IMDRF International Medical Device Regulators Forum

Update on EU regulatory developments

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IMDRF – 9
08-10 March 2016
Brasilia, BRASIL

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

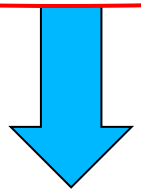
Directive 98/79/EC on *in vitro* diagnostic medical devices

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 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

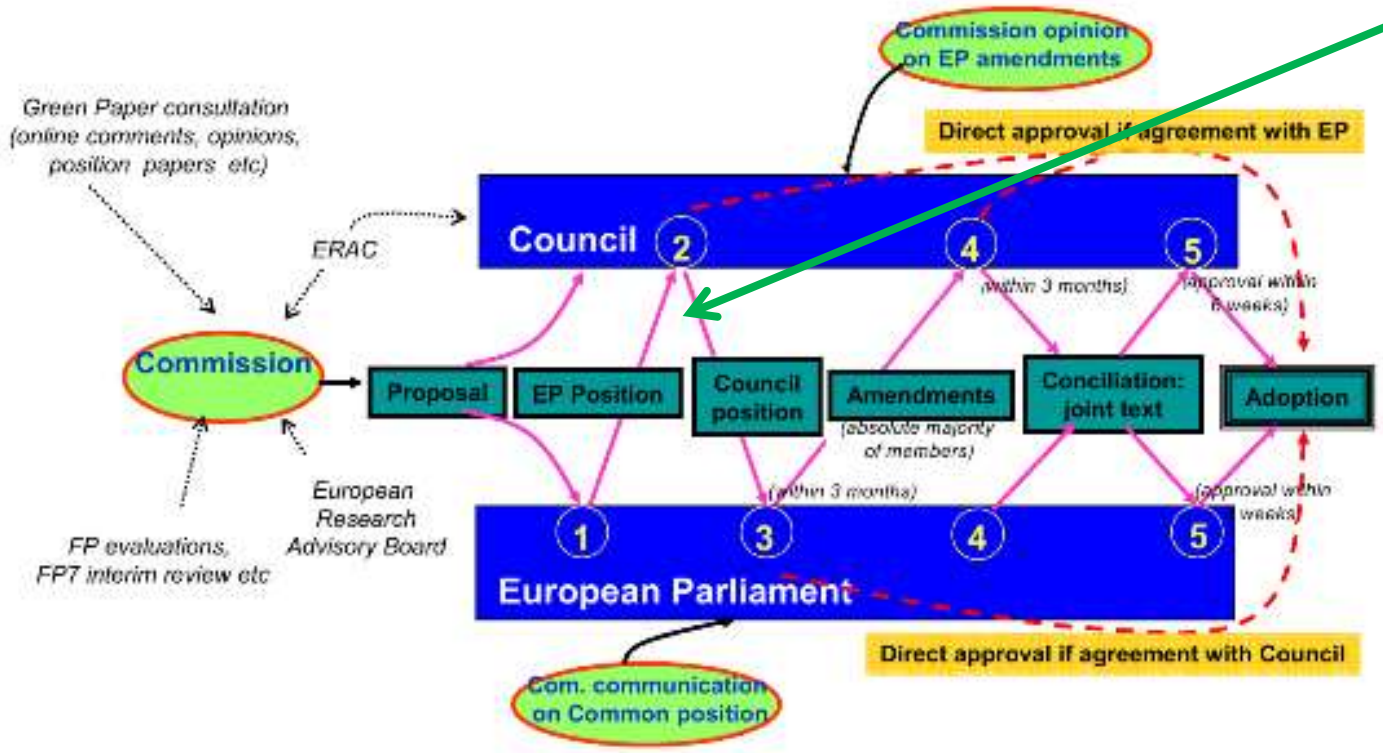


- Expected date for political agreement: mid 2016

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.

- 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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