Revision of the EU Medical Device Regulatory Framework

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Health and Consumers

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.*

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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).*

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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,*

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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.*

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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!

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