Regulatory framework for medical devices

Technology and Innovation of Human Implants

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Revision of the EU Medical Devices Legislation Background

Directive 90/385/EEC on active implantable medical devices
Directive 93/42/EEC on medical devices

Regulation on medical devices

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

Regulation on in vitro diagnostic medical devices

The new regulatory framework in the field of medical devices is expected to ensure...

- Better protection of public health and patient safety
- Legal certainty and innovation-friendly environment
- More transparency and patient empowerment
- A more European approach

Reinforced provisions on clinical evidence with special relevance for implants

- ✓ Clinical evaluation of class III implants reviewed by an EU-level expert panel, certificates notified to CA
- ✓ Compulsory clinical investigation (single-country or coordinated assessment) except if modified or equivalent
- ✓ Provisions on equivalence; guidance on equivalence, sufficient clinical data etc in preparation
- ✓ Detailed provisions for post-market clinical follow-up

Transparency and patient empowerment

- ✓ EU database on medical devices (Eudamed) with parts available to the public
- ✓ UDI traceability system
- ✓ 'Implant card' for patients with safety information about implanted device
- ✓ Summary of safety and clinical performance publicly available

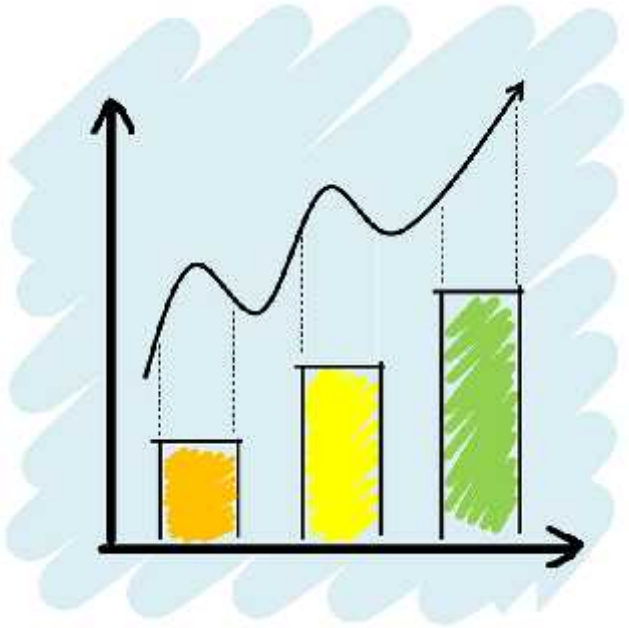
- ✓ New obligations for manufacturers and authorised representatives, aimed at protecting harmed consumers/ patients including financial coverage for liability

Special categories of devices

- ✓ Specific regime applicable to devices manufactured and used in the same health institution
- ✓ Special provisions for custom-made and investigational devices
- ✓ Stricter requirements related to the use of hazardous substances for certain devices
- ✓ For devices containing medicinal products or non-viable tissues and cells, consultation of EMA or Competent Authority

Data collection and analysis

- ✓ Post-market surveillance system of the manufacturer
- ✓ Periodic safety update reports sent by manufacturer to notified body
- ✓ Analysis of trends and signals in vigilance data in Eudamed
- ✓ COM and Member States shall encourage establishment of device registers and databanks



Thank you
for your attention