Use of Real World Evidence under European MDR

Japan-US Harmonization by Doing East 2017 Think Tank meeting
Tokyo - 7 December 2017
Andy Crosbie – Manager, Post Market Surveillance Strategy - MHRA
New European medical device regulations
New medical device regulations
Two EU Regulations - May 2017

Medical Devices Regulations

in-Vitro Diagnostic Devices Regulations

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

IVDR - Regulation (EU) 2017/746 – published 5 May 2017
New European Regulations: major upgrade

  - 60 pages
  - 23 Articles
  - 12 Annexes

- Regulation (EU) 2017/745 – 5 May 2017
  - 175 pages
  - 123 Articles
  - 17 Annexes
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 devices (notified bodies)
- Promoting transparency and traceability (includes mandatory Unique Device Identification)
Recording of UDIs will be mandatory

Manufacturers, importers, distributors and hospitals must store and keep UDIs by electronic means.
UDI improves post-market safety

Using Unique Device Identification (UDI) will facilitate real world data collection/use and enhances device safety:

- improved incident reporting
- better targeting of recalls
- better monitoring by competent authorities
- reduced medical errors
- helps fight against counterfeit devices
- as well as improving purchase-policy and stock-management by hospitals

* Regulation (EU) 2017/745: Recital 41
Scan4Safety programme – Vision

- **Right Patient**: Setting standards to make sure we always have the right patient and know *what* product was used with *which* patient, *when*.
- **Right Product**: Setting standards to make sure our staff have *what* they need, *when* they need it.
- **Right Place**: Setting standards to make sure that patients and products are in the right place.
- **Right Process**: Setting standards and implementing common ways of working to deliver better and more easily repeatable patient care.
UK *Scan4Safety* programme
– Implementation of GS1 *core enablers*

**Deliverables– Initial Core Enablers**

- **Location Identification**
  - Implementing GLNs, a global standard for location identification

- **Patient Identification**
  - Wristbands GSRN compliant can be scanned by patient systems

- **Catalogue Management**
  - All relevant processes use the GTIN as the primary product identifier

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**Unique Location Identification**

**Unique Patient Identification**

**Unique Device Identification**
**Scan4Safety** programme – Demonstrator sites

Established January 2016
Aim to complete first wave of work by December 2017
Scan4Safety – initial successes

Scan4Safety – some of the wins so far:

- Improved control of internal supply chain – cut waste
- Facilitate recalls
- Location of patients and equipment
- Reducing occurrence of critical medical errors - “never events”
- Better information re. operation efficiency

* Regulation (EU) 2017/745: Recital 41
Using UDI / GS1 standards will help to improve patient safety – implant tracking and surveillance

+ convergence with registries / real world data collection

- Implant / patient track-&-trace
- Post-market safety monitoring

More accurate and convenient registry and real world data collection
Thank you

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