IMDRF International Medical Device Regulators Forum

Update on EU regulatory developments

Erik Hansson

European Commission
Health Technology and Cosmetics

IMDRF – 7
24-26 March 2015
Tokyo, JAPAN

IMDRF International Medical Device Regulators Forum

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

IMDRF International Medical Device Regulators Forum

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 40 meetings of the Council Working Party under CY, IE, LT, EL, IT and LV Presidencies.

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.

- 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 !

Erik Hansson

European Commission
Health Technology and Cosmetics