Procedure file

Basic information

CNS - Consultation procedure Recommendation	1997/0315(CNS)	Procedure completed
Blood and plasma donors: suitability and screening. Recommendation Subject 4.20.04.02 Safety of blood and transfusion		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Consumer Protection	UPE CABROL Christian E.A.	04/02/1998
Council of the European Union	Council configuration	Meeting	Date
	General Affairs	2111	29/06/1998
	Health	2086	30/04/1998
	Health	2013	05/06/1997
	Health	1961	12/11/1996

Key events

12/11/1996	Resolution/conclusions adopted by Council		
05/06/1997	Resolution/conclusions adopted by Council		
17/11/1997	Legislative proposal published	COM(1997)0605	Summary
16/01/1998	Committee referral announced in Parliament		
18/03/1998	Vote in committee		Summary
18/03/1998	Committee report tabled for plenary, 1st reading/single reading	A4-0112/1998	
01/04/1998	Debate in Parliament		
02/04/1998	Decision by Parliament	T4-0206/1998	Summary
05/05/1998	Modified legislative proposal published	COM(1998)0290	Summary
29/06/1998	Act adopted by Council after consultation of Parliament		
29/06/1998	End of procedure in Parliament		

21/07/1998	Final act published in Official Journal		

Technical information

Procedure reference	1997/0315(CNS)
Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Recommendation
Legal basis	EC before Amsterdam E 129
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/4/09686

Documentation gateway

Legislative proposal		COM(1997)0605	17/11/1997	EC	Summary
Document attached to the procedure		SEC(1997)2298	10/12/1997	EC	Summary
Committee report tabled for plenary, 1st reading/single reading		A4-0112/1998 OJ C 138 04.05.1998, p. 0006	18/03/1998	EP	
Text adopted by Parliament, 1st reading/single reading		T4-0206/1998 OJ C 138 04.05.1998, p. 0139-0166	02/04/1998	EP	Summary
Modified legislative proposal		COM(1998)0290	05/05/1998	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

EP/Council Recommendation 1998/463
OJ L 203 21.07.1998, p. 0014-0026

Blood and plasma donors: suitability and screening. Recommendation

OBJECTIVE : to lay down common rules concerning the suitability of blood and plasma donors in the European Union and practical tests for blood donation within the Community. CONTENT : In order to help ensure a high level of health protection of European citizens and achieve self-sufficiency in blood and plasma supplies, and given the differences in both the legislation and the practices of the Member States in this field, the Commission proposes to set out joint requirements concerning blood donations. The proposed recommendations aim to promote good practices in this field and to achieve a coherent blood donor policy throughout the Community. The recommendations principally concern the suitability (or unsuitability) of blood donors, the volumes of blood donated and the practical screening of blood donation samples, as well as the proper protection of data on prospective donors. More specifically, the recommendations: 1) propose a common terminology for blood and blood products, donors and the suitability of donors; 2) provide a list of information to be given to prospective donors (for example, measures to raise awareness of donors, confidentiality of information on their health, etc.); 3) stipulate certain items of standard information to be obtained from the prospective donor (including identification of donor, medical history by way of a written questionnaire, an example of which is appended to this proposal, donor's written consent to donate blood and, possibly, to export the blood donated); 4) provide for a registration of donors in order to make it easier to check regular donors and the source of the donation at a later date (Member States should establish a mutually compatible system of donor identification/ registration); 5) lay down exclusion criteria governing the suitability of blood and plasma donors (the physical criteria which donors must meet are given in the Annex: these criteria are common to all and relate to factors such as age, weight, donor's blood pressure, etc.) ; 6) lay down criteria governing the unsuitability of donors, including criteria governing the permanent or temporary exclusion of donors with the complaints listed in the Annex. Provision is made for exclusion files for registering excluded prospective donors; 7) ensure proper protection of data on prospective donors (in particular, in application of Directive 95/46/EC on the protection of personal data); 8) provide for measures concerning the volumes of blood donated (joint standards for maximum volumes of blood and maximum intervals between donations); 9) provide for "harmonised" tests on blood samples (joint requirements for testing blood samples, together with common rules for the interpretation of reactions to initial screening tests, are proposed in the Annex). The text also proposes measures to encourage voluntary, as opposed to paid, blood donation. ?

Blood and plasma donors: suitability and screening. Recommendation

In a working document annexed to the procedure, the services of the European Commission presented the results of an inquiry conducted in the spring of 1997 into donations of blood within the Union. This study provided a basis for the Commission's presentation of a proposal for a Council regulation on suitability of blood donors and the screening of donated blood. In essence, the results collected from all 15 Member States provided information on the following aspects: - The provisions relating to blood varied between Member States. They included acts, decrees, regulations and guidelines. - The donor selection criteria were generally consistent, with a few rare variations from one Member State to another (for example, age between 18 and 65, haemoglobin, pulse, blood pressure, weight, frequency and maximum volume of donation). - Provisions relating to plasma were very similar to those for blood except as regards the frequency of donations and volume of plasma taken (higher). - The inquiry into the arrangements for physical examination before donating blood showed that not all the Member States imposed this kind of examination on donors. On the other hand, with one exception, they did require all donors to complete a written questionnaire on each visit. - The main reasons for excluding a donor in the interests of the recipient's safety were again very similar: permanent exclusion of those recognised as positive for hepatitis B, AIDS I/II, etc. In other areas, the exclusion periods could vary (hepatitis A, infectious mononucleosis, etc.). - With regard to the screening test, all Member States undertook these, though they did not always relate to the same illnesses (the tests carried out by all Member States related to anti-HCV, anti-HIV 1/2 and HBsAg). - The interpretation of the reactive result of a screening test varied from one Member State to another: for this reason, at the time of the survey, it had been requested that use be made of algorithms such as those presented in the document.?

Blood and plasma donors: suitability and screening. Recommendation

A Commission proposal on blood donations was approved with amendments by the Committee.The proposal puts forward a Council Recommendation on the suitability of blood and plasma donors and the screening of donated blood. The aim is to ensure the safety of both donors and recipients throughout the Community. Among other things, this means setting criteria for the rejection of donations in certain circumstances, eg in the case of chronic alcoholics, prostitutes, male homosexuals, those affected by AIDS and people in whose family Creutzfeldt Jacob Disease (CJD) has occurred. Adopting a report by Mr Christian CABROL (UFE, F) amending the proposal, the committee wants prospective donors to indicate when and for how long they have travelled outside the European Union and, in particular, whether they have been sexually active in Africa. It also wants Member States to agree to the establishment of a single donor identification and registration system common to them all. This could be consulted rapidly by any donor centre and would make it easier for donors responsible for contaminated donations to be tracked down. Donations should be voluntary and unpaid as defined by the Council of Europe. The committee also varied the frequency of donations proposed by the Commission. A list of all the donor centres in each Member State should be communicated to a central Community body, the committee believes, not simply transmitted to the other Member States and the Commission as suggested by the Commission. Prospective donors should be identified by a unique code common to all Member States, which should also be communicated to that central body. As regards the screening of blood, the committee wants epidemiological data on viral markers to be regularly collected, analysed and verified. Moreover, in the wake of the BSE crisis, it insists that the Commission exclude any risks related to the new variant of CJD. The proposal follows a Commission communication on blood safety and self-sufficiency, a report on which - also by Mr Cabrol - was adopted by Parliament in April 1996.

Blood and plasma donors: suitability and screening. Recommendation

In adopting the report by Mr Christian CABROL (UPE, F) on the suitability of blood and plasma donors, Parliament asked that the Member States bring forward binding legislation for the Union with respect to blood products, donated blood and plasma by the end of 1998 and no later than the end of 1999. It also called for the establishment of a centralized single donor identification and registration system common to all Member States. Parliament also stressed the voluntary and unpaid nature of the donation and called for inclusion of a reference to the Council of Europe recommendations on the non-remunerated nature of the donation and the safety of blood products. It also wanted measures to be taken to take account of the risk associated with the new variants of Creutzfeldt-Jakob Disease, in particular by using imports of blood between Member States. Parliament also considered that there was a need to: - ensure that donors were identified by a single identification common to all countries and that this identification should be notified to a central body, - notify the list of donation centres to this central body and not to the Member States or the Commission, - ensure that epidemiological data on viral markers was regularly collected, analysed and verified, use being made of uniform definitions, and that the data was updated regularly, - ensure that the exclusion of blood donors was based on scientific evidence (where it existed) and where there was none that the precautionary principle should prevail. It also suggested that the same test should be carried out on blood and plasma samples. With regard to the questionnaire, Parliament called for the following questions to be included: - does the donor have a 'partner' (not 'spouse') who is HIV positive?; - has the donor travelled outside the European Union? (instead of outside 'Western Europe and North America'); if so when and what was the length of stay. However it rejected the amendment on whether the prospective donor had engaged in sexual activity in Africa (country, time involved and partner to be specified). The Commission text which refers to 'Sexual activity in Africa' in the list of questions remains. In the list of questions Parliament rejected the question on sexual activity in countries other than those in Africa. The question on 'Men who have unsafe sex' instead of 'Men who have sex with other men' remains in the questionnaire. Permanent deferral for blood donors applies to chronic alcoholics, intravenous drug users, prostitutes and those suffering from infectious diseases or immune-deficiency diseases (AIDS, hepatitis). Homosexuals are thus not automatically excluded from donating blood, as suggested by the report. ?

Blood and plasma donors: suitability and screening. Recommendation

In its amended proposal the Commission accepted 16 of the 29 amendments adopted by Parliament and rejected 11. Among the significant amendments incorporated into the amended proposal, special reference should be made to the following: - CJD is taken into account in the recommendation, - establishment of national measures for the collection, analysis, publication and updating of epidemiological data using common definitions and criteria that are comparable throughout the Community, including data on viral markers, - assurance that the deferral criteria for blood donors are based on sound scientific evidence (where such evidence is not available the precautionary principle should

prevail), - identification of prospective donors and data verification by means of a unique coding system, - use of the same types of screening tests for both blood and plasma donations. With regard to the questionnaire, the Commission accepted Parliament's amendments on: - the deletion from the questionnaire of a question concerning a spouse who is HIV positive and the sexual activity of a prospective donor in countries other than Africa, - the addition of questions on the sexual behaviour of the prospective donor outside the Community (with the possibility of specifying which countries) and details of travel outside the Community, - the addition of questions on the sexual behaviour of the prospective donor that places them at risk of transmitting infectious diseases. ?