Procedure file

Basic information

COS - Procedure on a strategy paper (historic)	1994/2228(COS)	Procedure completed
Blood safety and self-sufficiency in the European Community 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	RDE CABROL Christian E.A.	01/02/1995
	Committee for opinion	Rapporteur for opinion	Appointed
	JURI Legal Affairs, Citizens' Rights	ARE PRADIER Pierre	22/02/1995
Council of the European Union	Council configuration	Meeting	Date
	Health	1845	02/06/1995

Key events

21/12/1994	Non-legislative basic document published	COM(1994)0652	Summary
20/01/1995	Committee referral announced in Parliament		
02/06/1995	Resolution/conclusions adopted by Council		Summary
20/03/1996	Vote in committee		Summary
20/03/1996	Committee report tabled for plenary	A4-0094/1996	
16/04/1996	Debate in Parliament		
17/04/1996	Decision by Parliament	T4-0185/1996	Summary
17/04/1996	End of procedure in Parliament		
13/05/1996	Final act published in Official Journal		

Technical information

Procedure reference	1994/2228(COS)
Procedure type	COS - Procedure on a strategy paper (historic)

Procedure subtype	Commission strategy paper
Legal basis	Rules of Procedure EP 142
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/4/06355

Documentation gateway

Non-legislative basic document		COM(1994)0652	21/12/1994	EC	Summary
Committee report tabled for plenary, single reading		A4-0094/1996 OJ C 141 13.05.1996, p. 0005	20/03/1996	EP	
Text adopted by Parliament, single reading		T4-0185/1996 OJ C 141 13.05.1996, p. 0087-0131	17/04/1996	EP	Summary

Blood safety and self-sufficiency in the European Community

In this document, the Commission reviews both the tremendous benefits from the therapeutic use of blood products and hence the fact that they are indispensable to medicine nowadays, and the huge dangers inherent in blood transfusions in the Community. In this respect, it expresses a number of thoughts on how to improve the safety of transfusions and proposes a series of Community measures in order to reduce the risk of transmission of serious diseases such as AIDS, hepatitis A, B and C, syphilis, borreliosis, malaria and septicaemia. In order to achieve this, the Commission calls first for greater awareness of the dangers of transfusion by increasing the public's awareness of the use of blood and plasma, the precautions needed in order to maximise safety and the measures needed in order to achieve self-sufficiency in blood. It calls on the Member States to apply strict selection criteria for blood donors and, within the framework of the free movement of blood in the Community, to harmonise donor selection procedures in force in the Member States in order to give a greater guarantee of the safety of blood products of Community origin. Along the same lines, the Commission raises the possibility of harmonising the systems of tests carried out on donated blood and plasma. The Commission would also like studies to be carried out on the use of blood products from the point of view of the patient (especially within the framework of medicinal products derived from human plasma), the donor, self-sufficiency (while guaranteeing optimum use of blood and plasma), good clinical practice and the financial implications. The Commission also refers to the need to introduce a blood surveillance system based on a network of European transfusion centres linked to epidemiological agencies in order to determine the level of risk (and eventually eliminate the risk) inherent in transfusions of infectious blood agents. Next steps: because blood and blood products move within the Community, a Community blood strategy needs to be defined in order to: - draw up scientifically reliable policies and common donor selection procedures in the Community; - use efficient, valid, reliable screening tests throughout Europe; - draw up quality evaluation criteria and good manufacturing practices for collecting and giving transfusions of blood and monitoring patients; - introduce a blood monitoring system in order to compile epidemiological data on the transfusion sector; - draw up educational programmes for health professionals on the optimum use of blood; - encourage the dissemination of information on blood and on blood collection, processing and transfusion procedures through awareness-raising programmes.?

Blood safety and self-sufficiency in the European Community

In a resolution on blood safety and self-sufficiency, the Council reaffirmed the need to define a strategy for reinforcing trust in the safety of the blood -transfusion chain and promoting self-sufficiency in the Community and stipulated that the main activities to be undertaken could include: - the development of policies and agreed procedures in the donor selection process among blood collection establishments; - the implementation of efficient, validated and reliable screening tests; - the development and use of quality assessment criteria and good practices regarding the collection, processing and transfusion of blood and blood products and patient follow-up procedures; - development of a haemovigilance system on the basis of existing networks; - encouragement of health professionals to make optimal use of blood and blood products; - the establishment of basic criteria for inspection and training of inspectors; - the dissemination to the public of information on blood and blood products and on collection, processing and transfusion procedures, taking account of socio-cultural differences. It invited the Commission: - to continue its collaboration with the Member States in the search to define a strategy for reinforcing trust in the safety of the blood transfusion chain and for promoting self--sufficiency in the Community through voluntary unpaid donations and to send it regular progress reports; - to continue its cooperation with the Council of Europe in the blood transfusion area; - to submit appropriate proposals in the specific areas mentioned in support of Member States? action and to encourage the development of a coordinated approach in the matter of blood safety.

Blood safety and self-sufficiency in the European Community

The draft report by Mr Christian CABROL (UFE, F) was adopted. On the question of safety, the Commission communication (COM (94) 652) reflects the efforts made by the European Union to promote quality and safety in the collection of blood, with particular regard to preventive measures against AIDS and other transmissible diseases. It points out that while blood has many therapeutic uses, it can also be a purveyor of disease. To achieve maximum safety in the transfusion chain, the Commission focuses on three key elements: the selection of donors, the testing of donations and the removal or inactivation of infectious agents in donated blood. Surveillance should be based on the existing network of blood transfusion centres linked to European Union epidemiological agencies. On the question of sufficiency, the committee's rapporteur, Mr Cabrol, who is a heart surgeon by profession, points out that a distinction should be made between whole blood and plasma

donations. While most Member States were self-sufficient in whole blood, there was a Community deficit in plasma obtained from non-remunerated voluntary donors. This had to be made good by obtaining blood from paid donors in third countries, particularly the United States, where there were no laws against payment. Speaking before the vote, Mr Cabrol told the committee: "Paid donors may not always be honest [about any diseases they might have]. There is always a risk. So it is best to rely on unpaid donors. Hence publicity should be made to encourage citizens to give their blood as often as possible." The motion for a resolution adopted by the committee called on the Commission to take the necessary measures to guarantee maximum safety in the supply and use of blood and its derivatives and to urge the Member States to take appropriate action to achieve self-sufficiency on the basis of voluntary unpaid donations. However, against the wishes of the rapporteur, the committee also called on the Commission and the Member States to remove rules, policies and practices preventing the free circulation of plasma-derived products in the Union. This decision reflected the committee's support for the view of the private sector that regulations which impeded the placing on the market of medicinal products derived from paid plasma created a monopolistic environment that could lead to increased cost for medicinal products to the detriment of patients and doctors. At the same time, however, the committee reaffirmed the fundamental principle of the inalienability and non-marketability of the human body and its parts and hence the need to select voluntary unpaid donors. In particular, donors should be selected on the basis of: * questionnaires identifying factors linked to a possible transmission of disease or endangering the health of the donor (medication being taken, the presence of diseases, recent surgery or childbirth, visits to endemic areas, recent vaccinations, dangerous sexual practices or drug addiction); * the examination of key physical parameters, such as blood pressure and haemoglobin level; * the psychological preparation of donors; * a comparison with the blood parameters of any previous donation. The committee stressed the need to guarantee absolute confidentiality for data supplied by donors. Test should be devised to screen for transmissible viral infections and to identify bacteria and parasites. Storage and maintenance conditions were important and the strictest standards of hygiene should be applied in laboratories and blood donation centres. Self-transfusion should be promoted wherever possible. The committee stressed the need for appropriate training for health professionals. Transfusion should be included in university medical courses and in training programmes for all health professionals involved in the blood transfusion chain. The Commission should support research into screening tests for blood and blood products in the Community. The committee also called for Commission support for publicity campaigns, including the dissemination of information in schools. It called for recognition of the significant safety benefits that arose from blood and plasma donors who donated repeatedly. It called on the Commission and Council to work towards the setting up of a European Blood Safety Supervisory Body to monitor blood and blood derivatives from the time of collection and conservation to the time of use. The Commission and Council should also look into the possibility of harmonizing the grantof licences to organizations involved in the collection, treatment, processing and distribution of blood and blood derivatives in the Community. ?

Blood safety and self-sufficiency in the European Community

Parliament adopted the report by Mr Christian CABROL (UPE, F) on the communication from the Commission on blood safety and self-sufficiency in the European Community. Parliament noted the European goal of self-sufficiency and called for the abolition of laws and administrative provisions which prevent the free circulation of plasma-derived products in the European Union. Reaffirming that the human body and its parts are inalienable and non-marketable, it stressed the need to take measures to guarantee maximum safety in blood supplies, but on the basis of voluntary, unpaid donations. It hoped, in particular, that support would be given to blood donor associations and voluntary organizations and called for the organization of a European Blood Donation Day. Parliament also called for common regulations to be drawn up applicable to the whole of the blood transfusion chain concerning the selection of donors, the devising of technical quality tests for screening for transmissible viral infections and identifying bacteria and parasites, the treatment of blood, plasma or blood derivatives (conservation and storage conditions) and its rational use. Wherever possible Parliament intends to promote the use of self-transfusion, for which there should be appropriate information. Parliament called on the Commission to support research activity on blood screening tests and to standardize infectious markers and also to launch and/or support action of all kinds which seeks to encourage the dissemination of information about blood and blood products and collection, treatment and transfusion procedures. It also stressed the need for appropriate training for health professionals. It called for a recognition of the significant safety benefits arising from donors who donate repeatedly and for the setting up of a European Blood Safety Supervisory Body responsible for monitoring blood from the time of collection to the time of use. Finally, it called for consideration of the possibility of harmonizing the granting of licences to organizations involved in the collection, treatment, processing and distribution of blood and blood derivatives in the European Union. ?