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 and next steps -

- European Parliament 1st reading vote: 2 April 2014
- Council: Adoption of a partial (without recitals) general approach on 19 June 2015
- Adoption of a full general approach by the Council foreseen at the beginning of October 2015
- Expected date for starting of the trilogue: October 2015
- Expected date for final adoption: end of 2015/beginning of 2016
Where we are now
Main issues to be discussed during the trilogue:

- **pre-market control** of high-risk medical devices;
- **reprocessing** of single-use medical devices;
- products without a medical purpose (**aesthetic products**);
- use of hazardous substances;
- certain exemptions for in-house medical devices and IVDs;
- **counselling and informed consent** in the case of genetic tests;
In the meantime…

• The Commission and the Member States are implementing the **Joint Plan for Immediate Action** in order to tighten up the application and controls under the existing legislation.

• A **Staff Working Paper** was published in June 2014 outlining the results of the Joint Plan for Immediate Action, which had been achieved until then.

• The Commission and the Member States are now implementing a second step of measures agreed by Health Ministers.

Thank you for your attention!

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