Revision of the EU legislation on medical devices and *in vitro* diagnostic medical devices

IMDRF-4

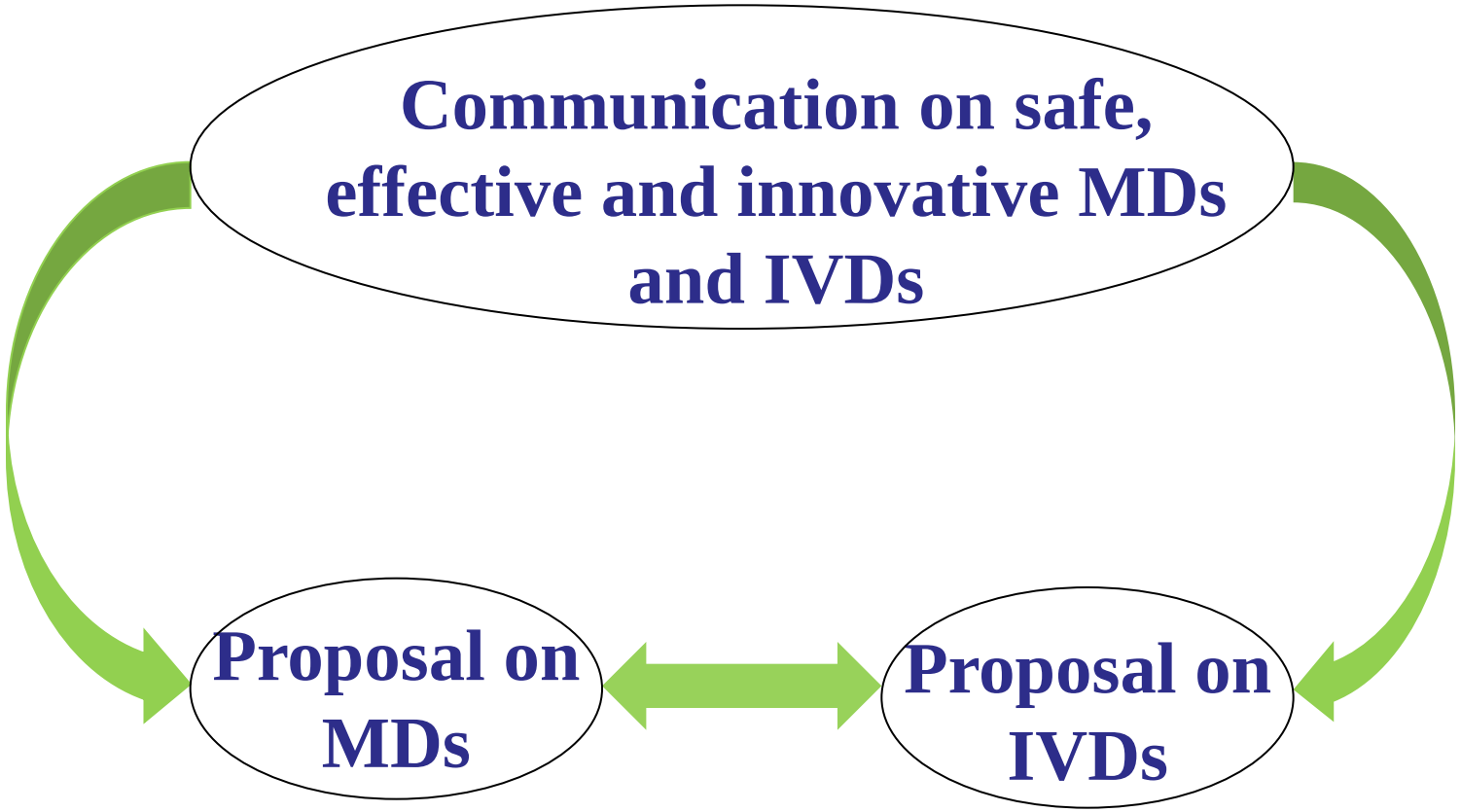
Update on the revision of the MD regulatory framework in the European Union

20 March 2013
Nice

Health and Consumers

European Commission

26/9/2012: Medical devices package



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Scope

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Proposal Reg. on Medical Devices

- **Extension of the scope to:**
  - Certain **implantable and other invasive products** regardless of a medical or non-medical (*e.g.* aesthetic) purpose (see Annex XV)
  - **Medical devices manufactured with non-viable human tissues or cells**
  - **Reprocessed single-use medical devices**

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Proposal Reg. on IVDs

Extension of the scope to:

- **Class D** IVD manufactured and used within a single health institution ("in house" tests)

- **Genetic tests** and **Companion diagnostics**

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Horizontal aspects

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Role of economic operators

- **Clear set of obligations and responsibilities**
  - **Manufacturers**
  - **Importers**
  - **Distributors**
  - **Authorised representatives**

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Traceability

Supply chain

- Identification of economic operators up and down the supply chain
- Identification of professional end users (health institutions, HC professionals)

Unique device identification (UDI)

- Gradual introduction of UDI system based on GHTF/IMDRF
- UDI database integrated in future EUDAMED

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Notified bodies

- **Tightened supervision of Notified Bodies**
  - **Reinforced minimum requirements** (independence, impartiality, competence, resources and processes)
  - New process for designation and monitoring ('**joint assessments**')
  - **Scrutiny mechanism** applicable to high-risk devices

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General safety and performance requirements

- Essential requirements **aligned with GHTF**
- Labelling requirements **aligned with GHTF**

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Clinical data

- **Clinical investigations / interventional performance studies**
  - Procedures **aligned with** proposed rules on **clinical trials** on medicinal products

- **Clinical evaluation / evidence**
  - More detailed requirements are set out in Annex XIII which addresses the **pre-market clinical evaluation** and **post-market clinical follow-up**. Together constitute a continuous process during the life cycle of a medical device.

Vigilance

- **EU vigilance portal**
  - To ensure **central reporting of serious incidents** and **FSCA by MFRs**
  - As a basis for **trend reporting** (for classes IIb/C and III/D)

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Market surveillance

- **Clearer rights and obligations** of authorities responsible for market surveillance (*e.g.* in-market controls)

- **Clearer procedures for national provisional measures** (*e.g.* safeguard clause, corrective actions against non-compliant products)

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Specific aspects regarding IVDs

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Risk classification

Current system→ positive list

i.e. Annex II to Directive 98/79/EC

no longer adapted to fast pace of technological progress *e.g.* vCJD assays

Risk classification

New system → risk-rule based classification*

- **4 classes**
  - **A**: low individual risk and low public health risk
  - **B**: moderate individual risk and/or low public health risk
  - **C**: high individual risk and/or moderate public health risk
  - **D**: high individual risk and high public health risk

- **7 classification rules**

*** Based on GHTF/SG1/N045:2008**

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Clinical evidence

- **Reinforcement of clinical evidence requirements**
  - Scientific validity of clinical data
  - Clinical performance

Thank you for your attention!

European Commission
Health and Consumers Directorate-General

Health Technology and Cosmetics Unit

http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm