

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 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,

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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.