GS1 Ireland Healthcare User Group (HUG) Information Day

Regulatory update Medical Devices and the impact for Irish Healthcare

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Medical Devices Regulation Update and the impact for Irish Healthcare

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28/03/17
Current European Legislation

Three primary European medical device Directives and related Statutory Instruments (European Directives are transposed into National law).

<table>
<thead>
<tr>
<th>Device</th>
<th>Directive</th>
<th>Statutory Instrument</th>
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<tbody>
<tr>
<td>General Medical Devices</td>
<td>93/42/EEC</td>
<td>S.I. No. 252 of 1994</td>
</tr>
<tr>
<td>In Vitro Diagnostic Medical Devices</td>
<td>98/79/EC</td>
<td>S.I. No. 304 of 2001</td>
</tr>
<tr>
<td>Active Implantable Medical Devices</td>
<td>90/385/EEC</td>
<td>S.I. No. 253 of 1994</td>
</tr>
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7 modifying/implementing Directives:

I. 2010/227/EU - EUDAMED
II. 2007/47/EC – Revision to MDD and AIMD
III. 2005/50/EC – Reclassification of joint replacements
IV. 2003/12/EC – Reclassification of breast implants
V. 2000/70/EC – Devices incorporating blood derivatives
VI. 722/2012 – Tissues of animal origin
VII. 920/2013 – Notified Bodies Designation
Timeframe for Date of Application
Key aspects of the new Regulations

01 Notified body requirements
02 Pre-market assessment requirements
03 Clinical data requirements
04 Product specific requirements
05 Market surveillance obligations & systems
06 Governance & cooperation
New elements to MDR/IVDR

Broader MDR scope - Annex XVI devices

Both Regulations extend the scope to all economic operators

UDI requirements are a core element of the new Regulations and improve device traceability.
UDI provision in MDR

Chapter III - Identification and Traceability of devices

Article 27 - UDI system

Article 28 - sets up a UDI database

Annex VI
- Part B: Core elements to be entered in database
- Part C: definitions and details of the system
UDI components

Definition:
• a series of numeric or alphanumerics characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market

It is made up of 2 components:
• UDI-DI: specific to a manufacturer and a device
• UDI-PI: identifies the unit of device production and if applicable the packaged devices
UDI Definitions

Basic UDI-DI: primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database.

Unit of Use: serves to associate the use of a device with a patient in instances in which a UDI is not labelled on the individual device at the level of its unit of use, for example in the event of several units of the same device being packaged together.
Issuing UDIs

The Commission will designate UDI issuing entities
GS1, HIBCC, ICCBBA

UDIs will be issued for all devices, except custom-made and investigational devices

Staggered application of labelling requirements.

- Class III & implantable devices from 4 yrs after EIF (2021)
- Class IIa and Class IIb from 6 yrs after EIF (2023)
- Class I from 8 yrs after EIF (2025)
Where will Basic UDI-DI be used?

- This is the main key for records in the UDI database
- Declaration of Conformity
- FSN
- Technical documentation
- Summary of safety and clinical performance
- Device certificate issued by Notified Body
- Certificates of free sale
Economic operators obligations

Verification obligations - importers and distributors verify manufacturer has assigned UDI

UDI Storage obligations for Class III devices - required to store, preferably by electronic means the UDIs for devices they have supplied or which are supplied to them

Member States can encourage and may require Health Institutions and Healthcare Professionals to introduce these storage obligations
## Economic Operators Obligations

**Distributor**

- Article 14
- Verify CE marked & Declaration of conformity
- IFU & Labelling Requirements
- Importer identified
- Verify UDI Assigned
- Serious risk/ falsified – inform the NCA
- Storage and transport conditions comply
- Cooperate with MFR/AR, importer and NCA on Corrective Actions
- Register of complaints/ non-conforming product
Field Safety Corrective Action
MEDDEV 2.12-1

An action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions, whether associated with direct or indirect harm, should be reported and should be notified via a field safety notice.
Field Safety Corrective Actions

It is likely that UDI will be included in field safety notices and field safety corrective action reports.

Work is underway at a European level to standardise the format of the field safety notice.

The inclusion of UDI will assist in the traceability of devices and expeditious reconciliation of the field safety corrective action.

The inclusion of UDI within field safety notices will likely also lead to their inclusion in HPRA safety communications (where appropriate).
Takeaway messages

Important introduction for traceability and patient safety.

Based on international guidance, ensure system compatibility.

Improved transparency provides the public with greater access to information via the electronic system.

Enhances post-market safety-related activities for devices.
MDR/IVDR Legislation

General introduction/background info on agreement at EU level

In June 2016, two new proposed Regulations on medical devices (MDR) and *in-vitro* diagnostics (IVDR) were agreed at political level between the three relevant European institutions – the European Council, the European Parliament and the European Commission. Since then these texts have been undergoing final review, translations in the different European languages and formal approval.

The HPRA anticipate that these Regulations will be formally published in the *Official Journal of the European Union* by the end of April 2017. This means that both Regulations will enter into force during quarter 2 of 2017. The Regulations will have a staggered transitional period with some aspects becoming legally binding after 6 months, full application of the MDR after 3 years and full application of the IVDR after 5 years.

The MDR and IVDR represent a significant development and strengthening of the existing regulatory system for medical devices in Europe and will replace the original Directives which have been in place for over 25 years.

The legislation now being in the form of a Regulation, rather than a Directive, means that the EU law is directly applicable at national level without requiring transposition through specific national legislation. This should allow for greater legal certainty and prevent variation in the approach taken or in the rules relating to medical devices that are applied across EU Member States.

- **Timeline and transition to the new Regulations**
- **Key aspects of the new regulations**
- **Key aspects specific to *in-vitro* diagnostic Regulations (IVDR)**
- **HPRA and Implementation of the Regulations**

This webpage will be updated regularly to provide additional information on the new Regulations and their implementation.
Further information


• HPRA has launched a new webpage “New EU Device Regulations”

• It will provide information on the new regulations and updates on the implementation process. It will be updated regularly.
Legal Text

• Link to **IVD Regulation**
• Link to **MD Regulation**

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Questions?