## REPORT

**Adopted by written procedure in accordance with articles 4 and 8 of the HMPWG Rules of Procedure**

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<th>Event</th>
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<td>30 July 2013</td>
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<tr>
<td>Transmission to HMA for publication on the HMA website</td>
<td>31 July 2013</td>
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On 30th and 31st of May, the 17th meeting of the Homeopathic Medicinal Product Working Group (HMPWG) was held in Dublin. The meeting was attended by representatives from various Members States (21 countries in total) as well as those from the EMA and the EDQM. The meeting was formally opened by Mrs Ann O’Connor Director of Human Products Authorisation & Registration, at the Irish Medicines Board. The HMPWG Chair warmly thanked the Irish team on behalf of the HMPWG for hosting the HMPWG. The Vice-Presidency was ensured by Dr. Gwen Glasgow, the Homeopathic Medicines Coordinator of the Human Products Authorisation and Registration Department of the Irish Medicines Board. No conflicts of interest were declared.

The following issues were discussed:

- Minutes and List of actions of the 16th meeting in Gdansk October 2012.

The minutes were adopted. The implementation of the actions as decided at the 16th meeting was presented:

- The updated Rules of Procedure document was forwarded to the HMA with a letter from the HMPWG providing information on the changes to the document and highlighting the lack of resources of the HMPWG. The HMPWG did not receive a response from the HMA. The Rules of Procedure were adopted by the HMA.
- The first public report of the HMPWG has been published on the website.
- The first List of justified homeopathic stocks has been published on the website for public consultation.
- The collaboration between the HMPWG and the CMDv has been intensified.
- The HMPWG consulted the European Commission on the Braille labelling requirements with respect to homeopathic medicinal products.
- The Document “List of terms used in Homeopathy” adopted by the HMPWG and commented on by the CMDv was published on the HMA website for public consultation.
- The assessment reports of Rheum and Matricaria recutita were published on the HMA website for public consultation.
- The HMPWG met the request of the EDQM members with regard to the Guide for the elaboration of monographs on homeopathic preparations.

- HMPWG documents

Management of documents

Basic internal and external rules of the management of HMPWG documents were reiterated.

Regarding the external rules, delegates were reminded in particular that before the Public consultation on the website, HMPWG documents are confidential, that the HMPWG documents are published according to the HMA-MG-PS Best Practice Guide, that consequently, the date of submission of the HMPWG documents to the HMA was not the date of publication and that commenting periods in the case of a public consultation should be 3 months from publication on the website.
Transparency

Improvement in transparency within the HMPWG and with the stakeholders has been discussed. Regarding the transparency with the stakeholders, it has been decided to draft a HMPWG template for 'submission of comments', a HMPWG template for 'overview of comments' for comments received and to publish on the HMA website the overview of comments.

- Homeopathic Use
The Chair of the Homeopathic Use subgroup gave an overview of the work performed. The first list of stocks whose homeopathic use is justified was adopted. A written procedure was decided for “the answer to the stakeholders on the comments received on the first list” (document already approved by several participants in the sub working group) and a new version of the preamble of the first list, taking into account, in particular, comments submitted during the HMPWG meeting. A written procedure was also decided regarding the second list of stocks whose homeopathic use is justified.

-Spagyry
A presentation of the therapy and of the products was made by Germany.

-First Safe Dilution
The Chair of the FSD subgroup made an overview of the work performed. The Mandate, the work programme and the Minutes of the meeting of the subworking group were adopted. The overview of comments on the first public consultation and the establishment of Questions and Answers are in progress. The Assessment Report on FSD of Natrium salts drafted by Belgium was adopted for public consultation with a commenting period of 3 months.

- Legislation

Paediatric regulation
Two presentations were made on the Regulation (EC) No 1901/2006 on medicinal products for paediatric use that concluded that this regulation does not apply to homeopathic medicinal products registered under article 14 of the Directive 2001/83/EC. However the question should need a further clarification for homeopathic medicinal products subject to article 16 of the Directive 2001/83/EC.

Braille requirements
The European Commission responded to the request of the HMPWG on this issue. The European Commission stated that the Braille labelling requirements apply in the case of a homeopathic medicinal product submitted for a possible Mutual recognition procedure or a Decentralised Procedure.

Excipients in the label and package leaflet of homeopathic medicinal products
The Homeopathic medicinal products subject to article 14 of Directive 2001/83/EC are not addressed in the Guidelines on “Excipients in the label and package leaflet of medicinal products for human use. However, it was highlighted that the warning statements relating to the presence of certain excipients should be mentioned on the label and if appropriate on the package leaflet of homeopathic medicinal products.

Commission Regulation (EC) No 1234/2008 concerning the examination of variations in the terms of marketing authorisation
The second recital of the regulation excludes from its scope the homeopathic medicinal products authorised on the basis of the simplified registration procedure . The views were expressed that in order to keep the documents (dossier and SmPC post approval) harmonized between the member states the Variation Regulation could still be applied by analogy, in case of MRP/DCP. In addition, the application of MRP/DCP in the field of the homeopathic medicinal products will be put on the next agenda of the HMPWG.
Proving / Clinical trials / Homeopathic Medicinal products
Directive 2001/20/EC
The European Commission had received a question on the 13/04/2012 that pertained to the problems raised by the clinical trials of homeopathic medicinal products, due to the fact that clinical testing standards did not take into account the specificities of homeopathic medicinal products. The European Commission answered on the 07/06/2012 that it did not envisage introducing specific requirements to European rules on clinical trials for homeopathic medicinal products. Homeopathic developments and new remedies are under consideration in Europe. The feasibility of performing clinical trials or provings on homeopathic medicinal products according to the Directive 2001/20/EC and to the principles of Homeopathy will be considered by the HMPWG at future meetings.

-Viral safety
The update of the document “Point to consider on Safety of Homeopathic Medicinal Products from Biological origin” was deferred.

- EDQM
A detailed presentation was made by Dr.J.M.Morris, Chair of the two working Groups on Homeopathic Medicinal Products of the EDQM and Chief Scientific Officer at the Irish Agency, on the establishment and role of the Ph.Eur., in the control of Homeopathic medicines, on Homeopathic Manufacturing Methods and on the work of the Homeopathy Working Parties.

The HMPWG was informed, by the EDQM representative, that the Guide for the Elaboration of monographs on homeopathic preparations had been approved by the Ph.Eur Commision at its June 2012 session and that this Guide included a new approach for setting the titles of monographs. The new monographs under development and the status of texts coming back from the public enquiry were also mentioned.

-Veterinary Homeopathic Medicinal Products
An overview of the regulation of veterinary Homeopathic Medicinal Products was made by the veterinarian representative of the HMPWG.

- Homeopathic Medicinal Products and Veterinary Homeopathic Medicinal Products in Ireland
A detailed presentation of the situation in Ireland in relation to both Human and Veterinary homeopathic medicines was made.

- The next meeting
Following a discussion and decision by the HMA, Germany announced its intention to host the next meeting on 21st and 22nd of November 2013.

The HMPWG thanked Ireland for the excellent organisation of the meeting and Germany for accepting to host the next meeting.