On 28th and 29th of May 2015, the 21st meeting of the Homeopathic Medicinal Product Working Group (HMPWG) was held in Strasbourg. The meeting was attended by various Member States as well as by the representatives of EMA, and of the European Commission. The meeting was formally opened by the Director of the European Directorate for the Quality of Medicines & Healthcare (EDQM). The meeting was chaired, by Biancamaria Bruno as Chair of the HMPWG. No conflicts of interest were declared.

The following issues were discussed:

**HMA -HMPWG**
The Chair presented some updates from the HMA regarding the HMPWG: templates, new rules for the publication of documents on the HMA website, as well as the development of an Intranet Area and Data Management System (DMS). The findings of a comparative study of the current HMPWG Rules of Procedure with other WGs were presented.

It was proposed to establish a Permanent Secretariat of the HMPWG: its composition, main tasks, and activities were outlined.

Furthermore, it was decided to draft a procedure on the elaboration of documents of the HMPWG.

**Minutes of the 19th meeting in Paris/ Minutes of the 20th meeting in Rome**
The Minutes of the 19th HMPWG and of the 20th HMPWG Meeting were both adopted.

The List of Action of 20th HMPWG Meeting were also approved.

**Homeopathic Use**
Belgium was elected as rapporteur of the Sub working Group Homeopathic Use of the HMPWG.

In order to harmonize the Rules of Procedure of the SWGs within the HMPWG (Homeopathic Sub working Group for the Quality and Sub working Group Homeopathic Use) it was envisaged to introduce an amendment to the Mandate of the Sub working Group Homeopathic Use with regard to the heading “IV RULES OF PROCEDURE”.

The third list of stocks of justified homeopathic use was adopted and it will be officially published on the HMA web site. With regard to the 4th list of stocks of justified homeopathic use, it was decided to postpone this to the next sub working group Homeopathic Use meeting.

The proposal of a link between the list of stocks with a justified homeopathic use and the “Titles used in Homeopathy” was postponed to the next meeting and a presentation on the nosodes was provided, taking into account the definition, the regulatory approach in Germany and their requirements for raw materials.
**First safe dilution, FSD**
The minutes of the fourth meeting of the FSD sub working group of the HMPWG on 27th April via teleconference were presented. The Overview of comments received on the questions 1 – 5 was adopted and will be published on the HMA web site. The Overview of Comments Question 6 and the Questions and Answers 1-6 will be subject to adoption by written procedure.

Following the discussion held in Rome, the FSDs assessments of Chimaphila umbellata, Atropa belladonna 2a, Rh, Atropinum sulfuricum were adopted. Some further examples of FSD assessments were also provided. These are to be discussed in the next meeting of the FSD Sub working Group after collecting proposals from the Member States.

**Safety/ FSD**
Draft concept papers on Hexavalent chromium and on Chelidonium majus were presented. All Member states are requested to send their own comments.

A number of new questions for the FSD Questions and Answers document were proposed. The drafting of guidance documents on Module 4 and FSD calculation were proposed for discussion in the next meeting.

**Pharmacopoeia**
Some information was given on the role of the Ph. Eur. in the European regulatory landscape: General concepts in the Ph. Eur. for homoeopathic products, Chapters, Specific Monographs, Reference Standards, as well as a focus on elemental impurities. An update on the outcomes of the last Commission session completed the presentation.

**Legislation**
The contents of an official letter to the European Commission regarding the Interpretation of “homeopathic medicinal products administered orally or externally”, as it was discussed in Rome, were agreed.

The document is going to be handed over directly to the European Commission.

An update on the impact of the Directive 2011/62/EC and its potential application on homeopathic medicinal products was provided.

Some clarifications were provided on the Notice to applicants 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 topic CMD Renewals: best practice and the CMDh Best Practice Guide On The Processing Of Renewals In The Mutual Recognition And Decentralised Procedures

Moreover, the necessity of sharing of statistical data on HMP by the Member States was highlighted.

**Quality**
Draft mandate, objectives and rules of procedure, along with a work programme of the established Sub working Group on Quality was discussed. Two updates were provided: Draft points to consider on the selection of the Ph. Eur. microbial limits for non-sterile homeopathic raw materials, stocks, preparations and products and the applicability to Homeopathic Medicinal Products of the Minamata Convention on Mercury. The level of information required on each supplier of raw materials in Module 3 was discussed with specific regard to cases of multiple suppliers.
Viral Safety
The Points to Consider on Safety of Homeopathic Medicinal Products from Biological origin was updated and adopted by the HMPWG.

Other Topics
A short presentation on the topic “Classification of homeopathic stocks and homeopathic dilutions in accordance with the ISO 11238 Substance standard and ISO 19844 Substance Implementation Guide – a proposal for a Technical Annex E” was provided. All Members States are invited to refer any comments to the national ISO-Contact points.

The Chair warmly thanked all participants for their attendance and active contributions. The Netherlands will host the next HMPWG meeting on 11th-12th November.