Update on EU regulatory developments

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IMDRF – 16
19-21 March 2019
Yekaterinburg, Russia

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 *in vitro* diagnostic medical devices

Regulation on *in vitro* diagnostic medical devices (IVDR)

Main novelties of the new Regulations (1)

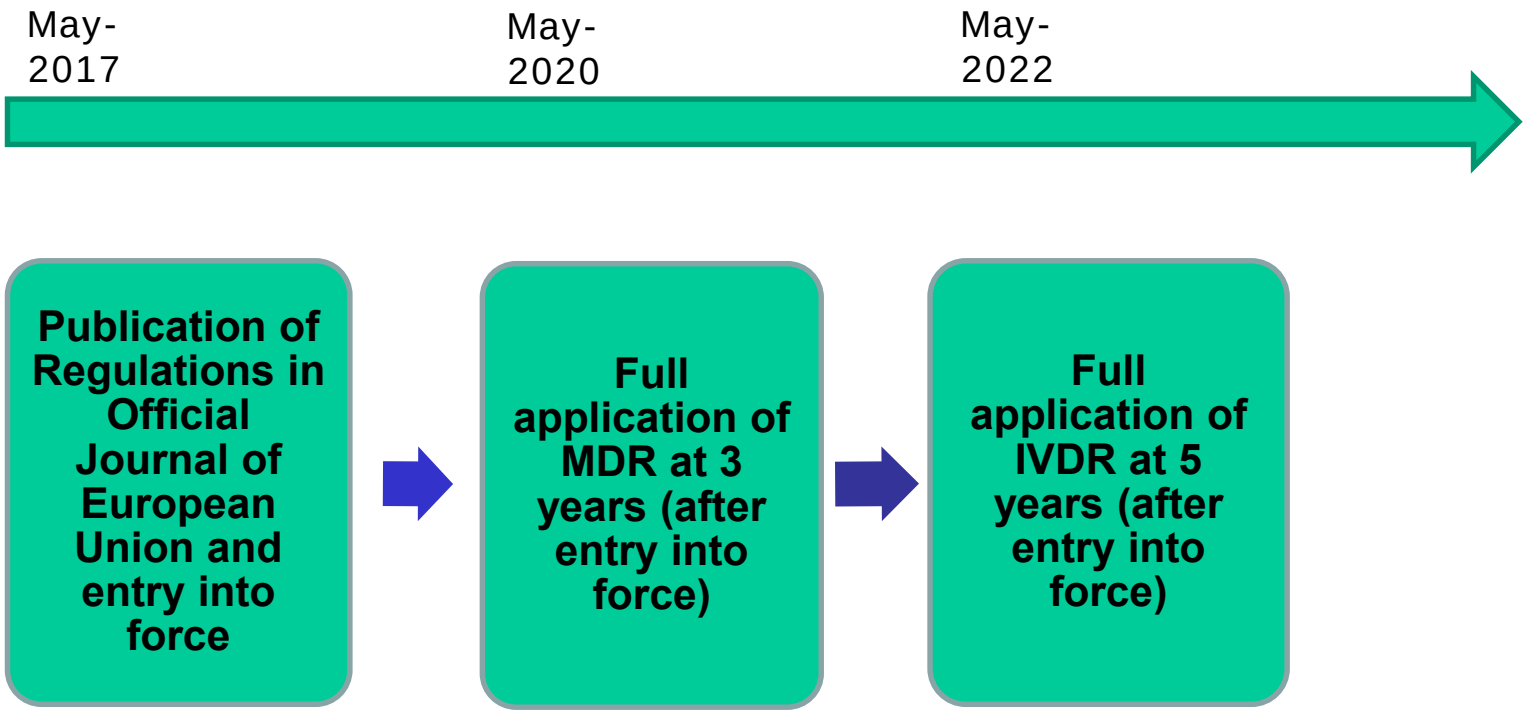
- Inclusion of certain aesthetic devices within the scope.
- EU minimum requirements related to reprocessing of single-use devices.
- Stricter pre-market control of high-risk devices with the involvement of a pool of experts at EU level.
- Reinforcement of the rules on clinical evaluation (and performance 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



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 1st 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

ec.europa.eu

> growth > sectors

> register of Commission expert groups > mdcg

> law > better-regulation > have-your-say

camd-europe.eu

> MDR/IVDR implementation

Thank you for your attention !

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Health Technology and Cosmetics