
1084 Meeting, 5 May 2010

6 Social cohesion

6.4 European Pharmacopoeia (EDQM)² –

European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH) –

Abridged report of the 3rd meeting (Strasbourg, 26-27 January 2010)

For consideration by the GR-SOC at its meeting of 22 April 2010

1. The 3rd meeting of the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH) took place in Strasbourg on 26 and 27 January 2010 under the Chairmanship of Dr Domenico Di Giorgio (Italy). The agenda has been set out as an appendix.
2. Dr Vesa Jormanainen (Medicines Agency, Finland) alternate for Ms Eija Pelkonen, Ms Maria Joao Morais (National Agency for Medicines and Healthcare (Infarmed), Portugal), Mr Jozef Slany (Ministry of Health, Slovak Republic) and Mr Janez Obreza (Agency for Medicinal Products and Medical Devices, Slovenia) attended for the first time a meeting of the CD-P-PH.
3. The CD-P-PH took note of the decisions taken by the Ministers' Deputies (in their composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia) at their 1063rd meeting in relation to the abridged report of the 2nd meeting of the CD-P-PH.

Decisions by the Committee of Ministers

4. The CD-P-PH took note of the decisions of the Minister's Deputies on the preparation of a future convention of the Council of Europe on the counterfeiting of medical products and similar crimes involving threats to public health, and in particular to approve the terms of reference of the Ad hoc Committee on Counterfeiting of Medical Products and similar Crimes involving Threats to Public Health (PC-ISP).

Priorities of the Swiss Chairmanship, 18 November 2009 - 11 May 2010

5. The CD-P-PH took note that the Swiss Agency for Therapeutic Products, Swissmedic, was organising under the aegis of the Swiss Chairmanship of the Committee of Ministers of the Council of Europe 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)" in Basel on 15-16 April 2010 in co-operation with the EDQM and supported by the Directorate for Standard-Setting within the Directorate General of Human Rights and Legal Affairs. It expressed appreciation for the support given by the Swiss Delegation and invited all delegations to participate and support the nomination of senior policy-making officials from the relevant national authorities for the above conference.

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

² 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.

Observer status within the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)

6. With a view to taking a decision on the request of the Sovereign Order of Malta, the CD-P-PH had requested the Secretariat at its 2nd meeting on 2-3 April 2009 to clarify the role of an observer within the CD-P-PH. The CD-P-PH took note that the Sovereign Order of Malta - not being a non-governmental organisation (NGO) within the meaning of Recommendation CM/Rec(2007)14 of the Committee of Ministers - could not be granted observer status under the present terms of reference.

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

7. The Chairman, representative of the CD-P-PH at the meetings of the Ad hoc Committee on the counterfeiting of medical products and similar crimes involving threats to public health (PC-ISP), informed the delegations about the debates and the text that had been negotiated and finalised by the PC-ISP.

8. The CD-P-PH invited the Committee of Ministers to consider the urgency of tackling medicines' counterfeiting and to adopt the MEDICRIME Convention and

9. called upon all delegations to encourage their home governments to support the process of adoption, signature and ratification, and implementation of the MEDICRIME Convention.

10. Considering the complex consequences of the counterfeiting of medical products and similar crimes for the health of patients and the integrity of national healthcare systems, the CD-P-PH emphasised the importance of a multisectorial monitoring mechanism to ensure the effective implementation of the MEDICRIME Convention.

11. With reference to the tasks entrusted by the Committee of Ministers in its terms of reference, the CD-P-PH expressed its continued commitment towards public health protection, risk management and prevention of counterfeit medical products and similar crimes, and offered to provide support to the Committee of the Parties as regards its functions set out in the draft MEDICRIME convention text.

12. The CD-P-PH underlined the importance of involving its subordinate Committee of Experts on minimising public health risks posed by the counterfeiting of medical products and related crimes (CD-P-PH/CMED) in the monitoring mechanism as set out in the draft MEDICRIME convention text through making technical expertise available, flagging public health risks and through continued action fostering awareness of the public and developing multisectorial actions through appropriate training,

13. called upon the EDQM to give adequate support to the CD-P-PH/CMED and

14. encouraged the CD-P-PH/CMED to include in its proposals for a mid-term strategy specific activities to support the MEDICRIME Convention's implementation through practical assistance for risk management and prevention including training and situation reports.

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

15. The Belgian delegation and Chairperson of the CD-P-PH/PHO urged minimum requirements for the quality and safety of medicines distributed via internet pharmacies and stated that the absence of such requirements could have a bearing on the decision to release a medicine from prescription status. The Dutch delegation and Vice-Chairman of the CD-P-PH pointed out the need for standards for electronic prescriptions, which are necessary to protect public health. One delegation stated that it was necessary to acquire a common understanding about the handling and protection of personal data used in electronic prescriptions.

16. The CD-P-PH approved the conclusions of the reports of the 46th meeting on 24-25 February 2009 and of the 47th meeting on 15-16 September 2009 of the CD-P-PH/PHO;

17. took note of the publication of the 2009 revision of the appendices of the Committee of Ministers' Resolution ResAP(2007)1 on the classification of medicines as regards their supply;

18. supported the inclusion of the quality and patient safety aspects of electronic prescriptions into the CD-P-PH/PHO working programme.

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

19. The Dutch delegation and Chairman of the CD-P-PH/PC informed the delegations about the significant progress of the activities carried out by the CD-P-PH/PC, which is as follows: the publication of survey report on pharmaceutical care in Europe, the organisation of an expert workshop on the assessment of the quality of patient-centred pharmaceutical care in Europe on 19 November 2009 and the organisation of an expert workshop on guidelines for the quality and safety assurance of pharmacy-prepared medicinal products on 24 September 2009. He pointed out the added value and effectiveness of undertaking the resource-consuming development of indicators as a joint effort among several countries and called upon the delegations for support.

20. One delegation underlined the importance of measuring the quality of pharmaceutical care with a view to patient oriented health policies having a pan-European approach and requested the CD-P-PH/PC to consider the utility of the indicators for health policies and professional standards.

21. One delegation considered the project to be of significant importance as regards the good use of medicines and high quality of pharmaceutical care and expressed its country's continued support.

22. One delegation stated that the project was very important and asked for information on whether the indicators were available to all states signatories to the Convention on the Elaboration of a European Pharmacopoeia, and to the stakeholders of pharmaceutical care, on the dimensions of the indicators and on whether the new roles of the pharmacist would be considered.

23. The Vice-Chairman referred to the compilation of facts on the impact of traditional Chinese medicine (TCM) on pharmaceutical practice in Europe prepared by the above Committee of Experts and recommended the compilation as a source of information providing the necessary background to further support the activity. He informed the delegations about the preliminary programme for an expert workshop to discuss the impact of practice and use of traditional foreign therapies including TCM in a western environment.

24. One delegation expressed support for the organisation of the above expert workshop.

25. Another delegation considered the activity dealing with foreign traditional therapies important and suggested as topics for the above-mentioned workshop: basic requirements on practicing traditional foreign therapies and training of practitioners.

26. The CD-P-PH approved the conclusions of the reports of the 63rd meeting (6-7 May 2009) and of the 64th meeting (4-5 November 2009) and

27. The CD-P-PH took note with appreciation of the publication of the CD-P-PH/PC survey report "Pharmaceutical Care. Where do we stand – Where should we go? (2009)" and

28. expressed support for the project dealing with the assessment of pharmaceutical care in Europe through indicators which provide policy-makers and professional associations with assessment tools for making patient centred health policies and for improving care standards for health professionals and encouraged the CD-P-PH/PC to proceed.

29. The CD-P-PH recognised the CD-P-PH/PC understanding of pharmaceutical care as a quality concept comprising benefits for the patient's quality of life taking into consideration their needs and expectations beyond the mere medication safety aspect,

30. expressed support for the approach used by the CD-P-PH/PC for the guidelines for the quality and safety assurance of pharmacy-made products for the needs of patients and

31. asked the CD-P-PH/PC to ensure that the guidelines will be complementary to and not contradictory to the standards and provisions developed by other expert bodies within the EDQM.

32. The CD-P-PH asked the CD-P-PH/PC to submit by 30 June 2010 for approval at the earliest convenience the final draft guidelines which could be recommended for implementation to states signatories of the Convention on the Elaboration of a European Pharmacopoeia while taking account of the interventions of its delegations at the 3rd meeting.

33. The CD-P-PH instructed the CD-P-PH/PC to discuss the risks and options as regards their containment with experts in the field at an expert workshop on 28 October 2010 and

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

34. The Chairman also chairing the CD-P-PH/CMED informed the delegations about the priorities within the risk management and prevention activities, in particular the further development of the multisectorial training concept on how to combat counterfeit medicines and protect public health. The EDQM had been supporting the training platform and providing assistance to the member states through training at the local and/or regional levels, such as the national training coorganised between the EDQM and the Italian Medicines Agency (AIFA) on 18 and 19 June 2009 and the regional training with the Portuguese National Authority for Medicines and Health Products (INFARMED) and for other Portuguese speaking countries in Africa and South-America on 21 and 22 January 2010. The delegations discussed other priorities of the CD-P-PH/CMED risk management and prevention activities such as information sharing, cooperation among a network of SPOCs and the building of specific intelligence which would support training, awareness-raising, and situation reports.

35. One delegation expressed strong support for the development of such a knowledge base which could be very important for enhancing the cooperation among different sectors and countries to combat counterfeit medicines and reduce public health risks.

36. In conclusion, the Committee CD-P-PH approved the conclusions of the reports of the 3rd meeting on 28-29 April 2009 and of the 4th meeting on 15-16 October 2009 of the CD-P-PH/CMED;

37. took note with appreciation of the progress of the training on how to combat counterfeiting of medicines and protect public health which had been delivered from 2007 to date to approximately 100 health and law enforcement officials from about 40 Council of Europe member states and expressed thanks to the AIFA and INFARMED;

38. welcomed that the EDQM, with a view to long-term consistency of training approaches and impact, continued its support for this training platform;

39. encouraged the delegations to promote national efforts to organise national and regional multisectorial training courses and to make use of the expertise and assistance available through the EDQM and

40. considered the development of a knowledge base on public health risk management and prevention of counterfeit medicines and similar crimes a useful tool for training, effective case management, sharing of experiences and for early detection of new phenomena and trends in this field.

Date and place of the next meeting

41. The CD-P-PH agreed to hold its next meeting on 15-16 September 2010.

Appendix

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. Ad hoc terms of reference - Opinions on Parliamentary Assembly Recommendations
- 2.3. Priorities of the Swiss Chairmanship, 18 November 2009 - 11 May 2010

3. **OBSERVER STATUS WITHIN THE EUROPEAN COMMITTEE ON PHARMACEUTICALS AND PHARMACEUTICAL CARE (PARTIAL AGREEMENT) (CD-P-PH)**

4. **DRAFT COUNCIL OF EUROPE CONVENTION ON THE 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)
 - Annual revision of the appendices of the Committee of Ministers Resolution ResAP(2007)1 on the classification of medicines as regards their supply
- 5.2. Committee of Experts on quality and safety standards in pharmaceutical practices and pharmaceutical Care (CD-P-PH/PC)
 - Assessment of the quality of pharmaceutical care in Europe
 - Impact of traditional (foreign) therapies on pharmaceutical practice in Europe: Traditional Chinese Medicine (TCM)
 - Quality and safety assurance guidelines for pharmacy preparations for the needs of patients
- 5.3. Committee of Experts on minimising public health risks posed by counterfeiting of medical products and related crimes (CD-P-PH/CMED)
 - Training programme "Working across disciplines and borders, best practices to combat counterfeiting of medicines and to protect public health"
 - Risk management and prevention: publications knowledge base

6. **ANY OTHER BUSINESS**