

Dutch Presidency of the Council of European Union
January - June 2016

**23RD MEETING OF THE HOMEOPATHIC
MEDICINAL PRODUCTS WORKING GROUP
(HMPWG)**



**2016, 14TH -15TH April, UTRECHT, The Netherlands
PUBLIC REPORT**

On 14th and 15th of April 2016, the 23rd meeting of the Homeopathic Medicinal Product Working Group (HMPWG) was held in Utrecht, the Netherlands, under the Dutch Presidency of the Council of the European Union at the meeting venue of the Medicines Evaluation Board (NL).

The meeting was attended by various Member States as well as by the representative of EMA. The meeting was formally opened by the Deputy Director of the Medicines Evaluation Board (MED). The meeting was chaired, by Biancamaria Bruno as Chair of the HMPWG. No conflicts of interest were declared.

The following issues were discussed:

Minutes of the 22nd meeting in Utrecht

The Minutes of the 22nd HMPWG Meeting were adopted.

The List of Action of 22nd HMPWG Meeting was also approved.

HMA - HMPWG

The Chair presented new updates on the draft amendment to the rules of the HMPWG hosting country as agreed during the last HMPWG meeting. It was decided to update the existing HMPWG Rules of Procedures by taking into account new specific paragraphs referring to the activities of the Host country.

A first draft on a guidance document referring to a specific procedure for the elaboration and the submission of documents to the HMPWG was also discussed.

Legislation

An update was provided on the published revised Notice to Applicants Vol. 2A – *Procedures for marketing authorisation, Chapter 1* - Revision July 2015 (3.3 on homeopathic medicinal products).

The main issue discussed was the definition of the term "*administered orally and externally*" as a requirement for the simplified registration procedure according to Article 14 of Directive 2001/83/EC. Since there is no agreement on the interpretation of this definition amongst NCAs, a

interpretation of the term "*administered orally and externally*" will not be elaborated on in next update of Chapter 1.

HMPWG was informed 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*. These documents are still under discussion at the Notice to Applicants group level.

The *Survey on the regulatory status of Homeopathic Medicinal Products for Human Use in EU/EEA Countries as well as* the responses received from the EU countries were presented. A final version of the survey will be circulated after gathering additional contributions from MSs.

A regulatory clarification on the required publication of a list of withdrawn products under article 123(4) of Directive 2001/83/EC, as amended, was presented.

Homeopathic Use

The overview of the comments received during the public consultation on the *Preamble to the consolidated list of stocks with a justified Homeopathic Use* and on the *draft of the 4th list of stocks of justified homeopathic use* were presented. A *consolidated list of stocks with a justified Homeopathic Use*, to include all previously released lists, will replace the current list on HMA- website after its adoption by HMPWG.

First safe dilution

The draft *1st List of FSDs* and the *Preamble to the 1st list of FSDs* were presented. These documents will be published on the HMA- website for public consultation after adoption by HMPWG.

The *Points to Consider on Non Clinical Safety of Homeopathic Medicinal Products of botanical, mineral and chemical origin* will also be discussed at FSD sub-working group for revision.

Safety

The comments raised by MSs on the draft *Guidance Document on Module 4* and *Guidance Documents on FSD calculation* were discussed.

The *Guidance Document on Module 4* will be updated to include a preamble at the next meeting. Meanwhile the *guidance on FSD calculation* will be discussed at the FSD- sub working group and included as part of the revision of the *Points to Consider on non clinical safety of Homeopathic Medicinal Products of botanical, mineral and chemical origin*.

The issue related to the *Contamination of herbal substances with pyrrolizidine alkaloids* was presented for discussion. Updates on this issue will be given at the next HMPWG meeting.

Quality

The activities of the newly established Quality sub-working group were reported. The Quality-sub working group will try to launch a work-sharing procedure on draft assessment of nosodes, as requested by HMPWG.

A draft Q&A document on quality issues was presented to the group with the aim to provide guidance for both the applicant and the assessors. This document will be circulated amongst HMPWG members in order to collect comments to be discussed at the next HMPWG meeting.

The comments received 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 discussed and the document was adopted by HMPWG. This document will be posted on HMA-website for public consultation.

A further update of the development of the Minamata Convention was given for information by the representative of EMA.

A preamble for quality documents was proposed for discussion at the CMDv in order to extend the application of quality documents to homeopathic medicinal products for veterinarian use.

European Pharmacopoeia

An update of the work of HOM and HMM WP was given for general information.

Viral Safety

The final *Points to Consider on Safety of Homeopathic Medicinal Products from Biological origin*, agreed by the Biological Working Party (BWP) at EMA was presented and adopted by HMPWG.

Other topics

The HMA- Data Management system was presented to the group. The HMPWG acting as volunteer will test it during the starting point of its Pilot phase II.

The Chair warmly thanked all participants for their attendance and active contributions. Switzerland has offered to host the next HMPWG meeting to be held on 10th-11th November 2016.