Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

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PURPOSE : to lay down standards of quality and safety for human tissues and cells intended for human applications. LEGISLATIVE ACT : Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. CONTENT : the transplantation of human tissues and cells is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases. The quality and safety of these substances should be ensured, particularly in order to prevent the transmission of diseases. This Directive aims to: - establish European Community legislation setting standards for the quality and safety of tissues and cells of human origin used for application in the human body; the directive provides for principles, minimum standards and obligatory procedures for the whole chain (donation, procurement, testing, processing, storage and distribution); - strengthen requirements related to the suitability of donors of tissues and cells and the screening of these donated substances of human origin in the European Union; - elaborate at Member State level requirements for establishments involved in the procurement, testing, processing, storage, and distribution of tissues and cells of human origin, as well as national accreditation and monitoring and inspection structures; - lay down provisions at Community level for the formulation of a register of accredited establishments; - lay down provisions at Community level for the formulation of a quality system for establishments involved in activities related to tissues and cells; - lay down common provisions at Community level for the training of staff directly involved in the procurement, testing, processing, storage, and distribution of tissues and cells of human origin, without prejudice to existing legislation; - establish rules for ensuring the traceability of tissues and cells of human origin from donor to patient and vice versa, which are valid throughout the European Union; - establish a system for the regulation of imports of human tissues and cells from third countries that ensure equivalent standards of quality and safety. The following points should be noted: - The Directive applies to tissues and cells including haematopoietic peripheral blood, umbilical-cord (blood) and bone marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells. It excludes blood and blood products. - The Directive does not interfere with decisions made by Member States concerning the use or non-use of any specific type of human cells, including germ cells and embryonic stem cells. If, however, any particular use of such cells is authorised in a Member State, the Directive requires the application of all provisions necessary to protect public health, given the specific risks of these cells based on the scientific knowledge and their particular nature, and guarantee respect for fundamental rights. Moreover, the Directive does not interfere with provisions of Member States defining the legal term 'person' or 'individual'. - Tissues and cells used for allogeneic therapeutic purposes canbe procured from both living and deceased donors. In order to ensure that the health status of a living donor is not affected by the donation, a prior medical examination is required. The dignity of the deceased donor must be respected, notably through the reconstruction of the donor's body. - Member States are urged to take steps to encourage a strong public and nonprofit sector involvement in the provision of tissue and cell application services and the related research and development. - As a general principle, the identity of the recipient(s) must not be disclosed to the donor or his/her family and vice versa, without prejudice to legislation in force in Member States on the conditions of disclosure, which could authorise in exceptional cases, notably in the case of gametes donation, the lifting of donor anonymity. ENTRY INTO FORCE : 7 April 2004. DATE OF TRANSPOSITION : 7 April 2006.