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Medical devices in Europe

AHWP – Asian Harmonisation Working Party Conference

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Recent developments in Europe

- Background EU regulatory framework
- Review Process and Follow-up
- Human tissue engineering.

EU Directives on Medical devices

- **93/42/EEC** of 14 June 1993 concerning medical devices
- **2000/70 EC** of 16 December 2000 on stable derivates of human blood or human plasma
- **90/385/EEC** of 20 June 1990 relating to active implantable medical devices
- **98/79/EC** of 27 October 1998 on in vitro diagnostic medical devices

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Basic elements of regulation

- Mandatory Essential Requirements
- Flexibility on technology used to meet ERs
- Presumption of conformity by using European ("harmonized") Standards
- Variety of conformity assessment procedures related to various classes of risks; clinical evaluation; pms
- "CE" marking
- Market surveillance and Vigilance
- Intervention mechanisms by public authorities

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	Annex VII	Annex III			Annex II	Annex II
DESIGN / PRODUCTION	MANUFACTURER DECLARATION	EC - TYPE APPROVAL			FULL QUALITY ASSURANCE	FULL QUALITY ASS / EC EXAMINATION CERT
		Annex IV	Annex V	Annex VI		
		EC VERIFICATION	PRODUCTION QA	PRODUCT QA		

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Intervention mechanisms for authorities

- Designation and monitoring of Notified Bodies
- Reclassification of devices
- Mandates for standards
- Formal objection to standards
- Safeguard clauses
- Precautionary principle
- Market surveillance
- Administrative cooperation
- Guidance

Other relevant documents

- Community Measures in relation to reclassification or follow-up to national measures based upon precautionary principle
- Common Technical Specifications for IVDs
- Commission Communications, providing interpretative guidance by Commission
- Guidelines (MedDevs) adopted by stakeholders in the framework of the Medical Devices Experts Group
- European Standards
- Guidance documents developed by Notified Bodies.

Actors involved in implementation

- European Commission
- National authorities
- Notified Bodies
- European Standards Bodies
- Industry

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Bodies and Committees involved

- MDEG: Medical Devices Experts Group
- Regulatory Committee set up by Directives

various other subgroups:

  - CETF: Clinical Evaluation Task Force
  - NBOG: Notified Bodies Operations Group
  - MSOG: Market Surveillance Operations Group
  - Notified Bodies Technical Forum
  - Scientific Committee for Medicinal Products and Medical Devices

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Report on the functioning of the MDD and Commission Communication

- Consensus based analysis and statement of issues, elaborated by the Medical Devices Experts Group (June 2002)
- Commission Communication (July 2003)
- Some 40 recommendations to be implemented by different means and actors
- http://europa.eu.int/comm/enterprise/medical_devices

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Main Conclusion of Review report

"The Medical Devices Directives provide in themselves an appropriate legal framework with a view to safety aspects and technological evolution.

However, there is room for improvement in implementation, to be achieved by all parties involved: national authorities, Notified Bodies, Commission and industry."

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Main areas identified

Conformity Assessment, in particular

- design review under integrated quality approach
- PMS
- Clinical Evaluation
- Market Surveillance and Class I devices
- EUDAMED, the European Database on Medical Devices

Improvements should be achieved through

- implementing measures at national level
- use of available instruments created by the Directive
- regulatory clarification
- guidance documents
- coordination and co-operation with/between Member States
- increasing awareness

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Issues considered for regulatory clarification in the framework of the “review”

- Scope
- Classification anomalies
- Annex II (design evaluation) and validity of certificates
- Retention of product files
- Expiry date for sterile medical devices
- Authorized representative
- Active implantable devices directive to be aligned on MDD and IVDD

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Review of Directives 93/42/EEC and 90/385/EEC

- Presently under discussion (co-decision procedure) in the European Parliament and the Council

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Review of Directives 93/42/EEC and 90/385/EEC

- Overall regulatory approach kept
- Main changes deal with:
  - interface with other Directives, including tissue engineered products
  - reinforce clinical evaluation and market surveillance
  - designation of notified bodies – conformity assessment bodies, and its monitoring

Awareness

- Medical devices is a large and evolving sector, with a wide variety of products and risks, increased complexity for users high impact on public health and public health expenditure

- Sector study in 2005 on economic dynamics, impact on public health and competitiveness

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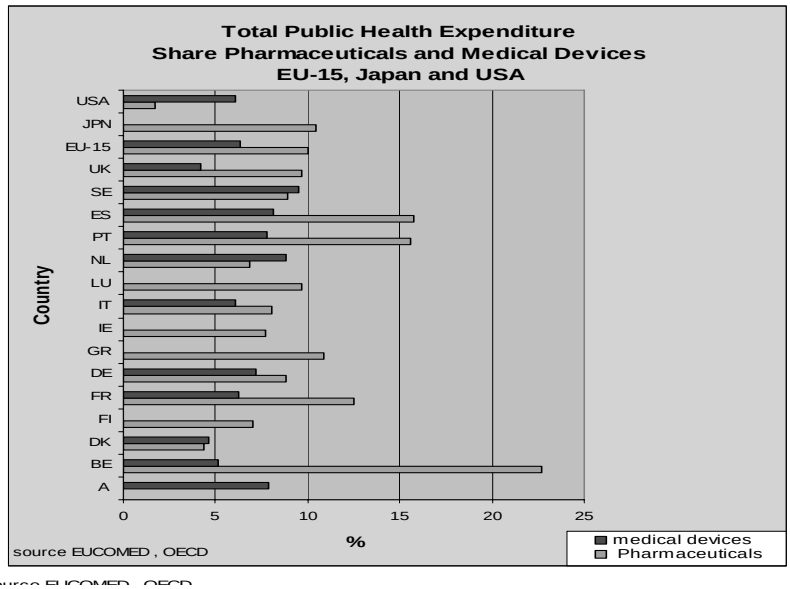
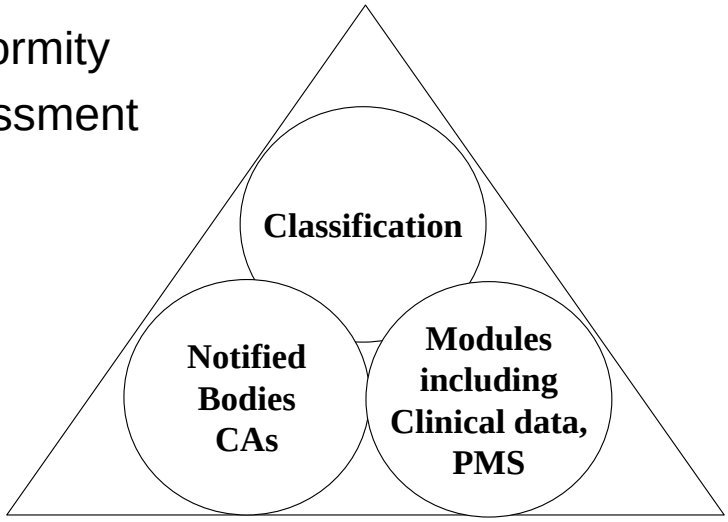


Conformity Assessment



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Increase transparency

- EUDAMED (European Data Base for Medical Devices) and GMDN indispensable tools
- Consensus for more openness to the general public changes with the “review” – art. 20 of the Directive 93/42/EEC
- Specific, pragmatic mechanisms developed for devices incorporating tissues of animal origin (Commission Directive 2003/32/EC)

Enlargement

- 10 countries joined in May 2004, increasing the European Market.
- The challenge of a successful integration

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Enlargement

- Two new Member States expected in 2007: Bulgaria and Romania
- Negotiations on course for further accessions: Croatia and Turkey

The global level

- Europe confirms commitment to GHTF
- Supports co-operation between CEN and CENELEC with ISO and IEC
- Mutual Recognition Agreements

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Article 95 (Treaty of Nice)

<< Approximation of laws >>

The Commission will as a base…ensure "a high level of protection"…and "absence of danger for human health".

"Treaty of Nice"

Mainstreaming:

- High level of health protection
- Environment protection
- Job creation

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GHTF
Global convergence and co-operation

- To maximise the benefits that rationally used healthcare technologies may generate in a given economical context
- To manage risks associated with healthcare technologies

GHTF
Global convergence and co-operation

Key points:

- Conformity assessment before placing on the market (quality, security, performance/efficacy)
- Product and manufacturer registration
- Post-market surveillance and vigilance

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GHTF
Global convergence and co-operation

Post-market surveillance

The key element

- reduces inappropriate use of devices
- increases patient safety

Post-market surveillance
GHTF - NCAR
National competent authorities reports – vigilance

- Presently – GHTF founding members and some other industrialised countries
- Need to enlarge it to other countries with medical devices regulatory systems

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Post-market surveillance
GHTF - NCAR

- What is “Public information”?
- What is “Confidential information”?
- Need for bilateral “confidentiality agreements”

Post-market surveillance
GHTF - NCAR

- Need to share information – in a standardized format
- The usefulness of GMDN – the global medical devices nomenclature

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GHTF
Global convergence and co-operation

… but, is “convergence” an acceptable alternative?
Is it feasible?

The answer is, YES!

GHTF
Global convergence and co-operation

Major points agreed overall

- Definition of medical devices
- Essential requirements
- Role of standards
- Labelling
- Classification (minor discrepancies)
- Post-market follow-up and vigilance

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Thank you!

http://europa.eu.int/comm/enterprise/medical_devices/index.htm