Ministerie van Buitenlandse Zaken

Medical Devices & In-Vitro Diagnostics

The new EU regulations in a nutshell

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1. Background new regulations

- PIP Scandal (2011)
- "Dali Action plan" (2012): reinforce oversight notified bodies and market surveillance
- European Parliament resolution: pre-market authorisation (2012)
- Commission proposals for new regulations on Medical Devices and In-Vitro Diagnostics (July 2012)
- Replaces current Directives on
  - medical devices (93/42/EEC),
  - active implantable devices (90/385/EEC) and
  - in-vitro diagnostic medical devices (98/79/EC).

2. State of play

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

Date of application

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

However, some derogations:

- designation of notified bodies (12 months),
- registration of devices (18 months),
- …

- MDR: 566 pages (compared to 60 in MDD), IVDR: 477 pages (compared to 37 in IVDD).
- Around 80 delegated and implementing acts.
- Much more detailed and explanatory, however, basic principles still there.

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 meausures (MF and AR)
- Risk and quality management systems (MF)
- Burden of proof (clinical data) (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 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)

3.3 Increased transparancy 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. The Big 5

- Genetic counselling
- Liability measures
- Scrutiny
- CMR substances and endocrine disruptors
- Reprocessing

4.1 Genetic counselling (IVD)

- Member States shall ensure information to patients on genetic testing, *as appropriate.*
- Scope: genetic counselling for diseases which cannot be cured (f.i. Huntington).
- Member States can go further, if they wish so.

4.2 Liability measures for manufacturers

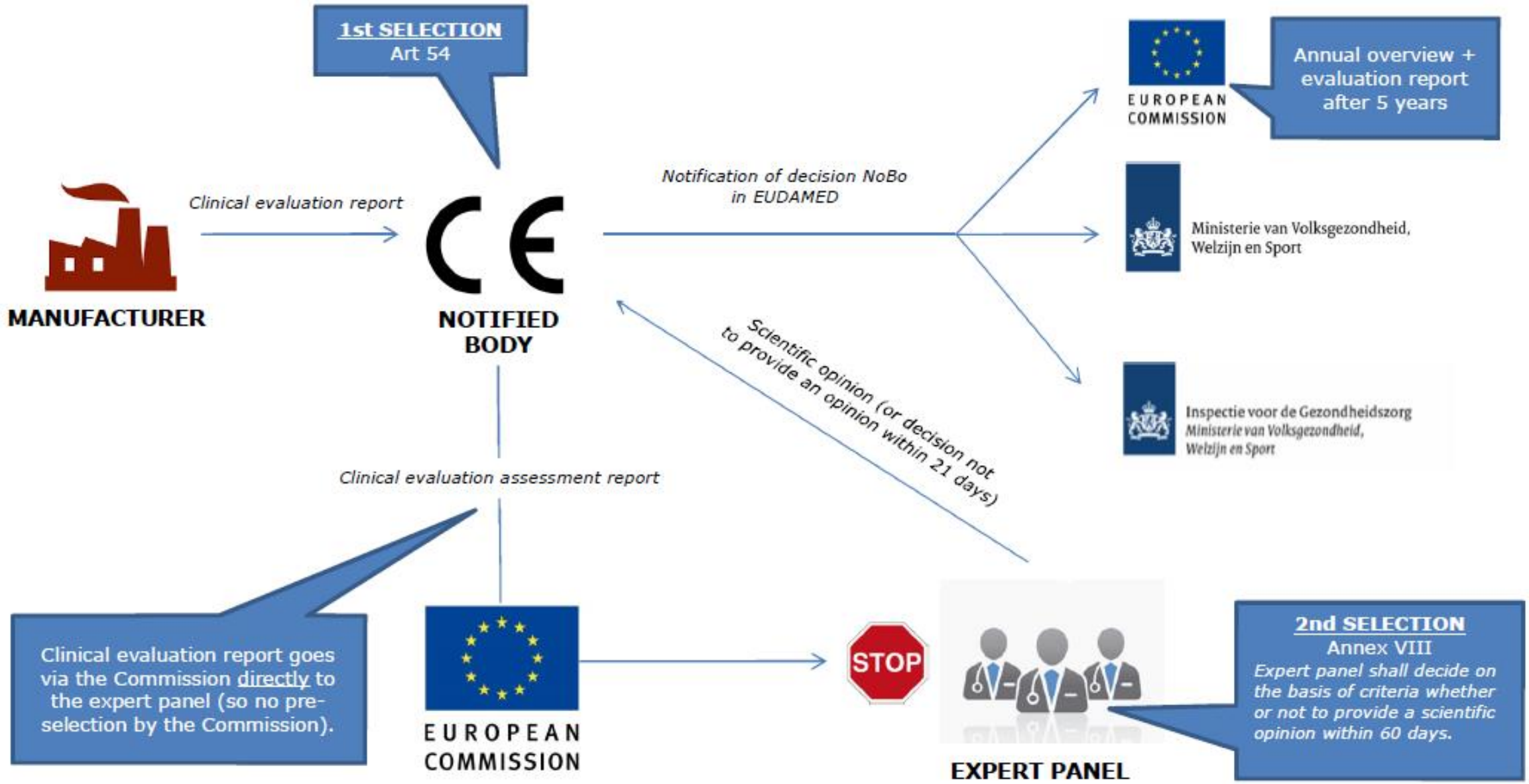
- Information component: competent authorities shall facilitate the provision of information in case of damage.
- Coverage component: measures for manufacturers to provide for sufficient financial coverage in respect of potential liability (cf Liability Directive).

4.3 Scrutiny

- Scope: class III implantables and class IIb active devices that administer/remove medicinal products (f.i. insuline pump).
- Procedure: use of expert panels with strict criteria when to undergo the procedure
- Transparency of procedure and oversight: annual overview and evaluation Commission after 5 years.

SCRUTINY PROCEDURE

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



4.4 CMR and endocrine disruptors

- No ban, but strict justification procedure for use in invasive devices.
- With scientific guidance of SCHEER.
- Starting with phtalates, then other CMR and ED.

4.5 Reprocessing of single-use devices

- Reprocessing allowed unless forbidden by national law.
- Exemptions for hospitals.
- Common specifications for safe reprocessing.

5. Implementation priorities

Commission

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

Netherlands, same +

- Clinical investigations

Thank you for your attention!

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