COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION No. R (90) 9

OF THE COMMITTEE OF MINISTERS TO MEMBER STATES

ON PLASMA PRODUCTS AND EUROPEAN SELF-SUFFICIENCY

(Adopted by the Committee of Ministers on 29 March 1990
at the 436th meeting of the Ministers' Deputies)

The Committee of Ministers, under the terms of Article 15.*b* of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, *inter alia*, by the adoption of common regulations in the health field;

Recalling its Resolution (78) 29 on harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances;

Recalling also its Recommendations No. R (80) 5 concerning blood products for the treatment of haemophiliacs, No. R (81) 14 on preventing the transmission of infectious diseases in the international transfer of blood, its components and derivatives, No. R (85) 12 on the screening of blood donors for the presence of Aids markers, No. R (84) 6 on the prevention of the transmission of malaria by blood transfusion and No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion;

Recalling the principles underlying the above recommendations, namely that, for both ethical and clinical reasons, blood donations should be voluntary and non-remunerated, that optimal use should be made of blood, and that member states should be self-sufficient for blood components and plasma derivatives;

Considering that these principles are in line with the ideals upheld by the Council of Europe;

Considering the particular importance of plasma derivatives in modern haemotherapy and that the need for source plasma for the preparation of coagulation factors is increasing in view of new methods of viral inactivation and higher use of concentrates in modern haemophilia therapy;

Considering that in many member states this need of source plasma is covered through importation from countries not following the principles established by the Council of Europe;

Considering that progress in gene engineering technology does not yet provide a solution for the production of plasma products;

Considering that respect of this principle is also important from a clinical and strategic point of view for the safety of products and especially the prevention of the transmission of infectious agents;

Considering the positive experience of some European countries in attaining self-sufficiency for plasma products through voluntary, non-remunerated donation and the need to harmonise policies in a European context, especially as concerns collection and use of human substances,

Recommends the governments of member states to:

i. promote self-sufficiency for plasma products on the basis of voluntary non-remunerated donation;

ii. improve co-ordination of the collection and production of plasma products, where appropriate in co-operation with other member states, by mobilising the necessary means in terms of finances, equipment and staff;

iii. draw up, in co-operation with other member states, European guidelines for the rational use of products;

iv. follow to this end the principles contained in the appendix to this recommendation.

Appendix to Recommendation No. R (90) 9

Objective: Achieving self-sufficiency for plasma products on the basis of voluntary non-remunerated donation

Health authorities of countries not having achieved self-sufficiency of source plasma should take the necessary measures to reach this goal as soon as possible.

For the collection of source plasma a country should rely exclusively on voluntary, non-remunerated donation for:

— ethical reasons, in order to guarantee full respect of the health of the donor;

— clinical reasons, in order to avoid as much as possible the risk of transmission of infection;

— social justice reasons, in order to ensure participation in donation by all social strata of the population, irrespective of economic status;

— reasons of independence from importation and hence stability in the supply of products and their pricing.

Methods: Establishing a co-ordinated plasma programme

In connection with promotion of donation, health authorities (HAs) should have an ongoing policy of informing donors that, although some products such as Factor VIII may be manufactured by gene technology, other essential products will continue to be derived from fractionation of human plasma.

In connection with collection HAs should:

— evaluate the needs for plasma products on the basis of scientific, clinical and technical criteria, and for this purpose:

- promote the collection of relevant statistics to assist them;

- institute a co-ordinated monitoring system allowing for constant assessment of the balance between needs and resources;

— improve the co-ordination of the collection of source plasma through voluntary, non-remunerated donation setting time limits for specific objectives, and bearing in mind the following factors of singular importance for increasing plasma procurement:

- whole blood and plasma should not be used when cellular components and plasma volume expanding solutions are equally or more clinically effective and safe;

- the use of optimal additive solutions should be promoted for suspension and storage of red cells in order to improve the yield of plasma;

- where sufficient plasma to meet fractionation needs cannot be recovered from whole blood donation, plasmapheresis should be promoted within the framework of blood transfusion services;

- research to increase Factor VIII yields should be promoted, with investment where appropriate, since essential steps to ensure safety of products have significantly reduced such yields.

In connection with production, HAs should:

— evaluate public and private fractionation capacities;

— establish co-ordination of fractionation activities at national and/or European level to better use existing facilities.

In connection with use of products HAs should:

— promote the adoption of modern principles of haemotherapy based on scientific and clinical criteria avoiding waste of precious human source material.

In connection with research and development HAs should:

— encourage ongoing programmes for product research and development aiming at the adoption of strict clinical indications;

— due to the very rapid developments in the use of biotechnology for haemotherapy products, blood transfusion services should increase their involvement in this field to ensure a smooth transition from old to new technology;

— consider, in consultation with blood transfusion services, the benefits of distributing biologically engineered haemotherapy products through blood transfusion services.

In connection with finances, HAs should:

— endeavour to identify the costs of cellular components and fractionated products so that pricing imbalances will not adversely affect self-sufficiency.

In connection with European co-operation, HAs should:

— co-operate closely to achieve European self-sufficiency in the framework of the European Community and the Council of Europe and to determine complementary strategies for the collection of source plasma, fractionation and provision of products;

— introduce legislation to require that when products are traded from one member state to another or imported into Europe, these should carry information about the origin of source plasma.

Means: Mobilising the necessary resources

HAs should materialise their commitment to non-commercialisation of human substances by mobilising the necessary means in terms of:

— expertise to formulate a co-ordinated strategy and draft the necessary guidelines;

— financial support for the promotion of donation campaigns and where necessary for plasmapheresis programmes;

— issuing of regulations to implement measures allowing for optimal recuperation of plasma;

— investment, if appropriate, in activities related to production, research and development;

— promoting the setting up of criteria for rational use of products and monitoring of blood use;

— initiating consultation with other member states to set up a calendar of action in order to reach self-sufficiency at European level.