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

2000/0323(COD) - 27/01/2003 - Final act

PURPOSE : to establish high standards of quality and safety for human blood and blood components. COMMUNITY MEASURE : Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. CONTENTS : the safety requirements of proprietary industrially prepared medicinal products derived from human blood or plasma were ensured through Directive 2001/83/EC. The specific exclusion of whole blood, plasma and blood cells of human origin from that directive, however, has led to a situation whereby their quality and safety, in so far as they are intended for transfusion and not processed as such, are not subject to any binding Community legislation. This Directive, therefore, contains provisions to ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain in all Member States. It applies to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for transfusion. The main provisions of the Directive are as follows: - Member States must designate the competent authority responsible for implementing the provisions of the Directive. Member States may introduce more stringent protective measures, including requirements for voluntary and unpaid donations; - activities relating to collection and testing, preparation, storage and distribution must be undertaken only by the blood establishments which have been authorised by the competent authority; - the competent authority must organise inspection and control measures at least every two years. Officials from the competent authority must be empowered to take samples and examine documents; - blood establishments must designate a responsible person to ensure that every unit of blood or blood components has been collected, tested, processed, stored and distributed in compliance with the law. The responsible person must fulfil prescribed minimum conditions of qualification; - each blood establishment must establish a quality system based on the principles of good practice. They must also maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms. Records of information must be kept for a minimum of 15 years; - there are provisions to ensure that blood can be traced from donor to recipient and vice versa. Data needed for full traceability must be kept for at least 30 years; - adverse events must be notified to the competent authority and blood associated with the event must be withdrawn; - there must be evaluation procedures for all donors; - a qualified health professional is responsible for examining donors and assessing eligibility; - Member States must encourage voluntary and unpaid donations and report on the measures taken to do so two years after the Directive enters into force; - donations must be tested in conformity with the Directive. DATE OF TRANSPOSITION : 08/02/05. ENTRY INTO FORCE : 08/02/03.