



24th Meeting of the Homeopathic Medicinal Products Working Group HMPWG

10-11 November 2016, Bern, Switzerland

PUBLIC REPORT

On 10th and 11th of November 2016, the 24th meeting of the Homeopathic Medicinal Product Working Group (HMPWG) was held in Bern, Switzerland, under the Slovakian European Union Council Presidency, kindly hosted by Swissmedic.

The meeting was attended by various Member States as well as by the representative of EMA. The meeting was formally opened by the Head of Authorization at Swissmedic and chaired by Biancamaria Bruno as Chair of the HMPWG. No conflicts of interest were declared.

The following issues were discussed:

Minutes of the 23rd meeting in Utrecht

The Minutes of the 23rd HMPWG Meeting were adopted.

The List of Action of 23rd HMPWG Meeting was also approved.

HMA - HMPWG

The Chair presented the letter received from ECHAMP on 20 September 2016 regarding the request of more transparency on HMPWG activities, taking into account the existing EMA procedures applied to HMPC. The EMA's policy on transparency and HMA documents on transparency published on HMA website were discussed.

The response letter was signed by HMPWG Chairperson and the Chairman of HMA Management Group. Clarifications on two specific aspects of the work of the HMPWG were provided, as highlighted by ECHAMP: (1) Members and participation in topics; and (2) Meeting agenda. (1) Members and participation in topics: It was underlined that HMPWG in accordance to its Rules of procedures, is a forum of exchange of regulatory and scientific expertise on homeopathic medicinal products for human and veterinary use and it is aware of the relevant role of stakeholders in the development of homeopathic medicinal products. The

HMA Procedure and Governance document explains that the contact information of the Chairperson of the HMPWG shall be made available to the public. In light of this, stakeholders are provided with a contact point in the context of potential communications with the HMPWG. The role of Chairperson, set out in Article 4(1) of the HMPWG Rules of Procedure, provides that the Chairperson (and Vice-Chairperson) “*will be responsible for the efficient conduct of the activities of the HMPWG*”. The responsibilities which are ascribed to the role of the Chairperson and the public availability of his/her contact details means that the Chairperson is intended to serve as the appropriate contact point concerning engagement with civil society stakeholders.

In addition, in accordance with Rules of Procedure, the HMPWG is not required to provide the contact details of all its members. In turn, it would not be practically possible to facilitate a request for information concerning the assignment of certain topics to individual member(s) of the working group.

(2) Meeting agenda: it was stated that HMPWG publishes a public report at the conclusion of each meeting and all reports are furnished under the “*Key documents list*” section concerning the HMPWG of the HMA website. In accordance to its Rules of Procedure, the HMPWG is not required to circulate information to the public prior to the meeting.

Finally it was pointed out that HMPWG is not bound by the same legal requirements and related policies which govern the conduct of scientific committees, working parties and related groups within the European Medicines Agency (“EMA”). In fact, under the regime of the EMA, scientific committees and working parties are subject to transparency requirements which are provided under clearly defined legislative provisions.

HMA Procedures and Governance and the HMPWG Rules of Procedure are applicable to HMPWG and so the same level of transparency as in the EMA policy is not applicable. The HMPWG cannot exceed the scope of its mandate and in this regard, the publication of contact information concerning individual members of its working groups and indeed the advance publication of meeting agendas is not foreseen.

Invitations to Conferences on Homeopathy received by ECH European Congress for Homeopathy to be held in Vienna (17-19 November 2016) and the World Integrated Medicine Forum on the regulation of homeopathic medicinal products: National and Global Strategies organized in Delhi (23-24 February 2017) have been extensively discussed. All HMPWG members are invited to attend the Conferences.

An information letter from ECHAMP was presented, regarding a new resource providing accurate and reliable scientific information on the subject of homeopathy. The Homeopathy Research Institute website has published “*Frequently Asked Questions*” available in five languages (English, French, German, Italian or Spanish) providing accurate, reliable and up-to-date scientific answers to the most commonly asked questions about homeopathy. Translations have been provided by ECHAMP.

A draft guidance document referring to a specific procedure for the elaboration and the submission of documents to the HMPWG was presented for further discussion.

Legislation

The results of the *Survey on the regulatory status of Homeopathic Medicinal Products for Human Use in EU/EEA Countries* were presented with additional contributions from MSs.

Discussions took place on the possible outcome of this document for an HMA publication.

A further update of the development of the Minamata Convention was given for information by the representative of EMA. The Commission is currently working on a new Regulation, however the current

provision of Regulation (EC) 1102/2008 of the European Parliament and of the Council of 22 October 2008, excluding medicinal products from the export prohibition, shall be maintained also in the future.

Topics related to the published revised Notice to Applicants Vol. 2A – *Procedures for marketing authorisation, Chapter 1* - Revision July 2015 (3.3 on homeopathic medicinal products), on the Revision 1 of Notice to Applicants Vol. 2B *Presentation and content of the dossier-Part 1 Summary of the dossier Part 1A or Module 1: Administrative information Application form - Homeopathic Medicinal product for Human Use* and on the *Draft revision 2 – VOLUME 2C – Guidelines – Medicinal products for human use – Safety, environment and information – Excipients in the labeling and package leaflet of medicinal products for human use* are still in progress at the Notice to Applicants group level.

Marketing authorization and registration procedures

Discussions took place on the procedure to be applied for Homeopathic Medicinal Products containing recombinant DNA. The issue is under discussion at EMA level.

Homeopathic Use

The overview of the comments received during the public consultation on the *draft of the 4th list of stocks of justified homeopathic use* and the *4th list of stocks of justified homeopathic use* to be included in the *consolidated list* were presented and adopted for publication on the HMA-website. *The Draft 5th list of stocks of justified homeopathic use* was presented and adopted for public consultation on the HMA-website.

The evaluation of the most commonly used nosodes for homeopathic medicinal products was discussed, these are *Medorrhinum*, *Luesinum*, *Psorinum*, *Tuberculinum* and *Pyrogenium* and finally the approach to be used for Bibliographic References used for assessment for Homeopathic use of the stocks was shared.

First safe dilution

The Overview of the comments received on public consultation on the *draft 1st List of FSDs* and the *Preamble to the 1st list of FSDs* were presented.

The new entries in the list of FSDs of the *Draft 2nd list of FSDs* were presented. The new 2nd draft list will be published for public consultation on the HMA- website after a HMPWG commenting period and adoption by HMPWG.

The opportunity to revise the *Points to Consider on Non Clinical Safety of Homeopathic Medicinal Products of botanical, mineral and chemical origin*, in particular table 1 and 2, was discussed. This document and the proposal of *Drafting Guidance Documents on FSD calculation* will be further discussed at FSD sub-working group level, after gathering MSs opinions.

Swissmedic Session

Swissmedic representatives gave an extensive and clear explanation on *Regulation of complementary and herbal medicines in Switzerland* and on *Pharmacopoeia and complementary medicines in Switzerland*.

International Publication

The WHO Traditional Medicine Strategy 2014-2023 was presented for information.

Safety

Issues on safety regarding the draft *Guidance Document on Module 4* and the *Draft Preamble to Guidance Documents on Module 4* are still in progress. Some MSs offered to elaborate these documents as volunteers.

The FDA Press announcement on warning for homeopathic teething tablets and gels and the EMA's request on the EU market presence of Hyland's teething products were discussed.

An update to the *Contamination of herbal substances with pyrrolizidine alkaloids* was presented. This issue still remains under discussion for the next HMPWG meeting.

Quality

Italy was elected as chair of the Sub working Group on "*Quality*". The activities of the newly established Quality sub-working group were reported. In particular the outcome of the discussion at the sub working group related to Homeopathic medicinal products manufactured with a stock from nosodes was presented, included were *Medorrhinum*, *Pyrogenium*, *Psorinum*, *Luesinum*, *Tubercolinum*. It was proposed to elaborate a guidance document on assessment of nosodes, taking into account the assessments by different MSs, sharing different positions and opinions.

The Draft quality "*Questions & Answers document*" (1-3) have been adopted by HMPWG for public consultation on HMA website.

New Draft quality questions on "*Questions & Answers document*" (4-8) were presented for commenting.

The comments received after public consultation on HMA website on the Draft *Points to consider on the selection of the Ph. Eur. microbial limits for non-sterile homeopathic raw materials, stocks, preparations and products* were presented with a new draft document

Considering the comments received, it has been decided to re- discuss the outcomes on the comments in order to find a common shared position. The document will be further discussed before final adoption.

The preamble for quality documents has been discussed and agreed at the CMDvet meeting. The sentence on extension of application of quality documents to homeopathic medicinal products for veterinarian use will be added in the quality session on HMA-HMPWG website for clarification.

European Pharmacopoeia

An update of the work of HOM and HMM WP was given for general information and HMPWG members were informed of the EDQM training course on "*Homeopathic products*" (6 December 2016).

The Chair warmly thanked all participants for their attendance and active contributions.

Malta has announced that they will host the next HMPWG meeting to be held on 26th -27th June.