New Medical devices regulations in the EU

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The Original Purpose of the EU

To secure peace between former enemies

How?

By controlling the production of coal and steel
Six founding countries (Belgium, Federal Republic of Germany, France, Italy, Luxembourg, the Netherlands) signed a treaty to run heavy industries (coal and steel) under common management in 1951:

The European Coal and Steel Community was born, precursor of the EU.
Treaty of Rome 1957: European Community
Widening the Union - EU Enlargements

Candidate Countries:
- Iceland
- FYR Macedonia
- Turkey
- Serbia
- Montenegro

Potential Candidates:
- Albania
- Bosnia & Herzegovina
- Kosovo*

* under UNSCR 1244
28 member states

Over 500 million combined population

24 official languages

4.3 million km² total surface area

22% of global GDP

20% of global exports and imports
Customs Union
Common agricultural policy
Single Market
The EU single market for medical devices

1. EU (28 Member States)

2. EFTA/EEA:挪威, 列支敦士登, 冰岛

3. 土耳其

4. 瑞士
Development of EU health policy

• **Health not explicitly on agenda of founders** (only occupational health and safety and restriction on movement of goods), "high level of health protection" as one of the objectives of single market,

• EU health-related legislation first linked to agriculture (animal and plant health), single market (drugs, medical devices, tobacco control), occupational health and safety

• Gradual and patchy development: "**crisis** development" (BSE, blood scandal, 9/11, PIP scandal), European **Court of Justice case law**

• **Health Department set up in 1997**, but: health systems is Member States competence; drugs/medical devices were long time in industry department (medical devices still is)
Some figures on the EU medical device sector

- Over 500,000 people employed in about 25,000 companies, most of which are micro, small and medium size enterprises
- €100 billion in annual sales
- Over 500,000 medical and in vitro diagnostic devices on the market
- 6-8% of medical devices annual sales and 10% of in vitro devices annual sales is re-invested in research every year
- Over 30% increase of patent applications since 2005
Previous EU Medical Devices Legislation

- Directive 90/385/EEC on active implantable medical devices
- Directive 93/42/EEC on medical devices
- Directive 98/79/EC on in vitro diagnostic medical devices
Main elements of previous legal framework

• Four risk classes

• No preauthorisation, but conformity assessment by notified body = certification

• Notified bodies are independent third parties (around 80 across EU) and designated, controlled and monitored by Member States

• Once certified by a notified body, devices bear the CE marking which allows them to circulate freely in EU single market + EFTA + Turkey
Reasons for change

Regulatory framework criticised

• for not sufficiently ensuring patient safety (PIP scandal 2010)
• for not being transparent (no access to information on how products were assessed) and for not allowing consistent tracing of products
• for having regulatory gaps
• for being implemented differently in 32 participating countries
• for not responding well enough to technical and scientific progress
Objectives of revision

1. Ensure high level of health and safety
2. Ensure functioning of the single market
3. Promote innovation in medical technology

Balance between patient safety and accessibility
Revision of the EU Medical Devices Law
From EU Directive to EU Regulation

- Directive 90/385/EEC on active implantable medical devices
- Directive 93/42/EEC on medical devices
- New Regulation on medical devices
- Directive 98/79/EC on in vitro diagnostic medical devices
- New Regulation on in vitro diagnostic medical devices
Main elements of revision

1) Extended scope for EU legislation
2) Stronger supervision of assessment bodies
3) More powers for assessment bodies
4) Clearer rights and responsibilities for manufacturers, importers and distributors
5) Extended EUDAMED database and transparency
6) Better traceability of products
7) Stricter requirements for clinical evidence
8) Updated classification rules
9) Better vigilance and market surveillance
10) Governance: Better coordination between national surveillance authorities and with European Commission
1) Extended scope

Multiple clarifications and extension to
• Aesthetic devices, aesthetic implants
• Software used for any purpose covered by MDR's definition of medical device
• Reprocessed single-use devices
2) Stronger supervision of assessment bodies

Tightened supervision of Notified Bodies

- Reinforced minimum requirements (independence, impartiality, competence, resources)
- New process for designation and monitoring of notified bodies
- Monitoring of notified bodies via joint assessments by MS and Commission experts
3) More powers for assessment bodies

- Tightened conformity assessment procedures and stronger assessment requirements
- Surveillance audits
- Unannounced audits at least every five years and sample testing
- Rotation of auditors
4) Clearer responsibilities and rights for economic operators

Clear set of obligations and responsibilities

- **Manufacturers**
  - Quality management system (stricter for high-risk devices)
  - Post-market surveillance system
  - Technical documentation
  - Qualified person for regulatory compliance
  - Financial coverage in case of liability for defective products

- **Authorised representatives**
  - Written mandate
  - Qualified person
  - Liability for defective products
• **Importers**
  - Responsible person in EU for placing on the market of products from outside EU
  - Appropriate check of conformity of products before placing on the market in EU

• **Distributors**
  - Appropriate check of conformity of products before making available
  - Repackaging and/or relabelling
5) Extended EUDAMED database - transparency

Publicly available information in EUDAMED regarding

• Devices on the EU market
• Summary of Safety and Clinical Performance Data for high risk devices
• Manufacturers, authorised representatives and importers
• Certificates issued by notified bodies
• Clinical investigations / clinical performance studies
6) Better traceability of products

Supply chain
- Identification of economic operators up and down the supply chain (particularly for Class III implantable devices)
- Introduction of the Single Registration Number for manufacturers, authorised representatives and importers

New device identification system
- Introduction of a UDI
- UDI database integrated in future EUDAMED
- Implant cards
7) Stricter requirements for clinical evidence, clinical data and evaluation, investigation

**Clinical evidence**/Sufficient amount to allow qualified assessment

**Clinical evaluation**/ Continuous systemic process, incl. post-market (clinical) follow-up

**Clinical Data**/ peer reviewed scientific literature and data from manufacturer's post market surveillance system

**Clinical investigations**/ interventional performance studies for IVDMD introduced

- Registration of clinical investigations in publicly accessible electronic system
- Application for clinical investigation
8) Updated classification

Adaptation of classification rules

- Both medical devices and in vitro diagnostic medical devices are divided into 4 risk classes

Classification determines conformity assessment

- **Class I**: Self-certification
- **Class IIa & IIb**: assessment of technical documentation on sampling basis
- **Class III**: assessment of the technical documentation & adequate testing (or examination), for some also further scrutiny (e.g. implantables) or further consultations (e.g. MD with ancillary medicinal substance, human tissue engineered MD)
9) Vigilance and market surveillance

Market surveillance
- Clearer rights and obligations of market surveillance authorities
- Mutual information
- Post-market surveillance plan
- Post-market surveillance report
- Periodic safety update report (For devices in Class IIa, IIb and III

Vigilance
- EU vigilance portal
- Central reporting of serious incidents and corrective actions
- Enhanced coordination between authorities
10) EU Governance

- **Reinforced coordination**
  - Medical Device Coordination Group (MDCG) - Experts representing national authorities, chaired by the European Commission
  - Technical, scientific and logistic support - European Commission
  - Expert panels / expert laboratories / reference laboratories
State of play and next steps

- 26 September 2012: adoption of the two Commission proposals on medical devices and IVDs
- 5 April 2017: Final adoption of the new Regulations
- 5 May 2017: Publication of the new Regulations in the EU Official Journal
- To be progressively applied over the 3 years (Medical Devices) and 5 years (IVDs) thereafter
Transitional period

- Entry into force of Regulations: 26 May 2017
- Full application of MDR at 3 years: 26 May 2020
- Full application of IVDR at 5 years: 26 May 2022
Key derogations

- 6 months after entry into force: Requirements on Notified Bodies; designation of Competent Authorities; establishment of the MDCG
- 12 months after entry into force: Cooperation among Competent Authorities
- 18 months after date of application: Registration of devices
- 1-5 years after date of application: Placement of UDI carrier
- 2(IVD)/4(MD) years after date of application: Maximum period of validity of certificates issued under current Directives
- 3(IVD)/5(MD) years after date of application: Making available of devices placed on the market pursuant to previous Directives
- 7 years after date of application: Coordinated procedure for clinical investigations
Towards implementation: some key aspects

Delegated Acts/Implemented Acts (18 mandatory) to be adopted

Implementing acts and delegated acts to be adopted according to the new Better Regulation framework, which normally includes a 4-week public feedback

Depending on type and sensitivity of the act possible Impact Assessment and 12-week public consultation at an early stage of the procedure
Thank you

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