Recommendation No R(96)11 of the Committee of Ministers to member states on documentation and record-keeping to guarantee the traceability of blood and blood products especially in hospital

(adopted by the Committee of Ministers on 2 October 1996, at the 574th 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;

Considering that whereas blood transfusion and blood products are given for the purpose of saving life and improving the health of the recipient but that sometimes they may inadvertently lead to transmission of disease or other undesired side effects;

Considering the importance of taking any necessary measures which will diminish the risk of such transmission, particularly for hepatitis B and C;

Recalling 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 (88) 4** on the responsibilities of health authorities in the field of blood transfusion, No. **R (95) 14** on the protection of the health of donors and recipients;

Recalling also the guidelines and principles defined in Recommendation No. **R (95) 15** on the preparation, use and quality assurance of blood components;

Bearing in mind the Council Directive of the European Communities 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 and the associated guidelines together with the requirements for market authorisations;

Bearing in mind Resolution 6936/95 of the Council of the European Union on blood safety and self-sufficiency in the European Community,

Recommends that the governments of member states ensure that measures are taken to ensure traceability of blood and blood products from the donor to the recipient, as well as from the recipient back to the donor, in accordance with the principles set out in the appendix to this recommendation.

Appendix to Recommendation No. R (96) 11

A. Field of application

This recommendation applies to :

i. the unit (static or mobile) collecting the blood or plasma;

ii. the blood bank in the hospital;

iii. the operating theatre, ward or clinic where the blood or blood product is transfused.

Note: i. and ii. may be one and the same entity.

B. Principles

National health authorities are responsible for determining the general principles under which blood transfusion operates in each country. The principles of good practice set out below are designed to ensure two-way traceability of blood and blood products from donors to recipients and recipients to donors. Because blood or blood products may cross national boundaries, traceability should also be ensured at the international level.

i. Unit collecting the blood or plasma

1. Details of the donor of any donation should be registered at the unit collecting the blood or plasma. These should include name, address and date of birth. Hard copy or computer records are acceptable.

2. All personal details should remain confidential and be kept in a secure place. Access should only be allowed to those who have a need to know.

3. Each donation should be given a reference number, preferably using a bar code. Each component from that donation should have the same number to which may be given a subsidiary code, if appropriate. Labelling should comply with the relevant national legislation and international agreements and should particularly include the producer's name and address (see Recommendation No. R (95) 15). Where components from individual donations are pooled to provide the required therapeutic dose (for example platelets), there must be a secure numbering system that allows all components of the pool to be traced.

4. Samples for testing for blood groups and markers of infection should be labelled with the relevant code number of the donation.

5. The detailed results of these tests, together with the relevant donation numbers, should be noted on a results sheet.

6. The blood group, and where appropriate the phenotype, should be given on the vessel containing the donation. Such information should also be entered in the confidential database.

7. The destination of each donation and of each component should be noted in a register. This must state whether the donation was sent for clinical use, for fractionation, for research or whether it was discarded.

8. The register should also give the precise address to which the donation or component was sent together with the person responsible for its receipt.

9. The transfusion unit should be able to identify the donor of any suspect donation.

10. The transfusion unit should be in a position to inform the blood bank quickly in the event that it discovers some problem with a donation. The blood bank should be in a position to identify the recipient.

ii. The blood bank in the hospital

11. The hospital blood bank should keep a register of each donation or component or blood product received. This should state the date and time of receipt and the relevant code or batch number.

12. When the hospital blood bank receives a request for blood or a blood product it should ensure that the request form contains details of the name and date of birth of the intended recipient and ward or clinic where the blood is to be sent. Details of the consultant responsible for the recipient should also be included. These details should be entered on a register in the blood

bank against the code or batch number for the blood or blood product.

13. The hospital blood bank should also ensure that it has received a sample from the intended recipient for grouping and cross-matching.

14. Where the laboratory responsible for testing the potential recipient is different from the hospital blood bank, it should also document the details of the recipient and the donation, applying the principles given above.

iii. The operating theatre, ward or clinic where the blood or blood products are transfused

15. The physician prescribing the transfusion or the nurse affecting it should ensure that details of the component or product being transfused are entered in the recipient's hospital notes. These data should include as a minimum the component or product name (for example erythrocytes, platelets, Factor VIII), the donation or batch number and blood group, where appropriate. They may be entered by removing part of the label and sticking it in the notes. In the case of fractionated blood products there is usually no label and so the details must be written in by hand.

16. It is particularly important to record these details in cases of acute emergency where life-saving measures may prevent immediate attention to these points.

17. Any untoward reaction is to be reported as soon as possible to the blood bank giving the donation or batch number involved, for example the occurrence of jaundice, haemolysis or anaphylaxis. These should be investigated at the place of transfusion and the detailed results should be made available to the blood bank and through it to the collecting unit as soon as they are available. Appropriate action should be taken locally and the collecting unit - and through it the blood bank - is to inform those to whom other fractions of that donation or previous donations have been sent if this is necessary.

iv. General

18. The time for which records are kept is determined by local or national requirements. The appendix to Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components states that the period should be at least 10 years. Samples used for microbiological testing should be retained for a period which takes account of the likelihood of a late report of an adverse reaction and of the amount of freezer space available.

19. Donations, components and products should be visually checked. If there is any indication whatsoever of a physical anomaly the transfusion centre should be informed and the suspect products should be returned to it. This should be noted in the registers at both the hospital blood bank and the transfusion centre.

20. Physicians, medical students and nursing staff should be educated to recognise adverse and unexpected reactions to blood or blood products. There should be an agreed protocol with the haematologist over what action is to be taken and how the event is to be reported.

v. Fractionated blood products

21. In the case of fractionated blood products, these may go directly from the fractionator or supplier to the physician treating the patient or to the hospital pharmacy or to the hospital blood bank. In these cases records need to be scrupulously kept by each department through which the product has passed. The physician should be able to identify the relevant recipient and the fractionator/supplier should be able to identify the relevant pool and from this information the relevant blood transfusion centre.

22. In the case of fractionated blood products used in home therapy, the hospital clinic needs to keep records of the batch numbers of supplies of blood products given to individual patients. Individual patients should keep a note of the batch number of products and the date when they are used. This is especially important where, for instance, brothers may share the same supply of Factor VIII.

23. For licensed pharmaceutical products it is necessary to follow national legal requirements in respect of responsibility for pharmacovigilance.

24. It also needs to be recalled that some blood products may be added as stabilisers, etc., to other pharmaceutical products