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 -

- **European Parliament** 1st reading vote: 2 April 2014
- **Council**: discussions on the proposals ongoing - More than 30 meetings of the Council Working Party under CY, IE, LT, EL and IT PRES.
Main issues subject to debate:

- the pre-market control of high-risk medical devices;
- the designation, monitoring and functioning of notified bodies;
- the reprocessing of single-use medical devices;
- the risk classification of certain medical devices;
- CMR substances and endocrine disruptors;
- vigilance;
- the in-house exemption for high-risk IVDs;
- counselling and informed consent in the case of genetic tests
In the meantime…

- The Commission and the Member States have been implementing the **Joint Plan for Immediate Action** under the existing legislation in order to tighten up controls and improve patient safety.

- A **Staff Working Paper** was published in June 2014 outlining the results of the Joint Plan for Immediate Action, which have been achieved until now and providing proposals for its continuation.

Thank you for your attention!

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