15th meeting of the Homeopathic Medicinal Product Working Group  
5th and 6th June 2012, Copenhagen Denmark

SHORT REPORT

On 5th and 6th of June 2012, the meeting of the Homeopathic Medicinal Product Working Group (HMPWG) was held in Copenhagen under the Presidency of Denmark. The meeting was attended by various Members States as well as the representatives of EMA and of EDQM. The meeting was formally opened by Jytte Lyngvig, Director, and by Steffen Bager the Vice-Chair of the meeting. The HMPWG Chair warmly thanked the Danish team on behalf of the HMPWG for hosting the HMPWG. No conflicts of interest were declared.

The following issues were discussed:

- **Minutes of the 13th meeting in Budapest June 2011**
  The minutes were adopted.

- **Minutes of the 14th meeting in Warsaw December 2011**
  The minutes had been available two weeks before the plenary meeting. Thus it was decided that comments could be forwarded to Poland and the Chair by the end of June. A new version will circulate in September for adoption by written procedure or at the next meeting depending on the comments.

- **Nomination of the rapporteur of the Homeopathic Use subworking Group**
  In accordance with article 9 of the Rules of Procedures, the HMPWG has appointed the member from Belgium, Marie-Anne Mouyart to the post of rapporteur of the Homeopathic Use subworking Group.

- **Mandate, objectives and rules of procedures**
  In accordance with article 9 of the Rules of Procedure, the mandate and objective of the subworking Group should be adopted also by the HMPWG. Therefore, the mandate and the work programme were discussed and it was decided that some amendments were necessary before the adoption, in particular the duration of the mandate of the rapporteur which should be of 3 years as for the mandate of the Chair.

- **Document “Points to consider on the justification of homeopathic use”**
  This new document related to single remedies had been circulated in the HMPWG from January 2012 with a commenting period until the 31st of March. Comments on the title had been received from France and Germany. A new version taking account of the comments had been forwarded to HMPWG members since May 2012. The title has been extensively discussed. After a majority vote, the document has been adopted with the title “Points to consider on the justification of Homeopathic Use of stock”. The document adopted by the HMPWG will be checked and sent to the HMA for adoption and publication on the HMA website.

**List of homeopathic stocks/preparations with a Justification of Homeopathic Use**

An informal meeting between ECH and HMPWG was held on the 14th of February 2012 at the Belgian Health Agency. ECH made a proposal of a database, which should facilitate the assessment of the Homeopathic use, as required by the Directive 2004/27/EC. The database proposed by ECH was a working programme based on an extension of the database Encyclopedia. This programme, mainly based on different tables making links between stocks, bibliography and symptoms should have permitted to directly reach the
bibliography in relation to the concerned stock. Consequently it was decided to have a pilot phase of 20 stocks in May.

Thus in May ECH has forwarded documents relating to 20 stocks to the chair who has sent them to the Homeopathic Use Subworking Group. The tables relating to the 20 stocks that were forwarded by the ECH had no link with the bibliography. Taking into account that the bibliography is the basis of the assessment of homeopathic use, these tables are not sufficient in themselves to draw a conclusion on homeopathic use for the 20 stocks.

**Braille requirements**

The lack of harmonisation on Braille requirements was raised by the stakeholders at the 12th meeting and this item has also been recently discussed at the CMD level in September. The UK interpretation of the Braille requirements was clearly presented. Thus, according to article 56 a Braille requirement applies to homeopathic medicinal products subject to article 16 of Directive 2001/83/EC but does not apply to homeopathic medicinal products subject to article 14 (article 69 makes provision for the labelling and mentions that no other information should appear). Besides, it has been noted that most products subject to article 14 were products prepacked in small containers making it difficult to include the mandatory information already required in accordance with article 69. All the Member States agree that the name of the product should be expressed in Braille for products subject to article 16 but some Member States have also this requirement for medicinal products subject to article 14. They apply article 56a which states that the name of the medicinal product as referred to in article 54 must also be expressed in Braille format on the packaging. However article 54 is not adapted to the name of a homeopathic medicinal product which is registered according to article 14.

A letter could be sent to the European Commission to clarify the labelling requirements of an application submitted for a possible Mutual recognition procedure. Nevertheless, the possibility of the application of article 54 to homeopathic medicinal products should be argued before asking clarification from the European Commission.

**Presentation on Pharmacovigilance new legislation**

The EMA representative has made a presentation on the new Pharmacovigilance legislation focused on the impact on homeopathic medicinal products. As stated in article 16(3) of the Directive 2001/83/EC, Title IX (Pharmacovigilance) shall apply to homeopathic medicinal products, with the exception of those referred in article 14. Thus a “risk management plan” and periodic safety update reports (PSUR) will be required for homeopathic medicinal products subject to article 16 after 2 July 2012. The derogation of PSUR applies to homeopathic medicinal products registered through the simplified registration procedure unless PSUR submission is requested by a competent authority in a Member State or the Commission/EMA on the basis of concerns relating to pharmacovigilance data or due to the lack of PSURs relating to an active substance after the MA/registration has been granted, or the substance is included in the EURD list. (Draft list of European Union reference dates and frequency of submission of periodic safety update reports.) Marketing Authorization Holders shall by 18 months after the entry into force of regulation, electronically submit to EMA information for all medicinal products authorised or registered in the Community.
Glossary of terms concerning homeopathic medicinal products

This document had been intensively discussed at the last HMPWG meeting. The Chair has reminded HMPWG members, in Copenhagen, that before sending a HMPWG draft outside the HMPWG for comments, it should be approved by the HMPWG and be mentioned in the List of actions. Indeed, this document still under consideration had been forwarded for comments to the CMDv after the last HMPWG meeting without any agreement from the HMPWG. The rapporteur of the draft and the chair have asked for the withdrawal of the document from the CMDv and to stop the consultation. The HMPWG proceeds methodically step by step according to the Rules of Procedure. The glossary is a set of specific definitions in the field of homeopathy which have to be adopted by the HMPWG. The Rules of Procedure of the HMPWG only foresees that documents approved by the HMPWG should be referred to the HMA for approval.

The document has been very extensively rediscussed. It has been decided that the rapporteur will circulate a new draft in July for comments before the 1st of September. If a consensus is reached the document will then be adopted by written procedure and sent to the HMA for publication on the HMA website for a commenting period of 3 months. In this case the HMPWG Chair will directly inform the CMDv Chair of the possibility of commenting on the document in the field of veterinarian homeopathic medicinal products.

Safety

The Assessments reports of the following stocks have been approved by the HMPWG for publication on the HMA website for a commenting period of 3 months:
- Atropa Belladonna 2a
- Atropa Belladonna Rh
- Atropinum sulfuricum
- Aurum iodatum
- Chimaphila umbellata
- Drosera
- Juglans regia
- Plumbago europaea
- Naphtoquinones (Chimaphila umbellata, Drosera, Juglans regia, Plumbago europaea)
- Kalium iodatum
- Rauwolfia serpentina 4a
- Rauwolfia serpentina Decoct
- Reserpinum
- Silybum marianum

Generalities

A brief overview of the latest activities of the HMPC has been given by the HMPC Chair. An update of the work of the Ph.Eur.HOM Working Party and of the Ph.Eur.HMM Working Party has been given by the EDQM representative. The HMPWG chair has informed that the HMA website would be soon overhauled. A detailed presentation was made on the regulatory situation of Homeopathy in Denmark.

Due to the lack of time, it has been decided that the following items of the Agenda would be studied at the next meeting: spagyry, viral safety, legislation on paediatric regulation, excipients and variations, and transparency of the HMPWG.

The next meeting

Cyprus had already announced that the HMPWG could not be hosted by Cyprus during the European Presidency of Cyprus. Poland announced its intention to host the next HMPWG meeting. The dates were not communicated as yet. The HMPWG thanked the Danish team for the excellent organisation of the meeting and the very interesting presentation.