Appendix 8
(Item 6.5a)

Terms of reference of the European Committee (Partial Agreement) on blood transfusion (CD-P-TS)

Fact sheet

Name of Committee:	European Committee (Partial Agreement) on blood transfusion (CD-P-TS)
Compliance with Resolution Res(2005)47:	YES, except for the term of office of chairperson (three years instead of one, renewable once).
Programme of Activities: project(s)	Under the authority of the Committee of Ministers, in its composition restricted to the representatives of the States members of the Partial Agreement of the Convention on the Elaboration of a European Pharmacopoeia, the Committee shall undertake the following actions: • examine questions related to human blood transfusion, notably as regards quality and safety standards and their implementation, including collection, preparation, storage, distribution and appropriate use; • assist member states in improving and, if needed, in restructuring their blood transfusion services by promoting principles of voluntary non-remunerated donations; • propose ethical, safety and quality standards on professional practices and on specifications of products; • ensure the transfer of knowledge and expertise and develop competencies of experts through training and networking; • monitor practices in Europe and assess epidemiological risks, in particular of the emergence of new transmissible diseases linked to blood and blood components; • promote quality assurance with the latest developments including the updating of the technical appendix to Recommendation R (95) 15 on the preparation, use and quality assurance of blood components; • ensure availability of rare blood products by means of the European Data Base and Bank of Frozen Blood of Rare Groups, according to the European Agreement on the Exchange of Therapeutic Substances of Human Origin (ETS No. 026).
Project relevance:	The importance of elaborating and promoting high ethical, safety and quality standards in the field of blood transfusion: • the European Agreement on the Exchange of Therapeutic Substances of Human Origin (ETS No. 026); • the Recommendation R (95) 15 of the Committee of Ministers to member states on the preparation, use and quality assurance of blood components.
Project added value:	• The Council of Europe is a leading regional agency in this field with a number of recommendations and 15 editions of the Guide to the preparation, use and quality assurance of blood components and Questionnaire on the collection, testing and use of blood and blood components in Europe; • the EC Directives take into account and refer to the Council of Europe documents;

	• the Council of Europe organises, jointly with the EU, a new external quality assessment international programme (PTS/QA) for the testing laboratories in the blood services; • the Council of Europe organises important assistance activities, in particular, in non-EU member states; • duplication is avoided by the close co-operation with the EC and the WHO.
Financial information:	The Committee in plenary meets at least once a year. The sending authorities of the member states will bear the travel and subsistence expenses for their representatives' participation in the meetings of the CD-P-TS. The budget for this activity is set out in Part 5 of the document CM(2009)130 Vol 3 which was adopted by the Committee of Ministers on 25 November 2009 (CM/Res(2009)30).

Terms of reference of the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS)

1. Name of Committee: European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS)

2. Type of Committee: Steering Committee (Partial Agreement)

3. Source of terms of reference: Committee of Ministers, in its composition restricted to the representatives of the States members of the Partial Agreement of the Convention on the Elaboration of a European Pharmacopoeia

4. Terms of reference:

Having regard to:

- the importance of elaborating and promoting high ethical, safety and quality standards in the field of blood transfusion;
- the European Agreement on the Exchange of Therapeutic Substances of Human Origin (ETS No. 26);
- the Convention on Human Rights and Biomedicine (ETS No. 164);
- Recommendation R (95) 15 of the Committee of Ministers to member states on the preparation, use and quality assurance of blood components;
- the orientations of the 7th Conference of European Health Ministers (Oslo, 2003) entitled "Health, dignity and human rights".

Under the authority of the Committee of Ministers, the Steering Committee (hereinafter the "CD-P-TS") shall undertake the following actions:

a. examine questions related to human blood transfusion, notably as regards quality and safety standards and their implementation, including collection, preparation, testing, storage, distribution and appropriate use;

b. assist member states in improving and, if needed, in restructuring their blood transfusion services by promoting principles of voluntary non-remunerated donations;

c. taking into account ethical aspects, propose safety and quality standards on professional practices and on specifications of products;

d. ensure the transfer of knowledge and expertise and develop competencies of experts through training and networking;

e. monitor practices in Europe and assess epidemiological risks, in particular of the emergence of new transmissible diseases linked to blood and blood components;

f. promote quality assurance with the latest developments including the updating of the technical appendix to Recommendation R (95) 15 on the preparation, use and quality assurance of blood components; in particular by pursuing the regular update, revisions and further developments of the "Guide to the preparation, use and quality assurance of blood components", its regular publication and promote its implementation;

g. ensure availability of rare blood products by means of the development of a European Data Base and Bank of Frozen Blood of Rare Groups, taking into account the European Agreement on the Exchange of Therapeutic Substances of Human Origin (ETS No. 26);

h. approve proposals for resolutions prepared for adoption by the Committee of Ministers, in its composition restricted to the representatives of the States members of the Partial Agreement of the Convention on the Elaboration of a European Pharmacopoeia. The latter may submit proposals for consideration by the Committee of Ministers in its full composition;

i. monitor the implementation of the above-mentioned activities and in particular revise and update any resulting documents concerning blood transfusion;

j. co-operate with the Steering Committee on Bioethics (CDBI) in the implementation of the Convention on Human Rights and Biomedicine (ETS No. 164) as far as blood transfusion is concerned;

k. while taking account of the progress of its work, prepare, under its own responsibility, proposals for the Programme of Activities for the coming years.

5. Composition:

5.A Members

Governments of Council of Europe States members to the Convention on the Elaboration of a European Pharmacopoeia are entitled to appoint a representative with expertise in area covered by these terms of reference. Each member shall have one vote.

The sending authorities of the member states will bear the travel and subsistence expenses for their representatives' participation in the meetings of the CD-P-TS.

A special assistance programme including support for attending relevant meetings can be applied to those member states which present a justified request to the CD-P-TS. If the request is approved, the travel and subsistence expenses will be borne by the EDQM's specific budgetary appropriations.

5.B Participants

The following committees may each send representatives to meetings of the CD-P-TS, without the right to vote and at the charge of the corresponding heads of the Council of Europe budget:

- European Health Committee (CDSP);
- Steering Committee on Bioethics (CDBI).

The CD-P-TS may invite representatives of other committees and bodies of the Council of Europe to specific meetings, depending on the agenda of the respective meeting, without the right to vote and at the charge of the corresponding heads of the Council of Europe budget.

5.C Other participants

i. Council of Europe member states other than those mentioned above under 5.A and other states with observer status with the European Pharmacopoeia Commission may send a representative to the meetings of the CD-P-TS, without the right to vote or defrayal of expenses.

ii. A special assistance programme including support for attending relevant meetings can be applied to those member states which present a justified request to the CD-P-TS. If the request is approved, the travel and subsistence expenses will be borne by the EDQM's specific budgetary appropriations.

iii. The European Union is entitled to appoint a representative to meetings of the CD-P-TS, without the right to vote or defrayal of expenses.

iv. The World Health Organisation (WHO) may send a representative to meetings of the CD-P-TS, without the right to vote or defrayal of expenses.

5.D Observers

Any international non-governmental organisation active in the field may ask for observer status with the CD-P-TS and be allowed to send a representative to its meetings, without the right to vote or defrayal of expenses.

Observer status is granted on the basis of a unanimous decision by the CD-P-TS. In the event where unanimity is not reached, the matter may be referred to the Committee of Ministers at the request of two-thirds of the members of the CD-P-TS.

6. Working methods and structures:

The CD-P-TS shall meet in plenary at least once a year. Meetings between the chairpersons and project leaders (referred to as Bureau) shall be planned at least once a year. Extraordinary meetings of the CD-P-TS can be convened upon a motivated request by the chairpersons.

The chair is elected for a period of three years. The chair shall not immediately be eligible thereafter for re-election. While he/she holds office, the chair shall not be a member of any delegation. The travel and subsistence expenses of the chair are borne by the specific budgetary appropriations of the CD-P-TS.

The CD-P-TS shall define its rules of procedure.

With a view to reaching its objectives, the CD-P-TS may arrange consultations, by means of hearings or by any other means, as appropriate.

7. Duration:

1 January 2010 – 31 December 2012.