Press Briefing 16 November 2005

Tissue-Engineering
&
Advanced Therapies

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Pharmaceuticals Unit
Medicinal products based on

- Genes: gene therapy
- Cells: cell therapy
- Tissues: tissue engineering
Medical and economic importance

- Promising new treatment opportunities, e.g.
  - Skin replacement in burn victims
  - Reconstruction of blood vessels
  - Cancer
  - Alzheimer
  - Parkinson
- Today a limited market, but with huge potential
The regulatory gap

Legislation

Medical Devices
93/42/EEC

Medicinal Products
2001/83/EC

Advanced Therapies

Medical Devices
Tissue Engineering
Cell Therapy
Gene Therapy
Biotech
Chemicals
## Today's regulatory patchwork

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### autologous products

### allogeneic products

Ref. : Joint Research Centre, European Commission, 2004
Overall objectives

• Guarantee a high level of health protection
• Harmonise and facilitate market access
• Foster competitiveness
• Provide overall legal certainty
Regulatory levels of the overall approach

1. Existing Legislation on Tissues & Cells, Medical Devices and Medicines
   - Regulatory framework
   - Regulation on Advanced Therapies

2. Technical Requirements

3. Guidelines

Proposal!
• No marketing without prior approval
• Demonstration of Quality, Safety & Efficacy against tailored technical requirements
• Scientific assessment by European Medicines Agency (new scientific Committee)
• Risk management & Long-term traceability
The approach provides e.g. for

- Direct access to the Community market
- Harmonised data protection of 10 years
- Accelerated assessment
- Scientific advice at reduced fee
- Special incentives for SMEs
• **Regulation** to be adopted by Council/European Parliament

• **Technical requirements** should be ready shortly after adoption of the Regulation

• More information
  http://pharmacos.eudra.org/F2/advtherapies/index.htm