Traceability – regulatory aspects

GS1 Healthcare Conference – 10 April 2019

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Medicines and Healthcare Products Regulatory Agency
Key topics

➢ Overview of new Medical Device Regulations

➢ Traceability requirements

➢ Supply chain – recalls – implant cards
New medical device regulations
Two EU Regulations

Medical Devices Regulations

in-Vitro Diagnostic Devices Regulations

UDI assignment and submission of UDI core data elements to the European database by 26 May 2020 (medical devices) or 26 May 2022 (IVDs)

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

IVDR - Regulation (EU) 2017/746 – published 5 May 2017
UDI is one small(!) part of a complete revamp of the European Medical Device (MDR) and IVD (IVDR) regulations.

New European Regulations: major upgrade

- 60 pages
- 23 Articles
- 12 Annexes

Regulation (EU) 2017/745 – 5 May 2017
- 175 pages
- 123 Articles
- 17 Annexes
UDIs enhance traceability and improve post-market 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
# GS1 = UDI

(though other UDI systems may also be acceptable!)

## Translation UDI to GS1

<table>
<thead>
<tr>
<th>UDI</th>
<th>GS1 Standards</th>
</tr>
</thead>
<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 Al(17) e.g. 141120</td>
</tr>
<tr>
<td></td>
<td>• Lot/Batch Al(10) e.g. 1234AB</td>
</tr>
<tr>
<td></td>
<td>• Serial Number Al(21) e.g. 12345XYZ</td>
</tr>
</tbody>
</table>

| DI + PI = UDI | GTIN -or- GTIN + Al(s) = UDI |
Requirements of the European UDI system

**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)

Centralised **European UDI database** (part of Eudamed)
How UDIs should 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
Traceability throughout the supply chain

Manufacturer → importer/distributor → hospital → patient
Recording of UDIs

Manufacturers, importers, distributors and hospitals must store and keep UDIs (both device identifier and production identifiers) by electronic means.
Using UDI / GS1 standards improves patient safety – implant tracking and surveillance

- Implant / patient track-&-trace
- Post-market safety monitoring
MHRA Medical Device Alerts

Medical Device Alert
MDA2015024 Issued: 25 June 2015 at 14:00

Metal-on-metal (MoM) hip replacements: Birmingham Hip™ Resurfacing (BHR) system (Smith & Nephew Orthopaedics)

Summary
Higher than expected revision rate for certain patient groups implanted with the Birmingham Hip Resurfacing (BHR) system. Guidance provided on implantation and patient management.

Action
- Do not implant BHR devices in:
  - male patients
  - patients requiring femoral heads sized 40mm or smaller.
- Only use 48mm BHR heads in the specific circumstance of intra-operative downsizing from a pre-operatively templated 50mm to a measured 48mm at the time of surgery.
- Reﬁn all unused BHR femoral heads sized 40mm and smaller and their corresponding acetabular and dysplasia cups to the manufacturer.
- Follow up patients implanted with BHR hips that fall within the scope of this Medical Device Alert i.e.,
  - asymptomatic patients
  - all female patients
  - all patients implanted with head sizes 40mm or smaller in line with recommendations in the table below (based on the advice given in MDA2012/194)

<table>
<thead>
<tr>
<th>Catalogue number</th>
<th>Unique Device Identifier (UDI)</th>
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</thead>
<tbody>
<tr>
<td>BHR head</td>
<td></td>
</tr>
<tr>
<td>T4130135</td>
<td>000699110053710</td>
</tr>
<tr>
<td>T4130140</td>
<td>000699110053450</td>
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<tr>
<td>T4130142</td>
<td>000699110052773</td>
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<td>T4130151</td>
<td>000699110052148</td>
</tr>
<tr>
<td>T4130146</td>
<td>000699110051816</td>
</tr>
<tr>
<td>BHR acetabular cup</td>
<td></td>
</tr>
<tr>
<td>T4130142</td>
<td>000699110062537</td>
</tr>
<tr>
<td>T4130140</td>
<td>000699110062444</td>
</tr>
<tr>
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<td>BHR Acetabular cup</td>
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<tr>
<td>T4130254</td>
<td>000699110062874</td>
</tr>
</tbody>
</table>

Patient follow-up
- Asymptotically for the life of the implant

Imaging: MRI or ultrasound
- Recommended in all cases

1st blood metal ion level test
- Yes

Results of 1st blood metal ion level test
- Blood metal ion level >700μg/L indicates potential for soft tissue reaction

2nd blood metal ion level test
- Yes - 3 months after 1st blood test if result was >700μg/L

Results of 2nd blood metal ion level test
- Blood metal ion level >700μg/L indicates potential for soft tissue reaction especially if greater than previous

Consider need for revision
- If imaging is abnormal and/or blood metal ion levels rising

Table footnotes:
- Blood metal ion testing is in whole blood
- 7 parts per billion (ppb) equals 1.196 nmol/l, 70 parts per billion (ppb) equals 10.9 nmol/l chromium
Field Safety Corrective Actions and Recalls

Manufacturers should:

➢ Reference UDIs in their Field Safety Notices (FSNs)
➢ Send customers and distributors electronic lists of all products affected by a FSCA in an Excel spreadsheet

"These recommendations give healthcare providers everything they need to implement more automated and secure GS1-based FSCA processes, in line with the Department of Health eProcurement strategy."

- Jackie Pomroy, Head of Supply Chain at NHS South of England Procurement Services
European implant cards
Thank you

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