Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

CHAPTER I

GENERAL PROVISIONS

Article 1

Objective

This Directive lays down standards of quality and safety for human tissues and cells intended for human applications, in order to ensure a high level of protection of human health.

Article 2

Scope

1 This Directive shall apply to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications and of manufactured products derived from human tissues and cells intended for human applications.

Where such manufactured products are covered by other directives, this Directive shall apply only to donation, procurement and testing.

2 This Directive shall not apply to:

- a tissues and cells used as an autologous graft within the same surgical procedure;
- b blood and blood components as defined by Directive 2002/98/EC;
- c 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.

Article 3

Definitions

For the purposes of this Directive:

(a) ‘cells’ means individual human cells or a collection of human cells when not bound by any form of connective tissue;

(b) ‘tissue’ means all constituent parts of the human body formed by cells;

(c) ‘donor’ means every human source, whether living or deceased, of human cells or tissues;

(d) ‘donation’ means donating human tissues or cells intended for human applications;

(e) 'organ' means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;

(f) 'procurement' means a process by which tissue or cells are made available;

(g) 'processing' means all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications;

(h) 'preservation' means the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues;

(i) 'quarantine' means the status of retrieved tissue or cells, or tissue isolated physically or by other effective means, whilst awaiting a decision on their acceptance or rejection;

(j) 'storage' means maintaining the product under appropriate controlled conditions until distribution;

(k) 'distribution' means transportation and delivery of tissues or cells intended for human applications;

(l) 'human application' means the use of tissues or cells on or in a human recipient and extracorporal applications;

(m) 'serious adverse event' means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity;

(n) 'serious adverse reaction' means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity;

(o) 'tissue establishment' means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells;

(p) 'allogeneic use' means cells or tissues removed from one person and applied to another;

(q) 'autologous use' means cells or tissues removed from and applied in the same person.

Article 4

Implementation

1 Member States shall designate the competent authority or authorities responsible for implementing the requirements of this Directive.

2 This Directive shall not prevent a Member State from maintaining or introducing more stringent protective measures, provided that they comply with the provisions of the Treaty.

In particular, a Member State may introduce requirements for voluntary unpaid donation, which include the prohibition or restriction of imports of human tissues and cells, to ensure a high level of health protection, provided that the conditions of the Treaty are met.

3 This Directive does not affect the decisions of the Member States prohibiting the donation, procurement, testing, processing, preservation, storage, distribution or use of any specific type of human tissues or cells or cells from any specified source, including where those decisions also concern imports of the same type of human tissues or cells.

4 In carrying out the activities covered by this Directive, the Commission may have recourse to technical and/or administrative assistance to the mutual benefit of the Commission and of the beneficiaries, relating to identification, preparation, management, monitoring, audit and control, as well as to support expenditure.