Human blood and blood components: quality and safety for the collection, testing, processing, storage and distribution

2000/0323(COD) - 13/12/2000 - Legislative proposal

PURPOSE : to increase public confidence in the safety of the blood and blood products administered for therapy by establishing Community provisions ensuring the quality and safety of blood and its components whatever the intended purpose. CONTENT : the aims of this proposal are to: - close existing gaps in Community legislation with regard to the setting of standards for the quality and safety of blood and blood components used in therapy; - strengthen requirements related to the suitability of blood and plasma donors and the screening of donated blood in the European Community; - establish at Member State level requirements for establishments involved in the collection, testing, processing, storage and distribution of whole blood and blood components, as well as national accreditation and monitoring structures; - to lay down provisions at Community level for the formulation of a quality system for blood establishments (QSBE); - lay down common provisions at Community level for the training of staff directly involved in the collection, testng, processing, storage and distribution of whole blood components, without prejudice to existing legislation; - establish rules for ensuring the traceability of whole blood and blood components from donor to patient, which are valid through the Community.