



CM(2009)104 8 June 2009¹

1063 Meeting, 8 July 2009

6 Social cohesion

6.3 European Pharmacopoeia (EDQM)² – European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH) –

Abridged report of the 2nd meeting (Brussels, 2-3 April 2009)

Item to be prepared by the GR-SOC at its meeting of 30 June 2009

1. The 2nd meeting of the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH) took place in Brussels on 2 and 3 April 2009 under the Chairmanship of Dr Domenico Di Giorgio (Italy). The meeting was hosted by the Belgian Federal Agency of Medicines and Healthcare Products. The agenda appears in the appendix.

2. 19 member States of the Partial Agreement were present: Austria, Belgium, Croatia, Cyprus, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, The Netherlands, Norway, Poland, Portugal, Switzerland, "the former Yugoslav Republic of Macedonia" and the United-Kingdom. Ms Eija Pelkonen (Medicines Agency, Finland), Ms Barbara Passek (Ministry of Health, Germany), Ms Marita Kinsella (Department of Health and Children, Ireland), Ms Marta Gramazio (Medicines Agency, Italy), Mr Joao C. Martins and Ms Maria Fernanda Matos (Medicines Agency, Portugal), Mr Bart Wijnberg (Ministry of Health, Welfare and Sport, Netherlands), Ms Nina Thoresen (Ministry of Health, Norway), Mr Sergey Glagolev (the Federal Service for Supervision in the sphere of healthcare and social development, observer, Russian Federation), and Mr Keith Ridge (Department of Health, United Kingdom) 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 of the Ministers' Deputies (in their composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia) to approve the revised terms of reference of the European Committee on Pharmaceuticals and Pharmaceutical care (CD-P-PH), and to take note of the abridged report of the 1st meeting of the CD-P-PH as a whole.

4. The CD-P-PH took note of the decisions of the Minister's Deputies on the European Committee on Crime Problems (CDPC) related to the preparation of a future convention of the Council of Europe on 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).

5. The Secretariat informed the CD-P-PH about the preparatory works related to the above mentioned future Council of Europe convention which were being supported through intersecretariat cooperation between the Council of Europe Directorate General of Human Rights and Legal Affairs, Directorate of Standard-Setting, Criminal Law Division, and the Directorate General of Social Cohesion, European Directorate for the Quality of Medicines & HealthCare, Biological Standardisation, European Network of Official Medicines Control Laboratories (OMCL) & HealthCare Department.

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.

6. The CD-P-PH appointed by unanimous decision Dr Di Giorgio as representative at the forthcoming meetings of the PC-ISP.

7. One delegation called for stressing back home the importance of the broad representation in the negotiations of the PC-ISP of sound and specific expertise relating to all types of medical products, e.g. medical devices. The delegation pointed towards the term “counterfeit medicines” having become controversial in the international context for its possible connotation related to intellectual property rights.

8. In the debates, individual delegations highlighted the importance of the protection of the integrity of the manufacturing and distribution chain of medicines, pointed out to problems in the area of medical devices, in general and in the context of drawing up a criminal law instrument, stated that the definition of counterfeit medicines should be more focused on the aspect of falsification, and considered counterfeit or falsified medical devices a very important issue.

9. In conclusion, the CD-P-PH invited all delegations to encourage their governments to nominate both senior officials with extensive expertise in criminal law and pharmaceutical and healthcare regulatory matters including medical devices, respectively, for participation in the meetings of the PC-ISP in order to produce a convention which will effectively protect public health.

10. Furthermore, the CD-P-PH invited all delegations to ensure the necessary communication with relevant counterparts in the respective national ministries and dependent bodies involved in negotiating and finalising the above draft convention.

Request by the Sovereign Order of Malta for being granted observer status with the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)

11. The CD-P-PH discussed the request for granting observer status with the CD-P-PH to the Sovereign Order of Malta.

12. One delegation wished to obtain further information about the possibilities for co-operation with the Sovereign Order of Malta as observer with CD-P-PH. The delegation saw a need for updating the Rules of procedure of the CD-P-PH as regards the role of observer status with the CD-P-PH in general and practical cooperation procedures.

13. In conclusion, the CD-P-PH postponed a decision and invited the Sovereign Order of Malta to participate in one of its forthcoming meetings and to make a statement on possible future co-operation with the Committee CD-P-PH.

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

14. The CD-P-PH approved the conclusions of the reports of the 44th meeting (27 and 28 May 2008) and of the 45th meeting (23 and 24 September 2008) of the CD-P-PH/PHO.

15. The CD-P-PH took note of the finalisation and publication of the 2008 revision of the appendices of the Committee of Ministers' Resolution ResAP(2007)1 on the classification of medicines as regards their supply.

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

16. The CD-P-PH discussed the summary and key recommendations of the survey report about key concepts in pharmaceutical care, performance indicators of good quality care, good quality services, the usefulness of existing databases and relevant stakeholders involved in pharmaceutical care at national level which had been prepared by the CD-P-PH/PC in order to provide background information pertaining to the development and implementation of indicators of the quality of pharmaceutical care in Europe.

17. Three delegations stated that three national academic institutions, each, would contribute on these delegations' behalf to the development and implementation of indicators of the quality of pharmaceutical care in Europe.

18. The CD-P-PH discussed the draft survey report and completed project proposal dealing with the impact of traditional (foreign) therapies on pharmaceutical practice in Europe, namely of traditional Chinese medicine (TCM) which had been prepared by the CD-P-PH/PC in order to analyse differences in or lack of provisions for the use of TCM products by therapists, prescribers and dispensers at national level, of the availability of information and knowledge about the use of TCM products and practices for professionals and patients and of the availability of specific vigilance systems.
19. In the debates, individual delegations stated that existing regulations at the EU level on traditional herbal medicinal products were not appropriate for a regulation of medical systems, such as TCM, and pointed out to the specific difficulties as regards authorisation, (for example the chemical analysis of complex TCM bulk, different concepts of disease and diagnosis, individual therapy).
20. One delegation stated that there were no gaps as regards the applicability of existing regulations to TCM products but agreed that there was no harmonised legislation with respect to "systems of medicines", and that in practice information, awareness and knowledge as regards the use of TCM products in Europe was not always adequate.
21. The CD-P-PH discussed the project proposal and draft survey report on quality and safety standards for pharmacy preparations which had been carried out by the CD-P-PH/PC among its delegations in order to analyse possible differences as regards national standards for ensuring the quality and safety of pharmacy preparations, differences or lack of provisions as regards sourcing out of pharmacy preparations, and possible quality and safety gaps between pharmacy preparations and medicinal products prepared by industry. It was proposed to develop guidance on how to ensure quality and safety of pharmacy preparations.
22. In the debates, individual delegations referred to other relevant international guidelines for good practices for the preparation of medicinal products in healthcare establishments which should be taken into consideration, pointed out that the implementation and impact of available international guidelines was dependent on the respective existing national provisions, which were different, and stated that the preparation of medicines in pharmacies should not be overregulated as it was an option for accommodating for specific needs of individual patients,
23. In conclusion, the CD-P-PH approved the conclusions of the reports of the 61st meeting (19 and 21 May 2008) and of the 62nd meeting (12 and 13 November 2008) of the CD-P-PH/PC.
24. The CD-P-PH expressed in principle its support for promoting pharmaceutical care in Europe as part of a comprehensive working programme, including inter alia the development of indicators to measure the quality of pharmaceutical care, recognised the wide and far reaching impact of pharmaceutical care on patients, and encouraged the delegations to contribute to the activity.
25. The CD-P-PH instructed the CD-P-PH/PC to develop, by 5 June 2009, a draft programme for an expert workshop on the assessment of pharmaceutical care in Europe through indicators to be organised on 19 November 2009. Upon the approval by the CD-P-PH, the expert workshop and the invitation to the CD-P-PH to nominate participants would be issued.
26. The CD-P-PH agreed that there were certain risks associated to public health caused by the present lack of awareness of and knowledge in the field of TCM in a western environment requiring spreading awareness on and building up specific knowledge and instructed the CD-P-PH/PC to proceed in this direction. The cooperation with the European Pharmacopoeia working programme on quality standards for herbal medicines was encouraged.
27. The CD-P-PH instructed the Secretariat to circulate on 6 April 2009 the survey questionnaire on quality and safety standards for pharmacy preparations among all delegations.
28. The CD-P-PH instructed the CD-P-PH/PC to submit for discussion at its next meeting an updated survey report and updated project proposal, which would identify possible "grey areas" in pharmacy preparation and the distribution of such pharmacy preparations, taking into account the different categories of pharmacy prepared medicines, and put forward options for ensuring appropriate quality standards taking account of existing ones.

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

29. In the debates, individual delegations asked the CD-D-PH/CMED to consider in future training the incidence of counterfeit medicines in pandemics and comparable crises, and stated that the guide on "*Counterfeit Medicines - Facts and cases: Practical Advice*", prepared and distributed by the CD-P-PH/CMED among trainees, cooperation partners within member states and international organisations and bodies, had proved very useful for undergraduate education in forensic pharmacy.

30. The Head of the Portuguese delegation announced that the Portuguese Medicines Agency offered to co-organise and host preferably at the beginning of 2010 in cooperation with the CD-P-PH/CMED and the EDQM training on how to combat counterfeit medicines and to protect public health.

31. In conclusion, the CD-P-PH approved the conclusions of the reports of the 1st meeting (5 and 6 May 2008) and of the 2nd meeting (28 and 29 October 2008) of the CD-P-PH/CMED.

32. The CD-P-PH took note with appreciation of the positive impact of the training activity in general for 75 trainees from 24 member states to date and in particular of the evaluation reports of the 2008 training organised in Strasbourg on 26-27 June, and of that hosted by the Health Authorities of Cyprus on 18 and 19 November 2008.

33. In this context, the CD-P-PH thanked the Italian Medicines Agency and the Portuguese Medicines Agency for hosting further follow-up training on 16 and 17 June 2009, and at the beginning of 2010.

34. The CD-P-PH asked the CD-P-PH/CMED to consider in further training on how to counter the increasing incidence of counterfeit medicines in emergency situations.

35. The CD-P-PH encouraged the delegations to promote national efforts to organise local and regional multisectorial training courses taking advantage from the experiences and expertise accumulated in this field by the CD-P-PH/CMED.

36. With a view to enhancing sustainability of training and transfer of proven training approaches to local and regional level, the CD-P-PH welcomed continued support and assistance by the EDQM for local and regional training.

37. The CD-P-PH endorsed the model approach "Counterfeit medicines in Europe: risk communication strategies for Drug Regulatory Authorities", and encouraged the delegations to support its use at national levels.

Other business

38. One delegation suggested proposing the topic counterfeit medicines with a focus on public health for inclusion into the priorities of one of the forthcoming Chairmanships of the Council of Europe Committee of Ministers.

39. In conclusion, the CD-P-PH encouraged the forthcoming Chairmanships of the Council of Europe Committee of Ministers to consider promoting Council of Europe activities aiming at public health protection from counterfeit medicines and similar crimes health within their priorities.

40. The CD-P-PH invited the delegations to identify for discussion at its next meeting topics related to the focus of and tasks carried out under its own terms of reference, which could give greater visibility and support to the member states' activities carried out in the frame of the Council of Europe and its EDQM.

41. The CD-P-PH noted with great appreciation that the Swiss delegation would explore possibilities for including the topic in the priorities of the Swiss Chairmanship of the Council of Europe Committee of Ministers (November 2009-May 2010).

Date and place of the next meeting

42. The CD-P-PH agreed to hold its next meeting in Strasbourg on 26 and 27 January 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 Spanish Chairmanship

3. REQUEST FOR GRANTING OBSERVER STATUS WITH THE CD-P-PH FOR THE SOVEREIGN ORDER OF MALTA

4. TASKS RELATED TO THE PUBLIC HEALTH PROGRAMME

- 4.1. 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
- 4.2. Committee of Experts on Quality and Safety Standards in Pharmaceutical practices and Pharmaceutical Care (CD-P-PH/CMED)
 - 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 standards for pharmacy preparations
- 4.3. 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 communication strategies for Drug Regulatory Authorities
 - Publication: Counterfeit medicines - Facts and cases: Practical Advice

5. ANY OTHER BUSINESS