12 December 2014
Revision to PUBLIC REPORT
19\textsuperscript{th} meeting of the Homeopathic Medicinal Product Working Group - 5-6 June, PARIS, FRANCE

The Public Report contains the following replacement
- on page 2 Legislation is amended as follows:

\begin{quote}
The requirement “administered orally or externally” mentioned in article 14 of Directive 2001/83/EC was discussed and the group decided that further analysis was necessary
\end{quote}
On 5\textsuperscript{th} and 6\textsuperscript{th} of June, the meeting of the Homeopathic Medicinal Product Working Group (HMPWG) was held in Paris. The meeting was attended by various Member States and the representative of the European Commission, the representative of EMA and the representative of EDQM. The meeting was formally opened by Jean-Claude Ghislain Deputy Director of the Division for Strategy and international Affairs of the French National Agency for the Safety of Medicines and Health Products (ANSM). The meeting was chaired by Laurence Girod from France and Christos Potsides from Greece, No conflicts of interest were declared.

The following issues were discussed:

- **Election of the Chairperson of the HMPWG**
  Due to the absence of candidature for the position of chairperson of the HMPWG, this election did not take place.

- **Election of the Chairperson of the HMPWG subworking group “Homeopathic Use”**
  Due to the absence of candidature for the position of chairperson of the HMPWG subworking group “Homeopathic Use”, this election did not take place.

- **Minutes of the 18\textsuperscript{th} meeting in Bonn**
  The minutes were adopted. The implementation of the actions, as decided by the 18\textsuperscript{th} meeting, were presented.

- **Homeopathic Use**

**List of stocks**
The third list of stocks whose homeopathic use is justified was adopted for publication for public consultation.

**Application of the lists to Homeopathic Veterinary medicinal products**
The veterinarian representative of the HMPWG has collaborated with the CMDv and it has been decided by the HMPWG and the CMDv that the following statement would clarify the application of the list to homeopathic veterinary medicinal products *"Bibliographic references on veterinary homeopathic use have not been included in the preparation of this list; the decision on the use of this list for the justification of the veterinary homeopathic nature of a stock shall be taken by the concerned member states on a case by case basis"*. 
Stocks from animal origin subject to heat treatment
The rapporteur made an overview of the work of the subgroup and of the results of a survey on this issue. The manufacturing process of homeopathic medicinal products from animal origin differs from that in former times, when these stocks were described in the Materiae Medicae, as nowadays heat sterilization is required in some cases. The heat process may have as a consequence a denaturation of the proteins. This may result in a different product which cannot be compared with the original stock. Consequently, in the case of heat treatment the consistency between the module 3 and the module 5 of an application of registration or marketing authorization should be clarified.

- Legislation

- The requirement “administered orally or externally” mentioned in article 14 of Directive 2001/83/EC was discussed and the group decided that further analysis was necessary.

- The EC regulation 1901/2006 on medicinal products for paediatric use and homeopathic medicinal products registered under article 16 of the Directive 2001/83 EC has been clarified by the European Commission representative. These Homeopathic Medicinal Products are exempt from Paediatric investigation plans but are subject to paediatric studies mentioned in article 45 and 46.

- First safe dilution

The chair of the FSD subgroup gave an overview of the work performed. The minutes of the FSD subworking group meeting were adopted. The Question and Answer N°6 (related to the safety factor of 100 introduced when the lowest human recommended dose is used for establishing the FSD) and the overview of comments received from public consultation of FSDs were adopted for public publication on the HMA website. Moreover the Revision of assessments of First Safe Dilutions- Chimaphila umbellate, Atropa belladonna 2a, RH, Atropinum sulfuricum- were adopted for a second public consultation on the HMA website.

-Quality assessment

The different quality requirements for fresh and dried plants and assessment of an excipient with no traditional use in homeopathic medicines were discussed.

- List of terms used in Homeopathy

The document “List of terms used in Homeopathy” was adopted for final publication on the HMA website.

- Viral safety

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

- HMA website

An improvement about the access to the different divisions of the agencies involved in the HMPWG was proposed.

The vice chairpersons warmly thanked all participants for their attendance and contributions; Italy informed the group that the next HMPWG meeting will take place in Rome 4-5th of December 2014.