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

2000/0323(COD) - 30/09/2005 - Implementing legislative act

LEGISLATIVE ACT : Commission Directive 2005/61/CE implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events.

CONTENT : In order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements dealing with traceability, a Community procedure for notifying serious adverse reactions and events and the notification format. Notification of suspected serious adverse reactions or serious adverse events should be submitted to the competent authority as soon as known. This Directive therefore establishes the notification format defining the minimum data needed, without prejudice to the faculty of Member States to maintain or introduce in their territory more stringent protective measures.

The Directive lays down those technical requirements, which take account of: Council Recommendation 98/463/EC on the suitability of blood and plasma donors and the screening of donated blood in the European Community; Directive 2001/83/EC on the Community code relating to medicinal products for human use; Commission Directive 2004/33/EC implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components, and certain recommendations of the Council of Europe.

Accordingly, blood and blood components imported from third countries, including those used as starting material or raw material for the manufacture of medicinal products derived from human blood and human plasma, intended for distribution in the Community, should meet equivalent Community standards and specifications relating to traceability and serious adverse reaction and serious adverse event notification requirements as set out in this Directive.

The Directive also determines common definitions for technical terminology in order to ensure the consistent implementation of Directive 2002/98/EC.

ENTRY INTO FORCE : 21/10/2005.

TRANSPOSITION : 31/08/2006.