

---

## **1032 Meeting, 9 July 2008**

6 Social cohesion

### **6.2 European Pharmacopoeia (EDQM) – European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)**

- a. Abridged report of the 1st meeting (Strasbourg, 2-3 April 2008)
- b. Revised draft terms of reference of the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)

For consideration by the GR-SOC at its meeting on 8 July 2008

---

1. The European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH) held its 1st meeting in Strasbourg on 2 and 3 April 2008.
2. Ms Susanne KEITEL, Director, European Directorate for the Quality of Medicines and HealthCare (EDQM) welcomed all delegates and addressed them.
3. As the Chair and the Vice-Chair of the CD-P-PH had not yet been elected, she opened the meeting and drew the delegates' particular attention to the importance of this meeting which was to set up working methods and structures for the programme of activities entrusted to the CD-P-PH in its terms of reference, which would ensure continuity of the transferred pharmaceutical activities whilst exploiting synergies with the working programmes carried out by the EDQM. She said that the EDQM was the suitable platform for co-operation between member states and stakeholders to establish policies linking the quality of medicines to the quality of medication use in Europe and which put public health ahead of economic considerations.

#### **Election of the Chair and Vice-Chair**

4. The delegations unanimously elected by open ballot Mr Domenico DI GIORGIO, Italy, as Chair and Mr Nico KIJLSTRA, Head of the Dutch delegation, as Vice-Chair for a term of office of three years.

#### **Decisions by the Committee of Ministers**

5. The CD-P-PH took note of the decisions of the Minister's Deputies (restricted to those representing the States Parties to the Convention on the Elaboration of a European Pharmacopoeia) to adopt the terms of reference of the European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH), to assign to the CD-P-PH 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), and to consider that any reference to the "Public Health Committee" in the said Convention and Protocol henceforth should mean the CD-P-PH.

---

<sup>1</sup> This document has been classified restricted until examination by the Committee of Ministers.  
Internet : <http://www.coe.int/t/cm/>

6. One delegation asked about the status of participation of the European Commission in the CD-P-PH as regards its role relating to the European Pharmacopoeia Commission as set out in its terms of reference. The Secretariat confirmed that it would consult in due course the Legal Advice Department of the Council of Europe and report back to the Committee.

7. One delegation asked whether medical devices, blood and tissues, and diagnostics were covered by the term “pharmaceuticals” and about the notion of “pharmaceutical care” in the terms of reference. The Secretariat drew the Committee’s attention to the programme of activities carried out by the European Committees on Blood transfusion (CD-P-TS) and Organ Transplantation (CD-P-TO) and invited the Committee to take a practical approach to the scope of its work programme in accordance with its terms of reference. The Committee noted that it would be informed regularly about the activities related to blood transfusion and organ transplantation at its forthcoming meetings.

8. The Secretariat of the Group of Specialists on counterfeit pharmaceutical products (PC-S-CP), Directorate General of Human Rights and Legal Affairs, made a statement about the specific mandate given by the Committee of Ministers to the PC-S-CP to prepare under the responsibility of the European Committee on Crime Problems (CDPC) a report focusing on the key elements which could be included in a binding international legal instrument to fight crime concerning counterfeit pharmaceutical products.

9. In conclusion, the CD-P-PH took note of its terms of reference and of the progress of the activities related to a possible binding international legal instrument to fight crime concerning counterfeit pharmaceutical products which were overseen by the European Committee on Crime Problems (CDPC).

#### **Terms of reference of subordinate bodies and working programmes**

10. The CD-P-PH recalled that the terms of reference of the former Committee of Experts on Pharmaceutical Questions (P-SP-PH), its subordinate bodies, the Committee of Experts on the legal classification of medicines as regards their supply (P-SP-PHO) and the Ad hoc Group on Counterfeit Medicines under the aegis of the Partial Agreement in the Social and Public Health Field, had expired on 31 December 2007.

11. The CD-P-PH discussed the draft revised terms of reference of the Committee of Experts on the classification of medicines as regards their supply (CD-P-PH/PHO) and of the Committee of Experts on the quality and safety standards in pharmaceutical practice and pharmaceutical care (CD-P-PH/PC), and the draft terms of reference of the Committee on minimising the public health risks posed by counterfeiting of medical products and related crimes (CD-P-PH/CMED).

12. A delegation requested that all subordinate bodies should avoid in their activities duplication of work carried out by the European Commission and the WHO.

13. In conclusion, the CD-P-PH adopted the revised terms of reference of the CD-P-PH/PHO and of the CD-P-PH/PC and the terms of reference of the CD-P-PH/CMED as discussed at the meeting, taking account of and in continuity with the former Committee P-SP-PH, the P-SP-PHO and the Ad hoc Group on Counterfeit Medicines under the aegis of the Partial Agreement in the Social and Public Health Field.

#### **Committee of experts on the classification of medicines as regards their supply (CD-P-PH/PHO)**

14. The CD-P-PH took note of the forthcoming 44th meeting of the CD-P-PH/PHO which would take place in Strasbourg on 27 and 28 May 2008.

#### **Committee of experts on quality and safety standards in pharmaceutical care and practice (CD-P-PH/PC)**

15. The CD-P-PH discussed a project proposal on the “Development and implementation of indicators for the documentation (assessment) of the quality of pharmaceutical care in Europe taking account of the new roles of the pharmacist”.

16. One delegation requested to delete the reference to the distribution of emergency hormonal contraception as an example of pharmaceutical services in the above project proposal.

17. The CD-P-PH discussed a project proposal on the “Impact of traditional (foreign) therapies on pharmaceutical practice in Europe”.

18. One delegation strongly insisted on the need to establish co-operation with the Committee of Experts on minimising public health risks posed by counterfeit medicinal products and related crimes. Another delegation recommended that one Medicines Regulatory Agency should be involved due to its specific and vast expertise in the field. Yet another delegation requested that the revised project proposal should contain an analysis of gaps in existing legislation and guidelines in relation to the current situation regarding traditional foreign therapies and the products on the market to sharpen the focus of the project.

19. The Committee agreed that the survey should be sent at least to all states parties to the Convention on the Elaboration of a European Pharmacopoeia and, as appropriate, to other Council of Europe member states that were observers.

20. The WHO representative informed the CD-P-PH that a specialist from WHO had contributed to the work on the project proposal under the aegis of the Partial Agreement in the Social and Public Health Field and would continue to do so, if the project was supported.

21. In conclusion, the CD-P-PH asked the CD-P-PH/PC to prepare by the end of March 2009 a preliminary report on survey Number 1 of the project proposal on the “Development and implementation of indicators for the documentation (assessment) of the quality of pharmaceutical care in Europe taking account of the new roles of the pharmacist”, which was restricted to 5 key elements, namely, definitions of key concepts in pharmaceutical care, performance indicators of good quality care, good quality services, the usefulness of existing databases and finally the relevant stakeholders involved in pharmaceutical care at the national level.

22. The CD-P-PH requested a completed project proposal on the impact of foreign traditional therapies on pharmaceutical practice in Europe with a particular focus on gaps in existing regulations, in particular those of the European Union, for products and practices in Europe used in traditional foreign therapies.

23. The CD-P-PH asked the CD-P-PH/PC to prepare by the end of November 2008 a preliminary report on the survey of all states parties to the Convention on the Elaboration of a European Pharmacopoeia on the impact of traditional (foreign) therapies on pharmaceutical practice (TCM) based on the project proposal that had already been supported in general by the CD-P-SP, which had described it as valuable and effective at its 80th session on 8 November 2007.

24. The CD-P-PH took note of the forthcoming 61st meeting of the CD-P-PH/PC, which would take place in Strasbourg on 19 and 21 May 2008.

#### **Committee of experts on minimising public health risks posed by counterfeiting of medical products and related crimes (CD-P-PH/CMED)**

25. The delegations discussed the draft terms of reference of the CD-P-PH/CMED and its work programme.

26. In conclusion, the CD-P-PH approved the programme of activities on the basis of the strategy paper on “Minimising public health risks posed by counterfeit medicines and other forms of pharmaceutical crime in Europe through practical measures and tools”, on the basis of the project proposal that had already been supported in general and described as valuable and effective by the Public Health Committee (CD-P-SP) (Partial Agreement) at its 79th session on 8 June 2007 and on the basis of previous work results in the field.

27. The CD-P-PH took note of the evaluation of the 2007 pilot training on how to combat counterfeit medicines and to protect public health and of the intention to host two follow-up training events in 2008.

28. The CD-P-PH noted that the 1st meeting of the CD-P-PH/CMED would take place in Strasbourg on 5-6 May 2008.

#### **Date and place of the next meeting**

29. The CD-P-PH agreed tentatively to hold its next meeting in Strasbourg on 20 and 21 November 2008.

## Appendix 1

### Agenda

1. **Agenda of the meeting**
2. **Terms of reference of subordinate bodies on:**
  - 2.1. Classification of medicines as regards their supply (CD-P-PH/PHO)
  - 2.2. Quality and safety standards in pharmaceutical practices and pharmaceutical care (CD-P-PH/PC)
  - 2.3. Minimising public health risks posed by counterfeiting of medical products and related crimes (CD-P-PH/CMED)

\* \* \* \* \*

## Appendix 2

### **Revised draft terms of reference of the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)**

#### **Introduction**

On 6 February 2008, the Deputies, in their composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia, adopted the terms of reference of the European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH).

They decided that the European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH) 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).

Furthermore, they agreed that any reference to the "Public Health Committee" in the said Convention and Protocol should be understood as from this date as referring to the European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH).

The practical implementation of the decision concerning the tasks of the CD-P-PH set out in the said Convention and Protocol taking account of current procedures in place for adopting decisions of a technical character relating to the European Pharmacopoeia suggests the need for more specific information on the status of the European Community as regards the said Convention and the Protocol and the programme of activities dealing with pharmaceutical care in the wording of the terms of reference of the CD-P-PH, item 5.C.

**The current document contains the draft revised terms of reference which the GR-SOC is invited to examine at its meeting on 1 July 2008. (The revision concerns item 5.C).**

**Draft revised terms of reference of the European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH)**

**Fact sheet**

<b>Name of Committee:</b>	European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH)
<b>Compliance with Resolution Res(2005)47:</b>	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.
<b>Programme of Activities: project(s)</b>	<p>The activities of the Committee are linked to the programme II.3.2. "European standards for crime control" – Project 2008/DGHL/1432 "Monitoring the operation of conventions on co-operation in the criminal field" of the Programme of Activities 2008.</p> <p>The Committee shall pursue the following activities:</p> <ul style="list-style-type: none"> <li>• 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;</li> <li>• contribute to improving public health care through harmonising provisions and practices involving pharmaceuticals in Europe;</li> <li>• minimise public health risks posed by counterfeit medicines and other forms of pharmaceutical crimes through multisectorial prevention and risk management strategies and the support to the elaboration and implementation of relevant national legislation and international legal instruments;</li> <li>• 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;</li> <li>• facilitate the maintenance and development of links with relevant European institutions and organisations active in field;</li> <li>• 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.</li> </ul>
<b>Project relevance:</b>	<p>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> <p>The reply of the Committee of Ministers to Parliamentary Assembly Recommendation 1794 (2007) – "The Quality of Medicines in Europe", (CM/AS(2007)Rec1794 final), adopted on 26 September 2007, in particular items 3 and 5.</p>
<b>Project added value:</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Through the 36 States 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.</li> </ul>

	<ul style="list-style-type: none"> <li>• 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 medicines and other pharmaceutical crimes.</li> <li>• 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).</li> </ul>
<b>Financial information:</b>	<p>The Committee 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 CD-P-PH will be served by the Secretariat with the total budget in 2008 of €255 200 (Staff-related expenditure €163 200, other expenditure €92 000).</p> <p>The budget for this activity is set out in Resolution CM/Res(2007)36 on the European Pharmacopoeia 2008 Budget (CM/Del/Dec(2007)1012, item 11.1. part 5, appendix 21)</p>

#### Draft revised terms of reference of the European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH)

1. **Name of Committee:** European Committee on pharmaceuticals and pharmaceutical care (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 Pharmacopoeia<sup>2</sup>

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);

<sup>2</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.

- the decision of the Committee of Ministers of 11 and 12 July 2007 (CM/Del/Dec(2007)1002/6.1), to entrust the Secretariat with the task of drafting revised terms of reference for the Public Health Committee (CD-P-SP) reflecting its functions in relation to the Convention on the Elaboration of a European Pharmacopoeia and to the pharmaceutical issues, hitherto carried out in the framework of the Partial Agreement in the Social and Public Health Field;

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 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 care through harmonising provisions and practices involving pharmaceutical products in Europe;
- iv. minimise public health risks posed by counterfeit medicines and other forms of pharmaceutical crimes through multisectorial prevention and risk management strategies and the support to the elaboration and implementation 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. 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;
- vi. 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);
- vii. 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;
- viii. 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 pharmaceutical policies, 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.

### **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 Commission is entitled to appoint a representative to the meetings of the CD-P-PH without the right to vote or defrayal of expenses.~~

**The European Community is entitled to appoint a representative to the meetings of the CD-P-PH, without 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.

The 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 Committee.

### 6. Working methods and structures:

The Committee 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 2010.

### Appendix 3

#### Revised terms of reference of the Committee of Experts on the classification of medicines as regards their supply (CD-P-PH/PHO)

1. **Name of Committee:** Committee of Experts on the classification of medicines as regards their supply (CD-P-PH/PHO)
2. **Type of Committee:** Committee of Experts
3. **Source of terms of reference:** European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH)
4. **Terms of reference:**

Having regard to:

- Statutory Resolution (93)28 on Partial and Enlarged Agreements and Resolution Res(2005)47 which applies only *mutatis mutandis* to partial agreements;
- the European Convention for the Elaboration of a European Pharmacopoeia contributing to public health protection by harmonising specifications of medicinal substances which are of general interest and importance to the peoples of Europe;
- the Third Summit of Heads of State and Governments of the Council of Action Plan (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;
- Committee of Ministers' (Partial Agreement) Resolution ResAP(2007)1 on the classification of medicines as regards their supply superseding Resolution CM(Partial Agreement) ResAP(2000)1 on the classification of medicines which are obtainable only on medical prescription entrusting the Public Health Committee (Partial Agreement) (CD-P-SP), predecessor of the CD-P-PH as regards pharmaceutical activities, to carry out, either itself or through subordinate bodies, an annual revision of the appendices to the above Resolution ResAP(2007)1;
- Committee of Ministers' (Partial Agreement) Resolution ResAP(2007)2 on good practices for trade in medicines by mail order which protect patient safety and the quality of the delivered medicine referring in its stipulations to the authorised conditions of sale or distribution of medicines being subject to mail order trade;
- the fact that the classification criteria set out in the Council of Europe resolutions on the classification of medicines have been taken over by the directive 92/26/EEC and by the directive 2001/83/EEC (art 70-75), which refer to the principles already established by the Council of Europe.

Under the authority of the European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH), and in relation to the implementation of the above-mentioned Committee of Ministers' (Partial Agreement) Resolution ResAP(2007)1, and based on the work previously accomplished by the Committee of Experts on the legal classification of medicines as regards their supply under the aegis of the CD-P-SP within the framework of the Partial Agreement in the Social and Public Health Field, and bearing in mind:

- the importance of the classification of medicines as regards their supply with or without a medical prescription on public health in particular patient safety, the accessibility of medicines to patients and the responsible management of health care expenditure,
- the fact that the classification of medicines as regards their supply varies considerably in Europe, falling under national competency of the member states members,
- the importance of preparing recommendations and publishing lists of conditions of use as prescription and non-prescription medicines in Europe for public authorities, industry and the general public;

the CD-P-PH/PHO shall, on the basis of the transferred programme of activities of the former Committee of Experts on the legal classification of medicines as regards their supply (P-SP-PHO), in the frame of the Partial Agreement in the Social and Public Health Field:

- a) carry out reviews on classification practice, underlying rationale and national requirements for medicines of specific interest or concerns for public health and develop good classification practices;
- b) monitor trends in and the impact of the classification of medicines on medicines' safety and accessibility to the patient;
- c) follow up the national implementation of the appendices to the above-mentioned Committee of Ministers' (Partial Agreement) Resolution ResAP(2007)1;
- d) prepare proposals for the revision of the text of the above-mentioned Committee of Ministers' (Partial Agreement) Resolution ResAP(2007)1, with a view to adapting it to changes in pharmaceutical care and practice;
- e) maintain and develop links with national, European and international institutions and organisations active in the sphere of the classification of medicines as regards their supply;
- f) develop further and co-ordinate the updates of a web published database presenting the classification status of medicines in the member states and the above-mentioned Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1 and its annually revised appendices;
- g) ensure continuity with the programme of activities and results by the former Committee of Experts on the legal classification of medicines as regards their supply (P-SP-PH) in the field of harmonising provisions and of classification practice and rationale concerning the legal classification of medicines as regards their supply, collection of national and European information relevant for the classification of medicines on an ongoing basis and the preparation of recommendations on the legal classification of medicines for authorities, industry and other stakeholders through annual updates of the appendices to the above-mentioned Committee of Ministers' (Partial Agreement) Resolution ResAP(2007)1.

## **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 representatives from the relevant public authority.

These may include experts responsible for the preparation and follow-up of national policies in the field of the legal classification of medicines. 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/PHO.

### **5.B Participants**

The CD-P-PH/PHO 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 expense 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/PHO, without the right to vote or defrayal of expenses.

- ii. The European Commission may send a representative to the meetings of the CD-P-PH/PHO, without the right to vote and without defrayal of expenses.
- iii. The World Health Organization may send a representative to the meetings of the CD-P-PH/PHO, without the right to vote or defrayal of expenses.

#### **5.D Observers**

International non-governmental organisations active in the field may ask for observer status with the CD-P-PH/PHO 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 unanimous agreement by the delegates of the CD-P-PH/PHO member states and after authorisation by the CD-P-PH.

#### **6. Working methods and structures:**

The CD-P-PH/PHO will hold regular meetings and will carry out its programme of activities using scientific and public health orientated approaches.

The CD-P-PH/PHO shall co-ordinate the updates of a web published database presenting the classification status of medicines in the member states and the above-mentioned Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1 and its annually revised appendices; This database contributes to the accessibility and validity of health-related data, and is a reference in this field.

With a view to reaching its objectives, the CD-P-PH/PHO may arrange consultations, by means of hearings or by any other means, and organise conferences and seminars, as appropriate. Where necessary, in order to expedite the progress of its work, the CD-P-PH/PHO may entrust a limited number of its members with a specific task.

#### **7. Duration:**

1 January 2008 – 31 December 2010

## Appendix 4

### Revised terms of reference of the Committee of Experts on quality and safety standards in pharmaceutical practice and pharmaceutical care (CD-P-PH/PC)

1. **Name of Committee:** Committee of Experts on quality and safety standards in pharmaceutical practice and pharmaceutical care (CD-P-PH/PC)
2. **Type of Committee:** Committee of Experts
3. **Source of terms of reference:** European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH)
4. **Terms of reference:**

Having regard to:

- Statutory Resolution (93)28 on Partial and Enlarged Agreements and Resolution Res(2005)47 which applies only *mutatis mutandis* to partial agreements;
- the European Convention for the Elaboration of a European Pharmacopoeia contributing to public health protection through harmonising specifications of medicinal substances which are of general interest and importance to the peoples of Europe;
- the Third Summit of Heads of State and Governments of the Council of Europe Action Plan (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;
- Committee of Ministers' (Partial Agreement) Resolution ResAP(94) on the rational use of medicines;
- Committee of Ministers' (Partial Agreement) Resolution ResAP(97)2 on the role and training of the community pharmacist;
- Committee of Ministers' (Partial Agreement) Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security;
- Recommendation Rec(2006)7 by the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care, in particular its stipulations for improved medication safety;
- the conclusions of the Council of Europe seminars on "The role and training of the community pharmacist" (1991), "The pharmacist and the challenge of new social trends" (1995), "The pharmacist at the cross roads of new health risks: an indispensable partner for their management" (1999), and of the Expert Meeting on Medication Safety (2002), which were organised by the Committee of Experts on pharmaceutical questions (P-SP-PH) under the aegis of the CD-P-SP, predecessor of the CD-P-PH as regards pharmaceutical activities, within the framework of the Partial Agreement in the Social and Public Health Field.

Under the authority of the European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH), and in relation to the implementation of the above-mentioned recommendation of the Committee of Ministers to the member states, the CM resolutions of the Partial Agreement in the Social and Public Health Field, the Parliamentary Assembly Recommendations and the above conclusions of the Seminar, and based on the work previously accomplished successfully by the Committee of Experts on pharmaceutical questions (P-SP-PH) under the aegis of the CD-P-SP within the framework of the Partial Agreement in the Social and Public Health Field, and bearing in mind:

- a prescribed medicine being the most frequent treatment in healthcare systems, in the community and in hospitals,

- the impact of current and ongoing demographic and societal changes in Europe, including migration, ageing, the breaking-up of traditional social structures, the availability of new technologies (e.g. the internet), in healthcare, multiprofessional approaches in healthcare, and healthcare budget constraints on current pharmaceutical practices and pharmaceutical care, posing a risk of impaired quality of medicinal treatment and of inequalities in healthcare,
- the critical importance of ensuring safety and effectiveness of medicines and their appropriate use for the individual patient in ambulatory care, primary care, hospital, assisted living, nursing home, home health care, hospice, and the society in general,
- the national competency of member states as regards pharmaceutical practices and care which are not subjected to European treaties,
- the need to promote pharmaceutical care throughout the medication chain, implying professional commitment in managing patient's medicine therapies and putting first the patient's quality of life with a view to meeting the current challenges for healthcare systems in Europe,
- the pharmacist's key role in pharmaceutical professional governance through patient-oriented, participative medication management and through co-operating and sharing pharmaceutical knowledge and skills with all partners throughout the medication chain, in particular doctors, nurses, and care-givers;

the CD-P-PH/PC shall, based on the transferred programme of activities of the former Committee of Experts on pharmaceutical questions (P-SP-PH), in the frame of the Partial Agreement in the Social and Public Health Field:

- a) improve public health care and practices involving pharmaceuticals in community, ambulatory care, primary care, hospital assisted living, nursing home, home health care, and hospice, through specific programmes and policies, putting first the needs of patients and society in general, valuing the social and ethical context of healthcare;
- b) develop and carry out a programme of activities aiming at improving public health care in Europe through promoting knowledge, skills, attitudes and values in practices and care involving pharmaceuticals, in particular:
  - carry out studies on
    - the implementation of quality assessment in pharmaceutical practice and care in Europe through quality indicators,
    - new roles of the pharmacist in pharmaceutical practice and care in Europe *inter alia* raising medication-related health literacy of the public,
    - relevant non-European traditional therapies used in Europe,
  - prepare proposals for harmonised provisions and practices involving pharmaceuticals in States Parties to the Convention on the Elaboration of a European Pharmacopoeia in the field of safety in practice and care involving pharmaceuticals,
  - contribute to the practical implementation of the above provisions and policies through programmes, raising awareness and providing practical guidance;
- c) assist in monitoring adequate implementation of the results of the relevant activities at national levels in States Parties to the Convention on the Elaboration of a European Pharmacopoeia and assist the CD-P-PH in evaluation and follow-up of the programme of activities mentioned in item b);
- d) promote the further development of pharmaceutical professional, expertise, roles and co-operation of all partners within the medication and care chain, in particular the pharmacist, the doctor and the nurse, and care-givers;
- e) maintain and develop links with national, European and international institutions, organisations and professional bodies active in the sphere of practice and care involving pharmaceuticals;

- f) ensure continuity with the programme of activities and results achieved by the former Committee of Experts on pharmaceutical questions (P-SP-PH) in the field of promoting the safety, quality and effectiveness of medicines and their appropriate use in society.

## **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 representatives from the relevant authorities dealing with pharmaceutical practice and care.

These may include experts responsible for the preparation of national policies in the field of pharmaceutical practice and care. 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/PC.

### **5.B Participants**

The CD-P-PH/PC 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 expense 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/PC, without the right to vote or defrayal of expenses.
- ii. The European Commission may send a representative to the meetings of the CD-P-PH/PC, without the right to vote or defrayal of expenses.
- iii. The World Health Organization may send a representative to the meetings of the CD-P-PH/PC, without the right to vote or defrayal of expenses.

### **5.D Observers**

International non-governmental organisations, relevant European and international institutions, International and European associations representing for example stakeholders of the medication chain, including professional associations and orders of pharmacists, doctors, and nurses, may ask for observer status with the CD-P-PH/PC 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 unanimous agreement by the delegates of the CD-P-PH/PC and after authorisation by the CD-P-PH.

## **6. Working methods and structures:**

The CD-P-PH/PC will hold regular meetings and will carry out its programme of activities using scientific and public health orientated approaches, where applicable.

The orientation of the programme of activities is multiprofessional.

With a view to reaching its objectives, the CD-P-PH/PC may arrange consultations, by means of hearings or by any other means, and organise conferences and seminars, as appropriate. Where necessary, in order to expedite the progress of its work, the CD-P-PH/PC may entrust a limited number of its members with a specific task.

## **7. Duration:**

1 January 2008 – 31 December 2010

## Appendix 5

### Terms of reference of the Committee of Experts on minimising public health risks posed by counterfeiting of medical products and related crimes (CD-P-PH/CMED)

1. **Name of Committee:** Committee of Experts on minimising public health risks posed by counterfeiting of medical products and related crimes (CD-P-PH/CMED)
2. **Type of Committee:** Committee of Experts
3. **Source of terms of reference:** European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH)
4. **Terms of reference:**

Having regard to:

- Statutory Resolution (93)28 on Partial and Enlarged Agreements and Resolution Res(2005)47 which applies only *mutatis mutandis* to partial agreements;
- the European Convention for the Elaboration of a European Pharmacopoeia contributing to public health protection by harmonising specifications of medicinal substances which are of general interest and importance to the peoples of Europe;
- the Third Summit of Heads of State and Governments of the Council of Europe (Warsaw, 16-17 May 2005) Action Plan 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;
- Committee of Ministers (Partial Agreement) ResAP(2001)2 concerning the pharmacist's role in the framework of health security;
- the replies of the Committee of Ministers on the Parliamentary Assembly Recommendations
  - 1673 (2004) – Counterfeiting: problems and solutions, adopted on 6 April 2005,
  - 1793 (2007) “Need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods”, adopted on 21 November 2007,
  - 1794 (2007) “The quality of medicines in Europe”, adopted on 26 September 2007, where the Committee of Ministers “...welcomes the training on practical procedures and networking between concerned stakeholders at the national and international levels which is being prepared by the Ad hoc group on Counterfeit Medicines in co-operation with the European Directorate for the Quality of Medicines and HealthCare (EDQM)...”. With a view to the transfer of the activities to the EDQM as from 1 January 2008, the Committee of Ministers stated that “*The recommendations of the Assembly will be borne in mind when the Committee of Ministers examines the EDQM's programme of activities...*”;
- the conclusions of the Council of Europe Seminar “Counteract the counterfeiters: Limiting the risks of counterfeit medicines to public health in Europe by adequate means and measures, Strasbourg, 21-23 September 2005, and the International Conference “Europe against Counterfeit Medicines”, Moscow, 23-24 October 2006 (“Moscow Declaration”), organised with expert support from the Ad hoc Group on counterfeit medicines under the aegis of the CD-P-SP within the Partial Agreement in the Social and Public Health Field;
- the specific mandate given by the Committee of Ministers on 10 October 2007 to the Group of Specialists on counterfeit pharmaceutical products (PC-S-CP) to prepare a report focusing on the key elements which could be included in a binding international legal instrument to fight crime concerning counterfeit pharmaceutical products;

- the forward-looking strategy on minimising the public health risk posed by counterfeit medicines and related crimes in Europe through the development of practical measures prepared by the Ad hoc Group on counterfeit medicines under the programme of activities of the Partial Agreement in the Social and Public Health Field, which was supported in general as valuable, effective and relevant by the Public Health Committee (Partial Agreement) (CD-P-SP), predecessor of the CD-P-PH as regards pharmaceutical activities, at its 79th session on 8 June 2007.

Under the authority of the European Committee on pharmaceuticals and pharmaceutical care (CD-P-PH), and in relation to the implementation of the above-mentioned replies of the Committee of Ministers to the Parliamentary Recommendations and the conclusions of Council of Europe international conferences, and based on the work previously accomplished successfully by the Ad hoc Group on counterfeit medicines under the aegis of the CD-P-SP within the framework of the Partial Agreement in the Social and Public Health Field, and bearing in mind that counterfeiting of medical products and related crimes

- present a serious threat to patient health violating the right to life enshrined in Art. 2 of the European Convention of Human Rights and Fundamental Freedoms (EHRC),
- undermine public trust in medical therapies and healthcare systems,
- are on the rise in western industrialised countries. This includes Council of Europe member states that have a high percentage of counterfeit products on the market and member states bordering regions assumed to be sources of counterfeit medical products,
- due to the availability of new communication technologies, (e.g. the internet), are international crimes and have regional particularities,
- are complex as regards causes and implications and require multisector and multi-organisation counterstrategies which respond to the situation in Europe and keep pace with criminal inventiveness,
- require urgently practical risk management and prevention programmes and model approaches for member states and other stakeholders in the field,

the CD-P-PH/CMED shall on the basis of the transferred programme of activities of the former Ad hoc Group on Counterfeit Medicines in the field of minimising the public health risk posed by counterfeit medicines in the frame of the Partial Agreement in the Social and Public Health Field:

- a) develop and promote the implementation of multisectorial risk prevention and management strategies, e.g. programmes and model approaches the field of public health protection from counterfeit medical products and related crimes, in particular
  - prepare studies on the training needs of officials in health and law enforcement and other stakeholders,
  - organise multisectorial training programmes for health and law enforcement officials and other stakeholders, evaluate and follow up their impact,
  - make available and update training materials,
  - assist to regional training programmes upon proposal by member states after prioritisation and in line with budgetary appropriations,
  - publish practical guides sharing proven practices and models,
  - prepare proposals for recommendations for states parties to the Convention on the Elaboration of a European Pharmacopoeia and proposals for their practical implementation;

- b) facilitate networking and co-operation within member states in the field of public health protection from counterfeit medical products and related crimes through activities promoting recognised networking models (e.g. the model for a network of SPOCs prepared by the Ad hoc Group on counterfeit medicines under the aegis of the CD-P-SP within the framework of the Partial Agreement in the Social and Public Health Field<sup>3</sup>);
- c) provide public health authorities with strategies for risk communication on counterfeit medical products and related crimes, in particular
  - prepare studies on strategies for risk communication,
  - prepare proposals for recommendations for member states and proposals for their practical implementation;
- d) maintain and develop further a specific multisectorial expertise with a view to adapting programmes and procedures to the rapidly changing patterns of crime involving healthcare products in Europe and in support of states parties to the Convention on the Elaboration of a European Pharmacopoeia and of other Council of Europe bodies, the European Committee on Crime Problems and the bodies of the European Directorate on the Quality of Medicines and HealthCare (EDQM);
- e) promote a favourable environment for the implementation of regional and international specific legal instruments in the field of counterfeit medical products and related crimes at national and international levels;
- f) establish and maintain links with national, European and international institutions and organisations being active in combating counterfeiting of medical products and related crimes;
- g) develop supportive tools for information exchange on management, prevention and follow-up of the risks posed by counterfeiting of medicines and related crimes ;
- h) ensure continuity with the programme of activities and results achieved by the former Ad hoc Group on Counterfeit Medicines (P-SP-PH/CMED).

## **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 representatives from the relevant health and other law enforcement authorities.

These may include experts from health and law enforcement sectors with relevant competencies and experiences as regards risk prevention and management in the field of combating counterfeiting of medical products and related crimes. 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/CMED.

### **5.B Participants**

The CD-P-PH/CMED 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 expense of the corresponding heads of the Council of Europe budget.

---

<sup>3</sup> Endorsed by WHO IMPACT at the 2<sup>nd</sup> General Meeting, Lisbon, 12-13 December 2007

### **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/CMED, without the right to vote or defrayal of expenses.
- ii. The European Commission may send representatives to the meetings of the CD-P-PH/CMED, without the right to vote or defrayal of expenses.
- iii. The World Health Organization may send a representative to the meetings of the CD-P-PH/CMED, without the right to vote or defrayal of expenses.

### **5.D Observers**

International non-governmental organisations, relevant European and international institutions, international and European associations representing for example the pharmaceutical manufacturing and distribution chain, including manufacturers of ingredients for pharmaceutical purposes, healthcare professionals, international and European police and customs organisations active in the field, may ask for observer status with the CD-P-PH/CMED 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 unanimous agreement by the delegates of the CD-P-PH/CMED and after authorisation by the CD-P-PH.

## **6. Working methods and structures:**

The CD-P-PH/CMED will hold regular meetings and will carry out its programme of activities using scientific and public health orientated approaches, where applicable.

The orientation of the programme of activities is multisectorial comprising public health and law enforcement, relevant private sectors and health professionals.

With a view to reaching its objectives, the CD-P-PH/CMED may arrange consultations, by means of hearings or by any other means, and organise conferences and seminars, as appropriate. Where necessary, in order to expedite the progress of its work, the CD-P-PH/CMED may entrust a limited number of its members with a specific task.

## **7. Duration:**

1 January 2008 – 31 December 2010