Medical Devices & In-Vitro Diagnostics

The new EU regulations in a nutshell

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Content

1. Background new regulations
2. State of play
3. Main changes in the new regulations
4. Specific IVD changes
5. Implementation priorities
1. Background new regulations

- PIP and metal on metal hip scandals (2010/2011) on top of review of experience with the medical devices directives leading to a list of desired improvements
- “Dalli Action plan” (2012): reinforce oversight notified bodies and market surveillance
- Commission proposals for new regulations on Medical Devices and In-Vitro Diagnostics (September 2012)
- Replace current EU Directives on
  - medical devices (93/42/EEC),
  - active implantable medical devices (90/385/EEC) and
2. State of play

- October 2012: start negotiations in Council and European Parliament
- June 2016 (NL Presidency): Political agreement Council, Parliament and Commission
- April 2017: formal adoption in Council and European Parliament (early second reading agreement)
- May 2017: publication in the Official Journal

It's a deal, Jean-Claude: new legislation on MD's and IVD's!!
Official Journal of the European Union

Volume 60
5 May 2017

Legislation

Contents

1 Legislative acts

REGULATIONS


Date of application

MDR: **3 years** after date of publication
IVDR: **5 years** after date of publication

However, some derogations:
- designation of notified bodies (sufficient number before date of application),
- registration of devices (fully applicable 18 months after d.o.a.),
- ...

New regulations versus “old” directives

- Much more detailed and explanatory, however, basic principles still there.

- Around 80 delegated and implementing acts still to be added to this (to be developed in the upcoming years).
3. Main changes in a nutshell

1. Strengthening the system as a whole
2. Strengthened rules for high-risk devices
3. Increased transparency and traceability
3.1 Strengthening the system as a whole (1)

**Economic operators**

- Manufacturers, importers, distributors and the authorised representative
- Liability coverage measures (MF and AR)
- Burden of proof (clinical data) (MF)
- CMRs and endocrine disruptors (MF)
- Post-market surveillance activities (reporting) (all)
3.1 Strengthening the system as a whole (2)

**Notified bodies**

- Reinforced designation and oversight of NBs by competent authorities
- Personnel and in-house expertise (independence)
- Reassessments of NBs by joint assessment teams
- Peer reviews among competent authorities
- Unannounced inspections MFs by NBs.
3.1 Strengthening the system as a whole (3)

Competent Authorities

- Market surveillance, vigilance
- Governance and cooperation
- Medical Devices Coordination Group (MDCG)
- EU expert panels, expert and reference labs (clinical expertise)
3.1 Strengthening the system as a whole (4)

Health institutions

- Unique Device Identification (UDI)
- Implant card
- Rules on reprocessing
- In-house MD and IVDs exemptions
- Post-market surveillance: incident reporting
3.2 Strengthened rules for high-risk devices

- Clinical investigations and clinical evaluations
- Post-market surveillance and post-market clinical follow-up by manufacturers
- Review notified body assessment of clinical evaluation report
- Scrutiny (extra pre-market controls)
SCRUTINITY PROCEDURE

Scope: class III implantable devices and IIb active devices that administer/remove medicinal products.
3.3 Increased transparency and traceability

- **Unique Device Identification (UDI)**
  - Registration, identification and traceability of devices in electronic system
  - For economic operators and health institutions

- Linked to **EUDAMED**
  - Databank to inform public and competent authorities about devices put on the market
  - Provided and withdrawn certificates, clinical investigations etc.
  - Summary of safety and clinical performance for all class III devices
4. Specific IVD changes

- Classification (A-D)
- Scrutiny class D
- Genetic counselling
- In-house exemptions
- Companion Diagnostics
5. Implementation priorities

Commission
- Notified Bodies: designation, joint assessments etc.
- Governance: MDCG, expert panels, expert/reference laboratories, etc.
- Reprocessing and devices without a medical purpose (common specifications)
- EUDAMED and UDI

Netherlands, same +
- Clinical investigations
Thank you for your attention!