Appendix 9
(Item 6.5b)

Terms of reference of the European Committee (Partial Agreement) on organ transplantation (CD-P-TO)

Fact sheet

Name of Committee:	European Committee (Partial Agreement) on organ transplantation (CD-P-TO)
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 the transplantation of organs, tissues and cells, notably as regards quality and safety standards and their implementation; • examine the organisational structures concerning organ transplantation with a view to improving these structures and addressing the causes of organ shortage; • develop links between the exchange organisations throughout Europe; • propose ethical quality and safety standards on professional practices; • ensure the transfer of knowledge and expertise and develop competencies of experts through training and networking; • contribute to awareness-raising of the population in general on organ donation for transplantation.
Project relevance:	Third Summit Action Plan Chapter II – Strengthening the security of European citizens, Articles 3. Combating trafficking in human beings and 6. Promoting ethics in biomedicine. The importance of elaborating and promoting the principle of non-commercialisation of organ donation, strengthening measures to avoid organ trafficking and, in general, elaborating high ethical, quality and safety standards in the field of organ transplantation: • the Convention on Human Rights and Biomedicine (ETS No. 164) and its Additional Protocol on Transplantation of Organs and Tissues of Human Origin (ETS No. 168).
Project added value:	• The 3rd Conference of European Health Ministers on Organ Transplantation (Paris, 1987) established as a practical objective for the Council of Europe to study the ethical aspects of organ transplantation in Europe; • the Council of Europe is a leading regional agency in this field with a number of recommendations and 3 editions (including addenda) of the Guide to safety and quality assurance for organs, tissues and cells and its valuable contribution on the Additional Protocol to the Convention on Human Rights and Bioethics; • the European Donation and Transplantation Day (established on a Council of Europe proposal); • the importance of assistance activities, in particular, in non-EU member

	states; • the EC Directives take into account Council of Europe documents; • duplications are avoided by 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-TO. 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 organ transplantation (CD-P-TO)

1. Name of Committee: European Committee (Partial Agreement) on organ transplantation (CD-P-TO)

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 the principle of non-commercialisation of organ donation, strengthening measures to avoid organ trafficking and, in general, elaborating high ethical, quality and safety standards in the field of organ transplantation;

- the Convention on Human Rights and Biomedicine (ETS No. 164) and its Additional Protocol on Transplantation of Organs and Tissues of Human Origin (ETS No. 168);

- 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-TO") shall undertake the following actions:

a. examine questions related to the transplantation of organs, tissues and cells, notably as regards quality and safety standards and their implementation; in particular by pursuing the regular update, revisions and further developments of the "Guide to safety and quality assurance for the transplantation of organs, tissues and cells", its regular publication and promote its implementation;

b. examine the organisational structures concerning organ transplantation with a view to improving these structures and addressing the causes of organ shortage;

c. develop links between the exchange organisations throughout Europe;

d. propose quality and safety standards on professional practices, taking into account ethical aspects;

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

f. contribute to awareness-raising of the population in general on organ donation for transplantation;

g. 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;

h. monitor implementation of the above-mentioned activities and in particular revise and update any resulting documents concerning organ transplantation, including the guide to safety and quality assurance for organs, tissues and cells;

i. co-operate with the Steering Committee on Bioethics (CDBI) in the implementation of all aspects of transplantation covered by the Convention on Human Rights and Biomedicine (ETS No. 164) and its Additional Protocol on transplantation of organs and tissues of human origin (ETS No. 168);

j. 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 of 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-TO.

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-TO. 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-TO, 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-TO 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 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-TO, 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-TO. 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-TO, 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-TO, without the right to vote or defrayal of expenses.

5.D Observers

i. The following international NGOs may sent a representative to meetings of the CD-P-TO, without the right to vote or defrayal of expenses:

- Eurotransplant;
- Scandiatransplant.

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

The observer status is granted on the basis of a unanimous decision by the CD-P-TO. 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 Committee.

6. Working methods and structures:

The Committee 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-TO can be convened upon 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-TO.

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

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

7. Duration:

1 January 2010 – 31 December 2012.