Eucomed
Medical Technology

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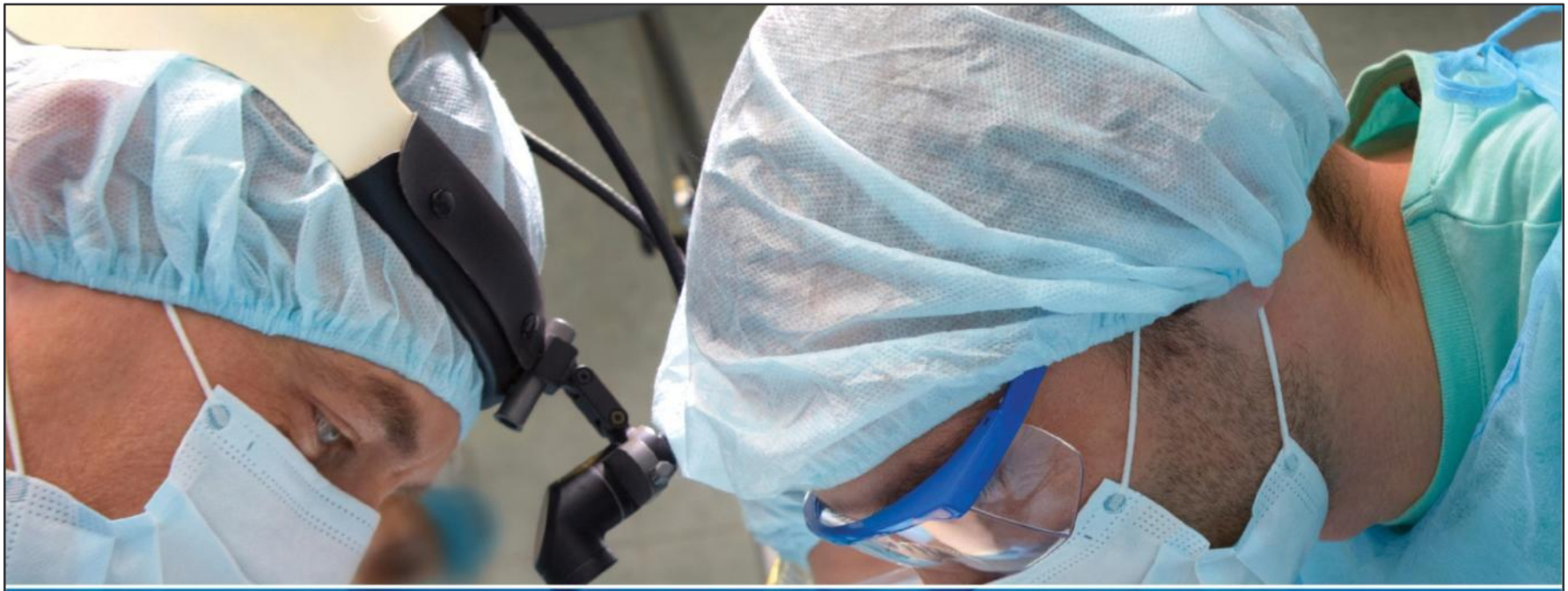


Industry's position on the Revision

Assemblée Générale UNAMEC - 9 mai 2012

Ing Dario Pirovano Consultant Regulatory Affairs, Eucomed

Safe, Smart and Sustainable

Our legislation needs to adapt and improve in order to guarantee the best future for patients, society and innovation.

It is a collaborative responsibility to build a ‘smart’ legal framework for that future, guaranteeing patients access to reliable and sustainable health.

Revision could sort out weaknesses of current system?

- **Lack of Transparency = Lack of trust in System**
  - Overly “confidential” system
  - Different expertise/performance of Notified Bodies
  - Perception that Authorities are divorced from the process, particularly for complex class III devices
  - Transparency of overall system, in particular no visibility of what’s on the market
  - Poor perception of system by those external to EU

- **Challenges to Innovation = Threat to patients’ choice**
  - Public Health Authority understanding of new technologies
  - Lack of Guidance including regulatory predictability and agreed clinical guidelines, in particular on innovative new technology

- **Fragmented Market = Threat to legal market access**
  - Multiple national registrations and overly bureaucratic processes
  - National ‘safeguard’ measures create multiple national requirements
  - Multiple national approaches to vigilance, borderline and classification

Expected timeline for the MDD revision

What's happening now?

- **Stress test:**

  DG SANCO analysis if drafted measures are sufficiently addressing failures of PIP case

- **Immediate Action Plan:**

  EC proposal for immediate actions concerning MDs announced 09 Feb 2012 = Additional measures possible after results of stress test

- **MDEG (Medical Devices Expert Group):**

  Draft parts of 'Revision' text circulated to MDEG meetings 06 & 13 Feb for feedback

- **Possible presentation to stakeholders of further text in June**

- **Draft Proposal:**

  Publication planned for September 2012

The “February” draft

- Set of proposed articles on:
  - Scope
  - Clinical investigations, Clinical evaluation
  - Essential requirements
  - Classification
  - Conformity assessment procedures
  - Role and obligations of economic operators
  - Traceability/UDI
  - Vigilance and market surveillance
  - External scientific expertise
  - Borderline cases

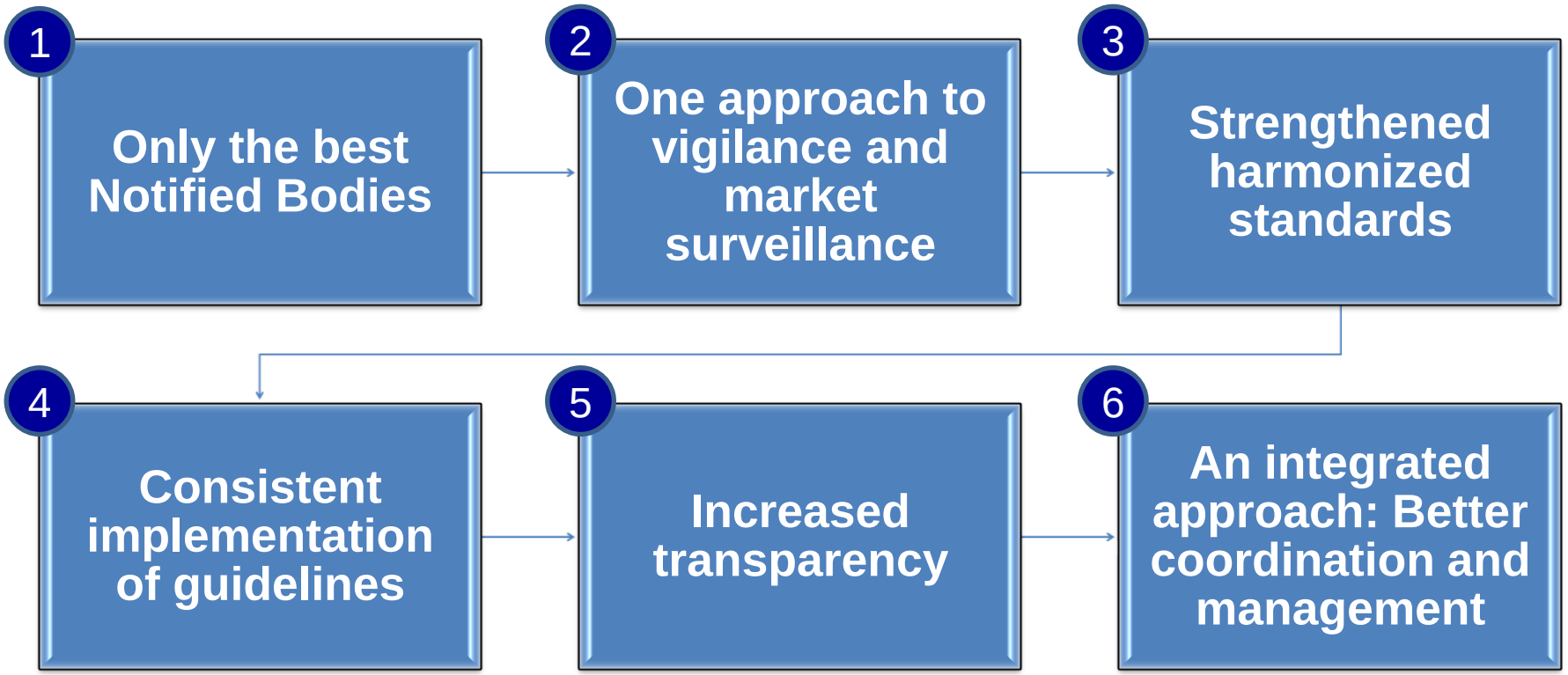
Conformity assessment procedure

- Enhanced involvement of CA in the evaluation of innovative, high risk products by Notified Bodies
- Text mixes innovation and vigilance driven measures
- Comes too late in the process for innovative products
- It is not a PMA, but “smells” PMA
- Uncertainity of the lenght of the process

Role and obligations of economic operators

- Reprocessors of SUD
- Responsibilities of Importers and Distributors
- Labelling requirements
- Support of parallel trade

6 steps to a smarter legal framework for medical devices:



1. Only the best Notified Bodies

In order to continue to guarantee a consistent approach to the quality of the work carried out by Notified Bodies as well as a high level of safety across the EU, a complete series of control and monitoring measures are needed:

1. **Precise and mandatory requirements for the designation of Notified Bodies;**

2. **EU-wide mandatory accreditation standards for Notified Bodies, that include standards for competence, training, staffing, transparency and expertise of Notified Bodies;**

3. **Precise, binding, transparent measures for Competent Authorities to control and monitor their Notified Bodies;**

4. **Audits of Notified Bodies by joint teams coming from different Competent Authorities and the European Commission;**

5. **EU level oversight of the way Member States designate and monitor their Notified Bodies.**

2. ONE APPROACH TO VIGILANCE AND MARKET SURVEILLANCE

An effective system to ensure a rapid and consistent EU-wide risk identification and response would require:

1. **A better defined legal framework on vigilance and greater harmonisation of Member States' market surveillance activities.**

2. **A centralised reporting and surveillance system, based on an EU portal for reporting of key data and situation assessment by Member States and the European Commission. Key features of this EU portal would include:**

   - **the possibility to exchange information and facilitate timely cooperation between all the stakeholders involved (i.e. European Commission, national surveillance authorities, customs authorities and distributors);**
   - **appropriate security and data protection measures;**
   - **the use of sound, independent scientific advice from the Commission's Joint Research Centre (JRC) – see also section 6;**
   - **the ability to report relevant information, including data on the products, identified risks, risk analysis, resulting measures and relevant best practices.**

3. **Existing and past experiences, such as the EUDAMED database and the ECCAIRS model should be considered as useful examples to build up a reliable reporting and surveillance system for medical devices**.

- EUDAMED, http://ec.europa.eu/consumers/sectors/medical-devices/market-surveillance-vigilance/eudamed/
- ECCAIRS, http://ec.europa.eu/dgs/jrc/index.cfm?id=2820&dt_code=HLN&obj_id=673

3. STRENGTHENED HARMONIZED STANDARDS

EU harmonised standards, developed jointly by regulators, industry, academia and other stakeholders, should continue to prevail as a core vehicle to ensure the safety and performance of medical devices. This points to the need to re-position Europe's Competent Authorities at the forefront of international safety standards in medical technology.

Processes and procedures in the revised framework for mandating and developing medical device standards must incentivise pro-active involvement of Member States in the drafting of those international standards in order to address and advance difficulties over the implementation across the EU.

4. CONSISTENT IMPLEMENTATION OF GUIDELINES

The inefficiencies in the development and the severe disparities in the implementation of guidelines must be addressed urgently on two fronts:

1. **Revising the current procedure for development of guidelines to:**

   a) **actively involve and commit the Members States to uniform implementation;**
   b) **use clearly defined and transparent drafting procedures including timelines;**
   c) **involve all affected stakeholders;**
   d) **seek independent scientific advice from the Joint Research Centre (JRC) when needed;**
   e) **involve the European Commission to ensure coherence with European law.**

2. **Upgrading the European Commission's current Medical Devices Expert Group (MDEG) from a voluntary committee to a formal Advisory Committee, under the future revised legal framework for medical devices. This committee could then establish and oversee a consistent guidance development process, which effectively supports Members States and industry in key areas such as good design control, risk management plans, new and emerging technologies, post-market clinical follow-up, vigilance, clinical evidence, labeling and decision-making on borderline products and classification.**

5. INCREASED TRANSPARENCY

The review of the EU legislative framework for medical devices must result in greater overall transparency and access to information for patients, consumers, healthcare professionals and manufacturers as well as for Notified Bodies, national Competent Authorities and the European Commission through increased use of Information and Communication Technology (ICT), in particular the establishment of a single EU database, with appropriate elements available to the public.

This database should ensure appropriate means of personal data protection and include relevant information on:

- **Devices on the market (including unique device identification, UDI)**
- **Registration of economic operators**
- **Vigilance**
- **Market surveillance**
- **Clinical investigation**
- **Notified bodies and enforcement**
- **CE certificates**

6. AN INTEGRATED APPROACH: BETTER COORDINATION AND MANAGEMENT

To strengthen the three crucial components - coordination, science and policy advice - in the regulatory framework for medical devices, the system will require resources from within the Commission by DG SANCO, supported by the Commission's Joint Research Centre (JRC). The JRC can actively play a crucial role in key areas such as:

1. **auditing Notified Bodies to ensure a comparable, high level of quality across the EU;**
2. **coordinating vigilance incident reporting systems;**
3. **more extensive horizon scanning and foresight intelligence on potential health concerns;**
4. **providing expert policy advice in medical technologies to support evidence-based decision making and legislation (expert networks);**
5. **providing scientific advice on medical technologies to Member States, the European Commission and innovators.**

Independent and experienced in the broad range of technologies that reflect the medical device industry, the JRC is the natural partner for DG SANCO and Member States to shape and drive a smart EU legislative framework for medical technologies, which will bring forward safety and innovation in order to face current and future broader healthcare challenges successfully. JRC is already responsible for similar tasks in the area of transport safety and hosts the European Co-ordination Centre for Aviation Incident Reporting Systems

October 2011: Eucomed favours JRC

Coordinating Committee of Member States
with Administrative Support from:

Option 1 — Oversight by Member States

Option 2 — Assistance of DG Research's Joint Research Centre and/or DG SANCO's Executive Agency for Health and Consumers 

Option 3 — Standalone Agency

Option 4 — Directorate in EMA

= Commission
= Member States (Heads of Agency approach)
= Agency

What is the Joint Research Centre (JRC)?

- **Part of EU Commission** (Status as a Commission service, under responsibility of Commissioner for Research and Innovation)
- **2,700 staff, annual budget of €320 million, comprises seven research Institutes in five EU Member States (Belgium, Germany, Italy, the Netherlands, and Spain).**
- Provider of **scientific policy advice and technical know-how** to support the implementation of a wide range of EU policies and legislations.
- **Contributing to the Europe 2020 strategy** by providing integrated socio-economic and policy support on research and innovation
- Already doing jobs related to health: helping DG SANCO and Member States with dedicated **Institute for Health and Consumer Protection, Ispra, Italy (300 staff and a 2007 budget of €30.2 million)**
- **JRC already collaborates with national authorities and networks on various issues at national level. For exploring what JRC does in your country click here .**

JRC: Potential new roles for medical devices*

1) auditing **Notified Bodies** to ensure a comparable, high level of quality across the EU;
2) coordinating **vigilance** incident reporting systems;
3) more extensive **horizon scanning** and foresight intelligence on potential health concerns;
4) providing **expert policy advice** in medical technologies to support evidence-based decision making and legislation (expert networks);
5) providing **scientific advice** on medical technologies to Member States, the European Commission and innovators.

* See also Eucomed position paper, November 2011

Current competences of JRC that are relevant for and can be extended to medical devices (I)

1. **Assists EU Commission and Member States on successful implementation of EU policies and legislation:**
   i. **On civil protection:** support implementation of EU policy on the control of major hazards prevention of major accidents by **scientific and technical activities** *(Major Accident Hazards Bureau)*
   ii. **On combating fraud:** support implementation of EU wine quality legislation, e.g. by **managing the European Wine Databank** *(European Office for Wine, Alcohol and Spirit Drinks)*
   iii. **On transport safety:** assist authorities in **vigilance by collecting, sharing and analyzing their safety information** *(European Co-ordination Centre for Aviation Incident Reporting System, will be extended to other public transport sectors soon)*

2. **Providing scientific and technical support on chemicals, food and consumer products, including risk-benefit assessment and analysis of traceability,** for DG SANCO and member states, *(JRC's Institute for Health and Consumer Protection, IHCP, in Ispra, Italy)*

3. **Quality control and safety testing of biologicals and biomaterials, including the biocompatibility of medical devices** *(European Centre for the Validation of Alternative Methods, ECVAM, hosted by IHCP)*

Current competences of JRC that are relevant for and can be extended to medical devices (II)

4. **Acts as a centre of reference through extensive networks with the relevant organisations in the Member States** and, where appropriate, international organisations, that gives scientific advice to policy-makers in issues related to metrology, **standardisation, harmonisation and quality of measurements and supplies certified reference materials for in-vitro diagnostic medical device applications** *(JRC's Institute for Reference Materials and Measurements, IRMM, in Geel, Belgium)*

5. Supports European co-operation for Accreditation (EA) of **notified bodies** with respect to **improving the quality of conformity assessment results**

6. **Horizon scanning and foresight intelligence on potential health concerns** *(e.g. Analysis report on the "Impact of engineered nanomaterials on health: considerations for benefit-risk assessment", Sept 2011)*

7. **Works in collaboration with the European Commission on eHealth** e.g. in collaboration with the Directorate General Information Society and Media (**DG INFSO**) on the 'SIMPHS' project dealing with **Personal Health Systems (PHS) and Remote Patient Monitoring and Treatment (RMT).**

JRC the best option for Medical Technology (1): Responsible Innovation in Health

JRC is the best option for doing the job that needs to be done, because it:

- Gives a 'positive signal' tlinking research, safety, innovation and health
- **DNA of the is similar to that of MedTech**
- **Sound independent policy and scientific advice on medical technology** and in particular innovative medical technology
- **Maintains the two pillars of system, Member States and Commission,** and strengthens both with high level **independent** scientific policy advice

The tasks of JRC already today mirror what is needed for Medical Technology:

- **Horizon scanning, safety standards, coordination of safety elements and education**
- Has a broad policy focus to **tackle the grand challenges in Health** (aging population and health)
- **Expert networks**
- High level **independent** scientific policy advice and **'risk-analysis'**
- Source of **scientific and technical advice** to entrepreneurs and innovators.

JRC the best option for Medical Technology (2): Effect on Economy (Investment and Jobs)

Involving the JRC in medical device regulation will send the right signal:

- JRC could **signal optimism**, which is a “plus” for innovation, a “plus” for patients, a “plus” for jobs and a “plus” for Europe
- Venture capital dropped from €22 billion in 2000 to €3 billion in 2010 in Europe (*President Barroso*). **Markets and Investors are watching developments closely**.
- If the MDD revision sends a **strong message to the markets** that Europe is fully behind innovation (JRC) investment will follow. If a message is sent that Europe is adding unnecessary bureaucratic burden and steering in the direction of FDA-like procedures, investment in Europe will dry up.
- This will not only negatively affect achieving the Europe 2020 strategy, it will **slow down our pace and ability to meet the grand challenge in health**.

THANK YOU