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COMMUNICATION FROM THE COMMISSION

TO THE COUNCIL, THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE

on

BLOOD SELF-SUFFICIENCY IN THE EUROPEAN COMMUNITY

1. INTRODUCTION

Increasing concern about the quality, safety and supply of human blood and plasma products, particularly as a consequence of the AIDS epidemic, served as background to an exchange of views on the free movement of blood products by the Ministers of Health meeting within the Council in November 1989.

In June 1989, in the framework of the development of the single market, the Council of the European Communities unanimously adopted Directive 89/381/EEC[1] extending the scope of existing pharmaceutical legislation to include medicinal products derived from human blood or plasma and prepared by industrial procedures. The Directive, which does not apply to whole blood, plasma or blood cells of human origin, has two main aims:

- introduction of stringent quality and safety criteria for medicinal products derived from human blood and plasma, particularly in relation to preventing the transmission of viral diseases;

- promotion of self-sufficiency of the European Community in human blood or human plasma through voluntary and non-remunerated donations.

With regard to self-sufficiency, the Directive provides that: "Member States shall take the necessary measures to promote Community self-sufficiency in human blood or human plasma. For this purpose, they shall encourage the voluntary unpaid donation of blood and plasma and shall take the necessary measures to develop the production and use of products derived from human blood or human plasma coming from voluntary unpaid donations. They shall notify the Commission of such measures."

At their meetings of 13 November 1989 and 11 November 1991, the Council of Health Ministers addressed these issues further and requested the Commission to prepare a report on the subject of self-sufficiency and the encouragement of voluntary unpaid donations within the Community.

Given the previous work of the Council of Europe in this field, and its continuing interest in this area, it was agreed that an enquiry into blood self-sufficiency should be conducted jointly. Ensuing difficulties in obtaining data from the Member States, however, resulted in delays in the preparation of the report.

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1. Council Directive of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or plasma. (O.J. L 181 of 28 June 1989, p.44-46).

A Commission Staff Working Paper[2] presented to the Health Council at its meeting of 15 May 1992 outlined the major issues dealing with the safety and supply of human blood in the Community and afforded Council members the opportunity to reiterate the importance of the principles outlined in the Directive and their keen interest in receiving the Commission's Communication on the subject of self-sufficiency. Interest in this issue was again expressed at the Council's meeting of 13 November 1992.

This Communication, prepared in response to the Council's request, is based on the results of the joint enquiry conducted for the Commission and the Council of Europe by Professor Van Aken of the Central Laboratory of the Netherlands, Red Cross Blood Transfusion Service, and takes into account the comments on his report[3] received from representatives of the Member States.

2. RATIONALE FOR SELF-SUFFICIENCY

2.1 Blood and its Derivatives

The vital and indispensable nature of blood, which is comprised basically of cells (red and white), platelets and plasma, and the fact that for therapeutic purposes humans are its only source at present, highlight the importance of ensuring its optimal use. This is achieved by separating it into its major constituents and whenever appropriate using these instead of whole blood in the treatment of diseases and injuries. These constituents can be divided into two main groups: labile (or unstable), which have a shelf life varying from a few days to one year depending on the constituent itself as well as the storage conditions; and stable medicinal products derived from blood or plasma, with a shelf life of several years.

Labile blood products include whole blood, red blood cell concentrate, white blood cells, platelets, and fresh frozen plasma. Red cell replacement is the therapy of choice when transfusions for correcting anaemia are required. Red cell concentrates alone, or supplemented with fresh or frozen plasma and/or serum albumin, are effective in most patients for intra-operative transfusions. Platelets are used for primary haemostasis. White blood cells are used occasionally for cases of severe septicemia.

The principal stable medicinal products derived from blood or plasma are: albumin, which is used primarily for restoring or maintaining blood volume; coagulation factors, such as Factor VIII, required for treating patients with haemophilia; immunoglobulins for preventing infectious and autoimmune diseases; and other plasma proteins.

While the largest portion of stable medicinal products derived from blood is currently extracted from plasma coming from whole blood, a certain quantity can be obtained by plasmapheresis - the process involving the removal of blood, separation of the blood cells by centrifugation, and reinjection of the packed cells suspended in a suitable medium. In addition, the serum portion of placental blood is also used as starting material for the preparation of albumin and immunoglobulins.

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2. 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.

3. W.G. Van Aken. The Collection and Use of Human Blood and Plasma in Europe. Council of Europe. 1993. 31p. (ISBN 92-871-2240-7).

In spite of the significant progress towards the synthesis of certain blood proteins and the existence of various substitutes, human blood is still irreplaceable. Therefore it is necessary to ensure:

- An adequate supply of labile blood components which, due to their limited shelf life, require expeditious use and frequent replacement;

- An adequate supply of blood or plasma as source material for use in the production of medicinal products.

2.2 Self-sufficiency

Availability of an ample supply of blood and appropriate blood products to an individual or group of individuals at the time of need is of the utmost importance. To ensure this, reliance may be placed: on products derived solely from blood or plasma coming from a specific population of which the individual or group of individuals is a part; on products coming from other populations; or on both. When reliance on products coming from other populations has been eliminated then a situation of self-sufficiency for the specific population in question is considered to have been realized. In practise, the specific populations in question correspond to those of the various countries. In order to minimize dependency on other populations, as well as for ethical and safety reasons, however, countries need to promote blood donations from within their own populations and strive towards satisfying their clinical needs for blood and plasma from them.

Ideally, the goal of self-sufficiency should be achieved through the promotion of voluntary and non-remunerated blood and plasma donations, in which the person gives blood, plasma or cellular components of his/her own free will without receiving payment, either in the form of cash or in kind which could be considered a substitute for money. This could include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursement of travel costs are compatible with voluntary, non-remunerated donations.[4]

2.3 Public Health Aspects

Because blood is vital to the life of numerous patients, it is considered essential that its quality and safety be assured and that the health of the donors themselves is protected.

Several viral, bacterial and parasitic diseases, including AIDS, hepatitis, and malaria, are transmissible by blood. Some are tested for specifically and some are not relevant for fractionated blood products.

In 1987, the Council took the view that the European Commmunity pharmaceutical legislation should be extended to cover medicinal products derived from human blood and plasma. In 1989, the Council thus adopted Directive 89/381/EEC, which covers stable medicinal products derived from human blood or plasma. Consequently, these products are now subject to the general requirements regarding manufacturing and marketing authorization. The principles of Good Manufacturing Practice, laid down in Commission Directive 91/356/EEC[5] and detailed in a guide intended for manufacturers, as well as the

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4. Definition agreed upon by the Council of Europe Blood Transfusion Expert Committee (SP-HM) and the League of Red Cross and Red Crescent Societies.
5. O.J. Nr L 193 of 17.7.91.

testing requirements laid down in Commission Directive 91/507/EEC[6], have become mandatory in order to demonstrate the quality, safety and efficacy of medicinal products in view of their authorization. In addition to these general requirements, which are applicable to all medicinal products, Directive 89/381/EEC contains certain elements which are specific for blood products, such as the implementation by manufacturers of validated manufacturing and purification processes, in order to ensure as far as possible the viral safety of these products. To this end, the Committee for Proprietary Medicinal Products (CPMP), in which the competent authorities of the Member States are represented, adopted two specific notes for guidance for manufacturers relating to medicinal products derived from human blood or plasma and to validation of virus removal/inactivation procedures.

The safety of labile blood components, including fresh plasma, is heavily dependent on the selection and testing of donors in order to prevent the transmission of disease. In spite of all the precautions, however, absolute safety cannot be guaranteed. Risks can be minimised by carrying out an adequate medical consultation in combination with a pertinent questionnaire, and conducting, where necessary, an appropriate examination. As a result, the donor can exclude himself/herself or be excluded from making a blood donation due to a specific pathology or a risk-factor identified during this process. If necessary, the donated blood or certain components can be rejected as a result of abnormal laboratory screening results or because its exclusion has been requested.

Care as to the amount of blood provided by donors, as well as by those who undergo plasmapheresis, must be exercised. As the capacity to replace proteins lost during blood donation is not unlimited, excessive repetition particularly of plasmapheresis, which is an industrial process carried out by both the non-profit and commercial sectors, can deprive a donor of his/her own plasmatic proteins and antibodies, rendering him/her more sensitive to infection, and possibly susceptible to risks associated with malnutrition. An equilibrium between quantity and frequency is needed since increasing either of these two parameters could be detrimental to the donor's health; maintaining them at relatively lower levels would necessitate an increase in the number of donors in order to maintain the same volume of blood or plasma donated during a fixed period of time.

Providing material benefits to blood donors in the form of cash or in kind, or other services, is contra-indicated: for clinical reasons - to avoid the risk of transmission of infection to the recipient and to safeguard the health of the donor; for social reasons - to ensure all levels of society, irrespective of economic status, participate in donations; and for ethical reasons - so as not to exploit or deprive vulnerable population groups either inside or outside the Community.

It is desirable, therefore, that the fundamental principles of voluntary and unpaid donation of human blood, as accepted by the Council of Europe, the International Federation of Red Cross and Red Crescent Societies, and the International Society of Blood Transfusion, and recommended by the World Health Organization, are reaffirmed.

3. THE STUDY ON SELF-SUFFICIENCY

3.1. The Inquiry

For more than 15 years, the Council of Europe has been a strong advocate of national self-sufficiency for blood and plasma products based on voluntary unpaid blood and plasma donations. In 1988, it conducted an enquiry on self-sufficiency based on voluntary non-

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6. O.J. Nr L 270 of 26.9.91.

remunerated donations in 1986 that resulted in the publication of a report[7] , and the adoption of "Recommendation R(90)9 of the Committee of Ministers to Member States on Plasma Products and European Self-sufficiency".

Given the experience and continuing interest of the Council of Europe in this area, and the fact that its efforts to promote voluntary unpaid blood and plasma donation, as stated in Directive 89/381/EEC, are entirely supported by the Community, it was decided that a joint Council of Europe/Commission enquiry should be conducted to ascertain the situation regarding self-sufficiency.

In 1990, a questionnaire was distributed to the Heads of the Transfusion Services or to the responsible services of the Ministries of Health in Europe, including the 12 Member States of the European Community, to elicit information about the situation as it was in 1989. Responses were submitted to Prof. Van Aken who analysed the results and prepared a report.

3.2 The Findings of the Van Aken Report

Despite the wealth of data provided by the 12 Member States in responding to the questionnaire, presenting an accurate profile of the situation with regard to self-sufficiency in the Community in 1989 has proved difficult. Some of the responses were not complete and data from one Member State to another were not always comparable. Some data were not available, some, such as that from non-public sources, were confidential, and some appeared to contradict those reported by other sources. Furthermore, one Member State provided data related to 1988 rather than to 1989.

However, based on the results of the enquiry and information obtained through direct contact with respondents Prof. Van Aken reported, *inter alia*, that:

3.2.1 The unpaid blood donor population in the European Community remained relatively stable from 1986 to 1989 at 8 to 9 million.

3.2.2 The number of whole blood donations increased by about 5% from 14.7 million in 1986 to 15.4 million in 1989.

3.2.3 In most Member States, more than 75% of whole blood collections were separated into plasma and red cell concentrates before being transfused. Use of whole blood remained relatively high, however, in Portugal (30%), Greece (46%), and Italy (60%). Compared to 1986, the relative use of both red blood cell and platelet concentrates increased in all countries.

3.2.4 An estimated 0.4 million litres of plasma could be saved for fractionation if usage of whole blood was more closely monitored.

3.2.5 There was a marked increase (+151%) in the number of unpaid donors who participated in plasmapheresis rising from 47,000 in 1986 to at least 118,000 in 1989.

3.2.6 More than 3.4 million litres of plasma were collected in 1989 by means of whole blood donations and plasmapheresis. Of this amount, an estimated 0.9 million litres were used directly for transfusions and

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7. Plasma Products and European Self-sufficiency: Collection, Preparation and Use. Council of Europe, 1992. 66p.

an estimated 2.5 million litres were used for the production of plasma products. The exact amount of plasma collected in the Federal Republic of Germany, however, was not known as the number of remunerated donations and the quantity of imported source material was unknown.

3.2.7 Importations of plasma for fractionation from outside the European Community, primarily by the Federal Republic of Germany, Italy and Spain, were estimated at between 1.6 and 1.9 million litres.

3.2.8 The two plasma products that play a dominant part in determining self-sufficiency are Factor VIII and albumin. For Factor VIII preparations, total consumption rose from 500 million International Units (IU) in 1986 to 614.9 million IU in 1989 - a 23% increase. Consumption in Denmark, France and Greece appeared to have decreased. The mean usage per patient ranged from 0.4 - 4.5 IU with variations in treatment regimen accounting for the differences. Clinical use of Factor VIII showed a continuous increase since 1986 largely because of its prophylactic administration to prevent bleeding episodes and chronic joint injury in persons suffering from haemophilia. For albumin, although specific questions regarding its clinical use were not included in the 1989 enquiry, estimated consumption varies between 200-500 kg per million in countries with fully-developed health care systems.

From the responses, it was also determined that for the year 1989 (1988 for France):

- Belgium, Greece, France, and Luxembourg reported that they were self-sufficient in Factor VIII although the level of use varied in the different countries. Denmark, Italy, Netherlands, and the United Kingdom expected to achieve it between 1990 and 1994. The situation in the Federal Republic of Germany and Ireland was not clear.

- Denmark, the Federal Republic of Germany, France, Ireland, Luxembourg, and Netherlands reported self-sufficiency in albumin. Belgium, Italy, and the United Kingdom expected to reach it between 1990 and 1994. The situation in Greece was unclear.

- Spain and Portugal reported that they were not self-sufficient in plasma products and gave no indication when they expected to be.

Based on these findings, the report concluded that self-sufficiency for plasma products derived from blood of unpaid donors is an attainable goal and several recommendations on how this could be achieved were presented. These were:

- Encouraging appropriate clinical prescribing of medicinal products derived from human blood and plasma in order to guarantee optimal use of plasma products.

- Increasing the number of donors and/or donations in order to guarantee a sufficient supply of plasma, and promoting plasmapheresis if this does not fully make up the shortage.

- Increasing the yield of fractionation procedures for Factor VIII.

- Promoting quality assurance of blood collection in all Member States, and identifying the origin (country and type of donation) of the source plasma when products are placed on the market in the Community.

- Ensuring that health authorities are able to supply data regarding the collection and use of plasma products so as to facilitate the analysis and monitoring of developments towards self-sufficiency, and encouraging the setting-up of a European data bank.

4. ISSUES RAISED BY MEMBER STATES

To ensure that the report prepared by Professor Van Aken accurately reflected the national situations in 1989, consultations were held with scientific consultants and national experts from the Member States and comments on both the factual and subjective or policy aspects as well as the recommendations, were elicited. While no fundamental objections to the overall findings nor to the general thrust of the report were raised, several key issues emerged relating to:

- The principle of self-sufficiency.
- The timeliness of the study.
- The character of blood and plasma donations.
- Blood Donors / Plasmapheresis.
- Optimal Use of Blood and Blood Derivatives.
- Quality and Safety of Cellular Blood Products.
- Information Exchange.

4.1 The Principle of Self-sufficiency

The principle of self-sufficiency, particularly in medicinal products derived from blood and blood products, is viewed as a goal of health policy and continues to receive the endorsement of the Member States. The degree to which this goal has been attained varies. Some Member States already have reached self-sufficiency in the supply of blood and cellular constituents but still import plasma and plasma products, another has reached self-sufficiency in whole blood for use in transfusions while pursuing a policy of seeking self-sufficiency in plasma-based products sourced from its own volunteer donors, and others have not yet achieved self-sufficiency.

While concensus on the principle of self-sufficiency exists, there is some ambiguity with regard to its practical implementation. The generally accepted definition, and that cited in the report[8], links a population and its potential needs in blood and blood products to the same population and the satisfaction of those needs. This implies that Community self-sufficiency will be achieved from within the Community itself. Concern has been raised,

8. Self-sufficiency - Provision of human blood and blood products from within a population to satisfy the clinical needs of that population. (CEC. III/3602/90. 25 January 1990. Informal meeting of European experts on medicinal products derived from human blood or plasma. Brussels, 9-10 January 1990).

however, that strict adherence to this definition imposes restrictions on the importation/movement of blood and blood products and hence impedes the clinical freedom of doctors to choose the most suitable product for individual patients, thus depriving them of access to advances in blood products, many of which originate in commercial pharmaceutical companies outside the European Community. Whilst recognizing the legitimacy of this concern, it was noted nevertheless that application of this practice contradicted the meaning of Community self-sufficiency and more accurately reflected the principle of sufficiency in which the related key factors of need, quality and safety, availability, and control (i.e assurance with respect to quality, safety and supply) are assured and through which the clinical needs of patients, and concomitantly the clinical freedom of physicians, are taken into account. It has to be noted, moreover, that as the provision relating to self-sufficiency in Directive 89/381/EEC applies only to human blood or human plasma as a starting material for the manufacture of medicinal products, it is narrower in scope than the definition presented above and that cited in the Van Aken report.

The view that Community self-sufficiency should be brought about through national self-sufficiency was also expressed by some Member States. How it will be achieved, however, is up to the Member States themselves. Those that have achieved self-sufficiency could offer to or be called upon by the Member States that have not to make available surplus supplies with preference given to products coming from voluntary unpaid donations. If supplies are not available from within the Community itself, however, then they will need to be obtained from elsewhere.

Conclusion

The attainment of self-sufficiency in blood and blood products at Community level through voluntary non-remunerated donations is the ultimate goal and there is a clear obligation on Member States to promote this for medicinal products derived from blood and plasma.

4.2 Timeliness of the study

Aware of the fact that difficulties in obtaining the relevant data delayed the preparation of the report, Member States nevertheless acknowledged that it addressed the situation with regard to self-sufficiency in the Community in 1989. Given that it was based on data that is now more than three years old, however, it was deemed not to be a precise foundation on which to take decisions but could serve as a basis for further examination of the issue.

In this regard, Member States agreed on the need to update the study on a regular basis in order that progress within the Community towards the goal of self-sufficiency could be measured and to supplement national data with data sought from industry. It was desirable that the next update be conducted as soon as possible and that the compiled data, even though incomplete, accompanied by brief explanations be disseminated quickly with the more extensive narrative to follow at a later date. To facilitate this effort, particularly in the compilation of the data by the Member States, the questionnaire used for the 1989 study, supplemented with questions of particular relevance to the pharmaceutical industry, was considered as the most appropriate way of obtaining the relevant data.

Conclusion

Recognizing the benefits that will accrue from having up-to-date information with regard to self-sufficiency and building on the experiences from the 1989 study, mechanisms should be put in place for the regular updating of the study and the timely dissemination of the results. To facilitate this effort, Member States should set up appropriate systems to improve their data collection.

4.3 Character of Blood and Plasma Donations

In keeping with Directive 89/381/EEC, there is general consensus that blood donations should be neither induced nor rewarded either in kind or monetary terms. This tenet is adhered to strictly in some Member States but not in others. Although a significant amount of blood and plasma is donated free-of-charge and material benefits in the form of payments in cash or in kind, or other services, are not normally provided nor are they considered desirable, incentives to encourage blood and plasma donations do prevail. These incentives range from the provision of small refreshments, certificates or little grants, to compensation for transportation costs, to days off work for public service employees in one Member State and for all employees in another. One Member State provides an "expense allowance" on a flat rate basis to compensate donors for loss of earnings due to time off work to give blood, costs incurred in travelling to and from the donor centre, and subsistence expenses, although this "allowance" is not intended to be a financial incentive to give blood. In another, a fee is paid to a donor organization for blood donor recruitment publicity. While it is acknowledged that some gray areas exist in which compensation would be deemed acceptable, such as in the case of a donor with a rare blood type who must travel long distances to give the donation, this should be the exception rather than the rule.

Although the pharmaceutical industry currently provides compensation for blood and plasma, Directive 89/381/EEC stipulates that it is the responsibility of the individual Member States to develop the production and use of products derived from human blood or human plasma coming from voluntary unpaid donations.

Conclusion

The principle of voluntary and unpaid blood donations has been endorsed and is being supported by all Member States. In practice, however, this principle is not strictly adhered to in all of them; those which tolerate lax attitudes in this respect should take measures necessary to eliminate practices which undermine this principle.

4.4 Blood Donors/ Plasmapheresis

An important factor in the effort to achieve self-sufficiency is the availability of sufficient resources. How best to ensure this is still the subject of discussion. Developing and expanding plasmapheresis programmes, which is viewed by at least one Member State as the only way of achieving self-sufficiency, has been promoted in some countries to cover the need for plasma products. In some cases this is being done in cooperation with blood donor services and the pharmaceutical industry. The idea that plasmapheresis should be stepped up only if supplies of whole blood donations are insufficient to meet requirements, however, was disputed on the grounds that plasma from plasmapheresis is superior to

plasma from whole-blood donations and better for further processing. In any event, the difference between the recommended limit on the amount of plasma collected from each donor per year, as cited in the Van Aken report (15 litres) and the figure quoted in the guidelines of the Medical Council of the Federal Republic of Germany (25 litres) needs to be clarified.

Efforts are underway in one Member State to increase the amount of plasma recovered from whole blood, which can be a cheaper method of obtaining material for fractionation.

Nevertheless, support was given in the Member States to continuing efforts in recruiting and retaining donors, both at regional and national levels, and encouraging cooperation between the bodies involved in recruiting donors i.e. blood banks and the Red Cross.

Conclusion

Consideration should be given to developing, at an appropriate stage, a basic set of principles at Community level to be used in public awareness campaigns about the need for blood donations and to motivate people to become voluntary unpaid donors, with the methodology to be the object of further deliberations.

4.5 Optimal Use of Blood and Blood Derivatives

In striving towards the goal of Community self-sufficiency, it is important to minimize the discrepancies between the actual needs for blood and blood products and the available resources. Promoting the optimal use of blood and its derivatives is seen as an important way of achieving this. The provision of information to hospitals and clinics, the introduction of reporting procedures to record the use of whole blood and plasma, and inter-institutional comparison of the medical indications on whose basis given blood products are administered, were suggested. The introduction of medical audit to the National Health Service in the United Kingdom, to promote the optimal use of blood derivatives, and the establishment of a Blood Product Committee under the National Health Committee in Denmark, to facilitate discussions between users and producers as well as administrators from national health services and hospitals, are two initiatives already underway.

In addition, the importance of informing clinicians about the optimal use of blood and blood products and the role of transfusion physicians in this regard was highlighted. Expanding the knowledge of physicians in this area through the development of an appropriate training programme was sought by the Member States.

Rationalization of treatment of patients within the European Community, which will come about as a result of the marketing authorizations for medicinal products derived from blood, will help to ensure the optimal use of blood and plasma. The adoption by the CPMP of harmonized summaries of product characteristics, with therapeutic indications and posologies, for the 20 main plasma derivatives, is also a valuable contribution towards optimal use.

Conclusion

To encourage the optimal use of blood and blood products throughout the Member States, mechanisms should be introduced to extend the knowledge of clinicians and pertinent laboratory personnel related to transfusion medicine.

4.6 Quality and Safety of Blood Products

Ensuring the quality and safety of blood and blood products is of major concern to the Member States. With the implementation of Directive 89/381/EEC, however, medicinal products derived from blood and plasma will be granted a marketing authorization only if their quality, safety and efficacy is acceptable. One Member State emphasized that it considers blood as a medicinal product within the meaning of the law governing medicines, and therefore subject to statutory quality and safety requirements.

Considering that the risks to blood supplies may not be the same in all countries, some Member States considered that requirements for identical tests to be carried out throughout the Community were not appropriate. While certain threats are common to all blood supplies, such as HIV, others are not, and the view was expressed that flexibility should be maintained in keeping with Council of Europe guidelines which allow for national variations in such matters as the tests to be applied to blood donations.

To ensure, however, that differences in the detailed screening tests carried out in the Member States did not become an obstacle to the free circulation of medicinal products, the CPMP adopted the note for guidance on Medicinal Products Derived from Human Blood or Plasma[9], which lays down harmonized tests on source material. Moreover, the European Pharmacopoeia (Council of Europe) recently adopted a monograph which lays down screening tests for plasma used as a starting material for the manufacture of blood products[10].

Regulations governing blood donations, which provide the necessary public health safeguards concerning donors' individual health, such as screening to detect diseases transmissible by blood or plasma, such as hepatitis B, hepatitis C, and AIDS, have already entered into force in the Member States.

Conclusion

The measures that have been implemented within the Community to ensure the quality, safety and efficacy of blood and plasma derivatives and the guidelines that have been developed by the Council of Europe for the screening of blood supplies should help to reassure patients and doctors alike with regard to the quality assurance of blood and blood products.

4.7 Information Exchange

With the opening of the internal market, the sharing of experience and the regular exchange of information is considered to be an important and welcome process and of significant value in clarifying misunderstandings, in finding common ground, and in identifying differences. A European data bank to compile this information could facilitate the monitoring of progress towards self-sufficiency and the changing policies and practices in the use of blood, blood components, and medicinal products.

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9. Rules Governing Medicinal Products in the European Community. Guidelines on the Quality, Safety and Efficacy of Medicinal Products for Human Use. Volume III. Addendum 2. CEC. May 1992. p.101.
10. Human Plasma for Fractionation. Council of Europe. 4p. 1993. Unpublished.

Although such a data bank would not solve the problem of European self-sufficiency, it would facilitate better analysis and monitoring of developments towards it. Rather than create a new central data bank, however, it was thought to be more effective to utilize an already existing facility and to explore ways of expanding its role. To ensure that the collection of data did not create difficulties and cause undue expense, consideration should be given as to how best to ensure that only useful data would be collected and to explore further what type of information should be stored and updated in order to respond to the needs of the Member States.

A comparative study commissioned by Germany on procedures in Sweden, the Netherlands, the United Kingdom, and Germany could serve as a basis for identifying the type of information to be collected. The results of this study will be available upon its completion in 1993.

Conclusion

Consideration should be given to the development and implementation of mechanisms to facilitate the sharing of experience and the exchange of information to respond to the needs of Member States.

5. ACTIONS FOR CONSIDERATION

In view of the continuing concern among the Member States about the quality, safety and supply of human blood and blood products, and taking into account the recommendations from the Van Aken report, the comments from the Member States, and the conclusions reached regarding the issues raised, the Community could consider undertaking the following actions in its efforts to promote self-sufficiency in human blood or human plasma through voluntary unpaid donations.

- Reinforcing the importance of the goal of self-sufficiency in blood and blood products at Community level while taking into account the progress achieved in the availability of substitute medicinal products.

- Assessing the knowledge, attitudes and behaviour of the general public and specific target groups in the Member States regarding voluntary unpaid blood donations, developing a basic set of principles at Community level to create public awareness about the need for blood donations, and fostering programmes to motivate people to become donors.

- Gathering information on the various types of remuneration or rewards given to blood donors.

- Encouraging the optimal use of medicinal products derived from human blood and plasma and extending the knowledge of physicians involved in transfusion medicine through the development of information programmes.

- Promoting quality assurance of blood collection in all Member States through adherence to the guidelines developed by the Council of Europe.

- Updating the report on self-sufficiency in the Community, using a revised questionnaire to include data from industry, and putting in place mechanisms for this to be done biannually.

- Facilitating the exchange among the Member States of experiences acquired in the Member States or elsewhere on blood donation campaigns and programmes and promoting discussions between the producers and the users of blood products.

- Assisting Member States to improve their data collection systems so as to facilitate the analysis and monitoring of developments towards self-sufficiency, and facilitating the sharing of this data through cooperative arrangements.

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