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

2002/0128(COD) - 28/05/2003 - Modified legislative proposal

The Commission accepted 35 of the 76 amendments made by Parliament, 16 in full and 19 in part, conditionally, or after reformulation. In the light of this, the Commission has drafted an amended proposal. The Commission has made a number of amendments to its original proposal, reflecting those modifications introduced by the European Parliament and accepted by the Commission. In addition, the Commission has made some revisions as a direct consequence of the Parliament's amendments, and in order to clarify the text. In the amended proposal, the Commission has also taken into account the current status of the dossier in the Council. Reflecting the key concerns of the European Parliament, the main amendments to the original proposal can be grouped as follows: - ethical provisions: the Commission can accept provisions related to the anonymity of donors and/or non-profit procurement. Other provisions, however, cannot be accepted as they fall outside the scope of Article 152 of the Treaty, which provides for public health protection and not for the implementation of ethical objectives. - scope of the Directive: this has been extended to include the donation, procurement and testing of autologous cells to be used for the manufacturing of medicinal products. The Commission states that this will facilitate a consistent approach to quality and safety measures for all substances of human origin, and is consistent with the approach already adopted in the Directive 2002/98/EC. The scope has been also widened to cover further steps in the process. The term 'transplantation' has been changed to 'human application', in order to clarify that other therapies, such as reproductive medicine (reproductive cells), are also covered for the processing, preservation, storage and distribution steps. This modification of the scope has implications for the definition of transplantation, and consequently for other provisions of the text. The range of establishments covered by the directive includes not only traditional tissue banks but also all establishments where activities related to the human application of human tissues and cells are undertaken. The Commission did not accept certain other amendments, notably those which introduce 'in vitro' research on tissues and cells into the scope of the Directive, an area outside the scope of Article 152. Use of any specific type of tissues and cells: the Commission accepts those amendments that strengthen the principle that the Directive should not interfere with Member States' decisions with respect to prohibition on the use of any specific tissue or cell. Accreditation: the accreditation of tissue establishments has been modified as a result of the extension of the scope of the Directive and the new concept of tissue establishments. These establishments can also procure tissues and cells. A direct consequence of this, in keeping with the orientations of the Council, is the importance of the authorisation of the procurement conditions and the staff involved - both key elements of the process. Import and export: the Commission accepts these amendments; it is equally important to ensure that no 'sub-standard' tissues and cells are exported to third countries. Anonymity and traceability: the amendments strengthen the provisions on traceability, extending it to materials in close contact with the tissues and cells, ensuring a minimum period of thirty years for keeping the data and including the final destination in the quality system. The Commission has amended its proposal as a consequence. The principle that tissue and cell donation should respect the anonymity of the donors and recipients is also respected in these amendments. However, the Parliament would like an exemption in the case of specific types of cells. The Commission proposal already introduces the possibility for Member States to keep or adopt different legislation in case of donors closely related to the recipient, but a modification has been introduced. The Commission did not accept Parliament's amendment with regard to the establishment of technical implementing provisions.