European Commission
Enterprise and Industry
Directorate General

Establishing Flexible Regulatory Regimes

Flexible…? Yes, but Robust !

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Directorate General Enterprise and Industry of the European Commission

The unit Cosmetics + Medical Devices is in charge:

- of developing, improving the Directives relating to these products, supervising their correct implementation,

… taking into account the competitiveness of the European industry :

- EU's Partnership for Jobs and Growth strategy, (Lisbon agenda)
- ➡ ie applying the principles of better regulation / simplification,

- the implementation of the Integrated Industrial Policy.

…in these two important application sectors.

- Medical device sector covers 8000+ products:

  - simple bandages and spectacles,
  - life maintaining implantable devices,
  - equipment to screen and diagnose disease,
  - sophisticated diagnostic imaging,
  - minimal invasive surgery equipment, …etc

- The European Union's involvement concerns mainly:

  - the regulatory level playing field of the internal market,

  - international trade relations and regulatory convergence

…for the competitiveness of industry.

Revision of the Directives: The situation today

- Three European Directives regulate the manufacture and putting into service of medical devices:

1. The Medical Device Directive 93/42/EEC,

2. The Active Implantable Medical Device Directive 90/385/EEC

3. The In Vitro Diagnostic Directive (IVDD) Directive 98/79/EC .

Never stop looking for improvement …

The Medical Device Directive 93/42/EEC

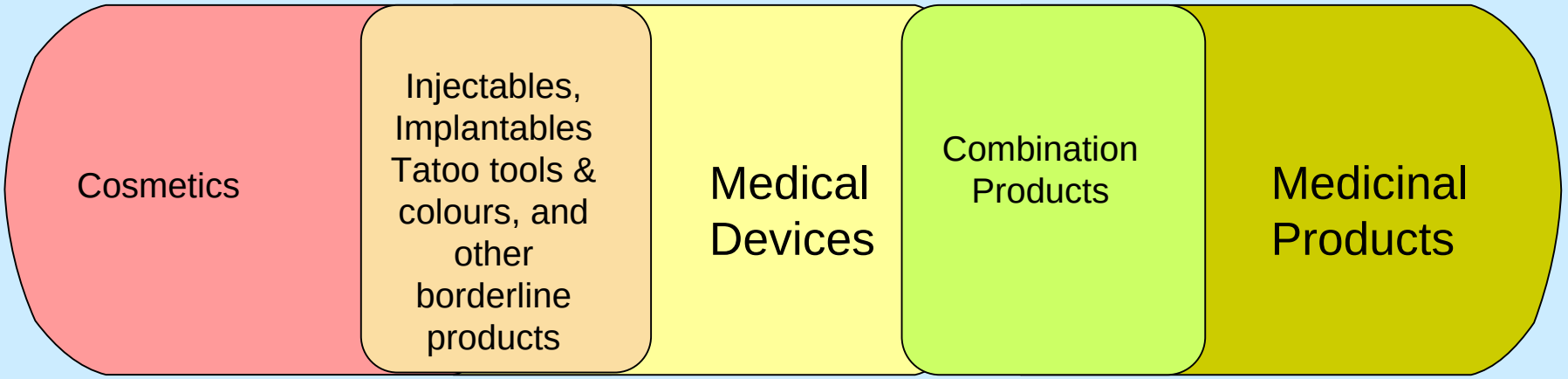
and the Active Implantable Medical Device Directive 90/385/EEC have just being revised (Formal Adoption in September 2007).

Furthermore, all three Medical Device Directives will be reviewed to prepare a recast proposal in 2008.

Why? … Because it's an never ending game to catch up:

- with technological development,
- with internet trade and globalization,
- with societies' increasing expectations

Borderlines' issues



Regulatory Framework: Two sides of the same coin

Internal Market

EU Directives

International Harmonisation

GHTF Guidance

European Industrial Policy for Medical Device Manufacturers in a Global Market

EUROPEAN PARLIAMENT

HEALTHCARE

ENTERPRISE

ENVIRONMENT

INTERNAL MARKET

TRADE

COMPETITION

EXTERNAL RELATIONS

EMPLOYMENT

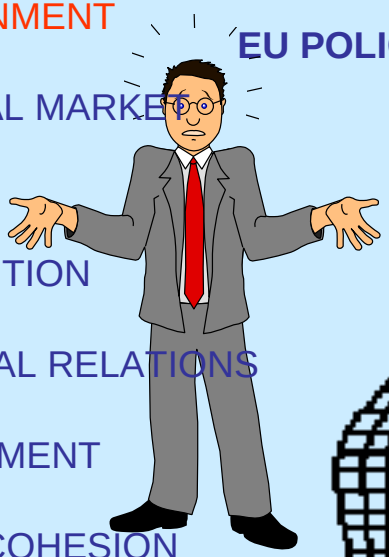
SOCIAL COHESION

EU POLICIES

MEDICAL DEVICE INDUSTRY

MEMBER STATES + INDUSTRY FEDERATIONS

NGOs



Difficulties

- To regulate or not to regulate? Which appropriate level?
  - EU Level
  - National Level
  - International Level

- Need for flexibility to share the same regulatory framework with more countries
- Need for a robust framework able to grant high safety standards

- How to assess the CAB
- How to maintain high training standard for the CAB

Thanks for your attention

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Cosmetics:
http://europa.eu.int/comm/enterprise/cosmetics/index_en.htm
Medical Devices:
http://europa.eu.int/comm/enterprise/medical_devices/index_en.htm