



Revision of the EU Directive on *in vitro* diagnostic medical devices (IVDD)

Workshop on Pharmacogenomics: from science to clinical care

Fabio Faraulo
European Commission

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State of play and next steps

➤ *26 September 2012 – Package on innovation in health:*

- a Communication on "safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals";
- a Proposal for a Regulation on medical devices;
- a Proposal for a Regulation on *in vitro* diagnostic medical devices.

➤ *Ordinary legislative procedure;*

➤ *Transitional period.*

Revision of the IVD Directive: IVD specific issues

1. New definition of ‘in vitro diagnostic medical device’

‘in vitro diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, **software** or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state;
- concerning a congenital abnormality;
- concerning the **predisposition to a medical condition or a disease**;
- to determine the safety and compatibility with potential recipients;
- to **predict treatment response or reactions**;
- to define or monitor therapeutic measures.

Specimen receptacles are considered to be in vitro diagnostic medical devices. For the purposes of this Regulation, ‘specimen receptacle’ means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Revision of the IVD Directive: IVD specific issues

2. Extension of the scope to:

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

-*in vitro* diagnostic medical devices **used in the context of a commercial activity** to provide a diagnostic or therapeutic service (by means of information society systems or by other means of communication) to persons established in the Union.



Revision of the IVD Directive: IVD specific issues

3. Risk-rule based classification system

Current system:

Annex II to Directive 98/79/EC → **Positive list.**

New system:

Built on GHTF principles and based on a new **risk-rule classification mechanism.**

Revision of the IVD Directive: IVD specific issues

4. Reinforcement of clinical evidence requirements

- Systematic intervention of a NB in the conformity assessment procedure for **genetic tests** and **companion diagnostics**;
- Alignment with **international guidance** documents;
- **Clinical evidence** as a **basis to demonstrate the device conformity** with safety and performance requirements;
- Definition of the main concepts and elements of **clinical evidence** for IVD;
- Clarification of requirements applicable to "**clinical performance studies**" to establish or confirm the clinical performance of a device.



Revision of the IVD Directive: IVD specific issues

- Introduction of the concept of '**sponsor**';
- Creation of a process for **coordination of the technical assessment** of clinical performance studies conducted in more than one Member State (excluding ethical and local aspects);
- Provisions aiming at ensuring a **uniform level of protection of subjects** enrolled in clinical performance studies;
- **Information** about clinical performance studies will be **partly accessible** to the public.



Revision of the IVD Directive: horizontal issues

1. Reinforced oversight of Notified Bodies

- **Stricter and more detailed minimum legal requirements** for designation of Notified Bodies;
- **"Joint assessments"** with experts from other Member States and the Commission;
- **Position of NBs vis-à-vis manufacturers** will be strengthened;
- **Rotation of the NBs' personnel** involved in the assessment of medical devices at appropriate intervals.

Proposal on *in vitro* diagnostic medical devices: horizontal issues

2. Changes to conformity assessment:

- The different **conformity assessment procedures** have been **tightened and streamlined**;
- Most significantly, the proposals introduce a "**scrutiny mechanism**" for high risk devices and, where necessary, for other types of devices on the basis of defined criteria (e.g. novelty, public health concerns);
- For class D IVDs, **reference laboratories** will have the task to verify compliance with the applicable Common Technical Specifications (CTS);
- For IVDs intended to be used as companion diagnostics: **consultation procedure** with a pharmaceutical authority (EMA or national CA).

Proposal on *in vitro* diagnostic medical devices: horizontal issues

3. Vigilance and market surveillance strengthened to reinforce post-market safety

- Creation of a process which ensures **consistent and timely corrective actions** where the same or similar incidents have occurred, or where a corrective action has to be taken, in more than one Member State;
- Introduction of an EU portal where manufacturers must **report serious incidents and corrective actions**;
- **Coordinated analysis of serious incidents** affecting several Member States;

Proposal on *in vitro* diagnostic medical devices: horizontal issues

4. Enhanced transparency

- Further development of **Eudamed**;
- New system allowing the EU-wide **tracking and tracing of devices**;
- Legal basis for a **European UDI** which is globally compatible;
- For certain high-risk devices - **publicly available summary** of safety and performance with key elements of the supporting clinical data;

EUDAMED

(Possible European MD databank in the future regulatory framework)

ES on UDI

Information on:

DI data elements

ES on Registration

Information on:

devices and
economic operators,
including
summary of safety
and clinical
performance
(Class III for MD and
Class D for IVD)

ES on Certificates

Information on
certificates:

issued
suspended
reinstated
withdrawn
refused
restricted

ES on Vigilance

Information on:

Incidents &
FSCA
[...]

ES on CIV and CPS

Information on:

Sponsor and/or MFR,
Description of device
CIV description
CIV purpose,
CIV status

[...]

ES on market surveillance

Information on
measures taken
by MS in case of:

Non-compliant devices
presenting a risk to
health and safety;

Compliant products
presenting a risk
to health and safety;

Formal non-compliance
of devices;

Preventive health
protection measures.

ES stands for Electronic System

Access to Eudamed

Eudamed shall be fully accessible to the:

- ☐ Competent authorities of the Member States,
- ☐ Commission.

To the extent necessary to comply with their obligations Eudamed shall also be accessible to the:

- ☐ Notified Bodies.
- ☐ Manufacturers,
- ☐ authorised representatives,
- ☐ importers.

Eudamed shall also be partly accessible to the:

- ☐ Public.

Proposal on *in vitro* diagnostic medical devices: horizontal issues

5. Governance of the system

- Creation of a statutory Medical Device Coordination Group composed of experts designated by the Member States to facilitate a Harmonised interpretation and implementation of legal requirements;
- Appropriate participation of stakeholders (manufacturers, Notified Bodies, healthcare professionals and patients) ensured;
- Scientific, technical and logistic support at EU level provided by the Commission.



Thank you for your attention!

European Commission
Health and Consumer Protection Directorate-General

Health Technology and Cosmetics Unit

Office DM24 02/098

Location: Rue Demot 24, B-1040 Bussels

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