Sustainable Competence
in Advancing Healthcare

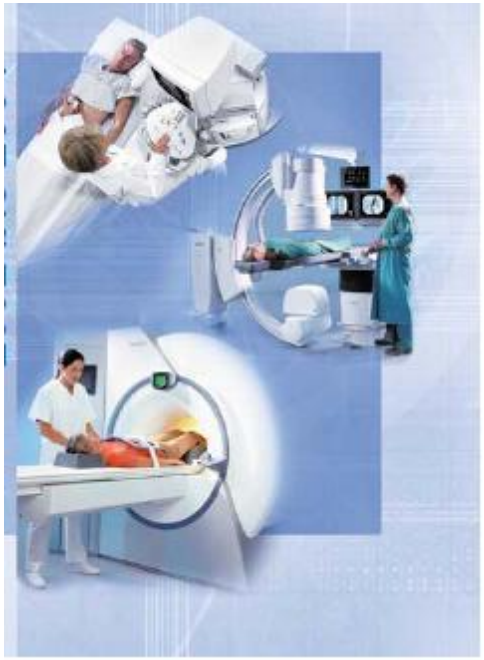
Q1 Productions 2nd Annual European Medical Device Regulation Conference

MDD Revision Formal Proposal Main Objectives & Clarification

***Thursday 18 April 2013,* Brussels**

Nicole Denjoy - *COCIR Secretary General & DITTA Chair*

What is COCIR?



COCIR represents the Industry Voice in Medical Imaging, Electromedical and Healthcare IT

Our Industry leads in innovative healthcare technologies and provides solutions for the complete care cycle

Visit our website: www.cocir.org

COCIR Member Companies

COCIR National Trade Associations Members

Belgium

Italy

UK

Spain

Netherlands

Finland

Netherlands

France

Germany

Sweden

Turkey

Germany

Summary

1. The General Context
2. European regulatory framework: industry priorities
3. Besides the regulatory framework
4. Future trends
5. The international scene
6. Conclusion

Medical technology Industry in Europe

Fact & Figures:

- About 22,500 medical technology companies in EU
- 80% SMEs
- 95 billion EUR annual sales; 8% re-invested in EU (28 billion EUR for COCIR)
- Nearly 500,000 employees
- > 500,000 products (10,000 generic groups)
- One new European patent every 38 minutes
- Healthcare Information systems touch every patient many times along the continuum of care
- One out of two patients in a hospital is imaged

Various sectors:

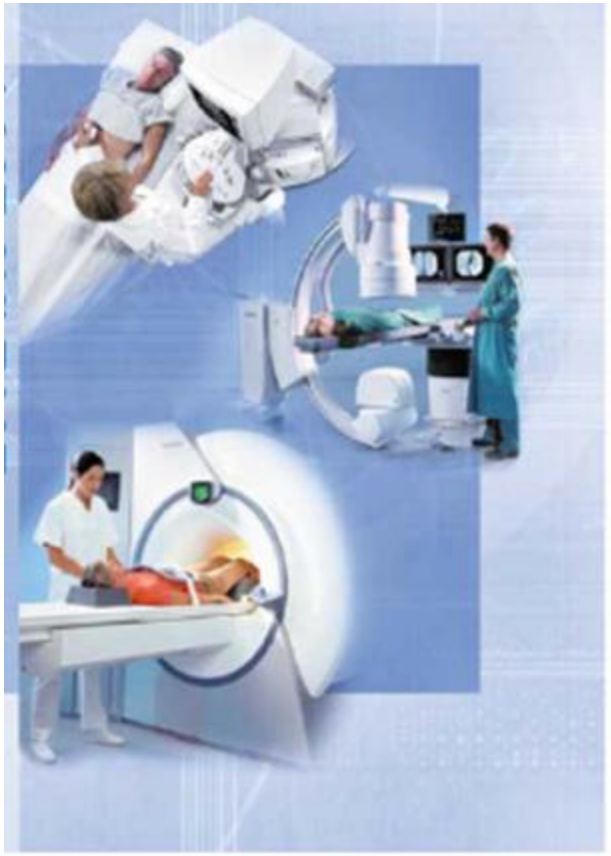
- Eucomed (Medical Devices)
- COCIR (Medical Imaging and Healthcare IT)
- EDMA: (*in vitro* diagnostic medical devices)
- And others (dental, vision care, hearing aids…)

The General Context

The General Context

- The (+)s:
  - COCIR has the lead on critically useful technology sectors (medical imaging and healthcare IT) shifting the mentalities from « sick care » to « healthcare »
  - Our sector is the most innovative in cost-efficiency solutions in the context of economic crisis
  - Our industry is global with the beauty to be composed of different sizes of industries. « We think globally, we act locally »

Changing Role of Healthcare Imaging

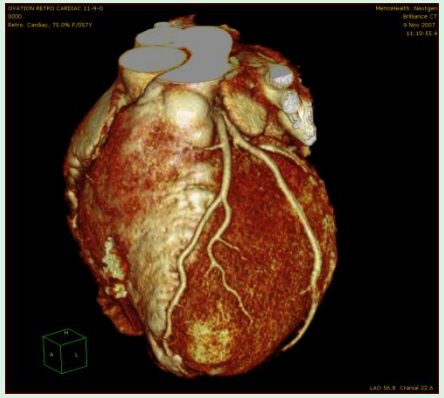


- Trend: **Minimal invasive procedures** (i.e. more gentle methods for the elderly) → more images for guiding Therapies than Diagnostic procedures
- Trend: Increasing number of **IVD tests** → Imaging tells the 'where'
- Request for **Screening**: One-third of all cancers could be cured if detected and treated early → earlier detection followed by less costly treatment / therapy
- Trend: **Personalized Medicine** → Biomarker research & imaging to characterize disease fundamentals

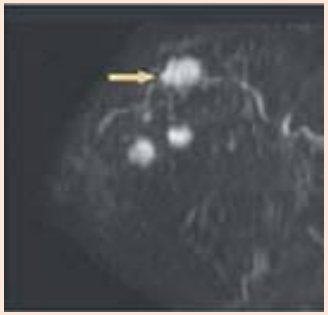
Medical Imaging: non invasive, faster, more accurate

Cardiac CT 1979

NOW



Breast MR 1998



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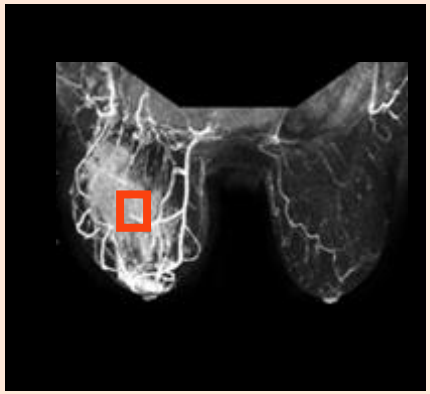
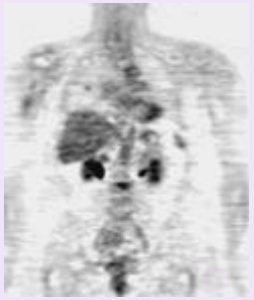


PET (FDG) 1995



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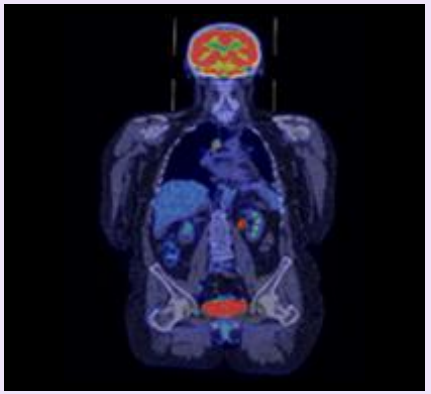
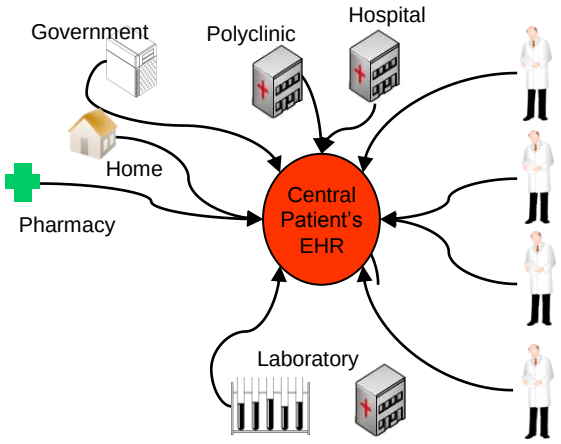


Enable new and more accurate diagnostics

Leverage the Power of Healthcare IT

- Healthcare IT and eHealth → proven high clinical and societal value
- Telehealth → linking patients with care providers
- IT infrastructure → ensure that systems derive maximal value from medical technology (Cloud computing)
- IT connectivity through IHE (Integrating the Healthcare Enterprise) → improving quality and reducing cost
- More investment in eHealth → best-practice clinical pathways / patient's mobility throughout Europe



The General Context

- The (-):

1. General economic crisis and Healthcare national budgets constraints
2. Scandals (growing concerns): PIP; Hip implant, breaking thin pacemaker leads, Pelvic floor meshes → Zero Risk is not a practical Goal
3. Regulatory science cannot keep up with rapid pace of device innovations
4. Several regulations recasts working in silos (datat protection, environment, radiation, EMF, MDD…)
    - Bringing some uncertainty about the future
    - Having the potential to create unexpected business burden and additional trade barriers
    - Hampering our research and capabilities to innovate

2. European regulatory framework: Industry priorities

What is important?

✓ The **protection and the well-being** of patients remains of the highest importance

✓ The **growth, jobs and competitive** European industry is also crucial

Evolution rather than Revolution

- Current system
  1. Implementing the current system
  2. Keep what is working well
  3. Better enforce existing rules

- Future regulation
  1. Regulation versus Directive
  2. What is needed?
  3. Eliminate known weaknesses
  4. Improve transparency and predictability

Current System 1/3
Implementing the current system

- Boost the 'Joint Immediate Action Plan':
  - Functioning of Notified Bodies
  - Market Surveillance and Vigilance
  - Unique Device Identification
- Importance of Coordinated Implementation amongst Member States
- Better use of Information and Communication Technology *(e.g. product registration and post market surveillance)*

Current System 2/3
Keep what is working well

- Maintain the risk-based system for classification of medical devices
- Maintain the "New Approach":
  - Performing Conformity Assessment Procedures
    - Under risk-based involvement of Notified Bodies
    - Under the supervision of Competent Authorities
    - Based on risk management and quality management system
    - Based on harmonized standards and clinical data
    - Under the primary responsibility of manufacturers regarding the CE marking
  - Fast availability of innovative medical devices
    - Early patient benefit
    - Strengthening the competitiveness of European medical device manufacturers

Current system 3/3
Better Enforce Existing Rules

- Strengthen market surveillance and vigilance systems:
  - Enforced surveillance by competent authorities of Member States
  - Better use of the instrument to perform unscheduled controls
  - Better enforcement of reporting requirements for adverse events

- Strictly enforcing the existing sanctions in the case of violations

Future regulation 1/4
Regulation versus Directive

- It will ensure the new regime is interpreted and applied consistently throughout all Member States.

- The new regulatory structure should remain robust, transparent and adaptable to scientific and technological progress.

- The over-riding objective must be for smart and efficient regulation delivering patient safety, high quality and rapid access to highly-innovative medical technology.

Future regulation 2/4

What is needed in the future regulation?

- **Coordination and cooperation of Authorities** on Notified bodies, Vigilance and Market Surveillance
- Certainty on EU and International **Standards and Guidelines** for Patient and Consumer Safety
- **Transparency** and Involvement of **Stakeholder Advisory Group** (Industry, Patients, Scientific Societies)
- **Traceability**; Unique Device Identification, **UDI** (Globally coherent)
- Enhanced use of Information and Communication Technology, **ICT to connect the system and monitor** post market performance (vigilance, registries, etc.)

Future regulation 3/4
Eliminate known weaknesses

- **Coordination and cooperation** between competent authorities of Member States
  - Exchange of data between authorities: Establishing a common database for registration of manufacturers, certificates, products, clinical trials and market surveillance data
  - Alignment of vigilance systems
  - Harmonized notification and surveillance of Notified Bodies
- **Improve and align** the functioning of Notified Bodies
  - Harmonized and higher quality level of Notified Bodies
  - Better expertise of Notified Bodies
  - Harmonized and stronger surveillance of Notified Bodies
- **Strengthening** the Notified Bodies
  - Clear assignment of tasks, e.g. mandatory unannounced audits

Future regulation 4/4
Improve Transparency and Predictability

- Transparent processes

- Clear responsibilities of all stakeholders:
  - Competent Authorities
  - Manufacturers
  - User (maintenance,…)
  - Healthcare provider (IT network, integrated/combined solutions, …)
  - Distributors/importers (ref to traceability, …)

Safety is a shared responsibility!

- Unambiguous, predictable and binding rules
  - Especially important for SMEs
  - Legal certainty regarding applicable standards and guidelines
  - Direct participation of all relevant stakeholders (authorities, Notified Bodies, industry, users, patients, academia, …)

The Key Priorities for Industries

Common work to support the system's safety and innovation elements:

Best practices in:

- Vigilance
- Clinical
- Standards

Implementation of:

- A sustainable regulatory model
- Unique Device identification, UDI
- Information and Communication Technology, ICT

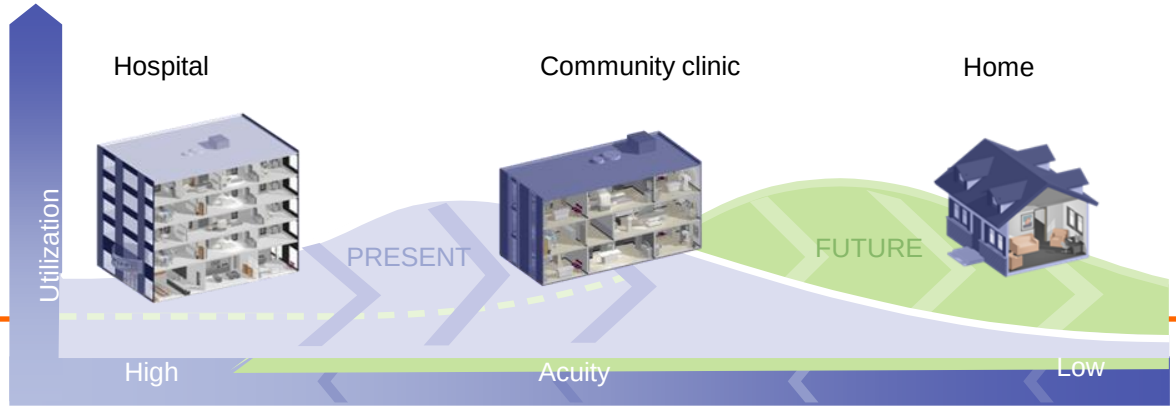
- Dagmar Roth-Behrendt MEP (ENVI) draft report published.
- Nora Berra MEP (IMCO) draft report published

- Timeline:
  - Deadline to submit amendments: 07 May 2013
  - European Parliament ENVI Committee vote: July 2013
  - European Parliament Plenary vote: November 2013

3. Besides the Regulatory Framework

Call for attention to public authorities

- Innovative technology as long-term investment
- EU and the Members States as drivers of implementation and uptake of innovative technology
- Need to accelerate adoption of new methods and technologies into clinical practice → Healthcare authorities should translate faster innovation from research to market
- Public procurement and reimbursement systems should incentivise innovative technologies and IT connectivity



Funding

- Simplify framework programs and enhance access to funding to promote innovative healthcare → Horizon 2020
- Need to optimise the use of structural funds in health and heathcare innovations
- Research funding should not neglect applied innovations
- The EU Research and Innovation landscape and its funding should focus more on supporting innovations that can address societal challenges
- Lack of long term planning of eHealth funding

4. Future Trends

Key issues for medical device/technology sector over next 5 years, 10 years

- Combination and integration of diverse technologies bringing innovative solutions for the benefits of patients but also increasing complexity
- Without concerted efforts of regulators we will have continued global products while still facing multiple local regulations
- Other regulations outside IMDRF control: radiation, dose reduction, RoHS, WEEE etc…
- Decentralisation of healthcare (remote diagnosis, mHealth, …)

Trends in medical device/technology innovation? The next generation

- New and emerging technologies (MR/PET, biomarkers, biosensors,etc)
- Integrated technologies (product and services) to cover the continuum of care
- Public Private Partnerships (establishment of consortia)
- Development of telehealth, mobile Health, cloud computing, remote care… with more ICT players
- Collaborative partnerships with academia, users and professional organizations (optimisation programs- e.g. CT dose, user training).

Trends in global manufacturing

- Continuation in the way to manufacture based on combination of several criteria:
  - regulatory pressure,
  - cost of labor,
  - close to appropriate resources and to raw materials
- Due to complexity of the technology, higher number of suppliers. Manufacturers are more frequently considered as ‘assemblers’
- Proactive approaches towards Green Technology for more sustainable solutions (e.g. Eco-Design)
- Contribute to recycling economy (remanufacturing…)

5. The International Scene

Various initiatives

- EU-US MoU on Interoperability
- EU-US trade initiative 'TTIP' on regulatory convergence
- IMDRF:
  - 5 Work Items
  - 1 on Medical Software

New!

Conclusions

COCIR Vision on global regulatory framework

- Provide ability to achieve worldwide harmonisation of regulatory framework for medical devices

- Goal “Approved once, Accepted everywhere” with concept of
  - One registration process
  - One conformity assessment process
  - One audit process
  - One post-market process

    … based on GHTF guidances

Thank you for your attention

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