
1137 Meeting, 14 March 2012

6 Social cohesion

6.2 European Directorate for the Quality of Medicines and HealthCare (EDQM)

b. European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH) – Abridged report of the 5th meeting (Strasbourg, 5-6 September 2011)

For consideration by the GR-SOC at its meeting of 23 February 2012

1. The 5th meeting of the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH) took place in Strasbourg on 6-7 September 2011 under the Chairmanship of Mr Domenico Di Giorgio (Italy). The agenda appears in appendix.

2. Ms An LE (Agence française de sécurité sanitaire des produits de santé (AFSSAPS)), Ms Lenka BALAZOVA (State Institute for Drug Control, Czech Republic) alternate for Ms Eliska Jarosova, Dr Marcello CHIAVONI (Italian Medicines Agency (AIFA)), Dr Katrin KOLLIST (States Agency of Medicines, Estonia), Ms Nino JAPARIDZE (Ministry of Labour, Health and Social Affairs, Georgia), Mr Fernando PIEDRA (Spanish Agency of Medicines and Medical Devices (AEMPS)), Dr Andrii ZAKHARASH and Mr Denys GURAK (State Administration of Ukraine on Medicines) were all attending a meeting of the CD-P-PH for the first time.

Election of the Chair and Vice-Chair

3. The CD-P-PH unanimously re-elected, by open ballot, Mr Domenico DI GIORGIO, Italy, as Chair and Mr Nico KIJLSTRA, the Netherlands, as Vice-Chair for second terms in office, from 2011 to 2013.

Decisions by the Committee of Ministers

4. 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 1101st meeting in relation to the abridged report of the 4th meeting of the CD-P-PH and the Committee's prolonged terms of reference, and at their 1103rd meeting where *inter alia* Resolution CM/ResAP(2011)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients had been approved.

5. With a view to further improving the impact of the tasks entrusted to it in its terms of reference, the CD-P-PH requested that its subordinate committees of experts set out concrete implementation plans in all project proposals in future.

¹ This document has been classified restricted until examination by the Committee of Ministers.

Priorities of the Chairmanship of Ukraine of the Committee of Ministers of the Council of Europe and forthcoming chairmanships

6. The CD-P-PH re-confirmed the following activities identified at its 4th meeting as being suitable for recommendation for inclusion in the priorities of future chairmanships, such as: implementation of the Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (MEDICRIME Convention); obtaining the best outcome and value of medicines particularly at times of increasing financial constraints; improving the accessibility of medicines in Europe and the quality of the medication chain through pharmaceutical care in Europe. It encouraged the delegations to develop proposals for priorities. It asked the Secretariat to bring the proposals to the attention of member States planning their chairmanships of the Committee of Ministers of the Council of Europe and to provide support as appropriate.

Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (MEDICRIME Convention)

7. Reiterating the urgent need to tackle counterfeit medical products and similar crimes in Europe and other regions of the world, the CD-P-PH welcomed the adoption of the MEDICRIME Convention by the Committee of Ministers. It called on all delegations to contribute to the rapid signature, ratification and implementation of the MEDICRIME Convention by their home governments.

8. The CD-P-PH asked all delegations to support the participation of senior officials and policy-makers in the health field in the International High-Level thematic Conference in Moscow, 26-28 October 2011, opening the MEDICRIME Convention for signature by States.

9. The CD-P-PH endorsed the progress report and proposal for a mid-term strategy "Promoting the Council of Europe MEDICRIME Convention in 2011-2013". The document was drafted by the Committee of Experts on Minimising Public Health Risks posed by Counterfeit Medical Products and Similar Crimes (CD-P-PH/CMED). It was based on the provisions of the convention and reflected the specific tasks related to the convention included in the terms of reference of both committees.

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

10. The CD-P-PH approved the conclusions of the reports of the 49th and 50th meetings of the CD-P-PH/PHO held on 4-5 November 2010, and 15-17 March 2011, respectively.

11. The CD-P-PH asked all delegations to support the participation of national nominees in the Expert Workshop on "*Good practices for the classification of medicines as regards their supply which protect public health and promote the accessibility of medicines in Europe*", organised by the CD-P-PH/PHO in Strasbourg (France), 8-9 November 2011. The workshop objectives were to discuss amongst participants from national authorities and European institutions good classification practices and to strengthen further the role of the CD-P-PH/PHO as a platform for co-operation of member States and as a pool of expertise supporting national authorities and European institutions.

12. The CD-P-PH expressed its support for the implementation of the 2010 edition of the appendices of the Resolution ResAP(2007)1 on the classification of medicines as regards their supply and noted that the update of the database on the classification of medicines in Europe (Melclass) was available to the public via the EDQM website.

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

13. The CD-P-PH approved the conclusions of the reports of the 66th and 67th meetings of the CD-P-PH/PC held on 2-3 November 2010, and 2-3 March 2011, respectively.

14. It noted with appreciation the conclusions of the Expert Workshop "*Indicators of the quality of pharmaceutical care: development approaches and preliminary results*" in Strasbourg on 10 December 2010, which had confirmed the scientific rationale for the proposed indicators and had given scientific orientation on the validation of indicators in practice in 2011-2013.

15. The CD-P-PH endorsed the progress report and proposal for a mid-term strategy "*Quality assessment of pharmaceutical care in Europe through indicators 2011-2013*". The document was drafted by the CD-P-PH/PC. It was based on the results of the work programme (2008-2010), the conclusions of the 2009 and the 2010 expert workshops and reflected the specific tasks related to pharmaceutical care included in the terms of reference of both committees.

16. The CD-P-PH underlined the importance of validated indicators of pharmaceutical care in Europe for responsible healthcare policies which would meet the needs of patients and societies and were suitable for developing appropriate professional standards.

17. The CD-P-PH supported a contribution on the above project to an international conference in 2012. The event will be co-organised between the Dutch health authorities and international organisations such as the WHO, with the support of professional associations and academic institutions. The contribution could promote support and awareness of the value of structured information from valid indicators about pharmaceutical care for policy-makers. It invited the delegations to inform the Secretariat by 15 October 2011 of their interest in supporting the preparation of a specific contribution.

18. The CD-P-PH invited the delegations to send information on national implementation plans/activities as regards Resolution CM/ResAP (2011) 1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients to the Secretariat by 15 October 2011.

19. The CD-P-PH welcomed follow-up activities providing detailed and specific guidance about certain articles of the above resolution, such as reconstitution and automated unit-dose dispensing.

20. The CD-P-PH welcomed the progress of the activities in the field of Traditional Chinese Medicine (TCM) practices in Europe such as the development of model curricula and of criteria for valid and balanced information for patients and the general public.

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

21. The CD-P-PH approved the conclusions of the reports of the 6th and 7th meetings of the CD-P-PH/CMED held on 30 November-1 December 2010, and 7-8 June 2011, respectively.

22. It expressed its thanks to the Italian Medicines Agency (AIFA) for co-organising together with the CD-P-PH/CMED the Expert Workshop "*Best practices – risk communication about counterfeit medical products and similar crimes*" in Rome (Italy), 29 November 2011. The CD-P-PH asked all delegations to support the participation of national nominees in the expert workshop, which aimed to discuss key elements of good communication practices about the risks of counterfeiting of medical products and similar crimes.

23. In this context, the CD-P-PH commended the AIFA for its long-term, significant support through expertise and financial support for the activities carried out by the CD-P-PH/CMED, in particular training events, expert workshops and publications, underlining that measurable effects had been achieved.

24. The CD-P-PH thanked the Norwegian Medicines Agency for hosting in Oslo (Norway) on 19-20 May 2011 the first advanced level training on how to combat counterfeiting of medical products and similar crimes and to protect public health for 25 officials from Estonia, Finland, Latvia, Lithuania, and Norway. Furthermore, it welcomed the fact that the health authorities of the United Kingdom would explore possibilities for hosting a training event in 2012, as indicated by the delegation of the United Kingdom at the 7th meeting of the CD-P-PH/CMED.

Date and place of the next meeting

25. The CD-P-PH agreed to hold its 6th meeting in Strasbourg on 4-5 September 2012.

Appendix

Agenda

1. Adoption of the Agenda
2. Election of the Chair and Vice-Chair
3. Committee of Ministers
 - 3.1. Decisions of the Committee of Ministers concerning the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)
 - 3.2. Priorities of the Chairmanship of the Ukraine of the Council of Europe Committee of Ministers, and of further Chairmanships
4. Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (MEDICRIME Convention)
5. Tasks related to the public health programme
 - 5.1. Committee of Experts on the Classification of Medicines as regards their Supply (CD-P-PH/PHO)
 - 5.2. Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC)
 - 5.3. Committee of Experts on Minimising Public Health Risks posed by Counterfeiting of Medical Products and Similar Crimes (CD-P-PH/CMED)
6. Other business
7. Date and place of the next meeting