The European Union Medical Device Regulatory Framework

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Explanatory part of the "screening "
(Croatia, Turkey)
Brussels, 18 January 2006

European Union's overall trade policy objective:

FACILITATE TRADE

But……

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”.

A “safe-guard” is included allowing intervention based on… “one of more…non-economic reasons”.

“Treaty of Nice”

Mainstreaming:

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

“Treaty of Nice”

Overlaps between Article 95 – the legal basis DG Enterprise – Medical Devices operates,

and

Article 152 - public health

and

Article 5 – principle of subsidiarity…

Community shall take action only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by Member States and can,…by reason of scale or effects…be better achieved by the community.

‹‹ Community Legislation ››

– Mandatory - Directives; Decisions; Regulations

– “Soft Law” - Communications; Recommendations; Opinions; Guidelines

‹‹ Community Legislation ››

Co-decision procedure – Article 251

- Commission – initiative
- Parliament – opinion
- Council – qualified majority

‹‹ New Approach ››

Concept - free movement of goods, a cornerstone of the single market

Mechanisms - prevention of barriers to trade, mutual recognition and technical harmonisation

‹‹ New Approach ››
(1)

New approach Directives are based on the following principles:

- Harmonisation is limited to essential requirements.
- Only products fulfilling the essential requirements may be placed on the market and put into service.
- Harmonised standards, are presumed to conform to the corresponding essential requirements.

‹‹ New Approach ››
(2)

Principles

– Manufacturers may choose between different conformity assessment procedures provided for in the applicable directive.

*New approach directives are total harmonisation directives – the provisions of these directives supersede all corresponding national provisions.

CE Marking

The CE marking symbolizes the conformity of the product with the applicable Community requirements imposed on the manufacturer.

Simultaneous application of directives

Where products are subject to several directives, which provide for the affixing of CE marking, the marking indicates that the products are presumed to conform to the provisions of all these directives.

Notified Bodies

- Designated by Member States' Designating Authority for carrying out the tasks concerning the conformity assessment procedures (class IIa, IIb and III).

  A certificate is delivered, to be used by the manufacturer/authorised representative to introduce a Declaration of Conformity and then qualify to "CE" mark the devices.

Features of the Medical Devices Sector

- A wide range of products and technologies
- A fast evolving market and technology
- Technically complex area
- High impact on public health expenditure
- A young regulatory framework
- Appropriate administrative structures still being build up
- Still largely unknown area

Challenges

- Decentralized implementation in an enlarged market
- Increasingly high consumer and patient expectations
- New technologies not (sufficiently) covered by current regulatory frameworks
- Convergence of various technologies and borderline issues
- Changing needs in the light of health policies and demography
- Increased coverage in Parliaments and media
- Increasingly high political profile

Medical Devices in the EU

Three main areas of involvement:

- Access to a common internal market
- Trade facilitation and regulatory convergence
- Competitiveness of industry

Medical Devices in the EU

Tasks of the Medical Device Sector:

- Implementation and enforcement of the existing regulation.
- Development of new legislation to cope with innovation and technological development
- International dimension (co-operation).

Medical Devices

Existing Directives

90/385/EC	on active implantable medical devices
93/42/EEC	concerning medical devices
98/78/EC	on in vitro diagnostic medical devices
2000/70/EC	on medical devices incorporating stable derivatives of human blood or human plasma
and	
2002/104/EC	
2003/32/EC	on MD utilising substances of animal origin.
2005/50/EC	Reclassification of hip, knee and shoulder joint replacements

Other relevant documents

- Community “Measures” in relation to reclassification or follow-up to national health monitoring measures;
- 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.

Basic Features of Community Regulatory Framework

- Definition of essential requirements, allowing for innovation and technological flexibility
- Access to Community market
- European standards giving presumption of conformity
- Variety of conformity assessment procedures, related to risks involved
- Manufacturer responsible for placing on the market and CE marking
- Intervention mechanisms for authorities

Regulatory Framework
(1)

The Directive leaves an important responsibility to manufacturers and Notified Bodies, in particular as there is no prior market approval mechanism

At the same time, in order to allow Member States to assume their responsibility for public safety, it defines authorities' responsibilities and creates various intervention mechanisms

Regulatory Framework
(2)

- Appointment and monitoring of notified bodies (art 16)
- Market surveillance; Verification of documents kept by the manufacturer (Article 2; Annexes)
- Vigilance (art 10).
- Wrongly affixed CE marking (Article 18)
- Safeguard clause (Article 8)
- National health monitoring measures (Article 14(b))
- Formal objection to standards (art 5)
- “Reclassification” (art 9, art13)
- Clinical investigation (art 15)
- Request for national languages (art 4)

Particular Health Monitoring Measures

- Precautionary principle

"Where a Member States…in order to ensure protection of health and safety and/or to ensure that public health requirements are observed…the availability of such products should be prohibited, restricted of made subject to particular requirements".

(Directive 98/75/EC Article 13)

EUDAMED

The European Databank on Medical Devices

- Regulatory data to be stored in a European Databank accessible to the Competent Authorities:
  - Data relating to registration of manufacturers and devices.
  - Data relating to certificates.
  - Data obtained in accordance with the "Vigilance procedure".

Review Process

General consensus in the Medical Devices Experts Group to carry out a review of the functioning of the regulatory framework

The MDEG Review Report (June 2002), a cconsensus based analysis and statement of issues

The Commission's Communication of July 2003, drawing the policy conclusions

The Council's Conclusions on Medical Devices of December 2003, endorsing the Review Process

Main Conclusion of Review Process

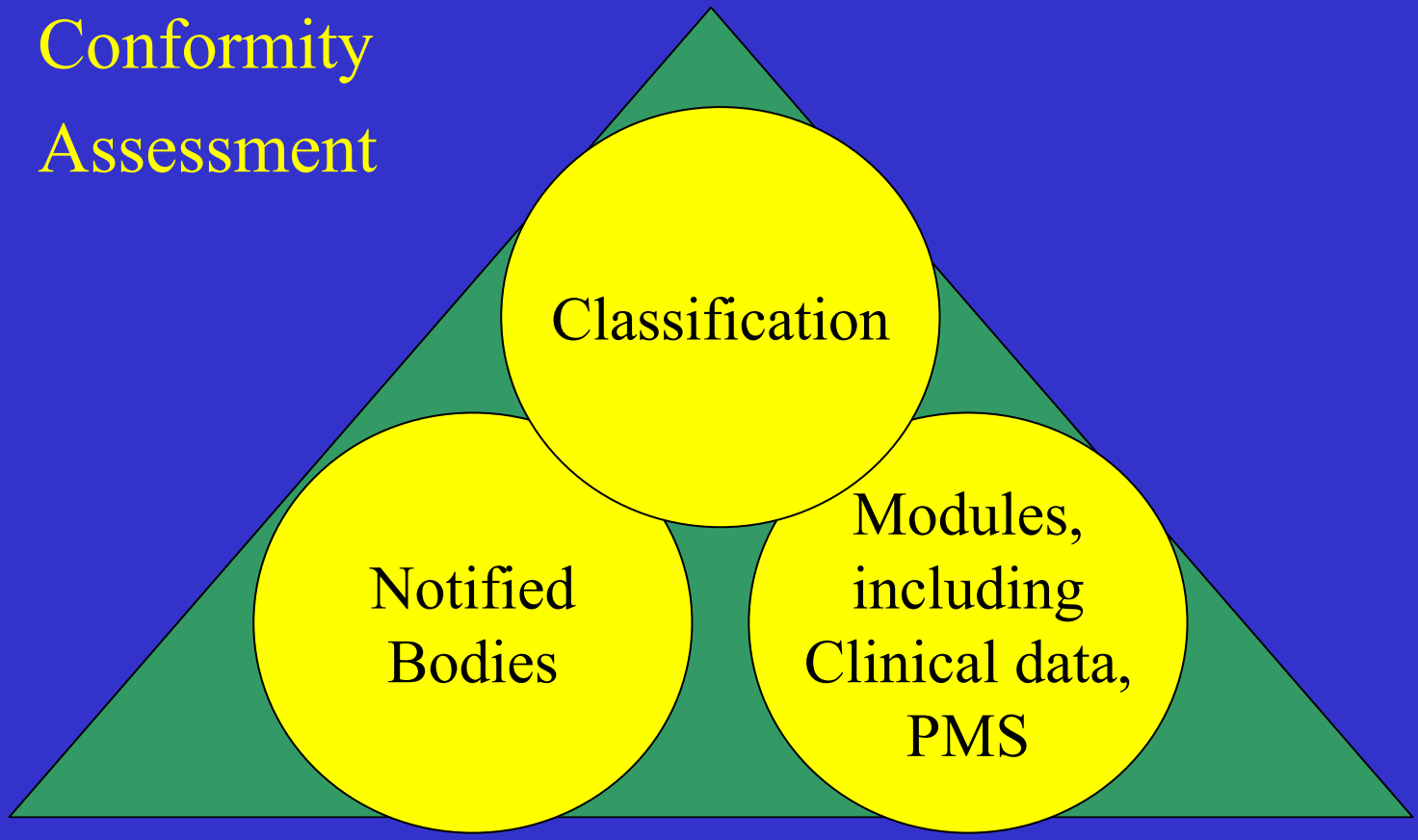
- The Medical Devices Directives provide in themselves an appropriate legal framework with a view to safety aspects and technological evolution.
- However, implementation must be improved by all parties involved: national authorities, Notified Bodies, Commission and industry
- The most critical area where improvements should be made concerns conformity assessment

Review Process

Draft text adopted by the Commission on December 22nd 2005.

Proposal sent to the Council and European Parliament.

- Conformity
- Assessment



Trade facilitation and Regulatory convergence

- Mutual Recognition Agreements
- Trade facilitation arrangements –exchange of letters; administrative co-operation
- Global Harmonization Task Force

Global Harmonization Task Force

"Regulatory convergence"

- Informal platform of authorities and industry
- Europe, US-Canada, Japan-Australia
- 80% of world market

Evolution in GHTF activities

- Coherent implementation of common elements in regulatory systems
- Common Projects on Vigilance, GMDN
- Regulatory guidance
- Common data sets
- Identification of new regulatory challenges
- Exchange of information

Impact of GHTF

- Europe and Australia are very much aligned on GHTF Guidance,
- Japan is involved in a major regulatory reform based on GHTF
- Other founding members are, to different degrees, in the process of implementing or using GHTF Guidance and documents
- GHTF, MRAs, acceptance of common data

European Chair 2004 – 2006

- Implementation of current priorities, in particular on common data
- Cooperation with WHO and international standards organizations
- New themes to be developed: design for patient safety, medical software and new technologies
- Review of the procedural documents – updated Rules available on the website: www.ghtf.org

Mutual Recognition Agreements

"To live with the difference"

- A concept difficult to implement
- MRAs exist US, Australia, Canada, and Switzerland; discussions to start with Japan
- The impact of unilateral national measures

Study on Competitiveness

- A project of Commission, Member States and Industry
- Monitored by joint Steering Group
- Carried out by the University of Siena
- Available since September 2005 on the website:

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

Study on Competitiveness

- Description of market
- The impact on health care and public expenditure
- Innovativeness analysis and strategic recommendations
- Competitiveness-analysis and strategic recommendations
- Information collection

Conclusion

As regulators, our task is

- to deliver a predictable and efficient legal environment.
- To ensure legal frameworks which are conceptually clear and easy to comply with so that businesses may make their investments and
- Consumers to have access to state of the art medical devices in order to ensure the highest possible level of health protection.

Thank you!

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