

## EU Directive 2004/23/EC: towards standards of quality and safety for human tissues and cells in Europe

The increased frequency and complexity of interventions involving the transplantation of human tissues and cells and the movement of these materials between Member States of the European Union (EU) and to/from third party countries makes regulation of this field an issue of extreme importance for everyone concerned, not least patients and donors.

The development and implementation of high standards of quality and safety for tissues and cells is a top priority of the EU. The main concern is to facilitate exchange of material within the Community, whilst ensuring a high level of health protection and reassuring patients that tissues and cells derived from donation in another Member State, or originating outside of the EU, carry the same guarantees as those in their own country. In this context Directive 2004/23/EC represents a milestone in the establishment of a regulatory framework for quality and safety standards in Europe.

### **Implementation of the Directive:**

Directive 2004/23/EC on setting standards of quality and safety for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells entered into force on 7 April 2004, following publication in the Official Journal of the European Union. Member States now have two years to implement the Directive through national legislation and administrative provisions. In the same time period the Commission will define the technical requirements in the annex document, which are to comprise a basic set of principles and detailed guidelines of good practice. These will be developed by a working group and approved by the Regulatory Committee established by the Directive.

### **Applicability:**

The Directive applies to all tissues establishments, including collection and laboratory processing facilities. Clinical transplant units remains outside the remit of the current directive, but this is an area that the EU also plans to regulate in the future.

Tissues and cells are defined to include “haematopoietic peripheral blood, umbilical-cord (blood) and bone marrow stem cell, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells”. The Directive excludes blood and blood products (other than haematopoietic progenitor cells), human organs and tissues of animal origin. Tissues and cells used as an autologous graft within the same surgical procedure and without being subject to any banking process are also excluded from the directive.

In 2004 the objective of the Commission is to finalize two sets of technical requirements:

- (1) donation, procurement and testing of human tissues and cells, which will be applicable for all tissues and cells
- (2) processing, preservation and storage of human tissues and cells, which will be specified in 2 separate sets of annexes, one for haematopoietic progenitor/stem cells and one for the reproductive cells and foetal and embryonic stem cells. Consultation will take place with members of the scientific community, as considered appropriate, prior to carrying out public consultation before the end of the year.

**Remit:**

The main areas addressed by the Directive are:

- Establishment of a register of entities operating in the field
- Designation of the competent authority (ies) in Member States
- Implementation of a quality system for tissue establishments, including specification of activities relating to a quality system (SOPs, guidelines, training & reference manuals, reporting forms, donor records, information on final destination of tissues or cells, etc.)
- Introduction of a system of accreditation of tissue establishments by Member States and a system for notification of adverse events and reactions
- Organisation of inspections and control measures within Member States
- Data protection and confidentiality.
- Assurance of traceability of tissues and cells through laboratory identification procedures, record maintenance and an appropriate labelling system
- Design of a single European coding system to provide information on the main characteristics and properties of tissues and cells

**Role of JACIE in implementing the Directive:**

Members of the JACIE Board are providing input to the Commission on the definition of the technical requirements to the Directive. In addition, JACIE Project activities in 2004 and 2005, particularly training courses for centres to set up a quality management system and training of inspectors, will prove instrumental in preparing BMT facilities and Member States to meet the technical requirements. JACIE will also be in a position to offer Member States a system of accreditation that meets the standards of quality and safety finally approved by the Commission, as well as a pool of trained and experienced inspectors who can act as or assist the competent authority (ies) in implementing the Directive at the national level. In a number of countries, including Switzerland, Italy and the UK the JACIE standards have already been incorporated to some degree into national requirements.

The Directive is available for download from the EBMT website at:

<http://www.ebmt.org/8TransplantGuidelines/tguide5.html> .

For any questions or comments regarding the Directive please contact the JACIE Office at [jacie@ebmt.org](mailto:jacie@ebmt.org)