THE REVISION OF EUROPEAN LEGISLATION ON MEDICAL DEVICES

November 2012
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About this consultation

Introduction
The Medicines and Healthcare products Agency (MHRA) is consulting on the European Commission’s proposals for two new regulations on medical devices and in vitro diagnostic devices to replace the European legislation that is currently in place.

We really value views from stakeholders on the Commission’s proposals, which will help to improve the quality of our analysis and policy-making. This is in accordance with the Government’s Code of Practice.¹

We have produced a short video introducing the consultation, which is available at: http://youtu.be/rafbmpUMDQc

We are keen to ensure that you have the opportunity to ask any questions you may have about the consultation. Our contact details are below and our webpage will be kept up-to-date with the latest information: http://www.mhra.gov.uk/Howweregulate/Devices/NewLegislationonMedicalDevices/

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Our approach
We have set out how the Commission has proposed to change the current regulatory system and the Government’s initial views on the changes. If you are interested, we have signposted the relevant articles of the Commission’s proposed regulations so that you can read, and comment on, the full text. The proposed regulations are available to read at: http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm

We want to hear what you think about our position, which we will use to negotiate with the other Member States of the EU and the European Parliament. We are also keen to receive analysis and evidence that will help us to achieve our negotiating objectives. Your input will be crucial to help us identify the full implications of the changes and areas of concern.

Timetable
We are consulting for ten weeks. We invite stakeholders to respond by 21 January 2013.

How to give your views

¹ http://www.cabinetoffice.gov.uk/sites/default/files/resources/Consultation-Principles.pdf
Responses should be sent by 21 January 2013 to medical.devices@mhra.gsi.gov.uk. Please feel free to answer as many or as few of the questions which concern you.

Alternatively, you can write to us at:

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After the consultation
We will publish a summary of the responses to the consultation on the MHRA’s website (unless individual respondents ask us not to publish their response).

Comments about the consultation process
If you have concerns or comments which you would like to make relating specifically to the consultation process, please contact:

Consultations Co-ordinator
MHRA
4-T Buckingham Palace Road
151 Buckingham Palace Road
London SW1W 9SZ
Consultations.co-ordinator@mhra.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of Information
We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the Freedom of Information Act, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The MHRA will process your personal data in accordance with the Data Protection Act and in most circumstances this will mean that your personal data will not be disclosed to third parties.
About the proposals for new European legislation

On 26 September 2012, the European Commission published proposals for two new regulations on medical devices and *in vitro* diagnostic devices (IVDs), which will replace the existing three directives\(^2\) which regulate medical devices in the European Union (EU).

The MHRA has been engaging with the Commission to influence its proposals as they have been developed over the last four years. We are pleased to see that they include measures that will improve the transparency, traceability, vigilance, and governance of the system, as well as the performance of notified bodies. However there are also areas of concern in the proposed regulations, notably those provisions which place additional burdens on industry and healthcare systems without a credible evidence base of the public health benefit.

Rationale
The original European legislation on medical devices was drafted over 20 years ago and since then there have been substantial changes. The number of Member States in the EU has more than doubled and there have been substantial leaps in device technology.

As a consequence, the application of the existing medical devices directives is different across the EU. This makes it difficult for the legislation to achieve its objectives: ensuring the safety of medical devices and their free movement in the EU’s single market.

Moreover it is imperative to learn lessons from recent events that have raised questions about the regulatory framework, including those involving the safety concerns of some metal-on-metal hip replacements and fraudulent PIP breast implants.

Proposed changes
The main features which cover both of the proposals:
- increase transparency;
- increase requirements on traceability in the supply chain;
- tighten up the designation and audit of notified bodies, which assess the safety of devices before they are placed on the market;
- subject higher risk devices to additional pre-market scrutiny;
- require more clinical evidence for higher risk and implantable devices;
- introduce central reporting of serious incidents and field safety corrective actions to a new central database;

• improve coordination between Member States;
• establish a new governance structure of Member State experts and centralised clinical expertise; and
• align with the EU’s recently updated New Legislative Framework for the internal market.

The main features of the proposal which only affect medical devices:
• extend the scope of the legislation to include invasive or implantable devices without a medical purpose (such as dermal fillers and aesthetic implants); and
• introduce regulatory requirements on the reprocessing of single-use devices.

The main features of the proposal which only affect IVDs:
• move from a classification system that uses specific lists of IVDs to a risk-based classification based on rules;
• increase controls on IVDs manufactured and used within the same health institution (which do not currently need to meet the requirements of the legislation) and exclude higher risk devices from this exemption; and
• clarify that companion diagnostics and other genetic tests with a medical purpose are within the scope of the regulation.

The European negotiation process
The European Union’s negotiation process essentially consists of the 27 Member States and the European Parliament having parallel discussions and negotiations between themselves about how they would like to change the Commission’s legislative proposals. There then also needs to be agreement between the Member States and the European Parliament on the final legislation.

Given the context of negotiation and compromise with a range of different political players, the earlier that we are able to seek your input through a consultation, the more this will be likely to influence the Government’s position.
Glossary of key regulatory terms

Global Harmonisation Task Force
A number of the changes proposed by the European Commission draw on the guidance and model provisions agreed by the Global Harmonisation Task Force (GHTF). The GHTF brought together the regulators of medical devices from across the world to see how regulatory systems can become more uniform, which helps to improve patient safety and market access for devices. The GHTF has recently changed to become the International Medical Device Regulators Forum (IMDRF).

New Legislative Framework
To facilitate the free movement of goods in the internal market, the EU has some framework rules. This includes, for example, how goods should be checked before they can be placed on the market, how the CE mark works, and how national authorities should conduct market surveillance. These rules were updated in 2008 in two pieces of legislation and are known as the New Legislative Framework.

Member States and the European Parliament are currently updating various pieces of product legislation in light of the New Legislative Framework. The Department for Business, Innovation and Skills is leading on this work which covers lifts and measuring instruments, amongst others.

Many of the amendments to the medical devices directives proposed by the Commission reflect the New Legislative Framework. They have been highlighted, where relevant, throughout the public consultation.

It is the Government’s view that the proposed regulations should keep to the rules and model provisions already agreed between Member States and the European Parliament in the New Legislative Framework wherever possible. We want to ensure that any deviation from the New Legislative Framework is based on clear evidence that a different approach is needed for medical devices.

Delegating power to the Commission
Throughout this public consultation, reference is made to power being delegated to the Commission to decide further details in the legislation or amend some parts of the legislation. This might be useful to amend technical details in the legislation in light of technological progress, for example. This system is comparable to secondary legislation in the UK and is legally known as ‘delegated or implementing acts’.

Should you choose to read the Commission’s legislative proposals you will see that these terms are often used. In summary:

- A delegated act allows the Commission to supplement or amend a non-essential part of the regulations. For example, the Commission has proposed to use a delegated act to amend the responsibilities of EU reference laboratories.

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3 Regulation 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and Decision 768/2008/EC on a common framework for the marketing of products
• An implementing act allows the Commission to establish rules which implement an aspect of the regulations in a harmonised way across the EU. For example, the Commission has proposed to use an implementing act to adopt the common technical specifications for a category of devices.

These acts involve varying level of control and oversight from Member States and the European Parliament, as is set out below. An important task for the Government is to decide to what extent it is appropriate to delegate this power to the Commission, which may involve less oversight and control from Member States than if the measure was agreed in the regulations themselves.
Chapter I: Scope and definitions

1. **Scope and definitions**: the medical devices regulation

1.1. The medical devices regulation has a larger and clearer scope; it:

- includes products manufactured utilising non-viable human tissues or cells that are substantially manipulated;
- excludes non-viable human tissues and cells that are not substantially manipulated;
- excludes products containing or consisting of viable biological substances, including micro-organisms;
- clarifies that food is excluded from the scope of the regulation;
- clarifies that a device, which has an IVD as an ‘integral’ part, is within the scope of this regulation provided that the principal intended purpose is a medical device (however the general safety and performance requirements in Annex I of the IVD regulation also apply to the integral IVD part);
- clarifies that devices which administer medicines are within the scope of the regulation;
- clarifies that devices which administer medicines and are sold as one non-reusable product are excluded from the scope of this regulation (but are regulated by European medicines legislation⁴);
- clarifies that when a medicine is an ‘integral’ part of a device but acts ‘ancillary’ to the device, such a device is within the scope of the regulation; and
- clarifies that when a medicine is an ‘integral’ part of a device but does not act as an ‘ancillary’ to the device, such a device is excluded from the scope of this regulation (but is regulated by European medicines legislation)⁵. In this case, the general safety and performance requirements set out in Annex I of this regulation also apply to the integral device part.

1.2. You can read about this in detail in Article 1 of the regulation.

1.3. The regulation makes it clear that 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 are within the scope of the regulation. Annex VII, which sets out the classification criteria for medical devices, classifies these devices as class III.

We think that changing the scope of the medical devices regulation in this way is helpful and clarifies which products fall under the legislation and which do not. Given that setting out the scope is such an important part of the legislation, there may be a need to consider amending the Commission’s wording to avoid any doubt as to what is covered by the legislation. Areas where this might be required include defining what is meant by ‘biological substance’ and ‘non-substantial manipulation’. We do not anticipate that these changes will have a significant impact on UK manufacturers.

We would prefer to exclude products composed of substances or combinations of substances that are intended to be ingested, inhaled or administered rectally or vaginally and that are

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⁴ Directive 2001/83/EC
⁵ Directive 2001/83/EC
absorbed by or dispersed in the human body from the regulation of medical devices. We have concerns that medical devices legislation does not fully take into account the safety aspects of these products. In particular, these products may significantly affect the safety or efficacy of the medication with which they are taken and special consideration needs to be given to the use of these products in certain patients, such as children or those with comprised renal or hepatic function. Therefore we consider that these products should be excluded from the scope of this regulation and be regulated under European medicines legislation.

Question 1 – Do you agree with our proposed position? If not, please explain why.

Question 2 – What impact do you think excluding the products composed of substances or combinations of substances that are intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body from the scope of the medical devices regulation would have? For instance, might some very low risk products be inadvertently excluded from devices legislation?

1.4. Definitions in the medical devices regulation are updated and amended. They:
- introduce the term ‘specific medical purpose’ in the definition of a medical device;
- extend the definition of a medical device to implantable or invasive products without a medical purpose listed in Annex XV. The regulation delegates power to the Commission to amend this annex in light of technical progress:
  - contact lenses;
  - implants for modification or fixation of body parts;
  - facial or other dermal or mucous membrane fillers;
  - equipment for liposuction;
  - invasive laser equipment intended to be used on the human body; and
  - intense pulsed light equipment;
- extend the definition of a medical device to products for disinfection or sterilisation of a medical device;
- define a nanomaterial. The regulation delegates power to the Commission to amend this definition in light of technical progress; and
- add and amend existing definitions in line with New Legislative Framework and guidance documents agreed by the Global Harmonisation Task Force.

1.5. You can read about this in detail in Article 2 of the regulation.

1.6. Weighing up the risks and benefits of a product which does not have a medical purpose is different than for medical devices. Therefore Annex I, which sets out the safety and performance requirements of devices, requires manufacturers of implantable or invasive products without a medical purpose to ensure that these products present either no or the minimum acceptable risk which is consistent with a high level of protection for the safety and health of persons. The instructions for use must also include information on the absence of clinical benefit for these products and the risk of using them.

In general, we support updating the definitions in light of legislative and technological developments. We will give consideration to areas where definitions need to be more precisely worded to avoid, as far as possible, any doubt as to the intention and scope of the legislation.
In particular, we support extending the definition of a medical device to some implantable or invasive products without a medical purpose. This will address an inconsistency in the current regulatory framework where, for example, corrective contact lenses are regulated as medical devices but cosmetic contact lenses are regulated under general product safety legislation. The conclusions of the review on cosmetic interventions by Sir Bruce Keogh in March 2013 will feed into our position on this issue. We are currently examining whether the Commission has included all the appropriate products in Annex XV.

We are of the view that intense pulsed light equipment does not fit the definition of an ‘implantable or invasive product’. However our view is that these products are appropriate to be regulated as devices. Therefore the term ‘implantable or invasive products without a medical purpose’ will need to change to be able to cover these products. One approach could be to incorporate ‘active products’ into the definition or the definition could be amended to cover high risk (class IIb and III) products more generally.

We also consider that the safety and performance requirements for these products set out in Annex I need further consideration and some aspects in relation to, for example, clinical evidence may not be appropriate for these products.

Question 3 – Do you agree with our proposed position? If not, please explain why.

Question 4 – Do you agree that the wording on ‘implantable or invasive products without a medical purpose’ needs to be expanded to incorporate intense pulsed light equipment? Do you have any other suggested wording for this definition?

Question 5 – Do you think that other implantable or invasive products that are not specified in Annex XV should be brought within the definition of a medical device?

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2. Scope and definitions: the IVD regulation

2.1. The proposed IVD regulation has a clearer and more limited scope. It:
- specifically excludes higher metrological order reference materials; and
- clarifies that an IVD, which has a medical device as an ‘integral’ part, is within the scope of this regulation provided that the principal intended purpose is an IVD (however the general safety and performance requirements in Annex I of the medical device regulation apply to the integral device part).

2.2. You can read about this in detail in Article 1 of the regulation.

We support these changes to scope, which will provide a greater degree of clarity.

Question 6 – Do you agree with our proposed position? If not, please explain why.

2.3. The regulation amends the definition of an IVD to clearly include software, genetic tests and companion diagnostics. Companion diagnostics and devices for near-patient testing are explicitly defined in the legislation.

2.4. More broadly, some of the other definitions are amended in line with the New Legislative Framework and guidance documents produced by the Global Harmonisation Task Force.
2.5. You can read about this in detail in Article 2 of the regulation.

We agree with the approach to clarify the inclusion of software, genetic tests and companion diagnostics within the scope of the IVD regulation. We are examining more closely whether the following proposed definitions are useful:

'companion diagnostic' means a device intended to select patients with a previously diagnosed condition or predisposition for eligibility of treatment with a specific medicinal product.

'device for near-patient testing' means 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

The definition of a companion diagnostic appears to be sufficiently narrow to pick up diagnostic tests used specifically in concert with a particular pharmaceutical. This is our preferred approach, rather than a broader definition, which would have a much larger scope.

Question 7 – Do you agree with our proposed position? If not, please explain why.

Question 8 – Are the above definitions of companion diagnostics and near patient testing useful? If not, how could they be improved?

3. Regulatory status of products: both regulations

3.1. The regulations delegate power to the Commission to make a binding decision on the regulatory status of products. The Commission’s decision is overseen and approved by Member States.

3.2. When making its decision, the Commission must draw on shared expertise between Member States, which the Commission will bring together in a group of experts on devices, IVDs, medicines, tissues and cells, cosmetics and biocides.

3.3. You can read about this in detail in Article 3 of the regulations.

In principle, we think that this mechanism could be a helpful way to provide legal certainty and consistency across the EU, which is one of the key problems with the existing legislation. We also welcome the proposal to set up an expert group to support the Commission’s decisions and consider that Member States will have an appropriate level of input to the decision-making procedure.

Question 9 – Do you agree with our proposed position? If not, please explain why.
Chapter II: Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement

4. Placing on the market and putting into service: the medical devices regulation

4.1. The regulation places a clear obligation on manufacturers to provide a clinical evaluation when demonstrating the conformity of their devices with the safety and performance requirements set out in Annex I.

4.2. The regulation changes the current ‘in-house’ exemption for medical devices. It clarifies that devices manufactured and used ‘in-house’ by a health institution are considered to be put into service and therefore need to comply with the obligations in the medical devices regulation. They are, however, exempt from the requirement to carry a CE mark or to meet the requirements on registration and traceability, provide a summary of safety and clinical performance and report to the new central European database.

4.3. You can read about this in detail in Article 4 of the regulation; please note that this is specific to the medical device regulation and separate considerations on the ‘in-house’ exemption for IVDs are outlined below.

We support the inclusion of text relating to the requirement on manufacturers to provide a clinical evaluation, which is an existing requirement but is usefully highlighted in this section.

We are aware that the new provision on ‘in-house’ devices is not in line with the MHRA’s current guidance on this topic. However, we recognise that this change is consistent with the current interpretation of this provision by the Commission and some other Member States and are minded to support the inclusion of this clarification in order to ensure a consistent implementation of the rules across the EU.

Question 10 – Do you agree with our proposed position? If not, please explain why. In particular, we would find it helpful to understand the potential impact of the change to the ‘in-house exemption’ on health institutions.

5. Placing on the market and putting into service: the IVD regulation

5.1. The regulations place a clear obligation on manufacturers to provide a clinical evaluation when demonstrating conformity with the general safety and performance requirements set out in Annex I.

5.2. The regulation changes the current ‘in-house’ exemption for IVDs. Class A, B and C IVDs (under the new risk classification outlined in more detail in section 19) developed and used ‘in-house’ are excluded from the provisions of the regulation, apart from the requirement on manufacturers to report serious incidents and field safety corrective actions and an obligation on health institutions to be accredited according to the ISO 15189 standard.
5.3. In contrast, class D IVDs must comply with the regulation, although not with the provisions on traceability and registration, the requirement to provide a summary of safety and performance data or to report to the central European database.

5.4. You can read about this in detail in Article 4 of the regulation.

We support tightening up the requirement on manufacturers to provide a clinical evaluation, which is an existing requirement but is usefully highlighted in this section.

We support placing additional requirements on the in-house manufacture of IVDs, such as the ISO 15189 standard. However, the exclusion of class D devices from the so-called ‘in-house exemption’ is a major concern for us. This will increase costs substantially for the National Health Service (NHS) and related bodies and is likely to result in some tests no longer being available to be used on patients, given that there are currently no CE-marked tests available for many genetic conditions and rare diseases.

The UK highlighted this as an area of concern in our response to the Commission’s public consultation in 2010, following consultation with our stakeholders, where it became clear that the development and use of assays and reagents in-house by laboratories within the NHS for use on their own patients is a widespread practice in the UK. We gathered some initial cost-data at the time which demonstrated that it would not be feasible for health institutions to CE-mark their in-house tests due to the wide spectrum of variants involved. Therefore, we will continue to argue strongly for the in-house exemption to apply to all IVDs.

Question 11 – Do you agree with our proposed position? If not, please explain why.

6. Internet sales: both regulations

6.1. The regulations clarify that a device or service involving a device for diagnostic or therapeutic purpose sold over the internet must comply with both of the proposed regulations. You can read about this in detail in Article 5 of both of the regulations.

We support the inclusion of this provision on sales at a distance.

Question 12 – Do you agree with our proposed position? If not, please explain why.

7. Harmonised standards: both regulations

7.1. Two main changes have been proposed as regards harmonised standards. Firstly, the scope of harmonised standards is extended to include system and process requirements on economic operators or sponsors. Secondly, the process whereby Member States or the Commission can object to harmonised standards is removed. You can read about this in detail in Article 6 of both of the regulations.

We support the ongoing use of harmonised standards but are concerned that Member States will no longer have the opportunity to object to a harmonised standard. This is important given that a harmonised standard may not entirely meet the essential requirements. Therefore it should be open to challenge and improvement. We will seek to reinstate this process.

Question 13 – Do you agree with our proposed position? If not, please explain why.
8. **Common technical specifications: the medical devices regulation**

8.1. The regulation introduces common technical specifications (CTS), which is a concept that is currently a feature of the existing IVD directive. CTS specify the general safety and performance requirements, as well as requirements for clinical evaluation and/or post-market clinical follow-up for a certain group of devices. Manufacturers must comply with CTS unless they can justify that they have met the equivalent level of safety and performance by different means. The regulation delegates power to the Commission to adopt CTS where there is either no or an inadequate harmonised standard.

8.2. You can read about this in detail in Article 7 of the medical devices regulation.

We are aware of concerns about how CTS will apply to medical devices that are not IVDs, however we consider that CTS have the potential to be helpful for manufacturers because they will provide more clarity and certainty about what is needed to meet the regulatory requirements – in particular in relation to clinical evaluation. We are therefore minded to support the extension of CTS to cover all medical devices. It is important that CTS are adopted proportionately where they will bring the most benefit.

**Question 14** – Do you agree with our proposed position? If not, please explain why.

9. **Common technical specifications: the IVD regulation**

9.1. The scope of common technical specifications (CTS) has been expanded to include all IVDs. You can read about this in detail in Article 7 of the IVD regulation.

We think that extending the scope of CTS will be helpful for manufacturers because they will provide more clarity and certainty about what is needed to meet the regulatory requirements. It will be important to establish clear criteria to ensure that CTS are developed in the most useful areas.

**Question 15** – Do you agree with our proposed position? If not, please explain why.

10. **General obligations of economic operators: both regulations**

10.1. The regulations set out more clearly the obligations on manufacturers, authorised representatives of non-EU manufacturers, importers and distributors. You can read about this in detail in Articles 8 to 12 of the regulations. In summary, the general obligations on economic operators include the following:

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<th>Obligation</th>
<th>Manufacturer</th>
<th>Authorised representative</th>
<th>Importer</th>
<th>Distributor</th>
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<tr>
<td>Designate an authorised rep</td>
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<tr>
<td>Designate a qualified person</td>
<td>X</td>
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<tr>
<td>Draw up documentation</td>
<td>X</td>
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<td>Keep documentation records</td>
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<td>Quality Management System</td>
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<tr>
<td>Ensure safe storage and transport</td>
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<tr>
<td>Post-market surveillance plan</td>
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10.2. These obligations are in line with the model provisions laid out in the New Legislative Framework, which aims to facilitate the free movement of goods in the internal market. The intention is for the obligations to be proportionate to the risk classification of the device.

10.3. The regulations introduce the concept of a ‘qualified person’, which draws on European medicines legislation and some Member States’ national laws on devices. The regulations require manufacturers and authorised representatives to have a person responsible for regulatory compliance who meets certain criteria as regards academic qualifications and professional experience. You can read about this in detail in Article 13 of the regulations.

10.4. As regards parallel trade, the regulations set out clear conditions and responsibilities for companies involved in the relabeling and/or repackaging of devices. Namely they will take on the responsibility of the manufacturers if they make a device available on the market under their name, if they change the intended purpose of a device, or if they modify a device in such a way that affects its compliance with the regulatory requirements. You can read about this in detail in Article 14 of both of the regulations.

10.5. The regulations also set out what information an agreement should contain when the manufacturer changes their authorised representative. You can read about this in detail in Article 10 of the regulations.

We support these changes which align the regulation of medical devices with the EU’s New Legislative Framework. We will be examining these in further detail to ensure that there are not additional, disproportionate requirements brought in on economic operators and that there is not an unnecessary duplication of tasks by different economic operators.

We fully support the concept of a ‘qualified person’ that has been introduced into the legislation and consider that this will help to support regulatory compliance and consistently high standards across the industry. It is also likely to support notified bodies’ interactions with manufacturers and authorised representatives.

We are concerned, however, about the potential for this to be a disproportionate requirement on small and medium-sized manufacturers and those who solely manufacture low risk (class I) devices. We will be considering further whether changes could be made to ease the burden by, for example, allowing the required qualifications to be shared between different personnel.

Question 16 – Do you agree with our proposed position? If not, please explain why.

Question 17 – Can you provide information on the estimated costs that meeting these

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<th>Ensure compliance</th>
<th>X</th>
<th></th>
<th>X</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inform manufacturer of</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>complaints</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Take necessary corrective action</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Cooperate with competent authorities</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
11. The reprocessing of single-use devices: the medical devices regulation

11.1. Under the current legislative framework, reprocessed single use devices can be approved by notified bodies, CE marked by reprocessors and circulate freely on the EU market without further controls.

11.2. The medical devices regulation places additional controls on the reprocessing of single use devices; reprocessors take on the responsibilities of manufacturers. Member States may ban the practice and/or use of reprocessed single use devices on their territory if they wish. Annex I on the safety and performance requirements adds that the label of a device must specify when a single-use device has been reprocessed.

11.3. Single-use devices for critical use (which are defined as surgically invasive devices) must not be reprocessed. The regulation delegates power to the Commission to make exceptions to this general rule and allow a single-use device for critical use to be reprocessed on the basis of the latest scientific evidence.

11.4. You can read about this in detail in Article 15 of the medical devices regulation.

We are minded to support this provision given that it brings in controls on what is currently a largely unregulated practice. We do, however, have some concerns about how manufacturers will be able to demonstrate conformity with the regulatory requirements.

We recognise the concern expressed in relation to the distortion of the single market by allowing individual Member States to take action unilaterally. In our view, however, this needs to be included, given that there are wider ethical considerations at stake which are for Member States to decide for themselves.

We consider that this provision will also cover the ‘in-house’ reprocessing of single-use devices by health institutions through the clarification provided in Article 4 of the regulation. Our best understanding is that this is not common practice among UK health institutions in light of MHRA guidance that advises against it. We therefore do not consider that this will have a significant financial impact on this sector.

We are keen to ensure that the list of single-use devices for critical use which can be reprocessed, decided by the Commission with oversight from Member States, secures a high level of patient safety. We are looking into whether an expert scientific committee, such as the Scientific Committee on Emerging and Newly Identified Health Risks, should advise the Commission on this issue.

Question 19 – Do you agree with our proposed position? If not, please explain why.

Question 20 – Do you agree with our assessment of the likely impact of this provision?
12. **Implant card: the medical devices regulation**

12.1. The regulation requires manufacturers of implantable devices to provide an implant card for patients. The regulation sets out what information needs to be included on the card: the Unique Device Identification code, any relevant warnings, the expected lifetime of the device and any follow-up of which the patient should be aware. This information must be in plain language. You can read about this in detail in Article 16 of the medical devices regulation.

In principle we support this new requirement. It became clear during the events involving fraudulent PIP breast implants that many patients did not know which breast implants they had. Implant cards will improve traceability and patients’ awareness. In our view, the benefits of this measure outweigh the relatively small burden that this will place on manufacturers of implantable devices (many of which already provide implant cards) and the NHS, which will need to provide patients with the cards.

We are aware that patients may have a large number of devices implanted in a single operation and those devices may be made up of a number of components. We will consider if there is a way to change this provision to avoid one patient being given a large number of different implant cards.

**Question 21 – Do you agree with our proposed position? If not, please explain why. In particular, do you have any views on how this concept could be improved?**

13. **Declaration and CE marking of conformity: both regulations**

13.1. In order to demonstrate compliance with the regulatory requirements, manufacturers draw up a declaration of conformity and CE mark their device.

13.2. Both regulations draw on the EU’s New Legislative Framework to go into more detail and set out the minimum content required in the declaration of conformity (Annex III). The regulation delegates power to the Commission to amend the annex in light of technical progress. You can read about this in detail in Articles 17 and 18 of the medical devices regulation and Articles 15 and 16 of the IVD regulation.

13.3. Annex IV on the CE marking of conformity remains the same as in the current directives.

We support the clarity which these updated provisions bring. We do not anticipate that they will have a significant impact in the UK because they clarify the existing rules rather than add to them.

**Question 22 – Do you agree with our proposed position? If not, please explain why.**

14. **Devices for special purposes, systems and procedure packs, parts and components, and free movement: both regulations**

14.1. The proposed regulations:

- clarify the existing rules on when devices for special purposes need not carry a CE mark. They add that competent authorities may request details about devices placed on their market by a custom-made device manufacturer;
• clarify the existing rules on the requirements related to placing devices and other products together in systems or procedure packs. They change the length of time that a statement needs to be kept in order to align with the requirements on manufacturers to keep technical documentation (at least five years for devices and at least 15 years for implantable devices);
• clarify the existing general requirement on Member States not to restrict the placing of devices on the market that comply with the regulations; and
• set out, for the first time, general requirements for placing parts and components on the market.

14.2. You can read about this in detail in Articles 19 to 22 of the medical devices regulation and Articles 17 to 20 of the IVD regulation.

We support the clarity which these updated provisions bring. We do not anticipate that they will have a significant impact on the UK. We are considering how the proposed wording below on the general requirements for placing parts and components on the market can be improved because we do not think it is sufficiently precise to provide legal certainty for manufacturers:

An article that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics of the device shall be considered a device.

Question 23 – Do you agree with our proposed position? If not, please explain why.

Question 24 – Do you have suggestions on how to improve the above wording on parts and components?
Chapter III: Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices

15. Identification, traceability and transparency of devices: both regulations

Identification

15.1. Both regulations set out how the new central European database will bring together the registration details of devices and economic operators. The necessary registration details are given in Part A of Annex V, which is not present in the current directives and can be amended by the Commission in light of technical progress.

15.2. The regulations add a further three requirements. Firstly, Member States may remove products from the market if the accuracy of the data is not confirmed within two and a half years. Secondly, micro enterprises will be exempt from paying a fee when they register. Thirdly, economic operators must hold details on the receipt and supply of devices.

15.3. You can read about this in detail in Article 23 of the medical devices regulation and Article 21 of the IVD regulation.

We support this measure because it substantially simplifies the existing system by replacing multiple national registrations with a single central registration. It will also mean considerable cost savings for manufacturers that place devices on the market in several Member States.

We support the requirements on the receipt and supply of devices because it will help the MHRA to trace devices along the supply chain. At the moment we are unclear of the extent to which this information is already held by economic operators and therefore to what extent it will represent an additional burden.

Question 25 – Do you agree with our proposed position? If not, please explain why.

Question 26 – To what extent will storing details on the receipt and supply of devices place an additional burden on economic operators?

Traceability

15.4. One of the major innovations of both of the proposed regulations is to establish a system of unique device identification (UDI). This is an exact code which manufacturers will have to place on each medical device that is linked to a database that holds more information on that device.

15.5. It enables the identification and traceability of devices because economic operators and health institutions must make an electronic record of the UDI and manufacturers must refer to the UDI in their technical documentation and when reporting serious incidents and field safety corrective actions. Implementation of the UDI system will be proportionate and risk-based.
15.6. Both of the regulations delegate power to the Commission, with oversight from Member States and the European Parliament, to decide the detail on how the UDI system will operate, for example, how to accredit the organisations which assign UDIs and to design the UDI database. The data elements of the UDI are set out in Part B of Annex V in both of the proposed regulations.

15.7. You can read about this in detail in Article 24 of the medical devices regulation and Article 22 of the IVD regulation.

We support the introduction of a UDI system. In light of the events surrounding fraudulent PIP breast implants, this is seen as a particularly effective tool to facilitate the recall of faulty devices. It also has the potential to enable more proactive analysis of the ongoing performance of an implant over its lifetime and reflects international discussions on compatible UDI systems at the Global Harmonisation Task Force.

We are aware that these obligations will generate costs for the NHS and manufacturers. It is difficult to quantify such costs at this stage for the NHS but they will include investing in the equipment to record UDI and changing procedures.

We are examining to what extent it is appropriate to delegate the power to set out so many of the details of the UDI system to the Commission.

Question 27 – Do you agree with our proposed position? If not, please explain why.

Question 28 – To what extent will this system place an additional burden on the NHS and manufacturers?

Transparency

15.8. The new publicly accessible central database includes information on registration, UDI, notified body certificates, clinical investigations, vigilance, and market surveillance. This will replace the existing ‘Eudamed’ database.

15.9. As regards practical implementation of the new database, the regulations delegate power to the Commission, with oversight from Member States, to put into place and manage the new system, as well as set out the details of the information that will need to be included on the database. You can read about this in detail in Articles 25 and 27 of the medical devices regulation and Articles 23 and 25 of the IVD regulation.

15.10. Both regulations place a new obligation on manufacturers of class III and implantable medical devices and manufacturers of class D and C IVDs to produce and publish a summary of safety and clinical performance. The information is then collected on the publicly accessible European database. You can read about this in detail in Article 26 of the medical devices regulation and Article 24 of the IVD regulation.

We support the establishment of a new central database; this will help to share information, facilitate cooperation between Member States and improve the transparency of information for patients. It also reduces the burden on the MHRA to maintain its own separate database and on manufacturers, who currently feed information into multiple national databases. The
potentially significant benefits of the database will only come to fruition if the database is well-designed, thus we will suggest that the Commission take on board lessons learnt from the existing ‘Eudamed’ database and existing national databases and that the Commission’s preparatory work is supported – and scrutinised – by interested Member States.

We support the requirement to produce a summary of safety and performance which will increase transparency for clinicians and patients. It is important that clinicians have access to the right information so that they can make more informed decisions about the devices available on the market. We think it may be valuable to provide more detail in the regulation on what level of information these summaries should include to ensure that they really add value to clinicians and patients, in particular in relation to clinical evidence. We do not anticipate the burden on manufacturers to be significant.

Question 29 – Do you agree with our proposed position? If not, please explain why.

Question 30 – What information do you think it would be helpful to include in the summary of safety and performance?
Chapter IV: Notified bodies

16. Notified bodies: both regulations

National authorities responsible for notified bodies

16.1. In line with the New Legislative Framework, the regulations set out clearer requirements for national authorities, which are responsible for designating notified bodies.

- The tasks of designating and assessing notified bodies must be undertaken by different personnel to ensure objectivity and impartiality.
- The authorities must explain to the Commission and other Member States how they oversee notified bodies.
- Each national authority must be peer reviewed by another authority every second year and peer review another authority in-between; this process is organised by the Member States.

16.2. There are general requirements on the Commission to organise the exchange of experience between national authorities responsible for notified bodies and provide for co-ordination and co-operation between notified bodies.

16.3. You can read about this in detail in Articles 28, 38 and 39 of the medical devices regulation and Articles 26, 36 and 37 of the IVD regulation.

We support the introduction of these requirements which will support improvements in the national authorities overseeing notified bodies. Apart from the new peer review system (which formalises the current voluntary system that has been in place for a number of years), the requirements will have a limited impact on the MHRA because it already complies with most of these requirements. However we do think that it would be more efficient if the Commission took on the administrative responsibility of organising the rotation of peer reviews, supported by the new committee of Member State experts, the Medical Device Coordination Group.

Question 31 – Do you agree with our proposed position? If not, please explain why.

Question 32 – Are there other activities that could support the quality and consistency of national authorities overseeing notified bodies?

General requirements on notified bodies

16.4. The minimum requirements on notified bodies are set out in Annex VI of the regulations. This includes a lot more detail than is currently set out in the current directives and includes their legal status and organisation structure, quality management system, process requirements, and more detailed resource requirements. For example, the annex requires notified bodies to have personnel with clinical expertise in order to scientifically challenge the clinical data presented by a manufacturer and make an objective clinical judgement about the assessment of the manufacturer’s clinical evaluation.
16.5. In addition, notified bodies must have clear oversight and responsibility for any subcontracted work or subsidiaries. You can read about this in detail in Articles 29 and 30 of the medical devices regulation and Articles 27 and 28 of the IVD regulation.

16.6. On a separate note, the legislation clarifies that certificates from the national accreditation body (the United Kingdom Accreditation Service in the UK) are sufficient to provide evidence of meeting certain requirements. You can read about this in detail in Article 31 of the medical devices regulation and Article 29 of the IVD regulation.

Overall, we support the principles of these new requirements, which should drive improvements in the operation of notified bodies. However we are as yet unable to quantify the impact these changes will have on notified bodies in the UK, nor have we been able to consider the full implications of all of the new requirements set out in Annex VI.

Question 33 – Do you agree with our proposed position? If not, please explain why.

Question 34 – To what extent will these changes have an impact on notified bodies in the UK? Is there anything else that should be included in the requirements of Annex VI that will improve the functioning of notified bodies?

Application and assessment to become a notified body

16.7. The regulations introduce a new joint assessment process before national authorities designate organisations as notified bodies. After receiving an organisation’s application to become a notified body, the competent authority drafts its preliminary assessment report and sends it to a joint assessment team in three official languages of the EU. This team is made up of experts from other Member States and the Commission. The team will have up to 90 days to assess the application and the new Medical Device Coordination Group (MDCG) of Member State experts then has 21 days to draw up a recommendation based on the joint assessment team’s work. The national competent authority must take due account of the MDCG’s recommendation but it is not binding. You can read about this in detail in Article 32 of the medical devices regulation and Article 30 of the IVD regulation.

16.8. Furthermore, new obligations are placed on Member States to submit information on upcoming notifications. Either a Member State or the Commission may raise objections to the designation of a notified body or its supervision within 28 days. Once the objection is received, the notification is suspended. The MDCG considers the objection and decides, without delay, whether to accept or reject it. You can read about this in detail in Article 33 of the medical devices regulation and Article 31 of the IVD regulation.

16.9. The Commission has clearer obligations to record and publish details on notified bodies. Power is delegated to the Commission to decide ‘the modalities’ of applying for notification, assessing the notification and setting up codes for notified bodies, which demonstrate the scope of devices for which they have been designated to assess. You can read about this in detail in Article 34 of the medical devices regulation and Article 32 of the IVD regulation.
We support the broad thrust of these proposed changes which will support more consistent oversight of notified bodies.

We do, however, have some concerns about how they will work. There should, for example, be shorter deadlines for the joint assessment team and the MDCG to produce their recommendation so as to not unduly delay the designation of notified bodies. We are also concerned about the additional cost on competent authorities if they have to submit preliminary assessment reports in three EU languages and the practicalities of Member State experts having the linguistic capabilities to assess organisations’ capacity to become notified bodies in other Member States.

We are as yet unable to quantify the impact these changes will have on notified bodies in the UK. In general, the additional responsibilities on notified bodies are likely to result in notified bodies charging higher fees to manufacturers. Additionally, the MHRA will need to supply personnel to undertake the peer reviews and joint assessments.

Question 35 – Do you agree with our proposed position? If not, please explain why.

Question 36 – To what extent will these changes have an impact on notified bodies and manufacturers, especially small and medium sized enterprises, in the UK?

Monitoring notified bodies

16.10. The regulations place more requirements on national authorities; authorities must set out how they will oversee notified bodies, coordinate their monitoring activities with other national authorities and report on their monitoring activities, a summary of which will be made publicly available. National authorities must also conduct an annual on-site audit of notified bodies. Every three years, an assessment by the national authority and a joint assessment team of different national experts takes place to determine whether the notified body still satisfies the requirements.

16.11. There is an explicit requirement on notified bodies to respond to requests from national authorities and for national authorities to facilitate requests for information from their own notified bodies. You can read about this in detail in Article 35 of the medical devices regulation and Article 33 of the IVD regulation.

16.12. Separately, a provision sets out powers for Member States to levy fees to cover their costs when they designate and oversee notified bodies. The regulations delegate power to the Commission, with oversight from Member States, to set the criteria and level of the fees. You can read about this in detail in Article 40 of the medical devices regulation and Article 38 of the IVD regulation.

We agree that tightening up the monitoring of notified bodies with assessments, audits and better communication is crucial to ensure a consistent level of scrutiny of manufacturers and devices across the EU. We are considering further what additional provisions on the transparency of these processes would support a consistently high level of notified body scrutiny across the EU and would welcome views on this.

Question 37 – Do you agree with our proposed position? If not, please explain why.
Changes to notification

16.13. Any extension of a notified body’s scope requires a joint assessment by different national experts. Any restriction of a notified body’s scope is assessed by the Member State where the notified body is located. A report is then submitted to the other Member States and the Commission. You can read about this in detail in Article 36 of the medical devices regulation and Article 34 of the IVD regulation.

16.14. There are also clearer obligations at national level. The national authority may instruct the notified body to suspend or withdraw any certificates which were unduly issued. Member States are obliged to safeguard the files of notified bodies when their notification is restricted, suspended or withdrawn.

16.15. Furthermore, Member States have the power to have concerns about other notified bodies duly considered by the Commission and the regulations delegate power to the Commission to take the necessary corrective action if a Member State fails to take the necessary action against a notified body.

16.16. You can read about this in detail in Article 37 of the medical devices regulation and Article 34 of the IVD regulation.

We agree with the principles of these changes. We are currently examining whether this delegation of power to the Commission is appropriate.

Question 38 – Do you agree with our proposed position? If not, please explain why.
Chapter V: Classification and conformity assessment

17. Classification: both regulations
17.1. Both of the regulations update how the Member States and the Commission apply the classification rules. Power is delegated to the Commission to determine how the application rules should be determined for a type of device and to classify a device by derogation from the classification rules with oversight from Member States.

17.2. Competent authorities must notify the Commission and the Medical Device Coordination Group (MDCG) 14 days before they make a decision on classification where there is a dispute between a notified body and a manufacturer. You can read about this in detail in Article 41 of the medical devices regulation and Article 39 of the IVD regulation.

We see these as useful changes which will provide more clarity and consistency for manufacturers. In terms of procedure, we would prefer for the competent authority to notify the Commission and MDCG after they make a decision to avoid undue delays to placing devices on the market, particularly given that neither the Commission nor the MDCG have a decision-making role in this process.

Question 39 – Do you agree with our proposed position? If not, please explain why.

18. Classification: the medical devices regulation
18.1. The classification criteria are laid out in Annex VII. In line with technical progress and drawing on experience with vigilance, the amendments to the current annex are as follows:
   • stand alone software is classified in its own right;
   • active implantable medical devices and their accessories are class III;
   • in vitro fertilisation (IVF) and assisted reproduction technologies (ART) are class IIb;
   • spinal disc replacement implants and implantable devices that contact the spinal column are class III;
   • devices manufactured utilising tissues or cells of human or animal origin, which are non-viable or rendered non-viable are class III;
   • devices incorporating nanomaterial are class III;
   • aphaeresis equipment is class III; and
   • 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 are class III.

Generally, we see these as useful changes which will provide more clarity and consistency for manufacturers. We note that this process will result in some devices being up-classified which increases the burden on manufacturers. We will be considering whether some of these changes are proportionate to the risk of the device. However it is very difficult to estimate this impact at this stage.

As outlined previously, we believe that 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 should be excluded from the scope
of the regulation and be regulated by European medicines legislation.

Question 40 – Do you agree with our proposed position? If not, please explain why.

Question 41 – Do you have any views – and accompanying evidence – on other changes to the classification rules that might be appropriate or whether some proposed changes are unnecessary?

19. Classification: the IVD regulation

19.1. The IVD regulation moves to classification rules that largely follow the approach outlined in the Global Harmonisation Task Force’s risk-based classification. The regulation classifies IVDs in ascending order of risk: A, B, C or D. This replaces the existing list-based classification system. The following table sets out which devices fall into which risk class according to the classification rules:

<table>
<thead>
<tr>
<th>Risk class</th>
<th>Devices covered</th>
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</table>
| **Class D** | Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion or transplantation.  
  Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or currently undefined risk of propagation.  
  Devices intended to determine the following markers:  
  o ABO system;  
  o Rhesus system;  
  o Kell system;  
  o Kidd system;  
  o Duffy system. |
| **Class C** | Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, excluding those specified as being class D.  
  Devices intended for:  
  o detecting the presence of, or exposure to, a sexually transmitted agent;  
  o detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation;  
  o detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested, or to the individual's offspring;  
  o pre-natal screening of women in order to determine their immune status towards transmissible agents;  
  o determining infective disease status or immune status, if there is a risk that an erroneous result would lead to a patient management decision resulting in an imminent life-threatening situation for the patient or for the patient's offspring;  
  o selection of patients, i.e. |
- Devices intended to be used as companion diagnostics; or
- Devices intended to be used for disease staging; or
- Devices intended to be used in screening for or in the diagnosis of cancer.
  - human genetic testing;
  - monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient or for the patient's offspring;
  - management of patients suffering from a life-threatening infectious disease;
  - screening for congenital disorders in the foetus.
- Devices intended for self-testing, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test.
- Devices intended for blood gases and blood glucose determinations for near-patient testing.

### Class B
- Devices intended for self-testing where the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test.
- Devices which are controls without a quantitative or qualitative assigned value.
- Devices not covered by any specific classification rule.

### Class A
- Reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for *in vitro* diagnostic procedures related to a specific examination.
- Instruments intended by the manufacturer specifically to be used for *in vitro* diagnostic procedures.
- Specimen receptacles.

19.2. You can read about this in detail in Article 39 and Annex VII of the IVD regulation.

Generally, we see these as useful changes which will provide more clarity and consistency for manufacturers and improve the quality of IVDs placed on the market. We note that this will result in a large number of IVDs bring brought within the scope of a conformity assessment by a notified body which will increase the burden on manufacturers. We will be analysing the rules further to identify any areas where the classification is not proportionate to the risk of the device. However it is very difficult to estimate the precise impact at this stage.

The proposed classification rules align very closely with the model rules developed by the GHTF but one aspect that they do not cover is the novelty of a device as a risk factor.

Question 42 – Do you agree with our proposed position? If not, please explain why.

Question 43 – Do you think that the novelty of a device should be incorporated into the classification rules? If so, how might this be achieved?
20. Conformity assessment: the medical devices regulation

Conformity assessment procedures
20.1. Conformity assessment procedures still depend on the risk classification of the device. The medical devices regulation clarifies and tightens up the conformity assessment procedures for higher risk devices. It:
- clarifies that notified bodies need to involve the relevant tissues or medicines authority when assessing devices with a medicinal product acting ancillary to the device, as well as devices incorporating non-viable human tissues;
- specifies that notified bodies must verify the measuring or sterilisation aspects when class I devices have a measuring function or are sold sterile;
- removes the option for manufacturers of class III, IIb and IIa devices to use production quality assurance;
- amends the requirements on full quality assurance for class IIb devices to include the assessment of design documentation on a representative basis; and
- delegates power to the Commission to set out further details on the requirements for conformity assessment.

20.2. You can read about this in detail in Article 42 of the medical devices regulation.

20.3. Annex II requires significantly more detail to be included in the content of the technical documentation which manufacturers need to draw up.

20.4. Annex XII sets out the new minimum content of certificates issued by notified bodies.

20.5. Annexes VIII, IX, X and XI set out more details on the conformity assessment procedures:
- conformity assessment based on full quality assurance and design examination (VIII);
- conformity assessment based on type examination (IX);
- conformity assessment based on product conformity verification (X); and
- conformity assessment procedure for custom-made devices (XI).

20.6. Of particular note is a requirement for notified bodies to undertake unannounced factory inspections and, in that context, to check samples from the manufacturing process for conformity with the technical documentation and/or design dossier. There is also a requirement for notified bodies to rotate the members of audit teams.

20.7. Power is delegated to the Commission to amend Annexes II, VIII, IX, X, XI and XII in light of technical progress and to specify how the conformity assessment procedures can be applied in a harmonised way by all notified bodies. This may include how often notified bodies should make unannounced visits to manufacturers’ factories and the laboratory tests which notified bodies should carry out during design dossier and type examination.
20.8. Annex I sets out the general safety and performance requirements which devices need to meet. In summary, the annex adds the following:

- requirements on manufacturers when they use substances with endocrine disrupting properties, phthalates in a device intended to treat children or pregnant women, devices with a special microbiological state and devices that contain nanomaterial which could be released into the user's body;
- requirements on the safe interoperability, adjustment, calibration and disposal of devices;
- requirements to minimise risks when users handle the connections of a device, when the device comes into contact with materials, liquids, and substances, and the risks of accidental ingress of substances into the device;
- requirements to minimise risks associated with the possible negative interaction between software and the environment within which it operates and for software to take into account the features of the relevant mobile computing platform;
- requirement for devices to be easy to use by lay people and to include a procedure which validates its intended performance;
- detail to be included on the label of the device (such as the Unique Device Identification);
- detail to be included in the instructions for use (such as when a user should consult a healthcare professional and how to report a serious incident to the manufacturer);
- option to provide electronic instructions or a single set of instructions for multiple device delivered to a single user; and
- updated references to other applicable European legislation.\(^6\) \(^7\)

We support these changes to the conformity assessment procedures, in particular the additional requirements on notified body audits.

We anticipate that removing the possibility for class III, IIb and IIa devices to use production quality assurance will have a minimal impact because these routes are already rarely used at present.

We have highlighted some of the main changes to the essential requirements but have not yet considered their full implications or if any further changes to the essential requirements might be appropriate. We would, however, welcome any views on the changes or whether there are additional areas that should be addressed in the legislation.

Question 44 – Do you agree with our proposed position? If not, please explain why.

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\(^6\) Manufacturers must pay special attention to carcinogenic, mutagenic or toxic to reproduction substances, which are listed in Part 3 of Annex VI to Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures.

21. Conformity assessment: the IVD regulation

Conformity assessment procedures
21.1. The following table sets out the changes to the conformity assessment requirements for IVDs. You can read about this in detail in Article 40 of the IVD regulation.

<table>
<thead>
<tr>
<th>Device</th>
<th>Conformity assessment requirements</th>
</tr>
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<tbody>
<tr>
<td>Class D IVDs</td>
<td>• existing requirements of Annex II List A devices from Directive 98/79</td>
</tr>
<tr>
<td></td>
<td>• additional requirement for notified bodies to verify compliance with applicable common technical specifications or other solutions used by manufacturer using a new EU reference laboratory</td>
</tr>
<tr>
<td>Class C IVDs</td>
<td>• existing requirements of Annex II List B devices from Directive 98/79</td>
</tr>
<tr>
<td></td>
<td>• removes the possibility of using EC verification (Annex VI of Directive 98/79) and requires design dossier examination on a representative basis for full quality assurance conformity assessment</td>
</tr>
<tr>
<td>Class B IVDs</td>
<td>• requires full quality assurance conformity assessment</td>
</tr>
<tr>
<td>Class A IVDs</td>
<td>• technical documentation and self-declared conformity</td>
</tr>
<tr>
<td></td>
<td>• requires notified body involvement for self-testing and near-patient testing devices and those that are sterile or have a measuring function</td>
</tr>
<tr>
<td>Companion diagnostics</td>
<td>• consultation by medicines competent authority or the European Medicines Agency (EMA)</td>
</tr>
<tr>
<td>Devices for self-testing and near-patient testing</td>
<td>• additional requirements in Annex VIII, irrespective of risk-class</td>
</tr>
</tbody>
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21.2. Annex II sets out the technical documentation which manufacturers need to draw up.

21.3. Annex XI sets out the new minimum content of certificates issued by notified bodies.

21.4. Annexes VIII, IX, X set out the details on the conformity assessment procedures:
• conformity assessment based on full quality assurance and design examination (VIII);
• conformity assessment based on type examination (IX); and
• conformity assessment based on product quality assurance (X).

21.5. Power is delegated to the Commission to amend Annexes VIII, IX and X in light of technical progress and to set out further details on the requirements for conformity assessment.

21.6. Annex I sets out the general safety and performance requirements which IVDs need to meet. In summary, the annex adds the following:
• requirement for manufacturers to consider the technical knowledge and experience of intended users;
• requirements on the safe interoperability, adjustment and calibration of devices;
• requirement for devices connected to or equipped with an energy source, upon which the safety of the patient depends, to be equipped with a means to determine
the state of the power supply and a requirement to include a procedure which warns
the user if the device fails to provide a valid result;

- requirement for software to take into account the features of the relevant mobile
  computing platform and to be developed according to the state of the art;
- requirement for devices to be designed in a way that removes or reduces risks when
  the device comes into contact with materials, liquids, and substances, from the
  possible negative interaction between software and the environment within which it
  operates, from the risks of accidental ingress of substances into the device, from the
  risk of incorrect identification of specimens or from the risk of any foreseeable
  interference with other devices;
- detail to be included on the label of the device (such as the Unique Device
  Identification and whether the device is intended for near-patient testing);
- detail to be included in the instructions for use (such as how to report a serious
  incident to the manufacturer and competent authority, appropriate warnings and
  precautions, the assay procedure, and clinical performance characteristics where
  relevant);
- requirements for devices for near-patient testing, in line with those which currently
  exist for self-testing (including details of the test procedure and information on any
  factors which can affect the test result); and
- updated references to other applicable European legislation.

We recognise that, coupled with the new conformity assessment procedures, these changes
will have a significant cost impact on manufacturers. Generally, we support these changes
which will tighten up the assessment of IVDs before they are placed on the market. One area
that we will wish to consider further is the requirement for notified bodies to be involved in
assessment of class A IVDs with a sterile or measuring function as this is likely to leave very
few IVDs that will be able to be self-certified by a manufacturer.

We support the requirement for companion diagnostics to be subject to consultation with a
medicines competent authority during conformity assessment because this will help to ensure
their suitability with to be used in conjunction with a specific medicine.

We have highlighted some of the main changes to the essential requirements but have not yet
considered their full implications or if any further changes to the essential requirements might
be appropriate. We would, however, welcome any views on the changes or whether there are
additional areas that should be addressed in the legislation.

Question 45 – Do you agree with our proposed position? If not, please explain why.

Question 46 – Do you think that notified bodies should be involved in assessing class A IVDs
with a sterile or measuring function?

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8 Manufacturers must pay special attention to carcinogenic, mutagenic or toxic to reproduction
substances, which are listed in Part 3 of Annex VI to Regulation 1272/2008 on classification, labelling
and packaging of substances and mixtures.
22. Derogations, choosing a notified body, and certificates: both regulations

Derogation from the conformity assessment procedures

22.1. The existing derogations are defined more broadly; they may be used in the interest of patient safety as well as public health. Member States must inform the Commission and other Member States when they use the derogation.

22.2. The proposed regulations also delegate power to the Commission to extend a national derogation to all Member States in the EU, should a Member State so request.

22.3. You can read about this in detail in Article 47 of the medical devices regulation and Article 41 of the IVD regulation.

Manufacturers' choice of notified body

22.4. Three main changes have been proposed. Firstly, the regulations specify that an application may not be made to more than one notified body for the same conformity assessment at the same time. Secondly, the regulations require notified bodies to inform other notified bodies where an application by a manufacturer is withdrawn prior to their assessment decision. Thirdly, they set out specific details on how a manufacturer should transfer from one notified body to another: notably an agreement must be drawn up.

22.5. You can read about this in detail in Article 43 of the medical devices regulation and Article 44 of the IVD regulation.

Certificates

22.6. Notified bodies may suspend or withdraw a certificate when a device no longer complies with the regulatory requirements. Moreover, certificates must be entered onto the new central European database. You can read about this in detail in Article 45 of the medical devices regulation and Article 43 of the IVD regulation.

Certificates of free sale

22.7. The regulations require Member States to provide certificates of free sale to manufacturers. Power is delegated to the Commission to establish a common model for these certificates across the EU. You can read about this in detail in Article 48 of the medical devices regulation and Article 46 of the IVD regulation.

We support the changes that aim to prevent forum-shopping between notified bodies by manufacturers, although we will consider whether there is more that could be done to address this issue – for example by requiring manufacturers to disclose their previous interactions with other notified bodies.

We do not anticipate that changes to either certificates or certificates of free sale will have a practical impact in the UK; the Department of Health already provides certificates for free sale.

We are considering whether it is appropriate to delegate power to the Commission to extend a national derogation to the rest of the EU.

Question 47 – Do you agree with our proposed position? If not, please explain why.
23. Additional pre-market scrutiny for higher risk devices: both regulations

23.1. The regulations introduce additional pre-market scrutiny of class III medical devices and class D IVDs by the Medical Device Coordination Group (MDCG) of Member State experts which screens the applications for assessment for high risk devices, selects certain dossiers for scrutiny and then provides advice to notified bodies on their conformity assessment. The diagram below sets out this process; you can read about this in detail in Article 44 of the medical devices regulation and Article 42 of the IVD regulation.

- Notified bodies inform the Commission of all Class III and Class D device applications for conformity assessments.
- (except when supplementing/renewing certificates)
- Commission notifies the MDCG
- Within 28 working days, the MDCG may request that the notified body submits a summary of the preliminary conformity assessment prior to issuing a certificate
- Notified body submits the draft conformity assessment
- Within 30 days, the MDCG may request additional information.
- (Clock is stopped on 60 day deadline until the information is received)
- Within 60 days, the MDCG or the Commission may submit comments.
- Notified Body considers the comments and explains its final decision.

The Commission may extend to other categories of devices if they:
- are novel;
- have increased risk;
- experience an increased rate of serious incidents;
- receive different conformity assessments from notified bodies; or
- are subject to public health concerns.
We strongly disagree with this new proposed mechanism. It is extremely unlikely to offer any additional safeguards to patients because it will be impractical for the MDCG to access the right expertise to evaluate the draft conformity assessments within the proposed deadlines. This is because of the breadth and complexity of class III devices that would go through this process; the Commission’s impact assessment estimates that around 2,500 new class III devices are placed on the market in the EU every year.

We consider that the provisions in the regulation to improve the functioning of notified bodies will address the shortcomings observed in relation to the pre-market scrutiny of devices. We do not consider that this process will add any benefit; rather it will simply delay patients’ access to new technology.

We would therefore prefer for this scrutiny mechanism to be removed and will be considering what alternative approaches to allow additional scrutiny to be placed on new and innovative high risk devices might be more appropriate.

Question 48 – Do you agree with our proposed position? If not, please explain why.

Question 49 – Do you have any views on whether a meaningful process of additional pre-market scrutiny is possible to achieve? What are the possible alternatives?
Chapter VI: Clinical evaluation, investigations, evidence

24. Clinical evaluation and general requirements on clinical investigations: the medical devices regulation

24.1. As regards clinical evaluations, manufacturers may no longer solely rely on data from clinical investigations. They must also include a clinical evaluation of literature to demonstrate the safety and performance of their devices. The regulation introduces the term ‘clinical evaluation report’ when referring to the outcome of a manufacturer’s clinical evaluation.

24.2. Furthermore, the regulation introduces the term ‘sponsor’ which may be the manufacturer, their authorised representative or another organisation. The sponsor takes responsibility for beginning and managing a clinical investigation.

24.3. You can read about this in detail in Articles 49 and 50 of the medical devices regulation.

24.4. Annex XIII sets out more details on clinical evaluation. This requires that a clinical evaluation is thorough, objective and proportionate to the risk and intended use of the device. The annex sets out the circumstances where manufacturers may use clinical data which is sourced from studies on a similar device (termed ‘equivalence’).

24.5. Annex XII also adds new requirements for manufacturers to undertake post-market clinical follow up. The annex specifies that this requires the manufacturer to proactively collect and evaluate clinical data from the use of a device in order to check its safety and performance and detect any emerging risks. The annex sets out the content of a post-market clinical follow-up plan, which includes how clinical experience will be gathered. The manufacturer’s post-market clinical follow-up evaluation report forms part of the manufacturer’s overall clinical evaluation.

We support the broad principles of these changes, which we consider to be important to drive an improvement in the standard of clinical evaluations by manufacturers and the assessments of clinical evidence by notified bodies. Given how important this aspect of assessment of a device is, we would welcome views on how the requirements on clinical evidence could be further strengthened.

Question 50 – Do you agree with our proposed position? If not, please explain why.

25. General requirements on clinical evidence and clinical performance studies: the IVD regulation

25.1. There are new requirements on clinical evidence and clinical investigations that are new concepts in IVD legislation. Clinical evidence will be required to demonstrate conformity with the general safety and performance requirements.

- There must be data on the ability of the test to provide information on a specific clinical condition.
- If a manufacturer does not use clinical performance data to demonstrate clinical evidence, they must duly justify doing so.
• A ‘clinical evidence report’ must be included in the manufacturers’ technical documentation.
• Manufacturers must keep available the relevant technical documentation on performance evaluation for five years after the end of the evaluation. Clinical performance data should be updated throughout the lifecycle of the device.
• There are new requirements for interventional clinical performance studies and other clinical performance studies where the study involves invasive procedures or other significant risks for the subjects of the study. These requirements are the same as for clinical investigations on medical devices and are set out below.

We support the broad principles of these changes, which we consider to be important to drive an improvement in clinical evaluation by manufacturers and assessment of clinical evidence by notified bodies. However, we will need to consider the detail of these further to ensure that these new requirements are appropriate for IVDs.

Question 51 – Do you agree with our proposed position? If not, please explain why.

26. Clinical investigations: the medical devices regulation and interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies: the IVD regulation

26.1. The requirements set out below apply to both clinical investigations of medical devices and interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies of IVDs (‘performance studies’). Most clinical performance studies on IVDs neither inform patient management nor have an impact on treatment decisions, therefore they are excluded from the scope of these requirements.

Application

26.2. The regulations set out the application process for a clinical investigation/performance study as follows.
• Manufacturers must register with the new central European database; this information will be publicly available.
• The Member State where the manufacturer is based must confirm that the application is complete within six days; if it does not do so then the application is considered complete.
• The sponsor has six days to respond if the Member State deems the application to be incomplete. No response from the sponsor at this stage means that the application is withdrawn.
• A Member State may object to a clinical investigation for reasons of ‘patient safety’, as well as for reasons of ‘public health or public policy’ as is currently the case.
• If no objection is raised, the clinical investigation/performance study begins after 35 days.

26.3. You can read about this in detail in Article 51 of the medical devices regulation and Article 49 of the IVD regulation.

We have concerns with the proposed changes to applications for clinical investigations/performance studies. Member States must retain the right to request further
information when manufacturers apply for clinical investigations. This is imperative in the interest of patient safety. Otherwise it may lead to competent authorities refusing clinical investigations/performance studies because of insufficient evidence provided by a sponsor. Member States must also be able to object to an application during 60 days, as in the current directives.

Question 52 – Do you agree with our proposed position? If not, please explain why.

Registration
26.4. Certain details about a clinical investigation/performance study must be uploaded onto the new central European database. Information held on the database will be available to the public in accordance with medical, ethical and data protection principles. You can read about this in detail in Article 52 of the medical devices regulation and Article 50 of the IVD regulation.

Electronic database
26.5. A new European database will hold information about clinical investigations/performance studies, including the exchange of information between Member States and the notification of adverse events. Power is delegated to the Commission to decide which data should be publicly available.

26.6. There must be a notification to the new European database if a Member State halts or refuses a clinical investigation/performance study, if a sponsor terminates a clinical investigations/performance study early, or if an application for a clinical investigation/performance study is withdrawn.

26.7. You can read about this in detail in Article 53 of the medical devices regulation and Article 51 of the IVD regulation.

We support these changes to registration and the introduction of a central European database which will simplify the existing national provisions and facilitate information sharing.

Question 53 – Do you agree with our proposed position? If not, please explain why.

Notification to the competent authority
26.8. The competent authority must be notified when:
- invasive or burdensome clinical investigations/performance studies further assess CE marked devices within their intended purpose;
- significant amendments are made to a clinical investigation/performance study (the competent authority then has 30 days to raise an objection);
- a clinical investigation/performance study ends, including when it is suspended or terminated on safety grounds (in the latter case, this must be notified within 15 days and a full report must be sent within a year); and
- adverse events or near misses occur during a clinical investigation/performance study.

26.9. You can read about this in detail in Articles 54 - 57 and 59 of the medical devices regulation and Articles 52 - 55 and 57 of the IVD regulation.
**Multi-site clinical investigations/clinical performance studies**

26.10. The regulations set out how to coordinate clinical investigations/performance studies across different Member States.
- A coordinating competent authority may be designated by the sponsor for clinical investigations/performance studies that take place in more than one Member State.
- If the designated competent authority does not want to take on the role, a process is put in place to decide which other competent authority takes on the role.
- If no competent authority wishes to take on this role, the responsibility reverts to the competent authority which was originally designated by the sponsor.
- The coordinating competent authority must assess the clinical investigations/performance studies and coordinate the assessment of adverse events.

26.11. Each Member State remains responsible for deciding whether or not the clinical investigation/performance study can take place on their territory.

26.12. You can read about this in detail in Article 58 of the medical devices regulation and Article 56 of the IVD regulation.

In our view, the introduction of a coordinating competent authority could be useful to facilitate cooperation between Member States. However it must not interfere with a Member State’s competence to assess applications for clinical investigations on patients in their territory or investigate an adverse event on their own, should they so wish.

For example, we do not think that the coordinating competent authority will necessarily be the best placed competent authority to assess adverse events during a multi-site clinical investigation/performance study. This would be better assessed by the competent authority(ies) in the country(ies) in which the adverse events occurred. Coordination can happen following this initial assessment.

We will therefore give consideration to how this proposal can be improved.

**Question 54 – Do you agree with our proposed position? If not, please explain why.**

**Further details**

26.13. Power is delegated to the Commission, with oversight from Member States, to set out further details in the following areas:
- how the new database functions and what information it holds;
- harmonised forms for reporting serious adverse incidents, applying for a clinical investigations/performance study, and notifying post-market clinical follow up;
- how to assess applications;
- the timelines for reporting serious incidents; and
- how competent authorities exchange information.

26.14. You can read about this in detail in Article 60 of the medical devices regulation and Article 58 of the IVD regulation.
26.15. Annex XIV on clinical investigations for medical devices includes more detail on the necessary documentation when applying for a clinical investigation, a Clinical Investigation Plan and more detailed obligations on sponsors.

26.16. Annex XIII on interventional clinical performance studies for IVDs places new requirements on the necessary documentation when applying for a clinical performance study and obligations on sponsors.

In general we support these measures. We are currently examining whether this delegation of power to the Commission is appropriate or whether it would be more appropriate to agree these details in the proposed regulations.

Question 55 – Do you agree with our proposed position? If not, please explain why.
Chapter VII: Vigilance and market surveillance

27. Vigilance: both regulations

Reporting of incidents and field safety corrective actions

27.1. The regulations place three main obligations on manufacturers. Firstly, manufacturers must report serious incidents within 15 days to the new central European database. If the relevant competent authorities agree, periodic summary reporting may be used as well. This information is then automatically forwarded to all of the Member States.

27.2. Secondly, the regulations introduce the concept of ‘trend reporting’. Manufacturers must report a significant increase in incidents that individually do not fulfil the criteria for reporting incidents involving class IIb and III devices to the central European database.

27.3. Thirdly, manufacturers are required to update their technical documentation with vigilance data, which must be made available to their notified body.

27.4. Furthermore, competent authorities are required to encourage healthcare professionals to report nationally. Finally, the regulations delegate power to the Commission to develop a standard electronic form for healthcare professionals, users and patients when they report.

27.5. You can read about this in detail in Articles 61, 62, 64 and 65 of the medical devices regulation and Articles 59, 60, 62 and 63 of the IVD regulation.

We support the establishment of a central vigilance database. However we have concerns that the proposals do not accurately reflect the current guidance on vigilance. In line with current guidance, we think that there should be a deadline for manufacturers to report field safety corrective actions (FSCAs), for example, no later than the FSCA has begun or within two days if there is a serious public health threat.

We think it would be more efficient if the coordinating competent authority proposed the use of periodic summary reporting and then the other competent authorities could object within a set deadline. We would also prefer to allow periodic summary reporting for common and well documented incidents.

Given that separate national reporting databases for healthcare professionals will coexist alongside the single European database for manufacturers, it will be imperative that the central database allows for easy search and input by competent authorities.

We support trend reporting by manufacturers because it is important to initiate a dialogue between manufacturers and competent authorities in areas of uncertainty. Therefore we do not think that trend reporting should be restricted to class IIb and class III devices.

Question 56 – Do you agree with our proposed position? If not, please explain why.
Analysis of incidents and field safety corrective actions

27.6. A number of new obligations are placed on competent authorities. They must notify the single European database of reports from healthcare professionals, users and patients. They must notify the relevant medicines or tissues authority when they assess an incident involving either a combination product or products incorporating non-viable human tissues or cells. When an incident spans more than one Member State, the competent authority where the manufacturer has registered their place of business coordinates the analysis. Furthermore, more detail is set out as to how competent authorities should undertake risk assessments.

27.7. Field safety notices from manufacturers are also publicly available on the European database.

27.8. You can read about this in detail in Article 63 of the medical devices regulation and Article 61 of the IVD regulation.

We support these changes which will ensure a more rigorous analysis of serious incidents and will make substantially more information available to the public about vigilance reporting.

Question 57 – Do you agree with our proposed position? If not, please explain why.

Further details

27.9. The regulations delegate power to the Commission, with oversight from Member States, to:
• define serious incidents for specific types of devices;
• establish a template form when manufacturers report incidents and Member States exchange information; and
• decide timelines for reporting.

27.10. You can read about this in detail in Article 66 of the medical devices regulation and Article 64 of the IVD regulation.

We are currently examining whether or not this is an appropriate delegation of power to the Commission or whether it would be better for these details to be agreed in the regulations.

Question 58 – Do you agree with our proposed position? If not, please explain why.

28. Market surveillance: both regulations

28.1. A number of new obligations are clarified or placed on Member States as regards their market surveillance activities. These changes are in line with the model provisions set out in the New Legislative Framework, which aims to improve the free movement of goods in the internal market. Member States must:
• undertake appropriate surveillance of devices on their market, a summary of which is made public;
• evaluate the risks of devices which are brought to their attention through vigilance reports;
• take action against operators which do not comply with the regulations; and
• follow good administrative practice when taking market surveillance action.
28.2. The new central European database, set up by the Commission, collates market surveillance information.

28.3. You can read about this in detail in Articles 67, 68, 69, 73 and 75 of the medical devices regulation and Articles 65, 66, 67, 71 and 73 of the IVD regulation.

28.4. On another note, when Member States take action in order to ensure the protection of health and safety or public health, power is delegated to the Commission to determine whether or not the national measure is justified. If justified, the measure may be extended by the Commission across the EU. You can read about this in detail in Article 74 of the medical devices regulation and Article 72 of the IVD regulation.

We support these changes which will simplify reporting of market surveillance and facilitate cooperation between competent authorities. We are examining whether or not this is an appropriate delegation of power to the Commission in legal terms and whether the Commission has the expertise to make such a decision.

Question 59 – Do you agree with our proposed position? If not, please explain why.

Non-compliant devices presenting a risk to health and safety

28.5. The regulations set out the procedure whereby competent authorities take action and follow up on manufacturers. Another Member State or the Commission can then object.

28.6. Firstly, competent authorities must take appropriate action with non-compliant devices that present a risk to health and safety. They must inform other Member States of their actions through the single European database. The economic operator must ensure that appropriate corrective action is then taken. If they do not, Member States must take action themselves.

28.7. Secondly, another Member State or the Commission may object to a Member State’s action. The Commission then evaluates and decides whether or not the national measure is justified. If unjustified, the national measure must be withdrawn.

28.8. You can read about this in detail in Articles 70 and 71 of the medical devices regulation and Article 68 and 69 of the IVD regulation.

In principle, we support these changes which we do not anticipate will mark a departure from existing practice. However we are concerned with the delegation of power to the Commission to decide whether or not a national measure is justified. The Commission must have the access to the right expertise to be able to correctly make these decisions.

Question 60 – Do you agree with our proposed position? If not, please explain why.

Compliant devices presenting a risk to health and safety

28.9. The regulations set out the procedure whereby competent authorities take action and follow up on manufacturers. Another Member State or the Commission can then object.

28.10. Competent authorities must take appropriate action with devices that comply with the regulations but present a risk to health and safety – for example where post-market
experience has shown that the devices are not performing as expected and may be presenting a risk to patients. They must inform other Member States of their actions through the central European database.

28.11. Then, another Member State or the Commission may object to the Member State’s action. If so, the Commission evaluates and decides whether or not the national measure is justified. If unjustified, the national measure must be withdrawn.

28.12. You can read about this in detail in Articles 72 and 73 of the medical devices regulation and Articles 70 and 71 of the IVD regulation.

In principle, we support these changes which we do not anticipate will mark a departure from existing practice. However we are concerned with the delegation of power to the Commission to decide whether or not a national measure is justified. The Commission must have the access to the right expertise to be able to correctly make these decisions.

Question 61 – Do you agree with our proposed position? If not, please explain why.
Chapter VIII: Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers

29. Cooperation between Member States: both regulations
29.1. The regulations set up a new Medical Device Coordination Group (MDCG), which meets regularly to provide expertise on the regulations and replaces the existing Medical Device Expert Group (MDEG). A maximum of two members per Member State participate in the group; members must be impartial and without any conflict of interests. Their declaration of interests must be made publicly available upon request. The MDCG may also establish sub-groups. The Commission supports cooperation between Member States and provides the secretariat for the MDCG.

29.2. The MDCG:
- scrutinises notified bodies;
- scrutinises some conformity assessments;
- develops guidance;
- facilitates coordination on vigilance, market surveillance and clinical investigations; and
- assists the Commission.

29.3. You can read about this in detail in Articles 78, 79 and 82 of the medical devices regulation and Articles 76 and 77 of the IVD regulation.

29.4. On other issues, the regulations:
- formalise the existing coordination arrangements between competent authorities;
- add that Member States may designate a separate national contact point for clinical investigations;
- oblige the Commission and Member States to participate in international work supporting cooperation between medical device regulatory authorities; and
- oblige the Commission and Member States to encourage the establishment of registers for specific types of devices in order to facilitate post-market evaluation.

29.5. You can read about this in detail in Article 76, 77 and 83 of the medical devices regulation and Article 74, 75 and 79 of the IVD regulation.

In principle, we support these changes which will have a beneficial impact if they succeed in improving collaboration and coordination between Member States and a more consistent application of the regulations across the EU. It will be important to ensure that the MDCG is an effective forum for decision-making.

It will also be important to ensure that the existing fora for Member State engagement are aligned with the MDCG; we would also welcome greater clarity about how the Commission intends to engage regularly with key stakeholders such as clinicians, patients and industry.

We do not think it is appropriate to require Member States to participate in international work although we agree this collaboration is valuable.
30. EU reference laboratories: both regulations

30.1. Drawing on best practice from European food legislation, the regulations delegate power to the Commission to set up EU reference laboratories for groups of devices which:

- provide scientific assistance to the Commission, Member States and notified bodies;
- set up and manage a network of national reference laboratories;
- support conformity assessment by notified bodies by providing advice, guidance and best practice;
- elaborate standards; and
- provide scientific advice to notified bodies.

30.2. Members of the EU reference laboratories must be impartial and without any conflict of interests. The declaration of interests must be made publicly available upon request. Power is delegated to the Commission to amend the requirements and responsibilities of EU reference laboratories.

30.3. As regards resources, Member States and notified bodies may be liable to pay for the advice they seek from the reference laboratories. The regulations delegate power to the Commission to set the structure and level of these fees, as well as the amount of funding from the EU budget.

30.4. You can read about this in detail in Articles 81 and 82 of the medical devices regulation and Article 78 of the IVD regulation.

This may be a cost-effective way to raise standards across the EU and gain access to scientific expertise. However, we must ensure that reference laboratories will deliver tangible benefits and address a current gap in access to scientific expertise before resources and funding are devoted to setting them up.

Question 63 – Do you think EU reference laboratories for devices and IVDs would be useful?

31. EU reference laboratories: the IVD regulation

31.1. During the conformity assessments which are either based on full quality assurance and design examination or on type examination, the regulation requires notified bodies to request the EU reference laboratories to verify the compliance of the IVD with the applicable common technical specifications (CTS) or the equivalent relevant specification. Notified bodies must not issue an EU design-examination certificate if the Reference Laboratory has found that the IVD does not comply with the CTS. You can read about this in detail in Article 40 and Annexes VIII and IX of the IVD regulation.

31.2. During the conformity assessments which are either based on full quality assurance and design examination or product quality assurance, the regulation delegates power to the Commission to decide the frequency that notified bodies must send class D IVD samples to the EU reference laboratories for them to test. You can read about this in detail in Article 40 and Annexes VIII and X of the IVD regulation.
We are currently examining the extent to which this would provide an added benefit to the conformity assessment of IVDs. We are concerned that this proposal will add additional costs on manufacturers without any clear additional benefits.

Question 64 – Do you think this particular conformity assessment role for EU reference laboratories for IVDs would be useful?
Chapter IX: Confidentiality, data protection, funding, penalties

32. Confidentiality, data protection, funding, penalties: both regulations

32.1. All parties involved in the proposed regulations must observe confidentiality in relation to personal data, commercially sensitive information and the effective implementation of the regulations. There is a reference to data protection obligations in the relevant European legislation. You can read about this in detail in Articles 84 and 85 of the medical devices regulation and Articles 80 and 81 of the IVD regulation.

We think that the default mode in the regulations must be transparency and that confidentiality must be kept to a minimum. We are currently looking into how the proposed regulations could be amended so that is the case.

Question 65 – Do you agree with our proposed position? If not, please explain why.

32.2. Member States are explicitly allowed to levy fees and charges in relation to their activities undertaken to implement the legislation, which must be proportionate to the services and activities undertaken by their competent authorities. The fees must be notified to other Member States and the Commission. You can read about this in detail in Article 86 of the medical devices regulation and Article 82 of the IVD regulation.

32.3. Member States must establish penalties for when the regulations are infringed. You can read about this in detail in Article 87 of the medical devices regulation and Article 83 of the IVD regulation.

We support these changes which formalise the existing practice across the EU.

Question 66 – Do you agree with our proposed position? If not, please explain why.

9 Directive 95/46/EC and Regulation 45/2001 on the protection of individuals
Chapter X: Final provisions

33. Final provisions: both regulations

Transitional measures

33.1. The regulations enter into force 20 days after they are published in the Official Journal of the EU. The medical devices regulation applies three years it enters into force. There are exceptions:
- provisions in relation to the designation of notified bodies apply six months after the regulation enters into force; and
- provisions in relation to the designation of organisations that assign Unique Device Identifiers and the establishment of the electronic system to collate information on certificates issued by notified bodies apply four and a half years after the regulation enters into force.

33.2. The IVD regulation applies five years after it enters into force. There are exceptions:
- provisions in relation to the manufacturer, authorised representative and importers registering with the new EU database; and
- the provision which obliges the Commission to set up an electronic system to collate information on certificates applies six and a half years after the regulation enters into force.

33.3. The regulations set out transitional provisions for certificates issued by notified bodies in an effort to ensure a smooth transition to the new regulatory requirements.
- Certificates issued by notified bodies under Directives 90/385 and 93/42 are valid until the end of the period on the certificate if they were issued before the proposed regulations entered into force.
- Certificates are valid for two years after the regulations apply if they were issued after the regulations entered into force or if they were issued under Annexes IV of Directives 93/42 and 90/385.

33.4. The Commission must review how the regulations have been applied seven years after they enter into force.

33.5. You can read about this in detail in Articles 94, 95 and 97 of the medical devices regulation and Articles 87, 88 and 90 of the IVD regulation.

We support these transitional measures in principle, although we will give consideration to whether a shorter period of transition might be appropriate. We recognise that it is important to give a longer transition time to IVDs given the significant changes to how they are classified, which will bring many IVDs within the scope of notified body assessments.

Question 67 – Do you agree with the Commission’s proposed transitional measures? If not, please explain why.
Procedural measures

33.6. The final provisions are primarily procedural and:

- form a committee of Member State experts which will oversee the Commission’s decisions where it has been delegated power;
- set out where the Commission has been delegated power; and
- amend or repeal corresponding pieces of legislation to provide legal certainty.

33.7. You can read about this in detail in Articles 88 - 93 and 96 of the medical devices regulation and Articles 84 - 86 and 89 of the IVD regulation.

We support these procedural provisions.

Question 68 – Do you agree with our proposed position? If not, please explain why.