IMDRF International Medical Device Regulators Forum

# Update on EU regulatory developments

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# 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**

# Revision of the EU Medical Devices Legislation

## - State of play -

- 26 September 2012: adoption of the two Commission proposals on medical devices and IVDs
- 2 April 2014: European Parliament adopts its first reading
- 5 October 2015: Council agrees on a 'general approach'
- 15 June 2016: Council and Parliament reach political agreement on the two Regulations, endorsed by Health Ministers on 17 June 2016.

# Next steps: timeline

- Formal Council political agreement in the early autumn followed by a legal linguistic check
- Adoption of the Council's first reading position  end 2016
- EP second-reading vote end 2016/ early 2017
- Entry into force on the twentieth day after its publication in the OJ
- Date of application: from three (MD)/ five (IVD) years after entry into force

# Main changes introduced by the new Regulations 1/2

- Inclusion of certain aesthetic products which present the same characteristics and risk profile as analogous medical devices under the scope of these Regulations;
- Introduction of a new risk classification system for diagnostic medical devices based on GHTF guidance;
- Reinforcement on the rules on clinical data, including an EU-wide coordinated procedure for the authorisation of multi-centre clinical studies on device;
- Stricter and clearer obligations for economic operators;
- Further reinforcement of the criteria for designation and processes for oversight of notified bodies in charge of certifying medical devices;

# 2/2

- Stricter pre-market control of high-risk devices with the involvement of a pool of experts at EU level;
- Reinforced requirements for manufacturers to collect data about the real-life use of their devices;
- Improved coordination between Member States in the fields of vigilance and market surveillance;
- Improved transparency through further development of the EU database on medical devices and of a device traceability system;
- Introduction of an EU-wide requirement for an “implant card” to be provided to patients containing information about implanted medical devices.

# Thank you for your attention !

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