On 4th and 5th of December 2014, the 20th meeting of the Homeopathic Medicinal Product Working Group (HMPWG) was held in Rome. The meeting was attended by various Member States as well as by the representative of EMA. The meeting was formally opened by the Head of the Registration and Evaluation Office of the Italian Medicines Agency (AIFA). The meeting was chaired, by Biancamaria Bruno (ITALY). No conflicts of interest were declared.

Biancamaria Bruno was elected as Chair of the HMPWG according to the Rules of Procedure of the Working Group.

The following issues were discussed:

**Election of the Chairperson of the HMPWG sub working group “Homeopathic Use”**
No candidature was presented. An update will be given in short time.

**HMA Meeting**
The Chair summarized the outcome of a Teleconference with the Management Group of the HMA, which took place last October and, aimed at discussing open issues common to other WGs within the HMA. It was pointed out, among others, the need to have a location and a permanent Secretariat on an established basis. A review of the current Rules of Procedure of the HMPWG was suggested taking into account in comparative perspective the Rules of Procedures of other WGs.

**Minutes of the 19th meeting in Paris**
The comments were discussed but a post meeting comment raised by Italy led to a re discussion. The minutes were not adopted and consequently will be redrawn for final adoption.

**Homeopathic Use**
The second list of stocks for which homeopathic use is justified was adopted. The proposal of a link between the list of stocks with a justified homeopathic use and the “Titles used in Homeopathy” published in Pharmeuropa 16.4 was discussed. Moreover a full account of the issue related to Homeopathic medicinal products manufactured with a stock from animal origin was presented including the following: Outcome of the questionnaire- Impact of heat treatments (pasteurisation or steam sterilisation) on the stocks.

**First safe dilution**
It was discussed the problem related to the resources available to establish FSDs. It was proposed to improve the existing process, with a modified and condensed procedure so that each Member State can contribute with its experience including the integration of existing data. The table template concerning the FSDs list was presented.
Public consultation of the questions 1 – 6 and the second public consultation of assessments of First Safe Dilutions Chimaphila umbellata, Atropa belladonna 2a, Rh, Atropinum sulfuricum: the overview of comments received from the stakeholders, all have to be discussed in the sub working group and the outcome will be presented at the next HMPWG meeting.

Public consultation of sodium salts and FSDs: it was decided to discuss the comments received from the stakeholders by written procedure.

Overview of comments on the draft standard procedure for deriving FSDs and drafting ARs: a revised draft procedure will be elaborated according to the proposal on the work related to the WG.

**Pharmacovigilance**

“The Italian Surveillance System of Suspected Adverse Reactions to Natural Products: Homeopathic Medicinal Products reports” and “Experience on Adverse Reactions to Excipients used in Homeopathic Medicinal Products” were presented.

**Legislation**

Interpretation of “homeopathic medicinal products administered orally or externally” by the request of the European Commission

Background:
The European Commission sent a letter to the Homeopathic Medicinal Products Working Group (HMPWG) requiring a proposal for the definition of the term “administered orally or externally” to be included in the “Notice to Applicants”.

This issue was discussed during the meeting of the HMPWG held in Paris, and due to a post meeting comment raised by Italy was re-discussed. However, on this specific issue no consensus was reached.

After a previous enquiry among the MSs about the application of the simplified registration procedure (Article 14 of the Directive 2001/83/EC) to routes of administration other than oral use, ointment or cream three different proposals were put forward:

Considering the interpretation of the term “administered orally or externally” by excluding all the route of administrations but cutaneous use (I), or delete any reference to the routes of administrations in the Notice to Applicants (II) or whether the requirement “administrated orally or externally” mentioned in article 14 in the Directive 2001/83/EC, where appropriate could include routes of administrations other than cutaneous use such as “nasal, rectal, vaginal, ocular or auricular use” on a case by case basis provided that the safety of the application is ensured. Injectables are excluded -(III).

All MSs were requested to express their point of view and cast their vote on one of the proposals.

A new letter to European Commission will be drafted taking into account all the different positions expressed by the MSs.

The possible impact of the Directive 2011/62/EC on homeopathic medicinal products was explained. Additional information regarding a possible application of the Directive on the Homeopathic Medicinal Products will be provided by the EMA.

The Italian representative explained the issue concerning Homeopathic Medicinal Products sold on the web.
Safety
A discussion on Safety case studies related to Chelidonium and Chrome took place and thus it was suggested that Chelidonium and Chrome would be the pilot assessments in the proposed new format for FSD assessments in collaboration with FSD sub working group.

The Global Ingredient Archival System (GInAS) was illustrated, this concerns the set of classifications regarding active ingredients. Information on its application to homeopathic products will be provided.
The need of guidance document for the labeling requirements according to article 69 of the Directive 2001/83/EC was raised.

Quality
The proposal to establish a Quality Homeopathic Sub working Group in order to deal with Quality issues raised during the quality assessment of homeopathic products was approved.

The application of the Ph. Eur. microbial limits to non-sterile homeopathic preparations/products/raw materials and stocks was discussed. At the discussion a representative of the EDQM took part via Teleconference. On this matter it was decided to elaborate a “Point to Consider” document with the aim of collecting proposals before the next HMPWG meeting.

The impact of the Minimata Convention on Mercury on Homeopathic Medicines will be postponed to the next meeting.

European Pharmacopoeia
An update was provided.

Viral Safety
The Points to Consider on Safety of Homeopathic Medicinal Products from Biological origin was updated. Comments received from MSs were discussed during the meeting. A new short deadline for comments was set.
In case of minor comments, the new draft document will be released for public consultation on the HMA-HMPWG website.

Homeopathic veterinary medicinal products
The Representative of the Italian Ministry of Health presented the situation of Homeopathic Veterinary Medicinal Products in Italy

The Chair warmly thanked all participants for their attendance and active contributions.
The Chair informed the group that the next HMPWG meeting, will be kindly hosted by the EDQM.