Appendix 5

Terms of reference of the Committee of Experts on Minimising Public Health Risks Posed by Counterfeiting of Medical Products and Similar Crimes (CD-P-PH/CMED)

1.	**Name of Committee:**	Committee of Experts on Minimising Public Health Risks Posed by Counterfeiting of Medical Products and Similar Crimes (CD-P-PH/CMED)
2.	**Type of Committee:**	Committee of Experts
3.	**Source of terms of reference:**	European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH)

4. Terms of reference:

Having regard to:

- Statutory Resolution (93)28 on Partial and Enlarged Agreements and Resolution Res(2005)47 which applies only *mutatis mutandis* to partial agreements;

- the European Convention for the Elaboration of a European Pharmacopoeia contributing to public health protection by harmonising specifications of medicinal substances which are of general interest and importance to the peoples of Europe;

- the Third Summit of Heads of State and Governments of the Council of Europe (Warsaw, 16-17 May 2005) Action Plan laying down the protection of health as a social human right among the principal tasks of the Council of Europe including support to work on equity of access to care of appropriate quality, and services, meeting the needs of the population in a patient-oriented way;

- Committee of Ministers (Partial Agreement) ResAP(2001)2 concerning the pharmacist's role in the framework of health security;

- the replies of the Committee of Ministers on the Parliamentary Assembly Recommendations
  - 1673 (2004) – Counterfeiting: problems and solutions, adopted on 6 April 2005,
  - 1793 (2007) "Need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods", adopted on 21 November 2007,
  - 1794 (2007) "The quality of medicines in Europe", adopted on 26 September 2007, where the Committee of Ministers "…*welcomes the training on practical procedures and networking between concerned stakeholders at the national and international levels which is being prepared by the Ad hoc group on Counterfeit Medicines in co-operation with the European Directorate for the Quality of Medicines and HealthCare (EDQM)…".* With a view to the transfer of the activities to the EDQM as from 1 January 2008, the Committee of Ministers stated that "*The recommendations of the Assembly will be borne in mind when the Committee of Ministers examines the EDQM's programme of activities...";*

- the conclusions of the Council of Europe Seminar "Counteract the counterfeiters: Limiting the risks of counterfeit medicines to public health in Europe by adequate means and measures, Strasbourg, 21-23 September 2005, and the International Conference "Europe against Counterfeit Medicines", Moscow, 23-24 October 2006 ("Moscow Declaration"), organised with expert support from the former Ad hoc Group on Counterfeit Medicines; the Conference Declaration of the International Conference "Towards the practical implementation of the Council of Europe Convention on counterfeiting of medical products and similar crime involving threats to public health (MEDICRIME Convention)", Basel, 15-16 April 2010, organised with expert support from the Committee of Experts CD-P-PH/CMED;

- the Council of Europe future Convention on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention) which ranks the prevention of threats to public health from counterfeiting of medical products and similar crimes on a prominent position among its purposes besides the combating of such crimes, and the MEDICRIME Convention Explanatory Memorandum, namely the chapters IV - Co-operation of authorities and information exchange, V - Measures for prevention, VII – International co-operation, and chapter VIII – Follow-up mechanism which foresees the contribution of relevant Council of Europe intergovernmental or scientific committees in order to contribute to a multidisciplinary and multiprofessional approach;

- the forward-looking strategy on minimising public health risk posed by counterfeit medicines and related crimes in Europe through the development of practical measures prepared by the former Ad hoc Group on counterfeit medicines,

Under the authority of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), and in relation to the implementation of the above-mentioned replies of the Committee of Ministers to the Parliamentary Recommendations and the conclusions of Council of Europe international conferences, and bearing in mind that counterfeiting of medical products and similar crimes:

- present a serious threat to patient health violating the right to life enshrined in Art. 2 of the European Convention of Human Rights and Fundamental Freedoms (ECHR);

- undermine public trust and cost-effectiveness in medical therapies and healthcare systems;

- are on the rise in western industrialised countries. This includes Council of Europe member states that have a high percentage of counterfeit products on the market and member states bordering regions assumed to be sources of counterfeit medical products;

- due to the availability of new communication technologies, (e.g. the internet), are international crimes and have regional particularities;

- are complex as regards causes and implications and require multisector and multi-organisation counterstrategies which respond to the situation in Europe and keep pace with criminal inventiveness;

- require urgently practical risk management and prevention programmes and model approaches for member states and other stakeholders in the field,

the CD-P-PH/CMED shall:

a) develop and promote the implementation of multisectorial risk prevention and management strategies, e.g. programmes and model approaches the field of public health protection from counterfeit medical products and related crimes, in particular

- prepare studies on public health implications of criminal phenomena pertaining to counterfeiting of medical products and similar crimes including training needs of officials in health and law enforcement and their stakeholders,

- organise multisectorial training programmes for health and law enforcement officials and other stakeholders, including e-learning methods, evaluate and follow up their impact,

- make available and update training materials,

- assist to regional training programmes upon proposal by member states after prioritisation and in line with budgetary appropriations,

- publish practical guides sharing proven practices and models,

- prepare proposals for recommendations for states parties to the Convention on the Elaboration of a European Pharmacopoeia and proposals for their practical implementation;

b) facilitate networking and co-operation within member states in the field of public health protection from
counterfeit medical products and similar crimes through activities promoting recognised networking models (e.g. the model for a network of SPOCs prepared by the former Ad hoc Group on counterfeit medicines;[1]

c) provide public health authorities with strategies for risk communication on counterfeit medical products
and related crimes, in particular

- prepare studies on strategies for risk communication,

- prepare proposals for recommendations for member states and proposals for their practical implementation;

d) as provided for in the future MEDICRIME Convention, and expanded in the MEDICRIME Explanatory Memorandum, make available scientific expertise to the Committee of the Parties to the Council of Europe MEDICRIME Convention as regards its specific functions such as the facilitation of information exchange on significant legal, policy or technological developments in relation to the application of the provisions of the Convention;

e) maintain and develop further a specific multisectorial expertise with a view to adapting programmes
and procedures to the rapidly changing patterns of crime involving healthcare products in Europe and in support of States Parties to the Convention on the Elaboration of a European Pharmacopoeia and of other Council of Europe bodies, the European Committee on Crime Problems and the bodies of the European Directorate for the Quality of Medicines and HealthCare (EDQM);

f) promote a favourable environment for the implementation of regional and international specific legal instruments in the field of counterfeit medical products and similar crimes at national and international levels;

g) establish and maintain links with national, European and international institutions and organisations being active in combating counterfeiting of medical products and related crimes;

h) develop supportive tools for information exchange on management, prevention and follow-up of the risks posed by counterfeiting of medical products and similar crimes;

i) assess the impact of the results of its work programme in the States Parties to the Convention on the Elaboration of a European Pharmacopoeia.

5. Composition:

5.A Members

Governments of Council of Europe States Parties to the Convention on the Elaboration of a European Pharmacopoeia are entitled to appoint representatives from the relevant health and other law enforcement authorities.

These may include experts from health and law enforcement sectors with relevant competencies and experiences as regards risk prevention and management in the field of combating counterfeiting of medical products and related crimes. Each member state shall have one vote.

The sending authorities of the member states will bear the travel and subsistence expenses for their representatives' participation in the meetings of the CD-P-PH/CMED.

[1] Endorsed by WHO IMPACT at the 2nd General Meeting, Lisbon, 12-13 December 2001

5.B Participants

The CD-P-PH/CMED may invite representatives of other committees and bodies of the Council of Europe to specific meetings depending on the agenda of the respective meeting without the right to vote and at the expense of the corresponding heads of the Council of Europe budget.

5.C Other participants

i. Council of Europe member states other than mentioned above under 5.A and other states with observer status with the European Pharmacopoeia Commission may send a representative to the meetings of the CD-P-PH/CMED, without the right to vote or defrayal of expenses.

ii. The European Union may send representatives to the meetings of the CD-P-PH/CMED, without the right to vote or defrayal of expenses.

iii. The World Health Organization may send a representative to the meetings of the CD-P-PH/CMED, without the right to vote or defrayal of expenses.

5.D Observers

International non-governmental organisations, relevant European and international institutions , international and European police and customs organisations active in the field, may ask for observer status with the CD-P-PH/CMED and be allowed to send a representative to its meetings, without the right to vote or defrayal of expenses.

Observer status is granted on the basis of unanimous agreement by the delegates of the CD-P-PH/CMED and after authorisation by the CD-P-PH.

6. Working methods and structures:

The CD-P-PH/CMED will hold regular meetings and will carry out its programme of activities using scientific and public health orientated approaches, where applicable.

The orientation of the programme of activities is multisectorial comprising public health and law enforcement, relevant private sectors and health professionals.

With a view to reaching its objectives, the CD-P-PH/CMED may arrange consultations, in particular with international and European associations representing for example the pharmaceutical manufacturing and distribution chain, including manufacturers of ingredients for pharmaceutical purposes, health professionals, by means of hearings or by any other means, and organise conferences and seminars, as appropriate. Where necessary, in order to expedite the progress of its work, the CD-P-PH/CMED may entrust a limited number of its members with a specific task. The CD-P-PHCMED will use structured and systematic approaches for proposals for new projects and for carrying out repeated activities such as surveys.

7. Duration:

1 January 2011 – 31 December 2013.