Draft*

COMMISSION DIRECTIVE ../…/EC

of […]

establishing a first series of technical requirements for blood and blood components under 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

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 Article 28 thereof,

Whereas:

(1) In its Directive 2002/98/EC, the Council and the European Parliament empowered the Commission to establish technical requirements and adopt any necessary changes thereto and to the Annexes in order to take into account scientific and technical progress.

(2) Areas for the establishment of such technical requirements and referred to in Article 29 of Directive 2002/98/EC, included traceability requirements, information to be provided to donors; information to be obtained from donors including: the identification, health history, and the signature of the donor; requirements concerning the suitability of blood and plasma donors and the screening of donated blood, including permanent deferral criteria and possible exemption thereto as well as temporary deferral criteria; storage, transport and distribution requirements; quality and safety requirements for blood and blood components; requirements applicable to autologous transfusions; Community standards and specifications relating to a quality system for blood establishments; and a Community procedure for notifying serious adverse reactions and events and notification format.

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* Provisional text; other linguistic versions to follow
Texte provisoire. Les autres versions linguistiques suivront
Vorläufiger Text; die anderen Sprachversionen werden noch zugesandt

1 OJ L 33, 8.2.2003, p. 30.

(3) This Directive establishes a first series of technical requirements, the foundations of which have already been well-established. In elaborating its provisions, account has been taken of Council Recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the EC[2], the recommendations of the Council of Europe, together with 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[3], recommendations of the World Health Organisation (WHO), as well as international experience in this field.

(4) According to Article 152(5) of the Treaty, measures referred to in Article 152(4)(a) shall not affect national provisions on the donation of blood. The provisions of this Directive, however, are necessary to ensure quality and safety of blood, as required by Article 152(4)(a) of the Treaty. This Treaty provision also states that measures setting high standards of quality and safety of blood shall not prevent any Member State from maintaining or introducing more stringent protective measures.

(5) [The nature of autologous transfusion necessitates a specific consideration in respect of how and when to apply quality and safety provisions.]

(6) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Article 28 of Directive 2002/98/EC.

HAS ADOPTED THIS DIRECTIVE:

Article 1

A first series of technical requirements related to blood and blood components, set up in this Directive in accordance with the provisions of Article 28 of Directive 2002/98/EC, addresses

(a) information to be provided to donors; (Annex I)

(b) information to be obtained from donors including the identification, health history, and the signature of the donor (Annex I)

(c) requirements concerning the suitability of blood and plasma donors and the screening of donated blood including (Annex II)

- permanent deferral criteria and possible exemption thereto
- temporary deferral criteria;

(d) storage, transport and distribution requirements; (Annex III)

(e) quality and safety requirements for blood and blood components; (Annex IV)

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2 OJ L 203, 21.7.1998, p. 14.
3 OJ L 311, 28.11.2001, p. 67.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by *day, month, year* at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the day following its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, […]

For the Commission
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Member of the Commission