New EU legislation on Medical Devices

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Presentation

- Drivers for change
- Commission proposals
- State of play in negotiations
- What do we do in the meantime?
Medical devices = essential for healthcare
Medical devices sector = growth & competitiveness

European Union

One of the largest markets
Some of the biggest companies
Ecosystem of SMEs / micro-enterprises
EU regulatory framework
- drivers for change

➢ Three directives transposed into national legislation based on common EU regulatory principles ("the New approach")

➢ From 12 to 33 countries - divergences in application and shortcomings in coordination
EU regulatory framework - drivers for change (continued)

- Technical and healthcare developments
  - Scientific and technological advances,
  - More focus on prevention, early diagnosis, self-monitoring and cost-effectiveness,
  - Evolving knowledge and expectations

- Globalisation

- Public expectations following the PIP breast implants scandal
Revision of the legislation - background

- Public consultation launched in 2008

- Build on the strengths …
  - Balance between pre- and post-market control
  - Flexible - Supportive to innovation
  - High safety levels
  - Rapid access to market - Cost-effective and SME friendly

- … but adapt and improve
Revision of the legislation

➢ 26 September 2012:

✓ Commission proposal for a Regulation on medical devices

✓ Commission proposal for a Regulation on in vitro diagnostic medical devices
Revision of the legislation (continued)

Aims at solving problems relating to:

- Scope of the legislation
- Governance of the system and transparency
- Obligations of notified bodies
- Clinical evaluation
- Risk classification and safety and performance requirements
Revision of the legislation (continued)

- Obligations of economic operators
- Vigilance and market surveillance
- Eudamed
- Traceability of medical devices

➢ High priority for European Commission

Proposed transition periods:
- Three years (MD)
- Five years (IVD)
Revision of the legislation (continued)

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

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

Council of the EU
Proposes amendments
(Process ongoing)

Negotiation
Example of issue debated: 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.

✓ Commission: scrutiny mechanism important.
Example of issue debated: 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’).

- **Commission**: need to **carefully assess** the added value of EMA involvement, as well as the necessary resources and financing.
Example of issue debated: Reprocessing of single-use medical devices

✓ Proposals made by the European Parliament:
  • All medical devices are considered suitable for reprocessing and reusable;
  • Reprocessor must provide scientific evidence;
  • Commission to adopt standards for reprocessing;
  • Possibility for Member States to ban the practice on their territory;

✓ Diverging views between Member States

✓ Commission: Commission proposal balanced approach
What do we do in the meantime?
Plan for immediate actions after PIP scandal

- Objective: strengthen controls on medical devices under the current regulatory system

- 4 pillars:
  - Functioning of notified bodies (NB)
  - Market surveillance
  - Coordination in vigilance and market surveillance
  - Communication and transparency
Plan for immediate actions after PIP scandal (continued)

Achievements:

- Re-assessment of qualifications and scope of activities of NBs
- Voluntary and mandatory joint audits of NBs
- 2 Commission acts
  - Criteria to be met for the designation of NB
  - Items to be verified by NB during an audit
- Monthly vigilance teleconferences
Plan for immediate actions after PIP scandal (continued)

➢ Achievements:

✓ Analysis of trends on incidents
✓ Commission Recommendation on traceability
✓ Dialogue with Member States on registers
✓ Report from Member States on market surveillance activities
Commission Staff Working Document on the implementation of the Joint Plan for Immediate Actions under the existing Medical Devices legislation and further steps

Deepening:

- Market surveillance
- Co-ordination and communication
- Use of registers
- Trend detection
- Peer training

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