



# Workshop on Stem Cells: Scientific advances and EU/US policies

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## EU policy and regulatory developments on stem cells

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# The roadmap to the clinic?

- Safety issues
- Different legal regulations in EU MS
- Embryonic stem cells and ethics
- ...



# EU regulatory framework for stem cells





## ■ Objectives

- guarantee a high level of health protection
- stimulate innovation
- provide overall legal certainty, while allowing for technical flexibility

## ■ Applicable framework depends on:

- type of activity (research, therapy)
- type of product (tissues/cells, medicinal product)
- EU financing requested or not



## Donation, procurement, testing

- tissues & cells + manufactured products derived from tissues and cells
- intended for application in the human body (research or therapy)

### TISSUES & CELLS FRAMEWORK

## Processing, storage, distribution,...

Tissues & cells for application in the human body not covered by other EU Directives

**TISSUES & CELLS FRAMEWORK:**  
- tissue and cells directive

**No marketing authorisation**

**Gene Therapy**  
**Somatic Cell Therapy**  
**Tissue Engineering**

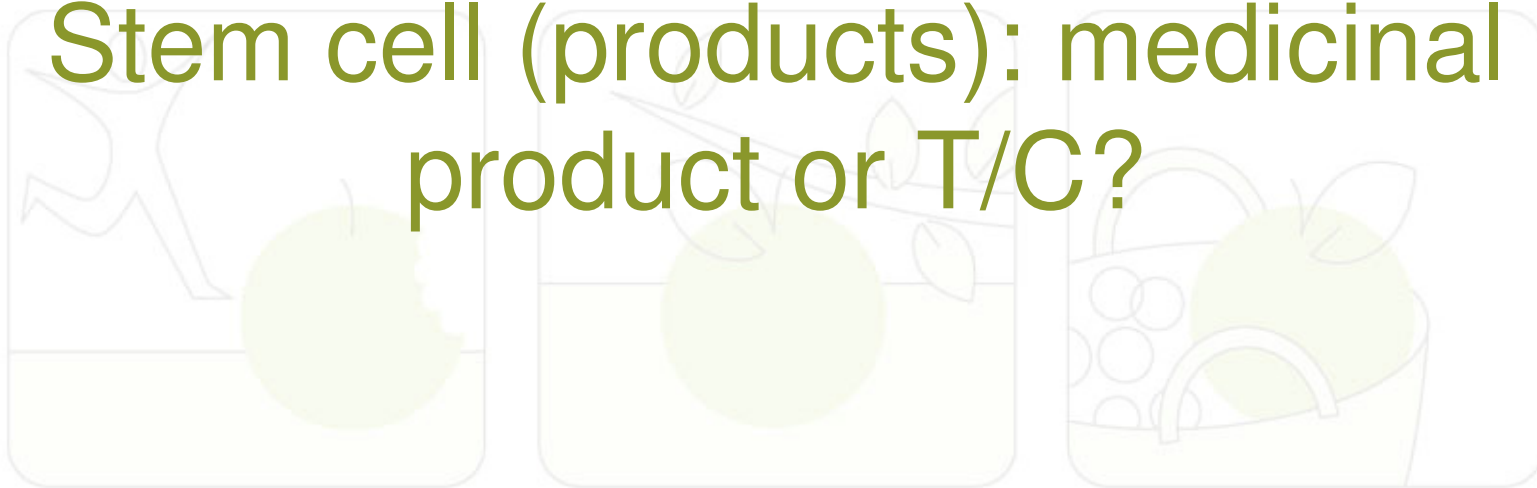
**MEDICINES FRAMEWORK:**  
-clinical trials  
-regulation on advanced therapies (proposal)

**Marketing authorisation**

**+ FP7 if financing by EU**



Stem cell (products): medicinal  
product or T/C?



## Advanced therapy medicinal products

- gene therapy
- somatic cell therapy
- tissue engineered products:
  - contains or consists of *engineered* cells or tissues:
    - substantial manipulation, or
    - non-homologous use, or
    - combination with device(s)
  - and is presented as having properties for, or is administered to human beings with a view to, regenerating, repairing or replacing a human tissue

## Tissues and cells

- tissues and cells
  - manufactured products derived from T&C
  - intended for human application
- example: stem cells for haematopoietic reconstitution



# Clinical trials framework

## Directive 2001/20/EC on clinical trials

- Directive 2003/94/EC Good Manufacturing Practice
- Directive 2005/28/EC on Good Clinical Practice

## Objectives

- protection of subjects participating in clinical trials
- information on clinical trials - including database
- single decision by competent authorities
- single decision by Ethics Committee



## Tissues and Cells framework

### Directive 2004/23/EC setting standards of quality and safety

- **Commission Directive 2006/17/EC**
- **Commission Directive 2006/86/EC**

- requirements for tissues and cells donation and procurement
- selection criteria and laboratory tests for donors
- Accreditation of tissue establishments and tissues and cells preparation processes
- inspection and control measures
- traceability/coding system
- import/export of human tissues and cells
- register of Tissue establishment and reporting obligations
- notification of Serious adverse events and reactions



## Advanced therapies framework

### Proposal for a regulation

To be adopted by September 2007

- No marketing without prior authorisation
- Centralised approval procedure:
  - demonstration of Quality, Safety & Efficacy
  - NEW Committee for Advanced Therapies
  - pooling of Community expertise
- Post-authorisation vigilance
- Special incentives for SME's



## More information?

- Tissues & cells (DG SANCO)

[http://ec.europa.eu/health/ph\\_threats/human\\_substance/tissues\\_en.htm](http://ec.europa.eu/health/ph_threats/human_substance/tissues_en.htm)

- Medicinal products (DG ENTR)

[http://ec.europa.eu/enterprise/pharmaceuticals/index\\_en.htm](http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm)