European Commission

Enterprise Directorate-General

Medical Devices and Medical Technology

EU Open Forum 2005 – Pharmaceuticals and Medical Technology

7-8 November 2005, Brussels, Belgium

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European Commission

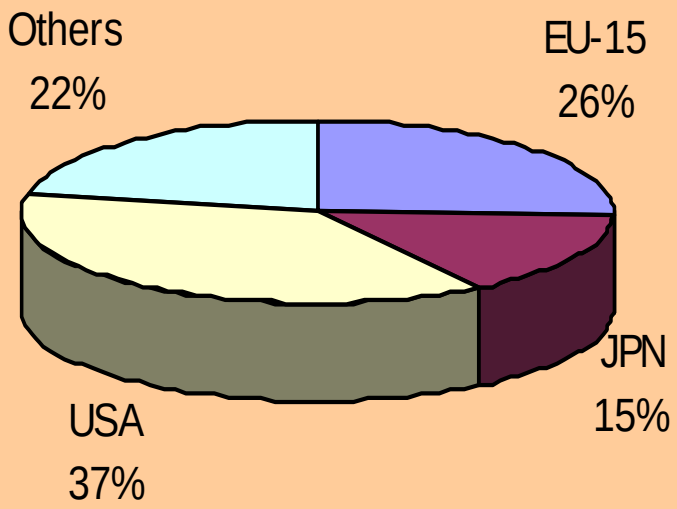
Introduction and legal basis

- The regulations
- Compliance
- GHTF
- Review of the Medical Devices Directive

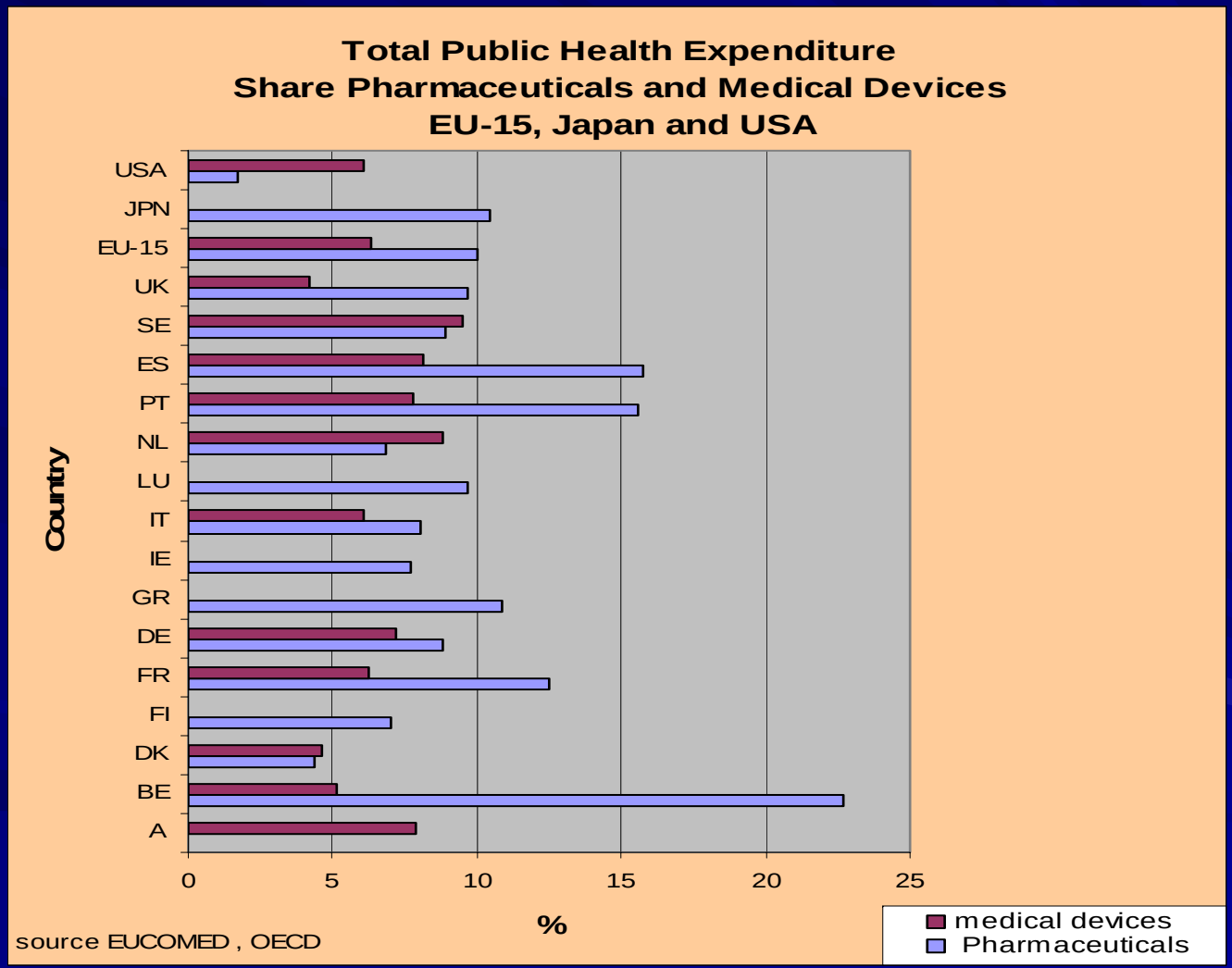
Features of the Medical Devices Sector

- 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 built up

World Medical Devices Market Share in 2000



source : EUCOMED 2000



source EUCOMED , OECD

Medical Devices in the EU

Three main areas of involvement:

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

Article 95 of the Treaty
(2)

…taking as a base “a high level of protection … based of scientific facts”, i.e. “danger for human health”…

…

…”the harmonisation … include a safeguard clause”.

Article 152 of the Treaty

"Public health"

…"a high level of human health protection shall be ensured in the definition and implementation of ALL community policies and activities"…

EU Directives on Medical Devices

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

Other EU Directives also apply to medical devices including:

- Electromagnetic compatibility
- Dangerous substances
- Ionizing radiation health protection
- Animal by-products regulation EC 1774/2002

Medical Devices

Definition-

Medical devices means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings, for the purpose of….

Medical Devices definition

Diagnosis, prevention, monitoring, treatment or alleviation of disease; alleviation or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception……..

Medical device definition

and which does not achieve its principal intended action in or on the human body by

Pharmacological
Immunological
Metabolic

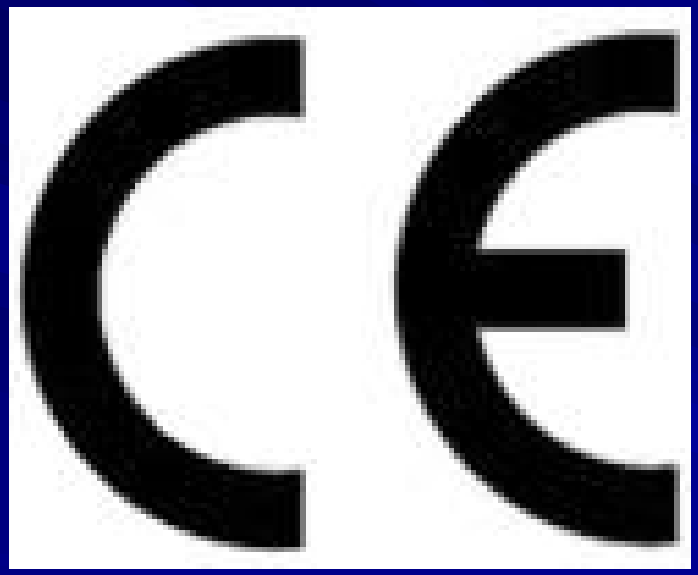
(but which may be assisted in its function by such means)

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

Actors involved in implementation

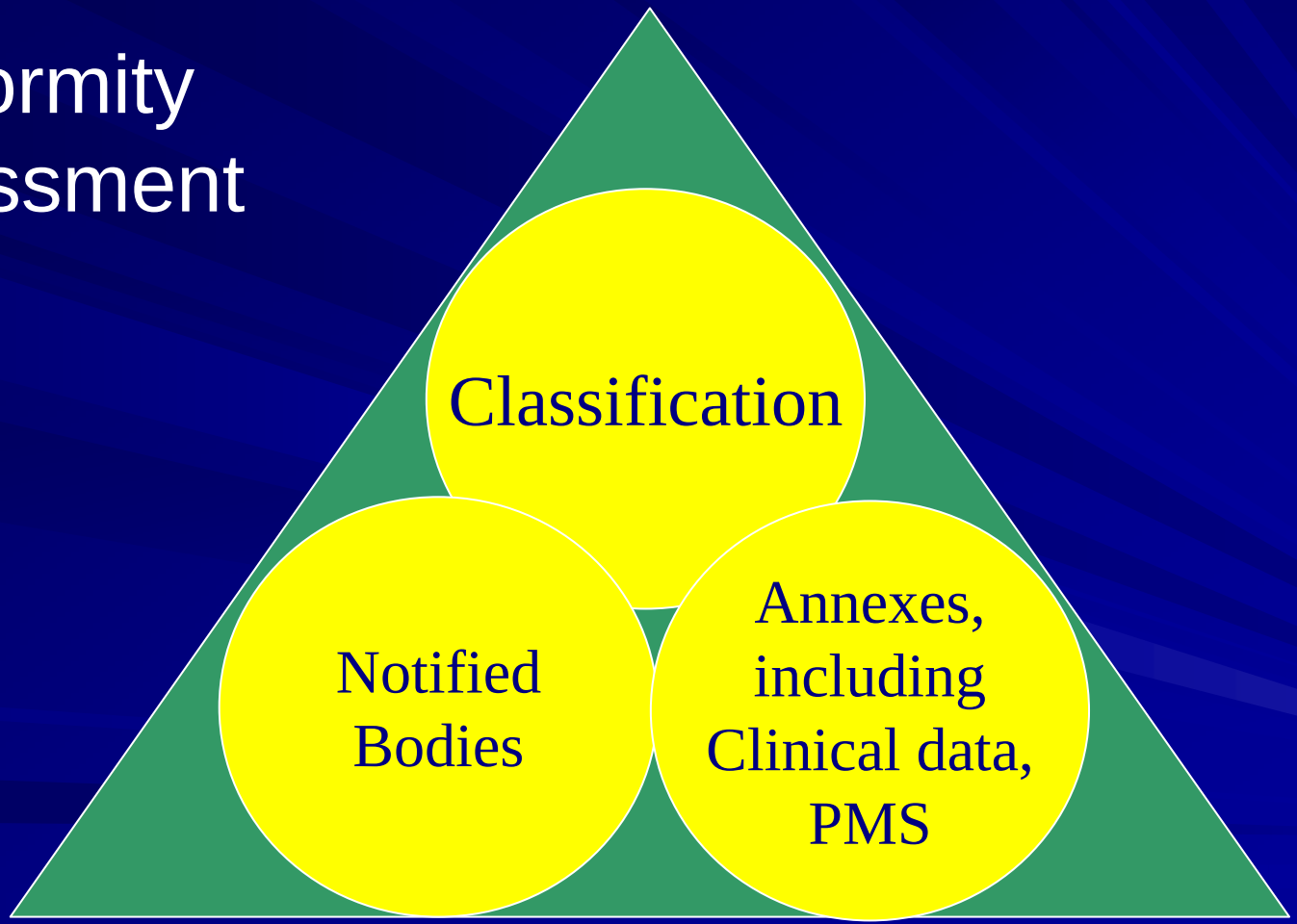
- European Commission
- National Authorities
- Notified Bodies
- European Standards Bodies
- Industry
- Advisory bodies (Scientific Committee)



CE Marking

- The CE marking symbolizes the conformity of the product with the applicable Community requirements imposed on the manufacturer.
- The CE marking affixed to products is a declaration by the person responsible that:
    - the product conforms to all applicable Community provisions, and
    - the appropriate conformity assessment procedures have been completed.

Conformity Assessment



Global Harmonization Task Force

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

Review of the Medical Devices Directive 93/42/EEC

History

- MDEG report - June 2002
- Commission Communication – July 2003
- Council Conclusions – December 2003
- First Commission draft due MDEG – October 2004

Issues

Significant issues

(in no particular order)

- AIMD approach
- Clinical evaluation
- Software
- Classified anomalies
- Single use devices
- Compliance of Custom-made devices

Issues

Significant issues

(in no particular order) continued

- Design Dossier review
- Electronic labelling
- Transparency
- EMEA

Future Timetable

- Inter-service consultation finished
- Translation
- Proposal to Council and Parliament – October/November 2005

Thank you for your attention

For Any Information please contact

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