Major provisions of the new medical devices regulations

Performance assessment and standardization in biophotonics

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

1. Better protection of public health and patient safety
2. Legal certainty and innovation-friendly environment
3. More transparency and patient empowerment
4. A more European approach
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 \textit{in vitro} diagnostic medical devices

Regulation on \textit{in vitro} diagnostic medical devices
Major timelines

- 26 September 2012: adoption of the two Commission proposals on medical devices and IVDs
- 5 April 2017: final adoption of the new Regulations
- 5 May 2017: publication of the new Regulations in the EU Official Journal
- 25 May 2017: entry into force of the two Regulations
- To be progressively applied over the 3 years (Medical Devices) and 5 years (IVDs) thereafter

Already applicable as from 26 November 2017:
- Medical Device Coordination Group (MDCG)
- Notified Body designation process
1. Better protection of public health and patient safety
- **Stricter pre-market control** of high-risk devices with the involvement of a pool of experts at EU level.
- Inclusion of **certain aesthetic devices** within the **scope**.
- **Reinforced designation and oversight** processes of **notified bodies**.
- Reinforcement of the rules on **clinical evaluation** (and performance evaluation) and **clinical investigation** (and performance studies)
- **Stricter rules for "substance-based" devices**
- **New classification system for IVDs** based on international guidance (80% of IVDs to be assessed by a Notified Body)
- Stricter requirements related to the **use of hazardous substances** for certain devices
- Introduction of a **UDI system**
2. Legal certainty and innovation-friendly environment
✓ Use of a **EU regulations** as a regulatory tool

✓ **Clarification of the scope** for both MD and IVDs.

✓ Stronger role for the Commission in the context of decisions on the **regulatory status of products**.

✓ Clarification of the specific regime applicable to **devices manufactured and used in the same health institution**.

✓ Clarification of the **role and responsibilities of economic operators**.

✓ New dedicated rules for **medical software and medical apps**.
3. More transparency and patient empowerment
Establishment of a comprehensive EU database on medical devices (EUDAMED) with large part of information to be made publicly available

Introduction of an EU-wide requirement for an 'implant card' to be provided to patients containing information about implanted medical devices

Summary of safety and clinical performance for all Class III and implantable devices available in EUDAMED

New obligations for manufacturers and authorised representatives, aimed at protecting damaged consumers/patients
4. A more European approach
✓ **Registration of devices and economic operators** at the EU level

✓ **Improved coordination between Member States** in the fields of **vigilance and market surveillance**.

✓ Confirmation and strengthening of the **EU joint assessment** procedure for notified bodies

✓ Introduction of a **coordinated assessment of clinical investigations** conducted in more than one Member State
The European governance map

- DG GROW – Policy & implementing legislation
- DG SANTE Unit F – Notified Body Joint Assessment
- DG JRC – Joint Research Centre Scientific and technical aspects

European Commission

Competent Authorities

Medical Device Coordination Group

Competent Authorities for Medical Devices

- Working Group
- Working Group
- Working Group
Coordination Group of Notified Bodies (Art. 49 MDR/45 IVDR)

Cluster A (Pre-market)
- WG1: NB oversight and JA
- WG2: Standards

Cluster B (Post-market and clinical)
- WG3: Clinical
- WG4: PMS and vigilance
- WG5: Market surveillance

Cluster C (Borderline issues and new technologies)
- WG6: Borderline and classification
- WG7: New technologies (including software, apps and cybersecurity)

Cluster D (Systems)
- WG8: EUDAMED
- WG9: UDI

Cluster E (International matters)
- WG10: International matters

Cluster F (IVDs)
- WG11: Implementation of IVD-specific aspects of the IVDR

MDCG consultation with stakeholders

Committee on Medical Devices (Art. 114 MDR/107 IVDR)
Implementation (1): Main steps completed

- **Notified Bodies**
  - Implementing Act on codes (26 November 2017)
  - Other regulatory and logistical matters related to designation procedures

- **Governance**
  - Setting up of MDCG (26 November 2017)
  - 5 MDCG meetings: endorsement of Rules of Procedure and Terms of Reference, guidance for NBs, endorsement of MIR form, UDI guidance, requirements for medical devices nomenclature

- **Mandate to SCHEER to produce guidelines on phthalates** – accepted by SCHEER in September 2017

- **Publication of a COM/CAMD roadmap containing the list of priority work items (including guidance) per subject to be finalised during the transitional period**

- **COM/CAMD workshops with stakeholders on 9 March 2017 and 18 October 2017**

- **EUDAMED**: more than 25 meetings of the Steering Committee and of ad hoc Working Groups related to the different modules

- **Clarification of transitional provisions** – 1st Q/A paper published on the CAMD website in January 2018
Implementation (2): Main steps completed

● Short term
  ✓ Next meeting of MDCG: December 2018
  ✓ Publication of first UDI guidance and requirements for medical device nomenclature: March 2018
  ✓ Launch of Communication campaign: beginning of April 2018
  ✓ EUDAMED functional specifications: by 31 October 2018
  ✓ Setting up of MDCG subgroups: by 30 November

● Medium-long term – main next steps
  ✓ Common specifications on Annex XVI products
  ✓ Common specifications on reprocessing
  ✓ Establishment of expert panels, expert laboratories and reference laboratories
  ✓ Establishment of the UDI system
  ✓ Design and establishment of EUDAMED
Thank you for your attention