COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION No. R (95) 15

OF THE COMMITTEE OF MINISTERS TO MEMBER STATES ON THE PREPARATION, USE AND QUALITY ASSURANCE OF BLOOD COMPONENTS

(Adopted by the Committee of Ministers on 12 October 1995 at the 545th 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 action 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 (84) 6 on the prevention of the transmission of malaria by blood transfusion, No. R (85) 12 on the screening of blood donors for the presence of Aids markers, No. R (86) 6 on guidelines for the preparation, quality control and use of fresh frozen plasma, No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion and No. R (93) 4 concerning clinical trials involving the use of components and fractionated products derived from human blood or plasma;

Taking into account the Council Directive 89/381/EEC 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 human plasma;

Taking into account Agreement No. 26 on the exchange of therapeutic substances of human origin;

Considering the importance of blood components in modern haemotherapy and the necessity to ensure their safety, efficacy and quality;

Considering that such components are of human origin and that hence specific ethical and technical principles have to be taken into account;

Considering the need for harmonisation of such principles in member states;

Considering that biotechnology does not provide substitutes for most blood products;

Convinced, therefore, of the need to provide health authorities, transfusion services as well as hospital blood banks and clinical users with a set of guidelines for the preparation, use and quality assurance of blood components;

Aware that the *Guide to the preparation, use and quality assurance of blood components* published by the Council of Europe has already become the generally-accepted European standard and that it is therefore appropriate to give a legal basis to this guide;

Considering that this guide will be regularly updated by the committee of experts of the Council of Europe,

Recommends that the governments of member states take all necessary measures and steps to ensure that the preparation, use and quality control of blood components are carried out in accordance with the guidelines set out in the appendix[1] to this recommendation.

1. The appendix is available from the Publishing and Documentation Service under the reference *Guide to the preparation, use and quality assurance of blood components*, ISBN 92-871-2687-9.