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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**

Rapporteur: Mrs Adriana CECI

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At the sitting of 13 September 1991 the President of the European Parliament announced that he had forwarded the motion for a resolution by Mr Martin on payment of compensation to non-haemophiliacs who have been infected with HIV, pursuant to Rule 63 of the Rules of Procedure, to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Legal Affairs and Citizens' Rights for its opinion.

At its meeting of 16 October 1992 the Committee on the Environment, Public Health and Consumer Protection decided to draw up a report and appointed Mrs CECI rapporteur.

At its meetings of 24 September 1992, 17 February 1993 and 24 February 1993 the committee considered the draft report.

At the last meeting it adopted the resolution unanimously with 3 abstentions.

The following took part in the vote: Collins, chairman; Schleicher, vice-chairman; Ceci, rapporteur; Barrera I Costa (for Mrs Bjornvig), Bowe, Breyer (for Quistorp), Diez de Rivera Icaza, Gonzalez Alvarez, Green, Hadjigeorgiou (for Spencer), Kuhn, Lannoye (for Staes), Muntingh, Partsch, Pollack, Puerta (for Muscardini), Raffin, Roth-Behrendt, Schwartzenberg, Scott-Hopkins, Valverde-Lopez, and White.

The Committee on Legal Affairs and Citizens' Rights decided on 21 November 1991 not to deliver an opinion.

The report was tabled on 25 February 1993.

The deadline for tabling amendments will appear on the draft agenda for the part-session at which the report is to be considered.

A

MOTION FOR A RESOLUTION

on self-sufficiency in and safety of blood and its derivatives in the European Community

The European Parliament,

- having regard to Directive 89/381/EEC[1] of 14 June 1989 on medicinal products derived from human blood or human plasma,

- having regard to the motion for a resolution by Mr Martin on payment of compensation to non-haemophiliacs who have been infected with HIV (B3-1051/91),

- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection (A3-0075/93),

A. whereas blood transfusion is used to treat a number of disorders and can have a considerable beneficial effect on health in both emergency situations and cases of chronic disease,

B. whereas the Community's principal duty is to ensure that all its citizens can avail themselves of transfusion therapy by ensuring that the demand for blood and its derivatives is fully met e.g. by means of exchange arrangements between the various Member States,

C. whereas the significant results achieved with transfusion therapy have been made possible by the readiness to give blood voluntarily and free of charge in a spirit of solidarity, particularly of those working in voluntary donor organizations, and by technological innovation in the industry,

D. whereas developments in transfusion therapy have made it necessary to use paid blood or plasma donors to ensure self-sufficiency,

E. whereas the sale of blood contradicts the principle that the human body is inalienable and there may be no trade in any of its parts,

F. whereas the European Community as a whole is not self-sufficient in blood and blood products,

G. whereas it will be possible to achieve self-sufficiency if all Member States combine their efforts under a Community-wide plan drawn up on the authority of the Maastricht Treaty; whereas an important contribution towards this can be made by using clinical protocols and developing products using biotechnologies and industrial sourcing and processing methods allowing better use to be made of coagulation factors,

H. whereas Directive 89/381 has not yet been transposed into the legislation of the majority of Member States, whereas this delay has an adverse effect on the health of consumers who continue to use products which do not bear

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[1] OJ No. L 181, 28.6.1989, p. 44

any indication of their source, and whereas their compliance with Community standards has not as of 31.12.1992 been assessed in all cases; whereas this directive needs to be properly enforced,

I. whereas it is extremely important that the abovementioned directive be fully implemented in all the Member States to ensure the quality, safety and efficacy of medicines derived from human plasma available in the EC; whereas, however, strategies must be implemented to achieve the goal of self-sufficiency,

J. whereas according to the Council of Europe report on 'Plasma products and European self-sufficiency' (the Van Aken report) not all Member States are at present able to guarantee that all their blood is being collected under the highest possible conditions of safety and under the best possible supervision with the result that although blood transfusion in the Community today is much safer than it was some years ago it is not completely shielded from avoidable risks,

K. whereas each Member State must, having due regard for data protection legislation, compile a national blood donation register which, when forwarded to the authorities, will provide them with information on both the place of origin and the address of the recipient so that the source of any contamination can be traced at any time in the interests of both the donor's and the recipient's health,

L. whereas the free movement of industrially produced blood derivatives must be safeguarded by defining uniform standards on quality, safety and efficacy,

M. whereas the biological risk following a blood transfusion should be given uniform recognition throughout the Community and whereas the Member States must make compensation available under appropriate legislation,

N. whereas the text of Title X, Article 129 as laid down in the Maastricht Treaty opens the door to the enactment of legislation on the transfusion of blood, plasma and their derivatives not only with reference to the internal market but also to a higher level of public health,

O. whereas it is a matter of priority to have available the requisite medicines in order to safeguard the right to health, while upholding the freedom of the doctor to prescribe the appropriate treatment for each patient,

1. Declares that the principle whereby the human body and its parts are inalienable and may not be used for trading purposes must command the Community's allegiance and consequently:

   (a) asks the Commission to inform the European Parliament of the progress made in implementing Directive 89/381 with particular reference to the deadline of 31.12.1992 by which all products derived from blood ought to have been reassessed in the light of new standards of safety, quality and efficacy;

   (b) asks the Commission to submit a proposal for amending Directive 89/381 to take account of the objections raised by some Member States together

with a follow-up communication governing blood donations, transfusions and blood banks, specifying that:

- products derived from blood must be obtained as quickly as possible form plasma given by healthy volunteer donors, it being understood that the same safety standards apply to the private and public sectors regardless of the source of the plasma,

- the source and the means of collection must always be clearly indicated by the manufacturer,

- authorization to products from third countries shall be granted if they comply with the existing safety, efficacy and quality standards to guarantee free access on to the marketplace and therefore free therapeutic choice of products to doctors and patients,

- the Community must retain its global responsibility, taking all the appropriate measures to ensure that third couontries, and particularly Third World countries, receive products of satisfactory quality;

2. Asks the Council to take all appropriate measures to promote the Community's self-sufficiency in blood and its derivatives and to encourage voluntary and unpaid donations of blood and plasma;

3. Asks the Commission to draw up and the Council to approve an action plan on self-sufficiency in and safety of blood and its derivatives based on the following points:

(a) encouragement of voluntary donation for reasons of solidarity and transfusion safety, encouragement of plasma donations,

(b) a European statute for donors and voluntary donor organizations defining their activities, rights, responsibilities and relations with public health departments and manufacturers,

(c) quality standards for the collection and processing of unstable products and the distribution of blood and its constituents,

(d) national registers compatible Europe-wide and a European register comprising full data on every unit collected and its subsequent use, and guarantees regarding their transparency and availability to all interested parties,

(e) promotion of clinical and therapeutic protocols for the use of blood including autotransfusion,

(f) support for pharmaceutical research to develop methods of treating blood which are safer and make optimum use of coagulation factors and other active substances, equally available to national programmes and to private industry,

(g) encouragement of biotechnological production methods, and the widest possible distribution of the products obtained thereby through such channels as transfusion centres and units;

4. Asks the Council to recognize the biological risk which may derive from the use of blood and its stable and unstable products and accordingly request the Member States to enact legislation which will:

(a) apply to all those receiving transfusions,

(b) cover the risk from all viral agents which have been identified and can be diagnosed,

(c) shift the burden of proof on to those who manufacture the product responsible for the damage, by virtue of a proven fault, or those who authorize its use,

(d) where compensation is granted, will not remove the right to take legal action, if a criminal liability exists,

(e) take account of the fact that recognition of the risk must not prove an obstacle to the health professions being exercised with respect for medical ethics and professional standards;

5. Instructs its President to forward this resolution to the Commission and Council.

B

EXPLANATORY STATEMENT

Blood transfusion is the oldest and most widespread form of organ transplant used for therapeutic purposes. Once known as an empiric emergency measure subject to a high risk of error, blood transfusion has become a complex and sophisticated discipline requiring human skill and technology.

A distinction should be made between the various types of transfusion:

The transfusion of whole blood

While this was the only type known and used until a few decades ago, it is now indicated in no more than 1 - 2% of cases. It is used as a lifesaving measure in cases of acute and heavy blood loss (accidents - sudden vasal rupture, etc.).

Transfusion of corpuscular constituents

According to the specific needs of the case, transfusion may be made of red cells (chronic, primitive or secondary anaemia), white cells (serious infection in patients receiving treatment for tumours) and platelets (haemorrhaging due to serious thrombocytopenia). The preparation of the corpuscular constituents takes place immediately after collection using separation and fractioning techniques with or without freezing.

Transfusion of plasma and plasma derivatives

The plasma which is separated out from whole blood using simple physical means can be used as it is (serious hepatitis, some nutritional disorders) or treated to recover individual components of which the most important are:

- albumin,
- coagulation factors (in particular the antihaemophilic factors),
- immunoglobulins.

Whole blood is collected in transfusion centres or blood banks or through the Red Cross and other blood donor NGOs.

Each year 18 million units of blood (1 U = 450-500 ml) is collected across the regions represented in the Council of Europe, of which about 15 million is collected in the Community.

According to the Council of Europe report (the Van Aken report) published recently but which is based on data collected in 1988, only 3.5 million litres (equal to 7 million units) are fractionated to make blood derivatives.

The main source of plasma to produce blood derivatives is plasmapheresis carried out by the fractionating industry which prefers to use paid donors.

In Europe plasmapheresis is also used with voluntary donors in non-profit-making centres such as the Dutch Red Cross, the French CNTS, the Italian AVIS etc.

The yield from 'non-profit' plasma is greater on average than that from 'profit' plasma, varying between 115 AU to 280 AU per litre of factor VIII.

The degree of complexity now reached in the transfusion system at the end of the twentieth century means that it is not only an essential tool of therapy but also one which is not without its dangers. While the problems arising from the incompatibility of donors and recipients have been overcome, account must still be taken of the following factors when evaluating the risks :

A. biological agents liable to give rise to disorders may be transmitted through blood from the donor to the recipient. The most common are agents relating to viral infectious hepatitis (B or C), and the most widely known is the complex responsible for AIDS. Other less common agents may cause infections including hepatitis (non-A, non-B, non-C), encephalopathy, rarer microbial infections etc.

B. scientific progress has made it possible to identify the presence of pathogens in blood but does not make it possible to carry out the full range of diagnostic tests required to guarantee total safety;

C. the risk involved in transfusion varies, depending on many different factors:

   - the type of transfusion (whole blood, constituents, products derived from plasma),

   - the type of donor (regular voluntary donor, occasional voluntary donor, paid donor),

   - the type of disorder for which transfusion is required (emergency, sporadic, surgical or chronic disorders),

   - the method of withdrawal, the quality of tests, and processing and production methods.

It is possible to counter each of the main risk factors effectively using appropriate scientifically validated methods.

1. Where whole blood or its constituents are being used, the quality and safety of the product will depend on the careful selection and screening of donors and the safety standards maintained in the transfusion centre.

In the case of derivative products made using industrial processing techniques, other factors come into play:

- the source of the material: a pool of donors or an individual donor, plasmapheresis, placental plasma etc.

- the processes used for production and inactivation and/or removal of contaminants (high driver, solvents, detergents etc.).

2. The use of 'paid for' blood, apart from raising ethical problems (which we shall discuss later), has to be rejected because it increases the danger of transfusion. This is particularly true when the blood derivatives industry procures its raw material in poor countries from donors who are in a precarious state of health.

A study carried out in the US amongst 915 drug addicts showed that approx. 15% of them were paid blood donors even though 20% were seropositive.

Similarly 24.1% of drug addicts giving blood (out of the approx. 3000 cases examined) were found to be seropositive in a study made in Baltimore.

The situation is worse in India where there is 78% seropositivity amongst blood donors. This figure was given at the San Francisco conference on AIDS where the continuing trade in blood was described as a very real disaster because of the danger that it might set off or maintain new AIDS epidemics.

The risk is lower when the blood is taken, as in the European countries that allow it, from a controlled population at hygienically safe centres which have the proper technology.

It should be remembered nonetheless that the blood derivatives used in EEC countries are very largely made from plasma coming from third countries and taken under a 'for profit' regime.

3. The persons most at risk of infection are those in receipt of multiple transfusions including haemophiliacs. Before 1995 (when highly specific diagnostic tests became available), the rate of AIDS seropositivity was very high (20-40%) amongst haemophiliacs. Since 1985 the introduction of widespread screening has limited but not eliminated the risk of transmission. In the United States this residual risk, due to the so-called 'window effect' is estimated at one in 100 000; the risk is proportionally up to ten times less than this in regions with lower rates of seropositivity.

At the 'window effect' stage, a donor does not yet have antibodies but already carries the virus. As the only test available, the PCR test, is still at the experimental stage, this risk cannot be entirely eliminated for the moment.

THE SITUATION IN COMMUNITY COUNTRIES

	BELGIUM	DENMARK	GERMANY	SPAIN	GREECE	FRANCE
Haemophiliacs	707	350	3 285	2 730	n.a.	3 000
Seropositive	27	115	1 809	300	n.a.	1 200
AIDS patients						
Deaths		4	309	205		200

	ITALY	IRELAND	LUXEMBOURG	NETHERLANDS	PORTUGAL	UK
Haemophiliacs	2 839	300	a few	1 277	n.a.	7 877
Seropositive	768	106		150	n.a.	1 217
AIDS patients	137		1			228
Deaths						189

These figures show that no country in the European Community is free of HIV contamination through blood transfusion.

It should not be forgotten that contamination is possible from a single transfusion, for example during surgery.

There is thus a need to reduce the use of whole blood or its derivatives in line with the real need for each product in accordance with precise indications.

Controlled clinical studies show that this reduction is possible, both in surgery (by introducing and developing the practice of autotransfusion) and in the medical field by making wider use of protocols on the proper use of blood and its derivatives.

For example the use of albumin varies in EEC countries between 200 and 450 kg per million inhabitants. Council of Europe experts believe that any consumption over 250 kg per million inhabitants is based more on commercial factors than medical ones.

4. A big reduction in the risk is expected from the increasingly extensive use of products obtained using biotechnological methods.

Biotechnology is used :

(a) in the purification of factor VIII obtained by fractionation with a desired increase in yield,

(b) the production by genetic engineering in vitro of various factors (VIII, IX and albumin).

Biotechnologies ought to be encouraged and supported economically so that these derivatives can be introduced into the normal transfusion system as soon as possible.

At present two products have already obtained authorization to be placed on the market under the centralized Community procedure.

5. The complete transfusion chain must be kept under supervision with particular attention being given to the initial phase (protection of the donor) and the final phase (protection of the recipient).

Although some progress has been made, partly thanks to the issuing of GLP guidelines by the EC Commission, there are still many aspects giving rise for concern :

(a) not all Member States have donor data banks which would enable them to track down the source of any contamination and/or protect the health of the donor himself,

(b) producers and importers are not obliged to indicate the source of the raw material and the nature of the plasma used on the packaging of each batch,

(c) uniform systems to prevent infection of all units collected and then used in transfusions are not yet fully operational,

(d) the inspection tests and the assessment of the compulsory HILV-I or HB-C tests are not the same in all countries,

(e) viral inactivation methods used during production vary and some Member States do not have even one of the safe technologies (dry heat or chemical methods).

COMMUNITY MEASURES ON BLOOD TRANSFUSION

A. Rules on the substances used for blood transfusions

To ensure that such tragedies as those caused by infection with the HIV virus or, in future, any other virus through a blood transfusion do not recur or, at least, are kept to a minimum, the Community Member States must, in cooperation with the Council of Europe and the WHO, pool their efforts to guarantee that blood, plasma and their derivatives are of the highest possible quality.

A number of important measures have indeed already been set in hand :

1. First of all, Directive 89/381/EEC of 14 June 1989 laying down special provisions for medicinal products derived from human blood or human plasma stipulates that Community public health rules applying to medicinal products in general shall also apply to industrially prepared stable derivatives (coagulating factors, albumin and immunoglobulins). It also provides for the compulsory application of the measures relating to selection and testing of blood donors recommended by the Council of Europe and the World Health Organization. Member States must ensure that donation centres and donors are

clearly identifiable and that the same standards are applied to products imported from third countries.

The Commission subsequently adopted two directives, one on tests to check the quality, safety and efficacy of medicinal products derived from blood and the other on manufacturing processes applicable to all biological medicinal products. Lastly, in February 1991 the Committee on Patent Medicines approved guidelines on the validation of methods for eliminating and inactivating viruses.

2. In response to the AIDS epidemic, the Community as such reacted by adopting a decision containing a plan of action within the framework of the 1991-1993 'Europe against AIDS' programme. This action plan involves, in particular, 'fostering Community self-sufficiency in blood products by encouraging voluntary unpaid donors and continuing the efforts made to ensure transfusion safety' and 'estimating the costs of HIV infection'. Finally, Article 3 of the decision stipulates that 'the Commission shall submit to the Council a report on the subject during the second half of 1992. This report shall also be sent to the European Parliament'.

3. Lastly, the Commission, in conjunction with the Council of Europe, issued a detailed questionnaire to assess the blood transfusion situation, the results of which were used as a basis for the Van Aken report.

B. Legislation on contamination from transfusion

The Danish Government was the first, under pressure from the haemophiliacs' association, to adopt a decree on 2 September 1987 on compensation for all haemophiliacs and non-haemophiliacs contaminated by the AIDS virus following blood transfusions. In France, Article 47 of Law 91-1406 of 31 December 1991 on various social provisions (OJ of the French Republic, 4.1.1992, p.178), followed by Decree 92-183 of 26 February 1992 on the compensation fund (OJ of the French Republic, 27.2.1992, p.2990) provides for compensation to be paid to persons who have suffered injuries as a result of contamination by the AIDS virus following a blood transfusion or injection of blood derivatives carried out on the territory of the French Republic (Article 47(I)). In Italy, a law was recently adopted on this subject. In Belgium, no action has yet been taken on a plan for compensating seropositive haemophiliacs.

Although not all Member States have adopted general laws on payment of compensation, all of them will eventually be obliged to tackle the problem of paying compensation to persons infected with the HIV virus.

Certain governments, without wishing to recognize the State's responsibility in the matter, have set up, helped to set up or financed public or private compensation funds. This is the case in Spain (Victoria Eugenia Foundation), Ireland (the Trust Fund) and the United Kingdom (MacFarlane Trust).

Other countries have not yet taken direct action. In Germany, there is no public intervention mechanism. Compensation is paid by the insurance companies of firms considered responsible for supplying contaminated products after 1 January 1979. In the Netherlands, the government subsidizes the Dutch Haemophilia Society, which is represented in a private fund responsible for reimbursing AIDS-related expenditure of haemophiliacs and their families. However, there is no compensation as such. Luxembourg provides legal aid for contaminated haemophiliacs taking legal action.

Member States therefore have different approaches to the problem of compensation. This is partly due to differences in their legal traditions, but mainly to the blood transfusion system in each country. In France, for instance, the State is responsible for supervising blood transfusion centres, which means that it has special responsibility, unlike other countries.

Where compensation is provided, the amount paid varies from one country to another. The average amount of compensation paid to a contaminated haemophiliac is as follows: Denmark - Dkr 250 000 (approx. FF 212 000); Germany - DM 80 000 (approx. FF 270 000); Spain - Ptas 3 million (approx. FF 150 000). In France, the average amount before adoption of the 1991 law was FF 325 000; the rate of compensation is now established by a compensation committee. In Italy, the proposed amount is Lit 18 million (approx. FF 90 000). In Ireland the amount varies between £Irl 76 000 (approx. FF 722 000) for a contaminated spouse and £Irl 100 000 (approx. FF 950 000) for a person married with child. In the Netherlands there are plans for setting up a life assurance scheme involving monthly payments of Fl 125 (approx. FF 475) or capital in the event of death amounting to between Fl 8000 and 21 000 (approx. FF 24 000 - 63 000).

In the United Kingdom, compensation varies between £2000 (approx. FF 20 000) for an un-contaminated spouse and £60 000 (approx. FF 600 000) for a person married with child.

However, it is not only the amounts of compensation which differ. In certain cases only haemophiliacs receive compensation. Compensation may be obtained in certain cases if a person agrees not to take any further legal action. In certain countries evidence of contamination by transfusion must be provided by the victim. Limits on the period of contamination may also be set, e.g. between 1981 and 1985. Compensation may or may not be reassessed on the basis of the patient's medical progress, etc.

This very brief analysis of systems of compensation paid to persons contaminated by the HIV virus following a transfusion in the Community shows considerable disparities in the Member States' method of tackling the problem. It highlights the different approaches of health and social security systems, which are the responsibility of the Community Member States.

LIMITATIONS OF COMMUNITY LEGISLATION ON BLOOD TRANSFUSION

Article 1 of Directive 65/65/EEC (OJ No. 22, 9.2.1965, p. 369/65) defines a medicinal product as 'any substance or combination of substances presented for treating or preventing disease in human beings' and lays down that this definition shall apply whatever the origin of the substance and that it covers blood and blood products.

In spite of this, the Community exercises its own authority only over that group of blood products which take on their final therapeutic form after industrial type processing (albumin, immunoglobulines, coagulating factors etc.) which are held to be medicinal products.

It was to these and only to these that Directive 89/381/EEC extended all the provisions applicable to medicinal products in general as they have been laid down over the last 28 years (Community law on medicinal products, Vol. I-V).

This approach does not seem satisfactory bearing in mind the following:

- it is not logical for the Community to take responsibility for supervising the finished product (Articles 1, 2, 4, 5, 6 and 7 of Directive 89/381) but merely suggest to the Member States the measures it thinks necessary to supervise the 'starting material' (Article 3),

- the Maastricht Treaty now recognizes 'public health' as an immediate Community responsibility and not one derived from the need to safeguard health within the procedures which are primarily to do with the completion of the internal market. There is thus a change and a widening of the Community's authority in this area;

- Directive 89/381 does not achieve the aims which were meant for it. This may be due in part to the ambiguity of the law underpinning it (is transfusion a market problem or a problem of public health?) and in part the option taken of delegating functions to other organizations (Council of Europe, WHO) which really belong to the Community. These organizations produce reports and recommendations of great importance but they have neither the responsibility nor the power to issue regulations;

- a single method of collection, common standards on processing, and high Community standards for protecting the health of the recipient and the donor are all necessary in order for there to be a clear definition of the responsibilities and risks, including those to be borne by the manufacturers and professional people concerned.

Directive 89/381/EEC had three main aims:

- to establish the free movement of blood-derived products within the context of achieving a single market in pharmaceuticals,

- to extend the rules already applied to other pharmaceutical products to cover blood-derived products to ensure their quality, safety and efficacy,

- to promote as far as possible self-sufficiency throughout the Community by means of voluntary blood and plasma donation.

Very few Member States have so far brought the directive fully into force and it has become increasingly clear that implementation will depend on far-reaching changes being made. Over recent years a great debate has arisen on the difficulty of reconciling the directive with national legislation and positions taken on ethical and public health questions by the various Member States and indeed, on 15 May 1992 at the request of Belgium, France and the Netherlands, the Council asked the Commission to revise the directive in the light of the problems to which attention had been drawn.

It should also be recalled that in a document dating from January 1992 the Commission stated that it was 'possible' for discussions to begin on a 'cooperation' scheme on blood, unstable blood products, therapy protocols and self-sufficiency.

Since to our knowledge no such proposal has been made, it is as well that the European Parliament has taken up the matter and, through this own-initiative report, will be pressing for real and effective action.

Let us then turn to the main comments made about Directive 89/381.

Since the directive defines stable blood products as 'medicinal products', it brings them under the rules drawn up as part of the creation of the free market.

This has meant on the one hand laying down common requirements for obtaining a licence to put a product on the market, guaranteeing higher, uniform standards of safety, quality and efficacy and, on the other (and more importantly, in terms of the internal market), ensuring there are no obstacles to the free movement of authorized products in the Community.

De facto this cancels out the ethical choice made in many States which is to only use products which come from voluntary donors.

The unpaid collection of blood accords with a universally recognized ethical principle which states that the human body and its parts cannot be the subject of a commercial transaction (WHO Geneva 1991). In 1985 the Council of the Transplantation Society expressed concern about the selling of blood which 'opens the door to a trade in organs'. Experience since then has shown this to be all too true particularly in the case of countries where the trade in blood has been most common.

As we have already said, the Council of Europe has also recommended using unpaid donors pointing out the huge differences between those who sell their blood for profit (they do it from time to time when they are in a desperate situation; they do so without supervision; they give blood much more often than people are supposed to; they belong to the categories most at risk; they are in fact the poor selling to the rich!) and the volunteers who donate regularly (who do it with enthusiasm out of a sense of solidarity; they respect the rules on health;

they are under good supervision; they share the aim of improving the health of those receiving the blood; they are found in all classes of society).

It could, furthermore, be extremely difficult, from the economic point of view, to keep products obtained from unpaid collection on the market. Private fractionating companies which under the single market can establish themselves in any Member State they like, might in fact be operating at reduced cost since they do not have to bear the costs of collecting and distributing unstable products. Costs could be even lower for companies using plasma taken from poor donors in third countries who are paid very little.

In conclusion, although there may not seem to be any reason for not applying the 'ethical' definition of medicinal product to stable (or even unstable!) blood products, there is similarly no justification for forcing human raw material on to the market place where it is not meant to be!

The experience of some processing companies working with voluntary associations, which have managed to promote growth instead of demotivating it, shows that there is nothing to prevent the European Community deciding to use donors' blood only, and not bought blood, without in any way affecting the free movement of industrially processed products.

For this to come about however it is absolutely essential that the Community achieve self-sufficiency.

At the present time only some Community countries come close to self-sufficiency (the Netherlands, France, Belgium, the United Kingdom) but, as the Van Aken report has already demonstrated (q.v.), it is not out of the question for the other countries to reach it too!.

The strategies suggested by the Council of Europe for reaching self-sufficiency are:

1. separating fresh plasma from whole blood for fractionating purposes as a regular practice,

2. an extension of plasmapheresis programmes,

3. the extensive use of the best additive solutions to increase the proportion of plasma which can be extracted from each unit by 28%,

4. information on the best use of blood and plasma in accordance with well-defined medical instructions.

The Community cannot merely make recommendations on measures to promote self-sufficiency. What is needed is a well-constructed plan on blood, information campaigns, campaigns to encourage new donors to come forward, a sensible public health policy based on the accountability of the health authorities and closer forms of international solidarity. Neither should it be forgotten that a few hundred thousand regular plasma donors could meet the needs of Europe's population, particularly for factor VIII, almost all supplies of which at the present time are brought in from the United States.

CONCLUSIONS

By the end of 1992, the year in which the first results of Directive 89/381 were expected, it became clear that the Community's legislation enacted to allow only stable preparations derived from human blood to move freely within the Community is quite inadequate.

In particular it does not resolve and indeed seems to accentuate the ethical problems posed by blood collection and has done nothing to bring about self-sufficiency. This means that it has had little effect in preventing contamination with agents of infection, which is still possible. It is also true that the biological damage done whenever this occurs is assessed unevenly in the various countries of the Community.

The need to raise the standard of public health acknowledged in the Maastricht Treaty means that wider Community action must be taken which does not neglect the problems which have been raised thus far.

The Council of Europe report drawn up with the Commission's help, whilst it confirms the existence of considerable problems to do with meeting demand, standards of service and the risk of contamination states that it is possible to reach self-sufficiency within the Community by means of the voluntary unpaid donation of blood.

It is now up to the Community's Institutions to take action to ensure this objective is met.