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 and next steps-

- European Parliament 1st reading vote: 2 April 2014
- Council: Adoption of a general approach by the Council on 5 October 2015
- Opening of the informal trilogue with European Parliament and Council on 13 October 2015: seven trialogues took place so far

- Expected date for political agreement: mid 2016
The “Ordinary legislative procedure” (ex “co-decision”)

Where we are now
"Nothing is agreed until everything is agreed"

Main issues to be discussed during remaining negotiations:

• pre-market control of high-risk medical devices;
• reprocessing of single-use medical devices;
• use of hazardous substances;
• 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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