COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 05.05.1998
COM(1998) 290 final

97/0315 (CNS)

Amended proposal for a

COUNCIL RECOMMENDATION

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

(presented by the Commission pursuant to Article 189 a(2) of the EC Treaty)

Explanatory Memorandum

In November 1997, the Commission presented to Council the Proposal for a Council Recommendation on the Suitability of blood and plasma donors and the screening of donated blood in the European Community (COM(97) 605 final). Given the attention that has been given by the European Parliament to blood safety and self-sufficiency in the Community, the Commission proposed that it be consulted.

In its November 18 1997 letter, the Council consulted the European Parliament.

On 15 January 1998, the President of the Parliament announced that he had referred the proposal to the Committee of the Environment, Public Health and Consumer Protection.

On 18 March, the Committee considered the Commission proposal and the rapporteur's draft report, and adopted the draft legislative resolution. The report was tabled on 19 March.

On 2 April, the European Parliament approved the Commission proposal as amended and adopted the legislative resolution.

The Commission has accepted fully or in part 16 of the Parliament's 29 amendments and rejected 11. Two did not affect the original English version.

Commission proposal
COM(97) 605 final

Modified proposal

THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty establishing the European Community, and in particular Article 129 thereof;

Having regard to the proposal from the Commission[1];

Having regard to the opinion of the European Parliament[2],

1. Whereas in accordance with point (o) of Article 3 of the Treaty, Community action must include a contribution towards the attainment of a high level of health protection;

2. Whereas the Commission's Communication on Blood Safety and Self-sufficiency in the European Community[3] of December 1994 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 Council in its Resolution of 2 June 1995[4], in response to the Commission's Communication, invited it to submit appropriate proposals in the framework of development of a blood strategy;

4. Whereas Council in its Resolution of 12 November 1996[5] on a strategy towards blood safety and self-sufficiency in the European Community invited the Commission to submit proposals as a matter of urgency with the view to encouraging the development of a co-ordinated approach to the safety of blood and blood products;

5. Whereas the European Parliament in its resolutions on blood safety and self-sufficiency through voluntary unpaid donations in the European Community[6] [7] [8] [9] has stressed the importance of ensuring the highest level of safety in the selection of donors and the testing of donations and has reiterated its continued support for the objective of Community self-sufficiency;

6. Whereas Council Directive 89/381/EEC[10] 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 it does not apply to whole blood, to plasma, or to blood cells of human origin;

---

1 O.J. ------
2 O.J.-----
3 COM (94)652 final. Brussels. 21.12.1994
4 O.J. No C164, 30.6.95, p.1
5 O.J. No C374, 11.12.96, p.1
6 O.J. No C268, 4.10.93, p.29
7 O.J. No C329, 6.12.93, p.268
8 O.J. No C249, 25.9.95, p.231
9 O.J. No C141. 13 5.96. p.131
10 O.J. No L181, 28.6.89, p.44

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 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 proprietary medicinal products, Article 3 of Council Directive 89/381/EEC refers to measures: covered by the modification, as to testing requirements, referred to in Article 6 of that Directive, to be taken by Member States to prevent the transmission of infectious diseases, comprising the application of the monographs of the European Pharmacopoeia and the recommendations of the Council of Europe and the World Health Organization as regards in particular 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 as to ensure that transmission of disease does not take place, and that 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;

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 as to minimise the risk of infectious agents being transmitted by blood; 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 of the European Community exist to serve its citizens, it is necessary to secure their confidence in the safety of these systems;

14. Whereas disparities in policies and practices among the Member States regarding the selection of donors and the screening of donations within the Community are such as to undermine confidence among its citizens as well as blood transfusion services in the safety of the blood and blood products and hinder the achievement of self-sufficiency;

15. Whereas the goal of Community self-sufficiency can only be achieved through co-operation among the Member States 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 and to the goal of self-sufficiency;

17. Whereas it is essential that all measures be taken to safeguard the health of those who provide their blood and plasma and to minimise the hazard of transmission of infectious diseases by blood or blood products;

18. Whereas uniformity and consistency throughout the Community in the acceptance of donors, the screening of donations and the recording of relevant data will help to contribute to the achievement of self-sufficiency and to increasing confidence in the safety of blood and plasma donations and the transfusion process; whereas in order to bring about such uniformity and consistency, and build confidence, measures are required at Community level;

19. Whereas measures at Community level should take into account existing guidelines, recommendations and standards in the area of blood at both national and international levels;

20. 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 requirements 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 safety of the transfusion chain among citizens, especially as they move about in the Community, and to contribute to the attainment of Community self-sufficiency as provided for in Community legislation;

21. 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;

22. Whereas recommendations by the Council, pursuant to Article 129 of the EC Treaty, are the appropriate means for doing so at Community level; whereas such recommendations must be congruent with the provisions of Directive 89/381/EEC;

23. Whereas recommendations on donor suitability and testing requirements form part of a strategy to enhance 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;

24. 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;

25. Whereas Directive 95/46/EC[11] on the protection of individuals with regard to the processing of personal data and the free movement of such data lays down special requirements for the processing of data concerning health;

25a Whereas it has been recognised that, although still theoretical, there may be a risk of nvCJD being transmitted by blood and blood products; whereas it is necessary to take appropriate precautionary measures;

HEREBY RECOMMENDS THAT

1. DEFINITIONS

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

2. PROVISION OF INFORMATION TO PROSPECTIVE DONORS

Member States provide to all prospective donors of blood or plasma:

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 AIDS, 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 embarrassment 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 undertaking that if test results shows evidence of any pathology, they will be contacted by the blood collection centre;

---

[11] O.J. No L281, 23.11.95, p.31

i. Specific information on the nature of the procedures involved in the donation process and associated risks for those willing to participate in apheresis programmes, whether for plasma or cellular components.

2.2 Confidentiality

a. The measures taken to ensure the confidentiality of: any health-related information provided to the authorised 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 private;

c. The option of requesting the medical staff of the blood collection centre not to use his / her donation.

3. INFORMATION REQUIRED FROM PROSPECTIVE DONORS

Member States ensure that, upon agreement of a willingness to proceed to donate blood or plasma, all prospective donors (whether first time, new, repeat or regular) provide to the blood and plasma collection establishment:

3.1 Identification

Identification, supported by valid official documentation providing name (first and surname), address, and date of birth.

3.2 Health history

a. Information on their health and medical history including any relevant social and behavioural characteristics that may assist in identifying and screening out persons whose donation could present a higher risk of transmitting infections as well as those who could have contracted a recent infection that may not yet be detectable in the screening tests;

b. Answers to questions about their health and medical history by way of a written questionnaire and a personal interview with a trained health care staff member which should address the elements and risk behaviours listed in Annex 2:

c. Their signature and that of the health care staff member conducting the interviews on the donor questionnaire acknowledging that the educational materials provided have been read and understood, the opportunity to ask questions has been presented, and satisfactory responses have been received;

3.3 Informed consent

a. Their informed consent in writing that they wish to proceed with the donation process;

b. The prospective donor's agreement that if their blood or plasma donation becomes excess to the needs of their own Member State, it may be shared with another Member State of the Community that is in need ;

a. Information on their health and medical history including any relevant social and behavioural characteristics that may assist in identifying and screening out persons whose donation could present a risk of transmitting infections as well as those who could have contracted a recent infection that may not yet be detectable in the screening tests;

4. REGISTRATION OF DONOR

Member States, in order to facilitate future verification of repeat and regular donors, future tracing of donations, and future exchanges of information, establish a mutually compatible donor identification / registration system to:

4.1 Donor centre identification

a. Permit every donation centre in each Member State to be uniquely identified, by communicating to all other Member States and to the Commission a list of centres and their identification comprising the country code and a suitable combination of letters and numbers at their discretion;

4.2 Donor identification and registry

a. Require that all relevant information regarding the identification of prospective donors be recorded in an automated or manual system for new and first time donors and be verified prior to each donation for repeat and regular donors;

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 traceability 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 SUITABILITY

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

5.1 Suitability criteria for the acceptance of whole blood and apheresis plasma donors

a. Ensure that general criteria for the acceptance of blood and plasma donors are clearly spelt out in every donation centre 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. Ensure that the responses given to the issues raised in the written questionnaire and / or the personal interview, as presented in Annex 2, 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. Ensure that the prospective donor meets the physical requirements criteria contained in Annex 3 in order that there are no detrimental effects to his / her own health as the result of the donation;

d. Ensure that the prospective donor's suitability is determined at each donation session;

Member States, in order to facilitate future verification of repeat and regular donors, future tracing of donations, and future exchanges of information, establish a mutually compatible donor identification / registration system, taking fully into account those already existing, to:

a. Permit every donation centre in each Member State to be uniquely identified, by communicating to all other Member States and to the Commission a list of centres and their identification comprising the country code and a suitable combination of letters and numbers at their discretion, while taking fully into account those systems already existing;

e. Prohibit or phase out the practice of using 'replacement donors';

f. Require the responsible physician to give his / her written authorisation as to the final determination of the suitability of a prospective donor, when this may be questionable.

6. DONOR INELIGIBILITY

Member States, in order to ensure that the prospective donors do not cause harm to their own health nor that their donation present a risk of transmission of infectious diseases:

6.1 Deferral criteria for whole blood and apheresis plasma donors

a. Ensure those who may show evidence of one of the characteristics listed in Annexes 4 and 5 should be rendered either permanently or temporarily ineligible to donate blood and plasma;

b. Ensure that appropriate provisions are in place in the donation centre for counselling, as appropriate, to prospective donors who are deferred.

6.2 Deferral registers

a. Maintain a record of any prospective donor deferral, whether permanent or temporary, including the reasons why;

b. Ensure that such donor deferral registers are set up so as to fully respect data confidentiality requirements but be available for consultation by authorised personnel of the blood collection establishment or appropriate authorities when matters of safety are concerned.

c. Ensure that epidemiological data on viral markers are regularly collected, analysed and verified using common definitions, and criteria that are comparable throughout the Community, and that they remain vigilant for the emergence of new markers;

d. Ensure that criteria on the nature and duration of deferral are based on the results of sound scientific evidence, which will have to be promoted, and that the precautionary principle should prevail when that evidence is not available;

7. DATA PROTECTION

Member States, in order to ensure the confidentiality of sensitive medical information about prospective donors:

a. Ensure that measures are in place for prospective donor identification and accurate data verification;

a. Ensure that measures are in place for prospective donor identification and accurate data verification by means of a unique coding system;

b. 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;

c. Ensure that procedures are in place to resolve data discrepancies;

d. Prevent the unauthorised disclosure of such information, while ensuring the traceability of donations;

e. Pay particular attention to compliance with the requirements of Directive 95/46/EC in particular its Article 8, when processing data related to blood and plasma donors.

8. VOLUMES COLLECTED FOR SAFETY OF DONOR

To protect the health of the donor, Member States:

a. Adhere to the maximum volumes of blood and plasma collected at a single donation and over a 12 month period presented in Annex 6;

b. Adhere to the minimum time intervals between donations as presented in Annex 6;

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

9. TESTING SAMPLES OF DONATED BLOOD

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

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

b. Ensure that all blood donations be found non-reactive for the transmissible disease markers listed in Annex 7;

c. Require re-testing of the blood samples found to be reactive in an initial screening test in accordance with the general algorithm set out in Annex 8;

10. ADDITIONAL MEASURES

a. Member States take the necessary steps for the dissemination of this recommendation to all parties concerned, and in particular to blood establishments in their territory;

b. Member States take all necessary measures to encourage the voluntary and unpaid donation of blood or plasma;

b. Ensure that all blood and plasma donations be found non-reactive in approved screening tests for the transmissible disease markers listed in Annex 7;

c. Member States take appropriate measures to minimise any hazard that might arise that is relevant to the possible transmission of nvCJD via blood components and manufactured plasma-derivatives;

d. Member States take the necessary steps to collect, analyse, publish and update epidemiological data using common definitions, and criteria that are comparable throughout the Community.

INVITES THE COMMISSION

To report on the application of these recommendations and keep the matters covered therein under review in order to take the necessary steps for revision and updating.

Done at Brussels

For the Council
The President

ANNEX 1
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 whole blood or plasma donations.

Blood component Therapeutic components of blood (red cells, white cells, plasma, platelets) that can be prepared by centrifugation, filtration, and freezing using conventional blood bank methodology.

Plasma derivative Highly purified human plasma protein prepared under licensed pharmaceutical manufacturing conditions

Cell-derivative A therapeutic product derived from a blood component (as derived from leukocytes - interferon, cytokines - or from outdated erythrocytes - haemoglobin solution)

Donor

First time donor Someone who has never donated either blood or plasma.

Deferred donor Someone who, for protection of their own health or that of potential recipients of blood products prepared from his / her donation, is not permitted to give blood or plasma.

Lapsed donor Someone who routinely had donated blood or plasma (regular donor) and has stopped presenting himself / herself to donate.

New donor Someone who has not donated blood or plasma within the last year or is not listed in the local donor registry.

Prospective donor Someone who presents himself / herself at a blood or plasma collection establishment and states his / her wish to give blood or plasma.

Repeat donor Someone who has donated before and within the last year in the same donation centre.

Regular donor Someone who routinely donates their blood or plasma at the permissible time intervals.

Replacement donor Donors recruited by patients to enable them to undergo elective surgery.

Medicinal product derived from blood or plasma
Same meaning as in Directive 89/381/EEC

Suitability Process by which an acceptance decision of a prospective blood or plasma donor can be made.

Personal data Any information relating to an identified or identifiable natural person who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors to his physical, physiological, mental, economic, cultural or social identity. (Directive 95/46/EC)

Voluntary, unpaid blood donation
Same meaning as in Directive 89/381/EEC

ANNEX 2

Common Elements to be Covered in a Donor Questionnaire

- Indication that the questionnaire is to be completed, signed and dated*
- General health of the donor

Whether prospective donor

- has recently consulted a doctor
- is taking any medication
- has haemophilia or related blood clotting disorders
- participates in hazardous sports (e.g. motor racing)
- undertakes employment that might cause problems within 24 hours after blood donation
- is pregnant or has delivered a child now under 1 year (for women)
- has received growth hormone or pituitary extract treatment
- has received a blood transfusion
- has had a corneal or dura mater transplant
- has undergone tattooing, acupuncture, body piercing by someone other than qualified and / or licensed professional
- has been in recent contact (<3 weeks) with contagious infections, chicken pox, measles
- has recently received a vaccination(polio, tetanus, holiday vaccinations)
- has recently (<5 days) ingested aspirin (or other pain killers)
- is working as a prostitute
- is HIV positive
- has a spouse who is HIV positive
- has a family history of Creutzfeldt-Jacob disease (CJD)
- self-injects drugs

Whether prospective donor has / had

- Brucellosis
- Epilepsy
- Hepatitis
- Jaundice
- Major surgery/serious illness
- Malaria

Whether prospective donor has travelled

- Outside Western Europe & North America
- Men who have sex with other men
- Sexual activity in Africa
- Sexual activity in countries other than those in Africa: (to specify country)
- Self-exclusion option

- has sexual behaviour that places them at risk of transmitting infectious diseases
- ~~has a spouse who is HIV positive~~

Whether prospective donor has travelled

- outside the European Community (individual countries may be specified)

Whether prospective donor has / had

- Sexual behaviour that places them at risk of transmitting infectious diseases
- Sexual activity outside the European Community (individual countries may be specified)
- ~~Sexual activity in countries other than those in Africa: (to specify country)~~

* The questionnaire has to be given and completed at every visit.

ANNEX 3

Common Acceptance Criteria for Blood and Plasma Donors

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 - 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.

Haemoglobin

The haemoglobin concentration should be determined prior to donation and shall 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 / l). For apheresis plasma donors, the minimum shall be 12.5 g/100 ml for both males and females.

Haematocrit

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

Donation interval

For whole blood, the time interval between donations should be greater than 8 weeks.

For apheresis plasma, this interval should not be less than 72 hours.

Donation frequency

For whole blood, the maximum number of times allowable for donations should be 6 / year for men, 4 / year for women and 3 / year for pre-menopausal donors.

For apheresis plasma, the maximum donation frequency should be twice per week,

Haematocrit

Where the haemoglobin concentration has not been determined, the packed cell volume (haematocrit) should be determined prior to donation and shall be no less than 38% for females and 40% for males. For apheresis plasma donors, the minimum shall be 38%.

ANNEX 4

Common Deferral Criteria for Blood and Plasma Donors (For protection of donor)

1. Permanent deferral

Prospective donors with any or a history of any of the following should be declared permanently ineligible to donate blood or plasma for the protection of their own health:

- Auto-immune diseases
- Cardiovascular diseases
- Central nervous system diseases
- Malignant diseases
- Abnormal bleeding tendency
- Fainting spells (syncope) or convulsions

Permanent deferral in cases where prospective donors have or have had a severe or chronic gastrointestinal, haematological, metabolic, respiratory, or renal disease, not included in the preceding categories, should be determined by a qualified physician in the blood collection establishment.

2. Temporary deferral

Ineligible for 1 year

- Abortion
- Pregnancy (after delivery)

NOTE: Additional reasons may exist for the temporary deferral of a donor for the protection of their own health. A decision as to length of time is at the discretion of a qualified physician in the blood collection establishment.

ANNEX 5

Common Deferral Criteria for Blood and Plasma Donors
(For protection of recipient)

1. Permanent deferral

Prospective donors with any, or a history of any, of the following should be declared permanently ineligible to donate blood or plasma for the protection of potential recipients.

- Auto-immune diseases
- Infectious diseases- persons suffering or having suffered from
  - Babesiosis
  - Brucellosis
  - Creutzfeldt Jacob disease (CJD) (persons in whose family this has occurred)
  - 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
- Alcoholic, chronic
- Cornea / dura mater transplantation recipient
- Intravenous (IV) drug use
- Males who have sex with other males
- Pituitary hormone of human origin (e.g. growth hormone) recipient
- Prostitutes (male and female)

2. Temporary deferral

Prospective donors with any of the following conditions should be declared ineligible to donate blood or plasma temporarily. The time interval for deferral varies according to the condition.

2.1 Ineligible for 3 years

- Tuberculosis (after recovery)

2.2 Ineligible for 1 year

- Accidental exposure to blood or blood contaminated instruments
- Acupuncture (if not performed by a qualified physician)
- Blood transfusion recipient
- Body piercing
- Drug allergy (after last exposure)
- Tattoo
- Toxoplasmosis (after recovery)
- Individuals who have had sexual relations with someone infected or at increased risk of infection with HBV, HCV, HIV

2.3 Ineligible for 6 months

- Mononucleosis infectiosa (after recovery)
- Surgery, major

2.4 Ineligible for 4 weeks

- Following administration of live attenuated viral vaccines

2.5 Ineligible for 48 hours

- Following administration of killed / inactivated viral / bacterial and rickettsial vaccines
- Following administration of vaccines (desensitising)
- Rabies vaccine (prophylactic administration)

2.6 Ineligible (time frame variable)

- Hepatitis A
- Malaria (does not apply to plasmapheresis donors)
- Prescribed medicines
- Tropical diseases (other)

NOTE: 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 at the discretion of a qualified physician in the blood collection establishment.

ANNEX 6

Common Volumes to be collected and time intervals for whole blood and plasma donations

Whole Blood

Maximum Volume per donation 500 ml
per consecutive 12 month period 3 litres

Minimum time interval between donations 8 weeks

Maximum number of donations per 12 month period
6 (males)
4 (females)
(3 for pre-menopausal women)

Automated plasmapheresis

Maximum Volume per donation

Donor Weight	Volume Collected (excluding anticoagulant)
50-67 kg	625 ml
68-79 kg	750 ml
80 kg or more	800 ml

Minimum time interval between donations 72 hours

Maximum number of donations per 7 day period 2

ANNEX 7

Common Testing Requirements for all Blood Samples whether a whole blood or plasma donation

For all blood and plasma donations

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**

In addition

For all, excluding plasmapheresis intended only for fractionation.

ABO group

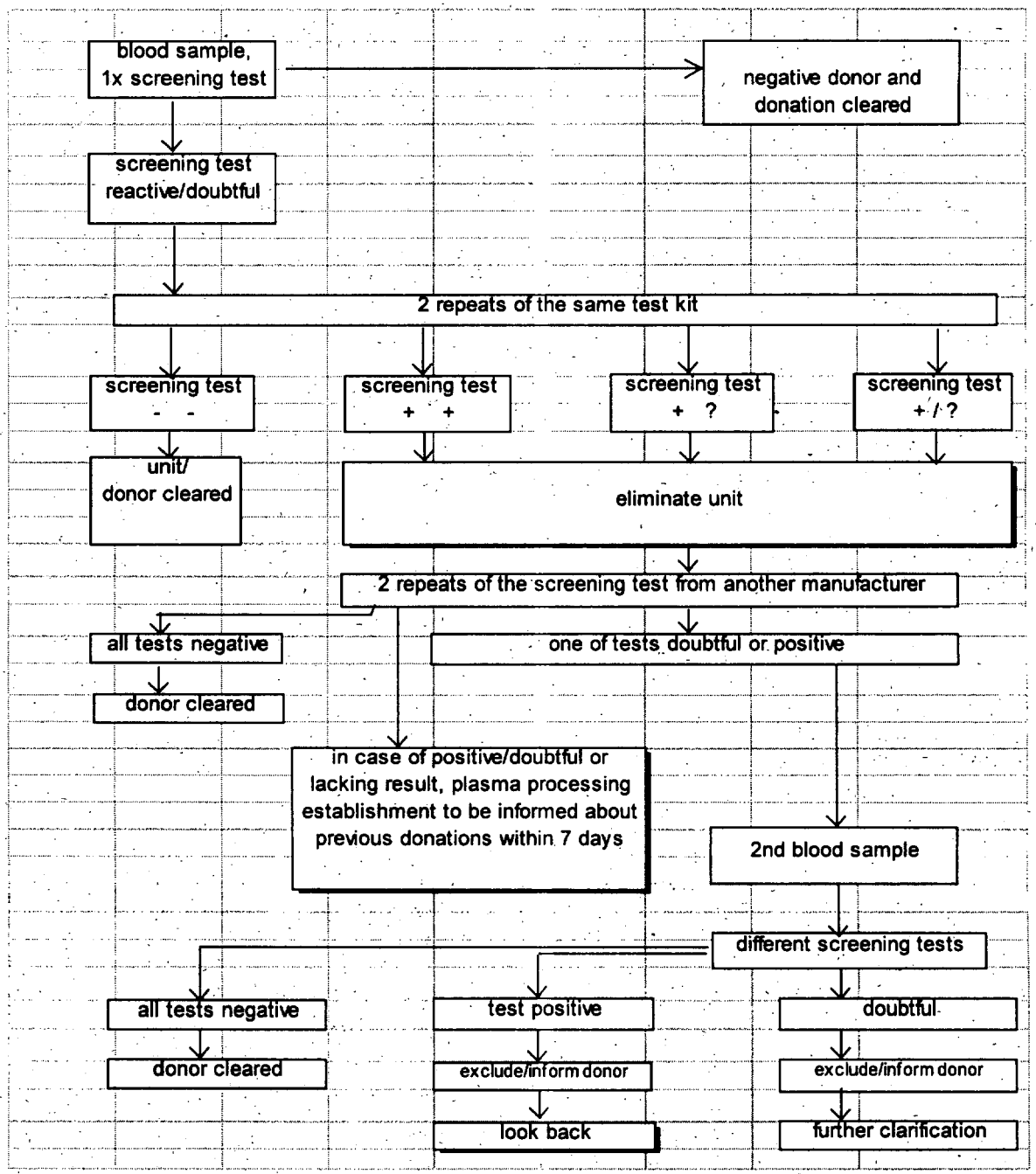
Rh type

Malaria for travellers to endemic areas

***Treponema pallidum* (syphilis)**

ANNEX 8

Common 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



FINANCIAL STATEMENT

PROPOSAL FOR A COUNCIL RECOMMENDATION ON THE SUITABILITY OF BLOOD AND PLASMA DONORS AND THE SCREENING OF DONATED BLOOD IN THE EUROPEAN COMMUNITY

The proposal for a draft Recommendation on the suitability of blood and plasma donors and the screening of donated blood in the European Community has no financial impact either on the operational budget or on any human or administrative expenses.

IMPACT ASSESSMENT FORM ON COMPETITIVENESS AND EMPLOYMENT

PROPOSAL FOR A COUNCIL RECOMMENDATION ON THE SUITABILITY OF BLOOD AND PLASMA DONORS AND THE SCREENING OF DONATED BLOOD IN THE EUROPEAN COMMUNITY

The proposal for a draft Recommendation on the suitability of blood and plasma donors and the screening of donated blood in the European Community has no impact on competitiveness and employment.

ISSN 0254-1475

COM(98) 290 final

DOCUMENTS

EN 05 15 01

Catalogue number : CB-CO-98-297-EN-C

ISBN 92-78-33208-9

Office for Official Publications of the European Communities

L-2985 Luxembourg