Medical Device Regulations Update

September 2021

Overview

Here is the schedule for today's webinar the purpose of which is to give an overview of compliance requirements for hospitals and community services and answer any questions you may have.

- Introduction – Mark Turner, Chair of the HSE Medical Device Regulations Steering Group
- HPRA Perspective – Andrew Dullea, Regulatory & Policy Assessor | Medical Devices, Health Products Regulatory Authority
- HSE Perspective – Ger Flynn, National Clinical Lead for Medical Devices
- Key Messages for Hospitals – Ciaran Browne, Acute Operations
- Q & A – Stephen McGrath, Communications
- Close – Mark Turner, Chair of the HSE Medical Device Regulations Steering Group

Note: Webinar participants can submit questions via the Q&A box during the webinar and we will address as many of these as we can during the Q&A slot. Both the HSE and HPRA slides presented during the webinar will be emailed to participants following the webinar.

Background/ Why new regulations?

What is the purpose of the Medical Device Regulations?

The new Medical Devices Regulation (MDR) (EU) 2017/745 and In-Vitro Diagnostics Regulation (IVDR) (EU) 2017/746 entered into force in May 2017. As a consequence of the global outbreak of Covid-19, full application of the MDR was extended and became fully applicable on 26 May 2021 with the IVDR becoming fully applicable on 26 May 2022. Both the new MDR and IVDR will replace the existing medical devices Directive (93/42/EEC) (MDD) and the active implantable medical devices Directive (90/385/EEC) (AIMDD). These new regulations will result in significant improvements and developments of the regulatory system for medical devices and in-vitro diagnostic devices.

Main Features of the MDR

Main Features

- Introduction of a UDI (Unique Device Identifier) including a traceability system.
- Enhanced provisions for market surveillance
- Provision of clear and easily accessible essential information on implant devices to patients including clear identification of the implant.
- Improved performance of notified bodies* for medical devices.
- Clearer requirements for clinical data on medical devices and its assessment.
- New obligations apply for economic operators (Article 22(1) and 22(3) that include post-market surveillance for devices they place on the market.
- More specific product requirements
- Improved pre-market assessment of high risk devices
- Governance, coordination and cooperation
- Stricter pre-market control of high-risk devices with the involvement of a pool of experts at EU level.
- Inclusion of certain aesthetic devices within the scope.
- EU minimum requirements related to reprocessing of single-use devices.
- Establishment of a comprehensive EU database on medical devices (EUDAMED) with large part of information to be made publicly available.

* A notified body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market.

Communications, Engagement & Implementation

To ensure compliance with these new regulatory requirements it is essential that all services within the HSE are aware of the new EU Regulations and the respective HSE obligations.

The HSE in partnership with the Department of Health (DoH) is in the process of completing an implementation pathway to ensure compliance with the various HSE responsibilities as obliged by the related articles under the regulations. A central component to the pathway of the new MDR compliance is engagement with relevant stakeholders within the HSE to clearly communicate the implementation requirements of the new Regulations such as:

- Provision to improve traceability of medical device within healthcare institutions.
- Obligations on distributors of medical devices.
- Reporting adverse incidents involving medical devices.
- Reprocessing of single-use medical device
- In-house manufacture of medical devices
- Clinical Investigations of medical devices

MDR Implementation 2021

The application of the MDR Regulations has commenced with the MDR becoming fully applicable as of 26th May 2021. The obligations associated with implementation of the relevant articles under the MDR will centre on number of key elements of implementation to ensure compliance with the new requirements.

HSE Key MDR Obligations & Responsibilities

The following 8 key elements relate to the HSE's obligations and responsibilities with regard to the implementation of the MDR:

- Economic Operator Obligations
- Traceability and UDI
- In House Manufacturing
- Patient Implant Cards
- Reporting Serious Incidents
- Reprocessing Single Use Devices
- MDR Compliance and continued supply
- Clinical Investigations of Medical Devices

Compliance in relation to certain aspects of the MDR will immediately apply regardless of medical device class e.g. in house manufacturing, clinical investigation requirements, economic operator obligations.

Full implementation of HSE obligations under the MDR will be progressed on a priority phased basis. The initial HSE implementation priority for MDR will focus on Class III implantable devices, ref Article 27(4) and patient implant cards, ref Article (18). **Class III** medical devices are those devices that have a high risk to the patient and/or user. Examples of Class III devices include implantable pacemakers and breast implants. **Class II** devices are intermediate-risk devices. Examples include computed tomography (CT) scanners, infusion pumps for intravenous medications, powered wheelchairs and some pregnancy test kits. **Class I** devices are low-risk devices. Examples include bandages, handheld surgical instruments, and nonelectric wheelchairs.

Obligations and Regulatory Requirements of Economic Operators

Economic operators include manufacturers, authorised representatives, importers and distributors (MDR and IVDR Articles 10 to 16).

For manufacturers, the Regulations add new requirements and reinforce existing requirements. Manufacturers have to put systems in place for risk and quality management, conduct clinical or performance evaluations, draw up technical documentation and keep all of this up to date. Manufacturers are also required to apply conformity assessment procedures in order to place their devices on the market. The level of clinical evidence needed to demonstrate the conformity of a device depends on its risk class.

Once they have completed their obligations, manufacturers should draw up a declaration of conformity and apply the CE mark to their devices.
The Regulations also clarify the distinction between vigilance and post-market surveillance. The former includes identifying and reporting serious incidents and conducting safety-related corrective actions. It requires direct and efficient cooperation between healthcare professionals, health institutions, manufacturers and national competent authorities for medical devices. Post-market surveillance involves monitoring the available information to periodically reconfirm that the benefits of the device continue to outweigh its risks.

The Regulations require manufacturers to implement post-market surveillance follow-up plans. This includes compiling safety reports and updating the performance and clinical evaluation throughout the life cycle of a device. This could lead to manufacturers calling on health institutions to provide more information about their experience with their medical devices. Health institutions could prepare for this by thinking about convenient ways to gather information about their experience with medical devices.

Manufacturers outside the EU market should have a contract with an authorised representative inside the EU.

Health Institutions as distributors and/or importers

Distributor & Importer

Health institutions may undertake the roles of a distributor and/or importer if they meet the definitions provided for in Article 2 of the regulations.

Distributor means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.

Importer means any natural or legal person established within the Union that places a device from a third country on the Union market; making available on the market' shall mean any **supply** of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge. Placing on the market shall mean the **first making available** of a product on the Community market.

Placing on the market

Under the MDR/IVDR the placing on the market/making further available of devices is dependent on a legal transfer of ownership. A health institution that transfers devices to another natural or legal entity (via a physical, legal or financial transfer of ownership) could be acting as an importer or distributor under Article 2. However, where the health institution is the end-user and does not transfer the device to another natural or legal person, the health institution would not be a distributor within the meaning of the MDR/IVDR.

Conversely, when a device is transferred (legally or financially) to a health institution from a non-EU entity, its release for 'free circulation' by customs authorities generally coincides with placing on the market. Therefore, health institutions that import medical devices from third countries are placing them on the market and are acting as importers, regardless of whether or not the devices are for onward supply.

For the devices that health institutions import or distribute, the roles and responsibilities of an importer or distributor called out in the MDR and IVDR will apply in full. These specific requirements are called out in Articles 13 (Importer obligations) and Articles 14 (Distributor obligations), however all economic operators are required to comply with the MDR/IVDR in full. Articles 13 and 14 call out the need for complaint handling, reporting, correct storage/transport and verification checks (e.g. of the CE mark and UDI assignment) in detail. Any entity which suspects their activities may qualify them as a distributor or an importer should review the definitions provided for in Article 2 and the obligations set out in Articles 13 and 14. To aid stakeholders, the HPRA has developed the Guide for Distributors of Medical Devices, an Economic Operators Obligations webinar and an FAQ on Importer Obligations.

Traceability & UDI

Traceability

A completely new feature of the Regulations is the unique device identification (UDI) system (MDR Article 27, which will apply to all devices placed on the EU market. The UDI will be a barcode, a QR code or any other machine-readable code. This will enhance the identification and traceability of devices and the effectiveness of post-market safety-related activities through targeted field safety corrective actions and better monitoring by competent authorities. Economic operators shall be able to identify any health institution or healthcare professional to which they have directly supplied a device (MDR Article 25). UDI should also help to reduce medical errors and fight against falsified devices. Use of the UDI system should also improve purchasing, waste disposal and stock management by health institutions and other economic operators.

UDI

Unique device identifiers (UDIs) will be used to uniquely and unambiguously identify devices, both individually and when packaged, or in the case of reusable devices by direct marking of the device itself. Each MD when applicable, each level of their packaging will have a UDI that will be indicated on the labels. UDIs will be added to labels in stages but will be completed by 2027, depending on the risk class of the device. For Class III implantable devices, health institutions shall store and keep – preferably by electronic means – the UDIs of the devices they have supplied, or with which they have been supplied (MDR Article 27(9)). The MDR invite Member States to encourage and to require health institutions to store and keep the UDIs of the devices with which they have been supplied. Also, Member States shall encourage, and may require, healthcare professionals to store and keep the UDIs of the devices with which they have been supplied.

The Regulations will increase transparency by making the UDI the key to publicly available information on devices and in studies. EUDAMED, the new European database for medical devices and in vitro diagnostic medical devices, will play a central role in making data available and increasing both the quantity and quality of data (MDR Article 33). The central European database will allow all stakeholders to access basic information on MDs, such as the identity of the device, its certificate, the manufacturer, the authorised representative and the importer.

In-house Manufacturing

The Regulations allow health institutions under certain conditions to manufacture, modify and use devices ‘on a non-industrial scale’ when equivalent ones are not available commercially (MDR and IVDR Article 5).

With the exception of the general safety and performance requirements set out in MDR/IVDR Annex I, in-house devices are exempt from the requirements of the Regulations as long as they are not transferred to another legal entity.

Nevertheless, health institutions should have appropriate quality management systems in place; compile documentation on the manufacturing process, the design and performance data of the devices, including their intended purpose; and review the experience gained from the clinical use of the devices and take all necessary corrective actions.

This information shall be made available to competent authorities on request, and a declaration with certain details should be made publicly available.

If healthcare professionals manufacture and use devices that do not comply with Article 5 they must follow the same rules as manufacturers.

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices that have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

Reprocessing of Single Use Devices

The MDR allows for reprocessing of single-use medical devices (SUDs) to enable their safe re-use, as long as this is also permitted by national law and only in accordance with MDR Article 17.

The Republic of Ireland allows reprocessing of SUD only in accordance with Article 17(2) of the MDR in accordance with SI 261/2021. As a result, any entity reprocessing SUDs in Ireland will be considered the legal manufacturer of the reprocessed device.

Health institutions can use reprocessed devices provided by commercial reprocessors, however such commercial reprocessors should be fully compliant with Article 17.2 and fulfil the responsibilities of a manufacturer in full.

The HSE current policy is that single use devices should not be re-processed as outlined in the HSE Standards and Recommended Practices for Central Decontamination Units

However, hospitals may undertake re-processing in line with the manufacturers' Instructions for Use (IFU) for operational reasons. This may be an occasion or continuous practice within a hospital. Where re-processing of single use devices is conducted in line with the manufacturers' IFU the hospital will not take on the role of the manufacturer under the MDR. If a hospital goes beyond the manufacturers' IFU for operational reasons, they will be considered the manufacturer under the MDR and will need to ensure a process is in place to deliver full compliance with all MDR requirements including Article 17.

Implant Cards

Provision of Implant Cards (IC) to be provided to achieve three main objectives:

- Enable the patient to identify the implanted devices and to get access to other information related to the implanted device (e.g. via EUDAMED, and other websites).
- Enable patients to identify themselves as persons requiring special care in relevant situations e.g. security checks.
- Enabling e.g. emergency clinical staff or first responder to be informed about special care/needs for relevant patients in case of emergency situations.

Manufacturer Implant Card Obligations
In accordance with Article 18 of the MDR, the manufacturer should provide the following 5 pieces of information on the Implant Card :

- Device Name.
- Serial Number, lot number.
- Unique Device Identification (UDI).
- Name, address and the website of manufacturer.
- Device type.

Health Institution or Healthcare Provider Implant Card Obligations:

In the context of national implementation of Article 18 of the MDR, only the following 3 pieces of information are required to be provided directly to patients implanted with a device by the health institution or healthcare provider on the Implant Card (together with the information provided by the manufacturer).

- Name of the patient or patient ID.
- Name and address of the health institution or healthcare provider who performed the implantation.
- Date of implantation.

Immediate HSE tasks - Class III & Implantable Medical Devices

Identification of the key stakeholders within the HSE relative to implantable devices and Class III devices.

Each hospital /service area designate a senior operational lead to oversee, co-ordinate and advance compliance requirements with the associated articles for Class III devices.

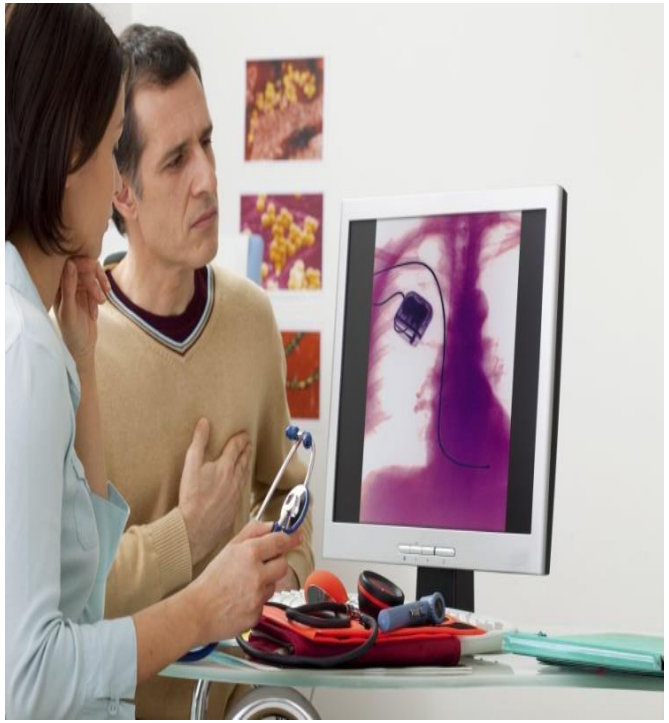
Engagement with manufacturers, authorised representative and distributors in the provision of assurances on their compliance with:

- Manufacturer assignment of UDI code for Class III devices and provision of data to UDI database
- Traceability system for Class III medical devices
- Provision of Patient Implant Cards
- Notified Body identification for the devices supplied
- Provision of a system to address any issues/complaints with their devices as effectively as possible

Hospitals electronically record all Class III medical devices including UDI codes together with the following data set as a minimum:

- Manufacturer / Distributor Company Name
- Device model / or name
- Device serial number / Unique device number / UDI code
- Patient Name
- Patient Contact Details

Reporting
Hospitals establish a local process for reporting and recording of Serious Incidents together with reporting to the National Incident Management System (NIMS) and to the Health Products Regulatory Authority (HPRA).



Transition from MDD to MDR

- Certificates issued by Notified Bodies under the Directives (MDD) will remain valid until their date of expiration or until 27 May 2024 at the latest, with some exceptions described in MDR Article 120(2)) for certain certificates.

- Valid MDD devices may continue to be made available on the market and circulate in the supply chain up until 2025.

- Until May 2025, MDR devices and some MDD devices will coexist on the market. Both will have equal status under the law, and no discrimination in public tenders may take place.

- Devices that are in stock in health institutions can still be used after 2025 until they reach their expiration dates. Furthermore, the Regulations do not regulate the further making available of devices, including after 25 May 2025, after they have already been made available or put into service, for example in the case of second-hand sales (MDR recital 3).

Reporting of Serious Incidents and Complaints

Reporting from health Institutions and healthcare professionals should continue in an uninterrupted fashion.

1. Serious incidents and complaints should be submitted directly to the manufacturer and/or authorised representative (for non-EU manufacturers).
   Distributors and importers are also obliged to keep a record of complaints and incidents from health institutions/healthcare professionals and forward these to the manufacturer or authorised representative.
2. Incidents can also be reported directly to the HPRA via the HPRA's online reporting system or by completing a HPRA incident report form.

Clinical Investigations of Medical Devices

The rules on clinical investigations for medical devices under the MDR have been reinforced. The new rules describe clearly how these investigations shall be designed, notified and/or authorised, conducted, recorded and reported. If you are a sponsor or take part in clinical investigations or performance studies, please read the relevant articles carefully (MDR Articles 62 to 82) so that you are informed of all the new obligations.

Key Message for Hospitals

Designated Senior Management Lead

- Designation of a senior manager / operational lead to progress MDR compliance
- Reviewing compliance (particularly networked hospitals)
- Reporting to senior hospital management team areas of compliance / non-compliance

Staff awareness of requirements

- Ensuring awareness of MDR compliance as it relates to them
- Procurement function
- Clinicians / Clinical Engineering
- Risk and Quality Management

Device related Incident Management

- Capability to track and trace patients
- Preparedness for use of national T&T system
- Risk management and incident reporting

Device Procurement

- All suppliers identified (Class III / Implantable)
- HSE contract suppliers already contacted
- Non-HSE contracted suppliers checked for compliance
- New suppliers
- Obligations if importer / distributor

Assessing Current HSE Situation

HSE Survey

- Aim – To give a brief overview of current situation
- Not a formal compliance audit
- Capture good practice
- Give feedback for national implementation process

Survey Timeline

- 19th September

Areas covered

- Senior Operational Lead for MDR
- Track & Trace Systems already in place
- Implant Cards
- Procurement compliance
- In house manufacturing
- Reprocessing Single use Devices
- Example of good practice
- Feedback to the national team

Further Information

Website General information on Medical Device Regulations is available at this link: https://www.hse.ie/eng/services/publications/pp/medical-device-regulations.html

Queries Specific queries from hospital and community staff in relation to Medical Device Regulations can be directed to the dedicated email address medical.deviceregulation@hse.ie