COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION No. R (88) 4

OF THE COMMITTEE OF MINISTERS TO MEMBER STATES

ON THE RESPONSIBILITIES OF HEALTH AUTHORITIES IN THE FIELD OF BLOOD TRANSFUSION

(Adopted by the Committee of Ministers on 7 March 1988 at the 415th 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 the 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 (83) 8 on preventing the possible transmission of acquired immune deficiency syndrome (AIDS) from affected blood donors to patients receiving blood transfusions and No. R (84) 6 on the prevention of the transmission of malaria by blood transfusion;

Recalling the principles underlying the above recommendations, namely that, for both ethical and clinical reasons, blood donation should be voluntary and non-remunerated and that optimal use should be made of blood;

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

Conscious of the fact that availability of blood products for the benefit of all patients depends on the recruitment of donors and the existence of a co-ordinated network of blood transfusion services;

Considering the need to ensure maximum protection of both donors and recipients and that progress made in the protection of recipients has also revealed its value in promoting the health of the population as a whole;

Considering that self-sufficiency with respect to blood products is one of the basic conditions for minimising the hazard of the transmission of infectious diseases by blood transfusion;

Conscious that the increasing use of blood and blood products as therapeutic substances throughout member states calls for a well-defined policy relating to blood transfusion and that increasing exchanges of blood products between member states calls for their harmonisation,

Recommends the governments of member states to bring their policy into conformity with the principles contained in the appendix to this recommendation.

Appendix to Recommendation No. R (88) 4

Definitions

1. The term "transfusion" is meant to cover all activities in connection with promoting the collection of blood, collecting, preparing, conserving, distributing blood, in addition to its administration.

2. The terms "blood" or "blood products" are meant to include all therapeutic substances derived from blood: whole blood, blood components and plasma derivatives.

Article 1

Health authorities (HAs) should have an obligation to promote the adoption of policies in line with the ethical principles of voluntary, non-remunerated blood donation; these principles ensure maximum security for the health of both donors and recipients.

Article 2

The organisation of transfusion at country level should be the responsibility of the HAs; they should in particular assume responsibility, either directly or indirectly, for the establishment of a country-wide collection, preparation and distribution programme so as to cover all the stages of transfusion and to meet the population's actual needs regarding blood-based therapeutic substances of human origin.

Article 3

HAs may decide to entrust all or part of the transfusion programme to non-governmental bodies and to supervise their activities; activities in connection with the promotion of donation of blood and plasma should be entrusted only to non-profit-making agencies; where this is not already the case, countries should seek to apply the same principle in respect of the collection of blood and plasma.

Article 4

To avoid wastage of blood as well as of technical and financial resources in the form of staff and equipment, HAs should ensure co-ordination of all activities of the transfusion programme, whether under their direct or indirect control.

Article 5

HAs should ensure that patients have access to all blood products in the most favourable conditions for applying the most appropriate treatment; this objective can be achieved either by providing blood products free of charge or through a system of social security or any other appropriate system of insurance of the patient; where the product is governed by reimbursement regulations, its price should be adjusted to cover its cost to the transfusion service, including promotion of blood donation, research and development.

Article 6

HAs should be responsible for regularly assessing the need for blood on the basis of scientific, clinical and technical criteria; it should be possible, by means of the assessment, to organise and co-ordinate transfusion activities in such a way that, as a result of adequate blood donor recruitment, blood products are available throughout the country.

Article 7

HAs should make provision for the periodical assessment of the quality and proficiency of transfusion services through suitable arrangements; to ensure the safety of transfusion for both donors and recipients, HAs should make provision for internal and external quality control throughout all the stages of the transfusion programme.

Article 8

HAs should foster close co-operation between the medical staff of transfusion centres and patient care services in order to enable optimal use of blood and thereby avoid wastage.

Article 9

When there is a shortage of blood, the physician in charge of the transfusion centre may have to decide on priorities in consultation with the attending physician(s).

Article 10

HAs should advocate the establishment of a transfusion and post-transfusion monitoring procedure so as to allow for the identification of possible risk factors involved in the preparation of blood products which are only detectable by epidemiological studies.

Article 11

A programme of self-sufficiency should be organised for blood and plasma. Pending the achievement of self-sufficiency, HAs may decide to authorise the importation of blood products. For ethical and security reasons, it is recommended that blood products are imported from countries where the legislation and practice governing the protection of donors and recipients meet the criteria laid down.

Article 12

Concerning the importation of blood and plasma products, the HAs of the importing countries should ask the competent authorities and/or producers in the exporting countries for the necessary guarantees and details of the means used to ensure the security of both donors and recipients; they should, in particular, ascertain the origin of blood and plasma which have been used as a source in the preparation of the exported products.

Article 13

If so requested by the importing country, HAs should not allow the exportation from their country of products which do not comply with their national standards or with the World Health Organisation's certification scheme on the quality of pharmaceutical products moving in international commerce.

Article 14

HAs should ensure that adequate compensation is provided for in the event of complications directly or indirectly related to the taking of blood; to this end, HAs should establish a system of rapid and appropriate compensation regardless of any action for redress between the parties, with regard for the principle of human solidarity which is the basis of blood donation.

Article 15

A donor should not be held liable for an accident occurring to a recipient following the administration of a product derived from the donation of his blood.

Article 16

Transfusion is a medical activity; as such, it should be covered by legislation and regulations covering liability.

Article 17

HAs should make provision, through the network of transfusion centres, for national and international exchanges of blood if the need arises, for updating donor files, including information to meet histocompatibility problems, and for the establishment of at least one reference laboratory.

Article 18

HAs should secure the help of an advisory body for transfusion matters composed from among their own representatives, blood transfusion specialists and directors of blood transfusion centres; its function should be to consider and co-ordinate all questions concerning transfusion and advise on co-ordination issues.