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

2002/0128(COD) - 19/06/2002 - Legislative proposal

PURPOSE : Proposal on setting quality and safety standards in relation to human tissue and cells.
CONTENT : This proposal for a directive aims to cover all human cells and tissues which are used for application to the human body, in order to ensure their quality and safety. It excludes blood and blood products (other than blood precursors), human organs as well as organs, tissues or cells of animal origin. Autologous cells used or medicinal products require a completely different regulatory approach and are therefore excluded from this directive. The aims of the proposal are 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; -strengthen requirements related to the suitability of donors of tissues and cells and the screening of donated substances of human origin in the EU; -establish 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 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 tissues and cells related establishments; -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 EU; -establish a system for the regulation of imports of human tissues and cells from third countries that ensure equivalent standards of quality and safety.