Minutes of the 13th meeting of the Homeopathic Medicinal Products Working Group  
7th and 8th June 2011, Budapest Hungary

On 7th and 8th of June 2011, the meeting of the Homeopathic Medicinal Product Working Group (HMPWG) was held in Budapest, under the Presidency of Hungary. The meeting was attended by most of the Member States as well as the representatives of EMA and EDQM. The meeting was formally opened by Dr. Éva Csekey Deputy Director of “National Institute of Pharmacy Directorate” of the National Institute for Quality and Organizational Development in Healthcare and Medicines and by Professor Tamas L. Paal, senior advisor of the Directorate and as the Vice-Chair of the meeting.

The vice chair presented the new/replaced members: Julia Maier for EDQM, Claudia Marschall as alternate for Austria and Cecilia Vellby as alternate for Sweden.

Apologies for absence were received from Ireland, Greece, Lichtenstein, Norway and Switzerland.

No conflicts of interest were declared.

A Chair has been elected according to the Rules of Procedure of the HMPWG (19 for /1 against). The current Chair is now Laurence GIROD, previously French member of the HMPWG. Catherine PRINTZ, previously French alternate of the HMPWG is appointed French member of the HMPWG.

The following issues were discussed:

1 Minutes of the 12th meeting in Liege December 2010
The comments may be sent to Belgium before the 31th of July. A new version with the comments will then circulate for adoption by written procedure.

2 Points to Consider on Declaration of homeopathic preparation in homeopathic medicinal products
This document outlines the principles for a harmonised declaration of active substances in homeopathic medicinal products regarding, the labelling and where appropriate, the package leaflet. The document is linked, in particular, to the title of monographs. The title of monographs is currently under discussion at the EDQM (European Directorate for the Quality of Medicines and Healthcare) in the Homeopathy Working Party (HOM WP). Thus the document “Points to Consider on Declaration of homeopathic preparation in homeopathic medicinal products” is put on hold during the European work on a technical guide for the elaboration of monographs.

3 Glossary of terms concerning homeopathic medicinal products
The glossary is intended to give harmonised definitions of terms related to homeopathy. The Netherlands will circulate a revised version of the document to Belgium, France, Germany, Hungary, Italy, Portugal and Spain. Then, a new proposal of glossary will be presented at the next meeting.

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4 Introduction to Alfresco CMS
Germany presented the Alfresco System CMS (Content Management System). Alfresco CMS is a software that enables to administrate documents online and to exchange and compile data. This system is already being used for the “First Safe Dilution” and the “Homeopathic Use” Working Groups.

5 The list of first safe dilution
The list of first safe dilutions applies to homeopathic preparations of botanical, mineral and chemical origin for human use. The first safe dilution is basically related to a PDE (Permitted daily Exposure), LHRD (Lowest Human Recommended Dose) or TTC (Threshold of Toxicological Concern).
The sub-working group FSD did not meet in between due to lacking resources. Nevertheless, the sub-working group is reactivated with Belgium, France, Germany, Portugal and Spain.

6 List of homeopathic stocks/preparations with a Justification of Homeopathic Use
The outcomes of the meeting of the Homeopathic Use Sub working group held on the 12th of May 2011 were presented by the Chair and Germany.
The following points were discussed:
- A new proposal for a methodology regarding the establishment of the list of homeopathic stocks/preparations with a justification of Homeopathic Use
The homeopathic use should be justified mainly by the materia medica. Because of different existing traditions, some stocks, with the same name, may be prepared from different raw materials (e.g. different part of the plant, different status fresh/dried...). The working group is establishing a clear list of stocks with several data justifying the homeopathic use. The description of the raw material in the materia medica is taken into account. Belgium asked to clarify the scope of the table related to the list and to delete any reference to combination.
The use of the Alfresco CMS (Content Management System) which permits to improve worksharing by compiling easily many data from different Member States into the actual version of the same document.

7 The Document “Points to consider on the justification of the homeopathic use”
The amended document “Points to consider on the homeopathic use”, currently published on the website of the HMA, is confusing because of the complete deletion of the part II and the maintain of part III. Indeed, parts II and III were linked.
The amended version does not correspond to the version adopted by the HMPWG, and this is in contradiction with Article 7 of the Rules of Procedures of the HMPWG adopted by HMA in July 2007, making provisions on the adoption of documents by its members. Moreover, the cover page does not reflect any amendment to the document.
The HMPWG is aware of the concerns of the European Commission related to point II.1 of the original document and is fully open to discuss it, as proposed by the European Commission.
Consequently, the Chair of the HMPWG will send a letter to the Chair of the HMA Management Group, asking to withdraw the amended document from the HMA website. The HMPWG will review the document taking into account the issues raised and will present a new version to HMA for endorsement and publication.

8 European Pharmacopoeia
The EDQM representative informed the HMPWG that the working group on raw materials and stocks (HOM) would focus its work on stocks containing toxic components.

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The Ph Eur Commission had decided to put non-toxic components on hold as there had been no consensus within the delegations regarding the assay. Two monographs on Hydrastis canadensis and Mother tinctures for homoeopathic preparations had been adopted at the March Commission session. The Commission also decided at its March session not to vote on spagyry at its June session. Delegations which were in favour of a deletion of spagyric topics from the work programme of the working group on Homoeopathic Manufacturing Methods (HMM) should send a request with a justification to the Ph.Eur. Secretariat. Spagyry would be discussed again at the next Commission session in June. Furthermore two new monographs on Pillules had been adopted at the March Commission session.

9 The Hungarian point of view
A presentation was made by Professor Tamas L. Paal on different issues raised by the assessment of Homeopathic medicinal products, in particular about the different national implementation of article 16 of the Directive 2001/89/EC amended by Directive 2004/27/EC and the lack of clinical trials.

10 Legal issues
A presentation was made by the representative of the EMA on the Comitology procedure, introduced by the Directive 2001/83/EC amended by the Directive 2004/27/EC. The complexity of this procedure was underlined.
A presentation was made by Belgium on the master files related to the pharmaceutical forms. The goal is to avoid multiple compilation and assessment of same data which are identical within different dossiers and thus to reduce the load of work.
A presentation was made by Spain on a proposal for a Summary of Product Characteristics (SPC) for Homeopathic Products subject to article 14. Then, it was clearly reminded that article 14 made no provision for any SPC. All the mentions related to the information to patient for a registered product are provided for in article 69. Those mentions, as “special warning” are very brief and would need to be specified. Thus, Spain and Portugal will make a proposal for a working document specifying and clarifying all the mentions provided for in article 69 of the Directive 2001/83/EC amended by the Directive 2004/27/EC, in particular, all different warnings.

11 Other issues
Other items were also briefly discussed.
The need of a communication between the Notice to Applicant Group and the HMPWG was highlighted by Belgium.
Belgium reminded the lack of harmonisation regarding the assessment of microbiological quality of non sterile homoeopathic medicinal products. The EDQM representative informed that a request for revision from a Member State would be necessary for discussion of this question at EDQM level.
The discussion on “Ethanol in Children” was postponed, it was suggested to all the members to send their position and comments to Belgium.
Hungary presented proposals of specific national mentions in the SPC. Hungary reported also on the previous meeting with ECHAMP in Budapest. The following points were presented by ECHAMP: the difficult regulatory situation and the lack of transparency between HMPWG and the industry.

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12 The next meeting
Poland announced that the Polish Presidency wouldn’t host the next meeting. The chair of the HMPWG, on behalf of the HMPWG should send a letter to Mr Grzegorz Cessak, President of The Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, to present the specificities of the mandate of the HMPWG, in particular that contrary to scientific committees being part of the European Medicines Agency (EMA), the HMPWG only meets twice a year during formal meetings and that consequently, each meeting is essential to maintain an effective worksharing.

The HMPWG thanked the Hungarian team for the excellent organisation of the meeting.