CONFERENZA NAZIONALE CNDM SUI DISPOSITIVI MEDICI

State of the Art of the New Medical Devices Legislation Approval Process

Sabine Lecrenier
DG Health and Consumers
European Commission

Direzione Scientifica
Direzione Generale dei Dispositivi Medici del Servizio Farmaceutico
e della Sicurezza delle Cure del Ministero della Salute

Revision of the Medical Devices Legislation

- Proposal for a Regulation on Medical Devices

and

- Proposal for a Regulation on *In Vitro* Medical Devices

adopted by the Commission in September 2012

Towards increased patient safety

- Measures adopted under the ***Joint Plan for immediate actions*** to reinforce patient safety within the limits of the current legislation:
  - Recommendation on a Unique Device Identification System;
  - Commission Regulation to ensure a consistent application of the criteria to be met by Notified Bodies;
  - Recommendation clarifying the tasks these bodies have to undertake when they perform audits and assessments in the medical devices sector;
  - Joint audits of Notified Bodies;
  - Monthly vigilance teleconferences.

Towards increased patient safety

- **Need for a revised legislation** to address:

- the **scope** of the legislation, which needs to be clarified;
- the **governance** of the system and its transparency, which need be strengthened;
- the obligations upon **Notified Bodies**, in particular, as regards unannounced audits, which need to be reinforced;
- the **risk classification** of devices and the safety and performance requirements, which need be adapted to technological and scientific progress;
- the obligations of **economic operators**, which need to be clarified;
- the **traceability** of devices, which needs to be improved.

Revision of the Medical Devices Legislation

- **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.

State of play of the legislative procedure

- In the **European Parliament:**
  - **IMCO and EMPL committees:** opinions adopted in June 2013;
  - **ENVI committee:** reports adopted in September 2013;
  - **Plenary vote** on a **mandate** to start trialogues: on 22 October 2013.

- In **Council**:
  - first examination of around 80% of the two proposals.

- **Objective**: adoption of the two Regulations under the current legislature

Pre-market control of high-risk devices

- Proposals made by the **European Parliament**: **case-by-case assessment by the Medical Devices Coordination Group ('MDCG')**, assisted by a committee of scientific experts, focused on clinical aspects.

- Divergent positions of **Member States**.

- **Importance** of the **scrutiny mechanism** in the pre-market phase.

Notified bodies

- **Parliament and Council**: good proposals to strengthen the designation, monitoring and functioning of notified bodies.
- **Parliament**: separate designation of "special Notified Bodies" competent for high-risk devices by the European Medicines Agency (‘EMA’).
- Need to **carefully assess** the added value of **EMA involvement**, as well as the necessary resources and financing.

Reprocessing of single-use medical devices

- **Proposals** made by the **European Parliament**:
  - System whereby all medical devices are considered as suitable for reprocessing and reusable;
  - Reprocessor must provide scientific evidence that a single-use device could be safely reprocessed and is considered as the manufacturer in terms of liability;
  - Commission to adopt, by implementing acts, quality and safety standards for reprocessing of single-use devices;
  - Possibility for Member States to ban the practice on their territory.

Reprocessing of single-use medical devices

- **Divergent views** among the Member States:
  - Some have had a positive experience and would like to continue regulating the practice at national level;
  - Others have strong reservations and would prefer an outright prohibition;
  - Many Member States welcome the pragmatic approach proposed by the Commission.

- Need to ensure the **highest and most homogeneous level of protection of health and safety**.

Conclusion

Importance of a rapid adoption of the new legislation for consumer and patient safety and the competitiveness of the sector

Thank you!

European Commission
Health and Consumers Directorate-General

Health Technology and Cosmetics Unit

http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm