COUNCIL OF EUROPE CONSEIL DE L'EUROPE

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pc-s-cp/documents/pc-s-cp (2008) 10 – e

EUROPEAN COMMITTEE ON CRIME PROBLEMS
(CDPC)

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

Revised terms of reference[1] of the Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP)

[1] As adopted by the Ministers' Deputies at their 1031st meeting on 2 July 2008.

Revised 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;
- European Convention for the Protection of Human Rights and Fundamental Freedoms and its Additional Protocols;
- 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 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[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 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.

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

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 Group is instructed to:

i. prepare a report, in the light of the instructions given by the CDPC and the 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 to strengthen 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;

ii. prepare a 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 (hereinafter the "preliminary draft convention") taking account of the instructions of the CDPC and the conclusions of the final report of the PC-S-CP on the key elements which could be included in a possible international legally binding instrument to fight crime concerning medical products. Such a draft instrument should take due account of international and domestic law and practice where existing and applicable, existing legal gaps, as well as of the need to ensure compatibility and coherence between any new instrument and international, including Council of Europe instruments, and national legislation.

5. Composition of the Committee:

5.A Members

The Group shall be composed of 11 specialists in the field of counterfeiting of medical products 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 organisation 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 (2-6 June 2008) and finalise the preliminary draft Convention by 28 February 2009.

With a view to increasing transparency of the drafting process, the meetings of the Group aimed at preparing a preliminary draft convention may, upon request, be enlarged, without defrayal of expenses, to representatives of member states.

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

Once the Bureau of the CDPC considers the preliminary draft convention sufficiently advanced for consideration and finalisation by all member states, it shall seek the authorisation of the Committee of Ministers to convene a multidisciplinary committee with the full participation all member states to negotiate the draft convention in 2009 under the aegis of the CDPC.

7. Duration:

These terms of reference will expire on 28 February 2009.