Revision of the EU Medical Device Regulatory Framework

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State of play and next steps

- Proposals adopted on 26 September 2012;
- Package consisting of:
  - 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.
- Discussion in the European Parliament and the Council (ordinary legislative procedure);
- Transitional period, allowing economic operators, notified bodies, Member States and the Commission to adapt to the changes.
Objectives of the legislation

- **Need for a regulatory framework which:**

  - Ensures highest level of patient safety;
  - Creates a supportive environment for innovation;
  - Enhances the competitiveness of European manufacturers;
  - Guarantees the free movement of medical devices within the internal market;
  - Takes into account the specificities of the products (development and life-cycle, functioning, role of the health professional);
  - But also recognises the growing interface between pharmaceuticals and medical devices, e.g. drug-device combination products, combined tissue engineered products, personalised medicine using companion diagnostics.
Revision of the EU medical devices directives

- The existing regulatory framework has demonstrated its merits but has also come under criticism in recent years.

- Decentralised approach to pre-market assessment: flexibility, fast and cost-effective pre-market review is; SME-friendly and supportive of innovation;

- However, debate on the way medical devices are approved in EU;

- Certain legal gaps and weaknesses of the current directives need to be remedied while the positive aspects of the current system need to be maintained;

- The key: effective enforcement and management (in particular through tightened oversight of Notified Bodies and strengthened market surveillance).
Main elements of the proposals

1) Address legal gaps and close loopholes (i.e. scope)

- Products manufactured utilising non-viable human tissues/cells or their derivatives, that have undergone substantial manipulation;
- Implantable or other invasive products without a medical purpose but similar to medical devices in terms of characteristics and risk profile;
- New provisions on the reprocessing of single-use devices;
- New provisions on relabeling and repackaging;
- Extension of the scope of the legislation to high-risk (Class D) IVD devices manufactured and used within a single health institution ('in house' tests);
- Genetic tests with a medical purpose, e.g. tests providing information to predict treatment response or reactions;
- Clarification that IVD used in the context of a commercial diagnostic service to a person established in the EU must comply with the legislation, even when not placed on the market or put into service in the EU.
Main elements of the proposals

2) Reinforced oversight of Notified Bodies

- Significant differences regarding the designation and monitoring of NBs and the quality and depth of conformity assessment performed by them;
- Stricter and more detailed minimum legal requirements for designation of Notified Bodies;
- "Joint assessments" with experts from other member States and the Commission;
- The 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.
Main elements of the proposals

3) Adaptation of the classification rules and conformity assessment

- The classification rules adapted to technical progress and experience gained from vigilance and market surveillance;
- 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);
- Adaptation of the classification rules and conformity assessment,
Main elements of the proposals

4) Update the general rules on clinical evaluation/ investigations (MDs) and establish requirements for clinical evidence/ clinical performance studies (IVDs)

- Alignment with international guidance documents;
- Introduction of the concept of 'sponsor';
- Creation of a process for coordination of the technical assessment of a clinical investigation or clinical performance studies conducted in more than one Member State;
- Resource- and work-sharing between national authorities;
- Provisions aiming to ensure a uniform level of protection of patients enrolled in clinical investigations or clinical performance studies;
- Public information about clinical investigations and clinical performance studies.
Main elements of the proposals

5) Vigilance and market surveillance strengthened to reinforce post-market safety (backbone of the regulatory system)

- 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;
- Market surveillance: main objectives are to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.
Main elements of the proposals

6) Enhanced transparency is key to reinforce trust in the EU regulatory system

- Further development of Eudamed;
- Integrated electronic systems on a European UDI, on registration of devices, relevant economic operators and certificates issued by notified bodies, on clinical investigations, on vigilance and on market surveillance;
- A large part of the information - publicly available;
- For certain high-risk devices - publicly available summary of safety and performance with key elements of the supporting clinical data;
- Establishment of a system which will allow the EU-wide tracking and tracing of medical devices (proportionate to their risk);
- Legal basis for a European UDI which is globally compatible;
- Introduction of an implant card.
Main elements of the proposals

7) Finally, some words about the management of the future system:

- Creation of a statutory Medical Device Coordination Group composed of experts designated by the Member States;
- Appropriate participation of stakeholders (manufacturers, Notified Bodies, health professionals and patients) will be ensured;
- Aim: harmonised interpretation and implementation of legal requirements;
- Scientific, technical and logistic support at EU level will be provided by the Commission.
THANK YOU!