

Appendix 9
(Item 6.4b)

Terms of reference of the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)

Fact Sheet

| | |
|--|---|
| Name of Committee: | European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH) |
| Compliance with Resolution Res(2005)47: | Resolution Res(2005)47 applies <i>mutatis mutandis</i> to Partial and Enlarged Agreements; Convention on the Elaboration of a European Pharmacopoeia; Statutory Resolution (93) 28 on Partial and Enlarged Agreements. |
| Programme: | <p>The activities of the CD-P-PH are linked to the draft Council of Europe programme “Strengthening the rule of law and common standards” – Expected result 2: “Promotion and facilitation of signatures of the MEDICRIME Convention” of the Draft Council of Europe Programme and Budget 2011 (CM(2010)130).</p> <p>The CD-P-PH shall pursue the following activities:</p> <ul style="list-style-type: none"> • fulfil the tasks of the Public Health Committee set out in the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50), as amended by the Protocol (ETS No. 134) Articles 2(a), 3 and 4; • fulfil the tasks of the Public Health Committee set out in Resolution ResAP(2007)1 on the classification of medicines as regards their supply; • contribute to improving public health and reducing health inequalities via developing harmonised provisions and practices including the rational use of medicines through implementing and promoting pharmaceutical care in Europe; • minimise public health risks posed by counterfeit medical products and similar crimes through multisectorial prevention and risk management strategies and the support to the elaboration, implementation and follow-up of relevant national legislation and international legal instruments; • contribute to the multisectorial and multidisciplinary follow-up mechanism ensured by the Committee of the Parties to the future MEDICRIME Convention; • ensure and monitor adequate follow-up of the results of the relevant activities of the Council of Europe and at national level in member states of the Partial Agreement; • facilitate the maintenance and development of links with relevant European institutions and organisations active in field; • approve proposals for resolutions prepared for adoption by the Committee of Ministers or adopt any document or specific activity programme to be implemented in relation with its terms of reference. |
| Relevance: | Third Summit Action Plan Chapter II: Strengthening the security of European citizens, Articles 2: Combating corruption and organised crime and 5: Combating cyber crime and strengthening human rights in the information society; Chapter III: Building a more human and inclusive Europe, Article 1: Ensuring social cohesion. |

| | |
|-------------------------------|--|
| | <p>The reply of the Committee of Ministers to Parliamentary Assembly Recommendation 1794 (2007) on “The Quality of Medicines in Europe”, (CM/AS(2007)Rec1794 final), adopted on 26 September 2007, in particular items 3 and 5.</p> <p>The decision of the Committee of Ministers (CM(2010)PVadd1, 11 May 2010), item 7a, adopted on 11 May 2010, welcoming the progress made under the Swiss Chairmanship in the preparation of the draft Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health and encouraging its relevant bodies to finalise their work with a view to opening the convention for signature before the end of 2010.</p> |
| Added value: | <ul style="list-style-type: none"> • The protection of health as a social human right is in line with the core values of the Council of Europe. Ensuring the safety and effectiveness of health care is of critical importance to the well-being of all Europeans. • Through the 37 Parties to the Convention on the Elaboration of a European Pharmacopoeia and its multisectorial competencies and co-operation of its bodies, the Council of Europe is well placed to carry out activities which have an impact on public health protection within Europe. • The International Conference “Europe against Counterfeit Medicines”, organised under the Russian Chairmanship of the Committee of Ministers (Moscow, 2006), laid down in the Moscow Declaration a plan of practical and legal measures in order to strive for the promotion and respect of member states’ obligations to defeat the counterfeiting of medical products and similar crimes. • The International Conference “Towards the practical implementation of the Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention)”, organised under the Swiss Chairmanship of the Committee of Ministers (Basel, 15-16 April 2010) underlined the need for signature, ratification or accession by states without unnecessary delay, for importance being attached to its implementation and discussed the practical implementation of the above convention, once adopted. <p>The specific Council of Europe approach to linking the promotion of safety and effectiveness as regards healthcare with the promotion of adequate quality of healthcare products is strengthened through regular co-operation with the European Commission and the World Health Organisation (WHO).</p> |
| Financial information: | <p>The CD-P-PH meets once a year for two days in plenary. 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-PH.</p> <p>The budget for this activity is set out in the Draft Council of Europe Programme and Budget 2011 (CM(2010)130), item “Ensuring social rights: European Directorate for the Quality of Medicine (EDQM, Pharmacopoeia) – Expected results: 3 and 4”, which was submitted for adoption to the Committee of Ministers 1099th (Budget) Meeting, 23-25 November 2010.</p> |

Terms of reference of the European Committee on pharmaceuticals and pharmaceutical care (Partial agreement) (CD-P-PH)

1. **Name of Committee:** European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)
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 Parties to the Convention on the Elaboration of a European Pharmacopoeia¹

4. Terms of reference:

Having regard to:

- the European Convention on the Elaboration of a European Pharmacopoeia;
- Resolution Res(2005)47 on committees and subordinate bodies, their terms of reference and working methods, which applies *mutatis mutandis*;
- the Action Plan of the Third Summit of Heads of State and Governments of the Council of Europe (Warsaw, 16-17 May 2005) laying down the protection of health as a social human right among the principal tasks of the Council of Europe including support to work on equity of access to care of appropriate quality, and services meeting the needs of the population in a patient-oriented way;
- the decision of the Committee of Ministers of 11 and 12 July 2007 (CM/Del/Dec(2007)1002/6.1) to transfer the activities related to pharmaceutical issues to the European Directorate for the Quality of Medicines and Healthcare (EDQM);
- the decisions of the Committee of Ministers of 6 February (CM/Del/Dec(2008)1017/6.3) and of 9 and 10 July 2008 (CM/Del/Dec(2008)1032/6.2) to adopt the revised terms of reference of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) which would carry out the tasks of the Public Health Committee set out in the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50), as amended by the Protocol (ETS No. 134) after the transfer of the activities related to pharmaceutical issues to the European Directorate for the Quality of Medicines and Healthcare (EDQM);
- its participation in the work of the former Ad hoc Committee on counterfeiting of medical products and similar crimes involving threats to public health (PC-ISP);
- the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention) which ranks the prevention of threats to public health from the counterfeiting of medical products and similar crimes on a prominent position among its purposes besides the combating of such crimes and the MEDICRIME Convention Explanatory Memorandum, namely the chapters IV – Co-operation of authorities and information exchange, V – Measures for prevention, VII – International co-operation, and chapter VIII – Follow-up mechanism which foresees the contribution of relevant Council of Europe intergovernmental or scientific committees in order to contribute to a multidisciplinary and multi-professional approach;
- the internationally recognised definition of pharmaceutical care by Hepler and Strand (1990)² adopted and amended by WHO/FIP.

¹ States concerned: 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.

² "Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve or maintain a patient's quality of life"

Under the authority of 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, the Steering Committee (hereinafter the CD-P-PH) shall:

- i. fulfil the tasks of the Public Health Committee set out in the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50), as amended by the Protocol (ETS No. 134), Articles 2, 3, 4 and 8;
- ii. fulfil the tasks of the Public Health Committee set out in Resolution ResAP(2007)1 on the classification of medicines as regards their supply;
- iii. contribute to improving public health and reducing health inequalities via developing harmonised provisions and practices including the rational use of medicines, implementing and promoting pharmaceutical care in Europe;
- iv. minimise public health risks posed by counterfeit medical products and similar through multisectorial prevention and risk management strategies and the support to the elaboration, implementation and follow-up of relevant national legislation and international legal instruments including the development of and training on best practices, the maintenance and development of a specific multisectorial expertise in this field, in co-operation with other relevant Council of Europe bodies, in particular the European Committee on Crime Problems (CDPC);
- v. contribute to the multisectorial and multidisciplinary follow-up mechanism ensured by the Committee of the Parties to the MEDICRIME Convention;
- vi. ensure and monitor adequate follow-up of the results of the relevant activities of the Council of Europe and at national level in States Parties to the Convention on the Elaboration of a European Pharmacopoeia;
- vii. facilitate the development and maintenance of links with relevant European institutions and international organisations being active in field, in particular the European Commission and the World Health Organisation (WHO);
- viii. approve proposals for resolutions prepared for adoption by the Committee of Ministers or adopt any document, guideline, or specific activity programme to be implemented in relation with its terms of reference;
- ix. while taking account of the progress of its work, prepare, under its responsibility, proposals for the programme of activities for the coming years.

5. Composition:

5.A Members

Governments of Council of Europe States Parties to the Convention on the Elaboration of a European Pharmacopoeia are entitled to appoint a representative with expertise and responsibility for the implementation of policies and programmes at national level: a senior official responsible for policies dealing with medical products³, such as the Chief Pharmaceutical Officer. Each member state 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-PH.

³ Note by the Secretariat: the scope of the future MEDICRIME Convention covers medical products encompassing not only medicinal products including active pharmaceutical ingredients and excipients but also medical devices, materials components and accessories and therefore the enlargement hereto.

5.B Participants

The CD-P-PH 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-PH, without the right to vote or defrayal of expenses.
- ii. The European Union is entitled to appoint a representative to the meetings of the CD-P-PH, without the right to vote, except for the fulfilment of the tasks mentioned under item 4.i, and without defrayal of expenses.
- iii. The World Health Organisation (WHO) may send a representative to the meetings of the CD-P-PH, without the right to vote or defrayal of expenses.

5.D Observers

Non-governmental organisations active in the field, may ask for observer status with the CD-P-PH 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-PH. 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-PH.

6. Working methods and structures:

The CD-P-PH shall meet once a year for two days. Additional meetings of the CD-P-PH can be convened upon motivated request by two-thirds of its members.

With a view to reaching its objectives and to enable multidisciplinary working methods, the CD-P-PH may, within the limit of budgetary attributions, create subordinate bodies and arrange consultations, by means of hearings or by any other means, as appropriate.

7. Duration:

These terms of reference shall expire on 31 December 2013.