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

SUMMARY MEETING REPORT

First meeting
2-5 June 2009

Agenda item 1: Opening of the meeting

The PC-ISP held its first meeting in Strasbourg from 2 – 5 June 2009 with Mr Fritz ZEDER (Austria) in the Chair.

Mr Jan KLEIJSEN, Director of Standard-Setting, and Ms Susanne KEITEL, Director of EDQM, welcomed the members of the Committee.

Agenda item 2: Information from the Secretariat

The Secretariat informed delegations about the Committee's terms of reference, the work undertaken by the drafting committee (PC-S-CP), the outcome of discussions in the Bureau of the European Committee on Crime Problems (CDPC) on the draft Convention text, as well as the time table foreseen for negotiation and adoption of the draft Convention.

A total of two sessions of the PC-ISP (2 – 5 June and 1 – 4 September 2009) are foreseen. The outcome of the negotiations in the PC-ISP will be submitted to the CDPC for further discussion at the occasion of that Committee's plenary meeting in October 2009. If the CDPC agrees on the text of the draft Convention as proposed by the PC-ISP, the Convention will be open for signature in 2010 after adoption by the Committee of Ministers and the Parliamentary Assembly.

Agenda item 3: Election of the Chair

Mr Fritz ZEDER (Austria) was elected as Chair of the PC-ISP.

Agenda item 4: Adoption of the Agenda

The agenda was adopted without amendments.

Agenda item 5: Presentation by Dr Lincoln TSANG on medical devices

In accordance with Point 6 of the Terms of Reference of the PC-ISP, Dr Lincoln TSANG has been appointed by the Council of Europe as scientific expert for the PC-ISP. Dr TSANG is a partner in the private law firm of Arnold & Porter (United Kingdom) and a legal expert on medical devices. The presentation of Mr TSANG is attached to the summary meeting report as Appendix II.

Agenda item 6: First reading of the draft Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health chapter by chapter

The Committee finalised a first reading of the draft Convention, article by article. It decided to provisionally amend the text as set out in track changes in the document attached to the summary meeting report as Appendix I.

In particular, the question of whether medical devices should be covered by the scope of the draft Convention was examined by the Committee. The majority of delegations found that medical devices should indeed be covered in order to avoid any loopholes in the criminalisation of counterfeiting of medical products, but that the terminology used in the draft Convention relating to medical devices, as well as certain provisions of the draft Convention, should be adapted in order to properly reflect the differences between medical devices and medicinal products in terms of the legal and other requirements to manufacturing and quality control procedures. In this context, the Committee also decided to bring accessories designated to be used together with medical devices under the scope of the draft Convention.

The Committee further decided to amend the provision on similar crimes in Article 6, focusing on the intentional illicit manufacturing and illicit supplying of (non-counterfeit) medical products, which have a potential risk to public or individual health.

The Committee held discussions on a series of provisions, in particular Article 8 on jurisdiction. The Committee decided to await the analysis made by the scientific expert appointed by the Council of Europe in accordance with Point 6 of the Terms of Reference of the PC-ISP, Mr Claude DEBRULLE, before making a final decision on the types of jurisdiction appropriate for the subject matter of the draft Convention.

Finally, the Committee introduced a number of editorial changes to the text of the draft Convention (see Appendix I).

One delegation presented its written proposal for a new, enhanced chapter on international cooperation (Chapter VII). After having heard the delegations on the proposal, the Chair concluded that despite the merits of certain elements of the new proposal, a majority of delegations preferred to keep Chapter VII as it stands.

Replying to a question raised by a delegation concerning the status of the CDPC's representative in the Committee, the Secretariat underlined that the representative of the CDPC has been appointed by, and is reporting to, the Bureau of that Committee and is consequently entitled to speak on behalf of the CDPC in the PC-ISP.

Agenda item 9: Next meeting

The second meeting of the Committee will take place in Strasbourg from 1 - 4 September 2009.