

# Harmonising the Legal Framework for the Use of Human Cells in Therapy in Europe didn't we forget something about Ethics?

Emmanuelle Rial-Sebbag\*, Aurélie Mahalatchimy\*, Anne-Marie Duguet\*, Anne Cambon-Thomsen\*

## Aim of the EU regulation

Maximizing the use of cells in therapy  
From Clinical Trials to Marketing authorisation for medicinal products

## Legal instruments

Binding instruments  
Same architecture:  
Scope, Objectives and Tools  
Focus on technical requirements

## Place of ethical questions

Debate on ethical issues between and within EU Institutions  
Member State in charge of solving the ethical questions

What is the new orientation for governing this field from an EU perspective? Is there a lack in addressing ethical concerns?

## REGULATORY STATE OF THE ART ON USES OF CELLS

- Legal instruments are adopted on the following legal basis
- The establishment and functioning of the internal market (art. 95 European Community Treaty)
- Public health Community action, measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures (art. 152§4 ECT)

### 1. GENERAL COMMUNITY LEGISLATION

#### CLINICAL TRIALS

*Directive 2001/20/EC*

- Only for clinical trials not for in vitro research
- To harmonise procedures within member states regarding the rules of clinical research
- Databases at EU level for notification of any research beginning in any EU Member State and for serious adverse reaction

#### STANDARDS ON QUALITY AND SAFETY FOR THE USE OF CELLS IN THERAPEUTIC

*Directive 2004/23/EC*

- For human cells including embryonic stem cells
- To develop common standards in order to ensure quality of tissues and cells for therapeutic uses
- Standard operating procedures (SOP) and traceability

### 2. SPECIFIC LEGISLATION ADDED REQUIREMENTS

#### ADVANCED THERAPY MEDICINAL PRODUCTS

*Regulation (EC) n°1394/2007*

- Regulation should supplement the existing rules with additional requirements, where appropriate
- Gene, cell and tissue engineered medicinal product
- To create an harmonised procedure in biotechnology field
- Common procedure for marketing authorisation, creation of a new Committee in charge of the evaluation

## PLACE OF ETHICS IN EUROPEAN LEVEL INSTITUTIONS

- Ethics remains a Member State competency
- At EU level
  - Ethical dimensions are addressed specifically by the European group on ethics of sciences and new technologies
  - Many ethical questions have been raised during the preparatory phase of the instruments. (European Parliament)
  - Most of them have not been addressed in the adopted texts
  - Ethics could be a part of a new way to build governance in life sciences in Europe and a domain of expression of European citizenship

## ETHICAL ISSUES

### CLINICAL TRIALS

- Discussions between Parliament and Commission on the legitimacy of conducting clinical trials on minors and persons unable to give their consent (regarding the benefit/risk balance)
- First attempt to include ethical issues in a legal binding text

### STANDARDS ON QUALITY AND SAFETY FOR THE USE OF CELLS IN THERAPEUTIC

- On the procurement of cells : semantic debate on how to qualify unpaid donation: "without any payment" or "Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells", the latter has been finally chosen
- Many proposals to integrate detailed ethical dimensions in the informed consent provisions

### ADVANCED THERAPY MEDICINAL PRODUCTS

- No mention of Embryonic stem cells
- Possibility for Member States to prohibit or restrict the marketing of medicinal products containing, consisting or derived from specific type of human cells and to invoke specific exceptions allowed by the EC Treaty.

## DISCUSSION ON CELL GOVERNANCE IN EU LAW

### COMPETENCY

- Most of the ethical arguments were rejected by the Commission « as they fall outside the scope of Article 152 of the Treaty, which provides for public health protection and not for the implementation of ethical objectives »
- Ethical questions were solved by the reference to the Charter of Fundamental Rights of the European Union and the Convention on human rights and biomedicine of the Council of Europe

### EQUAL ACCESS TO THE MARKET

- Harmonising access for patients to medicinal products
- Toward harmonising public health policies: a new challenge?

**Inserm**

Institut national de la santé et de la recherche médicale

\*INSERM Unité 558 Equipe 4  
Génomique et santé publique:  
approche interdisciplinaire  
© Correspondance :  
Emmanuelle RIAL-SEBBAG -  
Email : rialeb@cict.fr