COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Strasbourg, 15 January 2008 PC-S-CP (2008) 04

GROUP OF SPECIALISTS

ON COUNTERFEIT PHARMACEUTICAL PRODUCTS

(PC-S-CP)

REPORT OF THE 2ND MEETING

Strasbourg, Palais de l'Europe, 17-19 December 2007

BRIEF FOREWORD

The PC-S-PC at its second meeting discussed the draft Final Report, submitted by the Secretariat in light of the conclusions of the first meeting and agreed upon the scope of the possible legal instrument and the offences it should target.

In particular the PC-S-CP:

- took into account the current work being carried out in the field of counterfeiting of medical products by the World Health Organisation and the European Union;

- reiterated its view that counterfeiting of medical products and related crimes became a growing international problem, threatening public and individual health;

- expressed the reasons why it believed a Council of Europe convention against counterfeiting of medical products and related crimes should be prepared;

- considered that the objective of a possible future convention should be focused on protecting the individual and public health by introducing to that end new offences and penal sanctions for these offences, without prejudice to the need of protecting intellectual property rights;

- discussed and reached preliminary agreement upon a non-exhaustive set of offences to be established by a future convention and discussed the nature of sanctions;

- discussed issues relating to jurisdiction, procedural matters relating to international co-operation as well as preventive and administrative measures; and

- considered a number of proposals as to the possible follow-up mechanism to a future convention.

The PC-S-CP confirmed its intention to hold its final meeting on 5-7 March 2008 with the aim of approving the Final Activity Report and submitting it 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 second meeting at the Palais de l'Europe, Strasbourg, on 17-19 December 2007, with Mr Claude DEBRULLE (Belgium) in the Chair.

2. The Chair reminded members of the Group of its main objective – to prepare a Report containing key elements that could be included in a possible Council of Europe convention on the fight against counterfeit pharmaceutical products.

3. The Terms of Reference of the PC-S-CP appear in Appendix I to this Report. The representative of the European Commission Mr Christian Tournie and the representative of the Parliamentary Assembly Mr Bernard MARQUET took part in the second meeting of the PC-S-CP. The full list of participants is contained in Appendix II and the agenda of the second meeting is contained in Appendix III.

ADOPTION OF THE AGENDA

4. The agenda was adopted without any modifications.

MEETING DISCUSSIONS

Discussion of the draft Final Report in the light of the comments made by members of the Group

5. The PC-S-CP began the meeting by discussing the draft Final Report in the light of the comments received from its members. The Group decided to draw a clear distinction between counterfeiting of goods in general and counterfeiting of pharmaceutical products and stressed that even though counterfeiting of pharmaceutical products touches upon intellectual property issues, in reality it is a broader problem, which jeopardizes public health and the health of individuals.

6. The PC-S-CP reiterated its conviction that the objective of a possible future legal instrument should be to provide procedural and substantive provisions against counterfeiting of pharmaceutical products in a broad sense. The Group considered it necessary not to limit such a possible instrument to counterfeiting only, but to expand it to all related crimes that could infringe individual and public health.

7. The idea of introducing an umbrella notion of "pharmaceutical crime", under which specific offences could be included, found favour with the majority of the specialists. However, some members of the PC-S-CP strongly opposed using the term "pharmaceutical crime" as they considered it to be an undefined concept, which enabled various interpretations and could therefore not be used as the basis for introducing specific criminal offences.

8. The PC-S-CP made it clear that a possible future instrument should not aim at criminalizing the production of substandard pharmaceutical products by licensed manufacturers, without any criminal intent. Such a possible convention should target unauthorised production and distribution of counterfeit pharmaceutical products and should leave violations of good manufacturing practice or good distribution practice to the pharmaceutical regulatory sphere.

9. The PC-S-CP proceeded with discussing the key notions used in the Final Report. The participants agreed that the work of the PC-S-CP should follow closely the latest developments in the WHO and the EU, and in particular in the WHO IMPACT Group. The PC-S-CP took note of the results of the International Conference on Developing Effective Legislation to Combat Counterfeit Medical Products, organised by the WHO in Lisbon on 10-11 December 2007, especially as regards the latest definitions adopted at this Conference.

10. In particular, the PC-S-CP decided that the term "pharmaceutical products" could be usefully substituted by "medical products", which should include medicinal products and medical devices. Therefore, for greater clarity, the PC-S-CP decided to refer to "counterfeit medical products" and to explain this notion in the Final Report as well as in its Appendix I.

11. The WHO definition of “counterfeit medical product” was considered to be very useful as it covers identity (name, composition, strength, or any other element that may influence the judgment of health professionals, patients or consumers about the identity of the product), history (different stages of distribution) and source (manufacturer, country of manufacturing, country of origin, marketing authorisation holder, or any other element that may influence the judgment of health professionals, patients or consumers about the source of the product) of the medical product in question.

12. The Group confirmed its decision taken at the first meeting to exclude food, food supplements and cosmetic products from the scope of the Final Report.

13. As regards clinical trials, the majority of the PC-S-CP was of the view that they would fall outside the ambit of counterfeiting of medical products. The proponents of this opinion recognised that clinical trials could be subject to fraud for justifying the commercialization of a medical product, but considered that they would not be relevant for a criminal law convention against counterfeiting of medical products. However, a few members of the Group claimed that clinical trials are sometimes carried out in conditions that endanger the health of individuals and public health and considered that it could be a good political opportunity to deal with this problem as well.

14. The PC-S-CP reached preliminary agreement as regards the scope as well as definitions and terms, inspired by the existing WHO and EU texts, that it would advise using in a possible future convention, and decided to include these in the Appendix I of the Final Report.

15. The PC-S-CP continued the meeting by discussing the reasons for which the Council of Europe convention would be necessary. It agreed absence of harmonisation in international law of the offences relating to counterfeiting of medical products, the increasing global magnitude of this crime, affecting almost all states in the World, internationalization of trafficking of counterfeit pharmaceutical products, aggravated by internet trade, absence of strong criminal sanctions against counterfeiting of medical products in most jurisdictions and therefore a low or inexistent risk of facing such sanctions, are the most important reasons why an international legally binding instrument is necessary.

16. Another advantage of the Council of Europe’s possible future convention would be that it would promote creating networks and tools of inter-sectoral co-operation (between customs, police and healthcare authorities) not only at the inter-state level, but also at the national level. The PC-S-CP agreed that the time is ripe for the Council of Europe to prepare such a convention.

17. In relation to the new offences that a possible future instrument should introduce, the specialists agreed that these offences should be behaviour-centred, that is to say should prescribe those acts that would constitute a crime. In so doing, the main aspect to be taken into consideration is to what extent a particular act is considered to endanger public health and the health of individuals.

18. The majority of the Group considered that counterfeiting of medicines and related offences should constitute a crime *per se* even without causing any actual harm. However, some members opposed this view and stated that other elements of crime should also be present, in particular subjective elements (at least criminal intent and negligence).

19. The PC-S-CP agreed that the *mens rea* aspect should be present in an act if this act was to be criminalized. They decided to leave it to the drafters of a possible future convention to determine the liability threshold in accordance to the gravity of the offence in question.

20. The PC-S-CP then discussed specific types of offences that a future convention could introduce. A non-exhaustive list of possible offences was agreed by the Group and was included in Appendix I to the Final Report. The Group also considered it very important for the drafters of a possible convention to be given examples of the behaviour a future convention should seek to cover.

21. The representative of the European Commission, Mr Christian Tournie, stressed the importance of allowing for the confiscation of the tools and proceeds of this crime and their preferable destruction, as well as carrying out financial investigations in relation to counterfeit medical products, where appropriate.

22. The PC-S-CP at its second meeting also discussed matters relating to establishing jurisdiction over offences, especially when such offences are committed internationally. It was recalled that the existing instruments of the Council of Europe on international co-operation in the criminal field already contain useful provisions that lay down different circumstances to be borne in mind when establishing jurisdiction.

23. In view of the Group, in addition to the place of commission of the offence, the place where the effect of an offence occurred, the nationality of the offender and other relevant circumstances should be taken into account. For example, the location of the victim could be an additional criterion in determining jurisdiction.

24. The PC-S-CP noted that during the IMPACT Conference discussions in Lisbon, some of the participants requested that counterfeiting of medical products was subject to universal jurisdiction so as to allow any state to pursue the offenders, once captured. However, this idea did not find significant support.

25. The Group also discussed the need for the offences established by a possible future instrument to be extraditable. The majority of specialists agreed that for most serious offences double criminality requirement should be abolished, especially because in many states there is no criminal legislation against counterfeiting of medical products.

26. The PC-S-CP reflected on the procedural aspects of international co-operation, namely the assistance that the competent authorities of the states could render each other as regards the transmission of information concerning the discovery of counterfeit medical products, apprehending the suspects, investigation of offences and obtaining of evidence. The possibility of organising joint investigative teams was raised. The Chair proposed to contact the Consultative Council of European Prosecutors (CCPE) for an opinion on this subject.

27. The specialists recognised that counterfeit medical products are primarily discovered by the industry, but concurred that the state authorities should be more active in combating this activity and that there is a need to raise awareness about it. Measures need to be taken at the public level to defeat or at least prevent counterfeiting of medical products.

28. The PC-S-CP took note of a number of relevant United Nations conventions that regulate the issue of information exchange and international co-operation against crimes that are comparable to the seriousness of counterfeiting of medical products, including organised crimes. The Group took note that a compilation of the most relevant provisions would be sent to the Secretariat by Mr Jacques Franquet and would appear in Appendix II to the draft Final Report.

29. As to the nature of sanctions, the PC-S-CP highlighted that a future convention should provide the competent authorities with the possibility of taking all adequate measures to ensure that counterfeiting is effectively combated and prevented. Apart from imprisonment, where applicable, these should include seizure, destruction and withdrawal of all tools and materials used in the commission of an offence.

30. Along with criminal sanctions, additional administrative and disciplinary measures should be available against the perpetrators. These measures should include revocation/annulment of diplomas and licenses for professional activity, where relevant. Financial investigations should also be carried out as they allow for the detection of illegal assets via financial networks as well as financial seizure.

31. The PC-S-CP believed that the drafters of a future instrument should take into account the existing provisions concerning the nature of sanctions, contained in other Council of Europe conventions, which the Group decided to include in Appendix II to the draft Final Report.

32. The Group also discussed possible preventive and administrative measures and considered it useful to provide a number of examples of such measures in the draft Final Report, without necessarily including them in a future convention.

33. In particular, it was suggested that all operators in the manufacturing and the distribution chain should be subject to licensing and trading authorisation. In addition, professional training of responsible persons, should be included as a general recommendation to states.

34. Traceability of medical products and their components (active pharmaceutical ingredients, excipients, components used in medical devices etc.) are one of the effective practical ways to filter out counterfeit medical products. However, it involves technically complicated operations, which differ from one company to another, is extremely costly and at this stage are very difficult, if at all possible, to be harmonised.

35. Yet another aspect, which would not fall under the scope of a possible future legal instrument, is parallel trade, which makes the traceability of medical products even more complicated as it involves re-packaging often in less secure package, therefore making it easier to counterfeit such products. Some specialists suggested including a general clause in a future convention that any packaging, including repackaging should be of adequate security.

36. The PC-S-CP took note of the few proposed follow-up mechanisms, contained in the draft Final Report, and agreed that it was not up to this Group to identify the most appropriate. However, the specialists agreed that it would be useful to allow for a monitoring mechanism that envisages on-site visits to states parties to a future legal instrument. In any case, the follow-up mechanism could only be negotiated and decided upon in the context of a future legal instrument.

37. Furthermore, the Group agreed that considerable experience of operation of different monitoring mechanisms exist in the Council of Europe (Greco, MONEYVAL, CPT, etc.), which should be usefully taken into account.

WORKING METHODS OF THE PC-S-CP

38. The PC-S-CP agreed upon the importance of keeping the draft Final Report a succinct and well-substantiated document. The Chair proposed to structure it in two parts. The fist part would be an argumentative one, briefly, but eloquently explaining the position of the PC-S-CP on the discussed issues. The second part would consist of appended texts, unanimously agreed by the Group.

39. The Group instructed the Secretariat to send an updated version of the draft Final Report to its members by 10 January 2008 for the written consultation procedure. The PC-S-CP agreed that comments should be received from specialists by 10 February 2008 at the latest, on the basis of which the Secretariat with the Chair would further revise the draft Final Report in the light of the proposals received, also explaining the reasons for which the proposed amendments were or were not taken into account.

DATES OF NEXT MEETINGS

40. The PC-S-CP recalled that it would hold its third and final meeting on 5-7 March 2008 with the ultimate aim of adopting the Final Report and submitting it to the CDPC.

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[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);
- 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.

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

5. Composition of the Committee:

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

Ms Kerstin HJALMARSSON (Sweden), Assessor Medical Products/Enforcement, 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

PERSONS ACCOMPANYING MEMBERS OF THE GROUP /

RUSSIAN FEDERATION
M. Sergey DALECHIN, Conseiller adjoint au Représentant Permanent de Russie auprès du Conseil de l'Europe,

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PARLIAMENTARY ASSEMBLY – SOCIAL, HEALTH AND FAMILY AFFAIRS COMMITTEE/

M. Bernard MARQUET, Conseiller, Conseil National de la Principauté de Monaco,

Mme Agnès NOLLINGER, Secrétaire de la Commission des questions sociales, Assemblée Parlementaire, Conseil de l'Europe

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/ *bilingue*)

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

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

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

3. Discussion of the Draft Final Report in the light of the comments made by the members of the Group / *Discussion de Projet de Rapport Final dans la lumière des commentaires des membres du Groupe*

Working documents / *Documents de travail :*

- Report of the 1st meeting (6-7.11.2007) / Rapport de la 1ère réunion (6-7.11.2007) PC-S-CP (2007) 03
- Draft Final Report / *Projet de Rapport Final* *PC-S-CP (2007) 02*
- Comments of the PC-S-CP experts to the Draft Final Report / *Commentaires des membres du PC-S-CP sur le Projet de Rapport Final*
- Report by the PACE (Doc. 11227) / *Rapport de l'APCE (Doc. 11227)*
- Recommendation 1793 (2007) and the Reply by the Committee of Ministers / *Recommandation 1793 (2007) et la réponse du Comité des Ministres*
- PACE Recommendation 1794 (2007) and the Reply by the Committee of Ministers / *APCE Recommandation 1794 (2007) et la réponse du Comité des Ministres*
- Convention on Cybercrime, Budapest, 23.11.2001 / *Convention sur la cybercriminalité, Budapest, 23.11.2001*
- 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
- Model of a network of single points of contact (SPOCs) – 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

4. Items to be discussed at the last meeting of the PC-S-PC (5-7 March 2008) / *Points à discuter lors de la dernière réunion du PC-S-CP (5-7 mars 2008).*