Amended proposal for a Directive of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 89/381/EEC [1]

(2002/C 75 E/08)

COM(2001) 692 final — 2000/0323(COD)

(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 16 November 2001)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(a) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) The extensive therapeutic use of human blood demands that the quality, safety and efficacy of whole blood and blood components be ensured, whatever the intended purpose, in order to prevent the transmission of diseases.

(2) The availability of blood and blood components used for therapeutic purposes is dependent on Community citizens who are prepared to donate; in order to safeguard public health and to prevent the transmission of infectious diseases by blood components, all precautionary measures during their collection, processing, distribution and use need to be taken, taking full advantage of scientific advances in pathogen detection and inactivation.

(3) The quality, safety, and efficacy requirements of proprietary industrially-prepared medicinal products derived from human blood or human plasma were ensured through Council Directive 89/381/EEC of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma [2]; whole blood, plasma, and blood cells of human origin are specifically excluded from that Directive, and this has led to a situation whereby their quality and safety, in so far as they are intended for transfusion and not processed as such, are not subject to any binding Community legislation. It is essential, therefore, that whatever the intended purpose, Community provisions should ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain in all Member States, bearing in mind the freedom of movement of citizens within Community territory. The establishment of high standards of quality and safety, therefore, will help to reassure the public that human blood and blood components that are derived from donations in another Member State nonetheless carry the same guarantees as those in their own country.

(4) In respect of blood or plasma as a starting material for the manufacture of proprietary medicinal products, Article 3 of Directive 89/381/EEC mentions measures to be taken by Member States to prevent the transmission of infectious diseases, referring to the application of the monographs of the European Pharmacopoeia and the recommendations of the Council of Europe and the World Health Organisation as regards in particular the selection and testing of blood and plasma donors. Furthermore, by the same Directive, Member States should also take measures to promote Community self-sufficiency in human blood or human plasma; and to encourage voluntary unpaid donations of blood and plasma.

(5) In order to ensure that there is an equivalent level of safety and quality of blood components, whatever their intended purpose, technical in requirements for collection and testing of all blood and blood components including starting materials for medicinal products should be established by this Directive. Directive 89/381/EEC should be amended accordingly.

(6) It is necessary for the Commission and the Member States to step up biotechnological research into the production of blood components and products for therapeutic use and research into new technologies enabling blood and blood precursors and derivatives to be stored more effectively and for longer periods.

[1] OJ C 154 E, 29.5.2001, p. 141.

[2] OJ L 181, 28.6.1989, p. 44.

(7) The Commission's Communication of 21 December 1994 on Blood Safety and Self-sufficiency in the European Community ([1]) identified the need for a blood strategy in order to reinforce confidence in the safety of the blood transfusion chain and promote Community self-sufficiency.

(8) The Council in its Resolution of 2 June 1995, on blood safety and self-sufficiency in the Community ([2]), invited the Commission to submit appropriate proposals in the framework of the development of a blood strategy.

(9) The Council in its Resolution of 12 November 1996 on a strategy towards blood safety and self-sufficiency in the European Community ([3]) invited the Commission to submit proposals as a matter of urgency with a view to encouraging the development of a coordinated approach to the safety of blood and blood products.

(10) The European Parliament in its resolutions of 14 September 1993 ([4]), 18 November 1993 ([5]), 14 July 1995 ([6]), and 17 April 1996 ([7]) on blood safety and self-sufficiency through voluntary unpaid donations in the European Community has stressed the importance of ensuring the highest level of blood safety and has reiterated its continued support for the objective of Community self-sufficiency.

(11) In accordance with the principles of subsidiarity and proportionality set out in Article 5 of the Treaty, the objectives of the proposed action, namely to contribute to general confidence both in the quality of donated blood and blood components and in the health protection of donors, to attain self-sufficiency at a Community level and to enhance confidence in the safety of the transfusion chain among the Member States, cannot be sufficiently achieved by the Member States and can therefore by reason of its scale and effects be better achieved by the Community. This Directive confines itself to the minimum required in order to achieve those objectives and does not go beyond what is necessary for that purpose.

(12) In elaborating the provisions of this Directive account has been taken of the opinion of the Scientific Committee for Medicinal Products and Medical Devices as well as international experience in this field.

(13) Blood and blood components used for therapeutic purposes or for use in medical devices should be obtained from individuals whose health status is such that no detrimental effects to their state of health will ensue as a result of the donation and that any risk of transmission of infectious diseases is minimised; each and every blood donation should be tested in accordance with rules which provide assurances that all necessary measures have been taken to safeguard the health of Community citizens who are the recipients of blood and blood components.

(14) Modern blood-transfusion practice has been founded on the principles of voluntary and unpaid donor services, anonymity between both donor and recipient, benevolence of the donor, and absence of profit on the part of the establishments involved in blood transfusion services.

(15) All necessary measures need to be taken in order to provide prospective donors of blood or blood components with assurances regarding the confidentiality of any health-related information provided to the authorised personnel, the results of the tests on their donations as well as any future traceability of their donation.

(16) The Community entirely supports the principle of voluntary, unpaid donation of blood and blood components, to attain self-sufficiency throughout the Community in the supply of blood and blood components, and to ensure respect for ethical principles in their donation.

(17) Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data ([8]) requires that data related to the health of an individual be subject to reinforced protection. However, it covers only personal data and not that rendered anonymous so that the person is no longer identifiable. This Directive should therefore introduce additional safeguards to prevent any unauthorised changes to donation registries, or processing records, or the unauthorised disclosure of information.

(18) A common system of accreditation for blood establishments and notification of adverse events and reactions linked to the collection, processing, testing, storage, and distribution of blood and blood components should be established in Member States. Three competent authorities should be able to withdraw or suspend accreditation if a blood establishment does not comply with the requirements of this Directive.

(19) Blood establishments should establish and maintain quality systems involving all activities that determine the quality policy, objectives and responsibilities and implement them by such means as quality planning, quality control, quality assurance, and quality improvement within the quality system, taking account of the principles of good practice.

([1]) COM(94) 652 final.

([2]) OJ C 164, 30.6.1995, p. 1.

([3]) OJ C 374, 11.12.1996, p. 1.

([4]) OJ C 268, 4.10.1993, p. 29.

([5]) OJ C 329, 6.12.1993, p. 268.

([6]) OJ C 249, 25.9.1995, p. 231.

([7]) OJ C 141, 13.5.1996, p. 131.

([8]) OJ L 281, 23.11.1995, p. 31.

(20) Member States should organise inspection and control measures, to be carried out by officials representing the competent authority, to ensure the compliance of the blood establishment with the provisions of this Directive.

(21) Personnel directly involved in the collection, testing, processing, storage and distribution of blood and blood components need to be appropriately qualified and provided with timely and relevant training. The provisions laid down in this Directive as regards training should be applicable without prejudice to existing Community legislation on the recognition of professional qualifications and on the protection of workers.

(22) An adequate system to ensure traceability of whole blood and blood components should be established; traceability should be enforced through accurate donor, patient, and laboratory identification procedures, through record maintenance, and through an appropriate labelling system. The labelling system should also allow the identification of the establishments where the blood or blood components was collected.

(23) It is necessary that the best possible scientific advice in relation to the safety of blood and blood components is available to the Community. The Comission should consult the relevant scientific committee(s) for setting up the technical requirements and for adapting the provisions of this Directive to scientific and technical progress.

(24) The Commission should be empowered to establish technical requirements and adopt any necessary changes thereto in order to take into account scientific and technical progress.

(25) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.

(26) In order to increase the effective implementation of the provisions adopted under this Directive it is appropriate to provide for penalties to be applied by Member States.

(27) Responsibility for the organisation of health services and the provision of medical care should remain the responsibility of each Member State,

[1] OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Objectives

The objective of this Directive is to ensure a high level of protection of human health by establishing quality and safety standards for human blood and its components.

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, with the aim of ensuring high standards of safety and quality.

2. This Directive shall not apply to autologous transfusion.

3. This Directive shall not apply to blood stem cells.

4. This Directive shall apply without prejudice to the requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices [2], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [3], Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma [4], and Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data [5].

Article 3

Definitions

For the purposes of this Directive:

(a) 'Autologous transfusion' shall mean the transfusion of autologous blood obtained by means of pre-deposit, pre-operative normovolaemic haemodilution or peri-operative salvage.

(b) 'Blood' shall mean whole blood collected from a donor and processed either for transfusion or for further manufacturing.

[2] OJ L 331, 7.12.1998, p. 1.
[3] OJ L 169, 12.7.1993, p. 1.
[4] OJ L 313, 13.12.2000, p. 22.
[5] OJ L 281, 23.11.1995, p. 31.

(c) 'Blood component' shall mean a therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods.

(d) 'Blood product' shall mean any therapeutic product derived from human blood or plasma.

(e) 'Blood establishment' shall mean any structure or body that is involved in 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.

(f) 'Inspection' shall mean formal and objective control according to adopted standards to evaluate and assess compliance with this Directive and other relevant legislation to identify problems and approaches to their resolution.

(g) 'Adverse event' shall mean any untoward occurrence associated with the collection, testing, processing, storage, distribution, and transfusion 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) 'Adverse reaction' shall mean a harmful and 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) 'haemovigilance' shall mean a set of organised surveillance procedures relating to adverse events or adverse reactions in donors or recipients, related to the quality and safety of the blood or blood component involved.

(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) 'Accreditation' shall mean formal acknowledgement of compliance with accepted standards for procedures, activities, or services following an inspection by an authorised institute or organisation.

(l) 'Voluntary, unpaid donation' shall mean that the person gives blood or blood components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonably required for donation and travel. Small tokens, refreshments, and reimbursement of direct costs are compatible with voluntary and unpaid donation.

Article 4

Implementation

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

2. Member States shall ensure that the competent authority implements the structural, technological and organisational requirements for accreditation and organises inspections and other control measures intended to guarantee compliance with the provisions of this Directive.

3. This Directive shall not prevent a Member State from maintaining or implementing on its territory more stringent protective measures which comply with the provisions of the Treaty. Those more stringent measures shall be safety measures totally based on current scientific knowledge and not present an obstacle to the implementation of this Directive.

4. 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

Accreditation of blood establishments

1. The competent authority shall grant accreditation to blood establishments for the purposes of their activities as described in Article 2. Any substantial change in the particulars of the accreditation or any new activity must be approved.

To this end, the blood establishment shall deliver a notification to the competent authority, providing its name, address, telephone and fax numbers, as well as the name of the responsible person according to Article 8 and the information referred to in Article 28(1.a).

2. The competent authority empowered to grant the accreditation shall verify that the particulars submitted in the application comply with the requirements set out in this Directive and indicate whether the activities for which the blood establishment sought accreditation may proceed.

3. The blood establishment may commence the activities for which it sought accreditation only upon receipt of the competent authority's written approval and compliance with any conditions referred to therein.

4. If the competent authority finds that the prescribed standards have not been complied with, it may immediately withdraw or temporarily suspend accreditation, depending on the seriousness of the infringement.

In the event of temporary suspension, the competent authority shall carry out an inspection within a period of three months, which may lead to withdrawal of accreditation if the infringement has not been remedied or if other infringements are found.

Article 6

Provisions for existing establishments

Member States may decide to maintain national provisions for nine months after the date laid down in Article 31 so as to enable blood establishments operating under their legislation to comply with its requirements.

Article 7

Inspection and control measures

1. The competent authority shall organise inspections and appropriate control measures in blood establishments to ensure that the requirements of this Directive, in particular those laid down in Article 5, 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 one year.

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 the territory of its Member State entrusted by the holder of the accreditation referred to in Article 5 with the task of carrying out evaluation and testing procedures pursuant to Article 18;

(b) take samples;

(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 notification of this Directive and which place restrictions on these powers with regard to the descriptions of the method of preparation.

4. The competent authority may organise inspection and control measures at shorter intervals depending on the results of the previous inspection. It shall in any case organise an immediate and appropriate inspection in the event of an adverse event or adverse reaction.

CHAPTER III

PROVISIONS FOR BLOOD ESTABLISHMENTS

Article 8

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 accreditation procedure as required in Article 5,

— Implementation of the requirements of Articles 9, 10, 11, 12, 13, 14, 15, 18, 19, 20, 21, and 22 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 of at least 4 years, or a course of at least 3 years 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 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 9

Personnel

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

2. The training of the personnel shall be provided on recruitment, and then at regular intervals of at least once every year. It shall be repeated in the event of a transfer or a change of job, as well as following the introduction of any new technology.

It shall be assessed periodically and at least every two years (proficiency testing).

3. Training guidelines addressing the issues determined according to Article 28(1.c) shall be provided for personnel.

CHAPTER IV

QUALITY MANAGEMENT

Article 10

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 28(1.k) for to the activities relating to a quality system to be carried out by a blood establishment.

Article 11

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 7.

Article 12

Record keeping

1. Member States shall take all necessary measures to ensure that blood establishments maintain records of the information required under Article 28(1.f), (g), and (h), as well as the prevalence of transfusion transmissible infectious agents in blood and plasma donors, and confirmed positive seroconversions. These records shall be kept for a minimum of 30 years.

2. The competent authority shall keep records of the data received from blood establishments according to the provisions of Article 5 for a minimum of 30 years.

3. The competent authority shall keep records of haemovigilance data, which they possess according to the provisions of Article 13 or are notified to them according to the provisions of Article 14. These records shall be kept for a minimum of 30 years.

CHAPTER V

HAEMOVIGILANCE

Article 13

Traceability

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

To this end, Member States shall ensure that blood establishments implement a donor identification system and label each single blood unit and components thereof in such a way as to permit full traceability in accordance with the requirements referred to in Article 28(1.b).

2. Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored or distributed on their territory are labelled as required under Article 28(1.d), including an identification of the blood establishment where the blood or blood component was collected.

3. In respect of blood and blood components imported from third countries, Member States shall implement technical measures having equivalent effect to ensure that blood and blood components meet the same standards as blood and blood components collected in the Community.

Article 14

Notification of adverse reactions and events

1. Member States shall ensure that:

— Any 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 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.

— Each blood establishment has in place a procedure to notify such adverse reactions and events to the competent authority and to remove defective blood and blood components rigorously, effectively, and verifiably from distribution channels.

2. The Community procedure for notifying these adverse reactions and events, and the notification format, shall be established as referred to in Article 28(1.l). A retrospective research procedure shall also be established.

CHAPTER VI

PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

Article 15

General clinical tests

A medical examination, comprising at least an interview and blood pressure check by a doctor, shall be carried out before any donation of blood or blood components; the doctor shall be responsible to ensure, in particular, that donors are given the necessary information and that the required information is gathered from donors. The doctor is also responsible for assessing the eligibility of donors.

Article 16

Provision of information to donors and recipients

Member States shall ensure that all donors of blood or blood components on their own territory are provided with information as required under Article 28(1.e), and similarly to ensure that all recipients are provided with information about possible adverse transfusion reactions and events.

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 on their own territory provide the information required under Article 28(1.f) to the blood establishment.

Article 18

Eligibility of donors

1. Blood establishments shall ensure that in order to protect the health of both the donor and the recipient, there are evaluation procedures in place for all donors of blood and blood components and that the criteria for donation required under Article 28(1.g) are met.

2. Blood and blood components shall be collected from donors who meet the criteria for donation referred to in Article 28(1.g).

3. 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

Voluntary and unpaid blood donation

Member States shall encourage voluntary, unpaid donation of blood and blood components, and shall take the necessary measures to promote the use of blood and blood components derived from voluntary, unpaid donations.

Article 20

Testing of donations

Blood establishments shall ensure that each donation of blood and blood components is tested in conformity with requirements referred to in Article 28(1.h), taking full advantage of scientific advances in pathogen detection.

Article 21

Freezing, storage and transport conditions

Blood establishments shall ensure that the freezing, storage and transport conditions of blood and blood components comply with the provisions referred to in Article 28(1.i).

Article 22

Quality requirements for blood components

Blood establishments shall ensure that quality requirements for blood components meet high standards in compliance with the provisions referred to in Article 28(1.j).

CHAPTER VII

DATA PROTECTION

Article 23

Data protection and confidentiality

Member States shall take all necessary measures in accordance with Directive 95/46/EC to ensure that all data, including personal data and 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 24

Information exchange

1. The Commission shall meet regularly with the competent authorities designated by the Member States to exchange information on the experience acquired with regard to the implementation of measures for the protection of human health, pursuant to this Directive.

2. Information on the collection and distribution of blood and blood components and data on clinical use must be available for the purposes of implementing this Directive and charting the degree of national and regional self-sufficiency.

3. Where new epidemiological or scientific data suggest there are risks to human health related to the collection, testing, processing, storage and distribution of blood and blood components and derivatives, the Commission may arrange for emergency meetings.

Article 25

Reports

1. Member States shall send to the Commission, commencing on 31 December 2003 and every two years thereafter, a report on the activities undertaken in relation to the provisions of this Directive, including an account of the national 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, every three years, a report on the functioning of requirements in the Directive, and in particular those relating to inspection and control.

Article 26

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

Article 27

Committee procedure

1. The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by the representative of the Commission.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 28

Technical requirements and their adaptation to technical and scientific progress

1. The following technical requirements shall be determined in accordance with the procedure referred to in Article 27(2):

(a) information to be provided by the blood establishment to the competent authority before accreditation;

(b) traceability requirements including the possible establishment of a common coding system;

(c) training guidelines;

(d) labelling requirements for blood and blood components;

(e) information to be provided to donors;

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

(g) requirements concerning the suitability of blood and plasma donors and the screening of donated blood such as:

— physical acceptance criteria

— donation volumes and frequency

— permanent deferral criteria and possible exemption thereto

— temporary deferral criteria;

(h) requirements relating to the testing of donations of whole blood and blood components;

(i) freezing, storage, and transport requirements;

(j) quality and safety requirements for blood components;

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

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

2. The provisions referred to in paragraph 1 shall be reviewed and if necessary adapted to scientific and technical progress at least once a year under the procedure referred to in Article 27(2). Establishment of technical specifications and the adaptation to progress shall be performed taking into account relevant recommendations of the Council of Europe and the WHO as well as indications of relevant European institutions and organisations.

Article 29

Consultation of scientific committee(s)

The Commission may consult the relevant scientific committee(s) when setting up and adapting the technical requirements referred to in Article 28 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 30

Amendment of Directive 89/381/EEC

Paragraphs 1, 2 and 3 of Article 3 of Directive 89/381/EEC are replaced by:

'1. For the collection and testing of human blood and human plasma Directive .../.../EC of the European Parliament and of the Council [setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 89/381/EEC] applies.'

Article 31

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 2002. 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 32

Entry into force

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

Article 33

Addressees

This Directive is addressed to the Member States.