IMDRF International Medical Device Regulators Forum

Update on EU regulatory developments

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Health Technology and Cosmetics

IMDRF – 11
14-16 March 2017
Vancouver, CANADA

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

-Background-

Directive 90/385/EEC on active implantable medical devices

Directive 93/42/EEC on medical devices

Proposal for a Regulation on medical devices

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

Proposal for a Regulation on *in vitro* diagnostic medical devices

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

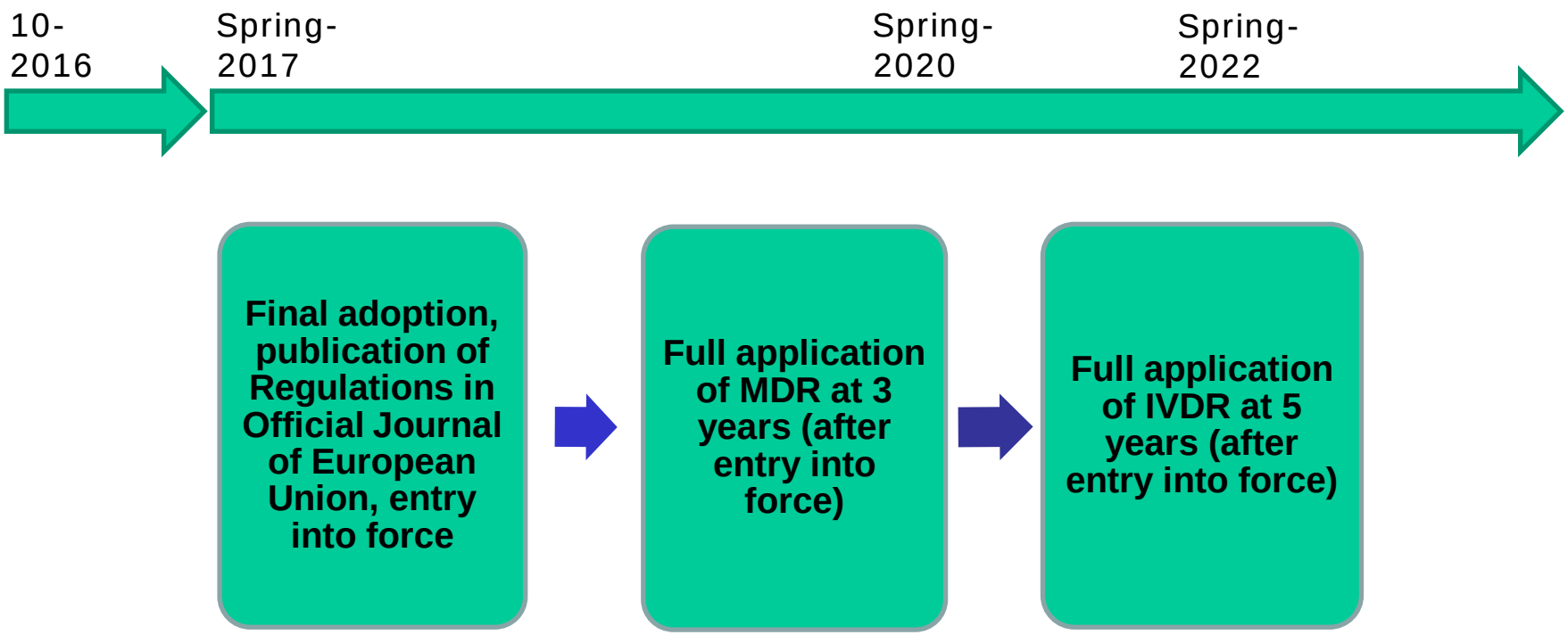
Main features of the new texts (2)

- 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.

State of play and next steps

- 26 September 2012: adoption of the two Commission proposals on medical devices and IVDs
- 15 June 2016: Council and Parliament reached agreement on the final text
- Spring 2017 (expected): Adoption
- To be progressively applied over the 3 years (Medical Devices) and 5 years (IVDs) thereafter

Towards implementation


10-2016
Spring-2017
Spring-2020
Spring-2022
Final adoption, publication of Regulations in Official Journal of European Union, entry into force
Full application of MDR at 3 years (after entry into force)
Full application of IVDR at 5 years (after entry into force)

Implementation: Commission priorities

Notified Bodies (details of application, fees and reimbursements related to JAs) – 6 months

Governance: Setting up of the Medical Device Coordination Group (MDCG)* - 6 months

Common specification on devices without a medical purpose and reprocessing of single-use devices – date of application MDR (3 years)

EUDAMED – date of application (3/5 years)

*The MDCG is the main body supporting the Commission in implementing the future Regulations. It comprises representatives from National Authorities and is chaired by the Commission

Thank you for your attention !

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