COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMUNICATION FROM THE COMMISSION ON

BLOOD SAFETY AND SELF-SUFFICIENCY IN THE EUROPEAN COMMUNITY

1. INTRODUCTION

Blood and the products derived from it have become an indispensable facet of modern medicine. Their use has brought about dramatic advances in therapy and surgery, saved countless lives, and improved significantly the longevity as well as the quality of life for those who suffer from long-term blood disorders such as haemophilia. Ensuring the safety and the supply of blood and blood products, therefore, is of vital importance - safeguards which are directly related to the public health objectives of Articles 3(o) and 129 of the Treaty establishing the European Community. These objectives, which focus on health protection and disease prevention, are particularly important considerations in the context of HIV/AIDS and certain other communicable diseases which can be spread through the provision of unsafe blood and blood products.

An essential requisite for health protection is the prevention of diseases, which entails minimizing exposure to risk factors implicated in their causation. It was bearing this in mind that the Council adopted Directive 89/381/EEC[1] related to medicinal products derived from human blood and plasma in order to ensure a high level of protection of public health. In addition to introducing strict manufacturing criteria, the Directive required Member States to take the necessary measures to prevent the transmission of infectious diseases and to promote Community self-sufficiency in human blood and plasma through voluntary unpaid donations. A report[2] to the Council on the state of Community self-sufficiency resulted in it adopting Conclusions[3] in which the need to achieve this goal through cooperation between Member States was reaffirmed and the continued promotion of the quality and safety of blood collection and blood-derivative production was *inter alia* agreed.

The Council's continuing concern about the quality, safety, and efficacy of blood and blood products resulted in it requesting, at its meeting of 13 December 1993, the Commission to prepare a report related to the legal provisions and current practices in the Member States on the collection, control, and treatment of blood and the distribution and trade in blood and blood products with a view to proposing common safety criteria. Immediately following this meeting, the Commission invited Member States to provide their legal regulations and administrative provisions in this area.

This Communication draws upon the responses provided by the Member States in written submissions and during meetings of experts on self-sufficiency and blood safety convened by the Commission. It addresses issues raised by the Ministers for Health, and provides, as a background, a review of progress towards blood self-sufficiency in the Community as well as coverage of this area by existing Community rules and regulations. Finally, it specifies the need for Community action in this area particularly in the context of the Council's Resolution concerning the field of public health[4] and the Commission Communication on AIDS and certain other communicable diseases[5].

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1 O.J. n° L 181 of 28.06.89. p.44

2 Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee on Blood Self-Sufficiency in the European Community. [COM(93) 198 final. Brussels, 25 May 1993. 13p.]

3 O.J. n° C 15 of 18.01.94. p.6

4 O.J. n° C 165 of 17.06.94. p.1

5 Communication from the Commission concerning a Community action programme on the

2. BLOOD AND ITS SIGNIFICANCE FOR PUBLIC HEALTH

As a consequence of significant scientific and technical advances both with regard to medical knowledge and surgical techniques, blood has come to be regarded as a major cornerstone of modern day medicine contributing significantly not only to saving but to improving the lives of many. Blood also has particular significance since in spite of its therapeutic uses, it can also be a purveyor of disease.

2.1 Blood as a therapeutic substance

Since early in the twentieth century, blood transfusion has increased in importance in the practice of medicine saving millions of lives throughout the world. With advances in technology and breakthroughs in research and development, however, the use of whole blood in transfusion medicine has progressively diminished with its individual components assuming major therapeutic importance. As outlined in the Commission's Staff Working Paper[6] and its Communication on blood self-sufficiency, blood is comprised of almost equal portions of the cellular components - red blood cells, white blood cells and platelets - and the clear yellowish fluid portion called plasma. Plasma can be separated from the cellular components through centrifugation or obtained by plasmapheresis (the process of removing whole blood, separating the red cells from the plasma and returning them to the donor), stored as fresh frozen plasma (FFP) and then, after thawing, transfused into a patient. It can also be fractionated into a number of stable industrially prepared derivatives - albumin, clotting factor concentrates, protease inhibitors and immunoglobulins.

The extent to which these blood products are used in medicine or surgery (Annex 1) ranges from the administration of red blood cell concentrates due to thalassemia; to albumin in cases of shock; to the use of immunoglobulins to prevent a variety of infectious diseases such as hepatitis, chicken pox, tetanus, and rabies; to regular and life-long treatment of haemophilia patients with clotting factor concentrates. Moreover, stem cells are being used increasingly for bone marrow transplantation.

2.2 Blood as a transmitter of diseases

In spite of notable therapeutic advances, blood continues to be one of several media by which diseases may be transmitted, as the tragic consequences surrounding the administration of HIV (human immunodeficiency virus) contaminated blood and blood products have made all too clear. Although HIV has attracted the attention of clinicians, governmental authorities, politicians, patients and the lay public, numerous other agents that are transmissible by blood do exist. Of the five main types of infectious agents - viruses, bacteria, spirochetes, parasites and fungi - transmission of the first four by blood transfusion has been reported (Annex 2).

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prevention of AIDS and certain other communicable diseases in the context of the framework for action in the field of public health. Proposal for a European Parliament and Council Decision adopting a programme of Community action on the prevention of AIDS and certain other Communicable diseases within the framework for action in the field of public health. [COM (94) 413 final. Brussels, 09.11.1994. 58p.].

6 Towards increased cooperation and coordination in the European Community to ensure adequate blood availability (Commission Staff Working Paper). [SEC(92)360. 24 February 1992. 8p.]

As viral infections can be transmitted by virus-infected blood cells or by the free virus in plasma, the virus-types transmissible by the cellular components and plasma differ. Viral infections transmissible by whole blood and blood cell concentrates (notably red cells and platelets) include the human immunodeficiency viruses, the hepatitis viruses, parvovirus B19, the human T-cell leukaemia viruses, cytomegalovirus and the Epstein Barr virus. The first three can also be transmitted by whole plasma and plasma derivatives.

Infection with these different viruses may lead to various diseases such as severe immunodeficiency from HIV and cirrhosis from the hepatitis viruses.

Several non-viral organisms transmissible by blood transfusion, such as spirochetes, parasites and bacteria can be the cause of infections, and blood from donations can become contaminated by bacteria (e.g. staphylococci) at the time of donation.

2.3 Blood as a Commodity

There are mixed emotions surrounding the use of blood as a commodity. On the one hand, there is strong sentiment that the human body and its parts are inviolable and that no profit or commercialization should be derived from them; on the other hand, there is an increasing demand for blood products, including high purity plasma derivatives that have been developed as a result of continuing research and development and at considerable expense. In spite of the altruistic and unpaid nature of many blood and plasma donations, however, the costs of the collection, testing, processing, handling, storage and distribution associated with blood products are high and have to be met in one way or another.

Trade in blood and blood products, therefore, has to be considered from the perspective of whole blood and its cellular components, on the one hand, and that of medicinal products derived from plasma on the other.

2.4 The blood transfusion chain

The numerous activities that occur from the moment an individual offers to donate blood or plasma until after the blood product has been administered to the patient can be described as the blood transfusion chain. The first link in this chain is the donor whose state of health is important not only for him/herself but for the recipient at the end of the chain. The second major link is the testing of the donation itself for any indication of a disease that could be potentially transmitted, removal and destruction of any donation that is infected, and medical consultation with those donors who are suspected of having a communicable disease. The third major link is viral inactivation of the medicinal products derived from plasma in accordance with agreed good manufacturing practices. The fourth crucial link is the appropriate and prudent administration of the blood product to the patient by the treating physician. And the final link is the follow-up of patients who have received any blood product in case they develop an immune reaction or other adverse side-effect.

By ensuring that the risks associated with each link are minimized, the overall safety of the blood transfusion chain thus can be assured.

2.5 Precautionary measures regarding blood safety

As blood and plasma are biological substances, there is always the danger that they will be contaminated by infectious agents. The risk of a disease occuring as a result of their transmission by blood and plasma varies depending on their prevalence in the population; the state of health of the donor who may have a natural immunity to certain viruses; the immunity of recipients who may have antibodies that neutralize certain infectious agents; and the quantity of the infectious agent in the blood or plasma donation.

To ensure the highest level of blood safety, three key elements need to be addressed - the selection of donors, the testing of donations, and the removal or inactivation of infectious agents. As donor selection is directed towards guaranteeing not only the safety of the recipient but also the health of the donor, questions that may identify factors linked to possible disease transmission or hazardous to the donor's own health, such as drug use, presence of diseases, recent surgery or child birth, or visits to endemic areas, need to be posed. In addition, examination of key physical parameters, such as blood pressure and haemoglobin level, needs to be carried out. Based on defined criteria, donors can then be accepted, deferred or not accepted for donation. In some such cases, medical treatment may be required. Awareness among donors themselves of the dangers of disease transmission by blood may also result in voluntary self-exclusion.

Testing blood donations takes into account blood group determination on the one hand and the identification of infectious agents on the other. Screening for viral infections transmissible by blood is carried out by the detection of specific antibodies or antigens (infectious markers) against the agent concerned. Specialized procedures, however, are required to identify bacteria and parasites. Donations found to be positive for infection should be discarded and the donor concerned should be invited to be retested, using confirmatory tests, which may result in deferment of further donations.

Efforts to develop safe and effective methods of removing bacteria and viruses from whole blood and its cellular components, without changing their integrity, continue. Donor selection and the screening of individual donations as well as proper processing and storage of these components are key elements in these efforts.

For manufactured medicinal products derived from plasma, viral inactivation procedures exist thus minimizing the risk of viral transmission. Techniques for virally inactivating fresh frozen plasma are currently clinically validated.

The on-going efforts of those concerned with the safety of blood and blood products have helped to reassure donors and patients that all possible measures are being taken to protect their health. Nevertheless, in order to ensure the delivery of safe blood and blood products there is a need to be ever vigilant to the prevalence of infectious markers, which differ from area to area, to the appearance of as yet unknown pathogens, as well as to the appearance of new variants of existing viruses.

3. ACTIVITIES UNDERTAKEN AT COMMUNITY LEVEL REGARDING BLOOD SAFETY

Within the European Community, specific measures have been taken and calls for further action have been made to ensure the safety of the blood supply as well as to protect the health of both the donor and the recipient.

3.1 Council

The free movement of industrially manufactured medicines, taking as a base a high level of health protection, has been the primary objective of Community pharmaceutical legislation. Its provisions include directives, guidelines for quality, safety and efficacy studies, marketing authorization procedures and requirements with regard to good manufacturing practice. As outlined in the Communication on blood self-sufficiency, recognition that existing provisions were inadequate with regard to proprietary medicinal products derived from human blood or human plasma led to the adoption of Directive 89/381/EEC, which includes reference to the goal of self-sufficiency, as well as requirements for good manufacturing practice (91/356/EEC[7]) and testing (91/507/EEC[8]). In addition, an early information exchange system on defective medicinal products was set up under Directive 75/319/EEC[9] in an effort to keep all competent authorities informed of problems that could result in the withdrawal of or major changes to the marketing authorization of a given product.

The Council's Conclusions (94/C15/03[10]) on self-sufficiency in blood in the European Community reaffirmed the need to achieve this goal through cooperation between the Member States and agreed *inter alia* to continue to promote the quality and safety of blood collection and of blood-derivative production.

With regard to the exchange of blood and its components in cases of emergency, the Council adopted Decision 86/346/EEC[11] accepting, on behalf of the Community, the European Agreement on the Exchange of Therapeutic Substances of Human Origin.

Council Decision 91/317/EEC[12] adopting the 1991-1993 "Europe Against AIDS programme" specifically identified, in the plan of action, the prevention of HIV transmission through the fostering of Community self-sufficiency in blood products by encouraging voluntary unpaid donors and continuing the efforts made to ensure transfusion safety. Council Resolution 94/C15/02[13] called for the extension of this plan of action until the end of 1994; following the Commission's proposals, the European Parliament and the Council are set to adopt a Decision under Article 129 prolonging the programme until the end of 1995.

With regard to the framework for Community action in the field of public health, Council Resolution 94/C165/01[14] agreed that priority should be given *inter alia* to AIDS and other

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7 O.J. n° L 193 of 17.07.91. p.30
8 O.J. n° L 270 of 26.09.91. p.32
9 O.J. n° L 147 of 09.06.75
10 O.J. n° C 15 of 18.01.94. p.6
11 O.J. n° L 207 of 30.07.86. p.1
12 O.J. n° L 175 of 04.07.91. p.26
13 O.J. n° C 15 of 18.01.94. p.4
14 O.J. n° C 165 of 17.06.94. p.1

communicable diseases as well as disease surveillance and the collection of reliable and comparable health data. It emphasized that Community action should be aimed at supporting and encouraging cooperation between Member States and promoting coordination of their policies and programmes for health protection in the priority areas.

Recognizing the risks of the spread of communicable diseases within the Community due to the existence of the single market and the free movement of persons and foodstuffs, Council adopted Resolution 92/C326/01[15] on the monitoring and surveillance of communicable diseases. In its Conclusions 94/C15/04[16] on this matter, Council stressed the need for an epidemiological network in the Community, covering all diseases but collecting data on communicable diseases as a priority with a view to acquiring better knowledge of their causes and their epidemiological context.

3.2 European Parliament

The concern of the European Parliament about the safety of blood and its derivatives and its support for the goal of Community self-sufficiency has been reflected in a report[17], numerous written and oral questions dealing with blood-related issues, as well as in the adoption of two Resolutions[18,19] which called *inter alia*, for an action plan to improve safety and promote self-sufficiency through voluntary unpaid donations, for the strengthening of controls to increase blood and blood product safety, and for the drawing up of an instrument which would guarantee monitoring of blood safety from donation to use. It also called on the Council to promote in-depth discussions on these issues and the setting up of a European blood safety authority.

Parliament has also taken considerable interest in the frequency and incidence of various communicable infectious diseases. It has adopted resolutions concerning the fight against AIDS which reflect its concern about the spread of the epidemic and the need for Community intervention. Parliament also expressed the need for epidemiological surveillance, analysis, and training in its resolution on public health policy after Maastricht[20], which called on the Commission to set up an epidemiological investigation service, to collect, analyse and disseminate data on notifiable diseases and to encourage the setting-up and operation of exchange schemes for health professionals.

3.3 European Commission

The Commission's Communication on self-sufficiency in blood and plasma in the Community presented *inter alia* key issues of concern to Member States and specific actions for consideration. Its acceptance led to a request for additional information related to legal and trade aspects of the blood transfusion chain with the view to proposing common safety criteria.

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15 O.J. n° C 326 of 11.12.92. p.1

16 O.J. n° C 15 of 18.01.94. p.6

17 Report of the Committee on the Environment, Public Health and Consumer Protection on Self-sufficiency in and safety of blood and its derivatives in the European Community. A. CECI. European Parliament. 25 February 1993. (A3-0075/93). 20p.

18 O.J. n° C 268 of 04.10.93. p.29

19 O.J. n° C 329 of 06.12.93. p.268

20 O.J. n° C 165 of 17.06.94. p.1

Regarding the safety and reliability of *in vitro* diagnostic medical devices, the Commission is preparing a proposal for a Directive laying down, in the context of blood transfusion, essential requirements to enhance health protection and safety of patients, users and third persons. It contains provisions covering reagents and equipment specifically intended for *in vitro* examination of blood (e.g. blood groups; HIV and hepatitis tests) which will be the subject of strict conformity assessment procedures implying the intervention of third party certification bodies.

Additional safety precautions related to plasma pool testing and batch release for medicinal products derived from blood have been introduced by the Committee for Proprietary Medicinal Products (CPMP) in which the competent authorities of the Member States are represented. Furthermore, tests to be carried out on samples of each production batch by an official laboratory prior to being placed on the market, should this be requested by a Member State, have been defined.

The Commission has prepared several Communications which address aspects relevant to the promotion of blood safety and self-sufficiency including: the implementation of the 1991-1993 "Europe Against AIDS" programme[21]; the framework for action in the field of public health[22]; the action programme related to health promotion, information, education and training[23]; and an action programme on the prevention of AIDS and certain other communicable diseases. It has also received the advice of its Group of Advisers on the Ethics of Biotechnology.

4. COMMUNITY SELF-SUFFICIENCY AND CONDITIONS FOR ITS ATTAINMENT

One of the measures that have been identified as helping to promote the safety of blood and its products has been the attainment of self-sufficiency through voluntary non-remunerated donations. Promoted by the Council of Europe and supported by the Community, it is based on the fundamental principle that the human body and its parts are inviolable and should not be used for the purposes of trade. Protecting the health of the donor and avoiding donor exploitation; minimizing the risk of infection to recipients; ensuring donor participation from all social strata of the population irrespective of economic status; and promoting independence from importation and hence stability in the supply and cost of products have been presented as complementary tenets to this principle.

In adopting Directive 89/381/EEC, which covers blood and plasma as the starting material for the preparation of medicinal products, Council accepted Community self-sufficiency (as distinct from national self-sufficiency) through voluntary unpaid blood and plasma donations as a goal. Its attainment, however, is influenced by several factors: the willingness of the citizens of the Member States to donate blood and plasma; the interpretation in the Member States of non-remunerated donations as defined by the Council of Europe; optimal use of these products by treating physicians taking fully into account the very special nature of their

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21 Programme 1991-1993 "Europe Against AIDS". Report from the Commission on the Implementation of the plan of action 1991-1992. [COM (93) 42 final of 10 March 1993].

22 Commission communication on the framework for action in the field of public health. [COM(93) 559 final. Brussels, 24 November 1993. 55p.]

23 Community action programme on health promotion, information, education and training [COM (94) 202 final].

source; and differing regulations and practices in the Community which may restrict the exchange of blood and blood products between Member States and hinder the attainment of self-sufficiency. Safety aspects of the blood transfusion chain, irrespective of the end use of the blood and plasma donation, also need to be considered particularly in relation to whole blood, plasma and blood cells of human origin, which were specifically excluded from Directive 89/381/EEC and to which its requirements do not apply.

4.1 Knowledge, Attitudes and Behaviour of Community citizens

The most important and fundamental consideration in the attainment of Community self-sufficiency is the willingness of the citizens of the Member States to donate the blood and plasma required both for direct transfusion and for the preparation of medicinal products. And their perceptions, realistic or not, play a crucial role.

As set out in its Communication on blood self-sufficiency, the Commission has now carried out a survey of the knowledge, attitudes and behaviour of the general public regarding blood and blood donations within the framework of the EUROBAROMETER public opinion surveys. In April 1994, approx. 13,000 European citizens of the 15+ age group were interviewed on a nationally representative basis in all 12 Member States regarding their perception and understanding of questions relating to blood.

The major findings showed that Community citizens are reasonably well-informed about blood and are aware of the existence of different blood groups. There is, however, general lack of awareness about the frequency with which blood can be donated, what plasma is and the fact that it can be donated instead of whole blood. Health problems or negative advice from doctors, lack of time, and fear of getting AIDS were the major reasons given for not donating blood. And in spite of general awareness that blood donations are tested for diseases, a large percentage of Europeans are afraid of having a blood transfusion, primarily because of the fear of contracting HIV/AIDS. Moreover, there is a general lack of awareness about the Community's goal of self-sufficiency through voluntary non-remunerated donations even though this goal is generally supported.

Based on the number of misconceptions that exist among European citizens regarding blood-related issues, there is a need to continue to ascertain people's knowledge about this important subject, in particular so that they can be provided with factual and reliable information.

4.2 Voluntary non-remunerated donations

Non-remunerated blood donation is one of many health care issues that are the subject of divergent views today. While regulations concerning donor recruitment have been established by some Member States, differences of opinion about the ethical principles and safety issues related to "incentives" or "compensations" given to blood and plasma donors persist. Furthermore, the definition of voluntary non-remunerated donation as put forward by the

Council of Europe[24] is viewed differently by the Member States particularly as it relates to the relevant provision in Directive 89/381/EEC.

4.2.1 Regulations

A survey carried out by the Commission shows that regulations and practices related to donor recruitment and voluntary non-remunerated donations in the Member States vary widely from explicit legislation, to general health regulations but with no precise reference to remuneration, to no specific stipulations. A few Member States stated that in their legislation non-compliance with the principle of voluntary non-remunerated donations could result in legal action.

In the Member States, donors are generally voluntary and under no pressure to donate. Some strictly prohibit directed donations by family or friends or where the donor and recipient know each other. In situations where blood shortages exist, however, friends and family members of patients in a few Member States may be asked to donate. In those that are not yet self-sufficient, physicians may make treatment conditional on the availability of blood, which could put pressure on the patient as well as on his/her relatives to donate. In some Member States, regular donors are contacted by telephone or letter by the transfusion services or by donor organizations.

It is not the practice in the Member States to collect blood in prisons and one specifically reported that it is not carried out in refugee centres. Some countries collect from soldiers in civil and military centres, others do not.

4.2.2 Practices

The incentives provided to both blood and plasma donors within the Member States range from absolutely no payment or reimbursement, to days off work, or to "expense allowances". Donors normally receive refreshments (a non-alcoholic drink and biscuits or sandwiches) in order to replace fluid loss and as a way of ensuring that they rest after the donation to reduce the risk of fainting. In all Member States, their generosity is generally recognized through medals, certificates, diplomas and small gifts of negligible commercial value, commensurate with the number of donations, as well as official award ceremonies and celebration parties for high frequency donors.

One Member State provides free medical care to donors when proposed by the blood services and provides its voluntary blood donor groups with meeting and record storage facilities, as well as financing for its promotional leaflets and telephone expenses.

Member States permit time off work for donations ranging from the net time to donate blood/plasma to one day off work which in one country is specifically restricted to a maximum of four days per year for blood and plasmapheresis donations. A voucher system for plasmapheresis (voucher ± 1.25 ECU) is in place in one Member State.

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[24] *A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components on his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered as substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donations.* ***(Council of Europe)***

Reimbursement of travel expenses ranges from none at all, not even upon presentation of a bus or train ticket, to actual travel costs when requested, particularly when the donor has to travel a long distance or at night. In one Member State, transportation, if required, is provided by blood banks and in a few cases (plasmapheresis combined with long journeys), reimbursement is given, when supported by documentation, to the employer for the time off work

Blood and plasma representatives, in one Member State, have adopted a recommendation that while no payment should be made for the donation of blood or plasma itself, an "expense allowance" of up to a maximum of 25 ECU per donation is justifiable and compatible with the guidelines of the WHO and the Council of Europe. These representatives have espoused, however, that no "expense allowance" should be paid for the first donation and an upper limit must be imposed in the case of frequent plasma donations so that the "expense allowance" cannot be assimilated to a payment. In this country, both state and local authority blood-donation services as well as commercial plasmapheresis centres provide donors with an "expense allowance" for direct costs (e.g. for the journey and time taken), which is granted as a lump sum in order to avoid administrative costs. Whole-blood collections organised by the Red Cross in the same Member State, however, are without any such "expense allowance".

From the foregoing, it is evident that the interpretation of the concept of non-remuneration is not uniform throughout the Community. Incentives to encourage blood and plasma donations do take place including time off work beyond that actually required for the donation and flat rate "expense allowances".

4.3 Optimal Use

Optimal use of blood and blood products without depriving patients of what they need can contribute to achieving Community self-sufficiency. Yet it is known that practices differ in the Community. A study, known as SANGUIS (Safe ANd Good Use of blood In Surgery)[25], was carried out between January 1990 and June 1992 within the framework of a European Community Research Concerted Action to assess when, why and how much blood, blood components, plasma derivatives, and artificial colloids were requested and transfused in specified elective surgical procedures carried out in university hospitals in Europe. This study showed that in a large number of teaching hospitals in the Community, utilization of specific products varied widely between hospitals in the same country and more so between hospitals of central-northern Europe and the Mediterranean countries. The use of whole blood in some hospitals was found to be quite high and in others where whole blood was not requested, red cells and plasma were often used together, effectively reconstituting whole blood and negating the widely accepted concept of blood component therapy. In some hospitals, plasma was used for volume replacement, thereby removing plasma from fractionation and effectively negating efforts elsewhere towards self-sufficiency.

One of the main conclusions of this study was the profound and totally unexplained variations in the use of blood products in six surgical procedures for similar categories of patients and showed *inter alia* the need for improved use of blood resources through agreement on best blood transfusion practice.

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[25] Safe and good use of blood in surgery (SANGUIS) - Use of blood products and artificial colloids in 43 European hospitals. EUR 15398. G. Sirchia et al (eds). European Commission. 1994. 235p.]

4.4 Progress towards Community self-sufficiency in 1991

Periodic updates regarding blood and plasma donations and the availability and use of blood products in the Community, as suggested in the Communication on blood self-sufficiency and endorsed by the Council on 13 December 1993, can provide an indication as to the progress that is being made towards Community self-sufficiency. The survey of the situation in 1991[26] showed *inter alia* that from 1989 to 1991:

- Whole blood donations increased in ten of the twelve Member States.

- Member States were almost entirely self-sufficient for whole blood and blood components in 1991, except Greece which requires large quantities of red cell concentrates for its thalassaemia patients.

- The volume of plasma obtained from voluntary, non-remunerated whole blood and plasmapheresis donations increased by 20%.

- The volume of plasma available for fractionation, derived both from whole blood and obtained through apheresis from voluntary, non-remunerated donors, increased by 36%.

- The degree of plasma self-sufficiency improved significantly despite increased use of certain plasma products notably factor VIII concentrates.

- Use of fresh frozen plasma and whole blood for transfusion decreased reflecting progress towards optimal use of blood and its components.

- Large differences still exist among the Member States regarding use of fresh frozen plasma, factor-VIII concentrates, and albumin.

- The plasma shortage for preparing medicinal products persisted necessitating importation of both plasma and final products from outside the Community mainly from the USA. The amount of plasma imported, primarily by the Federal Republic of Germany, Italy and Spain, increased by 5%. The amount of factor-VIII concentrates imported, primarily by the Federal Republic of Germany, increased by 16%.

Information about the situation regarding blood and plasma collection and use in 1993 is currently being compiled and a revised questionnaire for use in 1995 has been finalized.

4.5 Trade in blood and blood products

Irrespective of the method of collection, considerable expense is incurred in the collection, testing, processing, storage, distribution and use of blood and blood products as well as related research and development. These activities must be financed either through the health care system or through normal market procedures.

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26 The Collection and Use of Human Blood and Plasma in the European Community in 1991. W.G. van Aken. July 1994. European Commission. CEC/LUX/V/F/159/94. 39p.

As most Member States have achieved self-sufficiency in whole blood and cellular components, exchanges between Member States are limited. Exchanges of fresh components do occur but usually when shortages exist. Member States that have an excess of red blood cells do make them available at cost to third countries and one Member State that experiences a shortage of this blood component on a continuing basis currently obtains it from outside the Community.

The situation with regard to source plasma used in the preparation of medicinal products and the products themselves is quite different. Currently, there is a deficit throughout the Community in the quantity of plasma derived from voluntary non-remunerated donations to enable both the public and private sectors of the plasma products industry to produce sufficient medicinal products to satisfy existing demand. As a result, much of the source material, i.e. plasmapheresis plasma, used for fractionation by the private sector, is obtained from paid donors from third countries, in particular the United States where there are no laws prohibiting payment; and donors may receive USD10-15 for each donation of about 650 ml and may give up to 60 litres per year.

In addition, final products, such as factor VIII, albumin and immunoglobulins, are also imported. Curtailing such imports (both plasma and final products) at this time would have adverse consequences especially for hospital patients, those requiring emergency care, as well as those suffering from blood disorders such as haemophilia.

Eurostat data indicate that in the past trade in source plasma and plasma products between the Community and third countries has been conducted primarily with the USA and Austria. Importations from the United States are significantly higher than exportations to it due in part to the licensing and inspection requirements imposed by the US Food and Drug Administration. Exports from the Community in the past have been primarily to Austria.

Within the Community, manufacturing and marketing of medicinal products derived from blood and plasma is open to both the public and private sectors of the plasma products industry provided all marketing conditions are met. While it is estimated that the market share is currently divided between the public (40%) and private (60%) sectors, with the latter providing between 60-100% for particular products, the private sector considers that measures introduced in the name of national self-sufficiency on the basis of non-remunerated donations in some Member States deprives it of the opportunity of marketing its products in those Member States. It is also of the view that these regulations which impede the placing on the market of medicinal products derived from paid plasma create a monopolistic environment that could lead to increased costs for medicinal products and deprive patients and physicians of continued access to new technologies and products. This point of view is countered by several Member States that have established publicly-run systems which, in their opinion, address these concerns. Some Member States require certification that blood products are derived from voluntary unpaid blood donors.

Development of genetically engineered plasma derivatives and alternatives to cellular concentrates (i.e. soluble haemoglobin) may have significant consequences in the future on blood donations, the usage of products, the pricing of medicinal products derived from blood, as well as on the exchange of these products.

5. BLOOD SAFETY AND CONDITIONS FOR ITS ATTAINMENT

While significant advances have been made towards making blood and blood products safe, it must always be borne in mind that the biological nature of blood and plasma makes them susceptible to contamination and since new infectious complications cannot be excluded, the task of minimizing the risks associated with blood transfusion is far from complete. New technologies that continue to emerge will require close scrutiny for their ability to improve on current standards of screening for infectious diseases.

5.1 Collection process

Safety of blood and plasma collection involves two main activities - selection and testing. *Selection* refers to the clinical processes of enquiry involving some form of interaction between a blood transfusion service professional and the donor, based on a structured questionnaire and supported by additional detailed guidance documents. *Testing* is the laboratory examination of a sample of the donation to determine specific biological parameters and to detect, through so-called infectious markers, the presence of agents that produce communicable diseases.

5.1.1 Selection of donors

With the number and kind of infectious markers differing from Member State to Member State, and from region to region within a Member State, as well as a higher probability of these occuring in first time donors, donor selection is of vital importance. The donor selection process, however, differs across the Community. Whether the donation is for whole blood or plasmapheresis plasma, variations exist:

- in the frequency of the clinical examination, ranging from a medical examination at every donation to none routinely required;
- in the person who conducts the donor interview who varies from a physician to a trained staff member of the collection centre; and
- in the information programmes for both donors and the general public.

The process, however, generally includes the administration of a questionnaire which again differs both within and across Member States.

The reliability and effectiveness of questionnaires in eliciting information about potential risk factors or exposure to diseases, such as HIV, both from first time donors and those donating repeatedly has yet to be determined. This is significant when it is realized that the incidence of infectious markers is 5-20 times higher in first time donors. It should also be noted that many repeating donors may sign a donor declaration without carefully re-reading it. Donor selection, therefore, is a crucial link in the safety of the blood transfusion chain.

In view of the increased mobility of persons within the Community and the potential for the introduction of more obstacles to the movement of blood and blood products, 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.

5.1.2 Testing of donations

Directive 89/381/EEC and the accompanying provisions were aimed at harmonizing the quality, safety, and efficacy requirements for medicinal products derived from blood, thus ensuring their free circulation. Article 3.1 of the Directive requires that testing of human blood and plasma, when used as the starting material for the manufacture of medicinal products, shall comprise those measures recommended by the Council of Europe and the World Health Organization (WHO) as well as the application of the monographs of the European Pharmacopoeia regarding blood and plasma. The provisions of the latter have been made applicable by Directive 91/507/EEC and are supported by guidelines developed by the CPMP. As these Directives do not apply to whole blood, to plasma or to blood cells of human origin, divergences exist within the Community regarding the testing requirements for blood and plasma donations.

Some Member States do not differentiate at the collection stage between blood for transfusion and blood that is destined or may be used for fractionation; others do. As a consequence, testing requirements that may be compulsory in one Member State for blood and plasma for fractionation may not be in another. This can result in medicinal products derived from plasma manufactured in accordance with the regulations of one Member State being prevented from appearing on the market of another because a particular test has not been carried out. As an example, one Member State requires each donation to be screened for syphilis with the consequence that no product is allowed to be placed on its market, even coming from another Member State, that does not have a similar requirement.

Both the public and private sectors share the concern that these differing testing requirements in Member States throughout the blood transfusion chain are introducing barriers to trade of medicinal products derived from blood.

The scientific basis for some differences in testing requirements between blood for transfusion and for fractionation is clear. For example, HTLV-I and II appear only in the cellular fraction and are thus removed in the first manufacturing stage of the medicinal products derived from blood or plasma; the syphilis agent is rapidly inactivated by freezing the plasma, a process to which all collected plasma is subjected. A particular point of contention among the Member States is alanine aminotransferase (ALT) testing which was originally introduced as a surrogate test for post-transfusion hepatitis when specific screening for hepatitis C was not yet possible. This test is not included in the list of mandatory tests of the European Pharmacopoeia monograph on plasma for fractionation. As this monograph is worded so as to allow flexibility, however, some Member States require this test while others do not.

It is evident that the differing testing requirements in the Member States hinder the free movement of blood and blood products and are therefore an impediment to the goal of Community self-sufficiency.

5.2 Regulatory Controls

In each Member State, there are responsible bodies for authorizing the manufacturing of pharmaceutical products and the monitoring of procedures in order to ensure that high levels of quality and safety are maintained. Inspectors are required to make on-site visits to the manufacturer to ensure regulations are being followed and negative reports can result in closure until corrective measures are taken. In accordance with Community legislation, each Member State is responsible for inspections on its own territory, and information exchanges

between the competent authorities, such as through the CPMP, help to facilitate the resolution of problems between them.

In at least one Member State, blood is considered a medicinal product and is therefore subject to pharmaceutical regulation. This is not the case, however, in others. On the basis of an on-going survey being carried out by the Commission, there are preliminary indications that the regulatory controls regarding licencing and accreditation of blood collection establishments differ widely across the Member States. Many have no licencing requirements for the collection of blood or plasma; no standard requirements for collection centres across the country; no routine and/or unannounced inspections by national authorities nor peer inspections, and differing time periods for licence renewals. In one Member State, the extraction of blood and blood components for transfusion as well as the extraction of plasma for fractionation constitutes the manufacture of medicinal products, for which a licence is required. In others, this interpretation does not apply.

This existence of divergent national regulations concerning the collection and treatment of blood contributes to a reluctance, if not a refusal, on the part of certain Member States to accept blood and plasma coming from others. Serious consideration, therefore, needs to be given to harmonizing the licensing and accreditation of blood collection, processing and distribution establishments across the Community that do not fall within the scope of Directive 89/381/EEC.

6. THE NECESSITY FOR FUTURE COMMUNITY ACTION

6.1 Increased awareness

As a result of the AIDS pandemic as well as several incidents related to the distribution of contaminated medicinal products derived from blood and plasma in the Community, public confidence in the blood transfusion system has been seriously undermined. Patients and persons with haemophilia have been particularly affected. Demands for stricter regulations of the blood transfusion system have increased. It is extremely important that the confidence of the citizens of the Community is reestablished; this can be done by means of a number of measures including appropriate information and education campaigns.

The results of the Eurobarometer survey show that knowledge about blood-related issues in the Community is inadequate and is insufficient in relation to the goal of Community self-sufficiency. There is the need, therefore, to increase awareness levels among the population regarding blood and plasma, its uses, the precautions that are taken to maximize safety, as well as the goal of Community self-sufficiency. This could be done through better targetted campaigns of a general nature or specifically targetted to blood awareness. There is also the need to have more detailed information about the knowledge and attitudes of specific groups, such as students, regarding blood and blood donation with the view to enlarging the blood donor base. The latter could be done in cooperation with blood donor groups.

6.2 Donor selection criteria

The process of donor selection should be properly monitored and documented and its effectiveness should be demonstrated properly in particular by reference to an acceptable low level of frequency of infectious markers. In spite of the fact that several guidelines, including those of the Council of Europe, already exist in this area and certain Member States have

relevant requirements embodied in regulations, there is significant variation in the donor selection processes in the Member States. There is the need for common procedures among blood and plasma collection centres within the Community if obstacles to the movement of these products are to be overcome. These common procedures would help to provide the necessary reassurances of the safety of blood and blood products originating from whatever Community source.

A first step in this process could be taken by the development of a common and well-structured questionnaire with appropriate criteria for the selection of donors taking into account the differing social/cultural environments in the Community and the regulations and procedures currently in force. An examination of the efficacy of existing donor selection procedures could provide a basis on which to select the criteria for such a questionnaire so as to provide optimal guarantees for the safety of the donor and the recipient.

6.3 Testing of donations

Despite the existence of testing requirements in the Community, some differences remain in the screening of blood and plasma for transfusion and for fractionation in the Member States. As the importance of these screening tests cannot be overestimated, the available scientific data, both in favour and against specific screening tests, need to be compiled so that a sound basis against which to establish their validity can be developed. There is a clear need for harmonization in this respect to ensure the free circulation of medicinal products derived from blood but also to facilitate the future centralized procedure for authorization of medicinal products. Moreover, a comparative survey is needed of the currently used testing kits in the blood transfusion field, their proficiency and proper utilization, as well as the licensing of the critical diagnostics intrinsic to ensuring the safety of the blood supply and quality control measures in the Member States.

6.4 Optimal use

Attitudes towards blood transfusion and the use of medicinal products derived from plasma have changed in the last ten to fifteen years due to the emergence of blood-borne diseases (notably HIV), new medical technology, increasing health care costs, and the results of clinical trials. Knowledge about the clinical effectiveness of the varying approaches to the prescribing and use of blood and blood products across the Community, however, is hampered by a continuing lack of access to and provision of relevant information thus inhibiting the establishment of policies regarding their optimal use. Both the self-sufficiency surveys and the SANGUIS study have demonstrated wide variations in transfusion practices in the Member States. Consensus conferences and guidelines on the use of specific blood products do not appear to have had a significant impact on changing the behaviour of physicians and there is a need, therefore, to carry out studies on the optimal use of blood and blood products recognizing that its significance is directed towards: the patient - whose safety and therapy are of paramount importance; the donor - who should be guaranteed that his/her donation is used in the best possible way; self-sufficiency - ensuring that source materials (blood and plasma) are used optimally; good clinical practice - ensuring *inter alia* that blood and blood products are administered only when needed; and finally the financial implications. Moreover, there is a need to include in a standardized way in clinical records the reasons for transfusion, its actual administration and the outcome. Results of further studies could be used as the basis for establishing sound blood transfusion practices throughout the Community.

6.5 Regulatory system

With the increasing movement among Member States of blood products and blood units, which are being drawn in one country for transfusion in another, differing licensing and inspection requirements for both blood and plasma collection establishments across the Community stand in the way of the free movement of blood and blood products and thus the objective of Community self-sufficiency. Common requirements including quality control and quality assurance procedures and good manufacturing practice, which have been established for medicinal products derived from blood and plasma, need to be defined and agreed upon for blood collection establishments and inspection and certification programmes need to be put in place. The objectives of such programmes would be to verify the implementation of requirements agreed upon and to provide a tool for the improvement of practices as they relate to donors and patients. Such an inspection and certification programme would have to be determined in consultation with the responsible authorities of the Member States.

6.6 Haemovigilance

The minimization of risks associated with blood transfusion constitute a major priority. Because blood transfusion deals with a biological material in which infectious agents may be present, it is essential to be ever vigilant so that potential biological changes can be detected at any time. Moreover, since there is insufficient information as to the precise extent of infection or transfusion errors, there is the need to develop concrete measures for their prevention. This applies also to the immune reactions that may follow a transfusion as a result of previous immunizations (e.g. pregnancy, previous transfusion).

As indicated in the Commission's Communication related to AIDS and certain other communicable diseases, there is a need to improve, at Community level, the availability, quality, relevance and dissemination of data related to diseases transmitted by *inter alia* blood. Establishment of Community-wide surveillance systems on blood transmitted diseases and adverse reactions at both national and Community level could help to keep transfusion specialists informed, in a timely and orderly fashion, of new infectious agents in particular, their potential danger, and appropriate measures to be taken to avoid their transmission. Such a system could be based on a network of blood transfusion centres linked with national or Community epidemiological agencies which are looking at these issues on a broader scale. Existing haemovigilance and pharmacovigilance systems, therefore, would need to be examined in order to assess their contribution to such a system.

6.7 Continuing close cooperation with Member States

The Communication on blood self-sufficiency in the European Community was based *inter alia* on the results of a joint enquiry conducted for the Commission and the Council of Europe[27], took into account the comments received from representatives of the Member States, and identified issues and priorities for action. This Communication on blood safety and self-sufficiency has taken into account information provided by the Member States in these areas as well as issues of concern and activities to be undertaken expressed by the Member States at meetings held by the Commission.

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27 Collection and use of human blood and plasma in Europe. W.G. van Aken. Council of Europe. 1993. 31p. (ISBN 92-871-2240-7)

In view of the complexity of the issues related to blood transfusion as well as the importance of blood and blood products to the health of the citizens of the Community, the Commission will continue to draw upon the expertise of representatives from the Member States. Their medical, scientific, manufacturing and managerial expertise in relation to the operation of blood transfusion services, will continue to be of assistance to the Commission in addressing issues related to blood safety and self-sufficiency in the Community.

7. BLOOD SAFETY AND SELF-SUFFICIENCY: THE NEXT STEPS

In conclusion, there is a clear need to formulate a Community blood strategy aiming at improving confidence in the safety of the blood transfusion chain and promoting self-sufficiency in the Community.

To this end, the main activities to be undertaken could include:

- Development of scientifically sound policies and agreed procedures in the donor selection process among blood collection establishments within the Community in order to provide the necessary reassurances of the safety of blood products originating from whatever Community source.

- Implementation of efficient validated and reliable screening tests in the Community.

- Development of quality assessment criteria and good manufacturing practices regarding collection, testing, processing, and transfusion of blood and blood products and patient follow-up procedures.

- Development of a haemovigilance system for the collection of epidemiological data related to the blood transfusion chain.

- Development of educational programmes directed towards health professionals on the optimal use of blood and blood products.

- Support for the dissemination of information on blood and blood products and the collection, processing and transfusion procedures through promotional materials, films, campaigns.

The Commission will continue to collaborate with the Member States to develop this blood strategy and will report on the progress made in this regard in due course.

ANNEX 1

Therapeutic Uses of Blood Products

Blood Products	Therapeutic Use
CELLULAR COMPONENTS and PLASMA	
Red blood cell concentrates	RBCs are administered when the oxygen carrying capability of blood is diminished so that organs or tissues no longer function properly primarily as a consequence of blood loss due to trauma (e.g. car accidents), surgery, or delivery, or loss of red cells because of hereditary diseases such as thalassemia.
Platelet concentrates	Patients suffering from platelet deficiencies, particularly those undergoing treatment for blood disorders (e.g. leukaemia), and cancer patients receiving chemotherapy and irradiation, receive platelet concentrates to prevent life-threatening bleeding.
Fresh frozen plasma (FFP)	Plasma which after collection is frozen to a temperature that will maintain the activity of labile coagulation factors is called FFP. It is used to treat bleeding in patients undergoing liver transplantation and for some rare clotting factor deficiencies. It is also used postoperatively and inadvertently as a nutritional substitute.
PLASMA DERIVATIVES	
Albumin	Albumin is used primarily when loss of blood or severe infection (septicemia) causes a drop in blood pressure giving rise to shock. Albumin-deficiency, caused by its decreased synthesis (e.g. in patients with severe liver disease) or losses (e.g. severe burns) may also be an indication for its administration.
Clotting factor concentrates	These are used principally to treat bleeding episodes in patients with shortages in one or more of these proteins (e.g. haemophilia A); and regular injections improve both their quality of life (e.g. less joint injury) and longevity.
Protease inhibitors	Protease inhibitors (e.g. antithrombin III) curb excess clotting factor activity. Deficiency of these proteins may cause diseases such as venous thrombosis and lung emphysema which are prevented through treatment with protease inhibitor concentrates.
Immunoglobulins	These are plasma proteins that play a role in the defense mechanism against viral and bacterial infections. They are used mainly in the prevention of a variety of infectious diseases such as hepatitis, smallpox, chicken pox, tetanus, and rabies and in the treatment and prevention of haemolytic disease of the newborn due to Rh incompatibility. Increasingly high doses of immunoglobulins are being used to treat patients with auto-immune diseases and further indications for their use are increasing.

ANNEX 2

Major Infectious Agents Transmissible by Blood and Blood Products

INFECTIOUS AGENT	OUTCOME
Viruses*	
Human immunodeficiency virus type 1 (HIV-1) Human immunodeficiency virus type 2 (HIV-2)	AIDS
Human T-cell leukaemia virus type I (HTLV-I) Human T-cell leukaemia virus type II (HTLV-II)	myelopathy acute T-cell leukaemia
Hepatitis A virus (HAV)	acute hepatitis
Hepatitis B virus (HBV) Hepatitis C virus (HCV)	acute/chronic hepatitis liver cirrhosis liver cancer
Cytomegalovirus (CMV)	pneumonitis
Epstein-Barr virus	glandular fever
Parvovirus B19*	aplastic crisis foetal loss
Spirochetes**	
Treponema pallidum	syphilis
Borrelia burgdoferi	lyme disease (borreliosis)
Parasites** (rare in the Community)	
Plasmodium species	malaria
Bacteria	
Contamination with a variety of bacteria can occur at the time of donation.	septicaemia

* **Are not transmitted by virally inactivated plasma, with the exception of parvovirus B19**

** **Transmitted only by the cellular components**

ANNEX 3

Eurobarometer Survey

European citizens are reasonably well-informed about blood: 98% are aware of the existence of different blood groups; 90% are aware that donating blood does not permanently reduce its volume in the body; and 89% are aware that blood donations are tested for diseases. Television is the dominant information source.

There is a general lack of awareness about the frequency with which blood can be donated.

Knowledge about plasma is lacking with only 34% aware that it can be donated instead of whole blood with this most apparent in Greece (14%), Portugal (18%) and Denmark (18%)[28].

Donating blood is considered by about half those interviewed as the right thing to do. Interviewees would donate to support a relative or friend (33%), in case of a major disaster (30%), before an operation (26%), and because of the rarity of the blood group (25%).

There are significant variations in the acceptance of blood donated by anyone: overall (46%), Denmark (80%), U.K. (73%), The Netherlands (70%), Italy (33%) and Germany (24%).

The general opinion (78%) is that freely donated blood should be provided free of charge to people who need it; a charge to cover collection, testing and distribution costs would be acceptable to 13%; a charge over and above these costs to finance research, information and donor campaigns is supported by 6%.

Only 1% approved of selling blood as any other product while 55% considered that blood should be given for the sake of giving.

Over half (55%) believe that blood transfusions are safer today than they were 10 years ago, 14% believe they are as safe, while 23% doubt their current safety.

Because of AIDS, 70% are more afraid than before regarding the safety of blood and blood products. Giving blood is frightening for 27%, with this response much higher in Portugal (51%) and Spain (41%).

Receiving blood is of concern to a large percentage of Europeans (73%), particularly in Italy (87%); having an injection (35%) and having an operation (47%) is more frightening now than about 10 years ago.

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28 Note: Denmark has been self-sufficient in plasma derived from whole blood for several years.

ANNEX 4

Major Survey Findings on Self-sufficiency in 1991[29]

From 1989 to 1991:

- The number of whole blood donations increased by about 6% from 15.2 million[30] to 16.1 million.

- Use of red blood cell concentrates (RBC) remained unchanged (data from Germany not included); the number of whole blood transfusions declined by 7%; use of fresh frozen plasma dropped by 20%; and consumption of platelet concentrates increased by 32%.

- More than 4.1 million litres of plasma were collected from whole blood donations and plasmapheresis from voluntary, non-remunerated donors - a 20% increase.

- The volume of plasma derived from whole blood available for fractionation increased by 47% from 1.7 to 2.5 million litres; the volume obtained through apheresis from voluntary, non-remunerated donors increased by 22%. The total volume of plasma for fractionation increased by 36% - from 2.5 to 3.4 million litres.

- Importation of plasma for fractionation from outside the EC, primarily by the Federal Republic of Germany, Italy and Spain, increased by 5% from 2.0 to 2.1 million litres.

- Total consumption of factor-VIII preparations was 827.8 million IU - an 11% increase (As 1989 data for Germany was unavailable, it was not included in calculation). The mean usage per patient ranged from 0.4 (Greece) to 4.7 (Luxembourg) with varying treatment regimens accounting for the differences. Total consumption of albumin preparations amounted to 82,328 kg, an increase of 5%.

- The plasma volume required to satisfy the reported use for factor-VIII concentrates varies between 4.6 and 5.5 million litres depending on the final yield. Considering the 3.4 million litres available for fractionation, the resulting plasma shortage was 1.2 to 2.1 million litres.

- The quantity of factor-VIII concentrates imported (mainly from the USA), increased by 16% to 273 million units (primarily by Germany).

- Use of factor VIII products increased by 11% while the number of haemophilia patients treated regularly increased by 3%.

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29 The Collection and Use of Human Blood and Plasma in the European Community in 1991. W.G. van Aken. July 1994. European Commission. CEC/LUX/V/F/159/94. 39p.

30 Corrected figure based on revised data from the Member States

FINANCIAL ASPECTS

"The financial implications of this Communication have been taken into account in the proposal for the budget for 1995 and in the Commission proposal for a European Parliament and Council Decision concerning AIDS and certain other Communicable diseases within the framework for action in the field of public health. [See attached Financial Statement. Section 7.2. HIV/AIDS AND OTHER COMMUNICABLE DISEASES - Specific prevention measures (vaccination, safety of blood and blood products)]".

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