The challenge of regulating medical devices

COCIR 60 years anniversary, Brussels

Erik Hansson
Deputy Head of Unit
Health Technology and Cosmetics
DG Internal Market, Industry, Entrepreneurship and SMEs (GROW)
European Commission
Environment


26-05-2020  26-05-2022  05-2024
New legislation - new challenges

- Complexity and detail of requirements
- Information and awareness
- Coordination and governance
- Timelines and capacity

Our objectives

- Close cooperation with national authorities
- Stakeholder cooperation and engagement
- Promote consistent and clear interpretation on key issues
- Information campaign - guidance
- Monitor developments
Progress update (rolling plan)

- Governance
  - ✓ MDCG (Nov. 2017) – 13 MDCG technical subgroups – 3 COM DG:s

- Notified Bodies
  - ✓ Designation structure (Nov. 2017)

- Scientific structures
  - ✓ Expert panels, expert laboratories and reference labs (ongoing).
  - ✓ Call for experts closes 24.11 2019.

- New EUDAMED
  - ✓ Delay

- UDI system
  - ✓ 8 guidelines published, nomenclature and issuing entities selected

- Mandate for revision of standards (Q4 2019)

- Communication campaign

With CAMD:
- Implementation roadmap
- Clarification of certain transitional provisions
(Re-)designation of notified bodies

- Applications received by COM: 50+
- 40+ Joint Assessments
- 9 designated (7 MDR+2 IVDR)
Implementing/delegated acts

80 empowerments for implementing and delegated acts (including Common Technical Specifications – CTS)

Next in line:
- Standardisation mandate (Q4 2019)
- CTS on reprocessing of single-use devices (Q4 2019)
- CTS on devices without medical purpose (Q1 2020)
- EUDAMED
- EURLs (task/criteria, fees and designation)

Guidance documents

27 published, examples: Notified bodies, UDI Registration procedure and timelines, application of article 54(2), incident form, implant card, PRRC, EMA Q & A on application of Art. 117 MDR...

60+ in the pipeline: classification rules, clinical evaluation, vigilance, medical software/apps...
Critical issues

- Availability of notified bodies
- Establishment of Eudamed
- Resources and expertise

In addition:
- MRA:s, Customs Union Agreements, unilateral CE-acceptance, trade agreement negotiations
- Brexit
- Media interest
Call for expression of interest
Expert panels on medical devices and in vitro diagnostic devices

27 September – 24 November 2019
Useful links

- ec.europa.eu
  > growth > sectors
  > register of Commission expert groups > mdcg
  > law > better-regulation > have-your-say

- camd-europe.eu
  > MDR/IVDR implementation