European Quality System for Tissue Banking

Course in A Coruña

EU legislation on tissues and cells

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European Commission
Health and Consumer Protection Directorate General
Public Health and Risk Assessment Directorate
Health Measures Unit
The legal basis: Article 152 Public Heath

4 ...Shall contribute to the achievement of the objectives referred to in this Articles through adopting:

(a) Measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives, these measures not prevent any member States from maintaining or introducing more stringent protective measures.
Regulatory framework

**Directive 2004/23/EC**

of the European Parliament and of the Council setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

- codecision
- adopted by Parliament and Council on 31 March 2004
- transposed in all Member States by 7 April 2006
- basic principles
Regulatory framework

**Commission Directive 2006/17/EC**
Implementing Directive 2004/23/EC as regards certain technical requirements for the donation, procurement and testing of human tissues and cells

- comitology
- adopted by the Commission on 8 February 2006
- transposed in all Member States by 1 November 2006
- technical requirements
Regulatory framework

**Draft Commission Directive II**
Technical requirements as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells

- comitology
- to be adopted by mid 2006
- to be in force mid 2007
- technical requirements
Directive 2004/23/EC

GENERAL PROVISIONS

• Objective: Lay down standards of quality and safety for human tissue and cells intended for human applications, in order to ensure a high level of protection of human health.

• Scope

• Designation of Competent authority or authorities responsible for implementing the requirements of the Directive.

• Definitions
Directive 2004/23/EC. Scope

SOURCE

Donation, Procurement and Testing
Tissues and cells for application in the human body
Tissues and Cells Directive

PROCESSING

Processing, Storage and Distribution
Tissues and cells for application in the human body not covered by other EU Directives
Tissue and Cells Directive

REGULATION ON ADVANCED THERAPIES

Gene Therapy
Somatic Cell Therapy
Tissue Engineering
The Directive does not apply to:

- tissues and cells used as an autologous graft within the same surgical procedure
- blood and blood components (Directive 2002/98/EC)
- organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body
Directive 2004/23/EC

OBLIGATION OF MEMBER STATES AUTHORITIES

• Supervision of human tissues and cells procurement (persons with appropriate training and experience – conditions)
• Accreditation, designation, authorisation, or licensing of tissue establishments and tissues and cells preparation processes
• Regular inspection and control measures
• Traceability (including coding)
• Import/export of human tissues and cells: traceability – equivalent standards – by accredited tissue banks
• Register of Tissue establishment and reporting obligations
• Notification of Serious adverse events and reactions
Directive 2004/23/EC

DONOR SELECTION AND EVALUATION

• Principles governing tissues and cells donation (voluntary unpaid donation)
• Consent
• Data protection and confidentiality (render data to which third parties have access anonymous)
• Selection, evaluation and procurement
• Basic principles, technical requirements to be developed by Comitology
Directive 2004/23/EC

PROVISIONS ON THE QUALITY AND SAFETY OF HUMAN TISSUES AND CELLS

• Quality management
• Responsible person
• Personnel
• Reception
• Processing
• Storage
• Labelling, documentation and distribution
• Basic principles, technical requirements to be developed by Comitology
Directive 2004/23/EC

OTHER PROVISIONS

• Coding system
• Regulatory Committee
• Technical requirements and their adaptation to Scientific and technical progress Processing
Technical requirements: Commission Directives

Technical requirements for donation, procurement and testing.

- Requirements for the procurement of human tissues and cells;
- Selection criteria for the donor of tissues and/or cells;
- Laboratory tests required for donors;
- Cell and/or tissue procurement procedures and reception at the tissue establishment

Technical requirements for processing, preservation, storage and distribution.

- Requirements for the accreditation, designation, authorisation or licensing of tissue establishments
- Requirements for the tissue and cell preparation process
- Quality system, including training
- Requirements for traceability
- EU coding requirements
- Serious adverse reaction/event reporting
Directive 2006/17/EC on donation, procurement and testing

Requirements for the procurement of human tissues and cells
- Personnel
- Facilities
- Equipment and materials
- SOPs
Directive 2006/17/EC on donation, procurement and testing

Selection Criteria and laboratory tests for Donors

- HIV 1 and 2 | Anti-HIV-1,2
- Hepatitis B | HBsAg Anti HBC
- Hepatitis C | Anti-HCV-Ab
- Syphilis
- HTLV-I antibody testing must be performed for donors living in, or originating from, high-incidence areas or with sexual partners originating from those areas or where the donor’s parents originate from those areas.

- In certain circumstances, additional testing may be required depending on the donor’s history and the characteristics of the tissue or cells donated (e.g. RhD, HLA, malaria, CMV, toxoplasma, EBV, Trypanosoma cruzi).
Selection Criteria and laboratory tests for Donors of Reproductive cells

- Partner donation for direct use excluded
- Partner donation (processed and/or stored)
  - HIV 1 and 2 /Hepatitis B/ Hepatitis C
  - Exception for sperm processed for intrauterine insemination and not to be stored, if the risk of cross contamination and staff exposure has been addressed through the use of validated processes.
  - Positive results will not necessarily prevent partner donation in accordance with national rules.
Selection Criteria and laboratory tests for Donors of Reproductive cells

Donation other than by partners

- Donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional.
- HIV 1 and 2, Hepatitis B, Hepatitis C, Syphilis and Chlamydia.
- In certain circumstances, additional testing may be required depending on the donor’s history.
- Genetic screening for autosomal recessive genes known to be prevalent; after consent and information according with national rules.
Directive 2006/17/EC on donation, procurement and testing

- Donation and Procurement Procedures and reception at the tissue establishment
  - Consent and donor identification
  - Donor evaluation
  - Procurement procedures
  - Donor documentation: Procurement report to tissue establishment
  - Packaging and labelling
  - Reception at the tissue establishment
Draft: technical requirements as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution

- Requirements for the accreditation, designation, authorisation or licensing of tissue establishments
- Requirements for the tissue and cell preparation process
- Quality system, including training
- Requirements for traceability
- EU coding requirements
- Serious adverse reaction/event reporting

Fifty contributions were received from organisations at European and national level, tissues establishments and individuals.
Technical requirements II

Results of the Open consultation

- Separation of ART and Tissue banking
- Air quality
- The responsible person
- Costs of implementing quality management systems/time frame proposed
- Access to treatments vs. quality and safety
- Traceability and product recall
- Retention of serum samples
Technical requirements II

Requirements for the accreditation, designation, authorisation or licensing of tissue establishments

A. Organisation and management
B. Personnel
C. Equipment and materials
D. Facilities / premises
E. Documentation and records
F. Quality review
Technical requirements II

Requirements for the tissue and cell preparation process

A. Reception at the tissue establishment
B. Processing
C. Storage and release of products
D. Distribution and recall
E. Final labelling for distribution
Technical requirements II

Requirements for reporting serious adverse events/reactions

Commission

Competent Authority

Tissue establishments

Procurement organisations

Organisations responsible for human application
Procedure for a Commission Directive: technical requirements II

- Draft by experts (Spring 2005)
- Open consultation (June 2005)
- Readings by government experts (September and October 2005)
- Commission proposal (February 2006)
- Regulatory committee’s opinion (May 2006?)
- Commission decision (September 2006?)