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

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The committee adopted the report by Peter LIESE (EPP-ED, D) amending the proposal under the 1st reading of the codecision procedure. The key amendments focused on the scope of the directive, compensation for tissue and cell donation, donor consent, donor anonymity and ethical issues: - Member States should encourage strong public and non-profit sector involvement in the provision of tissue and cell transplant services and related research; - donations should be made with the donor's free will and without any payment except compensation, for example travel expenses. However, rules on compensation should be left to the Member States; - EU-wide rules should be laid down to ensure the traceability of tissues and cells of human origin. Although anonymity of donors was strongly supported, the committee said that in the case of gametes (sperm and eggs) in particular, Member States may waive anonymity in order to respect the right of children to know their genetic parents; - on the procurement of human tissues or cells, the committee wanted to go even further than the Commission with regard to mandatory consent requirements. It said that the EU Member States should take account of at least the following: before any procurement of tissues or cells, living donors must have given their prior, informed and express consent in writing or, in exceptional cases, orally in the presence of witnesses. Until the moment the donated or cells are actually used, donors shall have the right to withdraw their consent without having to face any negative consequences; in the case of procurement of tissues and cells from deceased persons, donors must not have expressly refused their consent during their lifetime. In the absence of any declaration by donors during their lifetime, tissues or cells may only be procured if the relatives of the deceased have given prior and express consent; cells and tissues may not be retrieved for the purpose of allogeneic donation from individuals who are not in a position to give informed legal consent; exceptionally regenerative tissue and regenerative cells may be retrieved under strict conditions, e.g. if the recipient is a brother or sister of a donor, the donation is potentially lifesaving for the recipient and the potential donor does not refuse; - Member States should at least prohibit research on human cloning for reproductive purposes and research designed to create human embryos solely for research purposes or to supply stem cells, including by means of the transfer of somatic cell nuclei. No tissues or cells derived from human embryos should be used for transplantation. Cloned human embryos, and human/animal hybrid embryos produced by cloning, aggregation or any other procedure, and cells and tissues derived from them, should be excluded as sources of material for transplant; - the committee clarified the directive's scope even further by including the research use of tissues, haematopoietic peripheral blood, placenta and bone marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells, adult and embryonic stem cells. However, it said that hair, nails and body waste products should be excluded from the directive; - lastly, the Commission was urged to bring forward before July 2003 a separate legislative proposal on human organ transplants, on the grounds that there was a need to take into account the severe shortages that were currently resulting in many patients going untreated.