IMDRF International Medical Device Regulators Forum

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-

- **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.

- The text of this Staff Working Document is available at http://ec.europa.eu/health/medical-devices/files/swd_pip_14_en.pdf -

Thank you for your attention !

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