Appendix 3

Terms of reference of the Committee of Experts on the classification of medicines as regards their supply (CD-P-PH/PHO)

1. Name of Committee: Committee of Experts on the Classification of Medicines as regards their Supply (CD-P-PH/PHO)

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 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(2007)1 on the classification of medicines as regards their supply superseding Resolution Committee of Ministers(Partial Agreement) ResAP(2000)1 on the classification of medicines which are obtainable only on medical prescription entrusting the Public Health Committee (Partial Agreement) (CD-P-SP), predecessor of the CD-P-PH as regards pharmaceutical activities, to carry out, either itself or through subordinate bodies, an annual revision of the appendices to the above Resolution ResAP(2007)1;

- Committee of Ministers (Partial Agreement) Resolution ResAP(2007)2 on good practices for trade in medicines by mail order which protect patient safety and the quality of the delivered medicine referring in its stipulations to the authorised conditions of sale or distribution of medicines being subject to mail order trade;

- the fact that the classification criteria set out in the Council of Europe resolutions on the classification of medicines have been taken over by the directive 92/26/EEC and by the directive 2001/83/EEC (art 70-75), which refer to the principles already established by the Council of Europe.

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 Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1, and bearing in mind:

- the importance of the classification of medicines as regards their supply with or without a medical prescription on public health in particular patient safety, the accessibility of medicines to patients and the responsible management of health care expenditure;

- the fact that the classification of medicines as regards their supply varies considerably in Europe, falling under national competency of the member states members;

- the importance of preparing recommendations and publishing lists of conditions of use as prescription and non-prescription medicines in Europe for public authorities, industry and the general public,

the CD-P-PH/PHO shall:

a) carry out reviews on the classification practice, underlying rationale and national requirements for medicines of specific interest or concerns for public health and develop good classification practices;

b) monitor trends in and the impact of the classification of medicines on medicines' safety and accessibility to the patient;

c) follow up the national implementation of the appendices to the above-mentioned Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1;

d) prepare proposals for the revision of the text of the above-mentioned Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1, with a view to adapting it to changes in pharmaceutical care and practice;

e) maintain and develop links with national, European and international institutions and organisations active in the sphere of the classification of medicines as regards their supply;

f) develop further and co-ordinate the updates of a web published database presenting the classification status of medicines in the member states and the above-mentioned Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1 and its annually revised appendices;

g) assess the impact of the results of its work programme, such as the Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1 and its annually revised appendices in the States Parties of the Convention on the Elaboration of a European Pharmacopoeia for example through statistics on the implementation of the appendices and the use of the database on the classification of medicines hosted by the EDQM.

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 public authority.

These may include experts responsible for the preparation and follow-up of national policies in the field of the legal classification of medicines. 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/PHO.

5.B Participants

The CD-P-PH/PHO 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/PHO, 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/PHO, without the right to vote and without defrayal of expenses.

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

5.D Observers

International non-governmental organisations active in the field may ask for observer status with the CD-P-PH/PHO 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/PHO member states and after authorisation by the CD-P-PH.

6. Working methods and structures:

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

The CD-P-PH/PHO shall co-ordinate the updates of a web published database presenting the classification status of medicines in the member states and the above-mentioned Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1 and its annually revised appendices. This database contributes to the accessibility and validity of health-related data, and is a reference in this field.

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