UDI Implementation Update

GS1 UK Healthcare Conference - 22 November 2017

John Wilkinson OBE
Medicines and Healthcare Products Regulatory Agency
Why new European medical device and IVD regulations?
Old medical devices legislation
Three EU Directives

EU in 1990
New medical device regulations
Two EU Regulations

MDR - Regulation (EU) 2017/745 – published 5 May 2017

Medical Devices Regulations

in-Vitro Diagnostic Devices Regulations

IVDR - Regulation (EU) 2017/746 – published 5 May 2017
Advances in technology

1990

2012
High profile issues
New European Regulations: major upgrade

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<tbody>
<tr>
<td>60 pages</td>
<td>175 pages</td>
</tr>
<tr>
<td>23 Articles</td>
<td>123 Articles</td>
</tr>
<tr>
<td>12 Annexes</td>
<td>17 Annexes</td>
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Major upgrade of the MDR/IVDR

Headline measures:

- Strengthening of the requirements for clinical investigation of medical devices (clinical trials)
- Promoting European cooperation in the control and monitoring of device manufacturing and marketing (notified bodies)
- Promoting transparency and traceability throughout the device supply chain
Main features of the new texts

- **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**.
- **Reinforced designation and oversight** processes of **notified bodies**.
- Reinforcement of the rules on **clinical evaluation** (and performance evaluation) and **clinical investigation** (and performance studies).
- **New classification system for IVDs** based on international guidance (80% of IVDs to be assessed by a Notified Body).
- **Establishment of a comprehensive EU database on medical devices (EUDAMED)** with large part of information to be made publicly available.
- **Stimulation of the competitiveness of the industry**.
- Clarification of the role and responsibilities of **economic operators**.
- **Introduction of a UDI system**.
What is Unique Device Identification?

A series of numeric or alphanumeric characters

Internationally accepted standards

Unambiguous identification of specific devices
UDI at a glance

UDI System

UDI (two parts)
- **DI** (static data)
- **PI** (dynamic data)

UDID (database)
- **DI** = primary access key
  - information associated with medical device identification + labeling

AIDC
- **DI** = Device Identifier
- **PI** = Production Identifiers
  - (i.e. lot/batch no., serial no. if applicable), expiry [use by] date, date of manufacture

Machine – readable data carrier
- Linear Bar Code
- 2D Bar Code
- RFID
- …
**GS1 = UDI (but there are other systems!)**

**Translation UDI to GS1**

<table>
<thead>
<tr>
<th>UDI</th>
<th>GS1 Standards</th>
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<tbody>
<tr>
<td>Unique Device Identification</td>
<td>Product Identification</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UDID</th>
<th>GDSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Elements linked to the Device Identifier</td>
<td>Attributes mapped to each UDID data element</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DI =</th>
<th>GTIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier (DI)</td>
<td>Global Trade Item Number</td>
</tr>
</tbody>
</table>

*Production data is not stored in UDI or GDSN databases*

<table>
<thead>
<tr>
<th>PI =</th>
<th>AI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production Identifier (PI) (if applicable)</td>
<td>Application Identifiers (AI)</td>
</tr>
<tr>
<td>Production Identifier data will vary by medical device type and manufacturer current practice.</td>
<td>• Expiration Date AI(17) e.g. 141120</td>
</tr>
<tr>
<td></td>
<td>• Lot/Batch AI(10) e.g. 1234AB</td>
</tr>
<tr>
<td></td>
<td>• Serial Number AI(21) e.g. 12345XYZ</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>DI + PI = UDI</th>
<th>GTIN -or- GTIN + Al(s) = UDI</th>
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UDI improves safety

Using a Unique Device Identification (UDI) system based on international guidance should significantly enhance the post-market safety of medical devices by:

- improving incident reporting
- better targeting of recalls
- better monitoring by competent authorities
- reducing medical errors
- fighting against counterfeit devices
- improving purchase-policy and stock-management by hospitals

Regulation (EU) 2017/745: Recital 41
US UDI system
Unique Device Identification in the US

- IMDRF guidance on Unique Device Identification (UDI) of Medical Devices
- Describes the global framework for regulatory authorities that intend to develop their own UDI systems
- Unique Device Identification System - Final Rule
  21 CFR Parts 16, 801, 803s
- Published September 2013 – all classes of devices to comply by September 2018
- Implements IMDRF UDI guidance in the United States
- Establishes US “Global” UDI Database (GUDID) in US only. Not global!
US – UDI for medical devices is already required*

September 2014
Highest risk devices

September 2015

September 2016

September 2018
Lowest risk devices

* FDA - UDI Final Rule - September 2013
European regulations: UDI
UDI is one small part of New European Regulations

Supersede existing Directives (1990s)

Published 5 May 2017

UDI is one small(!) part of a complete revamp of European Medical Device (MDR) and IVD (IVDR) regulations

European UDI system implements IMDRF UDI guidance throughout Europe
- Article 27 of MDR
- Article 24 of IVDR
Chapter III - Identification and Traceability of devices

Article 27 - UDI system

Article 28 - UDI database

Annex VI - Part B – core elements to be entered in database
Part C - definitions and details of the system
European UDI system – main requirements

UDI system should allow the identification and traceability of medical devices (excludes custom-made and clinical trial devices) and IVDs

UDIs should be in two parts:
- device identifier (UDI-DI) – *static*
- production identifier (UDI-PI) – *dynamic*

- UDIs should be placed on device labels (machine readable + plain text)

- UDIs should be stored by manufacturers, importers, distributors *and hospitals* (using electronic means)

Commission to establish and maintain a European UDI database
Where will Basic UDI-DI be used (regulatory)?

- Main key for records in the UDI database
- Declaration of Conformity
- Safety communications (FSN)
- Technical documentation
- Summary of safety and clinical performance
- Device certification issued by Notified Body
- Certificate of free sale
UDI issuing agencies in Europe

Key points:

The Commission will designate UDI issuing agencies - *probably same three as in US ie GS1, HIBCC, ICCBBA*

- They will have to give access to the systems to all interested parties – *includes patients*

- They must undertake to keep their systems in place for at least ten years – *long term commitment*
Traceability throughout the supply chain

Manufacturer → importer/distributor → hospital → patient
How UDIs will be used

UDI should be placed on the labels of devices and must:

- be used for reporting serious incidents and field safety corrective actions (recalls)
- be referenced in information provided to patients who have received implants (implant cards or electronic)
- be included in technical/ regulatory documentation
Recording of UDIs

Manufacturers, importers, distributors and hospitals must store and keep UDIs (both device identifier and production identifiers) by electronic means.
European UDI database

**Article 28 of MDR / Article 25 of IVDR:**

- require the Commission to set up and manage a European UDI database (UDID)
- require that the UDID should be publicly accessible
- refer to a detailed of information that manufacturers must submit to the European UDID annex (Annex VI – Part B)
European Databank (MDR EUDAMED)

UDI will form the foundation of this publicly accessible system
European UDI system – timelines
European UDI timelines – medical devices

Placement of the UDI carrier (e.g. barcodes on products) by:

- 26 May 2021\(^2\)
- 26 May 2023\(^2\)
- 26 May 2025\(^2\)
- 2 years after the date applicable for its respective class of devices\(^3\)

1. Regulation (EU) 2017/745 - 5 May 2017 - Article 123, paragraph 2
2. Regulation (EU) 2017/745 - 5 May 2017 - Article 123, paragraph 3(f)
3. Regulation (EU) 2017/745 - 5 May 2017 - Article 123, paragraph 3(g)
European UDI timelines – IVDs

All classes of IVDs - UDI assignment and submission of UDI core data elements to the database by 26 May 2022

Class D IVDs

Placement of the UDI carrier (eg barcodes on products) by:

26 May 2023

Class C and B IVDs

26 May 2025

Class A IVDs

26 May 2027


5. Regulation (EU) 2017/746 - 5 May 2017 - Article 113, paragraph 3(e)