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EUROPEAN COMMITTEE ON CRIME PROBLEMS
(CDPC)

AD HOC COMMITTEE ON COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH
(PC-ISP)

SPECIFIC TERMS OF REFERENCE WITH FACTSHEET

Appendix 29
(Item 10.3c)

Terms of reference for the Ad hoc Committee on Counterfeiting of Medical Products and similar crimes involving threats to public health (PC-ISP)

Fact Sheet

Name of Committee:	Ad hoc Committee on Counterfeiting of Medical Products and similar crimes involving threats to public health (PC-ISP)
Compliance with Resolution Res(2005)47:	YES
Programme of Activities: project(s)	Under the authority of the Committee of Ministers, on the suggestion of the European Committee on Crime Problems (CDPC): 2008/DG-HL/1432 – Monitoring the operation of conventions on co-operation in the criminal field
Project relevance:	1. Chapters II and III of the Third Summit Action Plan – Strengthening the security of European citizens and Promoting common fundamental values. 2. Contribution to core values, namely the development of the rule of law. 3. Committee of Ministers' decisions – Decisions taken at 985th meeting (follow-up to the High-level Conference of the Ministries of Justice and of the Interior, Moscow, 9-10 November 2006). Political justification – Declaration of the International Conference "Europe against counterfeit medicines" (Moscow, 23-24 October 2006) and Conclusions of the High-level Conference of the Ministries of Justice and of the Interior (Moscow, 9-10 November 2006). Consolidation, promotion, implementation of Council of Europe standards – examining the preparation of a new convention to fight pharmaceutical crime. Timeliness of project – the setting-up of this Committee is timely as the seriousness of the problem of counterfeit medicines and other forms of related pharmaceutical crimes and the gravity of its results require immediate action from states.
Project added value:	1. This work will cover a topic where no international legally binding instruments exist. 2. Other international organisations, such as the World Health Organisation and the European Union are considering some different effects of this problem and co-operation with them is already taking place. 3. One of the advantages of close co-operation with other organisations is ensuring that there is no overlap of Council of Europe activities with their work.

	4. Counterfeiting of medicines has become to some extent an organised crime and poses a very serious threat to public health. It has to be co-ordinated by a committee that is the most competent in dealing with crime problems, which is the CDPC.
Financial information:	The PC-ISP is composed of 47 members and 3 scientific experts. Two 4 day meetings are planned during the validity of the terms of reference. Budget per meeting: €60 200 for members' expenses and €7 800 for interpretation costs. This budget is shared on an equal footing between the Directorate General of Human Rights and Legal Affairs (DG-HL) and the European Directorate for the Quality of Medicines and Health Care (EDQM).

Terms of reference of the Ad hoc Committee on Counterfeiting of Medical Products and similar crimes involving threats to public health (PC-ISP)

1. Name of Committee: Ad hoc Committee on Counterfeiting of Medical Products and similar crimes involving threats to public health (PC-ISP)

2. Type of Committee: Committee of Experts

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;
- the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Additional Protocols;
- the Convention on the Elaboration of a European Pharmacopeia;
- the Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine, and its additional Protocols;
- 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;
- the reply adopted by the Committee of Ministers on 6 April 2005 concerning Recommendation of the Parliamentary Assembly Recommendations 1673 (2004) on "Counterfeiting: problems and solutions" and 1794 (2007) on "The quality of medicines in Europe";
- the survey report on counterfeit medicines prepared by the Ad hoc Group on Counterfeit Medicines (P-SP-PH/CMED) under the aegis of 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 "Europe against counterfeit medicines" (Moscow, 23-24 October 2006) and the declaration[1] 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);

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

- 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 binding and non-binding instruments of the Council of Europe in the fields of cybercrime, money laundering, search, seizure and confiscation of the proceeds from crime, mutual assistance in criminal matters, victims and other forms of international co-operation;
- the report prepared for the CDPC by the Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP) on the key elements which could be included in a possible international legally binding instrument to fight crime concerning counterfeit pharmaceutical products (document PC-S-CP(2008)fin – Report);
- the preliminary draft convention against counterfeiting of medical products and similar crimes involving threats to public health, such as tampering with and adulteration of medical products prepared by the PC-S-CP.

Under the authority of the European Committee on Crime Problems (CDPC), and in relation with the implementation of Project 2008/DG-HL/1432 “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 Committee is instructed to:

- negotiate and finalise a Council of Europe convention against counterfeiting of medical products and similar crimes involving threats to public health, such as tampering with and adulteration of medical products.

When preparing this convention, the Committee shall:

- consider that counterfeiting of medical products and similar crimes involving threats to public health are becoming a growing international problem, threatening public health and undermining the right to life enshrined in Article 2 of the European Convention on the Protection of Human Rights and Fundamental Freedoms;

- bear in mind that the objective of a future convention should be focused on protecting the public health by defining to that end constitutive elements of criminal offences related to the counterfeiting of medical products and similar crimes involving threats to public health and sanctions corresponding to those offences, taking into account the member states’ legal systems and legal traditions and without prejudice to the need of protecting intellectual property rights;

- work towards a Council of Europe convention that would be a significant contribution to the fight against counterfeiting and trafficking of counterfeit pharmaceutical products, and could have a worldwide impact by enabling non-member states of the Council of Europe to become parties to this convention;

- focus the convention to cover medical products, including medicinal products and medical devices, for human and veterinary use;

- put a specific focus on rights of victims of counterfeit medical products and similar crimes involving threats to public health bearing in mind the principles laid down in Recommendation Rec(2006)8 of the Committee of Ministers to member states on assistance to crime victims;

- define a monitoring mechanism to ensure compliance of States Parties with the provisions of the convention which target crime with an impact on public health and the sphere of healthcare;

- take into account the standards of the Council of Europe in the fields of human rights, criminal law and judicial co-operation which are specific to these offences, in particular on the basis of existing legal instruments in the sphere of public health protection, healthcare and the quality of medicines, such as the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50), and those instruments dealing with other serious forms of crime which are related to it such as the conventions on cybercrime, on money laundering, search, seizure and confiscation of the proceeds from crime, on mutual assistance in criminal matters, on compensation of victims and other instruments of international co-operation;

- consider the previous and current work carried out in the field of counterfeiting and in particular counterfeiting of medicines by the World Health Organisation, the European Union and the previous work of the Council of Europe in this area, including the Parliamentary Assembly of the Council of Europe and the previous and current work carried out by the European Committee on Pharmaceuticals and Pharmaceutical care (CD-P-PH) under the aegis of the European Directorate for the Quality of Medicines and HealthCare (EDQM) and the former Public Health Committee (CD-P-SP) under the aegis of the Partial Agreement in the Social and Public Health Field.

5. Composition of the Committee:

5.A Members

Governments of member states are entitled to appoint representatives of the highest possible rank and with the following qualifications: senior national officials with an extensive knowledge or expertise in criminal law, in particular pharmaceutical crime, and/or pharmaceutical and healthcare products regulatory matters.

The Council of Europe budget will bear the travel and subsistence expenses of one representative from each member state.

Governments of member states are invited to appoint their representatives bearing in mind Recommendation No. R (81) 6 of the Committee of Ministers on the participation of women and men in an equitable proportion in committees and other bodies set up in the Council of Europe. It is recalled in this connection that governments, entitled to appoint representatives, have the option of sending, at their own expenses, one or more additional representatives to sit on Council of Europe committees.

5.B Participants

i. The following committees may each send one representative to meetings of the Committee, without the right to vote and at the charge of the corresponding Council of Europe budget sub-heads:

- the European Committee on Crime Problems (CDPC);
- the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH);
- the Steering Committee on Bioethics (CDBI).

ii. The Parliamentary Assembly may send representatives to meetings of the Committee, without the right to vote and at the charge of its administrative budget.

iii. The European Pharmacopoeia Commission may send representatives to meetings of the Committee, without the right to vote and at the charge of its administrative budget.

5.C Other participants

i The European Commission and the Council of the European Union may send representatives to meetings of the Committee, without the right to vote or defrayal of expenses.

ii. The states with observer status with the Council of Europe (Canada, Holy See, Japan, Mexico, United States of America) may send one representative to meetings of the Committee, without the right to vote or defrayal of expenses.

iii. The following intergovernmental organisations may send one representative to meetings of the Committee, without the right to vote or defrayal of expenses:

- the World Health Organisation (WHO);
- the Organisation for Security and Cooperation in Europe (OSCE);
- the Organisation for Economic Co-operation and Development (OECD);
- the United Nations Office on Drugs and Crime (UNODC);
- the International Narcotics Control Board (INCB);
- Interpol;
- Europol;
- European Patent Office (EPO);
- the World Customs Organisation (WCO);
- the Network of Official Medicines Control Laboratories (OMCL).

6. Working methods and structures:

In line with the interdisciplinary approach to the issue of counterfeiting of medical products and similar crimes involving threats to public health set out in these terms of reference, the Committee should be assisted by a joint secretariat composed of staff of the Directorate General of Human Rights and Legal Affairs (DG-HL) and of the European Directorate for the Quality of Healthcare (EDQM).

The Committee will be assisted by three scientific experts in the fields of criminal law and pharmaceutical and healthcare products regulatory matters to be nominated by the Secretary General, without the right to vote but with defrayal of expenses of the budget envelope allocated to this Committee.

In the framework of its terms of reference and within the limits of its budgetary attributions, the Committee may have recourse to consultant experts. It shall have the possibility to have whatever contacts and consultations with organisations or professionals and others that it deems necessary for the implementation of its terms of reference, in particular through hearings or written consultations.

Other steering committees may be consulted at an appropriate stage of the drafting of the convention.

7. Duration:

These terms of reference will expire on 31 December 2009.