IMDRF International Medical Device Regulators Forum

Update on EU regulatory developments

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Health Technology and Cosmetics

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The EU single market for medical devices

1. EU

2. EFTA/EEA:
   Norway, Liechtenstein, Iceland

3. Turkey

4. Switzerland

Revision of the EU Medical Devices Legislation

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)

Application dates

- 5 May 2017: Publication of the two Regulations in the Official Journal of the EU
- To be progressively applied over the 3 years (MDR) and 5 years (IVDR) thereafter
- 26 November 2017 (1st deadline): Governance structure was established; Notified Bodies started to submit their applications for designation

The new regulatory framework in the field of medical devices is expected to ensure...

1. Better protection of public health and patient safety
2. Legal certainty and innovation-friendly environment
3. More transparency and patient empowerment
4. Better coordination at the EU level

Main features of the new texts (1)

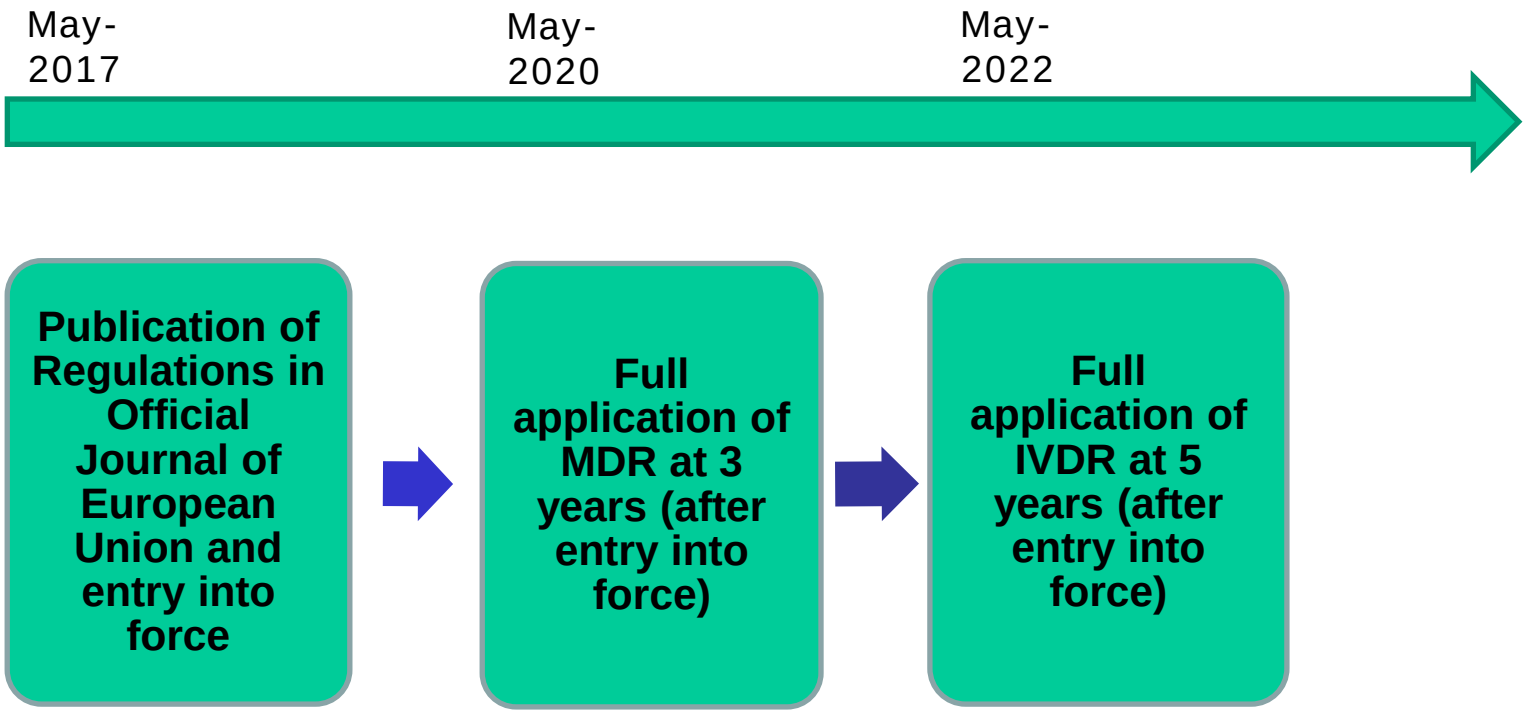
- Stricter pre-market control of high-risk devices with the involvement of a pool of experts at EU level.
- Reinforcement of the criteria for designation and of the oversight processes of notified bodies in charge of certifying medical devices.
- Coverage of certain non-medical products (mainly aesthetics) which present the same characteristics and risk profile as analogous medical devices.
- Introduction of a new risk classification system for in-vitro diagnostic medical devices based on international guidance.
- Improved transparency through the establishment of a comprehensive EU database on medical devices.
- Stricter regime related to the use of hazardous substances

Main features of the new texts (2)

- Introduction of an EU-wide requirement for an “implant card” to be provided to patients containing information about implanted medical devices.
- Reinforcement of the rules on clinical investigation, including an EU-wide coordinated procedure for the authorisation of clinical investigation on medical devices taking place in more than one Member State.
- Reinforced requirements for manufacturers to collect and analyse data about the real-life use of their devices.
- Improved coordination between Member States in the fields of vigilance and market surveillance.
- The introduction of a UDI (Unique Device Identification) system and strengthening of the device traceability system.
- Role and responsibilities of economic operators. Certain new obligations for authorised representatives.

Towards implementation

Transitional period



Implementation: Main steps completed

- **Notified Bodies**
  - ✓ Implementing Act on codes (by 26 November 2017)
  - ✓ Guidance related to application and designation procedures

- **Governance**
  - ✓ Setting up of Medical Device Coordination Group (MDCG) (by 26 November 2017)
  - ✓ 1st MDCG meeting took place on 28 November 2017: endorsement of Rules of Procedure and Terms of Reference

Implementation: next priorities

- **Notified Bodies**
  - ✓ Other regulatory and logistical matters related to designation procedures
- **Governance**
  - ✓ Setting up of MDCG expert groups
  - ✓ Establishment of expert panels, expert laboratories and reference laboratories
- **Launch of Communication campaign (expected in April)**
- **Design and establishment of EUDAMED**
- **Establishment of the UDI system**
- **Common specifications on devices without a medical purpose**
- **Common specifications on reprocessing of single-use devices**

Thank you for your attention !

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