COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Strasbourg, 26 November 2007 PC-S-CP (2007) 3

GROUP OF SPECIALISTS

ON COUNTERFEIT PHARMACEUTICAL PRODUCTS

(PC-S-CP)

REPORT OF THE 1ST MEETING

Strasbourg, Palais de l'Europe, 6 – 7 November

BRIEF FOREWORD

The PC-S-PC underlined the very serious effect of counterfeit pharmaceutical products and considered the matters to be included in the Report containing key elements for a possible Council of Europe convention on the fight against counterfeit pharmaceutical products ("the Final Report").

The PC-S-CP decided that any future convention should cover both medicinal products and medical devices, but not food supplements and cosmetic products.

The PC-S-CP discussed the following elements to be included in the possible future convention:

- measures to prevent pharmaceutical crime;
- offences to be criminalised (counterfeiting, adulteration, mislabelling etc.);
- rules to determine the jurisdiction of states parties to prosecute offences under the convention;
- mechanisms for effective international co-operation;
- monitoring mechanism

The Group underlined the relevance of the Cybercrime Convention to its work and agreed that any new convention would contribute to the fight against cybercrime.

The PC-S-CP discussed the work in progress as regards fight against counterfeit pharmaceutical products in other international organisations, in particular the European Union and the World Health Organisation. The Group agreed that the Council of Europe's work would bring much added value by setting new standards by a possible binding international legal instrument against counterfeit pharmaceutical products, focused on the protection of public health.

The PC-S-CP will hold two more meetings (17-19 December 2007 and 5-7 March 2008) and will submit its Final Report to the CDPC at its next plenary meeting in June 2008.

OPENING OF THE MEETING

1. The Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP) held its first meeting at the Palais de l'Europe, Strasbourg, on 6-7 November 2007, with Mr Claude DEBRULLE (Belgium) in the Chair.

2. The Chair underlined that the main task of the Group is to prepare a Report (hereinafter the Final Report) containing key elements that could be included in a possible Council of Europe convention on the fight against counterfeit pharmaceutical products.

3. The Secretariat informed the PC-S-CP that even though the terms of reference of the Group expire on 31 December 2008, the Final Report should be submitted to the CDPC at its next plenary meeting, which takes place in June 2008. The Chair underlined the short timeframe for the completion of this work, as well as the complexity of the topic.

4. The Group took note that owing to the multidisciplinary nature of the subject, the PC-S-CP was composed of specialists in criminal law and pharmaceutical fields and its Secretariat came from the Directorate General of Human Rights and Legal Affairs and the Directorate General III – Social Cohesion.

5. The Terms of Reference of the PC-S-CP appear in Appendix I to this Report. The list of participants is contained in Appendix II and the agenda of this meeting is contained in Appendix III.

ADOPTION OF THE AGENDA

6. The agenda was adopted without any modifications.

MEETING DISCUSSIONS

Terms of Reference and the scope of the Final Report

7. The PC-S-CP examined its terms of reference and held preliminary exchange of views concerning key elements that should be included in the possible future convention. The Group also took note of the discussions that took place at the last meeting of the CDPC concerning the future work of the PC-S-CP and agreed that for the success a possible international legally binding instrument it was necessary to clearly define:

   - the scope of products it should cover (medicinal products and medical devices only, or food supplements and cosmetics as well);
   - the measures to prevent pharmaceutical crime;
   - the offences to be criminalised (counterfeiting, adulteration, mislabelling etc.);
   - the rules to determine the jurisdiction of states parties to prosecute offences under the convention;
   - the mechanisms for effective international co-operation;
   - a monitoring mechanism for effective implementation of the convention.

8. The PC-S-CP noted that around 10% of medicines available on the global market are counterfeit[1]. It agreed that the Final Report should indicate the international character of the problem of counterfeiting in general and counterfeiting of pharmaceutical products in particular and illustrate the need to propose an international legally binding instrument on this subject. The Group agreed that the counterfeiting of pharmaceutical products raises at least two major concerns – violation of intellectual property rights and public health risks. Long discussion took place concerning the extent to which these types of offences need to be criminalised, during which the experts expressed diverging opinions.

9. The Group decided that the scope of the possible future convention should remain within the limits of medicinal products and medical devices for human and veterinary use, as well as clinical trials, and should not include food supplements and cosmetic products as the later would render it too extensive. It also agreed that the Final Report should recommend introducing new offences under the general heading of "pharmaceutical crimes", specifying them further in the convention.

10. Some members of the Group expressed their conviction that terms used in the Final Report and later in a possible convention should be clearly defined, whenever possible. This work should also take into account, where appropriate, existing definitions already adopted in the European Pharmacopoeia (as a co-operation partner within the International Conference of Harmonisation (ICH), the European Union (in particular, in the proposed regulations and directives on the authorisation and supervision of medicinal products for human and

[1] Parliamentary Assembly of the Council of Europe Recommendation 1794 (2007) "The quality of medicines in Europe".

veterinary use and on criminal measures aimed at ensuring the enforcement of intellectual property rights, aimed to supplement Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights) and the World Health Organisation (notably in the draft principles and elements for national legislation against counterfeit medical products, prepared by the International Medical Products Anti-Counterfeiting Taskforce (IMPACT)).

11. The Group took note of the document CDPC-BU (2007) 12 "Prioritised elements for a Council of Europe convention on the protection of public health against pharmaceutical and healthcare product crime", which is also referred to in the Terms of Reference, and agreed to use it as a basis for its Final Report. It also held preliminary discussions on other aspects of a possible international instrument on counterfeit pharmaceutical products, indicated in paragraph 7 above and instructed the Secretariat to reflect the conclusions of these discussions in the draft Final Report.

12. Given the fact that considerable amount of counterfeit medicines is distributed to the market via Internet, the PC-S-CP stressed the relevance of the Cybercrime Convention to the fight against counterfeit medicines. It agreed that a possible future convention on counterfeit pharmaceutical products would contribute to the fight against cybercrime by introducing new cyber offences, which would be complementary to the offences already established under the Cybercrime Convention.

The work of the other Council of Europe bodies and other international organisations in the field of fight against counterfeiting

13. The Secretary of the Committee on Social Affairs of the Parliamentary Assembly of the Council of Europe (PACE) Ms Agnes NOLLINGER presented the work of the PACE in the field of counterfeiting. The PC-S-CP took note of the Report by the Committee on Economic Affairs and Development of PACE "Need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods" as well as Recommendations 1793 (2007) on "Need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods" and 1794 (2007) on "The quality of medicines in Europe" and agreed to bear them in mind when preparing the Final Report.

14. The PC-S-CP took note of the information provided by the representative of the European Commission, Mr Christian TOURNIE, concerning the current state of affairs of the work within the EU regarding the preparation of the directive on criminal measures aimed at ensuring the enforcement of intellectual property rights. The Group highlighted that this work was mainly focusing on fighting against the infringement of intellectual property rights and the public health factor was only relevant as aggravating circumstance.

15. In the absence of representative from the WHO, the PC-S-CP members, familiar with current work of the WHO, provided the Group with the information concerning the forthcoming Conference in Lisbon, where the WHO was planning to present the Draft principles and elements for national legislation against counterfeit medical products, prepared by IMPACT. The Group noted that although the Draft principles contained significant provisions on criminalisation and sanctioning of certain conduct amounting to counterfeiting, as well as other valuable definitions of relevant terms, they were of a recommendatory nature and would not lead to preparing an international legally binding instrument.

16. With the above in mind, the PC-S-CP agreed that the work of other international organisations seemed to focus on the intellectual property aspect of counterfeiting and underlined that there was room for the Council of Europe's work on preparing a convention to fight counterfeit pharmaceutical products, with emphasis on the need to protect public health. Thus, the Council of Europe's work would be complementary to efforts of other organisations and would bring much added value by setting new standards for a possible binding international legal instrument in the future.

WORKING METHODS OF THE PC-S-CP

17. Taking into account the limited time given to the PC-S-CP to complete its work before the next CDPC plenary meeting, the Group decided to continue its work not only during the meetings but also by means of a written consultation procedure. To this end, the Group instructed the Secretariat to prepare, after each meeting, an updated version of the draft Final Report and send it to members of the Group for their written comments to be submitted to the Secretariat before the next meeting. The Group agreed to send the preliminary draft Final Report to the CDPC Bureau, which is going to meet on 15-16 January 2008.

DATES OF NEXT MEETINGS

18. The PC-S-CP agreed that its second meeting should take place on 17-19 December 2007 and the third, final meeting – on 5-7 March 2008.

APPENDIX I

TERMS OF REFERENCE OF THE GROUP OF SPECIALISTS ON COUNTERFEIT PHARMACEUTICAL PRODUCTS (PC-S-CP)

1. Name of Committee: Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP)

2. Type of Committee: Ad hoc Advisory Group

3. Source of terms of reference: Committee of Ministers, on the suggestion of the European Committee on Crime Problems (CDPC)

4. Terms of reference:

Having regard to:

- the Declaration and Action Plan adopted by the Third Summit of Heads of State and Government of the Council of Europe (Warsaw, 16-17 May 2005), in particular concerning the issue related to the security of citizens;
- Resolution Res(2005)47 on committees and subordinate bodies, their terms of reference and working methods;
- Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security;
- reply adopted by the Committee of Ministers on 6 April 2005 concerning Recommendation of the Parliamentary Assembly 1673 (2004) on "Counterfeiting: problems and solutions" and Recommendation 1794 (2007) on "The quality of medicines in Europe";
- the survey report on counterfeit medicines prepared by the Partial Agreement in the Social and Public Health field and the conclusions of the Seminar on counterfeit medicines (2005);
- the Declaration on "Combating IPR piracy and counterfeiting", adopted by Heads of State and Government at the G8 Summit meeting, St. Petersburg on 16 July 2006;
- the International Conference on "Europe against counterfeit medicines" (Moscow, 23-24 October 2006) and the declaration[2] adopted by its participants;
- the conclusions of the High-level Conference of the Ministries of Justice and of the Interior on "Improving European Co-operation in the Criminal Justice Field" (Moscow, 9-10 November 2006);
- the feasibility study prepared for the CDPC on counterfeit medicines and pharmaceutical crime and the report on prioritised elements for a Council of Europe Convention on the protection of public health against pharmaceutical and healthcare product crime;
- the Convention on Cybercrime (ETS no 185).

Under the authority of the European Committee on Crime Problems (CDPC), and in relation with the implementation of Project 2004/DGI/199 (to be entitled 2008/DG-HL/1432 at a later date) "Monitoring the operation of conventions on co-operation in the criminal field" of the Programme of Activities, and bearing in mind the criteria developed in document CM(2006)101 final, the Group is instructed to:

prepare a report, in the light of indications given by the CDPC and document CDPC-BU (2007) 12, focusing on the key elements, which could be included in a possible international binding legal instrument to fight crime concerning counterfeit pharmaceutical products. This report:

- should deal first with the criminal law aspects of counterfeit medicines and other medical products including the means to prevent such crime and strengthening of international co-operation;
- should focus on conducts, which may jeopardise public health, and take account of existing national legislation in this field;
- could indicate whether further provisions could be prepared to deal with specific issues concerning health care products;
- should take full account of other work being carried out at an international level, in particular by the European Union and the World Health Organisation.

5. Composition of the Committee:

[2] http://www.coe.int/t/dc/press/News/20061107_fin_medicaments_en.asp

5.A Members

The Group shall be composed of 11 specialists in the field of pharmaceutical crime and criminal law. The CDPC shall appoint one specialist who shall chair the Group. The Secretary General shall appoint the remaining specialists in consultation with the Chair of the CDPC. With this in mind, member states are invited to submit names of experts to the Secretary General, if they so wish.

The Council of Europe budget will bear the travel and subsistence expenses of the 11 above members of the Group.

5.B Participants

i. The Parliamentary Assembly may send (a) representative(s) to meetings of the Group, without the right to vote and at the charge of its administrative budget.

5.C Other participants

i. The European Commission may send (a) representative(s) to meetings of the Group, without the right to vote or defrayal of expenses.

ii. The following intergovernmental organisations may send (a) representative(s) to meetings of the Group, without the right to vote or defrayal of expenses:

- the World Health Organisation (WHO).

6. Working methods and structures:

The Group shall present its report at the next plenary meeting of the CDPC in 2008.

The Bureau of the CDPC will follow closely the progress made and, if appropriate, give further instructions concerning the work of the Group.

7. Duration:

These terms of reference will expire on 31 December 2008.

APPENDIX II

LIST OF PARTICIPANTS

MEMBERS OF THE GROUP

Mr Hugo K. BONAR (Ireland), Irish Medicines Board, Enforcement Manager, Earlford Center, Earlsford Terrace

M. Claude DEBRULLE (Belgium, CHAIR, elected by the CDPC)
Director General, Directorate General of Legislation, Fundamental Rights and Liberties, Ministry of Justice

Mr. Sergey V. GLAGOLEV (Russian Federation), Managing specialist-expert, Department of registration of drugs and active pharmaceutical ingredients, Federal Service for the Supervision in the Sphere of Public Health and Social Development (Roszdravnadzor), accompanied by M. Sergey DALECHIN, Deputy Advisor to the Permanent Representative of Russian Federation to the Council of Europe

M. Jacques FRANQUET (France), Honorary Prefect, Chair of the anti-counterfeiting coordination unit of Sanofi-Aventis Group – *Apologised*

Ms Kerstin HJALMARSSON (Sweden), Assessor Medical Products/Enforcement, Swedish Medical Agency, accompanied by Ms Sara ÅSTRÖM, Lawyer, Legal Affairs, Medical Products Agency, Swedish Medical Agency

M. Hendrick Jan de JONG (Netherlands), Institut de Recherches Int., President of the European Pharmacopoeia

Ms Popi Nicolaidou KANARI (Cyprus), Acting Director, State General Laboratory

Mr Konstantin KELLER (Germany), Bundesministerium für Gesundheit, Federal Ministry of Health, Gruppe Internationale Arzneimittelfragen, Department for International Pharmaceutical Affairs – *Apologised*

Ms Ksenija TURKOVIĆ (Croatia), J.S.D., Professor of Criminal Law, Faculty of Law, University of Zagreb

Mr Roy VANCAUWENBERGHE (Belgium), Inspector FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu – *Apologised*

Mr Fritz ZEDER (Austria), Leiter der Abt. II.2 im Bundesministerium für Justiz, Head of Unit II.2 in the Federal Ministry of Justice

PARLIAMENTARY ASSEMBLY OF THE COUNCIL OF EUROPE

Mme Agnès NOLLINGER, Secretary to the Social, Health and Family Affairs Committee

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OTHER PARTICIPANTS

EUROPEAN COMMUNITY

EUROPEAN COMMISSION

Mr Christian TOURNIE, National Seconded Expert, DG JLS – Justice, Freedom and Security, Organised Crime Unit

INTERNATIONAL INTERGOVERNMENTAL ORGANISATIONS

WORLD HEALTH ORGANIZATION (WHO)
Mr Valerio REGGI -, Coordinator, Medicines Regulatory Support, Department of Technical Cooperation for Essential Drugs and Traditional Medicine – *Apologised*

SECRETARIAT OF THE COUNCIL OF EUROPE

Directorate General of Human Rights and Legal Affairs

Law Reform Department

M. Carlo CHIAROMONTE, Head of the Criminal Law Division *ad interim*, Secretary to the CDPC

M. David DOLIDZE, Administrator, Secretary to the PS-S-CP

Mme Christiane WELTZER, Assistant

Ms Vasilisa NESHATAEVA, Trainee

Directorate General III – Social Cohesion

Partial Agreement in the Social and Public Health Field

Ms Sabine WALSER, Administrative Officer Deputy Secretary to the PC-S-CP

INTERPRETERS

Mme Christine FARCOT
Mme Maryline NEUSCWHANDER
Mme Monique PALMIER

APPENDIX III

AGENDA/ *L'ORDRE DU JOUR*
(bilingual/ *bilangue*)

1. Opening of the Meeting / *Ouverture de la réunion*

2. Adoption of the Agenda / *Adoption de l'ordre du jour*

3. Terms of reference of the PC-S-CP and its working methods / *Mandat spécifique du PC-S-CP et ses méthodes de travail*

Working documents / *Documents de travail :*

- Terms of Reference of the PC-S-CP / *Mandat spécifique du PC-S-CP*
- List of participants / *Liste des participants*
- Summary of the discussions of the CDPC concerning the PC-S-CP / *Résumé des discussions du CDPC concernant le PC-S-CP* PC-S-CP (2007) 01

4. The work of other Council of Europe bodies in the field of fight against counterfeit pharmaceutical products / *Les travaux d'autres organes du Conseil de l'Europe dans le domaine de la lutte contre les produits pharmaceutiques contrefaits*

Working documents / *Documents de travail :*

- Need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods – Report by the Committee on Economic Affairs and Development of the Parliamentary Assembly of the Council of Europe (Doc. 11227) / *Nécessité d'une convention du Conseil de l'Europe relative à la suppression de la contrefaçon et du trafic de produits contrefaits - Rapport par la Commission des questions économiques et du développement de l'Assemblée Parlementaire du Conseil de l'Europe (Doc. 11227)*
- Recommendation 1793 (2007) "Need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods" and the Reply by the Committee of Ministers / *Recommandation 1793 (2007) "Nécessité d'une convention du Conseil de l'Europe relative à la suppression de la contrefaçon et du trafic de produits contrefaits" et réponse du Comité des Ministres*
- Recommendation 1794 (2007) "The quality of medicines in Europe" and the Reply by the Committee of Ministers / *Recommandation 1794 (2007) – "Qualité des médicaments en Europe" et réponse du Comité des Ministres*
- Executive Summary of the Seminar "Counteract the Counterfeiters!" 21 – 23 September 2005, Strasbourg / *Rapport sommaire du Séminaire sur « l'action pour combattre les médicaments de contrefaçon » , 21-23 septembre 2005, Strasbourg*
- Declaration of the International Conference - Europe against Counterfeit Medicines, 23-24 October 2006, Moscow, Russian Federation / *Déclaration de la Conférence internationale : L'Europe contre les médicaments contrefaits, 23-24 octobre 2006 , Moscou, Fédération de Russie*
- Convention on Cybercrime, Budapest, 23.11.2001 / *Convention sur la cybercriminalité, Budapest, 23.11.2001*

5. Consideration of the Prioritised Elements for a Council of Europe convention on the protection of public health against pharmaceutical and healthcare product crime / *Examen des éléments prioritaires pour une convention sur la protection de la santé publique contre le crime pharmaceutique et le crime lié aux produits de santé*

Working documents / *Documents de travail :*

- Prioritised elements for a Council of Europe convention on the protection of public health against pharmaceutical and healthcare product crime / *Eléments prioritaires pour une convention du Conseil de l'Europe sur la protection de la santé publique contre le crime pharmaceutique et le crime lié aux produits de santé* CDPC-BU (2007) 12

- Feasibility study for a Council of Europe convention on counterfeit medicines/pharmaceutical crime / *Etude de faisabilité d'une convention du Conseil de l'Europe sur la contrefaçon de médicaments et le crime pharmaceutique* CDPC-BU (2007) 01

6. Scope of the Report and fundamental aspects of combating counterfeit pharmaceutical products that it should cover / *Portée du Rapport et les aspects fondamentaux de la lutte contre les produits pharmaceutiques contrefaits qu'il devrait traiter.*

a. **defining "pharmaceutical product" taking account of EC Directives and existing international (WHO) definitions /** *définition de « produit pharmaceutique », en tenant compte des Directives de l'UE et des définitions internationales existantes (OMS)*

b. **counterfeiting pharmaceutical products – definition, context and threats it poses to modern societies** / *contrefaçon des produits pharmaceutiques – définition, contexte et menaces qu'elle pose aux sociétés contemporaines*

c. **preventing counterfeiting pharmaceutical products at national and international levels – legislation and practice** / *prévention de la contrefaçon des produits pharmaceutiques aux niveaux national et international – législation et pratique*

d. **protecting the victims of counterfeit pharmaceutical products** / *protection des victimes des produits pharmaceutiques contrefaits*

e. **international co-operation in combating counterfeiting of pharmaceutical products – objectives, means to achieve them and difficulties** / *co-opération internationale dans la lutte contre la contrefaçon des produits pharmaceutiques – ses objectifs et les moyens de leur accomplissement*

Working documents / *Documents de travail :*

- Need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods – Report by the Committee on Economic Affairs and Development of the Parliamentary Assembly of the Council of Europe (Doc. 11227) / *Nécessité d'une convention du Conseil de l'Europe relative à la suppression de la contrefaçon et du trafic de produits contrefaits - Rapport par la Commission des questions économiques et du développement de l'Assemblée Parlementaire du Conseil de l'Europe (Doc. 11227)*

- Prioritised elements for a Council of Europe convention on the protection of public health against pharmaceutical and healthcare product crime / *Eléments prioritaires pour une convention du Conseil de l'Europe sur la protection de la santé publique contre le crime pharmaceutique et le crime lié aux produits de santé* CDPC-BU (2007) 12

- Model of a network of single points of contact (SPOCs) – English only

- Survey on the legislation / admin. Procedures, structures applicable to counterfeit medicines: Council of Europe Partial Agreement member states – English only

- Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use / *Directive 2004/27/CE du Parlement Européen et du Conseil du 31 mars 2004 modifiant la directive 2001/83/CE instituant un code communautaire relatif aux médicaments à usage humain*

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency / *Règlement (CE) N° 726/2004 du Parlement Européen et du Conseil du 31 mars 2004 établissant des procédures communautaires pour l'autorisation et la surveillance en ce qui concerne les médicaments à usage humain et à usage vétérinaire, et instituant une Agence européenne des médicaments*

- Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights / *Règlement (CE) n° 1383/2003 du Conseil du 22 juillet 2003 concernant l'intervention des autorités douanières à l'égard de marchandises soupçonnées de porter*

atteinte à certains droits de propriété intellectuelle ainsi que les mesures à prendre à l'égard de marchandises portant atteinte à certains droits de propriété intellectuelle

- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products / *Directive 2001/82/CE du Parlement européen et du Conseil du 6 novembre 2001 instituant un code communautaire relatif aux médicaments vétérinaires*

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices / *Directive 93/42/CEE du Conseil, du 14 juin 1993, relative aux dispositifs médicaux*

- Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices / *Directive 90/385/CEE du Conseil, du 20 juin 1990, concernant le rapprochement des législations des États membres relatives aux dispositifs médicaux implantables actifs*

- Terms of Reference for International Medical Products Anti-Counterfeiting Taskforce (IMPACT) in the World Health Organisation (WHO) – English only

- Draft Principles and Elements for National Legislation against Counterfeit Medical Products, prepared under the aegis of the IMPACT (WHO) – English only

- Conclusions and Recommendations of the WHO International Conference on combating Counterfeit Medicines, Declaration of ROME, 18 Feb 2006 – English only

7. Role of competent bodies in preventing counterfeiting of pharmaceutical products and sanctionning its perpetrators / *Rôle des organes compétents dans la prévention de la contrefaçon des produits pharmaceutiques et dans la sanction de ses auteurs.*

8. Dates of next meetings / *Dates des prochaines réunions.*