Update on EU regulatory developments

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IMDRF – 7
24-26 March 2015
Tokyo, JAPAN
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-

- European Parliament 1st reading vote: 2 April 2014
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 regulation of certain products without a medical purpose (**aesthetic products**);
- **CMR** substances and endocrine disruptors;
- the **in-house** exemption for high-risk IVDs;
- **counselling and informed consent** in the case of genetic tests;
- New **device identification and traceability requirements** and obligations of economic operators
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 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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