Changes in rules for manufacturing or modifying and use of medical devices including in vitro diagnostic medical devices

Who should read this briefing

This briefing will be of interest to anyone in NHS hospitals and organisations who is involved in the manufacturing or modification and use of medical devices and in vitro diagnostic medical devices. It will also be of interest to senior management staff of hospitals and to medical device management committees (or similar).

What this briefing is for

The briefing looks at the most significant changes coming up in the new legislation and focuses on the key areas of change for NHS organisations.

Key points

- The implementation of the new regulations will need to be achieved by 26 May 2020 for general medical devices (MDs) and 26 May 2022 for in vitro diagnostic medical devices (IVDs). We are informing NHS organisations now in order to give them an opportunity to feed in to the MHRA plans to implement these new laws.

- In NHS organisations there is widespread in-house production and use of diagnostic tests or modification of commercial kits to conduct essential specialised tests for specific groups of patients. NHS organisations also modify or produce medical devices, such as software for MRI scanners and devices for use on special groups of patients (for example, infants and children). Previously, such in-house manufacture and use was not covered by the legislation – in the future it will be.

- The implications for NHS organisations who wish to modify or manufacture devices in-house in the future, will be that they have to apply the health institution exemption. This will include meeting all the relevant requirements for safety and performance, providing a justification for not using a CE marked device, carrying out the manufacture under an appropriate quality management system and making publicly available certain details of the in-house manufactured medical devices.

- Other implications arising from the new regulations include putting systems in place for issuing patients with implant cards and storing device identification data electronically, particularly for high risk devices.
While compliance with the new regulations is already allowed, by May 2020 (2022 for IVDs), there will be a legal need to meet the new requirements. As this is after the deadline for the UK leaving the EU (set for March 2019), many may be asking is there a need to prepare for legislation which may not become UK law?

It is therefore true to say that there is a level of uncertainty about UK organisations transitioning to a new regulatory regime which may never be applied in the UK post Brexit. However, we have recent announcements and speeches from ministers that confirm that the UK is committed to a close partnership with the EU on medtech and pharmaceuticals, and that “the UK has already welcomed the new requirements of these regulations to protect patients while encouraging innovation”.

While clarification on the UK’s relationship with the EU on assessment standards and safety of medicines and medical devices needs to await the outcome of the negotiations with the EU, the statements we have from the UK government so far give us a clear idea that the MHRA believes the new standards are necessary and proportionate and should be implemented at national level. The information we have so far allows us to prepare for the new regulatory landscape as NHS organisations, whether we are in or out of the EU.

The MHRA has also already published an interactive guide to the IVD and MD regulations available on its website to help manufacturers to prepare. The MHRA also has a general page for guidance, and there is information on the NHS European Office’s website.

Background


These new EU regulations have come about in part because the old directives are ambiguous for various modern device cases, in part because as directives, there have been different interpretations in different Member States and in part due to concerns that the inspection processes lacked the strength to detect the fraudulent situation exposed by the PIP breast implant scandal.

The new regulations hope to ensure a consistently high level of health and safety protection for EU citizens using these products and have been adapted to the significant technological and scientific progress occurring in this sector over the last 20 years.

The implementation of the new regulations will need to be achieved by 26 May 2020 for general medical devices (MDs) and 26 May 2022 for in vitro diagnostic medical devices (IVDs).

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Will the implementation be impacted by Brexit?

While compliance with the new regulations is already allowed, by May 2020 (2022 for IVDs), there will be a legal need to meet the new requirements. As this is after the deadline for the UK leaving the EU (set for March 2019), many may be asking is there a need to prepare for legislation which may not become UK law?

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Why did the NHS European Office engage with the revision of these laws?

The NHS European Office, the Institute of Physics and Engineering in Medicine (IPEM) and the MHRA engaged in the development of this legislation because within NHS organisations there is widespread in-house production and use of diagnostic tests or modification of commercial kits to conduct essential specialised tests for specific groups of patients. NHS organisations also modify or produce medical devices, such as software for MRI scanners and devices for use on special groups of patients (for example, infants and children). Previously, such in-house manufacture and use was not subject to the EU directives.

These practices allow the NHS to provide state-of-the-art healthcare to patient groups needing specialised care, to respond rapidly to new or emerging threats, and to promote the development of more innovative solutions through collaboration by medical researchers with peers.

The original proposals for the regulations seriously threatened the ability of NHS hospitals to continue to modify or produce IVDs and MDs in-house for internal use. The proposed restrictions could have resulted in negative implications for patients, such as:

- delays in providing healthcare, with turnaround time for new industry manufactured devices for novel and/or emerging diseases significantly longer than those produced in-house
- lack of available CE marked tests and devices for certain conditions or groups of patients. Test devices for certain rare genetic and infectious diseases are not available on the market, and devices for rare conditions may not be manufactured where no commercial incentive exists; consequently, there could have been implications in terms of the ability to carry out some diagnostic tests for certain patient groups in the future
- lack of devices modified to make appropriate and safer for use on certain populations.

The NHS European Office, IPEM and the MHRA collaborated and engaged intensively throughout the EU process, informing EU decision makers of possible consequences of their proposals and suggesting changes in the interest of the NHS.

Thanks to our influencing work, EU decision makers recognised the need to ensure that hospitals can continue to produce in-house MDs and IVDs for internal use in the future, while ensuring that their quality and safety is guaranteed by fit for purpose provisions which are detailed in Article 5 of the new regulations.

What are the main changes for NHS organisations?

We are producing this briefing now so that NHS organisations may be aware of the changes coming up, while they can still engage with the MHRA on national implementation of the processes required by the new legislation.

General advice

As these new regulations will have a number of implications for NHS organisations, we strongly advise having someone in the health institution with knowledge and understanding of and responsibility for ensuring device safety and compliance with relevant standards and laws. The regulations require such a person to be available for commercial manufacturers and the roles and responsibilities are set out in Article 15. A similar role within an NHS organisation will help ensure that the requirements for a health institution (set out in Article 5), that allow for an exemption from full conformity assessment procedures, are understood and applied. If these requirements are not met, MDs and IVDs manufactured or modified and used in-house must go through the full CE marking process.

The implications for NHS organisations who wish to apply the health institution exemption include providing a justification for not using a CE marked device, carrying out the manufacture under an appropriate quality management system and making publically available certain details of the in-house manufactured medical devices.

Other implications arising from the new regulations include putting systems in place for issuing patients with implant cards and storing device identification data electronically, particularly for high risk devices. The MHRA has produced a simple one pager for NHS organisations to refer to when considering how to prepare for the changes ahead.
### In detail

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<td><strong>Health institution exemption (Article 5.5 of MDR/IVDR)</strong></td>
<td>Devices that are manufactured or modified and used within health institutions shall be considered as having been put into service. This means in-house manufacture or modification and use is now explicitly included within the MDR/IVDR. However, the full requirements of the MDR/IVDR shall not apply to such medical devices provided certain conditions are met including:</td>
<td>Familiarise yourself with the health institution exemption requirements in Article 5.5 and the general safety and performance requirements under Annex 1 of IVD and MDR.</td>
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| * For the purposes of this legislation, ‘health institution’ means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health. | • Health institutions follow the relevant general safety and performance requirements in Annex 1 of the new regulations (Annex I lists the general safety and performance requirements)  
• an appropriate quality management system is established  
• the health institution justifies that the target group’s specific needs cannot be met by an equivalent device on the market  
• information is made available to competent authorities on request  
• a declaration with certain details is made publicly available  
• the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions. | Start to collect a list of all MDs and IVDs which are currently manufactured or modified and used.  
Establish and maintain healthcare industry best practice for the in-house manufacture and support of medical device hardware and software. Strong quality management will help prepare you for IVDR/MDR compliance. |

- Liaise with the MHRA, which is consulting on draft guidance on how to apply the health institution exemption as well as voluntary forms which are designed to assist NHS organisations to fulfil the new requirements. The MHRA is currently engaging with stakeholders and has published a consultation on the draft guidance.

- MHRA will also be looking for early adopters who are happy to pilot the new health institution exemption requirements and who can test out the forms and guidance in practice.

- Contact: devices.regulatory@mhra.gov.uk or for health institution exemption consultation: HIE@mhra.gov.uk
### The issues and current situation

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<td><strong>Implant cards (Article 18 of the MDR)</strong>&lt;br&gt;Currently there are no requirements to provide patients with implantable devices with an implant card.</td>
<td>Health institutions will need to provide patients with implantable devices with an implant card, which shall bear the patient’s identity, as well as rapid access to certain information.</td>
<td>IT systems within trusts will need to change to enable rapid access to certain information. Trusts will also need to put in place processes to ensure that clinicians and surgeons can provide patients with implant cards.</td>
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<td><strong>UDI (Article 27 of the MDR / Article 24 of the IVDR)</strong>&lt;br&gt;The unique device identification (UDI) system does not exist, at least for these purposes (although some organisations may already do some scanning for logistics/procurement purposes). No scanning is currently required by NHS organisations of UDIs for implantable devices, or storage of these codes. The NHS eProcurement strategy (Scan4Safety) is currently being piloted with the plan of rolling out across NHS England trusts. This will require NHS trusts and their suppliers to adopt GS1 standards for the coding of products and for the structuring of master data attributes that are associated to a specific product. However, this will not necessarily fulfill all of the UDI requirements set out in the regulations.</td>
<td>The unique device identification (UDI) system will allow for things like safety alerts, potential recalls, as well as surveillance tasks more generally. For Class III implantable devices, health institutions will need to store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied. Health institutions may be required to do this for other devices also.</td>
<td>This will require some new scanning processes in hospitals and possible alterations to the organisation’s electronic system. The regulations do not require this to be linked to the patient’s record (with the exception of implantable devices), but trusts may choose to do so if considered helpful.</td>
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<td><strong>Single-use devices and their reprocessing (Article 17 of the MDR)</strong></td>
<td>Reprocessing of single use devices will become illegal unless permitted by national law and must meet certain conditions.</td>
<td>The MHRA will informally consult on its current position by mid-2018. If you or your organisation have examples of having conducted safe reprocessing on multi-use devices in the past and those devices have been changed to single use devices without clear justification by the manufacturers, these could be good examples to send to MHRA during their consultation.</td>
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Current MHRA guidance states that single use reprocessing of medical devices is not advised, but it is not illegal to do so.
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<td><strong>Other issues of interest:</strong></td>
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<td><strong>Clinical investigations / Performance studies (Article 73 of the MDR / Article 69 of the IVDR)</strong></td>
<td>There has been a significant alignment with the new regulation for clinical trials on medicinal products for human use (CTR), for example introducing damage compensation and ‘sponsor’. Manufacturers of IVDs will be required to produce significantly more performance evidence, which will need to be updated throughout the life cycle of the device.</td>
<td>You will only need to consider this in the case that the NHS organisation (rather than the industrial partner) is the ‘sponsor’ of the investigation.</td>
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<td><strong>3D printed devices</strong></td>
<td>Although the regulations do not set out specific requirements for devices printed using 3D printers, or the software or machinery used for 3D printing devices, these devices may be subject to more stringent requirements, and the MHRA will review these devices on a case-by-case basis.</td>
<td>The MHRA will update its guidance on 3D printing.</td>
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<td><strong>Software</strong></td>
<td>The regulations introduce additional safety requirements and will also result in some software being regulated more stringently. Software which is a medical device and has been developed or modified in-house and is used only within the same health institution may make use of the in-house exemption requirements and would not be required to be CE marked, provided that its development and use is managed in the ways described in Article 5.5.</td>
<td>MHRA has produced <strong>new guidance for medical device and IVD standalone software, including apps</strong>.</td>
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The NHS European Office

The impact of the EU agenda on the NHS is constantly increasing, bringing with it both challenges and opportunities. The NHS European Office is the conduit for the NHS to engage with the EU agenda. Hosted by the NHS Confederation, we are the representative body for the range of NHS organisations in England on EU affairs. Our work includes:

• making sense of how the UK exiting the EU may impact on NHS organisations and ensuring that decision makers are aware of the impact on the health sector and patients.
• facilitating access to EU funds for NHS bodies and their partner organisations
• supporting pan-European collaborations and sharing successful EU practices.

For more information on EU affairs of importance to the NHS and to get in touch with the NHS European Office, visit www.nhsconfed.org/europe or email european.office@nhsconfed.org