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)
- Publication of the Commission proposals for new regulations on Medical Devices and In-Vitro Diagnostics (July 2012) (revision of current directives)

2. Legislative process 2012-2017

- October 2012: start negotiations in the Council
- October 2015: start negotiations with the EP (“trilogues”)
- June/September 2016: Political agreement Council, EP and Commission
- **Now: translations and legal/linguistic checks**
- Early 2017 (expected): formal adoption in Council and European Parliament
- Date of application: 3 years (MDR) and 5 years (IVDR) after publication

It’s a deal, Jean-Claude: new legislation on MD’s and IVD’s!!

3. Main changes in the new regulations

1. Strengthening the system as a whole (pre- and postmarket)
2. Stricter rules for high-risk devices
3. Increased transparancy and traceability

3.1 Strengthening the system as a whole (1)

Manufacturers, importers and distributors

- ..and the authorised representative (new)
- Liability coverage meausures
- Risk and quality management systems
- Reporting of incidents and field safety corrective actions

3.1 Strengthening the system as a whole (2)

Notified bodies

- Reinforced designation procedures and oversight of NBs
- Personnel and expertise
- Reassessments of NBs by joint assessment teams
- Review of NB clinical assessments

3.1 Strengthening the system as a whole (3)

Market surveillance, vigilance and cooperation

- Periodic Safety Update Reports and PMS Annual Report
- Trendreporting and reporting of serious incidents
- Medical Devices Coordination Group (MDCG)
- EU expert panels and reference labs

3.2 Stricter rules for high-risk devices

- Stricter and more detailed rules on clinical investigations and clinical evaluations
- Stricter post-market surveillance and post-market clinical follow-up by manufacturers
- Review notified body assessment of clinical evaluation report
- Scrutiny (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
- ❑ Reprocessing
- ❑ Liability coverage measures
- ❑ Scrutiny
- ❑ CMR substances and endocrine disruptors

4.1 Genetic counselling (IVD)

- EP: counselling in cases of genetic testing (like prenatal screening)
- Council: national competence
- Deal:
  - 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 gan go further, if they wish so

4.2 Reprocessing

- = the process (desinfection, sterilisation) to reuse f.i. surgical instruments
- Council: controversial issue, many divergent positions
- Commission: concerns about negative list and exemptions for hospitals
- EP: flexible with few requests, f.i. traceability and information to patients
- Deal: Council position (reprocessing allowed unless forbidden by national law, exemptions for hospitals, common specifications) + deletion of the list

4.3 Liability coverage for manufacturers

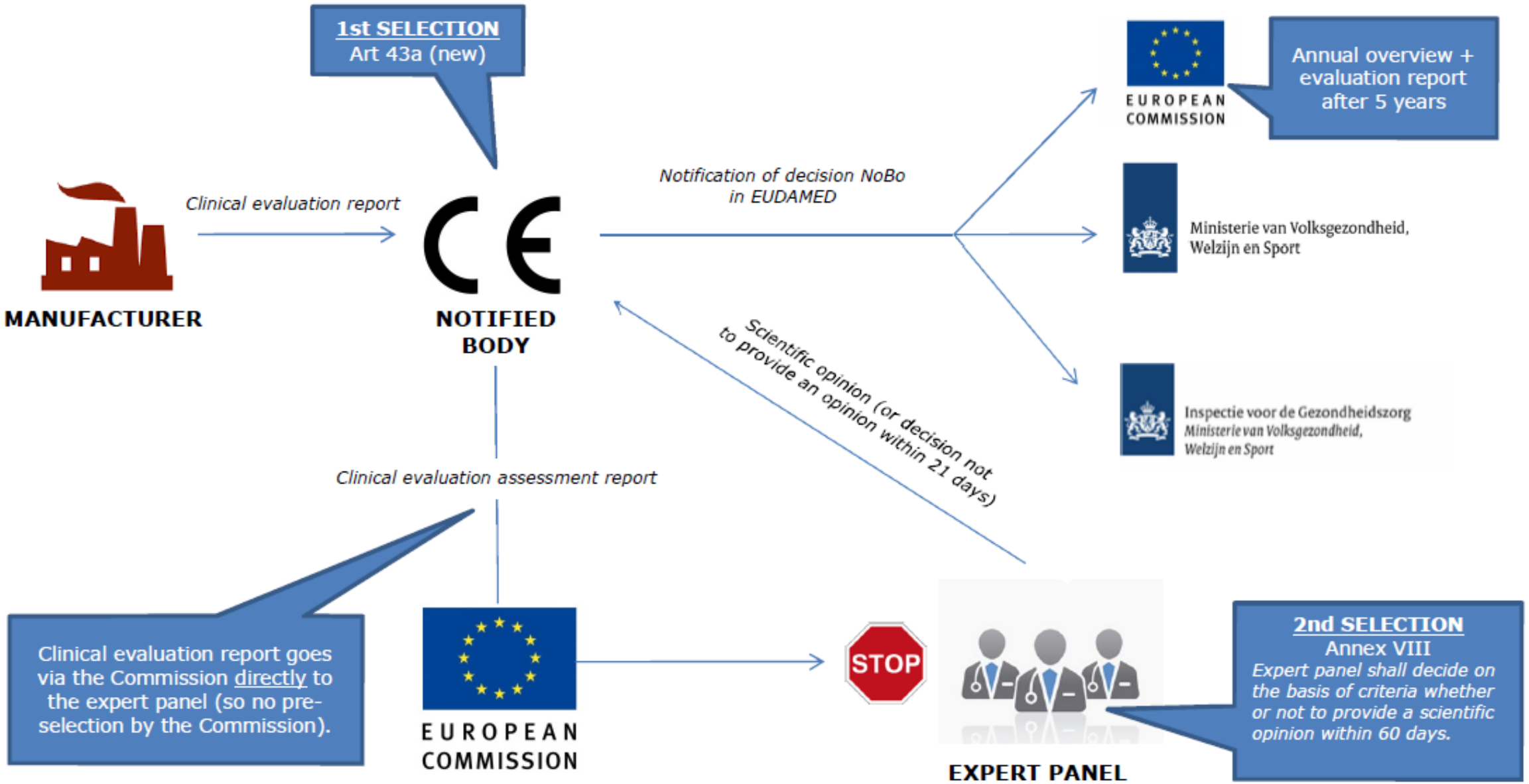
- Lenghty discussions on why, effectiveness and proportionality
- EP: manadatory liability insurance
- Council: disproportionate, burden of proof, national systems. Other ways of helping the patient.
- Deal:
  - Information component: competent authorities shall facilitate the provision of information in case of damage
  - Coverage component: measures for manufacturers to provide for sufficient financial coverage in respect of potential liability (cf Liability Directive)

4.4 Scrutiny

- ❑ Council: post-market
- ❑ EP/Commission: pre-market
- ❑ Deal:
  - 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.



4.5 CMR and endocrine disruptors

- CMR = carcinogenic, mutagenic or toxic for reproduction
- EP: ban, use alternatives
- Council: no ban, since alternatives not always available and uncertain risk/ benefit ratio
- Deal:
  - No ban, but strict justification procedure for use in invasive devices
  - With scientific guidance of SCHEER
  - Starting with phtalates, then other CMR and ED

Thank you for your attention!

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