Shifting paradigms for high-risk devices

Objectives of the new regulations

European Society of Cardiology

Brussels, 21 March 2018

Salvatore D’ACUNTO
Head of Unit
Health Technology and Cosmetics
DG Internal Market, Industry, Entrepreneurship and SMEs
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
Main features of the new texts

✓ Inclusion of certain aesthetic devices within the scope.
✓ EU minimum requirements related to reprocessing of single-use devices.
✓ Stricter pre-market control of high-risk devices with the involvement of a pool of experts at EU level.
✓ Reinforcement of the rules on clinical evaluation (and performance evaluation) and clinical investigation (and performance studies).
✓ Stricter requirements on the use of hazardous substances for certain devices.
✓ New classification system for IVDs based on international guidance (80% of IVDs to be assessed by a Notified Body).
✓ Establishment of a comprehensive EU database on medical devices (EUDAMED) with large part of information to be made publicly available.
✓ Introduction of a UDI system.
✓ Reinforced designation and oversight processes of notified bodies.
✓ Clarification of the role and responsibilities of economic operators.
✓ Stronger cooperation amongst national authorities.
✓ Enhanced role of the European Commission.
Reinforced coordination

- Medical Device Coordination Group (MDCG) and subgroups
  - Experts representing national authorities (MD and IVD), group for consultation of stakeholders
  - Chaired by the European Commission
- Technical, scientific and logistic support
  - European Commission: DG GROW, DG SANTE and DG JRC
  - Expert panels / expert laboratories / EU reference laboratories

Committee on Medical Devices - "Comitology"
- For medical devices and IVDs together
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
Organisational structure of MDCG (Work in progress)

- **Coordination Group of Notified Bodies** (Article 49 MDR)
  - Cluster A (Pre-market):
    - Working group 1: NB oversight and JA
    - Working group 2: Standards
  - Cluster B (Post-market and clinical)
    - Working group 3: Clinical
    - Working group 4: PMS and Vigilance
    - Working group 5: Market surveillance
  - Cluster C (Borderline issues and new technologies):
    - Working group 6: Classification and Borderline
    - Working group 7: New technologies (including software, apps and cybersecurity aspects)

- **Committee on Medical Devices** (Article 114 MDR)
  - Cluster D (Systems):
    - Working group 8: EUDAMED
    - Working group 9: UDI
  - Cluster E (International matters):
    - Working group 10: International matters
  - Cluster F (IVDs):
    - Working group 11: Implementation of IVD-specific aspects of the IVDR
The new structure: highlights

- **11 WGs and 6 Clusters (A-F)**
- **Evolution of current work group structure**
  - All the current expert groups transitioned to the new regime
  - Addition of specific working groups on standards, EUDAMED, international matters
  - Specificity of IVD reflected in creation of ad-hoc cluster
- **Functioning of Cluster structure:**
  - Groups in the same cluster, if possible, meet back-to-back or jointly
  - Optimise resources and increase joint efforts among groups
- **Membership of WGs:** 2 regulators-only WGs and 9 WGs having stakeholder as observers

Call for participation planned for May 2018
Entry into force of Regulations

26 May 2017

Full application of MDR at 3 years

26 May 2020

Full application of IVDR at 5 years

26 May 2022
Key derogations

- 26 November 2017: Requirements on Notified Bodies; designation of Competent Authorities; establishment of the MDCG
- 26 May 2018: Mandate to SCHEER for guidelines on phthalates
- 26 May 2018: Cooperation among Competent Authorities
- 26 November 2021 (MD) – 2023 (IVD): Registration of devices
- 26 May 2024: Maximum period of validity of certificates issued under current Directives
- 26 May 2025: Making available of devices placed on the market pursuant to current Directives
- 26 May 2027: Coordinated procedure for clinical investigations
Implementation: key aspects

- More than 80 empowerments for DAs/IAs (18 mandatory) to be adopted
  - Implementing acts and delegated acts to be adopted according to the Better regulation framework – 4 week public feedback
  - Depending on type and sensitivity of the act possible Impact Assessment and 12-week public consultation at an early stage of the procedure

- Guidance documents (MEDDEVs, etc.)
  - Scope and modalities for issuing of MEDDEV-like guidance under analysis
  - Regulation empowers the MDCG to issue guidance on a large set of issues
Implementation (1): Main steps completed

- **Notified Bodies**
  - Implementing Act on codes (by 26 November 2017)
  - Other regulatory and logistical matters related to designation procedures
- **Governance**
  - Setting up of MDCG (by 26 November 2017)
  - 2 MDCG meetings - 28 November 2017 and 5-6 March 2018: 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 (legal deadline was 26 May 2018)
- **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 20 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 next steps

**Short term**

- **Next meeting of MDCG:** May 2018
- **Possible publication of first UDI guidance and requirements for medical device nomenclature:** March 2018
- **Launch of Communication campaign:** beginning of April
- **EUDAMED: plan for implementation of functional specifications:** by 26 May 2018
- **Setting up of MDCG subgroups:** mid-2018

**Medium-long term**

- 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