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
26/9/2012: Medical devices package

Communication on safe, effective and innovative MDs and IVDs

Proposal on MDs

Proposal on IVDs
Scope
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
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
Horizontal aspects
Role of economic operators

- Clear set of obligations and responsibilities
  - Manufacturers
  - Importers
  - Distributors
  - Authorised representatives
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
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
General safety and performance requirements

➢ Essential requirements aligned with GHTF

➢ Labelling requirements aligned with GHTF
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)
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)
Specific aspects regarding IVDs
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
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
Clinical evidence

- Reinforcement of clinical evidence requirements
  - Scientific validity of clinical data
  - Clinical performance
Thank you for your attention!

European Commission
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