II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL RECOMMENDATION

of 29 June 1998

on the suitability of blood and plasma donors and the screening of donated blood in the European Community

(98/463/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 129(4), second indent,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament [1],

(1) Whereas in accordance with Article 3(o) of the Treaty, Community activity is to include a contribution towards the attainment of a high level of health protection;

(2) Whereas the Commission's Communication of 21 December 1994 on Blood Safety and Self-sufficiency in the European Community 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;

(3) Whereas, in response to the Commission's Communication, the Council adopted, on 2 June 1995, a Resolution on blood safety and self-sufficiency in the Community [2];

(4) Whereas the Council adopted, on 12 November 1996, a Resolution on a strategy towards blood safety and self-sufficiency in the European Community [3];

(5) Whereas the European Parliament in its Resolutions on blood safety and self-sufficiency in the European Community [4] [5] [6] [7] has stressed the importance of ensuring the highest level of safety in the selection of donors and the testing of donations and the principle of voluntary unpaid donations and has reiterated its continued support for the objective of Community self-sufficiency;

(6) Whereas Directive 89/381/EEC [8] extended the scope of pharmaceutical legislation to guarantee the quality, safety, and efficacy of proprietary industrially prepared medicinal products derived from human blood or human plasma; whereas that Directive as such does not apply to whole blood, to plasma, or to blood cells of human origin;

(7) Whereas therapeutic use of blood and medicinal products derived from human blood and plasma contributes significantly to saving lives and yields considerable benefits for those suffering from long term blood disorders; whereas, however, in spite of their significant therapeutic value, blood, blood

[1] OJ C 138, 4. 5. 1998, p. 139.
[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 141, 13. 5. 1996, p. 131.
[7] OJ C 249, 25. 9. 1995, p. 231.
[8] 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 relation to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma (OJ L 181, 28. 6. 1989, p. 44).

components, and blood and plasma derivatives have the potential to transmit infectious diseases;

(8) Whereas the availability of blood and plasma used for therapeutic purposes and as starting material for the manufacture of medicinal products is dependent on the willingness and generosity of Community citizens who are prepared to donate;

(9) Whereas donations should be voluntary and unpaid;

(10) Whereas in respect of blood or plasma as a starting material for the manufacture of medicinal products, Article 3 of Directive 89/381/EEC refers to measures covered by the amendments to testing requirements, referred to in Article 6 of that Directive, to be taken by Member States to prevent the transmission of infectious diseases, including the application of the monographs of the European Pharmacopoeia and the measures recommended by the Council of Europe and the World Health Organisation (WHO) particularly with reference to the selection and testing of blood and plasma donors; to promote Community self-sufficiency in human blood or human plasma; and to encourage voluntary unpaid donations of blood and plasma;

(11) Whereas it is not always possible to know at the time of whole blood or plasma collection which donation may be used for further manufacture rather than used in transfusion;

(12) Whereas all blood and plasma used for therapeutic purposes, whether for transfusion or for further manufacture into industrially-prepared medicinal products, 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 any risk of transmission of infectious diseases is minimised; whereas 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 products;

(13) Whereas given that the blood transfusion systems in the Member States exist to serve their citizens, it is necessary to secure their confidence in the safety of these systems;

(14) Whereas there are disparities in policies and practices among the Member States regarding the selection of donors and the screening of donations within the Community for epidemiological, historical and cultural reasons;

(15) Whereas to ensure sufficient supply for clinical purposes, cooperation among the Member States is essential in order to overcome such disparities and build mutual confidence in all aspects of safety of the blood transfusion chain;

(16) Whereas the suitability of an individual to donate blood and plasma is an essential component in contributing to the safety of blood and blood products;

(17) Whereas information should be sought from potential donors on the basis of a written questionnaire, which may vary from Member State to Member State, whose aim should be to identify common risk behaviour and diseases;

(18) Whereas it is essential that all measures be taken to safeguard the health of those who give blood or plasma and to minimise the hazard of transmission of infectious diseases by blood or blood products;

(19) Whereas convergence of practice throughout the Community in the acceptance of donors, the screening of donations and the recording of relevant data will help to contribute to increasing confidence in the safety of blood and plasma donations and the transfusion process; whereas in order to bring about such convergence of practice, measures are required at Community level;

(20) Whereas measures at Community level should take into account existing guidelines, recommendations and standards in the area of blood at national level and international level, in particular those of the WHO and of the Council of Europe;

(21) Whereas in accordance with the principle of subsidiarity, any new measure taken in an area which does not fall within the exclusive competence of the Community, such as donor suitability and testing of donations, may be taken up by the Community only if, by reason of the scale or effects of the proposed action, the objectives of the proposed action can be better achieved by the Community than by Member States; whereas commonly agreed recommendations on donor suitability and testing of donations need, therefore, to be introduced in order to contribute to the safety of donated blood and plasma and the health protection of donors and to permit confidence in the safety of the transfusion chain among citizens, especially as they move about within the Community, and to contribute to the attainment of Community self-sufficiency as provided for in Community legislation;

(22) Whereas however, Member States remain free, while respecting the provisions of the Treaty or measures adopted thereunder, to maintain or introduce requirements over and above the core criteria recommended in this Recommendation, and remain responsible for decisions about the import and export of donated blood and plasma;

(23) Whereas in accordance with the principle of proportionality, the means to be deployed at Community level for promoting sound practices and consistency throughout the Community in the suitability of blood and plasma donors and the screening of donated blood must be in proportion to the objective pursued; whereas recommendations by the Council, pursuant to Article 129 of the Treaty, are the appropriate means for doing so at Communhity level; whereas such recommendations must be congruent with Directive 89/381/EEC;

(24) Whereas recommendations on donor suitability and testing requirements form part of a strategy to enhance the safety of the blood transfusion chain, the other elements of which include the inspection and accreditation of blood collection establishments, requirements related to quality assurance of the processes involved, the optimal use of blood and blood products, haemovigilance and public awareness;

(25) Whereas it is necessary that the best possible scientific advice is available to the Community in relation to the safety of blood and blood products and that the precautionary principle prevails when scientific evidence is not available;

(26) Whereas Directive 95/46/EC of the European Parliament of 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 [1] lays down special requirements for the processing of data concerning health,

HEREBY RECOMMENDS THAT:

1. **Definitions**

For the purpose of this Recommendation, Member States should assign to the terms listed in Annex I the meaning given to them therein.

[1] OJ L 281, 23. 11. 1995, p. 31.

2. **Provision of information to prospective donors**

Member States should ensure that all prospective donors of blood or plasma are provided with:

2.1. *For donor awareness*

(a) accurate but generally understandable educational materials about the essential nature of blood, the products derived from it, and the important benefits to patients of blood and plasma donations;

(b) the reasons for requiring a medical history, physical examination, and the testing of donations; information on the risk of infectious diseases that may be transmitted by blood and blood products; the signs and symptoms of HIV/AIDS and hepatitis, and the significance of 'informed consent', self-deferral, and temporary and permanent deferral;

(c) the reasons why they should not donate which may be detrimental to their own health;

(d) the reasons why they should not donate which put recipients at risk, such as unsafe sexual behaviour, HIV/AIDS, hepatitis, drug addiction and the use and abuse of drugs;

(e) the option of changing their mind about donating prior to proceeding further without any undue enbarrassment or discomfort;

(f) information on the possibility of withdrawing or self-deferring at any time during the donation process;

(g) the opportunity to ask questions at any time;

(h) the assurance that if test results show evidence of any pathology, they will be informed and deferred from donation, as recommended in Annex II B and C, for their own safety as well as that of potential recipients; prospective donors who object to being so informed should be excluded from the donation process;

(i) specific information on the nature of the procedures involved in the donation process and associated risks for those willing to participate in whole blood donation or in apheresis programmes.

2.2. *For confidentiality*

(a) information on the measures taken to ensure the confidentiality of: any health-related information

provided to the health personnel, the results of the tests on their donations, as well as any future traceability of their donation;

(b) the assurance that all interviews with prospective donors are carried out in confidence;

(c) the option of requesting through a confidential self-deferral procedure the blood and plasma collection establishment not to use their donation.

3. **Information required from prospective donors**

Member States should ensure that, upon agreement of a willingness to proceed to donate blood or plasma, all prospective donors provide to the blood and plasma collection establishment:

3.1. *Identification*

Appropriate means of identification, providing name (first and surname), addresss, and date of birth, or alternative means allowing each donor to be uniquely identified.

3.2. *Health history*

(a) Information on their health and medical history, including any relevant behavioural characteristics, that may assist in identifying and screening out persons whose donation could present a health risk to themselves or a risk of transmitting diseases to others, by way of a written questionnaire addressing the criteria recommended in Annex II and a personal interview with a trained health care staff member.

(b) Their signature alongside that of the health care staff member conducting the interviews on the donor questionnaire or their signature on a separate attestation to acknowledge that the educational materials provided have been read and understood, that the opportunity to ask questions has been presented, and that satisfactory responses have been received; to give their agreement that their blood or plasma donation could be used for patients needing transfusion or blood products in the country where the donation is made or in another country, to which it would be transferred in accordance with the provisions of the legislation of the country where the donation is made, particularly with regard to the destination of the donation; and to indicate their informed consent that they wish to proceed with the donation process.

4. **Registration of donor**

Member States should ensure the establishment of a donor identification/registration system to:

4.1. *Donor centre identification*

Permit every donation establishment in each Member State to be uniquely identified;

4.2. *Donor identification and records*

(a) Record information regarding the identification of prospective donors in an automated or manual system which allows verification each time a donation is made;

(b) Provide for the keeping of records on donors and prospective donors in such a way as to ensure unique identification, protect the identity of the donor from unauthorised access to confidential information, but facilitate future traceabiity of any donation;

(c) Allow for the inclusion of information related to adverse donor reaction to the donation, reasons for preventing an individual from donating, whether on a temporary or permanent basis while ensuring confidentiality.

5. **Donor eligibility**

Member States, in order to ensure the eligibility of individuals to be accepted as donors of blood and plasma, should ensure that:

5.1. *Eligibility criteria for the acceptance of donors of whole blood and donors of components by apheresis*

(a) the general criteria for the acceptance of blood and plasma donors are publicised in every donation establishment and that clear messages are presented to donors as to the importance of their willingness to donate but also the importance of the acceptance criteria;

(b) the responses given to the issues raised in the written questionnaire and/or the personal interview provide the necessary confidence that the donation will not adversely affect the health of a future recipient of the products derived from that donation;

(c) the prospective donor meets the physical requirements criteria recommended in Annex II A in order that there are no detrimental effects to his/her own health as a result of the donation;

(d) the prospective donor's eligibility is determined at each donation session;

(e) the practice of using 'replacement donors' is phased out;

(f) a responsible physician gives his/her written authorisation of the acceptance of prospective donors, when their eligibility may be questionable;

5.2. *Deferral criteria for donors of whole blood and donors of components by apheresis*

Those who may show evidence of any of the conditions and characteristics listed in Annex II B and C should be declared either permanently or temporarily ineligible to donate blood and plasma;

5.3. *Deferral records*

Donation establishments should maintain a record of any prospective donor deferral, whether permanent or temporary, including the reasons why.

6. **Data protection**

Member States should, in accordance with Directive 95/46/EC, ensure the confidentiality of sensitive medical information about prospective donors, and in particular:

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

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

(c) prevent the unauthorised disclosure of such information, while ensuring the traceability of donations.

7. **Volumes and time intervals**

To protect the health of the donor, Member States should ensure that:

(a) volumes of blood and plasma collected are no greater than those recommended in Annex III;

(b) time intervals between donations are no less than those recommended in Annex III;

(c) medical attention is available to the donor in the event of an adverse event related to the donation.

8. **Testing samples of donated blood**

Member States, in order to ensure the safety of all blood and plasma donations, should:

(a) ensure that a sample of all donations of blood or plasma whether intended for transfusion purposes or for further manufacturing into industrially prepared medicinal products is tested for diseases transmissible by blood or plasma using approved screening tests to eliminate units that are repeat reactive;

(b) ensure that all blood and plasma donations be found non-reactive for the transmissible disease markers listed in Annex IV prior to use;

(c) require re-testing of the blood samples found to be reactive in an initial screening test taking account of the indicative algorithm set out in Annex V.

9. **Additional measures**

Member States should:

(a) ensure that appropriate provisions are in place in the donation establishment for counselling, as appropriate, to prospective donors who are deferred;

(b) encourage the collection, analysis and evaluation of epidemiological data concerning donors and donations, with a view to improving the safety of blood transfusion;

(c) take the necessary steps for the dissemination of this recommendation to all parties concerned, and in particular to blood collecting establishments in their territory;

(d) take all necessary measures to encourage the voluntary and unpaid donation of blood and plasma, and entirely support the efforts of the Council of Europe in this area; take account of the Council of Europe definition of voluntary and non-remunerated donation as follows:

'A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular 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 needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donations.'

INVITES THE COMMISSION

— to report on the application of these recommendations and keep the matters covered therein under review in order to make the necessary proposals for

revision and updating; to involve national experts from all the Member States in the preparation of such proposals;

— to promote as a priority, in the light of scientific studies, work on the potential health effects of departing from the maximum volume limits and minimum time intervals between donations set out in Annex III, in order in particular to determine whether or not adverse health effects may result from collecting, by apheresis, annual plasma volumes higher than those recommended in existing international guidelines; and to undertake work on common volume and frequency limits for other types of apheresis;

— to propose where appropriate common terminology for the purpose of further developing the Community strategy on blood safety and self-sufficiency;

— to examine as soon as possible, in close cooperation with the Member States, all the aspects related to the use of genome amplification technology (GAT), including polymerase chain reaction (PCR)-screening, in order to prevent the transmission of communicable diseases by blood transfusion.

Done at Luxembourg, 29 June 1998.

For the Council

The President

R. COOK

ANNEX I

COMMON TERMINOLOGY

Blood	Whole blood collected from a single donor and processed either for transfusion or further manufacturing
Blood product	Any therapeutic product derived from human blood or plasma
Blood component	Therapeutic components of blood (red cells, white cells, platelets, plasma) that can be prepared by centrifugation, filtration, and freezing using conventional blood bank methodology
Medicinal product derived from blood or plasma	Same meaning as that given in Directive 89/381/EEC
Donor	A person in normal health with a good medical history who voluntarily gives blood or plasma for therapeutic use
Prospective donor	Someone who presents himself/herself at a blood or plasma collection establishment and states his/her wish to give blood or plasma
First time donor	Someone who has never donated either blood or plasma
Repeat donor	Someone who has donated before but not within the last two years in the same donation centre
Regular donor	Someone who routinely donates their blood or plasma (i.e. within the last two years), in accordance with minimum time intervals, in the same donation centre
Replacement donor	Donors recruited by patients to enable them to undergo therapy which requires blood transfusion

ANNEX II

CORE CRITERIA FOR ACCEPTANCE OR DEFERRAL OF BLOOD AND PLASMA DONORS

A: Physical requirements criteria for acceptance of blood and plasma donors for their own protection

Age

Blood and plasma donors should be 18-65 years of age. Acceptance of first time donors age 60-65 is at the discretion of the responsible physician. Repeat donors may continue to donate after the age of 65 with the permission of the responsible physician given annually.

For whole blood, donors aged 17, and not legally classified as minors, may be accepted; otherwise written consent should be required according to applicable law.

Body weight

Donors weighing no less than 50 kg may donate whole blood or plasma.

Blood pressure

The systolic blood pressure should not exceed 180 mm of mercury and the diastolic pressure should not exceed 100 mm of mercury.

Pulse

The pulse should be regular and between 50 to 110 beats per minute. Those prospective donors who undergo intensive sport training and have a pulse rate lower than 50 beats per minute may be accepted.

Either:

Haemoglobin

The haemoglobin concentration should be determined at the time of the donation and should be no less than 12,5 g/100 ml for females and 13,5 g/100 ml for males (or equivalent values expressed in mmol/I).

or

Haematocrit

The packed cell volume (haematocrit) should be determined at the time of the donation and should be no less than 38 % for females and 40 % for males. For apheresis plasma donors, the minimum should be 38 %.

For plasmapheresis only

Protein should measure a minimum of 60 g per litre.

B: Deferral criteria blood and plasma donors for their own protection

If prospective donors have, or have a history of, any of the following, a qualified physician in the blood collection establishment should consider declaring them permanently or temporarily ineligible to donate blood or plasma for the protection of their own health:

1. *Permanent deferral*

— Auto-immune diseases
— Cardiovascular diseases
— Central nervous system diseases
— Malignant diseases
— Abnormal bleeding tendency
— Fainting spells (syncope) or convulsions
— Severe or chronic gastrointestinal, haematological, metabolic, respiratory or renal disease, not included in the preceding categories

2. *Temporary deferral*

Ineligible for nine months

— Pregnancy (after delivery)
— Abortion

Ineligible (time frame variable)

— Participation in hazardous sports
— Employment which might cause problems shortly after blood donation
— Other reasons.

C: **Deferral criteria for blood and plasma donors for the protection of recipients**

If prospective donors have, or have a history of, any of the following, a qualified physician in the blood collection establishment should consider declaring them permanently or temporarily ineligible to donate blood or plasma for the protection of potential recipients:

1. *Permanent deferral*

— Auto-immune diseases
— Infectious diseases — persons suffering or having suffered from:
  — Babesiosis
  — Hepatitis B (HBsAg confirmed positive)
  — Hepatitis C
  — Hepatitis, infectious (of unexplained aetiology)
  — HIV/AIDS
  — HTLV I/II
  — Leprosy
  — Kala Azar (leishmaniasis)
  — Q fever
  — Syphilis
  — Trypanosoma cruzi (Chagas' disease)
— Malignant diseases
— TSEs (or history thereof in the genetic family)
— Alcoholism, chronic
— Cornea/dura mater transplantation recipient
— Diabetes, if treated with insulin
— Intravenous (IV) drug use
— Pituitary hormone of human origin (e.g. human growth hormone) recipient
— Sexual behaviour which places them at a high risk of transmitting infectious diseases, including persons who have had sex in return for money or drugs

2. *Temporary deferral*

2.1 Ineligible for two years

— Tuberculosis (after declared cured)
— Toxoplasmosis (after recovery and absence of IgM antibodies)
— Brucellosis (after full recovery)

2.2 Ineligible for one year

— Accidental exposure to blood or blood contaminated instruments
— Acupuncture (if not performed by a qualified practitioner)
— Endoscopic examination
— Treatment involving use of catheters
— Blood transfusion or major surgery
— Tissue or cell transplant
— Body piercing
— Drug allergy, in particular allergy to penicillin (after last exposure)
— Tattoo
— Close contact with a case of hepatitis B or C
— Rabies vaccine (if post exposure)

2.3 Ineligible for six months

— Infectious mononucleosis (after recovery)

2.4 Ineligible for four weeks

— Following administration of live attenuated viral vaccines

2.5 Ineligible for two weeks

— Minor infectious diseases

2.6 Ineligible for one week

— Minor surgery

2.7 Ineligible for 72 hours

— Following administration of vaccines (desensitising)

2.8 Ineligible for 48 hours

— Treatment by dentist or dental hygienist
— Following administration of killed/inactivated viral/bacterial and rickettsial vaccines
— Rabies vaccine (prophylactic administration)

2.9 Ineligible (time frame variable)

— Hepatitis A
— Medicines
— Malaria (does not apply to plasmapheresis donors)
— Tropical diseases (other)

Additional reasons may exist for the temporary deferral of a donor for the protection of the recipient. A decision as to length of time is as the discretion of a qualified physician in the blood collection establishment.

ANNEX III

WHOLE BLOOD AND PLASMA DONATIONS

recommended maximum volumes and minimum time intervals between donations

Whole blood		
Maximum volume	per donation	500 ml
	per consecutive 12 month period	three litres
Minimum time interval between donations		eight weeks
Automated plasmapheresis		
Maximum volume (excluding anticoagulant)	per donation	650 ml
Minimum time interval between donations		At least two days should elapse between donations. No more than two donations should be permitted within a seven-day period

Existing guidelines at international level in the area of blood recommend 15 litres as the maximum annual volume of plasma to be collected via automated plasmapheresis; there is no scientific evidence of whether or not adverse health effects may result from higher volume collection; this area should be a priority area for scientific study.

In assessing individually appropriate donation volumes, account should also be taken of physical characteristics such as gender and body weight.

ANNEX IV

CORE SCREENING TESTS FOR ALL BLOOD SAMPLES WHETHER FROM A WHOLE BLOOD OR PLASMA DONATION

Antibodies to the hepatitis C virus	Anti-HCV
Antibodies to the human immunodeficiency virus 1	Anti-HIV 1
Antibodies to the human immunodeficiency virus 2	Anti-HIV 2
Surface antigen of hepatitis B	HBsAg

ABO-group [(A) (B)]
Rh-type [(A) (B)]

Malaria [(B)] for travellers to endemic areas (unless risk of malaria transmission is otherwise dealt with by a deferral period of three years for such travellers)

Treponema pallidum (syphilis) [(B)]

[(A)] If it can be proven that the blood group of an already known blood donor, whose blood group has been previously determined and verified from two separate donations, can be reliably transferred into the label of the blood component by using a validated automated information technology system, it is not necessary to repeat the determination of ABO- and Rh-groups at the time of every blood donation. In such a case the blood group of the blood donor should be periodically verified.

[(B)] Not required for apheresis plasma intended only for fractionation.

ANNEX V

Indicative Algorithm for Interpretation of reactive results in screening tests in relation to clinical use of donation and Reactive results in supplementary/confirmation tests in relation to donor deferral