Homeopathic Medicinal Products Working Group (HMPWG) meeting during Maltese Presidency

AGENDA

Monday 26 June – Tuesday 27 June 2017
Kempinski San Lawrenz Resort Hotel, Gozo

PUBLIC REPORT

On 26th and 27th of June 2017, the 25th meeting of the Homeopathic Medicinal Product Working Group (HMPWG) was held in Gozo-Malta, under the Maltese European Union Council Presidency. The meeting was attended by various Member States as well as by the representative of EMA and EDQM. The meeting was formally opened by the Parliamentary Secretary for Consumer Protection and chaired by Biancamaria Bruno as Chair of the HMPWG. No conflicts of interest were declared.

The following issues were discussed:

Minutes
The Minutes of the 23rd HMPWG Meeting already adopted were submitted with slight modifications and adopted.
The Minutes of the 24th HMPWG Meeting were adopted too.
The List of Action of 24th HMPWG Meeting was also approved.

HMA - HMPWG
The Chair presented an overview of the key steps completed in the last three years by HMPWG and some new proposals to be developed in the next period.
The chairpersons of the Homeopathic use, First safety dilution and quality sub-working groups gave a short summary on the activities completed and what will be done in the future within each sub-working group.

The Chair informed the group about the conference of World Integrated Medicine Forum on the regulation of homeopathic medicinal products: National and Global Strategies, held in Delhi 23-24 February 2017.
The Annual Report 2016 from the European Coalition on Homeopathic & Anthroposophic Medicinal Products (ECHAMP) was also presented. In this document the issue regarding transparency and the consultation phase of documents with HMPWG is raised. The European Committee for Homeopathy (ECH) submitted, last December, a formal request to HMA regarding harmonization of the CTD for registration of homeopathic medicinal products. A reply has been already sent by the HMA-MG to the Association and HMPWG has been kept informed on updates on the issue.

HMPWG was informed regarding requests submitted by Companies for information on EU MRP for homeopathic medicines and on import of non-EU homeopathic products. In addition a request from the Association of the European Self-Medication Industry (AESGP) on the implementation of ICH Q3D to homeopathic medicines was addressed.

The Chair presented the new HMA Data Management System (HMA-DMS) across the network HMA facilitating sharing of documents for working groups at HMA level. The system will be accessible via the secure private electronic network “EudraNet”. It is based on Microsoft SharePoint, a user-friendly software that delivers an immediate common workspace for the network. The HMA-DMS serves as an archive and collaboration platform at the same time where documents can be edited and saved directly through familiar Microsoft Office software (Word, PowerPoint, Excel, OneNote). A highlight of the system is the collaboration mode, where multiple users can work on the same document at the same time paragraph-wise.

HMPWG has extensively discussed management of the new system by the group in order to upload and update documents.

Considering the requests submitted by Associations and Companies the guidance document referring to a specific procedure for submission of documents, already discussed and commented by HMPWG, has been presented and adopted.

A presentation on Homeopathic Veterinary Medicinal Products Registered in the Member States was given for information.

Legislation
An update on the development of the Minamata Convention on Mercury (“Convention”) was given by the representative of EMA’s Legal Department. The Convention was adopted by the United Nations in 2013 with the aim to protect human health and the environment from the adverse effects of mercury.

Differing views on the procedure to be applied for Homeopathic Medicinal Products containing recombinant DNA have been discussed.
Topics related to the published revised 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 were provided after collecting an update with EC. A new Application form, adopted by Notice to Applicants for homeopathic medicinal products, was released in December 2016. This document will replace the existing one on the HMA website.

European Pharmacopoeia
An update of the work of HOM and HMM WP was given for general information by the EDQM representative.

Quality
The Chairperson of the Sub working Group on “Quality” gave an overview of the activities completed, in progress and discussed during the sub-WG meeting. A draft guidance document related to the quality of nosodes as stocks was presented. This will be further discussed and elaborated by the HMPWG.
The Draft quality “Questions & Answers document” (1-3), and the “Compilation of comments on Questions & Answers document (1-3)” received by the Stakeholders during the consultation phase were also presented.

New versions of the documents will be released after further consultation amongst HMPWG members.

Comments collected by the HMPWG on the document “Questions & Answers document” (4-8) were presented. It will be released for public consultation following adoption by written procedure, by HMPWG, in the coming months.

A document, regarding 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, was presented. A new draft ‘Points to Consider’ document, comprehensive of the outcome of the discussion that took place during the Sub working Group on “Quality” meeting, was also presented. Both documents were adopted by HMPWG.

First safe dilution
The Chairperson of the FSD-Sub working Group presented the work carried out during the last months by the sub-WG.

In particular the Overview of the comments received on public consultation on the draft 2nd List of FSDs and the updated list were presented and adopted.

The new entries in the list of FSDs of the Draft 3rd list of FSDs were presented. The new 3rd draft list, adopted by HMPWG, will be published for public consultation on the HMA- website for the public commenting period.
Safety
In conjunction with FSD-sub WG, the opportunity to revise the Points to Consider on Non Clinical Safety of Homeopathic Medicinal Products of botanical, mineral and chemical origin, was discussed. In particular a proposal to draft a new Guidance Documents on Module 4, that will take into consideration the discussion of the FSD sub-working group meeting, was considered. The new document will be comprehensive of all aspects of safety and it will replace existing documents.

The outcome of the use of homeopathic medicinal products in pregnancy and lactation, distributed to the MSs was also presented.

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

Homeopathic Use
The Chairperson of the Homeopathic use sub working Group presented the work done by the members. The overview of the comments received during the public consultation on the draft of the 5th list of stocks of justified homeopathic use and the 5th list of stocks of justified homeopathic use have been adopted by the HMPWG. In addition, a new consolidated list, including the contents from the 4th list, will be released on the HMA-website.

A draft First list of stocks of justified homeopathic use for nosodes, considering the stocks Medorrhinum, Luesinum, Psorinum, Tuberculinum and Pyrogenium, was presented. A discussion, on homeopathic manufacturing methods, to be used for nosodes not described in an official Pharmacopoeia of a MS, took place. Considering the definition of homeopathic medicines in the Directive 2001/83/EC: it was decided that further discussion and investigation on approaches used by the MSs and their legal interpretation of the Directive, is needed, following on from clarification from the EMA on the issue.

The Chair warmly thanked all participants for their attendance and active contributions. Considering that the next Estonia European Union Council Presidency is not able to host the HMPWG meeting, it was announced that Sweden is willing to host HMPWG in the last semester of 2017.