# Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components (Text with EEA relevance)

## COMMISSION DIRECTIVE 2004/33/EC

## of 22 March 2004

## implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components

## (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 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[(1)], and in particular points (b) to (g) of the second paragraph of Article 29 thereof,

Whereas:

(1) Directive 2002/98/EC lays down standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and for their processing, storage and distribution when intended for transfusion so as to ensure a high level of human health protection.

(2) 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.

(3) This Directive lays down those technical requirements, which take account of Council Recommendation 98/463/EC of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community[(2)], certain recommendations of the Council of Europe, the opinion of the Scientific Committee for Medicinal Products and Medical Devices, the monographs of the European Pharmacopoeia, particularly in respect of blood or blood components as a starting material for the manufacture of proprietary medicinal products and recommendations of the World Health Organisation (WHO), as well as international experience in this field.

(4) Blood and blood components imported from third countries, including those used as starting material/raw material for the manufacture of medicinal products derived from human blood and human plasma, should meet the quality and safety requirements set out in this Directive.

(5) With regard to blood and blood components collected for the sole purpose of, and exclusive use in, autologous transfusion (autologous donation), specific technical requirements should be laid down, as required by Article 2(2) of Directive 2002/98/EC.

Such donations should be clearly identified and kept separate from other donations to ensure that they are not used for transfusion to other patients.

(6) It is necessary to determine common definitions for technical terminology in order to ensure the consistent implementation of Directive 2002/98/EC.

(7) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2002/98/EC,

HAS ADOPTED THIS DIRECTIVE:

(**1**) OJ L 33, 8.2.2003, p. 30.

(**2**) OJ L 203, 21.7.1998, p. 14.