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## **1101 Meeting, 8 December 2010**

6 Social Cohesion

### **6.4 European Pharmacopoeia (EDQM)<sup>2</sup> – European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)**

- a. Abridged report of the 4th meeting (Brussels, 15-16 September 2010)
- b. Draft terms of reference of the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)
- c. Draft Resolution CM/ResAP(2010)... on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients

Item to be prepared by the GR-SOC on 16 November 2010

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1. The 4th meeting of the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH) took place in Brussels on 15-16 September 2010 under the Chairmanship of Dr Domenico Di Giorgio (Italy). The agenda has been set out in appendix 1.
2. Ms Josiane VAN DER ELST (Federal Agency for Medicines and Health Products, Belgium), Mr Hrvoje TUMIR (Agency for Medicinal Products and Medical Devices, Croatia) alternate for Mr Sinisa TOMIC, Ms Chloe SPATHARI (Ministry of Health, Pharmaceutical Services, Cyprus) alternate for Ms Panayiota KOKKINOY, Ms Nadine DAVID (Ministry of Health, France) alternate for Ms Danielle GOLINELLI, Ms Hilda KÖSZEGI- SZALAI (National Institute of Pharmacy, Hungary) alternate for Ms Zsuzsanna SZEPEZDI, Ms Roma MOCKUTE (State Medicines Agency, Lithuania), Mr Per Thomas THOMASSEN (Ministry of Health and Care Services, Norway) alternate for Ms Nina THORESEN, and Mr Torbjörn ARVIDSSON (Medical Products Agency, Sweden) attended for the first time a meeting of the CD-P-PH.

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

3. The CD-P-PH took note of the decisions taken by the Ministers' Deputies (restricted to those representing the States Parties to the Convention on the Elaboration of a European Pharmacopoeia) at their 1084th meeting in relation to the abridged report of the 3rd meeting of the CD-P-PH.

#### **Priorities of the Swiss Chairmanship of the Committee of Ministers of the Council of Europe and forthcoming Chairmanships**

4. The CD-P-PH thanked the Swiss Agency for Therapeutic Products, Swissmedic, for having co-organised in co-operation with the Council of Europe General Secretariat under the aegis of the Swiss Chairmanship of the Committee of Ministers the International Conference "Preparing the practical implementation of the Council of Europe convention on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention)", Basel, 15-16 April 2010.
5. Welcomed the declaration of the above conference and encouraged all delegations in the CD-P-PH to provide political support in their home countries for the calls included therein.

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<sup>1</sup> This document has been classified restricted until examination by the Committee of Ministers.

<sup>2</sup> 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey and United Kingdom.

6. The Chairman invited the delegations to hold an exchange of views on possible activities which could be proposed for inclusion into the priorities of future chairmanships. Many delegations suggested the promotion and effective implementation of the MEDICRIME Convention, once adopted. One delegation considered the identification of harm caused by counterfeit medical products, and the true impact of counterfeit medical products on public health including the waste of healthcare budgets not yet sufficiently addressed at the political level.

7. One delegation proposed as topics “achieving the best outcome and value of medicines, particularly at times of increasing financial constraints”, and “the improvement of the quality of pharmaceutical care in Europe”. It referred to the concept of pharmaceutical care as being able to reduce health inequalities which the Council of Europe 2011 priorities included as one area for action. The delegation informed the CD-P-PH that it would explore with the relevant authorities in his country the possibilities for inclusion of topics within the pharmaceuticals and pharmaceutical care fields into the priorities of the chairmanship held by their country in 2011.

8. The CD-P-PH asked the Secretariat to prepare a position paper on the activities which could be recommended for inclusion into the priorities of future chairmanships and, as appropriate, offer this input to member states planning their chairmanships of the Committee of Ministers of the Council of Europe.

### **Draft Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention)**

9. The Committee welcomed the decisions of the Committee of Ministers at its 120th meeting to “...encourage its relevant bodies to finalise their work on the (MEDICRIME) Convention with a view of opening the Convention for signature by the end of this year...” and

10. appealed to the Committee of Ministers and its relevant bodies to conclude their debates on the remaining issues with a view to its opening for signature and ratification as soon as possible, recalling the urgency of the counterfeit medicines’ problem in Europe and other regions of the world.

### **Terms of reference of the CD-P-PH and its subordinate committees of experts**

11. The CD-P-PH agreed in principle with its draft revised terms of reference as included in appendix 2 and invited the Committee of Ministers to consider them at one of their forthcoming meetings in 2010. In particular it invited the Committee of Ministers to consider in its tasks related to the implementation and follow-up of the MEDICRIME Convention, once adopted, its competencies in public health protection directly related to the objectives of the convention, and its ability to contribute to the multidisciplinary follow-up of the convention.

12. The CD-P-PH expressed its appreciation for the valuable results achieved in 2008-2010 by its subordinate committees of experts.

13. Subject to the adoption of its own terms of reference by the Committee of Ministers, the CD-P-PH discussed and revised the terms of reference of its subordinate committees of experts, the CD-P-PH/PHO, CD-P-PH/PC, CD-P-PH/CMED as included in the appendices 3-5.

### **Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO)**

14. The Chairperson of the CD-P-PH/PHO recalled that the legal reference for the working programme of the above committee of experts, the Committee of Ministers Resolution ResAP(2007)1 on the classification of medicines as regards their supply, was valid and supported a working programme fully complementary to the relevant European Union legislation which was also of great value to the non-EU member states. The decision on the supply conditions of medicines in Europe remained under the competency of national governments. The annually revised recommendations on the classification and supply conditions of medicines took account of patient safety and the accessibility of medicines to them. In 2008-2010 the CD-P-PH/PHO finalised three annual revisions of the above Resolution ResAP(2007)1, about fifty scientific reviews of classification practices, and carried out a survey on the impact of new modes of medicines’ supply on the classification practices of medicines in Europe. The regular updates of the database on the classification of medicines in Europe were done in cooperation with relevant European authorities and institutions and were available to the public via the Website of the EDQM.

15. The CD-P-PH approved the conclusions of the report of the 48th meeting of the CD-P-PH/PHO on 15-17 March 2010.

### **Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC)**

16. The Chairman informed the delegations that the CD-P-PH/PC had worked out quality and safety assurance requirements for medicinal products prepared in pharmacies as requested by the CD-P-PH at its 3rd meeting. A draft resolution on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients together with the comments received from eight health authorities had been submitted to the CD-P-PH for decision at this meeting. He stated that the above comments expressed in general support for the future resolution. The required modifications concerned technical aspects, were largely consensual and did not put in question the overall concept of the draft resolution.

17. The delegations discussed a possible follow-up and further implementation of the above draft resolution through the development of formularies, such as for paediatric medicines. The delegations revised the CD-P-PH/PC's terms of reference accordingly and supported the setting-up of a specifically mandated and competent working party under the CD-P-PH/PC in order to continue its work.

18. The Chairman of the CD-P-PH/PC summarised the progress of the pharmaceutical care project: preliminary results of the development and piloting of about fifteen indicators for the quality assessment of pharmaceutical care and the outlook for a future working programme would be presented by the experts (sixteen scientists from nine collaborating universities) at an expert workshop in Strasbourg on 10 December 2010. The progress of the work demonstrated the strong interest of public authorities and health professional associations in the implementation of pharmaceutical care as a quality concept, and in an EDQM hosted platform promoting the quality of pharmaceutical care in Europe. Six delegations expressed their strong support for the continuation and transformation of the project in a truly European platform for the promotion and assessment of pharmaceutical care.

19. The Chairman of the CD-P-PH/PC referred to the working results of the CD-P-PH/PC: In 2008-2010, the CD-P-PH/PC published two survey reports in the fields of pharmaceutical care and pharmacy-preparations, organised four expert workshops in the fields of pharmaceutical care, pharmacy-preparations and the impact of Traditional Chinese Medicine on pharmaceutical practices in Europe, and prepared the draft resolution on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients.

20. The CD-P-PH/PC approved the conclusions of the report of the 65th meeting of the CD-P-PH/PC on 1-2 June 2010 and

21. approved in principle the draft resolution CM/Res (2010)... on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients, as included in appendix 6, inviting the Committee of Ministers to adopt the above draft resolution.

### **Committee of Experts on Minimising Public Health Risks posed by Counterfeiting of Medical Products and Related Crimes (CD-P-PH/CMED)**

22. The CD-P-PH Chairman also chairing CD-P-PH/CMED referred to the work of the CD-P-PH/CMED in 2008-2010 which promoted further relevant national and international legislation combating counterfeiting of medical products and carried out practical assistance programmes. More than ninety officials, multidisciplinary national teams from more than thirty-five Council of Europe member states, had not only been trained on how to protect public health from counterfeit medicines and similar crimes, but had also been assembled into a sustainable network. In addition, a standard procedure to assist member states had been implemented to carry out local or regional training: Together with the EDQM, the Italian Medicines Agency (AIFA) co-organised in 2009 a local training for sixty officials and the Portuguese National Authority of Medicines and Health Products (INFARMED I.P.) co-organised in 2010 a regional training for Portuguese and some Spanish-speaking countries in Africa and South-America. The CD-P-PH/CMED had developed several model approaches for multisectorial networking between single points of contact (SPOCs) and risk communication and supported their implementation not only in Europe but also on a global level through co-operation with the WHO. In addition, the CD-P-PH/CMED had published four guide books to provide practical information for officials, training and under/post graduate education of health professionals.

23. Taking account of the CD-P-PH/CMED competencies and experiences in the field, multisectorial composition, past and current contribution to the development of the future MEDICRIME Convention, the delegations supported that the CD-P-PH/CMED could provide technical support for the Committee of the Parties of the future MEDICRIME Convention, in particular as regards its specific tasks as a clearing house of information.

24. The CD-P-PH approved the conclusions of the report of the 5th meeting of the CD-P-PH/CMED on 26-27 May 2010.

**Date and place of the next meeting**

25. Pending the adoption of its terms of reference by the Committee of Ministers, the CD-P-PH agreed to hold its 5th meeting in Strasbourg on 6-7 September 2011.

## Appendix 1

### Agenda

1. Adoption of the Agenda
2. Committee of Ministers
  - 2.1. Decisions of the Committee of Ministers concerning the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)
  - 2.2. Priorities of the Swiss Chairmanship of the Council of Europe Committee of Ministers, November 2009 – May 2010, and of the Chairmanship of “the former Yugoslav Republic of Macedonia”, 11 May 2010 – 18 November 2010
3. Draft Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention)
4. Tasks related to the public health programme
  - 4.1 Terms of reference of the CD-P-PH, terms of reference and work programmes of its subordinate committees of experts
  - 4.2. Committee of Experts on the classification of medicines as regards their supply (CD-P-PH/PHO)
  - 4.3. Committee of Experts on quality and safety standards in pharmaceutical practices and pharmaceutical Care (CD-P-PH/PC)
    - Draft resolution on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of individual patients
    - Assessment of the quality of pharmaceutical care in Europe
  - 4.4. Committee of Experts on minimising public health risks posed by counterfeiting of medical products and related crimes (CD-P-PH/CMED)
5. Other business
6. Date and place of the next meeting

## Appendix 2

## Draft 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:</b>	<p>The activities of the Committee 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 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>• fulfil the tasks of the Public Health Committee set out in Resolution ResAP(2007)1 on the classification of medicines as regards their supply;</li> <li>• 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;</li> <li>• 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;</li> <li>• contribute to the multisectorial and multidisciplinary follow-up mechanism ensured by the Committee of the Parties to the future MEDICRIME Convention;</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>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> <p>The decision of the Committee of Ministers (CM(2010)PVadd1/11 May 2010), item 7a, adopted on 11 May 2010, welcoming the progress 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>

<p><b>Added value:</b></p>	<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 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.</li> <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 medical products and similar crimes.</li> <li>• 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.</li> </ul> <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>
<p><b>Financial information:</b></p>	<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 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 will be submitted for adoption to the Committee of Ministers 1099th (Budget) Meeting, 23-25 November 2010.</p>

## Draft 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>3</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);
- 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 future 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)<sup>4</sup> adopted and amended by WHO/FIP.

<sup>3</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.

<sup>4</sup> "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 future 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 products<sup>5</sup>, 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.

<sup>5</sup> 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 Organization (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 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 2013.

### Appendix 3

#### Draft 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 Committee of Ministers(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 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:

- a) carry out reviews on the 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) assess the impact of the results of its work programme, such as the Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1 and its annually revised appendices in the States Parties of the Convention on the Elaboration of a European Pharmacopoeia for example through statistics on the implementation of the appendices and the use of the database on the classification of medicines hosted by the EDQM.

## **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 Union 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. The CD-P-PH/PHO will use structured and systematic approaches for proposals for new projects and for carrying out repeated activities such as surveys.

**7. Duration:**

1 January 2011 – 31 December 2013.

## Appendix 4

### Draft terms of reference of the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC)

1. **Name of Committee:** Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices 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)1 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 former Partial Agreement in the Social and Public Health Field;
- the internationally recognised definition of pharmaceutical care by Hepler and Strand (1990)<sup>6</sup> adopted and amended by WHO/FIP.

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 Committee of Ministers resolutions of the former Partial Agreement in the Social and Public Health Field, the Parliamentary Assembly Recommendations and the above conclusions of the Seminar: and bearing in mind:

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

<sup>6</sup> "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"

- 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, multi-professional 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 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:

- a) improve public health care 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 these activities comprise the implementation of a quality assessment in pharmaceutical practices and care through quality indicators, the provision of guidance on the quality and safety of pharmacy-preparations such as formularies on paediatric pharmacy- preparations, advice to governments as regards the safety of Traditional Chinese Medicines (TCM) practices for European citizens based on the conclusions of the expert workshop“.The impact of TCM on pharmaceutical practices in Europe” (2010), and dose dispensing systems;
  - 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 the 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 professionals, 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) assess the impact of the results of its work programme in the States Parties to the Convention on the Elaboration of a European Pharmacopoeia.

**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 practices 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 Union 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. The CD-P-PH/PC will use structured and systematic approaches for proposals for new projects and for carrying out repeated activities such as surveys.

**7. Duration:**

1 January 2011 – 31 December 2013.

## Appendix 5

### Draft terms of reference of the Committee of Experts on Minimising Public Health Risks Posed by Counterfeiting of Medical Products and Similar Crimes (CD-P-PH/CMED)

1. **Name of Committee:** Committee of Experts on Minimising Public Health Risks Posed by Counterfeiting of Medical Products and Similar 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 former Ad hoc Group on Counterfeit Medicines; the Conference Declaration of the International Conference “Towards the practical implementation of the Council of Europe Convention on counterfeiting of medical products and similar crime involving threats to public health (MEDICRIME Convention)”, Basel, 15-16 April 2010, organised with expert support from the Committee of Experts CD-P-PH/CMED;

- the Council of Europe future Convention on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention) which ranks the prevention of threats to public health from 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 multiprofessional approach;
- the forward-looking strategy on minimising public health risk posed by counterfeit medicines and related crimes in Europe through the development of practical measures prepared by the former Ad hoc Group on counterfeit medicines,

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 bearing in mind that counterfeiting of medical products and similar 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 (ECHR);
- undermine public trust and cost-effectiveness 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:

- 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 public health implications of criminal phenomena pertaining to counterfeiting of medical products and similar crimes including training needs of officials in health and law enforcement and their stakeholders,
  - organise multisectorial training programmes for health and law enforcement officials and other stakeholders, including e-learning methods, 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 similar crimes through activities promoting recognised networking models (e.g. the model for a network of SPOCs prepared by the former Ad hoc Group on counterfeit medicines;<sup>7</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) as provided for in the future MEDICRIME Convention, and expanded in the MEDICRIME Explanatory Memorandum, make available scientific expertise to the Committee of the Parties to the Council of Europe MEDICRIME Convention as regards its specific functions such as the facilitation of information exchange on significant legal, policy or technological developments in relation to the application of the provisions of the Convention;
- e) 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 for the Quality of Medicines and HealthCare (EDQM);
- f) promote a favourable environment for the implementation of regional and international specific legal instruments in the field of counterfeit medical products and similar crimes at national and international levels;
- g) establish and maintain links with national, European and international institutions and organisations being active in combating counterfeiting of medical products and related crimes;
- h) develop supportive tools for information exchange on management, prevention and follow-up of the risks posed by counterfeiting of medical products and similar crimes;
- i) assess the impact of the results of its work programme in the States Parties to the Convention on the Elaboration of a European Pharmacopoeia.

## **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>7</sup> Endorsed by WHO IMPACT at the 2nd General Meeting, Lisbon, 12-13 December 2001

**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 Union 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 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, in particular with international and European associations representing for example the pharmaceutical manufacturing and distribution chain, including manufacturers of ingredients for pharmaceutical purposes, health professionals, 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. The CD-P-PH/CMED will use structured and systematic approaches for proposals for new projects and for carrying out repeated activities such as surveys.

**7. Duration:**

1 January 2011 – 31 December 2013.

## Appendix 6

### **Draft Resolution CM/ResAP(2010)... on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients**

*(Adopted by the Committee of Ministers on ... 2010  
at the ... meeting of the Ministers' Deputies)*

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<sup>8</sup> (ETS No. 50),

Considering that the aim of the Council of Europe is to achieve greater unity between its members and this aim may be pursued, among others, by common action in the public health field including the adoption of common regulations;

Having regard to the standard-setting carried out under the Convention on the Elaboration of a European Pharmacopoeia and its Protocol (ETS No. 134) which endeavours to promote progress in every way possible, both in the social field and the related field of public health through the harmonisation of specifications for medicinal substances, which, in their original state or in the form of pharmaceutical preparations, are of general interest and importance to the peoples of Europe;

Underlining the need to apply where possible relevant international standards such as those developed by the World Health Organization and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S);

Recalling also the chapters and monographs of the European Pharmacopoeia containing general and specific requirements applicable to medicinal products prepared in pharmacies, in particular about standards and methods for the control of the chemical, pharmaceutical and microbiological quality of active substances and excipients, about dosage forms and containers;

Bearing in mind the measures proposed in the Committee of Ministers Resolution AP (93) 1 on the role and training of community pharmacists, Resolution AP (94) 1 on the rational use of medicines and Resolution AP (97) 2 on the development of the function of pharmacists and the adaptation of their initial training, and the need to implement them;

Recalling the measures proposed in the Committee of Ministers Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security, *inter alia* emphasising that community pharmacists are the health professionals most readily accessible to patients and that they help to personalise the delivery of patient care;

Bearing in mind the results of the international symposium "European cooperation and synergy in quality standards beyond the European Pharmacopoeia", held on 15 and 16 June 2007, and of the expert workshop "Promoting standards for the quality and safety assurance of pharmacy-prepared medicinal products for the needs of patients", held on 24 September 2009 at the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, in Strasbourg;

Considering that medicinal products manufactured by the pharmaceutical industry are not always authorised or available to cover the special needs of individual patients;

Noting that medicinal products manufactured on an industrial scale must obtain marketing authorisation issued by the competent regulatory authority before being placed on the market;

Considering that the preparation of medicinal products in pharmacies, which may be required as a consequence of the individual or medical condition of the patient in the absence or unavailability of appropriate medicinal products on the market, is indispensable for accommodating the special needs of individual patients in Europe;

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<sup>8</sup>. Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey and the United Kingdom.

Noting that the preparation of medicinal products in pharmacies is not harmonised throughout Europe and falls under the national competencies of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia;

Considering that pharmacists can legally prepare medicinal products in the pharmacy by virtue of their professional education, professional licence and licensing of the pharmacy's premises;

Emphasising that patient safety and the achievement of the therapeutic aim require that medicinal products prepared in pharmacies meet appropriate and specific criteria for quality, safety and added value also where no marketing authorisation is required;

Underlining that the requirements for the quality and safety assurance of medicinal products prepared in pharmacies through specific structures and processes, in addition to the relevant pharmacopoeial requirements, are necessary for ensuring appropriate patient safety in Europe and the added value of the preparation of such medicinal products in pharmacies;

With a view to avoiding quality and safety gaps between medicinal products prepared in pharmacies and those prepared on an industrial scale, recommends that the governments of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia adapt their regulations in accordance with the principles set out in the present resolution:

- added value of pharmacy preparations and responsibilities of health-care professionals;
- preparation process;
- product dossier;
- marketing authorisation;
- labelling;
- compliance with pharmacopoeial requirements;
- reconstitution of medicinal products;
- authorisation for pharmacies or licences for companies making preparations for pharmacies;
- transparency and safety;
- rational use;
- surveillance;
- communication and information to patients;
- distribution of pharmacy preparations.

In order to implement the present resolution States Parties to the Convention on the Elaboration of a European Pharmacopoeia will have to supplement it through additional practical guidance, taking into account the national frameworks.

*Appendix to Resolution CM/ResAP(2010)...*

## **1. Field of application**

This resolution covers medicinal products for human use only. Other products, such as medical devices or cosmetic products are outside the scope of this resolution.

This resolution applies to pharmacy preparations (unlicensed pharmaceutical preparations), namely, medicinal products which are prepared for the special needs of patients by community and hospital pharmacies and to comparable processes and preparations of medicinal products not carried out in pharmacies, but by companies under their licence and upon the request of pharmacies. It applies also to the reconstitution of medicinal products in health-care establishments.

The provisions cover all pharmacy preparations, both extemporaneous and for stock, and their applicability depends on the outcome of the risk-assessment of the pharmacy preparation.

## **2. Definitions**

Closed-system procedure for sterile medicinal products: a procedure whereby a sterile medicinal product is prepared by transferring sterile starting materials or solutions to a pre-sterilised sealed container, either directly or by using a sterile transfer device, and without exposing the solution to the external environment (such as intravenous infusion services: services for cytotoxic medical products or total parenteral nutrition (TPN)).

Dispensing pharmacy: the pharmacy which receives the prescription for a patient and which provides the pharmacy preparation to the patient (often, the preparing and the dispensing pharmacies are identical).

External supply (see Note 1, model procedure for risk assessment): any supply of pharmacy preparations by the preparing pharmacy other than directly to patients.

Good distribution practices (GDP): practices as specified in the European Commission "Guidelines on good distribution practice of medicinal products for human use" (94/C 63/03).

Good manufacturing practices (GMP): practices as specified in European Commission Directive 2003/94/EC and EudraLex, Volume 4, on guidelines for good manufacturing practices for medicines for human and veterinary use.

Good preparation practices (PIC/S GPP): "Guide to good practices for the preparation of medicinal products in healthcare establishments", in Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide PE 010.

Internal supply (see Note 1, model procedure for risk assessment): the direct supply of pharmacy preparations to patients by the preparing pharmacy.

Open-system procedure for sterile medicinal products: a procedure whereby a sterile medicinal product is prepared and the solution is exposed to the external environment.

Pharmaceutical equivalent: a medicinal product having the same active substances, irrespective of the excipients used, the same or similar intended purpose, equivalent strength and posology, and the same or similar route of administration.

Preparing pharmacy: produces the pharmacy preparation for a dispensing pharmacy (often, the preparing and the dispensing pharmacies are the same).

Reconstitution: manipulation to enable the use or application of a medicinal product with a marketing authorisation in accordance with the instructions given in the summary of product characteristics or the patient information leaflet.

### **3. Added value of pharmacy preparations and responsibilities of health-care professionals**

Pharmacy preparations are of added value if, due to medical, pharmaceutical or personal reasons, they are needed by a specific patient or by specific population groups with particular needs.

#### *3.1. Pharmaceutical equivalents on the national market*

Pharmacy preparations are not advisable if a suitable pharmaceutical equivalent with a marketing authorisation is available. Before preparation the pharmacist should verify whether a pharmaceutical equivalent is available on the national market, taking into consideration the pharmaceutical form and the strength.

#### *3.2. Added value and responsibility of health-care professionals*

The professionals involved in patient care should jointly assume responsibility for determining whether a pharmacy preparation could be of added value. They should take into account the medical need of the patient. A pharmacist should be able to refuse a prescription for a pharmacy preparation if a suitable pharmaceutical equivalent is available on the national market, inform the physician that a suitable pharmaceutical equivalent is available and discuss with the physician if there is a specific need to dispense a pharmacy preparation.

If the preparing pharmacy and the dispensing pharmacy are not identical, their different responsibilities, including the sharing of those elements of the product dossier essential for the safe use of the product by the patient, should be defined either in regulations or a contractual agreement. Pharmacy preparations should always be distributed by a dispensing pharmacy because this pharmacy receives the prescription for the patient. The preparing pharmacy should be responsible for ensuring that an appropriate quality assurance system is in place.

#### 4. Preparation process

All pharmacy-prepared medicinal products should be prepared using an appropriate quality assurance system. Before preparation, a risk assessment should always be carried out in order to define the level of the quality assurance system which should be applied to the preparation of the medicinal product.

A possible model procedure for risk assessment, described in section 5.2 and in Note 1, provides an aid to distinguishing between two risk levels (“high-risk preparations” and “low-risk preparations”) and between two levels of quality system based on a risk-graded application of quality assurance principles.

It is recommended that the GMP Guide be used as a reference for an appropriate quality system for “high-risk preparations”, and that the PIC/S GPP Guide be used for “low-risk preparations”. The application of other guidelines with an equivalent quality level is possible, depending on the national legislation or guidance.

Premises, facilities and pharmaceutical knowledge should be appropriate for the preparation of the medicinal product.

#### 5. Product dossier

Product dossiers, as described in Note 2, should be required only for stock preparations.

For extemporaneous preparations it will not usually be possible to compile a product dossier containing all possible information mentioned in 5.1. Compiling such a dossier would also be impractical because it could lead to a delay in the supply of necessary medicines. For extemporaneous preparations, however, the pharmacist and the prescriber should always consider the risks for the patient, which include the risks posed by a medicinal product without documentation specifying the added value of the pharmacy preparation and the quality assurance system applied to its production versus the risks related to the unavailability of this medicinal product.

##### *5.1. Topics to be covered by a product dossier*

The pharmacy should ensure a good balance between all possible disadvantages and the added value of the pharmacy preparation. The product-specific quality properties, as well as the site-specific manufacturing conditions of the preparation should be specified in a product dossier.

A product dossier should cover the following topics:

- a. demonstration of the added value of the pharmacy preparation;
- b. demonstration that the active pharmaceutical ingredients, excipients and containers meet relevant requirements, taking into account specific patient needs;
- c. description of the preparation process including, where appropriate, testing;
- d. development and background documentation of the preparation process;
- e. use of the product including information for the patient and the prescriber.

The contents and detail of information as mentioned in points a to e above depend on the risk assessment, which should be documented. The product dossier should be more comprehensive for preparations that carry a higher risk than for those carrying a lower risk.

This is taken into account by the model procedure for risk assessment, see Note 1.

Alternative risk assessment methods may be applied, provided that an appropriate assessment of the risk is obtained.

More details about the product dossier can be found in Note 2.

##### *5.2. Risk assessment of a pharmacy preparation*

When making a pharmacy preparation, the pharmacist should always undertake an appropriate risk assessment in order to determine the level of the quality system which should be applied to the preparation of the medicinal product.

This risk assessment should consider:

- a. dosage form and administration route;
- b. amount prepared;
- c. pharmacological effect of the medicinal product for the envisaged route of administration;
- d. therapeutical window (dose range for therapeutic doses);
- e. type of preparation process;
- f. supply.

The risk assessment should consider the contribution of active pharmaceutical ingredients and excipients to the safety profile of the pharmacy preparation.

Where appropriate, active pharmaceutical ingredients manufactured according to GMP and analysed according to pharmacopoeial standards should be used.

A risk assessment model can be found in Note 1.

### *5.3. Availability of data for authorities for inspection or upon request*

Pharmacies should have chemical, pharmaceutical and microbiological data or information (see 5.1, a-e), as applicable, concerning the pharmacy preparations available for inspection or upon request of the authorities.

The production of different batches should be documented in individual batch records, which should be included in the product dossier.

## **6. Marketing authorisation**

If the preparation is carried out on a scale comparable to the industrial level, if GMP is applicable, if distribution takes place and if an authorised medicinal product, or a pharmaceutical equivalent (see item 3.1), is on the market, the competent drug regulatory authorities should consider establishing, if they have not already done so, the requirement for obtaining a marketing authorisation for pharmacy preparations (see Note 1: refer to "high-risk preparation").

## **7. Labelling**

Correct labelling is essential for patient safety. The label should present the following information, as appropriate:

- a. name, address, and telephone number of the dispensing pharmacy;
- b. name and address of the preparing pharmacy;
- c. name of the pharmacy preparation, if applicable;
- d. full qualitative composition and the quantity of the active substance;
- e. batch number, if applicable;
- f. expiry date or information about limits for use;
- g. special storage conditions or handling precautions;
- h. directions for use, warnings and precautions;
- i. route of administration.

## **8. Compliance with pharmacopoeial requirements**

When a pharmacy preparation is needed and if it is applicable, a standard formula should be searched in a national pharmacopoeia or nationally recognised formularies.

Active pharmaceutical ingredients and excipients used for the pharmacy preparations, dosage forms and containers must comply with the relevant chapters and monographs of the European Pharmacopoeia or, in absence thereof, of a national pharmacopoeia of a State Party to the Convention on the Elaboration of a European Pharmacopoeia.

Where no applicable pharmacopoeial individual monographs or general chapters exist, the chemical, pharmaceutical and microbiological quality of the starting materials should be fit for pharmaceutical use and be demonstrated on the basis of validated methods.

## **9. Reconstitution of medicinal products in health-care establishments**

In general, reconstitution of medicinal products should preferably take place in a pharmacy, assuming that the requirements concerning the safe preparation of sterile products can be fulfilled. Reconstitution considered to be low risk can be done on the wards.

### *9.1. Risk assessment for reconstitution*

The risk assessment should consider the following topics:

a. complexity of the process and the availability of adequate instructions

- complexity of the reconstitution process, e.g. the number of steps in the process;
- processing instructions that define and document the steps to be followed in the reconstitution processes for the different products.

b. premises, equipment and the application of environmental monitoring

- premises and equipment used;
- availability of clean areas with the required air classification;
- availability of laminar air flow systems;
- environmental monitoring that demonstrates the effectiveness of the measures taken to minimise the risk of contamination of the product by the personnel.

c. nature of the product

#### *Sterile medicinal products*

In the case of reconstitution of authorised medicinal products for parenteral administration, the risk assessment should be documented.

System requirements comprise both closed-system procedures or open-system procedures.

d. relevant education and training

Hygienic behaviour and appropriate clothing should be ensured, in accordance with the instructions. Appropriate training must be documented. Qualification of personnel should be checked, based on the results of individual microbiological monitoring.

### *9.2. Responsibilities of the health-care establishment*

Based on the above risk assessment (see 9.1), the health-care establishment should decide and document which products should be reconstituted in pharmacies and which products can be reconstituted in the wards.

When reconstitution takes place in the ward, a pharmacist should approve written procedures and ensure that the staff involved in reconstitution are appropriately trained.

### *9.3. Role of the authorities*

As reconstitution is not generally considered a process in the frame of pharmacy preparations, national authorities should develop, in co-operation with the relevant professional bodies, specific legislation or guidance taking into consideration the elements in the present section 9.

## **10. Authorisation for pharmacies or licences for companies making preparations for pharmacies**

### *10.1. Authorisation for pharmacies*

In general, authorisation by the competent authorities or bodies is a pre-requisite for a pharmacy to carry out operations.

If considered appropriate to guarantee the quality and safety of pharmacy preparations, the authorities should provide for an additional authorisation or a licence for preparation. An additional authorisation or licence can be granted or suspended, depending on compliance with its conditions.

### *10.2. Licence for companies*

The rules for authorisation requirements apply to companies other than pharmacies, but making comparable preparations and carrying out processes under their licence at the request of pharmacies.

In some countries the preparation of medicinal products is performed at the request of pharmacies by companies which are not pharmacies. In this case, a manufacturing licence issued by the competent authority should be mandatory.

## **11. Transparency and safety**

### *11.1. Reporting of quality and safety issues*

All quality and safety issues arising from the use or making of pharmacy preparations should be recorded and notified to the competent national authorities. An appropriate system for reporting quality and safety issues should be put in place which allows for a link between this notification, the product, the preparing and dispensing pharmacies, and the preparation process.

### *11.2. Notification or announcement system*

With a view to dealing with high-risk preparations, the competent national authorities should obtain relevant information on the preparation activities performed in each pharmacy. The establishment of an appropriate notification system should be considered.

### *11.3. Inventory for pharmacy preparations*

With a view to transparency as regards pharmacy preparations for stock, the establishment of national inventories is encouraged.

The national inventory should cover the following topics:

- a. names of the preparing pharmacies;
- b. full composition of the available pharmacy preparations;
- c. preparing pharmacies' portfolio of different preparations.

### *11.4. Rational use*

Based on clinical criteria, member states should be encouraged to engage with clinical experts on rational use of the medicines established in the inventory.

### *11.5. Surveillance*

Based on the information obtained through the above-mentioned notification system, the competent authorities should perform risk-based inspections.

Competent authorities should have powers to suspend preparation activities.

## **12. Communication and information to patients**

Communication to patients and carers of patients receiving pharmacy preparations is of crucial importance.

### *12.1. Information about the pharmacy preparation*

Essential information should be given to the patient, if available, based on the product dossier. A leaflet containing product-specific information to patients is not needed for pharmacy preparations. General information to patients concerning the therapy and the use of the pharmacy preparation is recommended, including indications in some specific cases.

### 13. Distribution of pharmacy preparations

#### 13.1. Compliance with good distribution practices (GDP)

Pharmacies or companies preparing medicinal products under their responsibility upon the request of pharmacies should comply with good distribution practices (GDP).

#### 13.2. Export/import of pharmacy preparations

Other than to meet an individual patient's needs, export/import, of pharmacy preparations from a State Party to the Convention on the Elaboration of a European Pharmacopoeia to other states parties should not take place, unless bilateral agreements exist. As long as no uniform and mutually agreed quality requirements for medicinal products without marketing authorisation are available, and as long as the inspectorates' competencies are not regulated, export should not take place.

\* \* \*

#### **Note 1: Model procedure for risk assessment**

This is a proposed model for risk assessment as to whether a pharmacy preparation carries a high or a low risk as referred to in this resolution. Alternative risk-assessment methods may be applied provided that an appropriate assessment of the risk is obtained.

The risk assessment should also consider the contribution of the active pharmaceutical ingredients, excipients and containers to the safety profile of the pharmacy preparation.

Under the following sections 1 to 5, the decision criteria for the risk assessment of pharmacy preparations are specified. Each decision criterion has a graded risk factor ranging from 1 to 5. The multiplication of these risk factors results in a number, which indicates the level of the quality system required for the pharmacy preparation process. If the number is higher than 100 the preparation is considered a "high-risk preparation"; if the number is equal to or lower than 100, it is considered a "low-risk preparation". It is recommended that the GMP Guide be used as a reference for an appropriate quality system for "high-risk preparations", and that the GPP Guide be used for "low-risk preparations". The application of other guidelines with an equivalent quality level is possible, depending on national legislation or guidance.

#### **Risk-based decision matrix**

##### **1. Type of preparation**

a. parenteral preparations	= 5
b. eye preparations used in trauma or surgery	= 4
c. preparations for inhalation	= 4
d. dosage forms for sterile digestive administration (such as oral, sublingual and rectal administration)	= 4
e. cutaneous and transdermal preparations	= 4
f. dosage forms for digestive administration (such as oral, sublingual and rectal administration)	= 3
g. eye preparations used on the intact eye	= 1
h. cutaneous and transdermal preparations/dosage forms where sterility is not required	= 1

##### **2. Amount prepared annually (units)**

Depending on the type of preparation and the amount prepared annually, a risk factor between 1 and 5 should be determined, taking into account national legislation or guidance. It is recommended to define a separate set of risk factors (1-5) for the following types of preparation, with a risk factor of 1 for very small amounts:

- liquid preparations and solid preparations (e.g. powders);
- oral preparations (solid dosage forms);
- rectal preparations;
- cutaneous and transdermal preparations;
- eye preparations.

### 3. Pharmacological effect of the active substances

- |                |     |
|----------------|-----|
| a. very strong | = 5 |
| b. strong      | = 3 |
| c. mild        | = 1 |

While grading the pharmacological effect of the active substances, the following criteria should be considered: absence of a pharmacopoeial monograph at European level or at the level of a State Party to the Convention on the Elaboration of a European Pharmacopoeia, carcinogenetic properties, mutagenic properties, ecological toxicity, risk of allergy, therapeutical window, dosage, stability (light, O<sub>2</sub>, temperature, pH changes), and chemical, pharmaceutical and microbiological quality.

### 4. Preparation process

- |   |     |
|---|-----|
| a. aseptic filling  | = 5 |
| b. terminal sterilisation                                   | = 4 |
| c. dissolving, mixing not for the purpose of reconstitution | = 2 |
| d. diluting not for the purpose of reconstitution           | = 2 |
| e. filling only (non-sterile product)                       | = 1 |

### 5. Supply

- |                                      |     |
|--------------------------------------|-----|
| a. external only                     | = 5 |
| b. mainly external (I:E ≈ 1:2)       | = 4 |
| c. internal and external (I:E ≈ 1:1) | = 3 |
| d. mainly internal (I:E ≈ 2:1)       | = 2 |
| e. internal only                     | = 1 |

\* \* \*

#### **Note 2: List of topics to be covered in a product dossier, depending on the results of the risk assessment for pharmacy preparations**

1. Added value and preparation process of the pharmacy preparation
  - a. description of the final preparation process;
  - b. demonstration of the added value of the pharmacy preparation.
2. Composition
  - a. function;
  - b. demonstration that the active pharmaceutical ingredients, excipients and containers meet relevant requirements, taking into account specific patient needs;
  - c. specifications and traceability of origin of the starting materials;
  - d. specifications of the primary packaging material, etc.
3. In-process controls and quality controls of the finished product
  - a. product specific procedures;
  - b. records of prepared batches.
4. In-process controls and quality control of finished product
  - a. sampling
  - b. analytical methods
  - c. acceptance criteria, etc.
5. Results of test batches (namely, information on the development, background and evaluation of the preparation process, including testing)
6. Validation
  - a. of preparation process;
  - b. of analytical methods.
7. Stability considerations
  - a. a plan for own stability studies;
  - b. the evaluation of stability data, etc.
8. Use of the product and information for the patient