An introduction to the new regulations on medical devices and new provisions related to use of hazardous substances

Workshop | Can the Medical Devices Regulation be an engine for substitution?
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Salvatore Scalzo
Unit D4 - Health Technology and Cosmetics
DG Internal Market, Industry, Entrepreneurship and SMEs
European Commission

Revision of the EU Medical Devices Legislation Background

Directive 90/385/EEC on active implantable medical devices
Directive 93/42/EEC on medical devices

Regulation 2017/745 on medical devices (MDR)

Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDs)

Regulation 2017/746 on *in vitro* diagnostic medical devices (IVDR)

Main features of the new Regulations on medical devices (art 114-168 TFEU)

- ✓ Inclusion of **certain aesthetic devices** within the **scope**.
- ✓ EU minimum requirements related to **reprocessing of single-use devices**.
- ✓ **Stricter pre-market control** of high-risk devices with the involvement of a pool of experts at EU level.
- ✓ 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).
- ✓ **Reinforced designation and oversight** processes of **notified bodies**.
- ✓ Clarification of the role and responsibilities of **economic operators**.
- ✓ **Establishment of a comprehensive EU database on medical devices (EUDAMED)** with large part of information to be made publicly available.
- ✓ Introduction of a **UDI system**.
- ✓ Stricter requirements related to the **use of hazardous substances**.

Transitional period

Key derogations

- 26 November 2017: Requirements on Notified Bodies; designation of Competent Authorities; establishment of MDCG
- 26 May 2018: Cooperation among Competent Authorities
- 26 November 2020: Designation of reference laboratories
- 26 November 2021/2023: Registration of devices
- 26 May 2021/2023/2025 (MD) - 26 May 2023/2025/2027 (IVD): Placement of UDI carrier
- 27 May 2024: Maximum period of validity of certificates issued under current Directives
- 27 May 2025: Making available of devices placed on the market pursuant to current Directives
- 26 May 2027: Coordinated procedure for clinical investigations

Regulation of hazardous substances in medical devices according to the new medical device Regulation 745/2017 (1/2)

- **Conformity assessment of devices**

  - ✓ Manufacturers of medical devices required to provide adequate justification to the Notified Body with regard to the presence of CMR 1A and 1B and/or endocrine disruptors that are (cumulative)

    - ✓ contained in certain medical devices listed in the relevant provisions
    - ✓ above a certain concentration (0.1% weight by weight (w/w))

  - ✓ Justification to be based also on scientific opinions from relevant Scientific Committees (when available)

    - ✓ Commission is required to provide the relevant Scientific Committee (SCHEER) with a mandate to prepare guidelines on the presence of phthalates in devices – guidelines to be adopted by the application date
    - ✓ Commission, whenever appropriate, should mandate the SCHEER to produce guidelines for substances other than phthalates
    - ✓ Those guidelines shall cover at least a benefit-risk assessment of the presence of substances. The benefit-risk assessment shall take into account i.a. any available alternative substances and alternative materials, designs or medical treatments

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- **Transparency**
  - ✓ Presence of hazardous substances (subject to justification) to be indicated on the label of the device (in accordance with provisions laid down in Annex I 10.4.5)
  - ✓ Information labelled in accordance with Annex I 10.4.5 is one of the mandatory UDI data elements to be provided by the manufacturer to the UDI database
    - ✓ UDI data elements are accessible to the public
    - ✓ Future EU medical device nomenclature to enhance database search functions

Implementation: priorities

- **Notified Bodies**
  - ✓ Implementing Act on codes (by 26 November 2017)
  - ✓ Other regulatory and logistical matters related to designation procedures
- **Mandate to SCHEER to produce guidelines on phthalates (completed)**
- **Governance**
  - ✓ Setting up of MDCG (and subgroups)
  - ✓ Establishment of expert panels, expert laboratories and reference laboratories
- **Design and establishment of EUDAMED**
- **Establishment of the UDI system**
- **Common specifications on Annex XVI products**
- **Common specifications on reprocessing**
- **Clarification of certain transitional provisions (cooperation with CAMD)**

Implementation: past meetings and next steps

- **Past meetings**
  - ✓ Joint COM/CAMD workshop with stakeholders on 9 March 2017 and 18 October 2017 – preparation of a roadmap containing list of priorities for the implementation period
  - ✓ EUDAMED: 4 meetings of the Steering Committee and 12 meetings of *ad hoc* Working Groups related to the 1st set of modules: Registration, UDI & Devices, NBs & Certificates and Data Exchange (13 meetings scheduled until April 2018)
  - ✓ Draft Implementing Acts: 4 meetings with Member States on: 27-28 October 2016, 13-14 December 2016, 19 May 2017 and 5 October 2017
- **Next steps (in Autumn)**
  - ✓ Publication of CAMD/COM roadmap – next few weeks
  - ✓ Adoption Implementing Act on Notified Bodies codes: by 26 November 2017
  - ✓ Notified Bodies applications for designation: as from 27 November
  - ✓ Setting–up and first meeting of the MDCG: 28 November 2017
  - ✓ Launch of the procedure for a corrigendum to the two Regulations: December 2017

Thank you
for your attention