THE REVISION OF EUROPEAN LEGISLATION ON MEDICAL DEVICES

The response to the public consultation
April 2013
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Introduction

The public consultation
On 12 November 2012, the Medicines and Healthcare products Regulatory Agency (MHRA) opened a public consultation on the European Commission’s proposals for two new regulations on medical devices and in vitro diagnostic medical devices.¹

In the public consultation, the MHRA set out the Government’s view on the changes suggested by the Commission to the current regulatory framework on medical devices. We then asked for comments on the Government’s draft negotiating position. This included our draft position on:

- scope and definitions;
- making available of devices, obligations on economic operators, reprocessing, CE marking and free movement;
- identification and traceability, summary of safety and performance information;
- notified bodies;
- classification and conformity assessment;
- clinical evaluation and investigations;
- vigilance and market surveillance;
- cooperation between Member States and EU reference laboratories;
- confidentiality, data protection, funding and penalties; and
- the final technical provisions of the legislation.

Our aim was to understand the views of those interested in and impacted by the proposed new legislation and use them to test, challenge and strengthen the Government’s negotiating position.

The analysis of the evidence submitted
In this response to the public consultation, we have summarised the main points made by respondents in response to each of the questions posed in the public consultation. We have then highlighted how the MHRA will take account of these comments in the Government’s negotiating position.

A number of issues were raised in evidence submitted, which go beyond the questions we posed in the public consultation. These are addressed on page five of this document.

We received 116 responses to the public consultation. Annex A lists the organisations that responded to our consultation. We have not listed individuals’ details but we fully considered their evidence in our analysis and drafting of this report.

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<td>Individuals</td>
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<td>Healthcare professionals &amp; institutions</td>
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<td>Others: charities, notified bodies, regulatory authorities, standards &amp; quality institutions</td>
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What’s next?
This is not a one-off exercise and we want to continue to engage with stakeholders as the negotiations with the European Parliament and the other Member States of the EU progress.

It is worth highlighting that the final legislation is subject to negotiations by all countries in the EU and the European Parliament. Therefore the final legislation may differ from the UK’s policy position set out in this document.

¹ http://www.mhra.gov.uk/Publications/Consultations/Deviceconsultations/CON205361
We will continue to consider the available evidence and our proposed position where we have indicated in this document. In particular, we have committed to consult further on how the proposed regulations deal with software, define ‘companion diagnostics’ and ‘near patient-testing’, as well as the proportionate allocation of responsibilities on economic operators along the supply chain.

Our webpage will be kept up-to-date with the latest information and has contact details for the officials leading the work at the MHRA should you have any further questions or comments:

http://www.mhra.gov.uk/Howweregulate/Devices/NewLegislationonMedicalDevices

The new legislation on medical devices will not take effect until 2017 at the earliest, however the Government is clear that we must not wait until the new legislation is agreed to improve the safety of medical devices. We are therefore taking forward an immediate programme of action in collaboration with the other EU Member States. This includes work to improve the quality of notified bodies and to more proactively cooperate on market surveillance and vigilance activities.

The MHRA will shortly report on all of the progress made since Earl Howe’s review on PIP breast implants\(^2\), which will be available on the MHRA website.

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**Key points**

Respondents to the public consultation were broadly supportive of the Government’s policy approach. As a result, there are not any significant areas where we are substantially changing our policy position as a result of the consultation.

There was support for the changes to **scope and definitions** in the proposed regulations, including to bring in certain products without a medical purpose to the scope of the medical devices regulation. Respondents made helpful suggestions on the exact wording of the definitions, which we will consider further.

On **market issues**, there was mixed responses on whether or not to continue to exempt in-house medical devices and IVDs from the full regulatory requirements and reluctant support to allow the reprocessing of single-use devices. There was support for introducing the concept of a qualified person and a lot of useful suggestions on exactly how that role would function effectively. There are considerable concerns about the proportionate allocation of responsibilities among economic operators along the supply chain.

Respondents generally felt that more can be done to improve the consistent quality of **notified bodies** but that centralised scrutiny of notified bodies would not add value to the regulatory framework.

Respondents made helpful suggestions on how to improve the **classification and conformity assessment procedures** in both of the proposed regulations. There were concerns with the MHRA’s proposed policy position to classify devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body as medicines. There was support for the changes to the use of harmonised standards and common technical specifications.

There was support to improve the **identification, transparency and traceability** of medical devices, by establishing central databases, summaries of safety and performance information, implant cards, and a Unique Device Identification system. It is important that these new systems are well designed and implemented to ensure benefits.

There was support for the proposed improvements to **clinical investigations, market surveillance and vigilance**, as well as calls for more transparency, consistent interpretations across Member States and clear European guidance.

**Important issues raised in stakeholder evidence**

A number of respondents referred in their evidence to incidents involving PIP breast implants, certain brands of metal-on-metal hips, and vaginal tapes and meshes. The MHRA has listened to and understand the concerns that people have about these products.

PIP was a case of deliberate fraud; no regulatory system is designed to anticipate deliberate fraud. The Commission’s proposed regulations require notified bodies to make unannounced audits of manufacturers, which will help to avoid such cases of fraud in the future.

Problems with some brands of metal-on-metal hips became apparent many years after patients were implanted with the device. Analysis of data from the National Joint Registry for England and Wales was key to the worldwide action to recall the DePuy ASR metal-on-metal hip system in August 2010. The Commission’s proposed regulations place more requirements on manufacturers to follow-up their devices post-market and will significantly improve competent authorities’ ability to detect safety signals and fully co-ordinate their analysis of adverse incidents across the European Union.

The MHRA commissioned independent researchers to review the available literature on the safety and adverse effects associated with vaginal tapes and meshes. Whilst a small number of women have experienced distressing effects, the current evidence shows that when these products are used
correctly they can help with the very distressing symptoms of stress urinary incontinence and, as such, the benefits still outweigh the risks.
Scope and definitions

Scope of the medical devices legislation
There was strong support from respondents for the MHRA’s proposed position to update the scope of the medical devices regulation.

The main area of concern was in relation to the proposed wording around non-viable tissues and cells, which respondents felt was unclear and inconsistent with other legislation. In particular, evidence was submitted on why non-viable human tissues and cells that have been non-substantially manipulated should be within the scope of the new medical devices regulation. There were also requests from industry and clinicians for clearer definitions as regards the terms: ‘ancillary’, ‘substantially manipulated’, and ‘biological substances or organisms’.

The issue of substances that are intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed or dispersed in the human body is discussed in the section on classification on pages 25 and 26.

MHRA response: We agree that the clearer use of terms such as ‘ancillary’, ‘substantially manipulated’, and ‘biological substances or organisms’, which are in line with the relevant EU legislation on advanced therapy medicinal products, will be useful. We intend to pursue this in negotiations.

We also agree that the wording relating to non-viable tissues and cells needs to be improved. We will examine further how to make this provision clearer, ensure a clearer borderline with other relevant legislation and avoid any products falling into regulatory gaps.

Scope of the IVD regulation
The majority of respondents who responded to this question agreed with the MHRA on updating the scope of the IVD regulation. There were a few suggestions on how to improve the scope:

- remote monitoring and software should clearly be within the scope of the regulation; and
- there should be greater clarity on which regulation takes precedence for a combination product.

MHRA response: The regulation of software within both the IVD regulation and medical devices regulation requires further consideration; it is clear that there remains a great deal of uncertainty about this issue. The MHRA will consult further with stakeholders on this.

Medical devices definitions
There was strong support for the MHRA’s proposed position to update the definitions in light of legislative and technological developments. Industry and clinicians made specific recommendations to improve or add definitions on ‘accessory’, ‘interoperability’, ‘implantable device’, and ‘active device’.

List of implantable or invasive products without a medical purpose
There was strong support to extend the scope of the medical devices regulation to a list of implantable or invasive products without a medical purpose, for example, cosmetic contact lenses and implants to modify body parts. There was also strong support for including intense pulsed light equipment within this list, given the patient risks associated with these products.

There were specific suggestions on how to amend the list. For example, it was recommended that it should be made clear that facial or other dermal or mucous membrane fillers should be within the scope of the medical devices regulation but not topically applied fillers. There were also a number of suggestions on other products to include in the list, such as phakic lens implants, corneal inlays and cosmetic iris implants.

In addition, a few respondents stressed the need to keep this list up-to-date with technological developments and robustly define the risk acceptability criteria for these products, given that they lack medical benefit.
MHRA response: We will support the inclusion of intense pulsed light equipment in the list of certain implantable or invasive products without a medical purpose which are within the scope of the medical devices regulation.

We support the principle that invasive or implantable cosmetic devices presenting a high risk to patients should be included. We will consider the other recommendations to add or amend the list.

We are comfortable with the delegation of the power to the Commission to be able to more quickly update the list in light of technical progress. We recognise the need to define the risk/benefit criteria of these products, and consider that this could be addressed with harmonised standards or Common Technical Specifications.

IVD definitions
Overall, there was support for the MHRA’s proposed position to clarify the scope of the IVD regulation. There was a lack of clarity on to what extent software will be included in the scope of regulation and there were calls to ensure that this is proportionate.

Companion diagnostics
The European Commission’s currently proposed wording for ‘companion diagnostic’ reads as follows: ‘a device specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy’.

Respondents made a number of recommendations to refine this definition to ensure that it has the most appropriate scope:
- the reference to ‘targeted therapy’ traditionally refers to oncology and therefore is too narrow for this definition;
- the word ‘eligible’ may be too narrow, given that multiple factors are at play when a decision is being made about a patient’s treatment;
- the definition should be broadened to include targeting predictive or susceptibility testing; and
- the definition should refer to targeted therapy ‘with a specific medicinal product’.

In addition, several respondents emphasised that regulatory approval for therapeutics and their associated companion diagnostics should be as aligned as possible. Generally these respondents welcomed greater clarity in the regulation on medical devices on this point.

Near patient-testing
The Commission’s currently proposed wording for ‘near-patient testing’ is as follows: ‘any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient’.

Some respondents noted that ‘point-of-care testing’ is the more commonly used term in the UK and internationally. Respondents also made recommendations to clarify and broaden the definition to include terms such as:
- ‘medical, nursing or pharmacy consultation in a clinical environment’;
- ‘performed by a healthcare professional on a patient outside of a laboratory environment’; or
- ‘on-site laboratories in an acute care environment’.

MHRA response: These are very helpful comments. We are currently considering how to draft the definitions for ‘companion diagnostic’ and ‘near-patient testing’ more clearly and fully. We will present our alternate drafting suggestion to the MHRA’s stakeholder strategy group before pursuing amendments in negotiations.

The regulatory status of products
The majority of respondents who responded to this question agree with the MHRA’s proposed position to delegate power to the Commission to make a binding decision on the regulatory status of products,
given that this will help to establish more clarity and legal certainty. There was strong support for requiring the Commission to fully consult with stakeholders before taking a justifiable decision.

There were mixed opinions on whether the Commission should be able to act on its own initiative and some support for placing a deadline on the Commission to take a decision. One stakeholder suggested that the Commission and Member States should not be able to review the regulatory status of products which have already been placed on the market.

**MHRA response:** We agree on the importance of stakeholder consultation when deciding the regulatory status of a product. We will consider how to change the text of the proposed regulation to reflect this. In addition, we are of the view that the current Borderline & Classification working group of Member States and stakeholders should continue to play a role and we will pursue changes in negotiations to reflect this. The scientific reasons for a classification decision must be transparent.

We are happy for the Commission to be able to act on its own initiative to put the regulatory status of a product to a vote among Member States, given that the Commission represents the general interest of all of the countries in the EU. Moreover a qualified majority of Member States must support the Commission’s proposal before the regulatory status of a product can be changed.
Placing on the market and putting into service

Placing medical devices on the market and putting them into service
There was strong support for clarifying that manufacturers must carry out a clinical evaluation of their device before it can be placed on the market.

In-house medical devices
The majority of respondents supported requiring in-house medical devices (which are manufactured and used within a single health institution) to comply with the regulatory requirements. A small number of respondents currently manufacturing and using medical devices in-house already meet the requirements of the current medical devices legislation and consider that this change is reasonable. It was suggested that training on the regulatory requirements may help health institutions comply.

On the other hand, approximately one fifth of those who responded to this question expressed strong concerns with this regulatory change on the grounds that:

- health institutions would not be able to comply with the additional regulatory requirements and cover the additional costs;
- it may be impractical for a Trust, with many autonomous departments, to have a single quality management system;
- this would have a negative impact on innovation and the clinical need to improve the functionality and compatibility of devices (several examples were given of instances where this has brought benefits to patients);
- it does not take into account the reality on the ground that professional clinical engineering departments follow internal quality management procedures and other rules in place to protect against negligent in-house work, for example on liability; and
- in-house medical devices are not circulated on the internal market and therefore they should be regulated at national level and not by the EU.

MHRA response: We are grateful to respondents for highlighting the potential impact that the removal of this flexibility for in-house medical devices will have, principally on clinical engineering departments in NHS trusts. Our aim is to balance safety against risk proportionately.

The rationale for the MHRA supporting this change – and not the equivalent change for IVDs detailed below – is that we had understood that most in-house manufacturing of medical devices was adaptation of equipment anticipated by a manufacturer or the production of custom-made devices. Both of these scenarios would not require a healthcare institution to take on the role of a manufacturer and so would have a very limited impact.

In light of the evidence submitted, we will explore further the implications of this proposed change, including on innovation and product development, and will consider the Government’s position on this issue further. In this context, we will seek to change any requirement for in house manufacture of medical devices to take place under a health institution’s single quality management system, which is impractical and does not reflect a typical governance structure.

Placing IVDs on the market and putting them into service

There was strong support for requiring manufacturers to carry out a clinical evaluation of the clinical performance data of their IVD before it can be placed on the market. One respondent voiced concern that this may place a disproportionate burden on small and medium-sized enterprises (SMEs) if there is not clinical data available for some IVDs.

In-house IVDs
There was support for requiring health institutions which develop and use their own in-house class A, B and C tests, to comply with the ISO 15189 standard on quality and competence for medical laboratories. One respondent stressed the need for a smooth transition between the current Clinical Pathology Accreditation and the new ISO 15189 standard.
It was pointed out that the requirement on in-house tests to operate under a single quality management system does not take into account how genetic testing networks currently operate in the NHS.

There was mixed support for the MHRA’s proposed position to extend the in-house exemption to class D IVDs in the proposed regulation on medical devices so that in-house class D IVDs do not need to fulfil all of the regulatory requirements, as is currently the case. Slightly more than half of those who responded on this point agreed with the MHRA. Both clinical and commercial arguments were made for and against extending the exemption.

In support of the MHRA’s position to extend the in-house exemption to class D IVDs, it was pointed out that this would:

- mean that donor and patient screening, diagnostic and reference testing, and testing for rare and infectious diseases would continue to be available;
- mean avoiding placing large costs on health institutions;
- take into account the lack of CE marked equivalents for some in-house tests; and
- help to mitigate the lack of commercial incentive to develop IVDs for rare diseases.

In contrast, some respondents argued that the full regulatory requirements should apply to all in-house IVDs because:

- the risk to patients is the same whether a manufacturer or a health institution develops the test;
- manufacturers will have to raise their costs to meet the more new onerous IVD regulatory requirements which may encourage health institutions to develop their own in-house tests more cheaply;
- in-house tests are rarely subject to quality management checks and health institutions do not peer review the clinical performance assessments; and
- when taking into account all costs, in-house tests may not actually be cheaper for health institutions.

Respondents made a number of suggestions on how to amend the proposed IVD regulation to address the above concerns. This included extending the in-house exemption to Class D IVDs but raising standards by requiring competent authorities to keep an up-to-date register of class D in-house IVDs, allowing in-house class D IVDs on a case-by-case basis according to their risk, or only allowing class D IVDs where there is no equivalent commercially available CE-marked test.

MHRA response: Based on the evidence received, we continue to consider the in-house exemption to be absolutely critical for all IVDs to give health institutions the flexibility to develop tests for their patients where there are no commercially available IVDs available or where commercially available IVDs need to be adapted outside of their intended use. For example, we received evidence setting out how removing the in-house exemption for Class D IVDs would have an impact on dried bloodspot testing for HIV screening in difficult to reach populations, with clear negative public health implications as a result.

We recognise concerns about the potential inappropriate use of the in-house exemption where high quality, cost-effective CE marked tests are available. However we do not think that this issue should be addressed by either removing the in-house exemption or by qualifying it with additional rules and requirements. This is largely because of the difficulty of drafting legislation that would be able to address all of the potential scenarios involved in assessing, for example, when an in-house test is equivalent to a CE-marked alternative.

Rather we think it is important to address this legitimate concern through the broader management and governance of health institutions’ pathology laboratories. For example, we are exploring whether the proposed new requirement for health institutions producing and using in-house IVDs to be accredited to ISO 15189 might be a way to assess if hospitals use the in-house exemption appropriately.
Internet sales
Whilst there were few responses to this question, all respondents agreed that devices sold over the internet should have to comply with both of the proposed regulations. There were, however, concerns about how Member States will be able enforce this provision.
Harmonised standards and Common Technical Specifications

Harmonised standards

The majority of respondents supported the MHRA’s proposed position to extend the scope of harmonised standards but ensure that Member States can still object to a standard.

There was a strong call from some of the industry respondents to get harmonised standards right the first time round; competent authorities should be fully involved in the drafting of harmonised standards to avoid objections, confusion and cost implications for manufacturers once the standard has come into force. It was emphasised that Member States should only make well-substantiated objections.

Respondents also took this opportunity to call for a clear transition period for new standards coming into effect and for a swift resolution process if a Member State raises an objection.

It was noted that there is an existing provision in Regulation 1025/2012 that allows Member States to object to harmonised standards where these are provided for in relevant harmonisation legislation, which obviates the need for a separate provision in the medical devices or IVD regulation.

MHRA response: We agree in principle that Member States should be involved in drafting harmonised standards, that they should be high quality when they come into effect and that formal objections are undesirable. However the tight resource constraints on competent authorities may mean that they have to prioritise work in other areas.

We are grateful for reference to the provision in Regulation 1025/2012, which we consider to be appropriate to allow a Member State to raise a formal objection to a harmonised standard covering the medical devices or IVD regulations. A duplicate obligation is therefore not required.

Common technical specifications (CTS) for medical devices

There was strong support for the MHRA’s proposed position to proportionately introduce CTS for medical devices, which will provide clarity for manufacturers. There was strong support for involving stakeholders in the drafting of the CTS to ensure their high quality and legitimacy. Concern was raised, however, about the need to keep CTS up to date otherwise they risk becoming irrelevant or a hindrance to innovation.

There were different approaches on how to clarify the relationship between harmonised standards and CTS. There was concern on who would decide the insufficiency of a harmonised standard and concern that this should not be the Commission alone. A minority of industry called for CTS to only apply where harmonised standards do not exist (and therefore to not allow CTS where the harmonised standard has been deemed insufficient).

There was support for allowing manufacturers to not comply with the CTS if they have met a proven equivalent level of safety and performance. This ‘equivalent level’ should be consistently interpreted across all Member States to ensure an equally high level of patient safety.

MHRA response: We agree that CTS for medical devices are an improvement to the regulatory framework and that they could be particularly valuable to drive up standards on clinical evaluation and post-market surveillance for certain devices. They should be adopted where they can add the most value and respond quickly to changes in technology.

We think more needs to be done to plan how CTS will operate in practice, including on their relationship to harmonised standards. We agree that stakeholder involvement is important during the drafting of
CTS. We will consider whether changes to the proposed regulations would be appropriate to reflect this.
Responsibilities on economic operators

Qualified person

There was strong support for introducing the role of a qualified person (QP) to manufacturers and authorised representatives, with the exception of one industry respondent who argued that the provision is unnecessary because manufacturers already allocate responsibilities to certain personnel with the appropriate level of expert knowledge in the conformity assessment annexes to the proposed regulations.

There was limited support for the MHRA’s suggestion to split the qualified person responsibility across two people, although it was noted that this is currently allowed under national law in Germany. However there was strong support for clearly allowing manufacturers to contract a qualified person to ease the burden on SMEs.

There was strong support to amend the experience required in a qualified person to include criteria such as:

- experience which is relevant to the product and risk class;
- quality management and regulatory knowledge;
- verification by external monitoring;
- a minimum of three years professional experience;
- two years experience in medical devices regulatory frameworks; and
- a qualification in law (as is permitted in the case of a qualified person for an authorised representative).

There was some support for requiring notified bodies, importers and competent authorities to have qualified persons as well. It was noted by several respondents that there was likely to be a shortage of people with the qualifications and expertise to be a qualified person and there were calls for guidance and training on qualified person qualifications. In addition, there were some concerns that introducing the term ‘qualified person’ could lead to confusion because it overlaps with the same term used in EU legislation on medicines.

As regards the cost impact, there was concern from health institutions that the qualified person would be a disproportionate obligation for health institutions developing in-house class D IVDs. The estimated cost on health institutions varied between £45-50,000 per annum. Industry respondents’ cost estimates varied between nil (where manufacturers already comply) to £50-70,000 per annum. One individual estimated that this obligation may increase the wage bill of a microenterprise by 25-50%.

MHRA response: We think that the requirement on manufacturers and authorised representatives to have a qualified person is an important improvement to the regulatory system. We support industry contracting a qualified person to ease the cost burden, particularly for SMEs, and we will seek this clarification in the proposal. We will reflect further on the appropriate knowledge and expertise which an effective qualified person requires, although based on the evidence received we do not consider that significant changes are required to the current proposal.

Allocation of responsibilities

There were a significant number of concerns from industry respondents about how the proposed regulations allocate responsibilities among the different economic operators along the supply chain. In summary, the concerns were as follows:

Authorised representatives

- Only the details of the authorised representative should be labelled on devices manufactured outside of the EU so that there is one clear contact point for competent authorities.
- It is not appropriate for authorised representatives to have access to and be responsible for final release data.
- Authorised representatives do not need to duplicate the requirement on manufacturers to keep technical documentation and the declaration of conformity.
• Authorised representatives need a quality management system to be able to ensure compliance with the regulatory requirements placed on them.

**Importers**

• Importers should not have to duplicate the responsibilities carried out by authorised representatives or importers should only take on responsibilities that are specified in a written mandate between the importer and the authorised representative/manufacturer.
• Importers should not have to label products after they have been shipped, which may affect the quality of the devices.
• Importers do not have the expertise to rectify any failings by the manufacturer and any requirement on them to do so will raise costs on consumers without improving patient safety.

**Distributors**

• One industry respondent noted that they had very little knowledge of whether devices which they distribute conform to the regulatory requirements and that this would therefore be a burdensome requirement. They recommended that distributors not be required to assess or verify the manufacturer’s activities.

MHRA response: We recognise that the allocation of responsibilities among economic operators is a concern. Our aim is to ensure that the final legislation results in traceability and safety along the supply chain without duplicating roles and taking into account the diversity and complexities of the medical devices sector. We think that, in principle, the responsibilities on economic operators should be proportionate to their role in the supply chain and it should be clear to the users and the competent authorities which economic operator takes the lead responsibility for a device.

We will consider further how to improve the proposal in this regard and will discuss possible changes with interested stakeholders before pursuing changes in negotiations.
Reprocessing of single-use medical devices

There was a slim majority of support for the MHRA’s proposed position to allow the reprocessing of single-use devices if the reprocessors take on the responsibilities of the manufacturer. Much support for this change was reluctant; respondents noted that this regulates an unsatisfactory situation which contradicts the principle that manufacturers design single-use devices to be used once. Moreover this provision has the potential to undermine the single market if Member States can ban reprocessing on their territory.

Both industry and clinicians argued that allowing the reprocessing of single-use devices would be likely to encourage reprocessing in the NHS. One clinician highlighted that reprocessing low-risk devices could result in cost savings for the NHS.

Two respondents raised the issue that all reprocessed low-risk single-use devices must be checked for biocompatibility.

MHRA response: On balance we continue to support the Commission’s proposal because it brings in controls on what is currently an unregulated practice. However, we recognise that this is an imperfect solution and we intend to pursue the highest safety and quality standards for reprocessed single-use medical devices in the negotiations.

By bringing in clear controls on the reprocessing of single-use medical devices, we would expect this to bear down on this practice in the NHS, which MHRA guidance currently advises against[^3^], rather than encouraging it. Nonetheless we will ensure that clear guidance is in place in advance of any new requirements coming in.

Implant cards
There was strong support for introducing implant cards for patients, although a few respondents were concerned that patients would lose their implant cards.

Respondents gave suggestions on how to improve the benefits to patients of these cards. A clear minimum data set for the cards could include contact details in the case of any problems with the implant, MRI safety information, and details on the relevant surgeon. Some respondents pointed out that implant cards would be of limited use unless they are more closely linked in to current record keeping practice in hospitals. Therefore implant cards should be reinforced by an implant registry, GP records, a Quick Response (QR) code or the comprehensive European UDI database.

Respondents who responded to this question agreed with the MHRA that it would be unhelpful for patients to receive multiple cards. Implant passports or operation cards were suggested as two possible solutions to this problem.

As regards scope, respondents asked for clarity as regards which implants would require cards, for example by including a positive list in the proposed regulations. One clinician was concerned that implant cards will extend to all dental fillers, given the current proposed definition for an ‘implantable device’.

MHRA response: Based on the evidence received, we continue to consider that implant cards are a useful concept. Nonetheless we recognise that the current proposal poses practical problems, which we will look to take forward in the negotiations.

As regards the advantages of linking implant cards to patient records, this is an area of national competence. Therefore we will consider how we can take this issue forward outside of the European legislative process.

It is important to remember that implant cards are just one way to improve information for patients. Other measures, including the openly accessible summaries of safety and performance information linked to UDIs, are also important.
Declaration and CE marking of conformity
The majority of respondents who responded to this question agreed with the MHRA’s proposed position that the updated rules on the Declaration and CE mark of conformity add clarity. There were two main concerns from some industry respondents:

- information on harmonised standards and UDI should not be included in the Declaration of Conformity because this duplicates information recorded in Eudamed and the technical documentation; and
- there should be a common format for Declaration of Conformity forms across different pieces of European legislation.

MHRA response: We support greater clarity so that Declarations of Conformity contain an accurate summary of the important information about a device. We will consider further the information which may be duplicated elsewhere.

Medical devices for special purposes, systems and procedure packs, parts and components, and free movement
The majority of respondents agreed with the MHRA’s proposed position that the changes to these articles provide helpful clarity. The following suggestions were made to improve the definition of ‘parts and components’:

- the part or component should not conform with the regulatory requirements on its own but when it is in conjunction with the device;
- the definition should be expanded to include articles which are added to a device, including a software upgrade, (even if they do not replace parts or components of a device) if they significantly change the performance or safety characteristics of a device; and
- the definition needs to be clearer in the IVD regulations.

MHRA response: We will look into the definition of ‘parts and components’ in more detail. It seems reasonable to expand the definition to include articles which are added to a device and significantly change the device’s safety and performance.

It is useful to note that in the proposed regulations, articles which change the manufacturer’s intended purpose for the device would – in effect – make the device a different product which will need to be CE marked. Articles which do not change the manufacturer’s intended purpose for the device will only be subject to compatibility criteria.

Identification, traceability and transparency
Identification of devices along the supply chain
The majority of respondents agreed with the MHRA’s proposed position that the changes in the new regulations simplify and improve the identification of devices along the supply chain.

As regards the central registration database, it was recommended to involve industry in the design phase to help to ensure compatibility with other systems globally. One clinician respondent noted that it would be very helpful if the registration database could help radiographers establish whether or not an implant was MRI safe or not.

There were mixed views on whether or not storing details on the receipt and supply of devices will place a disproportionate burden on economic operators. The additional burden will depend on the size of the economic operator and the type of device. A number of industry and clinician respondents explained that they already comply with these requirements; therefore it appears that the impact will be most significant for SMEs. Nonetheless most industry stakeholders who responded to this question agreed with the MHRA that this cost was important to ensure device identification and traceability.

Finally, there were calls for more clarity on how data will be retained or recovered if an economic operator stops trading. It was also noted that it would be difficult for software, which is supplied electronically, to meet the identification requirements.
Central European database
There was support for establishing a publicly accessible central European database.

As regards the issue of transparency, an individual suggested establishing a website, modelled on that of the United States Food and Drug Administration, where patients can easily find information on all CE marked devices. One clinician respondent argued that health professionals should be able to use the central European database to assess quantifiable data on device failures and incidents. Some industry respondents flagged that Member States and the European Parliament should carefully consider how to treat commercially confidential information in the database to protect innovation.

There was considerable concern among respondents that the database might not work well in practice, therefore the Commission should design the database in close collaboration with Member States and stakeholders.

MHRA response: We agree on the importance of Member State and stakeholder involvement to design and implement the central European database. We have been discussing with the Commission the need to start work on this as early as possible. We agree that it is crucial to the success of the new regulatory system that the central database works well and is fit for purpose.

Traceability of devices along the supply chain
The majority of respondents who responded to this question support introducing a Unique Device Identification (UDI) system because it will facilitate recalls, save time with vigilance, and lower the risk of error in communications, which would also reduce costs on the NHS. Two individuals added that such an identification system would have enabled them to more accurately report their problems with TVT / meshes and clarify complication rates with these devices.

Industry respondents were divided between:
- acknowledging that it would be time-consuming and costly to implement but that UDI was imperative to improve traceability along the supply chain; and
- arguing that UDI should not apply to low-risk devices or consumer-care devices (which are distributed by supermarkets and pharmacies, which already have Universal Product Codes systems in place). This is in line with the proposed UDI system in the United States designed by the Food and Drugs Administration.

As regards effective implementation, some respondents suggested that appropriate transition periods will help to ease the burden on economic operators and health institutions implementing the UDI system. Cooperation between health institutions and regulators will also be important. Clinician respondents noted that it would be extremely challenging to put in place a single UDI system across the NHS. One respondent noted that it would be particularly burdensome for a health institution to record UDI for single-use and non-active devices.

Other specific comments included:
- the data elements of the UDI device identifier should be better defined in a delegated act rather than in an annex;
- disposals should be recorded to manage the size of the UDI database;
- the UDI database should link with up-to-date information on individual patient records (with their consent), Hospital Episode Statistics, the manufacturer, notified body, evidence base and post-market surveillance;
- there should be a mechanism to ensure that the UDI information is transferred if a health institution closes down;
- UDI for batch numbers may be proportionate in some cases; and
- the UDI system does not seem to have fully considered the implementation of software which is supplied electronically.

Compatibility
There was significant support for developing the European UDI system in line with that currently being
developed by the FDA and other global regulators. It was also noted that any European UDI system
should be compatible with the National Joint Registry’s work in the UK, which is currently being
expanded to include Australian and Norwegian registries.

Cost
It was generally deemed difficult to estimate the cost impact of UDI because the proposed regulations
do not specify how the system will be implemented. One industry respondent, which distributes 4.5
billion units every year, estimated that it would cost an additional £86 million per annum to implement
the UDI system. Clinician respondents gave varying evidence; some health institutions already have
systems in place which could record UDI, others noted that this would be a major cost investment to set
up from scratch.

MHRA response:
We recognise that it is difficult to quantify cost impacts at this stage. We agree that
UDI must be implemented according to risk and consider that the principles set out in the Global
Harmonisation Task Force (GHTF) guidance are an appropriate starting point for this approach.
Member States will consider the UDI requirements on low-risk devices in due course when the relevant
implementing legislation is agreed at EU level.

We agree that the European UDI system and the associated UDI database should be fully compatible
with other systems worldwide. This will ease the burden on manufacturers and ensure maximum
benefit for patients.

We fully recognise the importance of ensuring that UDIs are recorded as an integral part of patient
records. We are planning to set up a pilot scheme to look at the feasibility of incorporating UDIs for

Summaries of safety and performance information
Agreeing with the MHRA that requiring manufacturers to provide summaries of safety and performance
information was a positive step forward, many respondents made suggestions about which information
these summaries should include. Respondents most often cited the following information to include in
the summaries:

- key risks, warnings and performance specifications;
- critical incompatibilities and interfering substances;
- clinical test data or data on equivalent devices;
- summary of clinical evaluation report;
- efficacy or effectiveness information;
- selection criteria for patient evaluation, size of study group, range of situations for product
  use;
- reference to the instructions for use;
- vigilance information: number of field safety notices and reported events issued over a
certain number of years, device failure rates;
- clinical symptoms if a device has/will fail;
- post-market surveillance data over a set number of years; and
- specifically for IVDs: sample type and handling, analytical performance, clinical performance,
  limitations of the test.

Concerns with these summaries ranged from the need to safeguard commercially confidential
information, ensuring that lay people could correctly interpret the information, and ensuring that these
summaries were honest and upfront with patients. It was suggested that the approach used for
pharmaceuticals in the summary of product characteristics (SPC) could be a model on which to base
this information for medical devices.
MHRA response: We are currently considering the regulatory requirements for these summaries and are grateful for this helpful input. We do not consider that it would be appropriate to include this level of detail on the face of the legislation but this could be specified in an annex or an implementing act.

The MHRA agrees that these summaries should be openly accessible to all interested parties (for example via appropriate web links) and that they should be clearly cross referenced with the relevant UDI database information.
**Notified bodies**

**National authorities responsible for notified bodies**

Most respondents who responded to this question thought that national authorities can do more to improve the quality of notified bodies. Views on how to do this ranged from:

- requiring an independent organisation to monitor notified bodies;
- improving the consistent quality of competent authorities;
- requiring national authorities to request feedback from manufacturers on the performance of notified bodies;
- publishing the results of monitoring of notified bodies and peer reviews;
- monitoring advertising claims by manufacturers;
- involving an industry representative in the audits of notified bodies; and
- better sanctioning notified bodies that wrongly CE mark devices.

**Requirements on notified bodies**

Respondents made a number of suggestions on how to drive further improvements to notified bodies. One common theme was to improve notified bodies’ access to clinical expertise which should be specific to the device undergoing conformity assessment. It was also suggested that notified bodies could be replaced with a central organisation. As regards IVDs, one respondent recommended requiring notified bodies to consult with reference laboratories and to have access to expertise to assess clinical performance data.

As regards transparency, there were some calls for public conflicts of interest registers, the publication of notified bodies’ financial interactions with manufacturers, and the publication of summaries of conformity assessments.

There was some concern that placing additional regulatory requirements on notified bodies will mean raising costs for manufacturers. It was argued that additional requirements should be kept to the minimum required to improve notified body performance.

**MHRA response:** We support retaining and improving the notified body system. The Commission has proposed to tighten the regulatory requirements on notified bodies and strengthen the checks on their work by national authorities. We think that the Commission’s proposals can go further and we are currently considering additional requirements to ensure that notified bodies are more transparent and have access to high-quality and relevant clinical expertise. The evidence submitted will inform our discussions on this.

On the other points raised by respondents, the Commission has already proposed clear rules on conflict of interest for notified bodies in annex VI of the proposed regulations. We agree that any costs placed on manufacturers must be proportionate to the benefits to patient safety.

In addition, the MHRA is collaborating with other Member States in the EU and the Commission to carry out joint assessments of notified bodies on a voluntary basis before the new European legislation is adopted. This is helping to drive up the consistent quality of notified bodies in the short-term.

**Application and assessment to become a notified body**

There was strong support among respondents to require experts from different Member States to jointly assess organisations applying to become notified bodies. One clinician respondent was concerned that a national authority may still designate a notified body after the joint assessment team has made objections.

Some respondents agreed with the MHRA that this will place additional costs on manufacturers, which may be difficult for SMEs to absorb. This may mean it is harder for SMEs to start up or may mean products leave the market, two respondents suggested. However many respondents recognised that these changes were important to raise the standards of notified bodies and were therefore acceptable.

**Changes to notification**
There was strong support for Member States conducting a joint assessment when a notified body applies to extend its scope and for the Commission considering concerns about notified bodies. Two industry respondents noted that there should be minimal disruption to placing devices on the market if a notified body’s notification is withdrawn.

MHRA response: We think that pooling Member States’ regulatory expertise in joint assessments will help to raise the bar for notified bodies across the EU.

We recognise that a Member State may designate a notified body even if other Member States have raised objections in the joint assessment. However, designating notified bodies is a national competence and we do not think that this power should be given to the EU. We do think we can introduce further transparency in this procedure to ensure that the relevant Member State takes publicly justifiable action in response to any objections raised in a joint audit or by the Medical Device Coordination Group (MDCG).

Monitoring notified bodies
There was strong support for better monitoring of notified bodies, which must work well in practice. In addition, several respondents called for:
- competent authorities to publish their audits of notified bodies;
- EU guidelines on how to carry out audits;
- notified bodies to carry out random and unannounced monitoring; and
- fewer notified bodies assessing high-risk devices.

MHRA response: As outlined previously, we consider that transparency is a key lever to drive up the performance of notified bodies. We support publishing details about audits of notified bodies, which respect legitimately commercially confidential information. We will pursue this in negotiations.

There is guidance on how to carry out audits (the Designating Authorities Handbook⁴), which we consider will need to be updated to reflect the new legislation. Nonetheless it continues to be a useful resource.

Classification and conformity assessment

Classification

There was strong support for the MHRA’s proposed position to clarify the application of the classification rules by Member States.

One industry stakeholder disagreed with the MHRA’s position that Member States should inform the Commission and Medical Device Coordination Group (MDCG) after they have made a decision on classification. In their view, informing the Commission and the MDCG before a competent authority has made a decision on classification will allow the Commission and the MDCG to give Member States advice based on any other similar disputes between a notified body and a manufacturer.

Another industry stakeholder raised a concern that classification rules are an essential element of the regulations and therefore Member States should not delegate power to the Commission to amend them.

MHRA response: We understand the rationale that a competent authority, by informing the Commission and MDCG before it makes a decision on classification, may receive advice. However, in practice, the competent authority would be unlikely to receive meaningful feedback within the 14 day deadline proposed by the Commission. Given that it is clearly a national competence to make a decision on classification, we think that it is inappropriate for a competent authority to alert the MDCG and the Commission before making such a decision. The mechanism to allow implementing acts to specify the application of the classification criteria for specific devices or groups of devices will address any issues of inconsistent application of classification rules by different Member States.

More generally, delegating power to the Commission to amend an annex may be appropriate if it means being able to easily update legislation in light of technological progress. However we do not think this is appropriate where annexes include details which make up the core of the legislation, such as on classification and conformity assessment. Any changes to these important parts of the legislation should be fully debated by both Member States and the European Parliament in full negotiations (the ordinary legislative procedure).

As regards the classification rules for medical devices, there were some calls for the up-classification of devices, including to address the inconsistency of classification between single use or reusable surgical instruments. In addition, some patients and clinicians called for synthetic TVT/meshes, all joint implants, or all implantable devices to be classified as class III devices.

On the other hand, there were concerns from industry and some other respondents that the proposed regulation on medical devices up-classes certain medical devices disproportionately to the safety risks. Therefore this will raise costs without improving patient safety. This includes:

- contact lens and denture cleansers that are used overnight;
- reusable contact lenses;
- implantable devices that contact the spinal column;
- devices incorporating or consisting of nanomaterial where there has been a long history of safe use or a positive scientific opinion from a relevant European agency; and
- devices intended to be used for phaeresis.

There were also calls from clinician respondents to define ‘stand alone software’ more clearly.

Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body

The Commission has proposed to classify devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body as class III devices. In our public consultation, we set out our proposed position to regulate these products as medicines on the grounds that medical devices legislation does not fully take into account the safety aspects of these products.
There was significant opposition to both the MHRA and the Commission’s positions from respondents on the grounds that both approaches are disproportionate to the safety risks. In addition, these approaches contradict the fact that these devices achieve their principal intended action through physical means and therefore they have limited propensity for exposure or absorption. Some industry respondents are concerned that this up-classification will have a negative impact on a range of consumer care products, which include denture adhesives, lubricants for medical devices, lubricating eye drops, dentrifices for tooth sensitivity, vaginal lubricants and saline nasal sprays. These respondents suggest that the degree of invasiveness of a device should be a key factor in its classification.

In contrast, several respondents supported the MHRA’s proposed position on these products and commented that the urethral and ophthalmic administration routes should also be included. Some respondents also felt that a further benefit to this change would be that these products would need to comply with the stricter requirements on labelling and packaging that apply to pharmaceutical products.

MHRA response: In principle, we think that it is imperative to put patient safety first, take a proportionate and risk-based approach, and have clear and consistent rules across the EU. We will continue to give careful consideration to the evidence on all aspects of the classification rules for medical devices and draw on the evidence submitted in the public consultation.

We continue to consider that the safety risks of substances intended to be ingested and that are absorbed by or dispersed in the human body means that they should be regulated as medicinal products. These include the need to take into consideration drug interaction, vulnerable populations, chronic use, as well as novel and active ingredients.

There is less of a safety concern for products that are taken into the body through different routes, and we are therefore minded to take the approach that these products should be classified according to Rule 5 of Annex VII of the proposed regulation on medical devices, which classifies all invasive devices with respect to body orifices, other than surgically invasive devices. This addresses industry’s legitimate concerns that low-risk products should not be up-classified that already comply with Rule 5, for example, in the case of lubricants. We will need to consider how other aspects of the proposed regulation – such as the essential requirements – might need to change to ensure that these products are appropriately regulated to take account of the concerns raised.

However, it is worth noting that we do not consider that low-risk nasal sprays or artificial tears would be affected by the Commission’s proposal because nasal sprays are not intended to be inhaled into the lungs and artificial tears are not ingested except by drainage alongside tears.

We recognise that this is a finely balanced issue that has also generated interest amongst other Member States and the European Parliament and will continue discussions with stakeholders as we develop our position and respond to those of others.

As regards the classification rules for IVDs, there was strong support among respondents who responded to this question for establishing risk-based classification.

There was mixed support for MHRA’s suggestion to include novelty as a risk factor in the classification rules. On the one hand, clinical respondents argued that taking into consideration novelty would mean being able to apply more stringent rules until manufacturers collect further evidence. However, some respondents also pointed out that novelty is not a risk factor in the classification of medical devices, is not a prime determinant for patient safety, and it would be best to not deviate from the internationally agreed GHTF risk classification.

There were particular comments on the need to clarify the classification of human genetic testing (and take into account the increasing use of whole genome sequencing and exome sequencing), companion diagnostics, and reagents which possess specific characteristics. It was suggested that all self-testing devices be classified as class C.
MHRA response: We note the divided support on including novelty as a risk factor in the classification rules. We agree with the principle that we should only deviate from GHTF where it would clearly bring additional benefits. We will therefore look to see how else novelty can be addressed in the regulatory framework, for example by placing specific requirements on manufacturers to gather specific clinical evidence or carry out specific post-market surveillance studies.

Conformity assessment procedures and essential requirements for medical devices

As regards Annex I which sets out the general safety and performance requirements of devices, a majority of industry respondents called for requirements on endocrine disrupters, special microbiological state, and nanomaterials to be based on science.

There were a range of additional comments on Annex I from a small number of respondents:
- power should not be delegated to the Commission to amend this annex, given that these requirements are an essential element of the legislation;
- it is disproportionate to require combination products to meet both the regulatory requirements on medical devices and the requirements set out in Directive 2001/83 on the Community code relating to medicinal products for human use;
- the requirements on instructions for use need to be clearer to ensure that patients give informed consent;
- product quality assurance conformity assessment should remain available because it is used for class IIa devices and reduces auditing times for microenterprises and SMEs; and
- the requirement on a manufacturer to inform a notified body of changes to a device in the conformity assessment annexes for class III devices must be proportionate.

MHRA response: We are still considering the annexes on conformity assessment procedures and essential requirements in detail. The evidence submitted will inform our discussions on this. We think it is important for combination products to meet all relevant regulatory requirements.

As we explained as regards the classification of medical devices, delegating power to the Commission to amend an annex may be desirable if it means legislation can easily be updated in light of technological progress, for example. However we do not think this is appropriate where annexes include details which make up the core of the legislation, such as the classification and conformity assessment rules.

There was support among respondents for unannounced inspections by notified bodies of manufacturers, which will help to prevent cases of fraud, such as happened with PIP breast implants. Some respondents recommended improving this system by tasking the Medical Device Coordination Group with ensuring compliance of notified bodies with these unannounced inspections and setting criteria for their frequency.

There were calls for notified bodies to conduct these inspections at non-EU manufacturers to ensure a level-playing field. One expert suggested that short notice inspections would be preferable, as happens in the United States, to prevent failed inspections if the relevant personnel were not available, which is more likely among microenterprises and SMEs.

MHRA response: Member States and the Commission will mandate the minimum frequency of unannounced inspections by notified bodies of manufacturers in secondary legislation. We agree that a challenge is in implementing this provision will be auditing EU and non-EU manufacturers equally, which is difficult where non-EU countries require visas and a letter of invitation from a manufacturer.

Conformity assessment procedures and essential requirements for IVDs

In general, respondents agreed with the proposed changes to conformity assessment procedures for IVDs. Respondents made specific comments relating to:
- the clarity needed on the conformity assessment routes for repackaging and relabeling;
- the design of instructions for use for software-driven tests;
the need for a more clearly defined consultation with the relevant competent authority for medicinal products or the European Medicines Agency to avoid undue delays or duplication of work by the notified body;

- the expansion of the essential requirements on intended radiation to take into account the \textit{in vitro} diagnostic medical devices which emit radiation; and

- the quality assessment of analysers.

There was a mixed response to the MHRA’s question as to whether or not notified bodies should be involved in assessing class A IVDs with a sterile or measuring function. On the one hand, it was argued by some industry respondents that it is unnecessary because these IVDs have a different risk profile in comparison to medical devices. It was pointed out that the relevant validation requirements would be covered in ISO 13485 or 9001. Other respondents argued that notified body involvement will be useful to provide consistency across both of the proposed regulations and that, in addition, notified bodies should have the right competencies to carry out these assessments.

\begin{quote}
MHRA response: We will consider these comments and our position on conformity assessment routes for IVDs in more detail, taking on board the evidence submitted. In particular, we will examine further the rationale and proportionality of involving notified bodies in the assessment of class A IVDs with a sterile or measuring function.
\end{quote}
Derogations, choosing a notified body, and certificates

There was strong agreement from the majority of respondents who responded to this question with the MHRA’s proposed position to improve the regulatory framework to prevent forum-shopping by manufacturers and clarify rules on certificates and certificates of free sale.

As regards forum-shopping by manufacturers for a less stringent notified body, one stakeholder suggested that notified bodies register the applications they receive for conformity assessment in a central database, which would alert the Medical Device Coordination Group (MDCG). The MDCG could then oversee any conformity assessments where there has already been a withdrawn application.

As regards Certificates of Free Sale (CFS), two respondents recommended that Member States give CFS if the manufacturer has a registered place of business or if the manufacturer has a production site in an EU Member State. They argued that it would be impractical to limit the validity of the CFS to the validity of the certificate of conformity.

MHRA response: We support requiring manufacturers to disclose previous interactions with notified bodies to limit the practice of forum-shopping. We do not think that central scrutiny of conformity assessments is the most proportionate approach to improve patient safety. However we will look further into whether it is desirable to be able to increase the scrutiny of applications for conformity assessment which a manufacturer has withdrawn from one notified body and submitted to another.

We will look to see how CFS can become less burdensome for both competent authorities and manufacturers.
Additional pre-market scrutiny for higher risk medical devices

Three quarters of respondents who responded to this question agreed with the MHRA and did not support establishing centralised scrutiny of conformity assessments.

The following alternatives or improvements to the mechanism suggested by the Commission in the proposed regulations were suggested:

- the full use of Common Technical Specifications;
- post-market sampling of devices with increased rates of serious incidents, novel devices, or where there are discrepancies across conformity assessments by different notified bodies;
- consultation by notified bodies of reference laboratories during the conformity assessment process;
- central accreditation for notified bodies of class III devices;
- a narrower scope for the pre-market scrutiny mechanism to only include a change in risk/benefit profile, an increased rate of serious incidents, and public health concerns; and
- an appeals procedure for manufacturers during the pre-market scrutiny procedure.

Those that support the Commission’s proposal to establish additional pre-market scrutiny for higher risk devices argue that a small delay to placing devices on the market will improve patient safety or that – more radically – competent authorities should be able to check the conformity assessment of high-risk devices.

MHRA response: We recognise the importance of strengthening the pre-market assessment of medical devices. We think that during the negotiations Member States and the European Parliament can improve the Commission’s proposal to improve the quality of notified bodies, particularly the assessment by notified bodies of clinical evidence.

We are concerned that central accreditation for notified bodies would shift responsibility away from Member States and towards the EU. Instead we should not focus on who checks the quality of notified bodies but how well it happens.

As we outlined in the public consultation, we have great concerns about the Commission’s proposed mechanism to introduce a bureaucratic layer of centralised scrutiny of notified bodies’ draft conformity assessments. There is a clear lack of evidence to support this idea, which was highlighted as an area of concern by the Commission’s own Impact Assessment Board. For example, the scrutiny mechanism may delay placing devices on the market for much longer than the 60 day deadline if the MDCG requests and considers additional information.

There may be evidence to support additional scrutiny of genuinely novel devices. However the challenge is to accurately define the criteria so that any additional scrutiny is proportionate and only applies to the relevant devices.

We also agree on the need for better targeted post-market surveillance to improve patient safety, as we outline in further detail on page 36.

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Clinical evaluations and investigations
Clinical evaluations and general requirements on clinical investigations for medical devices
There was strong support among respondents who responded to these questions to strengthen the requirements on manufacturers to carry out clinical evaluations and undertake post-market clinical follow-up (PMCF). The following ideas were suggested to improve clinical evaluations further:
- notified bodies should access the right scientific and clinical expertise when assessing manufacturers’ clinical evaluations;
- manufacturers’ research methods should follow recognised standards;
- clinical data should be updated and peer reviewed;
- manufacturers should declare all known clinical studies;
- PMCF should be made public;
- the criteria for when manufacturers can use ‘equivalence’ should be more clearly defined; and
- manufacturers’ research methods should follow recognised standards.

A minority of respondents called for more stringent requirements, similar to those placed on clinical trials for medicines. On the other hand, a few respondents expressed concern that this approach would place disproportionate costs on manufacturers of low-risk devices.

MHRA response: We think that requiring pharmaceutical-style clinical trials for medical devices would be disproportionate. There is a limit to what extent devices can be assessed pre-market. Unlike medicines, it is not feasible to accurately predict the likelihood or time to failure for new medical devices via pre-market studies. In practice, such studies of sufficient size and diversity are either impractical or so onerous that they would block the product’s development process.

However we strongly support requiring manufacturers to undertake rigorous clinical evaluations that are fully scrutinised by a notified body and subject to more transparency. For example, the proposed regulations place more requirements on notified bodies to have appropriate clinical expertise in place to be able to assess clinical evaluations. In principle we consider that the manufacturer’s clinical evaluation should be commensurate with the risk associated with the innovation or change.

Clinical evidence and clinical performance studies for IVDs
There was strong support overall for strengthening the requirement on manufacturers to carry out clinical evaluations and clinical performance studies for IVDs. One stakeholder argued in favour of pharmaceutical-style clinical trials, which take into consideration clinical utility, and another argued that post-market surveillance would suffice without this additional pre-market work.

As with the above comments on medical devices, it was argued that manufacturers’ research methods should follow recognised standards and that clinical data should be updated and peer reviewed.

Finally, there were specific comments on companion diagnostics. A stakeholder stressed that the clinical evidence requirements on IVDs should be proportionate to the type of test and pathology. Another stakeholder noted that clinical performance studies were essential for companion diagnostics, given that these tests inform patient management and have an impact on treatment decisions.

MHRA response: As we outlined above, we consider it important to place tighter requirements on manufacturers to collect high quality clinical evidence but that pharmaceutical-style clinical trials would be disproportionate for IVDs. We think that Member States should remain responsible for the evaluation of clinical utility, given that it involves so many varying national circumstances.

Clinical investigations: application
The majority of respondents who responded to this question agreed with the MHRA’s proposed position that the new requirements are helpful but that Member States must retain the right to request further information when manufacturers apply for clinical investigations and object to the clinical investigation within 60 days. Additional comments included the following:
- the need for clear guidance setting out how to apply for clinical investigations;
it may take longer to set up a clinical investigation where the new medical devices regulation means revising the study documentation, which is needed to support financial and contracting arrangements;

• giving sponsors six days is too short to respond to a Member State if an application is incomplete; and

• Member States should only be able to object to the clinical investigation within 30 days.

MHRA response: We recognise the rationale for guidance on applying for a clinical investigation however there are varied approaches between Member States which would make common European guidance impractical. For example, in the UK there is an integrated ethics and regulatory application process, which is not the case in all Member States. We will consider the proposed timelines further, taking into account the need to balance the benefits of quick approval against the need for Member States to be able to fully consider an application.

Registration to an electronic database and notification to the competent authority
The majority of respondents who responded to this question supported registering clinical investigations and performance studies onto a new central European database. A considerable concern from industry respondents was the resourcing of the new database from the existing regulatory funds.

As regards transparency, a few respondents stressed that proof-of-concept should not become public at too early a stage. On the other hand, a number of respondents were enthusiastic about how transparent clinical investigations and performance studies will improve decision-making and public awareness of new therapies.

Additional comments included the following:

• clinical investigation requirements should not become too burdensome, such as the requirement for the sponsor to update the database within a week of any change; and

• the work on the Beyond Compliance initiative in the UK should not be deterred by the new regulatory requirements.

MHRA response: We agree that there should be more transparency, with due consideration for legitimate commercial confidentiality and protection of personal data. We agree that it is crucial to effectively design and fund the central database to ensure that it delivers benefits to the regulatory system.

Multi-site investigations
The majority of respondents who responded to this question supported more streamlined Member State cooperation on multi-state clinical investigations and performance studies. They also supported the MHRA’s proposed position to support the assessment of incidents by the competent authority where an adverse event happens. One stakeholder suggested that where a Member State does not want to be the coordinating competent authority, the sponsor should be involved in choosing which Member State takes on this role.

As regards timelines, one stakeholder suggested introducing time limits to competent authorities’ action to avoid delays to the assessment of clinical investigations and performance studies.

MHRA response: We will consider the sponsor’s role in deciding the coordinating competent authority in further detail. Where relevant, it is important to read across to the current EU negotiations on the proposed clinical trials regulation, which also establishes similar concepts for medicinal products.

Further details
The majority of respondents who responded to this question supported the proposed measures to delegate power to the Commission to define the details of the application process for clinical investigations and performance studies. Two respondents stressed the importance of consulting stakeholders when drawing up these details.
MHRA response: We agree on the added value of involving stakeholders in designing the application process.
Vigilance

Reporting of incidents and field safety corrective actions

The majority of respondents who responded to this question supported the proposed measures to require manufacturers to report incidents to a new central database, trend report, update their technical documentation, and for the Commission to develop a standard form for reporting by healthcare professionals. There were a range of additional comments:

- there should be a detailed and consistently applied interpretation of a 'serious incident';
- the 15 day deadline for manufacturers to report serious incidents is not long enough to investigate the root cause and therefore should be extended to 30 days;
- there should be clear guidance on trend reporting to ensure that trends are comparable;
- it is not proportionate to require manufacturers to report trends for all devices;
- healthcare professionals must be more strongly encouraged to report;
- the MHRA must be more proactive with following up complications data, which was not the case during problems associated with synthetic TVT / meshes;
- the MHRA should set up a compulsory register of all implantable devices;
- reporting forms must be easy-to-use for healthcare professionals and streamlined with existing national reporting requirements; and
- the national Black Triangle Scheme for medicines\(^6\) could be expanded to encourage reporting for particular high-risk devices.

MHRA response: We agree on the importance of having consistent interpretations of trend reporting and a 'serious incident'. We think that placing a 15 day deadline on manufacturers to report serious incidents is important for patient safety and follow-up reports can be submitted where the root cause has not been identified within the 15 day deadline.

Reporting by healthcare professionals is an extremely valuable source of information about the ongoing safety of devices, as has been raised by the House of Commons Science & Technology committee\(^7\) and Earl Howe's review. We are currently carrying out a programme of work to improve the culture of reporting by healthcare professionals for all categories of devices.

Analysis of incidents and field safety corrective actions

The majority of respondents who responded to this question supported the proposed measures to require competent authorities to notify the central European database of reports from healthcare professionals, users and patients, and for one Member State to coordinate an adverse event spanning more than one country. Field Safety Notices will be publicly available on the central database.

Suggested improvements to the proposed system include:

- requiring competent authorities to write to users with the relevant Field Safety Notices or inform them through the implant cards if they are electronic;
- more data transparency to allow the assessment of the type and frequency of adverse events and to allow competent authorities to explain to clinicians the follow-up they have taken to adverse events;
- clearly requiring Member States to evaluate a serious incident or field safety corrective action; and
- notifying manufacturers of any adverse event before this information is made public.

MHRA response: We will consider these proposed changes further. We support greater transparency but equally recognise that it is important to ensure that manufacturers are aware of information being placed into the public domain.

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Further details
The majority of respondents supported delegating power to the Commission to define serious incidents for specific types of incidents and timelines for reporting. Two respondents thought that this delegation of power was inappropriate, given that these details are central to the operation of vigilance. Finally, two respondents emphasised the importance of consulting with stakeholders when making these decisions.

MHRA response: As outlined previously, we are still considering whether the proposed delegations of power to the Commission are appropriate. We agree that stakeholder consultation is important when designing the details of the vigilance system.
**Market surveillance**
The majority of respondents who responded to this question supported clarifying Member State responsibilities for market surveillance. One stakeholder stressed that all competent authorities must carry out these responsibilities to a consistently high standard.

As regards the proposed provision to allow the Commission to extend a national patient safety measure across the EU, one stakeholder stressed that the Commission must have the expertise to do this. On the other hand, another stakeholder argued that it would be better if the Commission automatically extended the national measure across the EU before the Medical Device Coordination Group reviews whether this was justified or should be rescinded.

More broadly, there were a few suggestions on how the MHRA could improve its communications on market surveillance. This included expanding the Drug Safety Updates to devices, setting up an early warning system, and establishing a breast implant registry, as well as implant registries where vigilance data indicates the need for one or where evidence has not yet been gathered.

**MHRA response:** As outlined previously, we are still considering where the delegations of power to the Commission are appropriate. It will be crucial that the Commission has the expertise to fulfil any responsibilities given to it by the new legislation.

We do not consider it appropriate to delegate power to the Commission to extend a national measure across the EU, given that Member States may disagree on the most appropriate and effective approach to guarantee patient safety. We will always want to take a look at the evidence ourselves and consider the most appropriate approach for the UK.

**Non-compliant and compliant devices presenting a risk to health and safety**
The majority of respondents who responded to this question supported these changes to simplify the reporting of market surveillance activities and facilitate cooperation between competent authorities.

There were concerns from a small number of respondents that competent authorities will not consistently fulfil these requirements and that the Commission will not have the expertise to evaluate a national patient safety measure and decide whether or not it is appropriate to extend it across the EU.

**MHRA response:** As outlined previously, we are still considering whether the proposed delegations of power to the Commission are appropriate. It will be crucial that the Commission has the expertise to fulfil any responsibilities given to it by the regulations.

**Cooperation between Member States**
The majority of respondents agreed with the MHRA that additional measures were welcome to improve cooperation between Member States and participation in international medical devices cooperation. A majority of respondents supported stakeholder involvement in the Medical Devices Coordination Group (MDCG). One respondent suggested that the MDCG minutes be published.

A number of respondents also emphasised that MDCG needs proper funding to be fully effective.

**MHRA response:** We agree on the importance of involving stakeholders in the MDCG in a meaningful way and that it should work in a transparent manner.

**EU reference laboratories**
The majority of respondents who responded to this question agreed with the MHRA that EU reference laboratories should only be set up if they raise standards and harmonise test results across the EU in a cost-effective way.

Concerns about the implementation of EU reference laboratories included:
- the range of devices and therefore the range of necessary technical expertise;
- the validation of high risk devices already happens; and
• the need for close oversight and governance of EU reference laboratories to ensure impartiality and the maintenance of expertise. For these reasons, several respondents preferred a looser network of laboratories on types of devices or types of diseases.

Of those respondents which supported the establishment of EU reference laboratories, they highlighted that this would help to gather and analyse data from across the EU, including on explanted joints.

Specifically as regards the role of reference laboratories for IVDs, it was noted that notified bodies already request some reference testing from specialised laboratories and that it would be unnecessary duplication if the reference laboratory were to repeat the work already performed by the notified body.

There was some concern that the role of reference laboratories would lengthen the time to market for IVDs. In addition, a few respondents were concerned that EU reference laboratory work would become onerous if they had to advise on suitable reference materials on genetic variant databases and genome references or if there was a high frequency of testing without a universally agreed reference value.

MHRA response: The benefits of reference laboratories are more obvious for IVDs, for example, to verify compliance with the common technical specifications (CTS). However, they seem less appropriate for medical devices given that they span a greater range of complexity and diversity.

We are currently considering how clinical and scientific expertise needs to improve across the regulatory framework and therefore whether EU reference laboratories or another mechanism will provide the most useful, cost-effective support. We tend to agree that looser networks of experts are more likely to add value to the regulatory system than a hierarchical fixed structure of laboratories.
Confidentiality and data protection
There was some discomfort among respondents about how the MHRA set out its position in the public consultation that the default mode in the regulations should be transparency and confidentiality should be kept to a minimum.

All respondents who responded to this question agreed that transparency was important but the majority emphasised to different degrees the importance of keeping personal data and commercially sensitive information confidential. One stakeholder recommended that confidentiality provisions for medical devices should move to mirror those for pharmaceuticals, which are more geared to transparency and take into account wider public interest considerations.

In contrast, a number of respondents stressed the importance of complainants being updated on the progress of vigilance cases and patients being able to access any information which manufacturers can. One stakeholder argued that each application for access to data should be evaluated on a case-by-case basis, taking into account the public interest. This would help to facilitate independent public health research.

MHRA response: We agree on the importance of protecting personal data and legitimately commercially sensitive information. However we think that transparency is a powerful lever to improve the quality of the regulatory system and empower competent authorities, healthcare professionals and patients. The principles of the UK’s Freedom of Information Act and consideration of requirements in other product sectors, including pharmaceuticals, will guide our approach in this area.

Funding and penalties
There was support among respondents who responded to this question for the provision in the proposed regulations which explicitly allows Member States to levy fees, which formalises the existing practice.

In addition, three respondents argued that fees should be consistent and proportionate across the EU. One stakeholder suggested that a single fee to a central European fund could be dispersed equitably between Member States. Another stakeholder suggested that the Commission would then be able to evaluate which national system delivers the most value for money.

MHRA response: We agree with the principle that fees should be proportionate. We are currently considering possible reforms to the fee structure in the UK, which we will report upon in our progress report on work undertaken since Earl Howe’s review on PIP breast implants.

Final provisions
The majority of stakeholder who responded to this question agreed with the proposed transition periods before the regulations enter into force: three years for medical devices and five years for IVDs. It was also suggested that properly resourced notified bodies and competent manufacturers should not have trouble meeting shorter timelines.

On the other hand, a few respondents were concerned that these time periods were too short, considering that the Commission need to draft and adopt important secondary legislation to set out many of the details of the proposed regulations, as well as to validate and pilot test the new central European database. Furthermore, some respondents called for a longer transitional period for medical devices given the number of substantial changes, which include bringing in implantable or invasive devices without a medical purpose within the scope of the regulation.

MHRA response: We agree on the importance of making swift progress to agree high quality secondary legislation and a high performing central European database. Therefore we do not support lengthening the transition periods.
Annex I – respondents to the public consultation

### Industry, industry associations and other private sector

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### Healthcare professionals & institutions

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<td>Association for Clinical Biochemistry</td>
<td>Institute of Physics and Engineering in Medicine</td>
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<td>Medical Devices Committee, Stockport NHS Foundation Trust</td>
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<td>British Association of Dermatologists</td>
<td>NHS Blood and Transplant</td>
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<td>British Orthopaedic Association (BOA) (joint response with Arthritis Research UK)</td>
<td>NHS Pharmaceutical Production Committee</td>
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<td>Centre for Health Technology Evaluation, NICE</td>
<td>NHS Pharmaceutical Quality Assurance Committee</td>
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<tr>
<td>Clinical Engineering Special Interest Group, Institute of Physics and Engineering in Medicine</td>
<td>Patient Liaison Group, Royal College of Surgeons</td>
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<td>Clinical Research Network, National Institute for Health Research</td>
<td>Royal Academy of Engineering (joint response with Academy of Medical Sciences)</td>
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<td>Royal College of Nursing</td>
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<td>Royal College of Ophthalmologists</td>
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<td>Scottish Health Technologies Group, Healthcare Improvement Scotland</td>
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<td>Human Fertilisation &amp; Embryology Authority</td>
<td>Surgical Materials Testing Laboratory, Princess of Wales Hospital</td>
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<td>Independent Healthcare Advisory Services</td>
<td>UK Ophthalmic Pharmacy Group, Royal Pharmaceutical Society</td>
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<td>Institute of Biomedical Science</td>
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**Others: charities, notified bodies, regulatory authorities, standards & quality institutions**

| Arthritis Research UK (joint response with British Orthopaedic Association) | General Optical Council |
| British Heart Foundation | Juvenile Diabetes Research Foundation (JDRF) |
| British Standards Institution (BSI) | Foundation for Genomics and Population Health (PHG Foundation) |
| BSI Assurance UK | The Organisation for Professionals in Regulatory Affairs (TOPRA) |
| Cancer Research UK | The Wellcome Trust |
| European Quality Assurance Confederation | |