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 I

GENERAL PROVISIONS

Article 1

Objectives

This Directive lays down standards of quality and safety of human blood and of blood components, in order to ensure a high level of human health protection.

Article 2

Scope

1 This Directive shall apply 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.

2 Where blood and blood components are collected and tested for the sole purpose and exclusive use in autologous transfusion and are clearly identified as such, the requirements to be complied with in respect thereof shall be in accordance with those referred to in Article 29(g).

3 This Directive shall apply without prejudice to Directives 93/42/EEC[(1)], 95/46/EC or 98/79/EC[(2)].

4 This Directive does not apply to blood stem cells.

Article 3

Definitions

For the purposes of this Directive:

(a) ‘blood’ shall mean whole blood collected from a donor and processed either for transfusion or for further manufacturing;

(b) ‘blood component’ shall mean a therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods;

(c) ‘blood product’ shall mean any therapeutic product derived from human blood or plasma;

(d) ‘autologous transfusion’ shall mean transfusion in which the donor and the recipient are the same person and in which pre-deposited blood and blood components are used;

(e) 'blood establishment' shall mean any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks;

(f) 'hospital blood bank' shall mean a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities;

(g) 'serious adverse event' shall mean any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;

(h) 'serious adverse reaction' shall mean an unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

(i) 'blood component release' shall mean a process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification;

(j) 'deferral' shall mean suspension of the eligibility of an individual to donate blood or blood components such suspension being either permanent or temporary;

(k) 'distribution' shall mean the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusion.

(l) 'haemovigilance' shall mean a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors;

(m) 'inspection' shall mean formal and objective control according to adopted standards to assess compliance with this Directive and other relevant legislation and to identify problems.

Article 4

Implementation

1 Member States shall designate the competent authority or authorities responsible for implementing the requirements of this Directive.

2 This Directive shall not prevent a Member State from maintaining or introducing in its territory more stringent protective measures which comply with the provisions of the Treaty.

In particular, a Member State may introduce requirements for voluntary and unpaid donations, which include the prohibition or restriction of imports of blood and blood components, to ensure a high level of health protection and to achieve the objective set out in Article 20(1), provided that the conditions of the Treaty are met.

3 In carrying out the activities covered by this Directive the Commission may have recourse to technical and/or administrative assistance to the mutual benefit of the Commission

and of the beneficiaries, relating to identification, preparation, management, monitoring, audit and control, as well as to support expenditure.

CHAPTER II

OBLIGATIONS ON MEMBER STATES AUTHORITIES

Article 5

Designation, authorisation, accreditation or licensing of blood establishments

1 Member States shall ensure that activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage, and distribution when intended for transfusion, are undertaken only by the blood establishments which have been designated, authorised, accredited or licensed by the competent authority for that purpose.

2 For the purpose of paragraph 1, the blood establishment shall submit the information listed in Annex I to the competent authority.

3 The competent authority, having verified whether the blood establishment complies with the requirements set out in this Directive, shall indicate to the blood establishment which activities it may undertake and which conditions apply.

4 No substantial change in activities shall be undertaken by the blood establishment without prior written approval by the competent authority.

5 The competent authority may suspend or revoke the designation, authorisation, accreditation or licence of a blood establishment if inspection or control measures demonstrate that the blood establishment does not comply with the requirements of this Directive.

Article 6

Hospital blood banks

Articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 shall apply to hospital blood banks.

Article 7

Provisions for existing establishments

Member States may decide to maintain national provisions for nine months after the date laid down in Article 32 so as to enable blood establishments operating under their legislation to comply with the requirements of this Directive.

Article 8

Inspection and control measures

1 Member States shall ensure that the competent authority organise inspections and appropriate control measures in blood establishments to ensure that the requirements of this Directive are complied with.

2 Inspection and control measures shall be organised by the competent authority on a regular basis. The interval between two inspections and control measures shall not exceed two years.

3 Such inspection and control measures shall be carried out by officials representing the competent authority who must be empowered to:

a inspect blood establishments as well as facilities of any third parties on its own territory entrusted by the holder of the designation, authorisation, accreditation or licence referred to in Article 5 with the task of carrying out evaluation and testing procedures pursuant to Article 18;

b take samples for examination and analysis;

c examine any documents relating to the object of the inspection, subject to the provisions in force in the Member States at the time of the entry into force of this Directive and which place restrictions on these powers with regard to the descriptions of the method of preparation.

4 The competent authority shall organise inspection and other control measures as appropriate in the event of any serious adverse event or reaction or suspicion thereof in accordance with Article 15.

CHAPTER III

PROVISIONS FOR BLOOD ESTABLISHMENTS

Article 9

Responsible person

1 Blood establishments shall designate a person (responsible person), responsible for:

— ensuring that every unit of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, and distributed, when intended for transfusion, in compliance with the laws in force in the Member State,

— providing information to the competent authority in the designation, authorisation, accreditation or licensing procedures as required in Article 5,

— the implementation of the requirements of Articles 10, 11, 12, 13, 14 and 15 in the blood establishment.

2 The responsible person shall fulfil the following minimum conditions of qualification:

a he/she shall possess a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned;

b he/she shall have practical post-graduate experience in relevant areas for at least two years, in one or more establishments which are authorised to undertake activities related to collection and/or testing of human blood and blood components, or to their preparation, storage, and distribution.

3 The tasks specified in paragraph 1 may be delegated to other persons who shall be qualified by training and experience to perform such tasks.

4 Blood establishments shall notify the competent authority of the name of the responsible person referred to in paragraph 1 and other persons referred to in paragraph 3 together with information on the specific tasks for which they are responsible.

5 Where the responsible person or such other persons referred to in paragraph 3 are permanently or temporarily replaced, the blood establishment shall provide immediately the name of the new responsible person and his or her date of commencement to the competent authority.

Article 10

Personnel

Personnel directly involved in collection, testing, processing, storage, and distribution of human blood and blood components shall be qualified to perform those tasks and be provided with timely, relevant and regularly updated training.

CHAPTER IV

QUALITY MANAGEMENT

Article 11

Quality system for blood establishments

1 Member States shall take all necessary measures to ensure that each blood establishment establishes and maintains a quality system for blood establishments based on the principles of good practice.

2 The Commission shall establish the Community standards and specifications referred to in Article 29(h) for the activities relating to a quality system to be carried out by a blood establishment.

Article 12

Documentation

1 Member States shall take all necessary measures in order to ensure that blood establishments maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms.

2 Member States shall take all necessary measures in order to ensure that access is provided to these documents for officials entrusted with inspection and control measures referred to in Article 8.

Article 13

Record keeping

1 Member States shall take all necessary measures to ensure that blood establishments maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d). The records shall be kept for a minimum of 15 years.

2 The competent authority shall keep records of the data received from the blood establishments according to Articles 5, 7, 8, 9 and 15.

CHAPTER V

HAEMOVIGILANCE

Article 14

Traceability

1 Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, released and/or distributed on their territory can be traced from donor to recipient and vice versa.

To this end, Member States shall ensure that blood establishments implement a system for identification of each single blood donation and each single blood unit and components thereof enabling full traceability to the donor as well as to the transfusion and the recipient thereof. The system must unmistakably identify each unique donation and type of blood component. This system shall be established in accordance with the requirements referred to in Article 29(a).

With regard to blood and blood components imported from third countries, Member States shall ensure that the donor identification system to be implemented by blood establishments permits an equivalent level of traceability.

2 Member States shall take all necessary measures in order to ensure that the system used for the labelling of blood and blood components collected, tested, processed, stored, released and/or distributed on their territory complies with the identification system referred to in paragraph 1 and the labelling requirements listed in Annex III.

3 Data needed for full traceability in accordance with this Article shall be kept for at least 30 years.

Article 15

Notification of serious adverse events and reactions

1 Member States shall ensure that:

— any serious adverse events (accidents and errors) related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious adverse reactions

observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components are notified to the competent authority,

— blood establishments have in place a procedure accurately, efficiently and verifiably to withdraw from distribution blood or blood components associated with the notification referred to above.

2 These serious adverse events and reactions shall be notified in accordance with the procedure and notification format referred to in Article 29(i).

CHAPTER VI

PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

Article 16

Provision of information to prospective donors

Member States shall ensure that all prospective donors of blood or blood components in the Community are provided with information referred to in Article 29(b).

Article 17

Information required from donors

Member States shall take all necessary measures to ensure that, upon agreement of a willingness to commence the donation of blood or blood components, all donors in the Community provide the information referred to in Article 29(c) to the blood establishment.

Article 18

Eligibility of donors

1 Blood establishments shall ensure that there are evaluation procedures in place for all donors of blood and blood components and that the criteria for donation referred to in Article 29(d) are met.

2 The results of the donor evaluation and testing procedures shall be documented and any relevant abnormal findings shall be reported to the donor.

Article 19

Examination of donors

An examination of the donor, including an interview, shall be carried out before any donation of blood or blood components. A qualified health professional shall be responsible, in particular, for giving to and gathering from donors the information which is necessary to assess their eligibility to donate and shall, on the basis thereof, assess the eligibility of donors.

Article 20

Voluntary and unpaid blood donation

1 Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations.

2 Member States shall submit reports to the Commission on these measures two years after the entry into force of this Directive, and thereafter every three years. On the basis of these reports the Commission shall inform the European Parliament and the Council of any necessary further measure it intends to take at Community level.

Article 21

Testing of donations

Blood establishments shall ensure that each donation of blood and blood components is tested in conformity with requirements listed in Annex IV.

Member States shall ensure that blood and blood components imported into the Community are tested in conformity with requirements listed in Annex IV.

Article 22

Storage, transport and distribution conditions

Blood establishments shall ensure that the storage, transport and distribution conditions of blood and blood components comply with the requirements referred to in Article 29(e).

Article 23

Quality and safety requirements for blood and blood components

Blood establishments shall ensure that quality and safety requirements for blood and blood components meet the high standards in compliance with the requirements referred to in Article 29(f).

CHAPTER VII

DATA PROTECTION

Article 24

Data protection and confidentiality

Member States shall take all necessary measures to ensure that all data, including genetic information, collated within the scope of this Directive to which third parties have access have been rendered anonymous so that the donor is no longer identifiable.

For that purpose, they shall ensure:

(a) that data security measures are in place as well as safeguards against unauthorised data additions, deletions or modifications to donor files or deferral records, and transfer of information;

(b) that procedures are in place to resolve data discrepancies;

(c) that no unauthorised disclosure of such information occurs, whilst guaranteeing the traceability of donations.

CHAPTER VIII

EXCHANGE OF INFORMATION, REPORTS AND PENALTIES

Article 25

Information exchange

The Commission shall hold regular meetings with the competent authorities designated by the Member States, delegations of experts from blood establishments and other relevant parties to exchange information on the experience acquired with regard to the implementation of this Directive.

Article 26

Reports

1 Member States shall send to the Commission, commencing on 31 December 2003 and every three years thereafter, a report on the activities undertaken in relation to the provisions of this Directive, including an account of the measures taken in relation to inspection and control.

2 The Commission shall transmit to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, the reports submitted by the Member States on the experience gained in implementing this Directive.

3 The Commission shall transmit to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, commencing on 1 July 2004 and every three years thereafter, a report on the implementation of the requirements in this Directive, and in particular those relating to inspection and control.

Article 27

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. Member States shall notify those provisions to the Commission by the date specified in Article 32 at the latest and shall notify it without delay of any subsequent amendments affecting them.

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.**]**

[[F1]The 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

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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.

CHAPTER X

FINAL PROVISIONS

Article 31

Amendment of Directive 2001/83/EC

Article 109 of Directive 2001/83/EC shall be replaced by the following:

Article 109

For the collection and testing of human blood and human plasma, 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[3] shall apply.

Article 32

Transposition

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 8 February 2005. They shall forthwith inform the Commission thereof.

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

2 Member States shall communicate to the Commission the texts of the provisions of national law that they have already adopted or which they adopt in the field governed by this Directive.

Article 33

Entry into force

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

Article 34

Addressees

This Directive is addressed to the Member States.

(**1**) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1). Directive as last amended by Directive 2001/104/EC of the European Parliament and of the Council (OJ L 6, 10.1.2002, p. 50).

(**2**) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

(**3**) OJ L 33, 8.2.2003, p. 30.’