



COUNCIL OF EUROPE    CONSEIL DE L'EUROPE  
Committee of Ministers  
Comité des Ministres

## **Resolution CM/Res(2008)5 on donor responsibility and on limitation to donation of blood and blood components**

*(Adopted by the Committee of Ministers on 12 March 2008  
at the 1021st meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia,<sup>1</sup>

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

Taking account of the ethical principles set out in the Committee of Ministers' Recommendation No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion, and in particular Article 1 on voluntary non-remunerated blood donation;

Taking into account the requirements set out in Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components;

Considering the inherent risks of human blood and therapeutic substances of human origin,

Recommends that the governments of States Parties to the Convention:

1. ensure that blood components are produced solely from blood collected from safe blood donors;
2. foster co-operation and trust between blood establishments and blood donors, in particular by informing the public about the need and criteria for selection of blood donors;
3. guarantee that blood establishments provide prospective donors with clear and appropriate information, including at least the following:
  - 3.1. the essential nature of blood, blood donation procedure, testing of collected blood, components derived from collected blood;
  - 3.2. possible risks to the health of the donor associated with blood donation;
  - 3.3. possible risks for the recipient of blood or blood components of a given donor;
  - 3.4. the donor's duty to provide the blood establishment with all relevant information to the best of his/her knowledge, in particular on factors and activities which may increase risks for the recipient;
  - 3.5. the right to withdraw from donation at any time during the procedure for any reason, including doubts as to his/her suitability as a donor without any need to explain this decision;

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<sup>1</sup> Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey and United Kingdom.

- 3.6. the importance for the donor to give the blood establishment post-donation information if the donor has doubts about his/her suitability or in the event of change in health status after donation;
  - 3.7. the consequences of failure to provide the information as specified above during the donor assessment procedure;
  - 3.8. the confidentiality of all personal information given by donors to the blood establishment, notably those related to health and behaviour;
4. ensure that blood establishments are ultimately responsible for the quality and safety of the blood and blood components collected; in particular, blood establishments should:
    - 4.1. be responsible for the final acceptance or deferral of donors on the grounds of a risk assessment based on regularly updated epidemiological data, and bearing in mind the right of blood recipients to the protection of their health, and the resulting obligation to minimise the risk of transmission of infectious diseases. These rights and obligations override any other considerations, including individuals' willingness to donate blood;
    - 4.2. set up arrangements for fair compensation providing for cases where harm is caused to the recipient and/or the donor of blood and blood components.