26th meeting of the Homeopathic Medicinal Products Working Group HMPWG

5- 6 December 2017
Medical Products Agency, Uppsala Sweden

PUBLIC REPORT

On 5th and 6th December, 2017, the 26th meeting of the Homeopathic Medicinal Products Working Group (HMPWG) was held in Uppsala, under the Estonian European Union Council Presidency. The meeting was attended by 17 Member States, the representative of EMA, and a veterinary representative.

The 3 year mandate of the previous Chair of the HMPWG, Biancamaria Bruno, ended before the meeting and no new Chairperson was elected. In the absence of the Vice-Chair (the representative from the current EU-Presidency, Estonia), the meeting was chaired by the Swedish member Dr. Sandra Holt. No conflicts of interest were declared.

The following issues were discussed:

Chairperson of the HMPWG:
For this meeting no new Chair of the HMPWG was elected. There will be a call for candidates for Chairperson before the next meeting. An Interim secretariat was established to guarantee continuity in between meetings and in preparation for the next meeting. Interim secretariat from January – June 2018 consists of Sandra Holt, SE, Astrid Obmann, AT, Werner Knöss, DE, and Emiel van Galen, NL. After the meeting, a functional mailbox for the Interim secretariat has been set up (HMPWG-secretariat@hma.eu) to facilitate the contact with the HMPWG for interested parties.

Minutes of 25th HMPWG meeting
The minutes were not adopted. There will be an additional commenting period by written procedure before the next meeting.
The List of actions from the 25th meeting was approved.

HMA – HMPWG
HMPWG documents on HMA Data Management System (HMA-DMS)
The current use of HMA-DMS by members was evaluated, and it was decided to increase the use further for the written procedures between meetings.

Reply to EASAC Statement on homeopathic products and practices
A letter from the European Academies Science Advisory Council (EASAC) was received by HMPWG. The letter was in regard to homeopathic products and practices, and their clinical efficacy. It was decided that this letter requires an answer from the European Commission. An answer will therefore be sent, referring to present regulatory framework and the mandate of the HMPWG, and advising the EASAC to direct its statement to the European Commission.

Legislation
Minamata convention on Mercury
The EMA representative gave an update on the legal aspects related to Regulation (EU) 2017/852 on mercury, which entered into force on 16-08-2017. Several questions were raised by members during
the discussion regarding the effects on new applications for registration or authorization of homeopathic medicinal products manufactured from mercury.

It was decided that a letter asking for clarification will be sent to the European commission with questions on implementation, and specifically consequences for the availability of homeopathic medicinal products based on mercury.

*Interpretation of the definition of a homeopathic medicinal product*
As decided in the 25th meeting, a questionnaire has been developed on how the definition of homeopathic medicinal products in the Directive 2001/83/EC is interpreted in the member states. The questionnaire will be circulated after the meeting and the responses discussed at the next meeting.

*Q&A document on legal and regulatory issues*
A new draft document was presented on common questions where clarification has been received from the European Commission. Further questions will be added to the document for next meeting.

*European Pharmacopoeia*
A written update of the work of HOM and HMM WP had been submitted by EDQM, since no representative was present at the HMPWG meeting.

*Quality*
In the absence of the chair of the Quality subworking group, the activities were summarised by a member of the subworking group.

*Draft Guidance on Module 3.2.S for nosodes*
A first draft of the preamble for the guidance document was discussed. A short commenting period was decided. After the commenting period, the preamble will be included in the guidance document. The guidance document was adopted for public consultation.

*Draft Q&A documents on Quality*
The Answers on Q1 and Q2 were adopted but will not be published until Q3 and the document “Overview of comments received on draft document “Questions and Answers document on Quality of Homeopathic Medicinal Product (Q 1-3)” are adopted. A new draft of Q3 will be presented at the next meeting.

Four new Q&A were adopted for public consultation (Q4-Q7).

Three more (Q8-Q10) remain under discussion within the HMPWG.

*Discussion on the selection of assay limits in Ph.Eur.*
It is acknowledged that there is a disagreement between MSs on the need for assays as a quality control measure for non-toxic plants in Ph. Eur. monographs for homeopathic substances of botanical origin. This issue is preventing the development of further Pharmacopoeia monographs for important homeopathic substances of botanical origin. The issue will also be discussed in the Quality subworking group and the HMPWG, awaiting future developments at EDQM.

*First Safe Dilutions*
The activities of the FSD subworking group were presented by its Chair.

*Integrated list of FSD and HU*
The possibility of combining the consolidated lists of FSD and homeopathic use has been discussed. The issue needs further consideration within the subworking group.
Draft 3rd List of First Safe Dilutions
A short final commenting period was decided before adoption through written procedure.

Draft 4th List of First Safe Dilutions
A short final commenting period was decided before adoption for public consultation through written procedure.

Safety
Guidance document on non-clinical safety of homeopathic medicinal products
An outline to the new Guidance document on the non-clinical safety of homeopathic medicinal products was presented, where the different HMPWG documents on the assessment of safety, are combined into a new, extended Guidance document.

Contamination of herbal substances with pyrrolizidine alkaloids
An update on the issue was presented.

Homeopathic use
The activities of the homeopathic use (HU) subworking group were presented by its Chair. It has been decided to include the Latin name, the (traditional) name in the French homeopathic pharmacopoeia (FP), as well as the (traditional) name in the German homeopathic pharmacopoeia (GHP), in the list.

Update of consolidated list of stocks with a justified homeopathic use
Due to the introduction of traditional names in the lists, an update to the preamble to the Consolidated List was presented, and adopted for public consultation. With the inclusion of the 5th List, the Consolidated List of stocks with justified homeopathic use now contains almost 300 entries. The traditional names were included also in the Consolidated list. The updated Consolidated list was adopted for publication.

Draft 6th list of stocks with homeopathic use
In the 6th draft, there are 146 stocks with a description in an Official Pharmacopoeia. The 6th list was adopted for public consultation.

First list of Nosodes – discussion on comments
The document is on hold, until the interpretations of the definition of a homeopathic medicinal product have been clarified (see Legislation above).

Homeopathic combination products and homeopathic use
A clarification on the justification of homeopathic use for homeopathic combination products was requested by members of the HMPWG. Based on this clarification, no further action was required. It was suggested that the clarification is also included in the Q&A on legal/regulatory issues (see legislation above).

The ad hoc Chair expressed her gratitude to all participants for their attendance and active contributions to the meeting. Next meeting will be hosted by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), in Berlin, in spring 2018.