Update on EU regulatory developments

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The EU single market for medical devices

1. EU

2. EFTA/EEA: Norway, Liechtenstein, Iceland

3. Turkey

4. Switzerland
The new EU Regulations on medical devices (adopted 5 April 2017 and published 5 May 2017)

Directive 90/385/EEC on active implantable medical devices

Directive 93/42/EEC on medical devices

Regulation on medical devices (MDR)

Directive 98/79/EC on \textit{in vitro} diagnostic medical devices

Regulation on \textit{in vitro} diagnostic medical devices (IVDR)
Main novelties of the new Regulations (1)

- 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).
- Stricter requirements on the use of hazardous substances for certain devices.
Main novelties of the new Regulations (2)

- 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.
- Enhanced cooperation amongst national authorities.
- Stronger coordination role of the European Commission.
Towards implementation
Transitional period

- **Publication of Regulations in Official Journal of European Union and entry into force**
  - May-2017

- **Full application of MDR at 3 years (after entry into force)**
  - May-2020

- **Full application of IVDR at 5 years (after entry into force)**
  - May-2022
COM implementation priorities (1)

- **Notified Bodies**
  - Launch of designation procedure (November 2017)
  - 52 applications received up to date. Full scope of MDR and IVR covered
  - 4 Notified Bodies designated until Aug 2019. 20 Notified Bodies expected for MDR by the end of 2019

- **Governance**
  - Setting up of MDCG (November 2017)
  - MDCG technical subgroups (13) operational as from 1\textsuperscript{st} Mar 2019
  - Work on 70+ guidance documents ongoing or finalised

- **Scientific structures**
  - Establishment of expert panels, expert laboratories and reference labs
  - Act on designation of expert panels adopted on 10 Sep 2019

- **Design and establishment of the new EUDAMED**
  - Plan for implementation of functional specifications (May 2018)
  - Core modules of database to be available by May 2020

- **Establishment of UDI system**
  - 8 guidelines published, nomenclature selected in Feb 2019, designation of issuing entities finalised in Jun 2019, release of Q/A in Aug 2019
COM implementation priorities (2)

- **Mandate for revision of standards** (Q4 2019)
- **Communication campaign**
  - ✓ The new dedicated website and first updated library are live
  - ✓ Release of existing factsheets in all EU languages and some major non-EU languages
  - ✓ Release of new factsheets (healthcare professionals and institutions in June 2019)
- **Common specifications on devices without medical purpose** (expected Q1 2020)
- **Common specifications on reprocessing of single-use devices** (Q4 2019)

Planning of activities:
- Publication of Commission’s rolling plan on DG GROW website
Useful links

camd-europe.eu
> MDR/IVDR implementation

et.europa.eu
> growth > sectors
> register of Commission expert groups > mdcg
> law > better-regulation > have-your-say
Thank you for your attention!

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