Medical Device Regulation & Registries

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NORE and EFORT standing committee

Brussels

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Agenda

- Introduction
- Medical Device Regulation
- CIE Working Group
- Registries & Synergy
Introduction
Medical Devices
Clinical Evaluation

Post-Market & Registry Data

Clinical investigation

Clinical data
Medical Device Regulation
Changes with the MDR

- Size of Regulation
  - 23 – 123 Articles
  - 12 – 16 Annexes

- Legal Basis
  - Directive vs. Regulation
  - MEDDEV / ISO aspects incorporated

- Scope
  - AIMD
  - Annex XVI
MDR - Snapshot

- Common Specifications
- Scrutiny
- High risk devices
- Equivalence
Clinical Evaluation Consultation – ‘Scrutiny’

Criteria
- Novelty
- Risk-benefit
- Incident Reports

Expert Panel Review (CEAR)
- CEAR
- Risk-benefit
- C/W indication
- PMCF

- Due consideration by NB
- PMCF/ indication / SSCP

60 days – scientific opinion
MDR Implementation & CIE Working Group
MDR Implementation Work Packages

1. Clinical Evaluation
2. SSCP
3. Template & Eudamed
4. CIE / IVD Taskforce
Terms of Reference
Work Package 1: Clinical Evaluation

Outputs - guidance on: equivalence & sufficient clinical data (Article 61(6)(a))

Members:

- IE/UK (lead), FR, SE, DE, NL
- TEAM NB, NB MED, EUROMCONTACT, AESGP, MedTec Europe, ESC, COCIR

Timelines – TCs, kick-off meeting MHRA on 9th of February, drafts for public consultation 23 March, finalisation CIE 16-18 April
Work Package 2: SSCP

Outputs - Template and Guidance for SSCP

Members:

- SE (lead), DK
- EUROM VI, TEAM NB, NB MED, EUROMCONTACT, AESGP, MedTec Europe, ESC, COCIR, EPF, CGJA

Timelines – TCs, first draft 8 Feb, kick-off meeting SE on 20 Feb, draft for public consultation 26 Feb, commenting period 26 March, finalisation CIE 16-18 April
Work Package 3: Template & MDR EUDAMED

Outputs

• Template development - CEAR (IE), CI application (BE, IE), CI assessment (UK, CH), PMCF plan and report (BE, IT), SAE (DE, NL)
• The Co-Ordinated CI Assessment Procedure (with a focus on template and EUDAMED functionality)(COM lead)
• Interaction between the CIE and EUDAMED WG

Members: above + EUROM VI, TEAM NB, NB MED, EUROMCONTACT, AESGP, MedTech Europe, ESC, COCIR, CGJA
Call for Experts

Working Groups w.r.t. MDR

Issued by Commission

Expected in May 2018
MDR & Registries
What is a registry?

Generally, it is an **organised system** that collects and maintains structured records on a specific disease, medical product etc. for a specific **time** period and **population**

Range from ward based spreadsheet to large internationally harmonised registries
Elements of a Device Registry

- Observational vs. interventional
- Clinical data vs. other data (for example simply to be able to identify patients with X device)
- Use as intended vs. ‘off-label’ use
- Outcomes to be measured
- Purpose of registry
Registry design

Define the uncertainty to be studied
Long term outcome, sub-population etc.

Determine if a Registry is needed
Can passive PMS systems answer the research question?

Set a plan for data collection + analysis
Consider device iteration and other cofounders

Plan for data governance, sharing + transparency
Consider involving stakeholders early
Timing of outcome reports
Registries and the MDR

- **Registry data given specific emphasis in MDR**
- **Annex VI - Notified bodies** to take registry data into account w/ recertification review
- **Annex XIII - Manufacturers** to review suitable registry data as part of their post-marketing obligations

12/04/2018
MDR & Registries: Synergy
European and other Registry Initiatives

**PARENT** (the cross-border PAtient REgistries iNiTiative), co-funded by the European Commission and a number of Member States

**EUnetHTA** - European network for Health Technology Assessment

International Medical Device Regulators Forum (IMDRF)
Potential Use of Registry Data

- Initial CE marking
- Device tracking to patient level w/ FSCA
- Change to intended use
- PMS / PMCF
- Objective Performance Criteria - OPCs
- Breakthrough products
Integrating Registry Data and Regulation

**Data Sharing**
- Sharing with bodies responsible for safety: MFR / NB / NCA
- Sharing with other registries / researchers
- Harmonised core data set

**Governance**
- Conflict of interest and funding, and transparency
- Plan for data collection, processing

**Clear roles and responsibilities**
- Purpose of registry and data points collected
- Management plan for completeness, data-management, auditing etc.

**Data protection and transparency of data**
- Registry website? Level of access

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Thank You

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