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
- 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 transparency and traceability
3.1 Strengthening the system as a whole (1)

Manufacturers, importers and distributors

- ..and the authorised representative (new)
- Liability coverage measures
- 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 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. 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: mandatory 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. insulin 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.

1st SELECTION
Art 43a (new)

Clinical evaluation report

NOTIFIED BODY

Notification of decision NoBo in EUDAMED

Scientific opinion (or decision not to provide an opinion within 21 days)

Clinical evaluation assessment report

Clinical evaluation report goes via the Commission directly to the expert panel (so no pre-selection by the Commission).

EUROPEAN COMMISSION

Annual overview + evaluation report after 5 years

Ministerie van Volksgezondheid, Welzijn en Sport

Inspectie voor de Gezondheidszorg, Ministerie van Volksgezondheid, Welzijn en Sport

2nd SELECTION
Annex VIII
Expert panel shall decide on the basis of criteria whether or not to provide a scientific opinion within 60 days.

EXPERT PANEL
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 phthalates, then other CMR and ED
Thank you for your attention!

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