28th meeting of the Homeopathic Medicinal Products Working Group (HMPWG)

October 18–19th 2018
Vienna, Austria

Public Report

On 18-19 October 2018 the 28th meeting of the Homeopathic Medicinal Products Working Group (HMPWG) was held in Vienna, Austria under the Austrian Presidency of the Council of the European Union. Representative of 15 EU member states, the Swiss member, veterinary representatives, the EMA-representative, and the EDQM-representative (via teleconference on 18th October) attended the meeting. In the absence of a permanent chairperson, the current vice-chairperson (AT) chaired the meeting. No conflicts of interest were declared.

The following issues were discussed:

Chairperson of the HMPWG
The discussion started at the meeting in Berlin was continued. Amendments to the HMPWG Rules of Procedure regarding the role of chairperson, vice-chairperson and secretariat were discussed. The composition of the secretariat during the Romanian Presidency of the Council of the European Union will be: AT, DE, FI, NL, PT, RO. The Veterinarian representative left the secretariat.

Minutes of the 27th HMPWG-Meeting, Berlin
The minutes of the 27th HMPWG-Meeting in Berlin, as well as the related documents table of decisions and list of actions were adopted.

HMA-HMPWG/Interested Parties
Organisational matters regarding the HMA-HMPWG-Website and the HMA Data Management System were discussed. Furthermore, HMPWG discussed several questions and input provided by interested parties. AT provided a short report from the ‘Dialogue of HMPWG-members and Interested Parties’ that was held on 17 October at the Austrian Federal Office for Safety in Healthcare. HMPWG agreed to continue the dialogue (also face to face); a circle of three years was regarded realistic.

European Pharmacopoeia
The EDQM-representative provided a report of recent activities on relevant topics. Most important was the meeting of NPAs and regulators with EDQM in June 2018 to solve the disagreement amongst the member states. Finally a compromise was achieved that should enable HOM WP to continue its work.

Quality
In the absence of the chair of the subworking group on quality, the activities were summarized by a member of the group. A written report from the chair of the sWG-Q was presented. The last teleconference took place on 24 September 2018, in order to prepare documents for the 28th HMPWG-Meeting.

Documents on quality of homeopathic medicinal products
The final guidance on module 3.2.S for Nosodes together with the Overview of Comments received during public consultation was adopted for publication. Q&A 1-3 as well as Q&A 4-7 with Overview of Comments received were discussed and referred back to sWGQ. Rephrased Q&A 8 was adopted for public consultation. Q&A 9 was referred back to sWGQ. New Q&A 11 and Q&A 12 were adopted for public consultation. New Q&A 13 required further discussion in the sWGQ.

Legislation
Minamata convention/Regulation (EU) 2017/852
The EMA representative provided an update on Minamata convention/EU-regulation 2017/852 on Mercury and its impact on homeopathic medicinal products. In general homeopathic medicinal products qualify as mercury added products when mercury or mercury compounds are used, also if the final product is highly diluted. However, if mercury or mercury compounds are used as starting material, the products are not considered as ‘new’ according to article 8(1). Information about the ‘inventory’ (published by EC in July 2018) was shared; however, specific issues required additional clarification from EC.

Q&A document on legal and regulatory issues
A first draft of the document was provided and discussed.

Homeopathic Use
Future activities of the sWG-HU were discussed.

Safety
The chair of the sWG-FSD reported on recent activities. The draft 4th list of FSDs together with the OoC received were discussed and will be adopted by written procedure. The draft 5th list of FSDs was adopted for public consultation. The draft consolidated lists of FSDs was adopted for publication and will be published after adoption of the 4th list, in order to provide a consolidated document (1st, 2nd, 3rd, and 4th list).
Furthermore, HMPWG agreed on the publication of a consolidated overview document of substances, for which HU is proven and an FSD established. A short update was given about the work on a new guidance document on module 4.

The vice-chair expressed her gratitude to all participants for their attendance and contribution to the meeting.

The next meeting of HMPWG will be held on 23 – 24 May 2019 in Bucharest.