COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

Recommendation Rec(2003)11
of the Committee of Ministers to member states
on the introduction of pathogen inactivation procedures for blood components

(Adopted by the Committee of Ministers on 19 June 2003
at the 844th 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 among its members and that this aim may be pursued, *inter alia*, by the adoption of common action in the health field;

Taking account of the ethical principles set out in Recommendation No. R (88) 4 on responsibilities of health authorities in the field of blood transfusion;

Recalling its Recommendation No. R (95) 14 on the protection of the health of donors and recipients in the area of blood transfusion;

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

Welcoming the report on pathogen inactivation of labile blood products, produced by the European Health Committee (CDSP), setting out the benefit/risk and cost/benefit ratios of these procedures;

Recommends to governments of member states to take account of the following consideration regarding the introduction of pathogen inactivation procedures for blood components, if necessary by the relevant competent authorities:

1. current safety standards of blood components are high;

2. incremental costs of pathogen inactivation procedures are high in relation to the additional safety gained;

3. the cost effectiveness of pathogen inactivation methods and the evidence of health gain for the individual have not been established;

4. pathogen inactivation methods may have a negative impact on the efficacy of blood components and may harbour unexpected long-term adverse effects.