devolved Administrations in developing the regulations and will supplement legislative provisions with clear guidance. In addition, we will reflect on need for alignment with requirements for medicines.

The government also intends to set out the circumstances in which **requirements for informed consent might be waived**, as outlined in the consultation. This may apply to studies using left over or archived specimens, where they have been sufficiently de-identified and/or prior informed consent has been provided in a generic form to cover the use of the specimens for such purposes. Any waiver of informed consent would require approval by a research ethics committee, in line with international standards and existing best practice.

## Section 36 – Specific requirements for clinical investigations / performance studies

### 36.1 Proposals and feedback

The consultation sought views on whether additional requirements should apply to **clinical investigations or performance studies on minors**, as set out in the consultation. Of the 163 responses:

- 73% were in favour of this approach
- 12% were not in support of the proposal
- 15% did not know or had no opinion

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU MDR and IVDR, and relevant ISO standards. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through regulations.

Consultees were asked to suggest other requirements which could be introduced for clinical investigations or performance studies on minors. Responses can be summarised as follows:

- information provided to subjects/participants should be adapted accordingly
- we should consider the capacity of minors to consent and any safeguarding issues
- parental consent should be taken into account
- there should be no financial incentives offered for participation (other than compensation for expenses)
- there is a need to clarify how information pertaining to the health of the subject/participant should be communicated (including genetic information)
- consent should be sought later once the minor reaches the age of legal competence
- the subject's/participant's right to withdraw should be respected

- there is a need to clarify what is meant by ‘direct benefit’ (as set out in the consultation) – meaning whether this is a health-related or other type of benefit
- there is a need to clarify whether all or any of the requirements set out in the consultation would need to be met

The consultation sought views on whether additional requirements should apply to **clinical investigations or performance studies on pregnant or breastfeeding women**, as set out in the consultation. Of 160 respondents:

- 70% supported the introduction of additional requirements
- 13% were not in support of the proposal
- 17% did not know or had no opinion.

When asked to outline other requirements that should apply to such studies, some respondents felt that no additional requirements were needed beyond those set out in the consultation. A number of respondents considered that the UK regulations should align with international frameworks, such as the EU MDR and IVDR, the Declaration of Helsinki and relevant ISO standards. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through Regulations.

Suggestions for other requirements which could be introduced for clinical investigations or performance studies on pregnant or breastfeeding women were as follows:

- there should be long-term post-natal follow up on babies in cases where their mothers had participated in a clinical investigation or performance study during pregnancy
- counselling should be provided for studies that involve pre-natal genetic testing
- no financial incentives should be offered (beyond compensation for expenses)
- there is a need for specific risk assessment
- relevant documentation should be retained long-term
- procedures should be in place for recalls and remedial action

Respondents were asked to provide any reasoning and supporting evidence for the answers given in Section 36 of the consultation.

A number of responses were similar to points raised in previous questions, including the need for international and cross-UK alignment, as well as advocacy for the use of standards and guidance rather than legislation.

Other responses highlighted the importance of not excluding these groups from clinical investigations or performance studies. Some respondents commented that studies on ‘difficult to study’ patient populations, such as pregnant women, should not be limited by the participant’s medical condition as this approach may miss opportunities to fill evidence gaps for these populations.

### **36.2 The government response**

Having considered the views of respondents, it remains the government’s intention to proceed with the proposal to introduce additional requirements for **clinical investigations or performance studies on minors**. The government considers that there is a need to set out these requirements in legislation to provide clarity to manufacturers and sponsors and so that a consistent approach applies to public and private sector entities.

The government is mindful of the need for the UK medical devices regulations to complement existing frameworks and the MHRA will work closely with the Health Research Authority and the Devolved Administrations as we develop the legislation.

In addition to the consultation proposals, respondents raised the need to adapt information about the study to the maturity of the subject/participant, to ensure that no financial incentives or inducements are offered (beyond compensation for expenses), that the right to withdraw should be respected and that explicit consent should be sought from the subject/participant once they reach the age of legal competence. The government intends to also include these provisions in the regulations.

The government will also publish supplementary guidance on these matters and others raised in the consultation – for example on the definition of ‘direct benefit’ and on the reporting of genetic information to subjects/participants.

Having considered the views of respondents, it remains the government’s intention to proceed with the proposal to introduce additional requirements for **clinical investigations or performance studies on pregnant or breastfeeding women**.

In the consultation feedback, a number of respondents highlighted existing standards, legislation and guidance documents that outline best practice. The government considers that there is a need to set out in legislation, the requirements that apply to clinical investigations and performance studies on pregnant or breastfeeding women so that this is very clear to subjects/participants, manufacturers and sponsors and so that a consistent approach applies to public and private sector entities.

The government is mindful of the need to complement existing frameworks and avoid unnecessary duplication, and we will work closely with the Health Research Authority and the Devolved Administrations as we develop the legislation.

In addition to the points included in the consultation, respondents raised the need to ensure that there are no financial incentives or inducements for participation in clinical investigations and performance studies (beyond compensation for expenses). We will address these points in the regulations.

The government does not intend to omit the requirement for there to be an expectation that clinical investigations and performance studies on the above populations will produce a direct benefit to the minor / pregnant or breastfeeding woman, outweighing the risks and burdens involved. However, for pregnant or breastfeeding women, our intention is that the regulations will provide that sponsors should demonstrate that a study of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding. We will require a risk assessment to be conducted to demonstrate that the clinical investigation or performance study poses a minimal risk to the subject/participant concerned, or their embryo, foetus or child after birth.

## **Section 37 – Clinical investigations / Performance studies in emergency situations**

### **37.1 Proposals and feedback**

The consultation invited views on whether 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/participant in a clinical investigation or performance study due to an **emergency situation**. 144 responses were received, of which:

- 73% supported the proposal
- 5% were not in support of the proposal
- 22% did not know or had no opinion

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU MDR and IVDR, and relevant ISO standards. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through regulations.

Supporting evidence and comments for the responses given above can be summarised as follows:

- consent should always be sought
- delegated consent (for example from next of kin) is preferred
- there is a need to define what is meant by 'emergency situation'
- CTIMPs provide a model here

The consultation proposed that systems should be put in place for **compensation** for any damage suffered by a subject/participant as a result of participating in a clinical investigation or performance study conducted in Great Britain. In the consultation we noted that this could be in the form of insurance, a guarantee or a similar arrangement, proportionate to the nature and extent of the risk. Of the 143 responses received:

- 76% were in support of the proposal
- 9% were not in support of the proposal
- 15% did not know or had no opinion

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU MDR and IVDR, and relevant ISO standards. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through regulations.

Other supporting evidence and comments for the responses given in Section 37 can be summarised as follows:

- there is a need to confirm whether requirements would apply to both pre- and post-approval studies
- compensation requirements would help ensure manufacturer accountability
- this approach would deliver safety benefits
- insurance premiums can be cost-prohibitive, especially for the academic sector and SMEs, and the MHRA should liaise with the insurance sector on this matter
- the approach outlined in the consultation is bureaucratic - redress is already available
- we should put in place a collective or mutual insurance scheme

### 37.2 The government response

Having considered the views of respondents, it remains the government's intention to proceed with the proposal that 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/participant in a clinical investigation or performance study due to an **emergency situation**.

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU IVDR and relevant ISO standards. In developing the regulations, the government will take into consideration international approaches, including relevant standards.

The government will publish detailed guidance to supplement the legislative requirements and will work with Health Research Authority and the Devolved Administrations to ensure that the legislative requirements complement wider frameworks. In addition, we will reflect on need for alignment with requirements for medicines.

Having considered the views of respondents, it remains the government's intention to proceed with the proposal that systems should be put in place for **compensation** for any damage suffered by a subject/participant as a result of participating in a clinical investigation or performance study conducted in Great Britain.

On financial coverage / compensation requirements, it was noted that setting requirements out in the regulations would facilitate improved accountability and ultimately deliver patient safety benefits. The government will therefore set a requirement in the legislation so that compensation requirements apply to both clinical investigations and performance studies and will supplement this with guidance. The government is mindful of comments regarding impacts on SMEs and will work to minimise this impact.

## **Section 38 – Application for clinical investigations / performance studies**

### **38.1 Proposals and feedback**

The consultation proposed that the UK medical devices regulations could outline detailed requirements for the clinical investigation or performance study **application form and the accompanying documentation**, as set out in the consultation. Of 152 respondents:

- 80% were in favour of the proposal
- 9% did not support of the proposal
- 11% did not know or had no opinion

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU MDR and IVDR. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through regulations.

The consultation proposed that 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, as set out in the consultation. Of the 148 responses received:

- 81% were in support of this proposal
- 5% were not in support of the proposal
- 14% did not know or had no opinion

Some of those in favour of this proposal suggested that timescales should be based on risk stratification. Respondents also suggested that timescales should align with the EU MDR and IVDR and should include a degree of flexibility for more complex applications.

Respondents were asked to provide any reasoning and supporting evidence for the answers given in Section 38 of the consultation. A number of comments covered points raised in response to previous questions, including the need for international alignment, and advocacy of the use of standards and guidance rather than regulation. Other responses again called for an approach based on risk stratification and suggested that relevant timelines should not be set out in legislation.

### **38.2 The government response**

Having considered the views of respondents, the government intends to include in the regulations, requirements for the clinical investigation or performance study **application form and the accompanying documentation**. With regards to the application form specifically, and in light of consultation feedback, the government recognises the need for a degree of flexibility. We will

therefore give further consideration to requests that the detailed requirements for the application form be set out in supplementary guidance as we take forward this work.

Having taken account of consultation feedback, the government intends to outline in the UK medical devices regulations, 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. Having reflected on consultation feedback and given this matter further consideration, our intention is to retain the current 60 calendar day timescale for assessment for clinical investigations and we are considering further what an appropriate timescale would be for the assessment of performance studies. We consider that retaining the 60-day timescale for clinical investigations will be clearer and more straightforward for both applicants and the MHRA as it represents a continuation of current practice. We consider it important to set these requirements out in legislation to provide clarity and to support compliance. We will provide supplementary guidance to support manufacturers and sponsors.

## **Section 39 – Assessment of applications for clinical investigation/performance study by the MHRA**

### **39.1 Proposals and feedback**

The consultation sought views on whether the UK medical devices regulations should require that performance study applications be assessed by the MHRA (in addition to clinical investigation applications, which are already subject to MHRA assessment). Of 151 respondents:

- 60% were in favour of the proposal
- 15% were not in favour
- 25% did not know or had no opinion

The MHRA invited views on whether the detailed requirements for **assessment of the application for clinical investigations or performance studies** should be outlined by the MHRA, as outlined in the consultation. Of 153 responses:

- 75% supported the proposal
- 11% were not in support of the proposal
- 14% did not know or had no opinion

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU MDR and IVDR and the FDA, as well as relevant ISO standards, and noted the potential for a reduced level of assessment if approval has already been granted in other jurisdictions. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through regulations.

Respondents were asked to provide any reasoning and supporting evidence for the answers given in Section 39 of the consultation. A number of comments were similar to points raised in response to previous questions, including the need for international alignment, and a preference for use of standards and guidance rather than regulation. Other responses highlighted that greater transparency and clarity is needed on any requirements and that additional burden in submissions, cost and time could affect access to experimental devices. Some respondents suggested that there should be a risk-based approach to review which could apply, for example, only to high-risk studies.

### **39.2 The government response**

Having considered the views of respondents, it remains the government's intention to proceed with the proposals that the MHRA should be required to **assess applications for performance**

**studies** and that the **detailed requirements for assessment of the application for clinical investigations or performance studies** should be outlined in the regulations. There was support for this approach among consultees and we consider that it will add greater clarity and transparency to the application and assessment process.

## **Section 40 - Conduct of a clinical investigation / performance study**

### **40.1 Proposals and feedback**

The consultation invited views on whether the UK medical devices regulations should set out the **requirements on sponsors and investigators for the conduct of a clinical investigation or performance study**, as outlined in the consultation (including a requirement to have adequate processes in place to identify deviations from the clinical investigation plan, and record and report any such deviations immediately). Of the 152 respondents:

- 85% were in favour of the proposal
- 10% were not in support of the proposal
- 5% did not know or had no opinion

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU MDR and IVDR, as well as Good Clinical Practice guidelines and relevant ISO standards, or should align with requirements that apply to clinical trials for medicines. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through regulations.

Some respondents felt that not all deviations should be reported, and that setting a requirement for immediate reporting would be too strict. It was also proposed that deviations should be assessed and rated as 'critical', 'major' or 'minor'.

Some respondents suggested that timeframes for reporting deviations should be specified and potentially linked with the level of impact.

We invited views on whether the MHRA should be required to **inspect, at an appropriate level, clinical investigation, or performance study site(s)**. 154 responses were received, of which:

- 60% were in favour of the proposal
- 18% were not in favour of the proposal
- 22% did not know or had no opinion

Supporting rationale for the responses given in Section 40 of the consultation can be summarised as follows:

- there should be alignment with the EU MDR and IVDR
- there should be consideration of the role of standards
- this approach would support compliance with relevant requirements
- there is a need to define 'appropriate level' of inspection
- the regulations should create a power rather than a duty to inspect
- a preference for a spot check rather than blanket inspection approach
- there should be a risk-based / randomised approach to inspection
- inspection obligations could create unnecessary bureaucracy, which could lead to delays and ultimately supply issues
- there is a need to consider impacts on health institutions and the National Health Service (NHS)
- there is a need to clarify who would be inspected, whether this would be the sponsor or the manufacturer

- clear guidance and timescale information would be needed
- follow Good Clinical Practice guidelines
- limit requirements to cases where there is intention to commercialise devices

## 40.2 The government response

Having considered the views of respondents, it remains the government's intention to proceed with the proposal that the regulations should **set out the requirements for the conduct of a clinical investigation or performance study** as set out in the consultation. We remain of the view that all deviations should be reported as soon as the sponsor becomes aware of them.

Taking account of consultation feedback, the government intends to proceed with the proposal that the MHRA should be able to **inspect, at an appropriate level, clinical investigation, or performance study site(s)**. The approach taken here will differ slightly to that set out in the consultation as we intend to ensure the MHRA has the ability to inspect clinical investigation and performance study sites rather than make this a requirement.

We consider that this will allow the MHRA to take a pragmatic and flexible approach to inspection processes, which was broadly supported by consultees. The proposal will enable the MHRA to inspect clinical investigation and performance study sites at any time. As identified by consultation respondents, the government considers that enabling inspection will encourage compliance with the legislative requirements. We will give further consideration to the detailed approach and will provide supplementary guidance, addressing important points raised by respondents around the nature of inspections (randomised, risk-based etc.), entities to be inspected and relevant timings.

## Section 41 – Clinical investigations / performance studies regarding devices bearing the UKCA marking

### 41.1 Proposals and feedback

The consultation invited views on whether, in certain cases, a sponsor should be **required to notify the MHRA** within a specified timeframe prior to the start of a study, in cases where a clinical investigation or performance study is to be conducted to further assess a device which is already UK Conformity Assessed (UKCA) marked according to its intended purpose. Of the 147 responses:

- 59% supported this proposal
- 22% were not in favour
- 19% did not know or had no opinion

Some respondents felt that a notification of a clinical investigation or performance study in the above circumstances should not be required due to additional bureaucracy. Other respondents considered that the UK medical devices regulations should align with international frameworks, such as the EU MDR and IVDR with a time period of 30 days for notification.

### 41.2 The government response

Having considered the views of respondents, it remains the government's intention to proceed with the **notification requirements**, summarised above and outlined in the consultation, within a specified time period prior to the start of that clinical investigation or performance study. Our intention is to require that the notification is made at least 30 calendar days prior to the start of the study. This approach was supported by the majority consultees, is in line with international practice and a requirement would give the MHRA greater oversight of post-market clinical follow-up (PMCF) and post-market performance follow-up (PMPF) studies conducted on these devices.

## Section 42 – Modifications to clinical investigations / performance studies

## 42.1 Proposals and feedback

We invited views on whether the UK medical devices regulations should set out the **procedures for sponsors intending to introduce modifications** to a clinical investigation or performance study that are likely to have an impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation/study, as set out in the consultation. Of 135 respondents:

- 85% were in favour of the proposal
- 5% were not in support of the proposal
- 10% did not know or had no opinion

When asked to provide suggestions for procedures, other than those set out in the consultation, which should be introduced and/or the associated timeframes for notifying the MHRA, feedback included:

- a significant number of responses suggested that we should align with the EU MDR / IVDR
- some respondents suggested that we should align with relevant standards
- there should be a requirement to notify modifications with likely impacts on safety or the robustness of data
- this would be an unnecessary requirement and could cause delays
- we should follow the CTIMPs model
- modifications to clinical investigations and performance studies should not be made
- proposed timescales for notifying the MHRA of modifications included: 1 week, 2 weeks, same timescale as initial notification, 30 days, 35 days, 38 days, and 30-60 days
- modifications that are needed for safety purposes should not need up-front notification or approval, however retrospective notification should be possible
- there should be a requirement to alert participants and allow them to withdraw

Supporting evidence for the responses given in Section 42 of the consultation can be summarised as follows:

- clarity is needed on the timescales for notifying the MHRA of modifications
- we should align with the EU MDR and IVDR and international models
- we should follow relevant standards
- requirements should be covered in guidance rather than legislation
- the requirement to notify MHRA could lead to delays in the clinical investigation
- the requirement could be resource intensive for both the MHRA and sponsors
- a risk-based approach is needed
- modifications should only be notified if they are in response to adverse incidents

## 42.2 The government response

Having considered the views of respondents, it remains the government's intention to set out in the regulations, the procedures for sponsors intending to introduce **modifications to a clinical investigation or performance study**, as outlined in the consultation. The concerns raised regarding the approach potentially causing delays to clinical investigations and performance studies have been noted. We would like to clarify that all modifications and amendments to clinical investigations currently require review without any timescales associated with this. We therefore consider that the introduction of timescales will provide clarification and facilitate forward planning. In taking forward this work we will reflect upon feedback on the need for international alignment and the need for alignment with requirements for medicines.

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

### 43.1 Proposals and feedback

We invited views on whether the MHRA should be able to take **corrective measures** in cases where it is considered that the requirements of the UK medical devices regulations relating to a performance study have not been met, as set out in the consultation. This would align requirements for performance studies with the current measures applicable to clinical investigation studies. Of 141 respondents:

- 81% were in favour of the proposal
- 6% were not in support of the proposal
- 13% did not know or had no opinion

Suggestions for other measures that respondents considered should be introduced for either a clinical investigation or performance study were as follows:

- a significant number of responses said that no additional requirements were needed beyond those set out in the consultation
- a significant number of responses suggested that we align with EU IVDR and MDR
- some respondents noted that a risk stratification / risk-based approach is needed
- some respondents suggested that requirements could be set out in guidance rather than regulations
- some respondents proposed alignment with CTIMPs

The consultation proposed that, in cases where the MHRA has grounds for considering that the requirements for a performance study are not met and except where immediate action is required, **the sponsor or the investigator or both should be asked for their opinion regarding the corrective measures**. Of 136 respondents:

- 79% were in favour of the proposal
- 3% were not in support of the proposal
- 18% did not know or had no opinion

Suggestions for the specified **time period for the sponsor or investigator to give their opinion** ranged from 5 working days to 90 days, including timeframe grading according to case complexity.

The rationale provided for these suggestions included the need for alignment with the EU MDR and IVDR and a desire for a risk stratification approach.

### 43.2 The government response

Having considered the views of respondents, it remains the government's intention to proceed with the proposal that, where it is considered that the requirements of a performance study have not been met, the MHRA should be able to take certain **corrective measures** that would be laid out in the UK medical devices regulations, as set out in the consultation.

A number of respondents felt that the UK regulations should align with international frameworks, such as the EU IVDR and relevant ISO standards. In developing the legislation, the government will take account of international approaches and relevant standards.

In light of consultation responses, the government intends to proceed with the proposal that, except where immediate action is required, **the sponsor or the investigator or both should be asked for their opinion regarding the corrective measures**, as outlined in the consultation.

Having considered the views of respondents, we intend to set a timeframe of seven calendar days for the sponsor or investigator to give their opinion except where immediate action is required.

## **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**

### **44.1 Proposals and feedback**

The consultation proposed that the procedures which must be undertaken and the timeframes that should apply at the end of a clinical investigation or performance study, or in the event of a **temporary halt or early termination**, could be specified in the regulations. Of 133 respondents:

- 78% were in favour of this approach
- 5% were not in support
- 17% did not know or had no opinion

Responses to the follow-up question regarding appropriate notification timescales and procedures were limited, but where comments were provided, they suggested that the UK regulations should align with international frameworks, such as the EU MDR and IVDR. Some respondents also suggested that the detailed requirements could be covered by guidance rather than through regulations.

### **44.2 The government response**

Having considered the views of respondents, it remains the government's intention to clarify in the UK regulations, the procedures 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**.

The government intends to introduce requirements that a notification should be made to the MHRA within 15 days of a temporary halt or early termination, unless this is on safety grounds, in which case notification shall be made within 24 hours, or within 15 days of the end of the clinical investigation (last visit of last subject/participant unless set as different in clinical investigation plan).

We also intend to set out obligations for the sponsor, who will be required to submit a report and summary to the MHRA within 1 year of the end of the clinical investigation or performance study unless the study was terminated early or temporarily halted - in which case the report will need to be submitted within 3 months.

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

### **45.1 Proposals and feedback**

The MHRA sought views on whether sponsors of clinical investigations and performance studies should be required to **fully record and provide information** to the MHRA upon request on all of the following:

- a. any adverse event of a type identified in the clinical investigation or performance study plan as being critical to the evaluation of the results of that clinical investigation or performance study
- b. any serious adverse event
- c. any medical device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate

d. any new findings in relation to any event referred to in points (a) to (c)

Of 153 respondents:

- 88% were in favour of the proposal
- 6% were not in support of the proposal
- 6% did not know or had no opinion

The consultation asked whether sponsors should be required to **report adverse incidents, medical device deficiencies and new findings** without delay to the MHRA. Of 152 respondents:

- 86% were in favour of the proposal
- 10% were not in support of the proposal
- 4% did not know or had no opinion

The consultation proposed that, where necessary, **sponsors should be able to submit an initial report that is incomplete, followed up by a complete report.** Of 153 respondents:

- 82% were in favour of the proposal
- 7% were not in support of the proposal
- 11% did not know or had no opinion

The MHRA invited views on whether the UK medical devices regulations should require sponsors to report to the MHRA, any event (referred to in points (a) to (c) below) **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.

- a. any serious adverse event
- b. any medical device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate
- c. any new findings in relation to any event referred to in points (a) and (b)

Of 153 respondents:

- 84% were in favour of the proposal
- 8% were not in support of the proposal
- 8% did not know or had no opinion

Respondents were next asked to provide any reasoning and supporting evidence for the answers given in Section 45 of the consultation.

A number of respondents noted that the proposals would deliver safety and transparency benefits, while others felt that the UK regulations should align with international frameworks, such as the EU MDR and IVDR or align with medicines requirements. Some respondents noted that the requirement for reporting **all** incidents could be burdensome - suggesting, for example, that only serious incidents with a causal relationship either to the device or procedure should be reported, and that other incidents could be reported via an annual/final report. Other comments referenced the need for clarification over timescales, a need to have a definition of 'without delay' and a request to have in place an efficient method for reporting events.

## 45.2 The government response

Having considered the views of respondents, it remains the government's intention to proceed with the proposals laid out in Section 45 of the consultation. While noting that some responses suggested a requirement to report all incidents would be burdensome, it should be noted that this

is already a requirement for serious adverse incidents in relation to clinical investigations and, given the observational nature of many IVD performance evaluations, the risk of adverse incidents is likely to be minimal. Where interventional performance evaluations are conducted, the reporting of adverse incidents is essential to determine the cause and solution. Guidance will be provided to support those carrying out clinical investigations and performance studies.

## **Section 46 – Types of clinical investigations / performance studies and exemptions / authorisations**

### **46.1 Proposals and feedback**

The consultation sought views on whether **exemptions from some of the requirements of the regulations for certain types of clinical investigations and performance studies** could apply. Examples could include cases where an academic institute is working with a health institution to conduct a proof of concept or early feasibility study on a medical device without any input from industry, and there is no intention to place the device on the market. However, all such studies would still need to be registered with the MHRA before taking place. 158 responses were received, of which:

- 61% were in favour of this proposal
- 15% were not in favour of this proposal
- 23% did not know or had no opinion

The MHRA invited consultees to outline what types of clinical investigations and performance studies they considered should be exempted. Comments included:

- further guidance and clarity would be needed to support this
- further clarity is needed on what is deemed to be a medical device in proof-of-concept investigations
- industry involvement should not matter
- there should be a risk-based approach (exemption for low risk)
- there should be no exemptions
- there should be a lighter-touch approach for registration/notification
- we should align with the EU MDR and IVDR
- there should be requirements set out for studies that fall within exemptions (for example, a requirement that such studies are still subject to Research Ethics Committee approval)

The consultation invited views on whether health institutions should be required to notify certain types of clinical investigations / performance studies to the MHRA for authorisation before proceeding. The consultation noted that this could include larger pivotal or confirmatory clinical investigation studies which are conducted to provide the information necessary to evaluate the clinical performance, effectiveness or safety of the investigational device. Of the 157 responses:

- 70% were in support of the proposal
- 6% were not in support of the proposal
- 24% did not know or had no opinion

The consultation next asked respondents to outline the types of clinical investigations and performance studies that should be required to meet the requirements of the UK medical devices regulations. Comments included:

- align health institution requirements with industry, as there is no difference in risk
- larger pivotal and / or confirmatory clinical investigation for evaluating clinical performance, effectiveness or safety should be notified to MHRA

- high risk and invasive devices should be treated with higher scrutiny
- concern was expressed regarding the financial burdens to health institutions of registering studies where there will be no commercialisation of the devices
- registration requirements for all clinical investigations and performance studies should be considered
- we should align with the EU MDR and IVDR
- we should align with approaches that apply to medicines
- Good Clinical Practice guidelines should be followed

Respondents were asked to provide any reasoning and supporting evidence for the answers given in Section 45 of the consultation. Feedback can be summarised as follows:

- concerns were raised as to why risks from studies conducted by health institutions should be treated differently to those conducted by commercial manufacturers
- concerns were raised regarding perceived barriers for early feasibility and concept studies in cases where it is too early for an academic start-up to be planning a route to market. It was noted that an exemption could help address this to improve innovation - but would need careful consideration
- it was noted that it can be difficult to pass early development stage without any commercial sponsor or funding
- references were made to taking a device class / risk-based approach, questioning whether low risk devices need a clinical investigation when the risk posed is low
- it was also suggested that there should be consideration of benchtop testing as an alternative option

## 46.2 The government response

Having considered the views of respondents, it remains the government's intention to proceed with the proposal that 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 the consultation. We also intend to require that healthcare institutions should notify certain types of clinical investigation / performance studies to the MHRA before proceeding. We consider that this approach will help reduce barriers for certain organisations, such as academic institutions, that may wish to carry out certain types of clinical investigation or performance study and encourage innovation while continuing to protect patients.

## Section 47 – Summary of safety and clinical performance

### 47.1 Proposals and feedback

The consultation invited views on whether the UK medical devices regulations should require manufacturers to produce **a summary of safety and clinical performance (SSCP) for high-risk medical devices and IVDs**. 190 responses were received, of which:

- 73% were in support of the proposal
- 13% were not in support of the proposal
- 14% did not know or had no opinion

Respondents were asked to outline the classes/types of medical devices that they considered should require an SSCP. The 119 responses can be summarised as follows:

- the requirement should also apply to Class IIa and IIb devices
- all devices should be required to have an SSCP
- an SSCP should be required for all devices other than Class I
- we should align requirements with the EU MDR
- the requirement should only apply to high-risk devices

The consultation also invited views in the abridged version of the consultation (Chapter 17) as to whether we should introduce a **requirement for manufacturers to produce an SSCP**. Of the 53 responses:

- 90% supported this approach
- 4% were not in favour
- 6% did not know or had no opinion

The abridged consultation (Chapter 17) also invited respondents to select the types / classes of medical device that should be subject to SSCP requirements. Of the 49 responses received, the following selections were made:

- all implantable medical devices (**88%**)
- highest risk (Class III) medical devices (**55%**)
- highest risk IVDs (**47%**)
- medium risk (Class IIb) medical devices (**24%**)
- medium risk IVDs (**22%**)
- other (**8%**)

In terms of further commentary, some respondents noted that this approach would support transparency and patient safety, while others considered that the SSCP should be accessible and written in plain English. A number of respondents reiterated that the SSCP requirements should extend to medium and low risk devices.

In Chapter 7 of the consultation, we sought views on whether the UK medical devices regulations should set out the **minimum content of the SSCP**. Of the 182 responses received:

- 72% supported the proposal
- 14% were not in support of the proposal
- 14% did not know or had no opinion

Respondents were next invited to outline any other content which they considered should be included in the SSCP for a medical device. Feedback can be summarised as follows:

- we should align with the EU MDR / IVDR
- we should accept SSCPs that have been approved by EU Notified Bodies
- the requirement should only apply to devices that do not have an SSCP under the EU MDR
- we should not have an SSCP requirement
- we should require that the SSCP includes specific information, including that relating to chemicals, metals and indicated users, and Information for patients should also be included

The consultation sought views on requirements for manufacturers to upload the full SSCP or a link to the SSCP (hosted externally) to the MHRA registration system. When asked to select one of the following options, the majority of respondents picked option 'a':

- a. the manufacturer should upload the full SSCP to the MHRA registration system (**46%**)
- b. the manufacturer should upload a link to the SSCP to the registration system (**12%**)

- c. the manufacturer should not be required to upload the SSCP to the registration system **(15%)**
- d. other – please specify **(18%)**
- e. don't know/no opinion **(9%)**

Responses for 'other' included:

- the Approved Body should upload the form
- this should be available on the Public Access Database for Medical Devices

The consultation sought views on whether an Approved Body should be required to validate the SSCP for a medical device prior to upload to the MHRA registration system. Of the 185 responses:

- 59% were in favour of the proposal
- 19% were not in support of the proposal
- 22% did not know or had no opinion

Respondents made a range of suggestions regarding how an Approved Body should validate the SSCP for a medical device, as follows:

- they should cross check the SSCP against previous studies
- we should align with global regulations / EU MDR / IVDR
- this should be done remotely against specified minimum criteria or there should be hybrid inspection: desk based combined with onsite visit
- this should be conducted by an independent body with no conflict of interest
- the process should involve appropriate clinical and other experts
- this should be conducted as part of conformity assessment

Respondents were asked to provide any reasoning and supporting evidence for the answers given in Section 47 of the consultation. Feedback can be summarised as follows:

- we should align with EU requirements
- the SSCP should be easily accessible for stakeholders and patients
- these requirements would be bureaucratic, burdensome and costly - and could risk stifling innovation
- the SSCP assessment should be risk proportionate
- there is a need for guidance and further public engagement

## **47.2 The government response**

Having considered the views of respondents, it remains the government's intention to proceed with all the proposals covered in Section 47. Based on consultation feedback, our intention is to require the manufacturer to upload the **full SSCP** to the MHRA registration system, and for it to be made publicly available. We have noted that some respondents requested that the SSCP requirements should apply to all device classes; however, our intention at this point, is to introduce this for high-risk devices only. We will keep our position under review and will give further consideration, as necessary, to the need to expand these requirements to lower risk devices.

## 8 – Post-market Surveillance, Vigilance, Market Surveillance

The consultation proposed changes to the medical devices regulations to set out clearer requirements for the manufacturer's post-market surveillance system and to require the manufacturer to summarise and report their post-market findings to the MHRA. Existing requirements are laid out in guidance. However improved regulation will help to achieve better harmonisation across manufacturers placing devices on the UK market.

**The proposed changes will improve the ability of both the manufacturer and the MHRA to identify issues with a medical device and, where necessary, take appropriate action to safeguard public health. This will help improve patient safety and strengthen the level of post-market surveillance activities conducted across all manufacturers placing medical devices on the UK market.**

### Section 48 – Post Market Surveillance

#### 48.1 Proposals and feedback

The consultation invited views on whether manufacturers should be required to implement a post-market surveillance system based on a post-market surveillance plan, which collates and utilises information from a range of sources such as those listed in the consultation text. Of the 267 responses:

- 93% supported the proposal
- 4% did not support the proposal
- 3% did not know or had no opinion

The consultation also sought views on whether the UK medical devices regulations should provide a detailed outline of what the post-market surveillance plan should address. 267 responses were received, of which:

- 87% were in favour of the proposal
- 10% were not in favour of the proposal
- 3% did not know or had no opinion

We invited consultees to outline any other elements that they considered a post-market surveillance plan should address. Feedback from the 144 respondents can be summarised as follows:

- aligning with the EU would provide economic and operational benefits to manufacturers
- patient involvement should be outlined within the post-market surveillance plan
- details as to what should be included should be outlined in guidance
- the level of detail required should be determined using a risk-based approach

When asked whether the UK medical devices regulations should outline what should be included in the **post-market clinical follow-up (PMCF) or post-market performance follow-up (PMPF) plan**, 253 responses were received, of which:

- 80% were in support of this proposal
- 12% did not support this proposal
- 8% did not know or had no opinion

On whether manufacturers should be exempt from the requirement to perform PMCF/PMPF for a medical device or *in vitro* diagnostic medical device (IVD) pursuant to a PMCF/PMPF plan if such manufacturers provide sufficient justification, 255 responses were received, of which:

- 67% supported this proposal
- 22% did not support the proposal
- 16% did not know or had no opinion

We asked consultees whether 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. 256 responses were received, of which:

- 83% supported this proposal
- 11% did not support this proposal
- 6% did not know or had no opinion

On whether manufacturers should upload post-market surveillance data to the MHRA devices register upon registration renewal, 254 responses were received, of which:

- 63% were in support of the proposal
- 35% did not support the proposal
- 13% did not know or had no opinion

We The consultation invited respondents to provide reasoning for their answers in Section 48. Feedback from the 155 respondents can be summarised as follows:

- many commenters felt that Class I devices should be subject to such reports
- some commenters felt that these requirements should be required for all devices
- distinguishing between the requirements placed on high and low risk devices is a proportionate approach and places less burden on manufacturers and Approved Bodies
- aligning with the EU would provide clarity for manufacturers and end users
- requiring uploading of data could duplicate work and increase burden on manufacturers
- requiring uploading of data could improve transparency within the system
- the current system is operating effectively

## 48.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposal to amend the UK medical devices regulations **to clarify and strengthen the requirement for manufacturers to implement a post-market surveillance system**, in respect of all medical devices they have placed on the UK market. We intend to provide an outline of what this should address within the regulations.

Some respondents also indicated that more guidance may be necessary to ensure patient involvement and address device-specific issues. The government aims to further clarify the requirements of post-market surveillance plans in published guidance.

## Section 49 – Reporting of serious incidents and field safety corrective actions (or 'FSCAs')

### 49.1 Proposals and feedback

The consultation invited views on whether the UK medical devices regulations should include requirements for manufacturers to report incidents and FSCAs to the MHRA including points (a) and (b) below:

- a. any serious incident, including those which are expected side effects (for example, those listed in the instructions for use)
- b. any FSCA (see Section 47), including any FSCA undertaken in a non-UK country in relation to a medical device which has also been made available on the UK market.

241 responses were received, of which:

- 85% supported the proposal
- 12% did not support the proposal
- 3% did not know or had no opinion

The consultation invited views on proposed definitions for 'serious incident', 'serious deterioration' and 'serious public health threat' which were set out in the consultation text. Of 241 responses received:

- 87% supported the proposed definitions
- 10% did not support the proposed definitions
- 3% did not know or had no opinion

The consultation invited respondents who did not support the proposed definitions to outline what they would change about the definition. Feedback from the 61 respondents included:

- definitions should mirror EU MDR/IVDR
- definitions should mirror those for licensed medicines as closely as possible
- definitions should cover mental health impacts

The consultation asked whether the manufacturer should be required to report any serious incident in line with the time periods outlined in points (a) to (c) below:

- a. 2 days after they become aware of the incident, in the event of a serious public health threat
- b. 10 days after they become aware of the incident, in the event of death or an unanticipated serious deterioration in a person's state of health
- c. 15 days after they become aware of any serious incident which is not covered under parts (a) or (b) above.

239 responses were received, of which:

- 85% supported the proposal
- 12% did not support the proposal
- 3% did not know or had no opinion

Written comments regarding alternative timeframes for reporting serious incidents and other suggested changes to the criteria for reporting serious incidents and field safety corrective actions were received from 70 respondents. Key themes can be summarised as follows:

- definitions should cover life-changing effects
- guidance documents may need to define additional terms such as 'chronic'
- aligning with the EU would provide consistency for manufacturers and patients
- mental health impacts should be covered as a part of serious incident reporting

The consultation invited views on whether the UK medical devices regulations should specify further procedures for manufacturers regarding the reporting of serious incidents and FSCAs including (but not limited to) points (a) to (c) below:

- a. the manufacturer can submit an initial report that is incomplete followed up by a complete report
- b. manufacturers must report any field safety corrective actions in advance of the field safety corrective action being undertaken, except in cases of urgency
- c. manufacturers can provide periodic summary reports instead of individual serious incident reports for serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action that has been implemented, or where the incidents are common and well documented, where agreed by the MHRA

Of the 235 responses:

- 76% were in favour of the proposal
- 16% were not in favour of the proposal
- 8% did not know or had no opinion

The consultation invited respondents to outline any other requirements which they considered should be introduced regarding reporting of serious incidents and field safety corrective actions. The 86 responses can be summarised as follows:

- serious incident reporting / field safety notice (FSN) / FSCA data should be available to Approved Bodies
- aligning with global standards will provide further clarity to manufacturers
- wording on timescales must be clear to ensure that patient safety is not jeopardised
- manufacturers should be required to include the Unique Device Identification (UDI) when reporting (see Chapter 4 on UDI-DI)
- guidance on the process for submitting FSNs to the MHRA is required to improve clarity

The abridged consultation in Chapter 17 invited views on whether manufacturers should be required to consult with patients when investigating device incidents. Of the 58 responses received:

- 57% supported the proposal
- 26% did not support the proposal
- 17% did not know or had no opinion

Those who supported the above proposal were invited to comment on how manufacturers should consult with patients when investigating incidents. The following themes were raised by the 26 respondents:

- the majority of respondents felt that engagement should be via a third party – with some suggestions to do so through formal patient groups or a patient engagement advisory committee
- some felt that manufacturers could contact patients or a sub-set of patients utilising a database of all patients implanted with a medical device

Respondents to the abridged consultation in Chapter 17 were asked to provide their reasoning for their answers to the previous two questions or any general comments on patient and public engagement during incident investigation. The following themes were raised by the 24 respondents:

- concerns about the practicality of requiring manufacturers to contact patients directly
- the importance of patient engagement and having a means for patients to feedback on their experiences

## 49.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposal to amend the UK medical devices regulations to include the **definitions of 'serious incident', 'serious deterioration' and 'serious public health threat'**. The government acknowledges the support for the introduction of the definitions proposed in the consultation. However, upon review of the responses, the government has decided to amend the definition of 'serious incident' by replacing "the permanent or temporary serious deterioration of a patient's, user's or other person's state of health" with the "serious deterioration of any person's state of health". We consider that that the terms "permanent" and "temporary" are superseded by the definition of "serious deterioration" (as defined in the consultation).

The government notes the comments made around the inclusion of mental health impacts in serious incident reporting and considers that, at this time, appropriate mechanisms are not in place to sufficiently regulate the inclusion of these impacts. The government does however acknowledge the seriousness of such impacts and will keep this issue under review to consider again following a suitable period for the new system to bed in. The government aims to further clarify the requirements in published guidance. The government also acknowledges the suggestion that the definitions should mirror those set out in the EU regulations. The proposed definitions are closely aligned however, the amendments outlined in this section, are intended to provide additional clarity.

## Section 50 – Trend Reporting

### 50.1 Proposals and feedback

The consultation invited views on whether manufacturers should be required to report any statistically significant increase in the frequency or severity of incidents/erroneous results as set out in points (a) and (b) below.

- a. for general medical devices and IVDs - any statistically significant increase in the frequency or severity of incidents that could have a significant impact on the benefit-risk analysis
- b. for IVDs - any significant increase in expected erroneous results established in comparison to the stated performance of the IVD or respective assays.

Of the 219 responses received:

- 76% supported the proposal
- 16% did not support the proposal
- 8% did not know or had no opinion

When asked to provide reasoning for their answer to the above question, 121 respondents provided comments, which can be summarised as follows:

- this requirement would improve public awareness, safety and promote design improvements
- reporting in this way will have a more significant impact on low-volume devices
- this should be included within the post-market surveillance reporting system to avoid additional manufacturer burden
- trend analysis allows for earlier reaction to issues
- clarity is needed on this requirement to ensure that trend reports can be correctly submitted

## 50.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposal to amend the UK medical devices regulations to require manufacturers to report statistically significant data as outlined in Section 50.1 above. The government acknowledges the concerns raised that this may disproportionately affect low-volume devices and will consider this in additional published guidance and wider policy development.

### Section 51 – Analysis of serious incidents and field safety corrective action (or 'FSCAs')

#### 51.1 Proposals and feedback

The consultation sought views on whether 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. Of 228 respondents:

- 81% supported the proposal
- 12% did not support the proposal
- 7% did not know or had no opinion

When asked whether the UK medical devices regulations should set out the minimum requirements for the content of field safety notices issued by manufacturers, 228 respondents provided views, of which:

- 91% supported the proposal
- 5% did not support the proposal
- 4% did not know or had no opinion

The consultation sought views on whether 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. Of 230 respondents:

- 91% supported the proposal
- 6% did not support the proposal
- 3% did not know or had no opinion

The consultation asked: "if the MHRA 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?". Written comments provided by 146 respondents can be summarised as follows:

- this should be outlined in MHRA guidance
- International Organization for Standardization (ISO) standards should be taken into account
- patient involvement should be a required for all devices
- data collection methods put forward included questionnaires, patient surveys, focus groups and interviews

The consultation invited consultees to indicate what stages they would expect manufacturers to engage patients and the public. 217 respondents selected the options below from a multiple-choice list, as follows:

- a. periodically once their medical device is on the market (**34%**)
- b. only when they or the MHRA becomes aware of a safety issue with the device (**36%**)
- c. other – please specify (**30%**)

Feedback provided in relation to the 'other' option can be summarised as follows:

- throughout the product life cycle
- only where patient populations are willing and able to engage
- immediately after a patient reports an incident

When asked respondents to provide reasoning for their answer to the above questions, 126 respondents provided comments, which can be summarised as follows:

- align with EU MDR and IVDR
- patient and public involvement should not be mandated
- the MHRA should make available a template for FSNs
- ongoing vigilance should provide much better underpinning of patient safety

## 51.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposals to amend the UK medical devices regulations to require manufacturers to issue field safety notices (FSNs) and to amend the regulations to include the **minimum requirements for the content of the FSN**. This is to ensure that all FSNs are drawn up to the same standard and that they contain all the information that the MHRA considers important. The government acknowledges the support for the proposal to introduce the requirement for manufacturers to submit the content of their FSN to the MHRA for comment, except in cases of emergency. Appropriate systems need to be available to deliver this, which are not yet in place, therefore this requirement is suspended for future consideration.

The government acknowledges the support to introduce the proposal that the MHRA should be required to notify the manufacturer or UK Responsible person of new risks it has identified through active monitoring of data, it is the government's intention to proceed with this proposal. The government has noted the support and concerns raised in relation to the proposal to introduce a requirement to mandate patient and public involvement as part of vigilance obligations. Upon review of the responses, it is the government's intention not to proceed with the proposal to mandate patient and public involvement as part of vigilance obligations however, the government intends to publish guidance to manufacturers on engaging with patients and the public as part of vigilance obligations. The government acknowledges that patient and public engagement as part of vigilance obligations must be proportionate to the risks and intended use associated with a particular device.

## 9 – *In vitro* Diagnostic Medical Devices

The consultation proposed amendments to the UK medical devices regulations to reflect new developments within the field of *in vitro* diagnostics. The proposed amendments to our regulatory framework for *in vitro* diagnostic medical devices (IVDs) will enable us to keep pace with fast-moving developments and innovation and will bring our approach into line with current international standards.

**The aim of these proposals is to update the regulations in this area, bringing significant improvements in patient safety and to ensure more robust pre- and post-market requirements for IVDs.**

### Section 53 – IVD Classification Rules

#### 53.1 Proposals and feedback

The consultation invited views on whether the classification rules for IVD products under the UK medical devices regulations should be amended to align to the EU approach to IVD classification, as set out in the EU IVDR. Of 138 responses:

- 80% supported the proposal
- 13% did not support the proposal
- 7% did not know or had no opinion

The MHRA asked consultees whether the classification rules for IVD products under the UK medical devices regulations should be amended to align to the International Medical Devices Regulatory Forum (IMDRF) approach to IVD classification. Of 136 respondents:

- 56% supported the proposal
- 20% did not support the proposal
- 24% did not know or had no opinion

The consultation invited views on whether the current IVD regulatory requirements for each class of IVD are proportionate to their risk. Of 135 responses:

- 21% felt they are proportionate
- 57% felt that they are not proportionate
- 21% did not know or had no opinion

When asked whether the current approach to classification sufficiently covers the digital/software aspect of IVD, 136 respondents provided views, of which:

- 11% felt the current approach is sufficient
- 51% felt that the current approach is not sufficient
- 38% did not know or had no opinion

We invited respondents to provide reasoning for their responses to questions in Section 53. 96 responses were received, which can be summarised as follows:

- many respondents indicated that alignment with the EU would provide economic and operational benefits to manufacturers
- some respondents note that global harmonisation (both in the context of the EU and the IMDRF) would provide wider choice to patients
- global harmonisation (both in the context of the EU and the IMDRF) would make the UK a more attractive destination to manufacturers

- clear definitions need to be provided to ensure regulations are interpreted consistently
- many respondents felt that mirroring a risk-based approach to classification would be favourable
- software must be more clearly defined in IVD regulation (see Chapter 1 on scope of the regulations)

## 53.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposal to amend the UK medical devices regulations to **amend the IVD classification rules** to increase the level of scrutiny applied to IVDs, using a series of rules which align the UK more closely with the structure used by the IMDRF. This will support global harmonisation efforts and assist in providing a risk-based approach to classification of IVDs.

## Section 54 – Genetic Testing

### 54.1 Proposals and feedback

The consultation invited views on whether the UK should introduce requirements around the information and data provided to individuals on the nature, significance, and implications of genetic tests. Of 114 responses:

- 81% supported the proposal
- 7% did not support the proposal
- 12% did not know or had no opinion

When asked whether the UK medical device regulations should be amended to align with the EU approach to the classification of genetic tests as set out in the IVDR, 116 respondents provided views, of which:

- 72% supported the proposal
- 14% did not support the proposal
- 15% did not know or had no opinion

When invited to provide reasoning for their responses to questions on genetic testing, consultees made a range of comments, which can be summarised as follows:

- the scope of the regulations should be expanded to include 'direct-to-consumer' testing
- aligning with the EU would provide greater clarity for both patients and manufacturers
- clearer guidance documents are required on the regulations for genetic testing

### 54.2 The government response

Having carefully considered consultation responses, it is the government's intention to amend the regulations to require that the individual being tested or, where applicable, his or her legally designated representative is provided with **relevant information on the nature, the significance, and the implications of the genetic test**, as appropriate.

The consultation responses reflected the need for greater scrutiny to be placed on genetic tests. The new IVD classification system will classify genetic tests proportionate to their risk - i.e., where there is a risk that an erroneous result could lead to a serious adverse event, these genetic tests will be classified as Class C (second highest risk category). This reflects responses that advocated alignment with the EU IVDR (Class C) while ensuring that the risk classification is proportionate to the risk presented by a particular device. This approach will ensure that genetic tests are subject to greater regulatory scrutiny in accordance with their risk. Following specific concerns raised about

direct- to- consumer genetic testing, the government will ensure *that genetic tests put into service in the UK are regulated in a way that is proportionate to their risk under the new provisions.*

Some respondents also indicated that more guidance may be necessary to clarify the application of genetic testing regulation. The government aims to further clarify the requirements placed on manufacturers in published guidance.

## **Section 55 – Companion Diagnostics**

### **55.1 Proposals and feedback**

The consultation invited views on whether Companion Diagnostics should be treated differently to other IVDs (with respect to classification). Of 110 respondents:

- 39% supported the proposal
- 40% were unresponsive
- 21% did not know or had no opinion

When invited to comment on possible methods for ensuring that the clinical evidence requirements for Companion Diagnostics are clear, appropriate and proportionate to the risk, 64 respondents provided a range of views, which can be summarised as follows:

- the MHRA needs to provide clear guidance on all Companion Diagnostic products
- clinical evidence requirements should be set, using a risk-based approach to ensure they are proportionate to the products intended use.
- clinical evidence requirements should ensure products are tested on a diverse population
- some respondents felt there was benefit in aligning with the EU IVDR
- many respondents felt there was benefit in aligning to the IMDRF's risk-based approach

### **55.2 The government response**

After careful consideration of responses, the government's intention is to proceed with the proposal to amend the UK medical devices regulations to **introduce classification rules specifically for Companion Diagnostic devices**. In the development of these rules, we will take into consideration the approaches taken by both the EU and IMDRF. Respondents supported using a risk-based approach to clinical evidence requirements and considered that differentiation according to whether a Companion Diagnostic device is used to predict treatment benefit or toxicity alone would be overly simplistic. The government intends to proceed with a risk-based approach to the clinical evidence requirements relating to companion diagnostics, this risk-based approach will also be reflected in the classification rules.

Some respondents also indicated that more guidance may be necessary to clarify clinical evidence requirements for Companion Diagnostics. The government aims to accompany each of the IVD classifications with guidance to provide clarity on this.

## **Section 56 – Distance Selling**

### **56.1 Proposals and feedback**

The consultation asked consultees whether it should 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 that apply to economic operators in the traditional supply chain. Of 108 respondents:

- 91% supported the proposal
- 7% did not support the proposal

- 2% did not know or had no opinion

The consultation asked whether those selling testing services, which include the provision of IVDs into the UK should be required to register their medical devices with the MHRA. Of the 106 responses:

- 93% supported the proposal
- 6% did not support the proposal
- 1% did not know or had no opinion

When asked to set out their reasoning for their responses to the above questions, 63 respondents raised a number of points, which can be summarised as follows:

- if an IVD is supplied on the UK market the same rules should apply irrespective of how it is supplied
- ensuring distance sales are appropriately regulated would protect patients
- aligning with international approaches will benefit manufacturers from an economic and operational perspective
- regulations should not only apply to test kits, but should apply to services such as single site assays undertaken outside of the UK for UK samples

## **56.2 The government response**

Having considered the views of respondents the government is minded to explore further, the scope to proceed with the above proposals and will have further cross-government discussions to ensure our approach aligns, where appropriate, with similar measures in place for other products placed on the UK market. See Section 9 in the Economic Operators Chapter (Chapter 4) and section 59 of the Software as a Medical Device Chapter (Chapter 10) for further details on Distance Sales.

## 10 – Software as a Medical Device

Software as a medical device (SaMD) - being standalone software and software included in wider hardware and including artificial intelligence (AI) as a medical device (AIaMD) - has grown in market share, public health significance and complexity in recent years. It has applications in health and social care that could not have been envisioned when existing regulations around medical devices were developed, and it is anticipated that these applications will continue to increase in coming years.

**The current medical device regulations contain few provisions specifically aimed at regulating SaMD or AIaMD. The proposals outlined in the consultation would amend the UK medical devices regulations to both better protect patients and support responsible innovation in digital health. The proposals aim to ensure that the regulation of SaMD is clear, effective, and proportionate to the risks these medical devices present. The majority of change required in this area is likely to be in the form of guidance rather than legislation and the questions asked in the consultation helped to draw out the distinctions between the two approaches.**

### Section 57

Section 57 of the consultation set out some background information regarding the current regulatory approach to SaMD and AIaMD. This section did not contain any proposals or questions.

### Section 58 - Scope and definitions

#### 58.1 Proposals and feedback

The consultation asked whether the UK medical devices regulations should introduce the following definition of the term 'software' to the UK medical devices regulations: "a set of instructions that processes input data and creates output data". This definition is consistent with the definition in the EU's [MEDDEV 2.1/6](#). Out of 208 responses:

- 83% supported the introduction of this definition
- 10% did not support the introduction of this definition
- 7% did not know or had no opinion

In regard to whether there are other definitions that need to be added to, or changed in, the UK medical devices regulations to further clarify what requirements apply to placing SaMD on the UK market, 198 responses were received, of which:

- 51% felt that further definitions were needed
- 19% did not feel that any further definitions were needed
- 30% did not know or had no opinion

Within this, a larger proportion of those who responded as part of an organisation supported the use of further definitions (55%), compared to 37% of individual respondents who in contrast responded don't know or had no opinion.

Other information provided in comments from respondents relating to defining the term 'software' revealed no reasons to change the proposed policy position as set out in the consultation document. There was a consistent set of additional terms which should be defined, although not necessarily in the regulations.

The majority of the comments covered the need to:

- align definitions with EU, International Medical Device Regulators Forum (IMDRF), Medical Device Co-ordination Group (MDCG) or international standards
- provide additional clarity around the definition of 'software'
- provide additional clarity in guidance rather than in the regulations
- extend the definition of 'software'
- include other definitions

Some respondents commented that the proposed definition of software was too vague and did not address the distinction between software as a medical device and software in a medical device.

Those who were not supportive of the introduction of the definition of 'software' into the regulations cited these comments:

- there is a need for clearer explanations
- use IMDRF definitions
- specifically consider *in vitro* diagnostic medical device (IVD) software
- use only International Organization for Standardization (ISO) and/or International Electrotechnical Commission (IEC) definitions
- suggested definition is too vague
- define AI separately
- list specific exclusions

Other definitions that respondents suggested for inclusion in regulations included, but were not limited to:

- software as a medical device
- software in a medical device
- cyber security
- predetermined change control
- software accessory
- IVD software
- AI
- software driver
- input data
- output data

## 58.2 The government response

After careful consideration of the responses, it remains the government's intention to proceed with the proposal to clarify the meaning and scope of the term 'Software', by adding a **new definition of Software to the UK medical device regulations**.

As proposed, we plan to add the following definition of 'Software' to the UK medical devices regulations: "*A set of instructions that processes input data and creates output data*".

The MHRA recognises that there is interest in defining other terms related to software and will ensure there is sufficient clarity of these as we produce supporting guidance in this area.

## Section 59 - Distance sales

### 59.1 Proposals and feedback

The consultation outlined that SaMD can be deployed in the UK by websites hosted in other jurisdictions. The consultation sought views on whether there is a need for greater/clearer requirements with regards to such deployment. Of the 161 responses:

- 78% were in favour
- 11% were not in favour
- 11% did not know or had no opinion

The consultation invited views on whether the definition of ‘placing on the market’ could be modified to clarify when SaMD deployed on websites, app stores (for example Google Play and Apple stores) and via other electronic means accessible in the UK, amounts to ‘placing on the market’. Of the 158 responses received:

- 74% supported the proposal
- 16% did not support the proposal
- 10% did not know or had no opinion

There was an overall positive response to the accompanying free-text questions in this section, reflecting significant interest in having greater clarity around the requirements for deploying software as a medical device to the UK market through websites hosted in other jurisdictions, with considerable support for further clarifying the term ‘*placing on the market*’. There was a call for a ‘level playing field’, which would see manufacturers who place software products on the UK market needing to meet the same requirements as manufacturers of physical devices.

Several respondents suggested there is a need for greater clarity on the use of the terms:

- ‘placing on the market’
- ‘operational use’
- ‘deployment’
- ‘putting into service’
- ‘software as a service’
- ‘making available’
- ‘being available’

Several references were also made to the need for additional guidance to further clarify the role of app stores. Reference was also made to the need for alignment with existing definitions set out in the EU Blue Guide or by the Medical Device Coordination Group. Other points referred to the management of open source coding, cloud-based services and to managing app stores and vendors.

## 59.2 The government response

Having considered the views of respondents the government is minded to explore further, the scope to proceed with the above possible changes and will have further cross-government discussions to ensure our approach aligns, where appropriate, with similar measures in place for other products placed on the UK market. See Section 9 in the Economic Operators Chapter (Chapter 4) and section 56 of the IVD Chapter (Chapter 9) for further details on Distance Sales.

As set out above in the Economic Operators chapter (Chapter 3), the MHRA will further consider the scope to clarify and strengthen regulatory requirements and guidance applicable to medical devices sold via **distance sales**. While the MHRA do not currently see the need for SaMD-specific regulation change in relation to distance sales, the MHRA recognises there may be a need for suitable guidance that makes clear to what extent SaMD provided to the UK market via distance sales is subject to requirements under the UK medical devices regulations.

The MHRA also acknowledges that there is interest in defining a range of terms related to placing software as a medical device on the market and will consider providing greater guidance on such terms.

## Section 60 - Classification: risk categorisation

### 60.1 Proposals and feedback

We asked whether the classification rules in UK medical devices regulations should be amended to include the IMDRF SaMD classification rule (with supporting definitions and implementing rules), and to set out their rationale and any impacts they expected this change would have. Of the 189 responses:

- 82% were in favour of the proposal
- 10% did not support the proposal
- 8% did not know or had no opinion

Many respondents provided further detail of their opinion of this framework, including their rationale for their answer and any impacts expected from the possible change. The main reason for following the IMDRF framework is to further for international alignment and that it was seen as a logical, clear, proportionate method for SaMD risk classification. The main impact that was mentioned by respondents was re-classification. Further comments included that the IMDRF framework does not include any information for SaMD that drives or influences the use of a device in the same way as implementing rule 3.3 in the EU MDR and stated that clarity would be needed for this.

Respondents also noted how the wording for implementing rule 3.3 could be edited to make it compatible with the SaMD definition. In addition, it was noted that the IMDRF framework does not distinguish between SaMD regulated as a medical device and an *in vitro* diagnostic medical device (IVD) and further clarity is needed to understand how this would work in the UK medical device regulations.

There was a theme of responses stating the need for clearer definitions, including of:

- 'diagnose / treat'
- 'driving patient management'
- 'informing clinical management'
- 'prediction' / 'prognosis'

It was also emphasised that definitions need to allow for future technological advancements.

### 60.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposal to **amend the classification rules in UK medical devices regulations to include the IMDRF SaMD classification rule** for general medical devices, not IVDs (with supporting definitions and implementing rules).

The MHRA wants to ensure the scrutiny applied to SaMD is more commensurate with their level of risk and therefore better protect public health.

In addition, GB is currently out of alignment with other major regulators in relation to software as a medical device classification. The MHRA wants the UK to be in international alignment. This will likely have a positive affect with respect to the availability of these devices and the UK being regarded as a favourable place in which to research, develop, and manufacture these devices.

A move to follow this IMDRF categorisation framework we consider a logical, clear, proportionate method for SaMD classification (excluding for IVDs) which allows for international alignment. This classification was supported by a clear majority of respondents to the public consultation. We have

chosen not to include IVDs at this stage because this significantly diverges from the EU IVDR classification system.

Taking into account the responses from the public consultation, we propose to adopt the risk categorisation in the [IMDRF Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations](#) for classifying SaMD that are general medical devices (not IVDs) with consequential implementing rules and definitions and clear guidance.

## **Section 61 - Classification: airlock classification rule**

### **61.1 Proposals and feedback**

Introducing an 'airlock classification rule' is a provision that would allow for a temporary classification to be applied to some SaMD (which is likely to involve monitoring and restricting the SaMD as if it were a high-risk device) where the risk profile is unclear. This could allow early access to market for novel and innovative SaMD whilst ensuring the safety of users and patients until the risks of the device are properly understood.

We invited views on whether the UK medical devices regulations should introduce an airlock classification rule for SaMD with a risk profile that is not well understood. 163 responses were received, of which:

- 60% were in support of the proposal
- 14% did not support the proposal
- 26% did not know or had no opinion

Of those who were in favour of introducing an 'airlock classification rule', the most common rationale for this was to support innovation and access. In addition, respondents also noted that a system was required and that this approach seemed logical.

However, other responses mentioned that there could be alternatives to the airlock rule, for example conditional approvals, and that this type of pathway could also be used for IVDs and other medical devices.

Many responses also mentioned that, for this to work, there would need to be clear guidelines for manufacturers and for patient safety. Comments included recommending stakeholder feedback to refine the proposed change in detail and recommending a similar process to the U.S. Food and Drug Administration (FDA) De Novo pathway. Further responses cautioned that if additional requirements are too burdensome, this rule could actually increase cost and slow down innovation.

Those against the introduction of an airlock classification, emphasised that risk should be understood, and risk controls established before being placed on the market, and that if IMDRF classification rules are clear enough this rule may not be needed. In addition, it was noted that medical device regulation already allows for quicker access to market than for medicines and therefore this rule is not warranted.

### **61.2 The government response**

Having considered the responses provided in relation to introducing an **airlock classification rule** for SaMD with a risk profile that is not well understood, the government remains interested in the potential to introduce an airlock conditional authorisation and intends to consider this further, taking into account the feedback raised by consultation respondents.

The MHRA plans to scope further detail about this possible change and include it in a future possible public consultation in order to obtain further feedback from stakeholders before potentially adding it to the UK regulations. This is necessary because many respondents commenting on it,

whilst supportive, felt that further details would be required to come to a decision on whether to take an airlock classification rule for SaMD forward.

## **Section 62 - Pre-market requirements**

### **62.1 Proposals and feedback**

Participants were asked whether additional essential requirements should be in place (beyond those that apply to medical devices more broadly) to assure the safety and performance of SaMD specifically. Of the 172 responses received:

- 61% supported the proposal
- 26% were not in support of the proposal
- 13% did not know or had no opinion

A higher proportion (83%) of respondents who classed themselves as 'individuals' considered that additional essential requirements should be in place compared with 55% of those who responded as part of an organisation. Conversely, 30% of organisations responded 'no' compared with only 10% of individuals.

We invited consultees to set out reasoning for their response to the above question and any expected impacts, with 121 responses provided. Those who supported the introduction of additional essential requirements to assure the safety of SaMD specifically, the most common rationale given was that many want the UK to align with EU MDR/IVDR, specifically General Safety and Performance Requirement (GSPR) 17 in the EU MDR. Some respondents gave non-specific recommendations, noting that extra essential requirements are needed for SaMD, but did not elaborate further.

Respondents suggested possible additions/alterations, including:

- cyber security
- data protection, privacy, or confidentiality
- better alignment to core Data Coordination Board (DCB) standards
- GSPRs specific to AI

A minority of respondents commented that the current essential requirements were sufficient to cover SaMD. Whilst the government broadly agrees with this point, it is felt there are necessary additions to be made.

Multiple respondents commented that they thought guidance was better placed to cover requirements for SaMD. The government will ensure that any additional and current essential requirements specific to SaMD are supported by guidance but disagrees that we can adequately protect patients and public merely through guidance alone; additional essential requirements are necessary.

The consultation invited views on whether the regulations should set out SaMD essential requirements separate from those for other general medical devices. Out of 168 responses:

- 49% were in favour of the proposal
- 37% were not in favour
- 14% did not know or had no opinion

We also asked whether regulations should set out SaMD essential requirements separate from those for other general medical device types. Many responses requested the essential

requirements to be subdivided for SaMD rather than separate to general medical devices. Of the respondents that identified as being part of an organisation, 42% thought that SaMD essential requirements should **not** be separate from those applicable to other general medical devices, versus 18% of those who responded as an individual.

The majority of respondents in favour of the regulations setting out SaMD essential requirements separate from those for other general medical devices gave justification relating to the clarity and ability to clearly define which essential requirements apply to SaMD in particular.

Conversely, most respondents not in favour of the regulations setting out SaMD essential requirements separate from those applicable to other general medical devices, cited the need to harmonise with the EU MDR. Many commented that such separation would be confusing, arguing for sub-division not separation, or that there was no need for essential requirements for SaMD in particular.

A clear majority of respondents were in favour of *sub-division* rather than having separate essential requirements for SaMD. They typically were in favour of:

- harmonisation with EU MDR/IVDR, with the SaMD GSPRs being a sub-division of the general GSPRs
- a desire to avoid having separate essential requirements for SaMD, noting a preference for wanting sub-division

## 62.2 The government response

Having considered the views of respondents, the government wants to ensure that a SaMD receives adequate pre-market scrutiny to assure its safety, quality and performance and to ensure that appropriate essential requirements are in place meet this need. In light of this, the government intends to proceed with the proposal to introduce further essential requirements to assure the safety and performance of SaMD specifically.

The government has considered key themes raised, as follows:

- Cyber security - our policy position is to include cyber security as an essential requirement.
- Data protection, privacy, or confidentiality - we will work closely with the Department for Digital, Culture, Media & Sport (DCMS), Information Commissioner's Office, the National Data Guardian, and the Health Research Authority to ensure that patient data is protected.
- Better alignment to Data Coordination Board (DCB) standards - shifting essential requirements to match DCB standards would risk international divergence for the benefit of national convergence. We shall instead work with NHS Digital and NHSX to map and align where possible, also using guidance to better harmonise with these standards.
- We consider requirements specific to AI as a medical device are best clarified via guidance on how to meet a GSPR akin to EU MDR's GSPR 17.2 (which includes verification and validation) rather than setting up a separate essential requirement/GSPR specific to AI as a medical device.

As highlighted in responses, a key feature of this approach will be the introduction of essential requirements/GSPRs that closely mirror EU MDR, Annex I, GSPR 17 (and its EU IVDR equivalent in relation to IVDs).

The MHRA considers that other suggested essential requirements for AIaMD specifically, as expanded on above, are generally better captured by GSPR 17 and guidance clarifying how it applies to AI in particular.

Further to this and after careful consideration of responses, it is the government's intention **not** to separate out essential requirements/GSPRs for software but to subdivide the essential requirements/GSPRs for software largely mirroring the EU MDR/IVDR. It is the government's view that this is the preferred position, as it:

- protect patients and the public through updating the essential requirements/GSPRs to better capture safety requirements for SaMD; and
- minimise burdens to industry through close alignment with the EU MDR/IVDR, which could help ensure that the UK market remains an attractive place for medical devices

## **Section 63 - Post-market requirements**

### **63.1 Proposals and feedback**

The consultation set out proposals for the MHRA to:

- a. allow accurate and swift reporting via the digital Yellow Card Scheme – noting that SaMD should have a hyperlink to MHRA endorsed websites where a person can 'report an adverse incident with a medical device' where appropriate, and
- b. provide for certain SaMD change management processes such as 'predetermined change control plans' (PCCPs).

We invited views on whether the UK medical devices regulations should **mandate a 'report adverse incident' link**. 178 responses were received, of which:

- 51% were in support of the proposal
- 31% were against this proposal
- 18% were not sure or had no opinion

Consultees were asked to provide reasoning for their responses to the above question. Of those who supported the mandating of a 'report adverse incident' link, the majority commented that it would make it easier to report incidents due to accessibility, it would encourage more people to report incidents, it will allow analysis of large volumes of information, and it will allow for easier investigations of potential faults.

Respondents also highlighted that this approach may give valuable insight into areas where reporting is higher, which could highlight areas where additional regulatory changes may be needed, and that a similar link is used by other worldwide health agencies including FDA.

Other respondents commented that the current system for Yellow Card has certain challenges and may not be understood by some patients. Therefore, requiring manufacturers to provide a link could raise awareness of the scheme and make it clear that the MHRA expects adverse events to be reported through this route.

Respondents who were unsupportive of mandating the link commonly reasoned that not all SaMD will have the user interface necessary to support the link. It was suggested that the link could be included in the user manual. However, some respondents indicated that this would not be applicable for software that do not have access to internet.

Other respondents indicated that a 'report adverse incident' link would be a country specific software feature, which could cause complexity in the development of SaMD and may be overly burdensome. They noted that a requirement here could impact the software build, verification and validation process, which could prove difficult for manufacturers. Some responders were concerned that issues could arise from the link - for example, if the destination address were to be changed by the MHRA or the link were to break, the manufacturer would have no knowledge. It was also noted that the proposal is not in alignment with other international jurisdictions.

Multiple respondents commented that issues should be raised with the manufacturer directly instead of being reported to the MHRA. Here, respondents reasoned that the manufacturer should first have an opportunity to triage and determine which events are in fact reportable. A number of responses also raised concerns that users may send false complaints or may abuse the link and encourage false reporting, which could create excessive amount of work for both manufacturers and the MHRA.

Many of those who were unsure about whether a 'report adverse incident' link should be required stated that the MHRA would need to clarify how such a requirement would be implemented in order for them to provide an informed view as to whether or not they supported such a policy.

The consultation invited views on whether the regulations should enable **predetermined change control plans (PCCPs)**. Of the 168 responses:

- 50% were in favour of the proposal
- 14% were not in favour
- 36% did not know or had no opinion

Of those who supported the introduction of PCCPs, many noted that they would improve performance and safety, and promote innovation. Others reasoned that PCCPs could simplify regulations for expected changes that do not impact intended use - such as software updates, bug fixes, user interface/user experience (UI/UX) changes and routine updates for security. Others commented that there should be a structured change control plan that is well documented, which should be dependent on the manufacturer's Quality Management System (QMS) which is routinely evaluated and certified by an Approved Body.

Further responses indicated that we should align with the FDA and PCCP frameworks within other countries. Respondents suggested that the PCCP should be:

- based on FDA's framework by including the SaMD Pre-Specifications and the Algorithm Change Protocol
- utilised across all SaMD, in contrast with the FDA which only focuses on modification for Artificial Intelligence / Machine Learning
- aligned with the FDA and limited to AI / Machine Learning model only

Respondents who were not in favour of proposals to introduce the introduction PCCPs highlighted that once software has been tested and approved, it should not be changed. Here, respondents noted that:

- minor code change could have unpredictable effects
- it may slow clinical risk response
- PCCPs will limit the creativity and innovation of companies
- it would be harder for regulators to observe issues

One respondent indicated that the FDA is still exploring this method and it may take time to fully develop, suggesting postponement on this basis.

Over a third of respondents answered 'don't know or no opinion' to this question - and the majority of these responses indicated that they were unsure what PCCP would entail or what types of change would be required as this was not defined in the consultation.

Those who were supportive of PCCP also suggested certain topics that they considered should be covered in guidance:

- define PCCP and include representation examples

- clarity is needed regarding regulatory expectations and what change management documents need to be provided
- types of change that would not require pre-market approval
- types of changes that would require pre-market approval
- specify how and how often software would be updated
- how and when significant changes are reported and recorded

### 63.2 The government response

Having considered the responses provided in relation to the UK medical devices regulations **mandating a 'report adverse incident' link**, the government does not intend to adopt this possible change at this time.

Although there was support for mandating a 'report adverse incident' link, with many respondents noting that this would ease reporting of incidents, would encourage more people to report incidents and that it may give valuable insights into areas where reporting is higher; there was no clear consensus view on this possible change.

In light of this, we plan to further explore this possible change further, which will include further consultation to explore, in particular, what devices would be best suited to mandatory reporting link requirements and implementation considerations.

Currently, data suggests that the MHRA receives only a weak safety signal with respect to SaMD. It is clear that this safety signal does not represent a lack of SaMD incidents - rather a lack of reporting. The MHRA has observed that, where a 'report an adverse incident' has been mandated via the exceptional use authorisation process, this had led to an appreciable increase in reports. Therefore, requiring the manufacturer to provide a link in future would raise awareness of the scheme and make it clear that the MHRA expects adverse events to be reported through this route.

After careful consideration of responses, it remains the government's intention to proceed with the proposal to enable **predetermined change control plans (PCCPs)**. In implementing this approach, we intend to work with international partners wherever possible.

Currently, change management processes require all 'significant' or 'substantial' changes to be reported, either to the MHRA or to the relevant Approved Body. However, the proper interpretation of these requirements is difficult to find in guidance (for instance, in [Notified Body Operations Group Best Practice Guidance](#)), which can be cumbersome for manufacturers of software and AI. In light of this, a clear legislative foothold to manage change for software is required. Predetermined change control plans are one method to streamline these processes.

PCCPs will be enabled but on a voluntary basis, the MHRA recognises that there is a need to encourage the use of PCCPs in guidance and may consider the potential to mandate PCCPs in the future.

The government considers that proceeding with the consultation proposals on PCCPs will

- implement a robust post market surveillance and MHRA market surveillance system that produces a strong and clear safety signal, allowing for quicker and thorough capture of adverse incidents for SaMD
- utilise real world evidence to provide further assurance that SaMD functions as intended, maintains performance, and continues to provide assurance with respect to safety
- articulate clear change management requirements for SaMD
- encourage assured changes to SaMD and AIaMD that improve the performance of the devices

## Section 64 – SaMD cyber security

### 64.1 Proposals and feedback

The consultation invited views on whether the UK medical devices regulations should include cyber security and/or information security requirements. Of the 170 responses received:

- 88% were in favour of this approach
- 5% were not in favour
- 7% did not know or had no opinion

The consultation asked those in favour of introducing cyber security/information security requirements to outline what this should entail and why, as well as the expected impacts. 132 respondents provided feedback. Many respondents recommended alignment with other international regulators, existing frameworks and existing standards.

Many respondents noted that the EU MDR Annex I 17.4 comprises the ideal set of requirements and commented that, ideally, the UK follow would these. Respondents reasoned that this would avoid an unnecessary increase in the regulatory burden placed on UK manufacturers. Respondents suggested that liaison with other national regulators in this space, such as NHS Digital, NHS Transformation Directorate and Information Commissioner's Office (ICO) would be beneficial.

Several respondents advocated the need for specific essential requirements/templates to be established (minimum requirements to be set out, such as minimum safety standard and encryption), and to comprise part of the risk management process for manufacturers.

Other key comments included:

- There is a need for guidance. Including examples, to help navigate the requirements
- Requests to implement cyber security requirements on a risk-based approach, in order to avoid excessive regulatory burden for lower risk class products
- Acknowledgment that cyber security should be an ongoing process for the lifetime of the device. Suggestions were made for this process to be revisited in appropriate time intervals to ensure its effectiveness. Cyber security assessment/evaluation should also take into account the use of the device in specific environments and in relation to other systems
- General acknowledgment that cyber security is a collective and shared responsibility between manufacturers, healthcare establishments and users. Respondents highlighted the need to identify specific roles/responsibilities in this ongoing process (identification of liability was also identified as a concern, as this is often difficult to establish). In particular, importance must be given in considering interaction/risks with other systems connected with the medical device (for example, when these are deployed in hospitals or in other specific operating environments)
- The need for cyber security to be a central part of post market surveillance activities. This aspect was highlighted in several comments, with the aim of allowing post market surveillance to play a key part in ensuring the cyber security of medical devices is maintained throughout their lifecycle

Of those **not** in favour of introducing cyber security/information security requirements or those who did not know or had no opinion, the main themes raised were:

- cyber security should not be part of medical device regulations, but guidance would be helpful
- cyber security is already addressed by the essential requirements

- cyber security should be part of the QMS/Risk Analysis process

## 64.2 The government response

The government wants to ensure that sufficient cyber security and information security measures are in place for SaMD - both for the purposes of the **direct safety** of the device (e.g., whether its functioning could be tampered with) and consequent impacts on patients and the public, and also the **security of personal data** held on or in relation to the device.

After careful consideration of responses, it remains the government's intention that manufacturers of SaMD will be required to meet certain minimum requirements relating to security measures and protection against unauthorised access.

The position on cyber security is linked to that set out in the Pre-market Requirements section of this Chapter. The government intends to introduce a requirement akin to EU MDR General Safety and Performance Requirement (GSPR) 17.4 (for medical devices) and EU IVDR GSPR 16.4 (for IVDs) covering cyber security and associated requirements. Having considered the views of respondents, the government notes that its introduction would form a sound basis to bring forward guidance. There is a strong argument, as set out by consultees, to retain alignment with the EU in this area, unless divergence is necessary for the protection of UK patients.

Compared to other device categories, SaMD often exhibits a novel risk profile in a number of respects, this includes the premise that connected medical devices facilitate continuity of service but are also vulnerable to cyber-attack, thereby also presenting a novel risk profile. The objectives of applying relevant GSPR requirements are to further safeguard peoples' health, including by:

- ensuring that cyber security is adequately reflected in SaMD requirements and in post market surveillance requirements
- clarifying, bolstering, and making consistent, reporting requirements for cyber security incidents and vulnerability that might translate to adverse events from manufacturers

We anticipate that the addition of provisions akin to the EU MDR's GSPR 17.4 and IVDR GSPR 16.4 will also help ensure that the UK is harmonised with other jurisdictions that require similar evidence, thereby protecting patients and the public. In addition, we consider that the approach will have a neutral or positive impact on the UK's ability to access these devices and upon the UK as an attractive destination to innovate and supply devices.

## Section 65 – AI as a Medical Device

### 65.1 Proposals and feedback

Artificial Intelligence as a medical device (AIaMD) is a subset of software as a medical device (SaMD). With this in mind, the MHRA considers that the changes outlined in the SaMD chapter above would also be beneficial for the regulation of AIaMD.

Consultees were asked whether there are additional statutory changes required to effectively regulate AIaMD over and above the changes detailed for SaMD in the sections above. Of the 169 responses received:

- 38% supported additional statutory changes
- 24% did not support statutory changes
- 38% did not know or had no opinion

The consultation invited those who considered that additional changes are required to effectively regulate AIaMD to outline the changes that should be introduced. Of the 122 responses, the

majority did not support legislative changes in particular, but instead wanted to highlight areas of concern relating to AIaMD. There were several recurrent themes, for example: adaptivity, bias, interpretability, autonomy, all of which have been picked up in the wider SaMD scope and we intend to address through guidance.

Beyond these comments, other respondents provided specific areas where legislation should be utilised, including:

- to define AIaMD
- to mandate explainable AI
- on separate design requirements/essential requirements for AIaMD

Further analysis of both the supportive comments and comments from those who were unsure about whether additional requirements should be introduced, revealed that only a very small number of respondents actually supported additional statutory changes. Instead, respondents commented that they supported the use of guidance and flexibility over statutory changes.

The consultation outlined that the MHRA is considering making additional changes to the regulations specific to AIaMD. This included a proposal to require **performance evaluation methods** for diagnostic AI which would take a comparable approach to performance evaluation methods used for IVDs 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](#).

Participants were asked whether they considered 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. Of the 165 responses received:

- 56% supported this approach
- 11% did not support this approach
- 33% did not know or had no opinion

The follow-up question asked whether the UK medical devices regulations should be amended to require this, with a similar spread of responses. Of the 160 responses received:

- 51% were in favour
- 13% were not in favour
- 36% did not know or had no opinion

A review of the free-text comments provided in relation to questions in this section suggests that almost the responses (both positive and negative) were in fact supportive of the proposal - with only a couple suggesting that mandating AI requirements would be heavy handed. This discrepancy seems to have arisen from respondents combining their free text responses to these questions with the following question (regarding logging) in the consultation.

Therefore, there is support for requiring the use of IVD performance evaluations methods and we wish to proceed with the proposed policy position.

Participants were asked whether the UK medical devices regulations should mandate **logging of outputs of further auditability requirements** for all SaMD or just AIaMD for traceability purposes. Out of 161 responses:

- 37% were supportive of this proposal
- 21% were not supportive

- 42% did not know or had no opinion

We invited consultees to set out their reasoning for responses in this section. Of those who were supportive of the proposals, a few caveated their response with the need for further clarity and proportionality to avoid overburdening the market.

Feedback from respondents who indicated a lack of support for these proposals is summarised below:

- agreement with mandating for AIaMD but not SaMD
- concerns about cost and complexities of storage of “outputs”
- need more detail on what is meant by “outputs”
- concerns over data protection/privacy of stored data
- supportive of the intent but details are needed in guidance
- impact of this on legacy software

This leads to quite a mixed response to summarise, however there appears to be general support for empowering traceability, auditability and PMS, especially in AIaMD products for safety reasons. However, there are also many questions relating to the practicality and implementation of such a process should it be mandated, highlighting the need for highly detailed guidance.

## 65.2 The government response

Having considered the responses provided in relation to whether other statutory changes are required to effectively regulate AIaMD over and above the changes detailed for SaMD in the sections above, the government does not intend to introduce any AIaMD-specific requirements in legislation.

The government does not propose to define AIaMD or set specific legal requirements beyond those being considered for SaMD, as this would risk being overly prescriptive.

Some respondents indicated that further guidance may be necessary to effectively regulate AIaMD, and the MHRA is aligned with market concerns on the themes identified and will address these through robust guidance.

The government has carefully reviewed the consultation responses and we do not consider that there is a need for further AIaMD-specific legislative change. Instead, the MHRA will achieve the objective of encouraging **clinical performance evaluation methods** (akin to that outlined by IMDRF’s Software as a Medical Device (SaMD): Clinical Evaluation document) for SaMD by producing guidance that makes plain that this is expected as part of meeting a combination of GSPRs or essential requirements or state of the art.

Having considered the responses provided in relation to **mandating logging of outputs to enable auditability** for SaMD and AIaMD, the government does not intend to introduce this requirement at this time.

Broadly, the consultation responses were supportive of the above proposal on grounds of traceability and auditability for safety purposes, but many highlighted that an informed response would require specific details of what such a provision would encompass.

Accordingly, the government is of the view that this requirement should be considered further as part of a future possible targeted public consultation.

# 11 – Implantable Devices

Implantable medical devices bring with them some unique challenges. Procedures using these devices, either to introduce them or remove them, can be highly invasive. Implantable medical devices are often used for a longer duration than many other types of medical devices and their removal brings additional risks or may not be possible.

**The consultation invited views on how implantable medical devices can be better regulated, including proposals to ensure that implantable medical devices receive adequate scrutiny before they reach the market, and to ensure sufficient post-market surveillance and responsiveness to any post-market issues with implantable medical devices. The proposals have potential to improve the overall safety of implantable medical devices.**

## Section 66 - Implantable devices

### 66.1 Proposals and feedback

The MHRA invited views on whether there should be any **changes to the scope** of medical devices regulated as implantables. There were 244 responses, of which:

- 68% were in favour of change
- 17% did not support the possible change
- 15% did not know or had no opinion

There was a difference in the responses provided by individuals and organisations. In both cases, the majority supported the possibility, but with stronger support of changes expressed by individuals (82%), compared to organisations (51%).

When asked to set out any implantable devices that should be brought into or removed from the scope of implantable devices regulated under the UK medical devices regulations, 134 respondents provided comments. Dermal fillers, temporarily implanted medical devices, and breast implants were commonly raised as possible additions to the above scope, and some respondents suggested that 'all implantable medical devices' be brought into scope.

Some respondents provided the rationale for their suggested additions. The reasons given for expanding coverage to encompass temporarily implanted devices included a need to ensure sufficient pre-market scrutiny, post-market surveillance, and clinical data to evaluate possible additional risks, side effects and overall enhance patient safety.

Those suggesting that temporarily implanted medical devices be brought in scope commonly reasoned that these devices carry similar risks to other types of implantable medical devices (however, this view was not universal – other respondents were of the opposite view). Many respondents also sought clarification or definition of what products are classified as temporarily implantable medical devices. Those commenting dermal fillers should be brought into scope were largely driven by patient safety concerns, wanting to ensure that such products be made available on a prescription only basis and be limited to administration by medical practitioners. Those calling for breast implants to be brought into scope largely cited patient safety benefits.

A small number of responses proposed possible exclusions from the scope of regulated implantable medical devices, including Ophthalmic Viscosurgical Devices (OVDs). One respondent felt there should be exemptions from requirements for certain implantable devices, such as screws and staples, in line with the approach taken under the EU MDR. A small number made general comments on classification rather than scope. Others noted that the scope of implantable medical

devices regulated under UK medical devices regulations should align with EU regulations which could reduce compliance costs for some manufacturers wishing to place devices on multiple markets.

The MHRA invited views on a range of possible **changes to pre-market requirements** for implantable medical devices, including requirements around clinical investigations, technical documentation requirements and possible exemptions to pre-market evidence requirements.

The consultation also asked whether **requirements for clinical investigations** should be more robust for implantable medical devices than those conducted for non-implantable devices. Of the 243 responses received:

- 65% were in support of the possibility
- 17% were not in support
- 18% did not know or had no opinion

The consultation invited views on whether **requirements for technical documentation** for implantable medical devices should be more robust than those conducted for non-implantable devices of the same risk category. Of the 240 responses received:

- 60% supported this proposal
- 18% did not support this proposal
- 22% did not know or had no opinion

There was a difference in the response between individuals (70% were in support and 11% were not in support) and organisations (with 48% in support and 27% not in support).

The consultation invited views on whether there should be **exemptions from pre-market evidence requirements** for certain implantable devices (for example, screws and wedges). 242 responses were received. Of which:

- 27% were in support of such exemptions
- 32% did not support such exemptions
- 41% did not know or had no opinion

The consultation invited respondents to share their **rationale for their response to the above questions on possible changes to pre-market requirements**. 128 responses were received. In those no clear rationale was presented. However, common comments included:

- exempting Well Established Technology (WET) and/or aligning with exemptions under the EU MDR (or going beyond EU MDR exemptions, for example, to exempt nails)
- having clear definitions / guidance on exemptions
- considering other international approaches (for example, those of the U.S. Food and Drug Administration (FDA) and the Australian Therapeutic Goods Administration (TGA)).

The MHRA invited views on having **additional conditions** to the introduction of new implantable medical devices to the UK market, including the **controls** that should be in place, for how long, and to what type of device controls should apply. Key themes in 103 responses included:

- a small number of respondents considered no further controls around implantable devices are needed
- of those that raised possible changes in controls, many comments expressed a desire to limit the availability of implantable medical devices (or specific types of implantable devices such as dermal fillers) to medical practitioners or healthcare settings

- some commented that controls should depend on the risk of a device and not on the fact that it is implantable
- a small number considered that requirements should align with EU requirements, and not surpass EU / US requirements
- a small number raised possible impacts that could result from the introduction of further controls - including device availability and safety, burden on manufacturers (and small and medium sized enterprises (SMEs) in particular), and supporting innovation
- a small number also expressed interest in changes in **post-market surveillance requirements** for implantable medical devices, including the need for ensuring robust post-market surveillance for implantable devices and identification of long-term issues with a device
- a number raised clinical evidence requirements, including interest in ensuring robust clinical data and technical documentation to support safety and effectiveness of the device, robust post-market clinical follow up, human trials should be carried out and results available to potential implantees
- some interest in increasing the transparency of evidence relating to the safety and performance of medical devices

The consultation also invited views on whether there should be **more stringent controls over medical devices**. There were 238 responses, of which:

- 71% supported the possibility
- 17% did not support the possibility
- 13% did not know or had no opinion

There was a difference in the responses between individuals (86% in favour and 7% not in favour) and organisations (53% in favour and 28% not in favour), with stronger support of this possibility from individuals than from organisations.

The MHRA asked consultees to indicate which controls in the list below should be introduced in relation to high-risk implantable devices. 63 responses were received and the percentage in favour of each control is set out below:

- administered with proactive follow up with patients (**83%**)
- being supplied only to medical device users in centres specialising in their use (**62%**)
- being supplied to medical device users by practitioners with specialist expertise and experience in the treatment of the condition requiring the device (**76%**)

The consultation invited views on whether any other controls over implantable devices should be introduced. A small number of respondents raised possible additional controls. Among those responses a common comment was that only licenced/approved users should be permitted to implant devices (e.g., dermal fillers, mesh). The following points were also raised:

- need for better implant traceability, with patient cards and better records kept by healthcare professionals
- longer/lifelong patient follow-up should be put in place for recipients of implants
- an obligation should be on manufacturers to hold funds specifically for compensation purposes
- potential for tighter controls to stifle innovation
- extension of the period for which manufacturers are required to provide device replacement parts for discontinued devices

The MHRA set out that the UK medical devices regulations could be amended to require manufacturers of implantable devices to provide **patient implant information** with the medical device when placing it on the market, in both digital and physical card or leaflet format. The consultation outlined that health institutions could be required to make this information available to patients having implantable devices both during the process of seeking informed consent to a procedure for an implant, and at the point where a procedure introducing an implant has been completed. It suggested that the UK medical devices regulations could require health institutions to hold this information securely and to log this information in patient records.

The consultation invited views on whether **post-market requirements** for implantable devices could be enhanced by clarifying or strengthening the requirements around use of obsolete models of implantable medical devices. Out of 238 responses received:

- 64% supported this proposal
- 13% did not support this proposal
- 24% did not know or had no opinion

The consultation also asked whether post-market requirements for implantable medical devices could be strengthened by introducing a requirement for **implant information** to be provided to recipients of implantable devices. Out of the 239 responses received:

- 79% supported this proposal
- 7% did not support this proposal
- 14% did not know or had no opinion

The abridged consultation in Chapter 17 invited views on whether the UK medical devices regulations should include requirements for manufacturers and health institutions to provide patients with implant information. Of the 72 responses received:

- 88% supported this proposal
- 0% did not support this proposal
- 13% did not know or had no opinion

The consultation asked whether the UK medical devices regulations should require manufacturers of implantable devices to provide implant information for recipient patients with the device when placing it on the market, as set out in the consultation text. Of the 240 responses received:

- 77% supported the proposal
- 8% did not support the proposal
- 15% did not know or had no opinion

The consultation also invited views on whether manufacturers should be required to provide implant cards/leaflets to healthcare settings/professionals. Of the 255 responses received:

- 83% were in favour of the proposal
- 7% were not in favour of the proposal
- 10% did not know or had no opinion

The consultation invited views on what information could be included in implant cards and patient leaflets for implantable medical devices. A range of ideas shared by the 135 respondents to this question, including

- describing the nature of device
- contact details, such as contact points for issues with a device
- the facility, physician

- the date related to the implantation of the devices
- size and duration of device
- risks and adverse events (associated with a device)
- side effects
- supporting evidence
- possible implant alternatives
- information on redress should adverse events arise
- information on the intended use
- instructions relating to use of the device
- complication rates
- composition of the device
- how to report via the Yellow Card scheme
- patient contraindications
- place of manufacture
- batch number
- safety checks that have been undertaken
- common interactions between the device and the body or medicines
- after care advice and side effects
- safety data
- information contained in a medical passport
- implant card information as defined in guidance document [EU MDCG 2019-8](#)
- this should be similar to drug information leaflet

When asked the same question in the abridged consultation (Chapter 17), 19 respondents raised the following themes:

- components and materials used in the implantable medical device
- risks and benefits associated with the implantable medical device
- manufacturer contact information to request more information

Some respondents to the main consultation were unsupportive of requiring that manufacturers produce a leaflet to accompany an implant, noting that it would be difficult for a manufacturer to provide this 'direct' (which we understand to mean directly to a person being implanted with a device) at the pre-implant stage as the clinician may not select the specific implant until the time of surgery.

The consultation also asked whether manufacturers should be required to make available implant information in both physical and digital formats. Out of the 232 responses received:

- 72% supported the proposal
- 11% did not support the proposal
- 16% did not know or had no opinion

The consultation asked whether the manufacturer should be required to update the digital implant information where appropriate. Of 229 responses received:

- 83% supported the proposal
- 5% did not support the proposal
- 12% did not know or had no opinion

The consultation invited views on whether health institutions should be required to make the information outlined in the consultation text available to patients who have been implanted with the device. 232 responses were received, of which:

- 84% were in favour
- 5% were not in favour
- 11% did not know or had no opinion

Consultees were asked whether health institutions should be required to log the implant information onto the records of the patient implanted with the device. Of the 233 responses received:

- 86% supported the proposal
- 18% did not support the proposal
- 22% did not know or had no opinion

The consultation asked whether any implants should be excluded from the requirements to have accompanying implant information. 235 responses were received, of which:

- 25% supported the proposal
- 43% did not support the proposal
- 32% did not know or had no opinion

There was a difference in the response views between respondents who identified as individuals (12% supported the proposal and 58% were not in favour) and those representing organisations (41% supported the proposal and 25% were not in favour).

Respondents were also invited to outline the types of implants that they considered should be excluded from the requirements to have accompanying implant information and their reasoning for this. Of the 57 responses:

- many were in favour of aligning with exemptions in the EU MDR or certain exemptions set out in the EU MDR
- some respondents proposed specific possible exemptions including for: dental plates and screws, absorbable implants, and nails

Respondents to the abridged consultation (Chapter 17) were asked to provide their reasoning for their answers on patient implant information or any general comments on patient implant information. The following themes were raised by 19 respondents:

- information provided directly to patients should be simple and signpost more detailed electronic information
- the information provided should be published by an independent and unbiased source

The MHRA invited views on whether there is further **information that could be captured and share about implantable medical devices in particular**. Of 222 responses received:

- 31% were of the view that there is further information we should collect and share about implantable medical devices
- 23% were of the view there is not further information should be captured and shared
- 46% did not know or had no opinion

The consultation asked respondents to set out the rationale for their response to the above question. Across 87 responses to this there was:

- interest in sharing information, including on UDI, device performance, device safety, adverse events, and device complications
- interest in having an accessible central source of safety information / registries.
- some device specific concerns raised, including regarding dermal fillers, mesh and silicone devices.

The consultation asked respondents to share views on **implementation considerations** for bringing in the changes to the regulation of implantable medical devices raised in this chapter of the consultation. A small number of respondents shared views, including:

- interest in aligning with EU regulations
- in terms of transition to future requirements, take lessons from EU implementation, allow sufficient time for transition, allow for phased implementation, and further consult with professional regulators before enacting changes
- dermal fillers should be on a prescription only basis and administered by healthcare professionals
- regarding equivalence, there were mixed views, with some respondents suggesting that the option to claim equivalence to predicate devices as part of the clinical evaluation process be removed and others noting that equivalence is necessary in terms of servicing small clinical populations and reducing burden on assessors. Equivalence is covered in more detail in Chapter 7 on Clinical Investigations and Performance Studies.

The MHRA invited respondents to highlight any **other considerations** on the regulatory framework for implantable medical devices. We received wide-ranging feedback from 78 respondents, including:

- interest in aligning with the EU, FDA or other international regulations,
- requests for guidance/clarification on the pathway for dealing with obsolete devices that need revisions
- post-market surveillance considerations for implantable devices, including: the data collection systems used by stakeholders to collect performance data for implantable devices, the methodology for follow up, the need to ensure robustness and meaningful analysis, financial and resourcing impacts for health institutions who manufacture up to class IIb devices, and parallel imports
- concerns on proposed equivalence requirements
- interest in a controlled market release for new devices
- interest in having an exemption list for the requirement for implant information to accompany implantable medical devices

Finally, the consultation also invited respondents to provide any additional information relating to questions relating to regulation of implantable medical devices contained in Section 66. The consultation received 61 responses to this ask, which included:

- agreement with the possible additional requirements applying to implantable medical devices set out in the consultation
- desire to seek alignment with the EU MDR, or approaches in other jurisdictions
- concern about the impact of implant card requirements on health institutions and capacity to implement them

- concern about the implementation period for these requirements and suggestion that longer transition timescales are needed

## 66.2 The government response

The government has carefully considered the consultation feedback relating to the potential **expansion of scope** of implantable medical devices regulated under the UK medical devices regulations. It is considered that the products proposed by respondents are either already in scope of the regulations or there is no strong rationale for amending the scope to include or remove them. The government does not plan to introduce any changes to the scope of medical devices regulated as implantable medical devices at this time. Below are some key considerations on suggestions raised:

- **include dermal fillers** – dermal fillers are already in scope of the UK medical devices regulations where they have an intended medical purpose. The government recognises the strong interest and merits of expanding the regulations to include dermal fillers without a medical purpose – see more detail in the Scope chapter of this response (Chapter 1)
- **include breast implants** - breast implants are already in scope of the regulations
- **include temporarily implanted medical devices** – currently, by reference to Directive 93/42, to be classified as implantable medical devices in under UK medical devices regulations must be intended to remain in place in the human body for at least 30 days after the surgical procedure. Further consideration is needed of the extent to which temporarily implanted medical devices are in scope to determine whether any changes to it are warranted.
- there was no clear rationale provided by respondents for excluding **ophthalmic viscosurgical devices (OVDs)** from the scope of regulated implantable medical devices
- **exemptions from requirements** – this is considered separately below.

The government has carefully considered the points raised on possible **changes to pre-market requirements** for implantable medical devices. It is noted that changes in classification (expanded on in the Classification and IVD Chapters) will have implications for the level of scrutiny a device undergoes. In addition, it is intended to strengthen clinical evidence requirements for all medical devices, including implantable devices, as set out in the chapter on clinical investigation and performance studies (Chapter 7). See also the Conformity Assessment Chapter for enhancements to how Approved Bodies will review implantable medical devices in particular. After careful consideration, we do not consider at this time that further implantable-specific requirements are warranted to technical documentation and clinical evidence requirements.

It is recognised that a number of respondents showed interest in having certain **exemptions to clinical evidence requirements** for specific implanted devices such as screws and wedges. This included interest in aligning with exemptions that apply in the EU or the US. However, no strong rationale for these exemptions was presented. Following careful consideration, it is not intended to introduce exemptions from clinical evidence requirements at this time for any types of implantable devices on the basis they are of a certain type (e.g., screws and wedges). While mindful this differs from the approach taken elsewhere, for example in the EU, it is considered important to assuring the safety and performance of implantable devices.

The government has also carefully considered consultation feedback on whether there should be **more conditions on the introduction of implantable medical devices**, including interest in the following possible controls:

- that implantable medical devices should be administered with proactive follow up with patients

- that such devices should be supplied only to medical device users in centres specialising in their use
- that such devices should be supplied to medical device users by practitioners with specialist expertise and experience in the treatment of the condition requiring the device
- making dermal fillers available on a prescription only basis
- requiring dermal fillers be administered by health practitioners, as noted in the Scope Chapter (Chapter 1).

Regarding making dermal fillers available on a prescription only basis, please see the Scope Chapter (Chapter 1) for detail of our response. Regarding respondents' interest in requiring dermal fillers be administered by health practitioners, as noted in the Scope Chapter (Chapter 1), the regulation of practitioners falls within the remit of the Department of Health and Social Care (DHSC). DHSC has recently announced its intention to strengthen the regulation of cosmetic procedures, specifically through proposals to introduce a licensing regime for non-surgical cosmetic procedures such as injectable Botulinum toxin (for example, Botox®) and fillers: [Government to crack down on unregulated cosmetic procedures - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/news/government-to-crack-down-on-unregulated-cosmetic-procedures). The consultation feedback has been shared with the relevant DHSC team, for consideration as part of this work. It is considered that proactive follow up of patients will be strengthened through the post market surveillance measures intended to be introduced that will apply to implantable medical devices (set out in Chapter 8 Post Market Surveillance).

After careful consideration of the responses received, and implications of implantable medical devices being supplied via **centres specialising in implantable devices use**, the government acknowledges the interest in this proposal but is of the view that this would require more detailed consideration and scoping before introducing such a change.

After careful consideration, the government intends to take forward a number of measures that were raised by respondents, including:

- measures to improve implant traceability, including through the introduction of requirements for implant information. See below in this section for further detail on plans to introduce requirements for implant information. See the UDI and Registration chapter (Chapter 4) for information on traceability more broadly.
- reducing the ability for manufacturers to rely on equivalence to a predicate device as part of the pre-market approval process for implantable medical devices (see the Clinical Investigation and Performance studies Chapter for further detail of the government's position on equivalence)
- requiring longer/lifelong patient follow-up for recipients of implants (see the post-market surveillance chapter (Chapter 8) for further detail on measures that will be taken forward to strengthen follow up on implantable medical devices)
- considering introducing clearer requirements for seeking informed consent for patients (to the extent this relates to clinical investigations and performance studies, as set out in Chapter 7)

A number of suggestions made by respondents will not be taken forward by the government at this time. Some respondents showed interest in better records being kept by healthcare professionals. This is outside the MHRA's remit as it relates to the regulation of health practitioners. In addition, it is not intended to require manufacturers to set aside funds specifically for compensation purposes. Instead, as set out in Chapter 3 on Economic Operators, manufacturers will be required to have in place sufficient financial coverage to respond in the event of an adverse incident.

In relation to **post-market requirements**, there was strong support for requiring that implant information be provided to recipient patients, and support for the proposed implant card and leaflet

requirements set out in the consultation. The government therefore intends to take forward these proposals. Respondents signalled strong support for requiring manufacturers of implantable medical devices to provide implant information for recipients of an implanted medical device with the device when placing it on the market as set out in the consultation and requiring manufacturers to provide implant cards/leaflets to healthcare settings/professionals. Consultation respondents' suggestions for information that should be included were largely captured in the list proposed in the consultation. The government considers that the remaining suggestions could be adequately captured in supplementary guidance, which would provide clear, practical examples of information that could be included in implant information cards/leaflets.

After careful consideration of responses following proposals, it remains the government's intention to proceed with the following requirements concerning implant card information:

- requiring implant information to be provided to recipients of all implantable medical devices
- requiring manufacturers of implantable devices to provide implant information for recipient patients with the device when placing it on the market, as set out in the consultation
- requiring a manufacturer to provide implant cards and leaflets for healthcare settings/professionals
- requiring manufacturers to make available, implant information in both physical and digital formats
- requiring health institutions to make this information available to patients who have been implanted with the device
- requiring that health institutions log the implant identification information, such as the UDI number (if any), onto the records of the patient implanted with the device.

Of those respondents that expressed a view on whether there should be **exemptions to implant card requirements**, the majority were in favour of there being no exclusions from this requirement. The government notes there was some interest in **exclusions to the requirement to provide implant information** to patients in receipt of an implantable medical device. The government is minded to create limited exemptions to the requirements for implant information (as set out in the consultation) for certain devices, being:

- exempt implantables: non-resorbable sutures and staples and dental fillings
- exempt non-implantables: dental braces, tooth crowns

These exemptions are considered warranted as it would not be proportionate to their risk or workable in practice to require implant information for these devices, in light of the scale on which these products are used.

The government recognises the value in having clear and transparent **information about implantable devices and their use captured and shared** and has outlined a number of measures in other sections of this response which will further this. See Chapter 4 on Registration and UDI. In addition, further consideration will be given to how obsolete implantable devices are regulated. More detailed work would be needed to look at precisely what changes would be beneficial and to quantify their possible impacts before making a specific change here.

The government also recognises the value in ensuring **robust post-market follow up** of implantable medical devices use. As outlined in Chapter 8, it is intended to introduce more stringent post market follow up requirements that will apply to implantable medical devices.

In light of consultation feedback, while not looking to introduce it at this time, the government has also identified a need to consider further, the potential for requiring a manufacturer to provide device replacement parts for a longer period of time after a device has been discontinued (i.e., has become **obsolete**).

The government notes the **other considerations** raised by consultees such as the clear call for guidance, adequate transition time, and a preference for EU alignment. These will be taken into account when progressing plans set out in this response for the future regulation of implantable medical devices. See also Chapter 15 on Transitional Arrangements for more information concerning transition arrangements.

## 12 – Other Product Specific Changes

The consultation considered whether a number of potential regulatory amendments could be made in relation to four distinct policy areas: the re-manufacturing of single use devices; systems, kits and procedure packs; parts and components; and custom-made devices.

**The consultation invited views on the possibility of introducing additional legislative requirements for the re-manufacturing of single-use medical devices, which would bring this practice into the scope of the UK medical devices regulations rather than continue to rely on the guidance-based approach currently in place. This would provide additional clarity on the legal obligations that apply to re-manufacturers.**

**The consultation set out a number of additional requirements that could be put in place for assemblers of systems, kits and procedure packs. Our intention is that the UK medical devices regulations should include clearer requirements, particularly in relation to systems that include a combination of general medical devices, *in vitro* diagnostic medical devices (IVDs) and/or other products, with the aim of strengthening and clarifying the regulatory requirements to enhance patient safety.**

**The consultation invited views on introducing a number of regulatory requirements applicable to medical device parts and components, with the aim of ensuring that the safety of medical devices is not compromised in any way by the installation of replacement parts or components.**

**Custom-made devices are already covered by the UK medical devices regulations. The MHRA consulted on introducing additional safeguards for custom-made devices, including enhanced technical documentation requirements, obligations for manufacturers to have in place a Quality Management Systems (QMS) and more stringent post-market surveillance requirements**

### Section 67 - Re-manufacturing single-use devices

#### 67.1 Proposals and feedback

The consultation invited views on whether the UK medical devices regulations should include specific requirements for re-manufacturers of single-use devices, including Quality Management System (QMS), post-market surveillance and labelling obligations, as outlined in the consultation. Out of 111 responses:

- 72% were in favour of introducing these requirements
- 10% were not in favour
- 17% did not know or had no opinion

Respondents were invited to outline any other requirements which they considered should be introduced for the re-manufacturing of single-use devices. A number of respondents reiterated their support or disagreement with the approach set out in the consultation. In addition, key themes can be summarised as follows:

- a re-manufactured device should be required to bear a label identifying it as re-manufactured
- need to consider implications (e.g., commercial sensitivity) associated with the re-manufacturer needing to have access to the original manufacturer's technical files

- a need to consider whether patient consent is required for the use of re-manufactured single-use devices
- requirements should align with the EU MDR and the International Medical Device Regulators Forum (IMDRF)
- clear definitions are needed of the terms 're-manufacturing' and 're-processing'

The consultation invited views on whether the UK medical devices regulations should introduce requirements for re-manufacturers of single-use devices on behalf of healthcare institutions. This included requiring that supply should be through a closed loop contract between the re-manufacturer and health institution and that the re-manufactured device should only be used on an individual patient during a single procedure - and be returned to the contracted re-manufacturer after that use, as set out in the consultation text. Of the 109 responses received:

- 62% were in favour of this approach
- 16% were not in favour of this approach
- 21% did not know or had no opinion

Consultees were asked to outline any other requirements which they considered should be introduced for the re-manufacturing of single-use devices within healthcare institutions. Key themes can be summarised as follows:

- the need to clearly define a 'closed-loop contract' and 'healthcare institution'
- the need to clarify where the legal liability lies – e.g., in cases where an injury is caused by a re-manufactured single-use device (that is unrelated to it being re-manufactured)
- a rationale should be required for use of a re-manufactured rather than a newly manufactured single-use device, including an evaluation of safety and sustainability risks and benefits

The consultation invited views on whether the MHRA should allow the re-manufacturing of Class I single-use medical devices. Of the 106 responses received:

- 31% were in favour of the proposal
- 41% were not in favour of the proposal
- 27% did not know or had no opinion

There was a difference in the response here between individuals and organisations, with the majority of individuals being unsupportive of this proposal (61%), and organisations being evenly split, with 35% in support and 34% unsupportive of this proposal.

When asked to outline what requirements should be in place for the re-manufacturing of Class I single-use medical devices, respondents raised a number of themes, which can be summarised as follows:

- a need to consider the approach taken by other countries
- suggestion that there should be an abbreviated Approved Body process for re-manufactured Class I single-use devices
- suggestion that re-manufactured single-use devices should be subject to the same testing requirements as the original device

The consultation invited views on whether the MHRA should allow the re-processing of single-use devices. Of the 107 responses:

- 38% supported this proposal
- 36% did not support this proposal

- 28% did not know or had no opinion

There was a difference in response between individuals (with 24% in favour, 55% not in favour and 21% being unsure or having no opinion) and organisations (with 31% in favour, 29% not in favour and 40% being unsure or having no opinion). Here, the majority of individual respondents were opposed to this change, with organisations being more evenly split.

The MHRA invited consultees to outline what requirements they considered should be in place for the re-processing of single-use devices. Respondents raised a number of points, including:

- an appropriate QMS should be required
- we should require evidence that the re-processed device has undergone assessment procedures that match or exceed those undergone by the original device
- a need to clearly define 're-processing', 're-manufacturing' and 'single-use device'
- the device and packaging should clearly indicate that reprocessing has taken place

When asked to provide reasoning for the responses in Section 67, respondents raised a number of themes. These included:

- the need for careful regulation to maintain patient safety
- the need to ensure traceability of re-processed/re-manufactured medical devices
- approach would lead to more environmentally sustainable manufacture of medical devices
- identification of cost saving benefits to the original manufacturer and health institutions
- need to clearly define 're-manufacturing' and 're-processing'
- devices that can be reused or re-processed should not be marketed as 'single use'

## 67.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with proposals to **regulate the re-manufacturing of single-use devices**, as set out in the consultation. The majority of respondents were supportive of the consultation proposals, which would bring into scope of the UK medical devices regulations, factors that are currently set out in guidance. This will include requiring that the packaging and instructions for use clearly state that the single-use device is a re-manufactured version of the original and that the re-manufacturer can be clearly identified on the packaging and labelling.

We consider that a move from guidance-based best practice to regulatory requirements will provide clarity and increase patient safety, ensuring that appropriate enforcement can be taken against re-manufacturers who fail to abide by the regulatory requirements. In developing the regulations, we will give careful consideration to the important issues raised around patient consent and the commercial sensitivity issue raised around re-manufacturers being able to access an original manufacturer's technical file. We will supplement the regulatory changes with supportive guidance and ensure that any technical terms are clearly defined.

The majority of respondents were in favour of introducing requirements **for persons who re-manufacture single-use devices on behalf of healthcare institutions**. After careful consideration of feedback, it is the government's intention to proceed with the approach outlined in the consultation. As such, we intend to require that the supply of re-manufactured single-use devices be through a closed loop contract between the re-manufacturer and the healthcare institution, and that a re-manufactured single-use device should only be used on an individual patient during a single procedure and, after that use, the single-use device should be returned to the contracted re-manufacturer.

The government has reflected upon feedback and intends to require that single-use devices that are **re-manufactured on behalf of a healthcare institution** be labelled as 're-manufactured'. We consider that this approach will provide clarity and transparency for clinicians deploying re-manufactured single-use devices.

In light of consultation feedback, the government intends to prohibit the **re-manufacture of Class I single-use medical devices**. We note that the largest proportion of respondents supported this approach and consider that the lack of Approved Body oversight for these devices would, at present, pose an unacceptable risk to patient safety. The government will, however, keep this issue under review with a view to considering it again in future, once the requirements relating to the re-manufacture of higher risk devices have bedded in.

Having taken account of consultation feedback, the government intends to introduce legislation that prohibits the **re-processing of single-use medical devices**, reflecting the policy approach set out in current MHRA [guidance](#). Views on this matter were fairly evenly split among consultees, with a slight preference for allowing this practice. However, we consider that the potential benefits that this practice could yield would be outweighed by risks to patient safety, for example through misuse or cross-infection. It should be noted that the re-processing of multiple use devices will not be impacted by this decision.

Comprehensive guidance will accompany the new regulations in this area, to ensure that new regulatory requirements and relevant terminology are explained, including areas indicated by respondents, such as: definitions of 're-manufacture', 're-processing', 'closed-loop contracts', and 'health institutions'.

## **Section 68 - Systems, kits and procedure packs**

### **68.1 Proposals and feedback**

The consultation invited views on whether the UK medical devices regulations should include the term 'kit' when referring to medical devices and products which are assembled together. Of the 141 responses received:

- 72% were in favour of including the term 'kit'
- 12% were not in favour
- 16% did not know or had no opinion

The consultation sought feedback on whether the definitions of 'systems', 'procedure packs' and 'kits' should allow external software (for example, a specific app identified in the labelling) to be considered as a component of the system, procedure pack or kit. Out of 140 responses:

- 72% supported the proposal
- 6% did not support the proposal
- 21% did not know or had no opinion

Consultees were asked whether assemblers of systems, kits and procedure packs should be required to implement additional procedures relating to the selection and control of suppliers, risk management, handling of complaints and management of corrective and preventive actions with verification of their effectiveness. The consultation noted that the regulations could require that these procedures be outlined in the assembler statement / declaration. Of the 137 responses received:

- 70% were in favour of this proposal

- 13% were not in favour
- 21% did not know or had no opinion

When asked to outline any other requirements which should be introduced for system and procedure packs and the sterilisation of system and procedure packs, respondents raised the following themes:

- a need for clear guidance, e.g., covering requirements for labelling, packaging, cleaning and decontamination procedures and Declarations of Conformity
- suggestion that requirements should align with the EU MDR
- suggestion that an appropriate QMS should be required
- suggestion that full QMS should be required in accordance with ISO 13485
- suggestion that the assembler should be responsible for the handling and storage of each component and be able to sufficiently control that the storage and transit of the pack is compatible with each component

The MHRA next invited consultees to provide any reasoning for responses to section 68. Key points included:

- a need for traceability of the device and constituent parts
- suggestion that systems and procedure packs need to work safely for the intended purpose
- we should ensure a level of compliance that can be consistently implemented and assessed
- UK regulations should be aligned with other jurisdictions (such as the EU), and published IMDRF guidance to enable goods to move freely, reduce burden on manufacturers and facilitate a smooth implementation

## 68.2 The government response

After careful consideration of the feedback received, it is the government's intention that the UK medical devices regulations will include **the term 'kit'**. We also intend that the definitions of systems, procedure packs and kits will allow external **software** (for example, a specific app identified in the labelling) to be considered as a component of the system, procedure pack or kit. We will also consider the need for further guidance on this topic.

In addition, the government intends to proceed with the introduction of **additional requirements for assemblers of systems, kits and procedure packs**, as outlined in the consultation text. We also intend to require that an appropriate QMS be put in place. We intend for the regulations to require that the required procedures be outlined in the assembler statement / declaration. We will reflect on the need for international alignment and consider the need for detailed guidance to accompany the regulatory changes.

## Section 69 - Parts and components

### 69.1 Proposals and feedback

The consultation invited views on whether 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. Of the 133 responses received:

- 86% supported the proposal
- 5% did not support the proposal
- 9% did not know or had no opinion

Consultees were asked whether 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. Of the responses received:

- 79% were in favour of this approach
- 9% were not in favour
- 11% did not know or had no opinion

The MHRA invited consultees to set out any reasoning for responses to section 69. Key themes included:

- components should be regulated as medical devices in their own right
- service providers should be regulated as manufacturers
- components for a device that are not made by the original device manufacturer should continue to be available

## 69.2 The government response

After careful consideration of responses on **replacing defective or worn parts**, the government intends to proceed with the proposal to require 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 to ensure that the item does not negatively affect the safety and performance of the medical device.

In addition, we intend to require that components which make a significant change to the safety and performance of a medical device are to be **regulated as medical devices in their own right**. We consider that, where a replacement part or component elicits a significant change to a device that affects its performance and safety, this invalidates the documentation associated with the device's UKCA marking. Therefore, such parts and components should be regulated accordingly.

## Section 70 – Custom-made devices

### 70.1 Proposals and feedback

The consultation invited views on whether the UK medical devices regulations should include more detailed requirements for the **technical documentation** that must be drawn up and kept by the manufacturer of a custom-made device, such as a clinical evaluation report, as set out in the consultation. Of the 108 responses received:

- 79% supported the proposal
- 9% did not support the proposal
- 11% did not know or had no opinion

The MHRA asked consultees whether the UK medical devices regulations should introduce more stringent requirements for the **post-market surveillance of custom-made devices** such as an obligation to produce periodic summary update reports or post-market surveillance reports. 107 responses were received, of which:

- 51% were in favour of the proposal
- 28% were not in favour of the proposal
- 21% did not know or had no opinion

The consultation sought views on whether the UK medical devices regulations should require manufacturers of custom-made devices to implement a **Quality Management System (QMS)** which must be certified by an Approved Body. Of the 106 responses:

- 66% were in favour of this approach
- 14% were not in favour
- 20% did not know or had no opinion

The consultation asked respondents to outline the **types/classes** of custom-made devices should fall under the **requirement to implement a QMS**. The following suggestions were made:

- all device classes
- all device classes except Class I
- higher risk class medical devices (Class III and / or IIb)
- exclude custom-made dental crowns and bridges from the requirement

The consultation invited views on whether the UK medical devices regulations could be changed to clarify that the prescription written by a medical practitioner, who prescribes specific characteristics to the design of the custom-made medical device, can be an **electronic prescription**. Of the 103 responses received:

- 81% were in favour of this proposal
- 2% were not in favour
- 18% did not know or had no opinion

Consultees were invited to outline any further requirements which should be introduced for manufacturers of custom-made devices and to set out any reasoning for their responses to questions on custom-made devices. Key themes included:

- suggestion that the approach should align with IMDRF guidance
- a certified QMS should be required
- the term 'medical practitioner' needs to be defined
- having a clinical evaluation report is not practical for individual patients but there should be a 'general' one
- clear guidance is required

## 70.2 The government response

After careful consideration of responses and in light of the high level of support, it remains the government's intention to proceed with the proposal to include in the UK medical devices regulation more detailed requirements for the **technical documentation** that must be drawn up and kept by the manufacturer of a custom-made device, as set out in the consultation.

We also intend to proceed with the introduction of more stringent requirements for the **post-market surveillance of custom-made devices**, as set out in the consultation. Although views on this proposal were relatively mixed, the highest portion of respondents were supportive. We consider that introducing these obligations will improve transparency and safety, allowing the MHRA and manufacturers of custom-made devices to identify issues and take action where necessary.

After careful consideration of responses regarding the requirement for manufacturers of certain custom-made devices to **implement a Quality Management System** which must be certified by an Approved Body, it is the government's intention to proceed with this proposal for certain custom-made devices.

The government considers that Class III and IIb custom-made devices should require a certified QMS. A number of consultees were supportive of requiring a certified QMS for all custom-made medical devices. However, we consider that it would not be feasible to require a certified QMS for all custom-made medical devices as this would place a burden on Approved Bodies that is not commensurate to risk, particularly for custom-made dental crowns/bridges. It would be a requirement for class I and IIa custom-made devices to have an appropriate QMS in place - but the QMS will not require Approved Body certification.

We are grateful for the suggestions made by consultees regarding **further requirements** that could be introduced for manufacturers of custom-made devices. However, after careful consideration, we do not consider that additional requirements are needed beyond those outlined in the consultation. This matter will be kept under review.

It remains the government's intention to proceed with the proposal to clarify in the UK medical devices regulations that the prescription written by a medical practitioner, who prescribes specific characteristics to the design of the custom-made medical device, can be an **electronic prescription**. The majority of consultation respondents supported this approach.

# 13 – Environmental Sustainability and Public Health Impacts

As set out in the consultation, there are a number of ways in which the future regulatory regime for medical devices can improve and safeguard public health by driving more environmentally sustainable manufacture, use and disposal. Climate change is a health emergency, and the consultation included a number of possible options that could be taken forward to ensure that the new regulatory framework supports the government's 'Net Zero' agenda where possible to do so, without infringing on other regulatory areas.

## Section 71 - Environmental sustainability and public health impacts

### 71.1 Proposals and feedback

Respondents were asked to comment on the extent to which they or their organisation are already implementing, or planning, activities to reduce the impact of medical devices on the environment – and to outline key activities in this area.

Respondents identified a wide range of measures, indicating a considerable level of concrete action already underway, as well as interest in pursuing sustainability goals. The list below provides a snapshot of some of the activities referenced by respondents:

- measures to reduce carbon emissions at manufacturing sites and across the medical device supply chain, including in support of the delivery of NHS Net Zero targets, with support, guidance and training provided by Trade Associations
- waste management initiatives, including designing out waste – for example, through smaller products with fewer components, investment in recycling programmes, landfill diversion, move away from single use products, and recycling of plastic waste
- eco-design of products and packaging
- sustainable transport strategies, for example, through modal shift or 'light-weighting' of products and packaging
- reduction of hazardous materials in medical devices, including Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and the Restriction of Hazardous Substances (RoHS) compliance
- reduction of packaging and increased use of recycled packaging
- sustainability and circularity strategies and targets, with buy-in from senior management
- use of procurement as a lever for sustainable practices

A small number of respondents, did not note any sustainability activities underway or planned, answering 'none', or 'not applicable'. However, it is encouraging to see that a significant majority of respondents were actively engaged with sustainability initiatives, viewing this as a key priority.

The consultation invited views on whether there is a need for additional requirements to encourage economic operators to consider and/or mitigate the environmental impact of medical devices that they place on the UK market. Of the 202 responses received:

- 51% were in favour of this proposal
- 32% were not in favour of this proposal
- 17% did not know or had no opinion

Those who were in favour of additional requirements reasoned that there is a need to incentivise economic operators to act more sustainably, for example through encouraging the reduction of single-use products and plastics - or making certain components reusable, with patient-contacting components being single use. Respondents also highlighted that it would be beneficial to incentivise refurbishment and recycling of medical devices and avoidance of planned obsolescence. It was also noted that the information generated through environmental and public health impact assessments would increase transparency, thereby supporting sustainable decision making within health institutions. Some respondents noted a preference for incentives (such as tax relief) rather than legislative requirements and others caveated their support, stating that regulation in this area should not prevent the marketing of otherwise beneficial products that would address an unmet need. A number of respondents noted that activity in this area should be aligned with the NHS Net Zero ambition.

Those who were unsupportive of or unsure about this proposal noted that careful consideration must be given to any measures to promote sustainability, to ensure that patient safety is maintained and prioritised. For example, some respondents were concerned that measures to encourage reduced packaging could lead to devices enjoying less protection or a risk that sterility could be compromised. Some respondents were also concerned that additional measures could lead to increased bureaucracy and burden, particularly for small and medium sized enterprises (SMEs), which may in turn lead to delays in products reaching the UK market. Other consultees reasoned that action in this area is and will continue to be market driven, noting that manufacturers are already, for example, able to voluntarily adhere to relevant standards (International Organization for Standardization (ISO) standard 14001 was cited) and a preference for guidance rather than regulation. Reference was also made to cross-cutting regulations (such as the Plastic Packaging Tax Regulations) and levers (such as NHS procurement frameworks) that already address sustainability concerns - and a preference for horizontal rather than sector-specific regulation in order to avoid duplication. Finally, some respondents noted that environmental considerations are historically outside of the MHRA's scope and expertise and felt that the Agency should maintain its focus on patient and public safety.

Respondents were asked for views on the options for change outlined in the consultation, which were:

- a. introduce a requirement for manufacturers to complete an environmental and public health impact assessment as part of the conformity assessment process for a medical device, and to make publicly available a summary of this assessment
- b. introduce waste management responsibilities into the medical device supply chain which could concern the reduction of the environmental impact associated with a device, and to consider using less hazardous materials that are easier to dispose of safely
- c. introduce a requirement that devices must be designed and manufactured in a way that reduces, as far as possible, the risks posed to public health by substances or particles that may be released from the device including wear debris, degradation of products and processing residues
- d. broaden the circumstances in which electronic (rather than paper) labels and instructions for use can be used for medical devices.

There was a considerable amount of support for the above proposals and acknowledgement that they would drive environmental sustainability within the medical devices sector. From the detailed comments, respondents were generally more supportive of options C (reduction of substance and particle release, including from wear debris) and option D (electronic instructions for use), than options A (environmental impact assessment) and B (waste management responsibilities). A

significant portion of responses specifically called out support for wider use of electronic instructions for use and e-labelling and a small number suggested that we should require both paper and digital instructions for use for accessibility purposes and for consistency with obligations that apply to international markets.

Other comments and considerations that were highlighted included:

- Suggestion that there is a risk of duplicating other regulations and frameworks (for example, REACH, RoHS, CLP)<sup>1</sup>
- Suggestion that the UK medical devices regulations are safety regulations, which should continue to be the priority, with respondents noting that careful consideration would need to be given to introducing sustainability requirements and that the UK medical devices regulations may not be the most appropriate vehicle for this
- Some respondents noted that environmental impact assessment requirements could be burdensome to SMEs and felt that they should not be linked to conformity assessment
- One respondent noted that Country of Origin information should be made available
- It was also suggested that local infrastructure and training are needed to support reuse, reprocessing, recycling and access to renewable materials

The MHRA invited views as to what other changes or key considerations are needed to ensure more environmentally sustainable medical devices. Several respondents emphasised the importance of the re-manufacturing and re-processing of single use devices and recycling of packaging. Others suggested that regulation should be agile and cost effective, and any new legislation should take into account the wider policy landscape to avoid setting duplicative requirements. Respondents also highlighted the importance of considering international regulations.

Some respondents felt that sustainability should be taken into account when designing medical devices so that it is considered at the earliest stages of manufacture and across the whole product lifecycle. It was also noted that financial support may be required to support businesses to adopt more sustainable practices and that a transitional period would be needed so that any new requirements could be phased in.

Respondents were next asked to set out the key implementation considerations for options A-D outlined above. Here, some respondents noted that clear regulation and guidance would be needed to ensure a shared understanding of the requirements - and that this should be linked to a clear overarching strategy. Again, reference was made to the need for a transitional period to allow for the phasing in of any new requirements.

Some respondents highlighted again, potential burdens or costs associated with the proposed requirements. Others felt that the focus should be on packaging recycling, waste management, e-labelling, electronic instructions for use, plastic reduction and reusability. There was also a suggestion that pharmacy take back schemes could be implemented.

Respondents were asked to identify which options they felt could be introduced quickly (within 1-2 years) and which could be introduced within a longer timeframe. Some respondents felt that a

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<sup>1</sup> CLP: Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (retained EU law), REACH: Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (retained EU law), RoHS: Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012/3032

longer time period would be needed for all options. Others felt that only options A-C would require a longer time period, and that option D (electronic instructions for use) could be introduced more quickly. Respondents highlighted again that a transitional period would be required, should additional requirements be introduced.

## **71.2 The government response**

Having considered the views of respondents, it is clear that there is a high degree of interest in the topic of environmental sustainability, with a wide range of views expressed. Many respondents noted that their products and practices are already subject to environmental regulation (for example, REACH, RoHS and carbon reporting were referenced) and there is a need to avoid setting duplicative requirements.

Respondents also raised important safety concerns, noting that caution should be exercised, and that careful consideration should be given to the introduction of sustainability measures, with the safety of medical devices being paramount. We would like to clarify that the intention of the proposals is to drive better environmental outcomes that compliment or enhance patient safety. It is recognised that climate change will have wide ranging detrimental impacts for public health and that medical device regulation has a role in supporting a move to Net Zero.

There was strong support for introducing option D and broadening the circumstances in which electronic instructions for use can be deployed instead of printed copies. On this basis, our intention is to extend this provision so that it applies to software and apps that are supplied directly to end users, as well as to health care professionals. In doing this, we will ensure that appropriate risk assessment and data protection requirements are put in place. We do not intend to extend this provision further at this point but will keep our position under review.

Based on consultation feedback, we also intend to introduce option C and will update the essential requirements to specify that devices must be designed and manufactured in a way that reduces, as far as possible, the risks posed to public health by substances or particles that may be released from the device including wear debris, degradation of products and processing residues. We consider that there is a strong patient safety case for taking this approach.

In light of the consultation feedback, we think there is a need to give further consideration to options A and B, possibly including further consultation, to gather further evidence that would provide a better understanding of the capacity and infrastructure concerns that were raised. This approach would also allow us to give more detailed consideration to consultation feedback regarding the need for horizontal, rather than product-specific regulation (thus avoiding duplication with cross-cutting requirements) and to identify any gaps in the policy and regulatory landscape and areas for which the MHRA can feasibly and appropriately provide support.

While we do not intend to introduce new regulatory requirements on these issues at this point, we will keep this under review, with a view to gathering additional evidence and consulting further (as noted above). Given that respondents outlined a range of existing sustainability frameworks and initiatives, we will consider publishing guidance on best practice covering this topic to support alignment with government Net Zero Ambitions and NHS Net Zero Supplier Roadmap: [Greener NHS » Suppliers \(england.nhs.uk\)](https://www.england.nhs.uk/greener-nhs/suppliers/).

## 14 – Alternative Routes to Market

**Introducing alternative routes to market could bring a number of benefits, for example in enhancing the supply of devices to the UK market and in supporting the MHRA’s ambition for medical devices regulation to become globally harmonised. Patient safety will remain a priority, and the proposals outlined in the consultation included consideration of how these routes could be introduced with appropriate levels of scrutiny applied to medical devices to ensure they are safe and that they perform as intended.**

### **Section 72 - MDSAP and Domestic Assurance**

#### **72.1 Proposals and feedback**

The consultation invited views on whether we should introduce an alternative route to market which utilises Medical Device Single Audit Program (MDSAP) certificates. Of the 211 responses received:

- 86% supported the proposal
- 8% did not support the proposal
- 7% did not know or had no opinion

The consultation invited views on whether the MHRA should introduce an alternative route to market which utilises approvals from other countries (Domestic Assurance route). 210 responses were received, of which:

- 84% were in favour of the proposal
- 7% were not in favour
- 9% did not know or had no opinion

The abridged consultation (Chapter 17) invited views on whether the MHRA should introduce a tailored pathway to market approval for manufacturers whose quality management system has been certified under the MDSAP. Of the 67 responses received:

- 78% were in favour of the proposal
- 7% were not in favour
- 15% did not know or had no opinion

The abridged consultation (Chapter 17) also invited views on whether the MHRA should introduce a tailored pathway to market approval for medical devices that have regulatory approval from elsewhere. Of the 66 responses received:

- 74% were in favour of the proposal
- 11% were not in favour
- 15% did not know or had no opinion

Other information provided in comments from respondents to questions in both Chapters 14 and 17 relating to the utilisation of MDSAP and domestic assurance can be summarised as follows:

- the use of MDSAP aligns the UK more closely with international practices
- adopting this approach provides economic and operational benefits to industry
- adoption should not be mandatory
- both routes would allow greater choice for patients
- safety standards must be equivalent to those set out in the UK

## 72.2 The government response

After careful consideration of responses, it remains the government's intention to proceed with the proposal to utilise both **MDSAP certificates and Domestic Assurance** as alternative routes to market in the UK. The MHRA will require UK Approved Bodies to consider MDSAP assessments; however, adoption will be optional for manufacturers. Domestic Assurance routes will allow an abridged assessment with the appropriate scrutiny, and UK Approved Bodies will be able to reject applications under the Domestic Assurance route if they do not consider the evidence provided to be sufficiently robust to undergo assessment via this route.

## Section 73 - Pathway for Innovative MedTech

### 73.1 Proposals and feedback

The consultation invited views on whether 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. Of the 201 responses received:

- 90% supported the proposal
- 3% did not support the proposal
- 6% did not know or had no opinion

The abridged consultation (Chapter 17) invited views on whether the MHRA should introduce a tailored pathway to market approval for innovative devices. Of the 65 responses received:

- 69% were in favour of the proposal
- 9% were not in favour
- 22% did not know or had no opinion

The consultation asked whether the MHRA should have powers to conduct conformity assessments and issue approvals in certain scenarios, e.g., for use on certain groups of patients and/or within specific healthcare institutions where there is an identified need. Of the 199 responses received:

- 88% supported the proposal
- 9% did not support the proposal
- 3% did not support the proposal

Consultees were invited to provide further information in support of their responses to questions in this section. Key themes can be summarised as follows:

- a flexible approach is required
- this approach would increase choice and treatment options for UK patients
- both SME's and larger manufacturers should be considered for this pathway
- this approach requires tight regulation to ensure safety
- this pathway makes the UK a more attractive destination for innovators

### 73.2 The government response

Having considered the views of respondents, the government notes that **an innovative MedTech route to market** could benefit patients, clinicians, and manufacturers. In light of this, the government intends to proceed with the proposal to establish this route. As outlined in the consultation paper and recognised by respondents both in favour of and opposed to this proposal, a key feature is that the MHRA would hold additional powers to grant initial market approval. The government acknowledges the concerns raised by some respondents that stringent safety

measures must be applied. Therefore, this route will be limited to specific, defined, circumstances. Additionally, the MHRA will partner with the National Institute for Health and Care Excellence (NICE) and other key healthcare partners to establish critical end-to-end oversight. Guidance will be published outlining further details.

## 15 – Transitional Arrangements

The consultation considered a number of ways in which new requirements for medical devices could be phased in, depending on, for example, the device type or the level of risk it presents (its classification).

**A phased introduction of the new requirements would ensure that there is a proportionate approach to implementation, recognising that the medical devices sector requires time to make the necessary changes. This approach would minimise risks to patients and ensure the continued safe supply of devices to the UK market. It would also mean that clinical investigations devices that are underway at the point of transition would be able to continue uninterrupted.**

### Section 74 - Transitional Arrangements

#### 74.1 Proposals and feedback

The MHRA consulted on a number of transitional arrangement possibilities, which could work alone or in combination, as outlined below. This would assist with the smooth transition between the current and new regulatory framework and support the ongoing safe supply of essential medical devices to the UK market.

Options 1 and 2 considered whether medical devices and *in vitro* diagnostic medical devices (IVDs) already lawfully placed on the market with a valid UK Conformity Assessed (UKCA) certificate/declaration of conformity (Option 1) or CE certificate/declaration of conformity (Option 2) before 1 July 2023 should be able to remain on the market after this date and for how long:

**Option 1: for certification/declarations of conformity** for medical devices certified before the future framework applies: medical devices and IVDs 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 - 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 one 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 IVDs 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, 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 one additional year beyond the specified date.

The consultation invited views on the introduction of the transitional arrangements for UKCA certificates/declarations of conformity, as set out in Option 1 above. Of the 258 responses received:

- 68% were in support of Option 1
- 17% were not in favour of Option 1
- 15% did not know or had no opinion

Those who responded as part of an organisation were slightly more strongly in favour of the proposal (70%), versus 61% of individual respondents.

The consultation invited views on the introduction of the transitional arrangements for CE certificates/declarations of conformity, as set out in Option 2 above. Of the 255 responses received:

- 68% were in support of Option 2
- 18% were not in favour of Option 2
- 14% did not know or had no opinion

Consultees were asked to provide reasoning for their previous responses in this section and 166 responses were received. Those who were in support of either of the two above options for transitional arrangements reasoned that the options would allow for as many products as possible to continue to be placed on the market whilst manufacturers adapt to the requirements of the new regulations, noting that this approach would ensure market access and device availability.

Many respondents, both in favour of or unsupportive of these options, noted that allowing sufficient time to transition is key (as evidenced in the introduction of the EU MDR and EU IVDR) and that this approach is fundamentally linked to Approved Body capacity.

More clarity was requested around what a light touch assessment would involve in Option 2 and whether it would add any value. Respondents commented that a risk-based approach to transition would be the most beneficial for market supply.

Options 3 and 4 (set out below) briefly laid out possible transitional requirements for device registrations (Option 3) and Approved Body designations (Option 4). Questions on these options were posed in Chapters 4 and 5 of the consultation. For more information on the responses to these options please see the relevant Chapters above.

**Option 3: device registration requirements** would be phased in according to the risk classification of a device and UDI requirements would be introduced over time, including for devices already on the market.

**Option 4:** Approved Body designations are expanded on in Chapter 5. The MHRA wants to amend the UK medical devices regulations to set out that Medical Device and Active Implantable Medical Device Approved Body designations issued prior to July 2023 will be 'rolled over' until expiry of the designation.

Option 5 covered transitional arrangements related to clinical investigations as laid out below.

**Option 5:** Clinical Investigations which commence under the existing regulations before 1 July 2023 would continue to be conducted from 1 July 2023 providing that any additional reporting requirements laid out in the future regulations for clinical investigations that commence on or after 1 July 2023 are met, such as around serious adverse events or device deficiencies.

The consultation invited views on whether the transitional arrangements suggested in Option 5 should be introduced. Of the 251 responses:

- 63% supported the 'Option 5' proposal
- 8% were not in support of this proposal
- 29% did not know or had no opinion

The consultation asked consultees to provide reasoning for their response to the previous question. 102 responses were received. Of those who were supportive of this proposal, many reasoned that it would be impractical to impose a timeline or cut off for a clinical investigation

submitted and approved before 1 July 2023 and that accepting studies that have already been submitted would prevent unnecessary disruption, allowing the UK to remain attractive for clinical investigations and maintain clinical investment in the UK, and support innovation.

The consultation asked consultees to set out any other transitional arrangements or considerations that they considered necessary for putting in place a future regime for medical devices in the UK. 109 responses were received. Respondents noted the need for an adequate transition period, the need for increased Approved Body capacity and highlighted the importance of having clear guidance in addition to the regulations on transitional arrangements.

Consultees were asked for how many years after 1 July 2023 the MHRA should accept UKCA certificates/declarations of conformity (Option 1) issued before 1 July 2023. Of the 226 responses:

- **15%** selected 'for a further 2 years' (until 30 June 2025)
- **47%** selected 'for a further 3 years' (until 30 June 2026)
- **38%** selected 'other'

Those that responded with 'other' were able to specify further and the majority were in favour of the MHRA accepting UKCA certificates/declarations of conformity issued before 1 July 2023 for a further 5 years (until 30 June 2028). A small minority responded with "until certificate expiry".

Respondents were asked for how many years after 1 July 2023 should the MHRA accept CE certificates/declarations of conformity (Option 2) issued before 1 July 2023, with the responses as follows:

- **18%** selected 'for a further 4 years' (until 30 June 2027)
- **49%** selected 'for a further 5 years' (until 30 June 2028)
- **33%** selected 'other'

Of the 'other' responses, there was no one clear majority view, but comments included a suggestion that the MHRA should accept CE certificates/declarations of conformity issued before 1 July 2023 until certificate expiry, and a suggestion that this should be accepted for 3 years (until 30 June 2026).

The majority of those who supported the longest time period for transition (3 years for UKCA certificates and 5 years for CE certificates) reasoned that the longer the transition, the greater the chance of compliance and effective change control. Some respondents commented that the timeframe for accepting UKCA certificates should be the same as CE certificates to allow manufacturers sufficient time to transition. Many respondents also expressed concern regarding the lack of Approved Body resource and capacity and the impacts that this could have on meeting relevant deadlines.

Respondents were asked to select from a list of options regarding how long after the expiry of the certificate/declaration of conformity or after the 'specified date' devices covered by the transitional options 1 and 2 should be permitted to be supplied to the UK market, with responses as follows:

- **6%** of respondents selected '6 months'
- **69%** of respondents selected '12 months'
- **25%** of respondents selected 'they should not be permitted to be supplied after the cut-off date'

The majority of those who supported a 12-month transitional period reasoned that this time period would allow a steady distribution of medical devices to users and would be likely to reduce interruptions in supply.

Respondents were asked to outline what additional checks, if any, they would consider necessary to allow CE marked products to remain on the Great Britain market after 1 July 2023. The majority of the 140 respondents felt that no additional checks would be required, noting that the EU MDR and IVDR represent an acceptable 'quality standard'. Others thought that the CE marking process combined with device registrations and the appointment of a UK Responsible Person would be sufficient to allow CE marked products to remain on the market after 1 July 2023.

Further comments included:

- it might be necessary for additional checks to be in place for high-risk devices
- a light touch Approved Body review could be established

## 74.2 The government response

After careful consideration of responses, it remains the government's intention to introduce the **transitional arrangements for UKCA marked devices**, as set out below, with patient safety as the first priority. This would apply to general medical devices and IVDs that hold a valid certification/declaration of conformity to the UKCA standard, before the new regime takes full effect.

The government would like to establish a transitional arrangement for these products which will allow, at a minimum, products to be placed on the market until either the certificate expires or for three years after the new regulations take effect (in the case of general medical devices) or five years (in the case of IVDs), whichever is sooner.

The caveats that will apply to this arrangement are:

- devices that are subject to significant changes in design or intended purpose will be excluded from these provisions
- all post-market requirements applicable to the new regulatory framework will need to be complied with for all products which benefit from the transitional arrangements

After careful consideration of responses, it is the government's intention to put in place **transitional arrangements for CE marked devices** across two different categories as outlined below. We have taken account of consultation feedback on the need for appropriate transitional arrangements and propose, in certain cases, to go beyond the timescales set out in the consultation.

First, the government intends to introduce the transitional arrangements general medical devices and IVDs that hold a valid certification/declaration of conformity to the CE standard, **issued under the EU Medical Devices Regulation or the EU *in vitro* Diagnostic Medical Devices Regulation**. The government would like to establish a transitional arrangement for these products which will allow products to continue to be placed on the market until either the certificate expires or for five years after the new regulations take effect, whichever is sooner. This will apply even if the certification/declaration of conformity is dated after the new regulations take effect. Products certified to this standard will be permitted to be placed on the Great Britain market for up to five years from the date on which the new regulatory framework takes effect, with a view to reviewing this provision at the end of the five-year period.

The requirement that the product will need to have been lawfully placed on the Great Britain market by registering with the MHRA, with the certificate/declaration of conformity issued and the product registration completed before the new regulatory framework takes full effect will not be taken forward, in light of feedback received during the consultation.

Secondly, the government intends to introduce the transitional arrangements, as set out in Option 2, for general medical devices and IVDs that hold a valid certification/declaration of conformity to the CE standard, **issued under the EU Medical Devices Directive, the EU Active Implantable Medical Device Directive or the EU *in vitro* Diagnostic Medical Devices Directive** before the regulations take effect. The government would like to establish a transitional arrangement for these products which will allow, at a minimum, products to be placed on the market until either the certificate expires or for three years (for general medical devices) and five years (for IVDs) after the new regulations take effect, whichever is sooner. As above, the requirement that the product will need to have been lawfully placed on the Great Britain market by registering with the MHRA, before the new regulatory framework takes full effect will not be taken forward, in light of feedback received during the consultation.

The caveats that will apply to both categories of CE marked devices covered by these arrangements are:

- devices that are subject to significant changes in design or intended purpose will be excluded from these provisions
- all post-market requirements applicable to the new regulatory framework must be complied with for all products which benefit from the transitional arrangements

The requirement that all products which benefit from these transitional arrangements must undergo a light touch assessment that the device continues to meet the regulatory requirements will not be taken forward, due to feedback received during the consultation.

After careful consideration of all consultation responses, it remains the government's intention to proceed with the proposal for the **transitional arrangements for clinical investigations**, as set out in Option 5. This will apply to clinical investigations which commence under the existing regulations before the new regulations take effect and which would not be completed before the new regulations take effect. This will not cover performance evaluations, for which we do not propose any transitional arrangements due to the significant changes to the regulatory provisions being proposed in this area.

The government would like to permit such clinical investigations to continue without a requirement to re-apply to the MHRA, on the proviso that the clinical investigation complies with all reporting requirements set out in the new regulations for clinical investigations which commence once the new regulations come into effect.

This approach will ensure that clinical investigations that straddle both regulatory frameworks will be able to continue without impediment, that clinical investigations will not be delayed from commencing if there is a risk that they will run beyond the date at which the new regulations take effect and that increased safety protocols will apply to all clinical investigations underway from the date of application of the new regulations in the form of the reporting requirements.

The arrangements laid out above will ease the transition, supporting the continuity of supply of medical devices to the UK and avoiding unnecessary duplication of resource in notifying the MHRA of activities.

All these arrangements will be temporary, with a fixed time of application in place for each of them or a point of review. On expiry of the transitional window, all products and clinical investigations will need to comply with the UK medical devices regulations in full.

## 16 – Feedback

**The consultation sought feedback from respondents on the overall ambition of the changes proposed in its text and whether the changes proposed in the text were proportionate. This section of the consultation also provided a means for respondents to provide any additional information they would like to be considered.**

We asked for views on the level of ambition set out in the consultation. This question was answered by 213 respondents, as follows:

- excellent (11%)
- very good (29%)
- good (52%)
- poor (6%)
- very poor (1%)

We also asked if respondents considered the changes to the medical devices regulations proposed in the consultation are proportionate. The question was answered by 214 respondents, as follows:

- yes (67%)
- no (18%)
- don't know or no opinion (15%)

When asked to provide further information about the answers given to this question, 117 responses were received which provided feedback on the question asked, raising the following common themes:

- global harmonisation of medical devices regulation is a key consideration (51 responses)
- supportive of the proposals outlined in the consultation (23 responses)
- patient safety improvements are very important (8 responses)
- a risk-based approach should be adopted (6 responses)
- difficulty in forming a view until the new regulations are made available (6 responses)
- the regulations need to be proportionate to the size of the UK market (4 responses)
- the burden on manufacturers needs to be considered (4 responses)

Finally, respondents were asked to provide any additional comments or feedback and 114 responses did so. The comment themes in the responses were:

- global harmonisation of medical devices regulation is a key consideration (26 responses)
- views about the formatting of the consultation, both positive and negative (16 responses)
- supportive of the proposals outlined in the consultation (14 responses)
- a risk-based approach should be adopted (8 responses)
- further engagement on some of the proposals should be carried out (5 responses)
- the burden on manufacturers needs to be considered (4 responses)

The issues raised in this section of the consultation are broadly in line with the comments received in the technical chapters or the public chapter (the answers to which have been subsumed into the relevant technical chapter).

We have reviewed all of the comments received and thank everyone who took the time to contribute to this wide-reaching consultation on the future regulation of medical devices.