A revised EU framework for medical devices

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Health and Consumers

Current regulatory framework for medical devices

- **Dir. 90/385/EEC** on active implantable medical devices
- **Dir. 93/42/EEC** on medical devices
- **Dir. 98/79/EC** on *in vitro* diagnostic medical devices

Current regulatory framework for medical devices

Main objectives

- High level of **patients and users safety**
- **Free movement of devices** within the EU internal market

Current regulatory framework for medical devices

Main strengths

- **Flexibility**
- **Cost-effectiveness**
- **SMEs** friendly
- Support to **innovation** and **competitiveness**

Revision of the current regulatory framework for medical devices: Why?

Main reasons

- To adapt to **technological and scientific progress**
- To address the **weaknesses of the system**
- To provide **transparency**
- To ensure a **uniform application of the rules**
- To take over **international developments**
- To respond to **public expectations**

Future regulatory framework

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- Communication on safe, effective and innovative medical devices and *in vitro* diagnostic medical devices for the benefit of patients, consumers and healthcare professionals

- Proposal for a Regulation of the European Parliament and of the Council on **medical devices**

- Proposal for a Regulation of the European Parliament and of the Council on ***in vitro* diagnostic medical devices**

Impact Assessment

Problems definition

- Oversight of Notified bodies
- Post-market safety (Vigilance and Market Surveillance)
- Regulatory status of products
- Lack of transparency and harmonised traceability
- Access to external expertise
- Unclear and insufficient obligations and responsibilities for economic operators
- Management of the regulatory system

Impact Assessment

Overall objectives

- Ensure a high level of protection of human health and safety
- Ensure the smooth functioning of the internal market
- Provide for a regulatory framework which is supportive of innovation and competitiveness

Specific objectives

IA – specific issues for MD

- Scope - regulatory gaps and uncertainties
- Adaptation of requirements to technological, scientific and regulatory developments
- Clinical evaluation and clinical investigations

IA - Specific issues for IVD

- Scope - regulatory gaps or uncertainties
- Classification of IVD and their conformity assessment
- Adaptation of requirements to technological, scientific and regulatory developments

PIP stress test

- Reinforced role of Notified Bodies
- Implant card
- Person responsible for regulatory compliance

Future regulatory framework

Main changes

- Scope
- Pre-market obligations
- Post-market obligations
- Transparency
- Governance

Future regulatory framework: main changes

Scope

- Products manufactured utilising **non-viable human tissues/cells**
- Invasive **devices without medical purpose** (*e.g.* aesthetic)
- **Reprocessing** of single-use devices
- **Genetic tests**
- **Companion diagnostics**
- **"In house" tests**
- Devices used for **diagnostic services at a distance**

Future regulatory framework: main changes

Risk classification for MD adapted

- **Experience on the application of the current rules**
  Examples: in vitro fertilisation products
- **Scientific and technological progress**
  Examples: devices containing nanomaterials
- **Vigilance issues**
  Examples: devices used for apheresis
- **Development at international level (GHTF)**

Future regulatory framework: main changes

New risk classification for IVD

- **Class A** : Low Individual Risk and Low Public Health Risk

  Example: specimen receptacles

- **Class B** : Moderate Individual Risk and/or Low Public Health Risk

  Example: vitamin B12 tests

- **Class C** : High Individual Risk and/or Moderate Public Health Risk

  Example: genetic tests

- **Class D** : High Individual Risk and High Public Health Risk

  Example: HIV tests

Future regulatory framework: main changes

Notified Bodies

- Stricter and more detailed **minimum legal requirements**
- Uniform practice for **designation and monitoring**
- **"Joint assessment"** for new designations and monitoring

Future regulatory framework: main changes

Notified Bodies

- **Unannounced factory inspections, testing of products**

- **Rotation of the personnel**

- **"Scrutiny mechanism"** for high risk devices

Future regulatory framework: main changes

Clinical evidence

—**Clinical data** to be submitted for pre-market assessment

—**Post-market (clinical) follow-up**

—Rules on **clinical investigations / clinical performance studies** and assessment coordination

Future regulatory framework: main changes

Vigilance and market surveillance

- **Centralised reporting of serious incidents**
- Enhanced **coordination between national CAs**
- **Trend analysis**
- **Community measures**
- Strengthened **involvement of HC professionals and patients**

Future regulatory framework: main changes

Transparency

- **Central registration** system **for devices and operators**
- **Summary of safety and (clinical) performance**
- **Unique Device Identification**
- **Implant card**

Future regulatory framework: main changes

Governance

- Harmonised interpretation and implementation:
  Medical Device Coordination Group

- **Scientific, technical and logistic support** (incl. IT infrastructure) by the Commission;

- **Cross-sectoral solution of borderline cases**

Future regulatory framework: main changes

Access to external expertise

Designation of "**EU reference laboratories**" to provide scientific advice and technical assistance to the Commission, MS and NBs.

THANK YOU FOR YOUR ATTENTION!

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