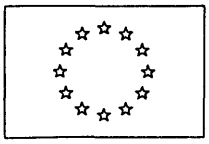

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.11.1997
COM(97) 605 final

97/0315 (CNS)

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)

Explanatory Memorandum

1. INTRODUCTION

1. Continuing concerns about the quality, safety and efficacy of blood and blood products in the European Community motivated the European Commission to recommend, in its Communication of December 1994[1], the development of a Community blood strategy in order to improve confidence in the safety of the blood transfusion chain and to promote Community self-sufficiency, The Council in its Resolution of June 1995[2] invited the Commission to continue its efforts to define such a strategy using as a basis the activities it had proposed. In November 1996, Council's Resolution[3] on a Strategy Towards Blood Safety and Self-sufficiency in the European Community further refined the constituent elements of the strategy by calling for a co-ordinated approach to the safety of blood and blood products, and calling on the Commission to submit proposals as a matter of urgency, drawing upon the Conclusions and Recommendations of a Colloquium on blood safety and self-sufficiency held in Adare, Ireland.[4] Responding to this invitation, the Commission has been pursuing activities to advance the development of this strategy and as a first step has concentrated on the need for common requirements regarding the suitability of blood and plasma donors and the testing of their donations. Such requirements can make a significant contribution to ensuring the quality and safety of needed blood and plasma, restoring the confidence of Community citizens in the blood transfusion system, and contributing to the continuing efforts to achieve Community self-sufficiency through voluntary unpaid donations.

2. THE BLOOD TRANSFUSION CHAIN

2. The blood transfusion chain comprises an extensive number of complex and interrelated activities extending from the willingness of an individual to provide blood or plasma for therapeutic use; through the elaborate precautions taken in the preparation of both labile blood components (red blood cells, white blood cells, platelets and plasma) and stable industrially-prepared derivatives (e.g. albumin, clotting factor concentrates, protease inhibitors and immunoglobulins); to the administration of any of these products to a patient and subsequent follow-up. Each of these steps requires meticulous attention to safety.

3. One of the most crucial links in this chain, however, are the requirements for ensuring the acceptance of an individual as a blood or plasma donor and those for testing the donated blood or plasma for infectious diseases. As the Commission noted in its 1994 Communication, the donor selection process differs across the Community and "it would be beneficial if an agreement is reached as regards the rules and practices for donor selection, including new and repeat donors as well as donors of whole blood, cellular components and plasma, to be applied across the Community". It also referred to the differing testing requirements that exist in the

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1 Communication from the Commission on Blood Safety and Self-sufficiency in the European Community. COM(94) 652 final. 21.12.1994. 23p.

2 O.J. No C164. 30.6.95. p.1

3 O.J. No C374. 11.12.96. p.1

4 Department of Health, Ireland. Conclusions and Recommendations. Colloquium on Blood Safety and Self-sufficiency: An Agenda for the European Community. Adare, County Limerick, Ireland. 4-6 September 1996.

Community hindering the transfer of blood and the free movement of blood products and impeding the goal of self-sufficiency in blood and plasma as starting material used for the preparation of medicinal products. These existing variations among the Member States of the European Community contribute to a lack of confidence not only among patients but among the blood establishments themselves.

4. Donor selection and the screening of donations were among the topics discussed at the Adare Colloquium by Member States experts who recommended, *inter alia*, that existing guidelines on donor selection be reviewed "with a view to making proposals for common criteria to be used in the European Community" and that "a minimal set of screening tests should apply in all Member States for the testing of whole blood and components for transfusion as well as plasma for fractionation". Moreover, they stressed the need for criteria at Community level regarding donor identification and determining the core elements and risk behaviours that should be identified through a donor screening questionnaire.

5. In order to establish the basis for common criteria, the Commission in early 1997 conducted a survey of the current regulations and practices in the Member States regarding the selection of donors and the screening of their blood donations. This survey addressed the current legislative requirements in the Member States and guidelines of the Council of Europe and the World Health Organization; the criteria for the selection of whole blood and plasma donors; elements covered in the donor questionnaire and physical examination; the major reasons for donor deferral for the safety of recipients; the current screening tests required for individual whole blood donations and plasma obtained through apheresis; and the interpretation of a reactive result in the initial screening test for infectious agents (e.g. HIV, HBV, HCV, syphilis) in relation to the clinical use of the donation. The outcome of the survey, which was discussed at a meeting of national experts in June 1997, and the deliberations at the meeting itself clearly reflected variations in regulations and practices in the Member States. The results of the survey are being presented in a working paper of the Commission Services entitled "The suitability of blood and plasma donors and the screening of their donations: a 1997 survey of the regulations and practices in the Member States of the European Community".

3. EXISTING AND PROPOSED REQUIREMENTS

6. Directive 89/381/EEC[5] extended the scope of pharmaceutical legislation to encompass the quality, safety and efficacy requirements for industrially prepared medicinal products derived from blood and plasma but specifically excluded whole blood, plasma and blood cells of human origin. In respect of measures covered by the modification as to testing requirements, referred to in Article 6 of that Directive, to be taken by the Member States to prevent the transmission of infectious diseases by blood and plasma used as a starting material for the manufacture of medicinal products, Article 3 refers to the application of the monographs of the European Pharmacopoeia and to recommendations by the Council of Europe and the World Health Organization as regards in particular the selection and testing of blood and plasma donors. The Directive makes no provision for adaptation to requirements recommended or published on donor selection that may have arisen after its adoption in 1989 nor to scientific and technical progress. Moreover, since Article 1(2) of the Directive specifically excludes whole blood, plasma or blood cells of human origin from its scope, difficulties may arise in practice when the final destination of the donation is not known.

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5 O.J. No L181, 28.6.89, p.44

7. Council Decision 94/358/EC[6] accepted on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia which aims to harmonise quality specifications for active substances and excipients in order to facilitate the free circulation of medicinal products in the countries party to the Pharmacopoeia. This harmonisation simplifies pharmaceutical and biological testing requirements for marketing authorisations. The European Pharmacopoeia's monograph on 'Human Plasma for Fractionation' makes only a reference to Council of Europe recommendations regarding the selection of donors which are therefore not mandatory.

8. Council Directive 95/46/EC[7] addresses the protection of individuals with regard to the processing of personal data and the free movement of such data. This Directive requires that certain sensitive data in particular that related to the health of an individual be subject to reinforced protection. It covers only personal data and not that rendered anonymous so that the person is no longer identifiable. Processing of medical data is prohibited unless the data subject gives his explicit consent. This prohibition is not applicable, however, if the processing of the data is for the purpose of preventive medicine, medical diagnosis, the provision of care and treatment or the management of health services, and the data are processed by a health professional subject to the obligations of professional secrecy.

9. At the level of the Member States, the Commission's survey highlighted the significant variations in legislative requirements regarding the selection of donors and the testing of donations. These range from extensive and detailed legislation developed in recent years, to regulations dating to 1980, to non-binding national guidelines. Legislative revisions in the area of blood are currently underway in two Member States. These variations hinder the transfer of blood (and plasma) and the free movement of blood and plasma products, thus impeding the achievement of Community self-sufficiency.

10. Therefore, in keeping with the goal of making a contribution towards ensuring a high level of health protection to the citizens of the Community, and providing for the attainment of self-sufficiency in blood and plasma through voluntary unpaid donations, and in view of the variations both in legislation and practice in the Member States, the Commission considers it imperative that common requirements be introduced by all Member States based on agreed recommendations. These should be based on the outcome of its survey and the latest scientific evidence regarding the determination of the suitability of donors and the screening of their donations. As stated in a recent report by the Swedish National Working Group on Blood Self-sufficiency[8] "many European citizens do not trust the quality and safety of blood products originating from countries other than their own. Only by implementing common standards can we increase the trust between Community Member States, enhance the free movement of blood and blood products, and reach the goal of Community self-sufficiency". These requirements must, pursuant to Article 129 of the EC Treaty, be based on Council recommendations, which should aim at promoting sound practices and consistency throughout the Community without being disproportionate with regard to the overall objectives being pursued, namely the safety and sufficiency in the Community of blood and plasma and the health protection of the donors. To that end, the proposed recommendations should address donor suitability and eligibility, volumes collected, and the screening of samples of donated blood, and should be congruent with the provisions of Directive 89/381/EEC.

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6 O.J. No L158, 25.6.94, p.70.

7 O.J. No L281. 23.11.95. p.31

8 Swedish National Working Group on Blood Self-sufficiency. European self-sufficiency in blood and blood products: Balancing supply and demand. Background Paper to the statement by the Swedish Minister of Health and Social Affairs, Margot Wallstrom, (Health) Council Meeting, Luxembourg, June 5 1997. 6p.

4. DONOR SUITABILITY

11. Ascertaining the suitability of an individual who has offered to donate blood or plasma is essential in order to ensure that there are no detrimental effects to the prospective donor's health and to protect that of future recipients of the blood products emanating from that donation. The initial step in this process is the provision of accurate and understandable information to the prospective donor about the benefits and hazards, both to their own health and that of future recipients, associated with blood and plasma donation. Agreement by the prospective donor of a willingness to proceed should be followed by the identification and registration of the donor, the recording of this information in an appropriate data file, the verification of certain physical parameters, and the compilation of a medical history to identify and screen out those who may be at some health risk either to themselves or to recipients of their donation.

12. Although the true effectiveness of written questionnaires in screening out donors with high risk behaviours has not yet been fully demonstrated, and the need for a Community-wide comprehensive and common questionnaire not established due especially to cultural differences in the Community, it is essential that several core elements and risk behaviours be addressed during the pre-donation process. These should be addressed in the written questionnaire, or the interview with a trained health care staff member, or both and should cover a number of diseases and conditions, as well as certain risk factors, on which there is solid scientific consensus for their inclusion.

13. Acceptance criteria for donors of whole blood and apheresis plasma should be clearly established to ensure that there are no detrimental effects to the donor's health and additional criteria need to be imposed for the protection of future recipients of the blood products deriving from their donation. Donors, who for one of many reasons may be deemed ineligible to donate blood either temporarily or permanently should be given appropriate counselling. The discretion of the physician is paramount in the final determination of eligibility of a donor.

5. DONOR INELIGIBILITY

14. A prospective donor may be considered ineligible to donate blood or plasma, either temporarily or permanently, at any time during the donation process. Such individuals are said to be "deferred" and the period of time during which they are considered ineligible varies according to different factors. It is important that appropriate records of such deferrals are maintained in such a way that while the confidentiality of the data is maintained, the information is accessible to authorised individuals whether at a donation site or when matters of safety are concerned. Such manual or computerised records are often referred to as donor deferral registers (DDR).

15. The survey of the requirements and practices in the Member States revealed general agreement regarding permanent deferral for particular situations such as HIV / AIDS, hepatitis C, syphilis, etc.. Temporary deferral showed both commonality among Member States for some situations, and considerable variation for others. For example, temporary deferral ranged from 6 - 12 months for tattoos; 2 - 5 years after recovery from tuberculosis; 1 - 2 years after recovery from toxoplasmosis; from "each service / doctor has own criteria" to 5 years for hepatitis A. These variations appear to reflect an absence of conclusive scientific data about the time frame for deferral of donors on which sound decisions can be made. Supplementary survey information submitted to the Commission following the meeting of experts also reflected the variations in practices. In order to arrive at suggested common criteria, therefore, a mean time frame of the

responses received is proposed. The scientific basis upon which these deferral periods are made must be kept under review.

16. In those situations where a donor is deferred temporarily, provisions must be made to allow him / her to be considered for donation again at the end of the deferral period.

6. DATA PROTECTION

17. Although the measures taken by Member States to ensure the protection of data related to a blood or plasma donor were not addressed in the Commission survey, relevant requirements are laid down in Directive 95/46/EC. Measures to ensure positive donor identification, the verification of data, safeguards against unauthorised access to information, data additions, deletions or modifications, data irregularities and discrepancies and the security of confidential data all need to be taken into account. This is particularly applicable in cases where an individual is deferred.

18. Article 8 of the Directive refers to the processing of special categories of data including that concerning health. According to this Article, the processing of such data shall be prohibited in the Member States. It establishes, however, certain cases in which this prohibition shall not apply such as when the data subject has given his / her explicit consent to the processing of those data, when the data processing is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation. The Article also establishes that Member States may, for reasons of substantial public interest, lay down exemptions to the prohibition with such measures notifiable to the Commission.

7. VOLUMES COLLECTED

19. The maximum amount of whole blood or plasma collected from a donor at any one sitting and over a 12 month period, the time interval between the donations, and the allowable frequency over a given time period have been established in order to prevent any adverse effects to the health of the donor as a consequence of the donation. For whole blood, the maximum volume collected during an individual donation (450 ml ± 10%) and the minimum time interval between donations (8 weeks) are practically the same in all the Member States and are in keeping with recommendations of the Council of Europe (1997) and the World Health Organization (1994). Two Member States as well as the standards of the American Association of Blood Banks (AABB), however, permit a higher volume (500- 525 ml).

20. For apheresis plasma, the maximum volume collected during an individual donation and over a 12 month period varies among the Member States - from 550 to 650 ml per donation; 0.5 to 1 litre per week; and 10 to 25 litres per year. The frequency of donations varies between twice per week and twice a month and the maximum number of donations varies between 4 and 50 per year. This wide variation may be attributed in part to the differences between manual and automated plasmapheresis.

21. As a significant volume of plasma and plasma products, sourced from donors who are paid, is imported into the Community from the United States of America, it has to be noted that the allowable maximum plasma volume per individual donation, and over a 12 month time frame,

are higher in the USA than those currently permitted in several Member States. The maximum volume of plasma allowed per donation in the USA depends in practice on the weight of the donor: 625 ml for donors weighing between 50-67 kg; 750 ml for donors weighing between 68-79 kg; and 800 ml for those weighing 80 kg or more.

22. According to the 1997 report of the Swedish National Working Group on Blood Self-sufficiency, "the volume of plasma collected is based mainly on theoretical calculations about how much fluid can be lost without risk to the donor. In the US where the body size of the donor is used to determine the allowable volume, the donor's blood status has been systematically monitored without detecting disturbances."

23. In view of the Community's goal of self-sufficiency and the lack of progress towards it, serious consideration has to be given to allowing an increase in the maximum allowable volumes of plasma currently prevailing in the Member States. This would contribute to the goal of self-sufficiency. The view espoused by some that higher volumes are detrimental to the health of the donor does not appear to be substantiated by scientific evidence. On the contrary, the United States Department of Health and Human Services stated in 1992 in a memo[9] to licensed source plasma establishments that "An analysis based on comparison between the allowable volume of source plasma derived from whole blood collected during manual plasmapheresis and the experience to date with all of the approved equipment (automated plasma collection devices) indicates that there is no discernible impact on donor safety, or product quality with the use of the current limits in preference to any other".

24. Until scientific evidence is adduced to show that permitting an increase in the volume of blood or plasma collected from a donor or reducing the time interval between donations has a detrimental effect on the donor's health, and in view of the benefits for Community self-sufficiency, it is proposed that increased volumes such as those accepted in the United States scheme be recommended for application by the Member States. Programmes using increased volumes should be monitored closely to ensure that no detrimental effects accrue to the donor.

8. SCREENING OF SAMPLES OF DONATED BLOOD

25. Whether it is a donation of whole blood or components intended for transfusion purposes or plasma collected through apheresis and intended for transfusion or further manufacturing into medicinal products, sample specimens of the blood taken from the donor at the time of collecting the blood and plasma should be tested for markers of infections that can be transmitted to recipients. In order that the citizens of the Community have the highest degree of confidence in the safety of the blood and blood products administered for therapy, Member States should apply the same screening tests to the common source for both whole blood and components used for transfusion and plasma used for fractionation with one exception, namely when plasma is collected by plasmapheresis for the sole purpose of fractionation some tests may not be required because the virus is not transmitted by plasma-derived products.

26. The survey showed that whether the donation is of whole blood or plasma, almost all Member States require a sample of the donor's blood to be tested for antibodies against the hepatitis C virus (anti-HCV), antibodies against the human immunodeficiency virus type 1 and 2 (anti-

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[9] Department of Health and Human Services. FDA. Memo to All licensed Source Plasma Establishments. 4 November 1992.

HIV 1 and 2), the surface antigen of the hepatitis B virus (HBsAg), and syphilis. With the exception of syphilis, this reflects the mandatory requirements of the European Pharmacopoeia monograph on 'Human Plasma for Fractionation' for all blood and plasma donations used as source material for the preparation of industrially manufactured medicinal products. As syphilis is not transmissible by plasma-derived products, the Biotechnology Working Party of the Committee for Proprietary Medicinal Products (CPMP) advised in 1995 that this test is not required for plasma for fractionation[10]. Only one Member State does not test for syphilis.

27. Requirements for other tests for markers of various diseases transmissible by blood transfusion vary among the Member States. A malaria test is generally not required but five Member States allow for it "when required" or required "for travellers to endemic areas". Testing for antibodies to human T-cell lymphotropic virus (anti-HTLV I and II) is carried out in six Member States with one indicating that it is carried out on first time donors and another reporting that although not required it is done. Testing for hepatitis B core antibodies (anti-HBc) is carried out in five Member States for whole blood donations with three requiring it only for first time donors. HIV p24 antigen test is not required in any of the Member States but is a pilot project in one. Only one Member State requires neopterin testing for whole blood donations.

28. The survey substantiated earlier reports regarding tests that are required in some Member States and not in others leading to impediments on the utilisation of excess plasma, the free movement of plasma-derived products, and therefore to a lack of progress towards Community self-sufficiency. This difficulty arises particularly with reference to alanine aminotransferase (ALT) which is not required by the European Pharmacopoeia. Plasma collected by some Member States that has not undergone this test is rejected for use by others. It is noteworthy that an expert panel at the National Institute of Health of the United States recommended that its use be discontinued since, as shown by scientific data, it had outlived its usefulness and was of little value now given the availability of the HCV test. This view was reiterated by the experts to the Adare Colloquium who considered that ALT screening had become redundant because of the specific screening for HBsAG and antibodies to hepatitis C.

29. It follows from the above that a set of scientifically-based and broadly-supported requirements, as well as a procedure for making decisions, depending on the results of the various tests that donated blood undergoes, should be established based on agreed recommendations for the Community.

9. COMMON TERMINOLOGY

30. A fundamental requirement for arriving at common criteria related to the suitability of donors and the testing of donations is the use of common terminology. Confusion and misunderstandings often arise as a result of different interpretations of the same terminology. In spite of the existence of several glossaries, there is still no consistent use of several terms in this sector such as blood products, repeat donors, etc. Therefore common terminology for use throughout the Community is proposed.

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[10] DGIII/5941/94. "Selection and screening of donors for blood / plasma as starting material for medicinal products. Position paper for CPMP on harmonisation of selection and screening of donors/exclusion criteria" in "Inventory of Provisions relating to Medicinal Products Derived from Human Blood or Plasma", Brussels, March 1995.

10. SCIENTIFIC COMMITTEE AND REPORTING

31. The dynamic and rapidly-evolving environment of transfusion medicine, such as cytapheresis, total blood apheresis and cord blood collection as well as the questions posed by the availability or introduction of new technologies such as genome amplification technology (GAT) - a highly sensitive technique capable of detecting viral genomes even when serological tests are negative - as a possible screening test, demands that mechanisms be in place for the Community to have ready access to scientific and technical guidance and be able to respond quickly to changing technology and scientific information. Consideration will be given by the Commission to establishing a Scientific Committee on blood to advise it on these and the other matters covered in the proposed recommendation.

32. Moreover, in order to ensure that all Member States are fully aware of developments that have implications at Community level and to keep the Council informed of the measures that have been taken towards the implementation of common criteria in the Community, the Commission could prepare reports as appropriate.

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

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;

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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;
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;

HEREBY RECOMMENDS THAT

1. DEFINITIONS

For the purpose of this Recommendation, Member States assign to the terms listed in Annex 1 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;

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

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;

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 ;

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;

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.

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;

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;

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

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* 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,

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

		Donor Weight	Volume Collected (excluding anticoagulant)
Maximum Volume	per donation	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**

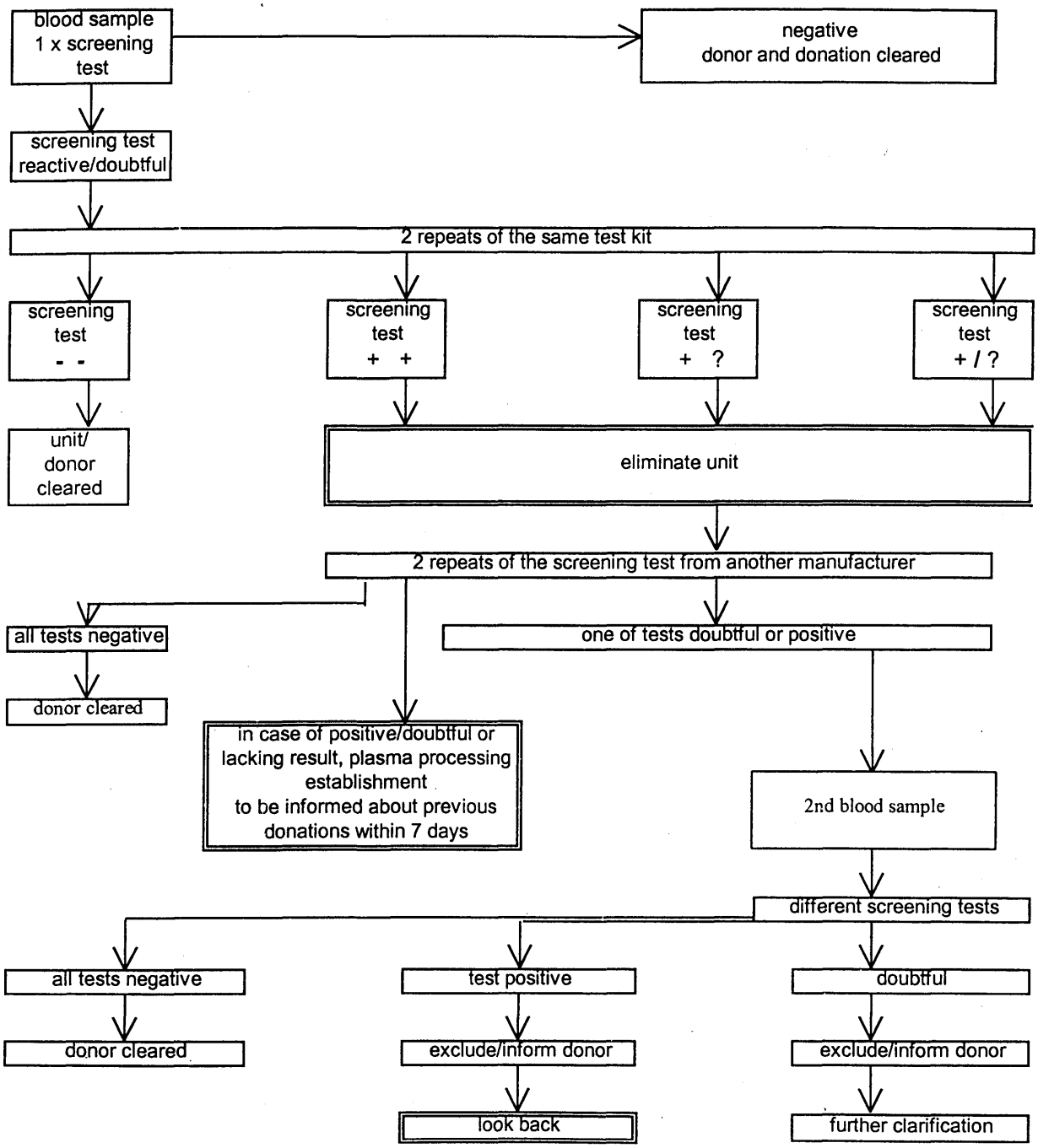
In addition

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

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