Revision of the medical devices legislation

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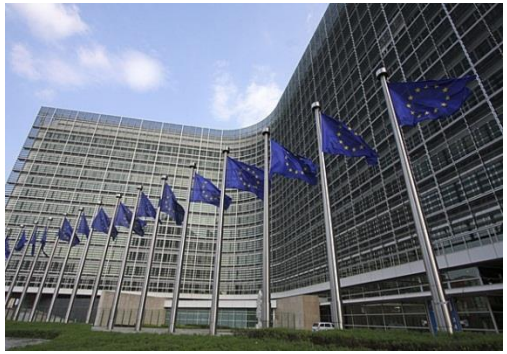
Revision of the legislation

European Commission
Proposes legislation
(Proposals : 26/9/2012)



European Parliament
Proposes amendments
(1st reading vote : 2/4/2014)

Negotiation

Council of the EU
Towards a Council position

Revision of the legislation

European Parliament:

- First reading plenary vote on 2nd April 2014
- Mandate to enter into trialogues on 5th November 2014

- **Main issues:**
  - ✓Pre-market assessment of high-risk IVDs
  - ✓Reprocessing of single-use devices
  - ✓Counselling and informed consent – genetic testing

Revision of the legislation

Council:

- Over 45 meetings of the Council Working Party
- LV Presidency's goal: agreement in Council

- **Main issues:**
  - ✓Pre-market assessment of high-risk IVDs
  - ✓Reprocessing of single-use devices
  - ✓Regulation of in-house tests

Revision of the legislation

- **Aims at solving problems relating to:**
  - ✓ Scope of the legislation
  - ✓ Risk classification and safety and performance requirements
  - ✓ Designation and monitoring of notified bodies
  - ✓ Obligations of notified bodies
  - ✓ Scrutiny mechanism for high risk devices

Revision of the legislation

- ✓Obligations of economic operators
- ✓Reprocessing of single-use medical devices
- ✓Clinical evidence
- ✓Vigilance and market surveillance
- ✓Eudamed
- ✓Traceability of devices
- ✓Governance of the system and transparency
- ✓Alignment on international guidance

Implications for HTA

- ✓ Specific considerations going beyond the requirements for placing on the market
- ✓ Sufficient and more robust clinical data
- ✓ Possible future involvement of panels of scientific experts
- ✓ Better information exchange between authorities as regards the real-life performance of devices

Thank you!