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 \textit{in vitro} diagnostic medical devices

Proposal for a Regulation on \textit{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'
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;
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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