



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 23.8.2002
COM(2002) 479 final

2000/0323 (COD)

OPINION OF THE COMMISSION

**pursuant to Article 251 (2), third subparagraph, point (c) of the EC Treaty,
on the European Parliament's amendments
to the Council's Common Position regarding the**

proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**setting standards of quality and safety for the collection, testing, processing, storage, and
distribution of human blood and blood components and amending
Council Directive 2001/83/EC**

**AMENDING THE PROPOSAL OF THE COMMISSION
pursuant to Article 250 (2) of the EC Treaty**

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1. INTRODUCTION

Article 251(2), third subparagraph, point (c) of the EC Treaty provides that the Commission is to deliver an opinion on the amendments proposed by the European Parliament at second reading. The Commission sets out its opinion below on the eight amendments adopted by Parliament.

2. BACKGROUND

On 26 January 2001, the Commission submitted to the Council and to the European Parliament a proposal based on Article 152 of the EC Treaty for a Directive of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 2001/83/EC (COM (2000) 816 final) - 2000/0323(COD).

The Economic and Social Committee and the Committee of the Regions delivered their opinions on 30 May and 20 September 2001 respectively.

On 6 September 2001, the European Parliament delivered a first opinion on the Commission proposal and adopted a report with 70 amendments.

On 15 November 2001, having examined the amendments proposed by the European Parliament, the Commission adopted an amended proposal in accordance with Article 250 of the EC Treaty.

On 14 February 2002, the Council adopted its Common Position in accordance with Article 251 of the EC Treaty.

The Commission delivered its opinion on the Common Position on 26 February 2002.

On 12 June 2002, the European Parliament adopted its second reading legislative resolution, including eight amendments to the Common Position of the Council.

3. OBJECTIVE OF THE COMMISSION'S PROPOSAL

The proposal is for a Directive of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 2001/83/EC. It attempts to close the existing gap in Community legislation related to ensuring a high quality and safety of blood and its components. It aims to:

- Set standards for the quality and safety of blood and blood products used in therapy;
- Strengthen requirements related to the suitability of blood and plasma donors and the screening of donated blood in the European Community;
- Establish at Member State level requirements for establishments involved in the collection, testing, processing, storage and distribution of whole blood and blood components, as well as national accreditation and monitoring structures;
- Lay down provisions at Community level for the formulation of a quality system for blood establishments;
- Lay down common provisions at Community level for the training of staff directly involved in the collection, testing, processing, storage and distribution of whole blood and blood components, without prejudice to existing legislation; and
- establish rules for ensuring the traceability of whole blood and blood components from donor to patient, which are valid throughout the Community.

4. OPINION OF THE COMMISSION ON THE AMENDMENTS BY THE EUROPEAN PARLIAMENT

The second reading report of the European Parliament is based on the Common Position.

The following paragraphs provide the Commission' comments on each of the amendments. Prior to the vote in Plenary session, the Commission stated that it could fully accept six amendments (9, 12, 13, 15, 25, 27), partially accept two (14, 20) and reject none. In view of the results of the vote in Parliament and in order to facilitate a final agreement on these amendments between Council and Parliament, the Commission now considers it justified to accept all amendments fully.

Amendments that can be accepted by the Commission

- **Amendment 9** presenting a definition of 'inspection' is acceptable.
- **Amendment 12** requiring haemovigilance data to be maintained for at least 30 years is acceptable to the Commission even though onerous. A less onerous but also effective alternative could be to limit the application of the 30-year time period only to traceability data (a major component of haemovigilance data).
- **Amendment 13** requiring Member States to report on voluntary unpaid donations to the Commission every three years is acceptable as it coincides with the general reporting requirements.

- **Amendment 14** requires that blood-donation testing is conducted in line with procedures reflecting best practices as defined, reviewed and updated in consultation with experts. This is already foreseen in the Directive through the Comitology framework in Article 27 and 28 as well as through the scientific committees foreseen in Article 29. These would ensure an appropriate expert update and review process for the tests to be used, taking into account scientific progress. This amendment, therefore, is acceptable to the Commission.
- **Amendment 15** providing for meetings of the Commission with delegations of experts is acceptable to the Commission.
- **Amendment 20** states that voluntary unpaid donations **ensure** a high level of health protection. While the Commission would prefer replacing the words ‘**to ensure** a high level of health protection’ by ‘**in order to contribute to ...**’, it is prepared to accept the text in order to obtain agreement.
- **Amendment 25** obliging an examination of donors is acceptable to the Commission.
- **Amendment 27** presenting a definition of ‘haemovigilance’ is acceptable to the Commission.

5. CONCLUSION

The Commission is in favour of the eight amendments to the Common Position voted by the European Parliament.