Appendix 4

Terms of reference of the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC)

1. Name of Committee: Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC)

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 through 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 Action Plan (Warsaw, 16-17 May 2005) 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) Resolution ResAP(94)1 on the rational use of medicines;

- Committee of Ministers (Partial Agreement) Resolution ResAP(97)2 on the role and training of the community pharmacist;

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

- Recommendation Rec(2006)7 by the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care, in particular its stipulations for improved medication safety;

- The conclusions of the Council of Europe seminars on "The role and training of the community pharmacist" (1991), "The pharmacist and the challenge of new social trends" (1995), "The pharmacist at the cross roads of new health risks: an indispensable partner for their management" (1999), and of the Expert Meeting on Medication Safety (2002), which were organised by the Committee of Experts on pharmaceutical questions (P-SP-PH) under the aegis of the CD-P-SP, predecessor of the CD-P-PH as regards pharmaceutical activities, within the framework of the former Partial Agreement in the Social and Public Health Field;

- the internationally recognised definition of pharmaceutical care by Hepler and Strand (1990)[1] adopted and amended by WHO/FIP.

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 recommendation of the Committee of Ministers to the member states, the Committee of Ministers resolutions of

[1] "Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve or maintain a patient's quality of life"

the former Partial Agreement in the Social and Public Health Field, the Parliamentary Assembly Recommendations and the above conclusions of the Seminar: and bearing in mind:

- a prescribed medicine being the most frequent treatment in healthcare systems, in the community and in hospitals;

- the impact of current and ongoing demographic and societal changes in Europe, including migration, ageing, the breaking-up of traditional social structures, the availability of new technologies (e.g. the internet), in healthcare, multi-professional approaches in healthcare, and healthcare budget constraints on current pharmaceutical practices and pharmaceutical care, posing a risk of impaired quality of medicinal treatment and of inequalities in healthcare;

- the critical importance of ensuring safety and effectiveness of medicines and their appropriate use for the individual patient in ambulatory care, primary care, hospital, assisted living, nursing home, home health care, hospice, and society in general;

- the national competency of member states as regards pharmaceutical practices and care which are not subjected to European treaties;

- the need to promote pharmaceutical care throughout the medication chain, implying professional commitment in managing patient's medicine therapies and putting first the patient's quality of life with a view to meeting the current challenges for healthcare systems in Europe;

- the pharmacist's key role in pharmaceutical professional governance through patient-oriented participative medication management and through co-operating and sharing pharmaceutical knowledge and skills with all partners throughout the medication chain, in particular doctors, nurses, and care-givers,

the CD-P-PH/PC shall:

a) improve public health care in community, ambulatory care, primary care, hospital assisted living, nursing home, home health care, and hospice, through specific programmes and policies, putting first the needs of patients and society in general, valuing the social and ethical context of healthcare;

b) develop and carry out a programme of activities aiming at improving public health care in Europe through promoting knowledge, skills, attitudes and values in practices and care involving pharmaceuticals. In particular these activities comprise the implementation of a quality assessment in pharmaceutical practices and care through quality indicators, the provision of guidance on the quality and safety of pharmacy-preparations such as formularies on paediatric pharmacy- preparations, advice to governments as regards the safety of Traditional Chinese Medicines (TCM) practices for European citizens based on the conclusions of the expert workshop".The impact of TCM on pharmaceutical practices in Europe" (2010), and dose dispensing systems;

   - prepare proposals for harmonised provisions and practices involving pharmaceuticals in States Parties to the Convention on the Elaboration of a European Pharmacopoeia in the field of safety in practice and care involving pharmaceuticals,

   - contribute to the practical implementation of the above provisions and policies through programmes raising awareness and providing practical guidance;

c) assist in monitoring the adequate implementation of the results of the relevant activities at national levels in States Parties to the Convention on the Elaboration of a European Pharmacopoeia and assist the CD-P-PH in evaluation and follow-up of the programme of activities mentioned in item b);

d) promote the further development of pharmaceutical professionals, expertise, roles and co-operation of all partners within the medication and care chain, in particular the pharmacist, the doctor and the nurse, and care-givers;

e) maintain and develop links with national, European and international institutions, organisations and professional bodies active in the sphere of practice and care involving pharmaceuticals;

f) 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 authorities dealing with pharmaceutical practice and care.

These may include experts responsible for the preparation of national policies in the field of pharmaceutical practices and care. 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/PC.

5.B Participants

The CD-P-PH/PC 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/PC without the right to vote or defrayal of expenses.

ii. The European Union may send a representative to the meetings of the CD-P-PH/PC 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/PC without the right to vote or defrayal of expenses.

5.D Observers

International non-governmental organisations, relevant European and international institutions, International and European associations representing for example stakeholders of the medication chain, including professional associations and orders of pharmacists, doctors, and nurses, may ask for observer status with the CD-P-PH/PC 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/PC and after authorisation by the CD-P-PH.

6. Working methods and structures:

The CD-P-PH/PC 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 multiprofessional.

With a view to reaching its objectives, the CD-P-PH/PC may arrange consultations, 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/PC may entrust a limited number of its members with a specific task. The CD-P-PH/PC 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.