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

CHAPTER IX

COMMITTEES

[F1 Article 28

Committee procedure

1 The Commission shall be assisted by a Committee.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 29

Technical requirements and their adaptation to technical and scientific progress

[F1The adaptation of the technical requirements set out in Annexes I to IV to technical and scientific progress shall be decided by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 28(4) as regards technical requirements set out in Annexes III and IV.**]**

[F1The following technical requirements and their adaptation to technical and scientific progress shall be decided by the Commission:**]**

(a) traceability requirements;

(b) information to be provided to donors;

(c) information to be obtained from donors including the identification, health history, and the signature of the donor;

(d) requirements concerning the suitability of blood and plasma donors and the screening of donated blood including
— permanent deferral criteria and possible exemption thereto
— temporary deferral criteria;

(e) storage, transport and distribution requirements;

(f) quality and safety requirements for blood and blood components;

(g) requirements applicable to autologous transfusions;

(h) Community standards and specifications relating to a quality system for blood establishments;

(i) Community procedure for notifying serious adverse reactions and events and notification format.

[[F2]Technical requirements referred to in points (a) to (i) of the second paragraph, being measures designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(3).

On imperative grounds of urgency the Commission may have recourse to the urgency procedure referred to in Article 28(4) as regards technical requirements referred to in points (b), (c),(d), (e), (f) and (g) of the second paragraph.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

F2 Inserted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 30

Consultation of scientific committee(s)

The Commission may consult the relevant scientific committee(s) when establishing the technical requirements referred to in Article 29 and when adapting the technical requirements set out in Annexes I to IV to scientific and technical progress, in particular with a view to ensuring an equivalent level of quality and safety of blood and blood components used for transfusion and blood and blood components used as a starting material for the manufacture of medicinal products.