On 21st and 22nd of November, the meeting of the Homeopathic Medicinal Product Working Group (HMPWG) was held in Bonn. The meeting was attended by various Member States and the representative of the Heads of Medicines Agencies Management Group Professor Thomas Heberer. The meeting was formally opened by Mr Karl Broich, Vice President of BfArM at the German Medicines Board. The HMPWG chair warmly thanked the German team on behalf of the HMPWG for hosting the HMPWG and Professor Thomas Heberer for his presence. The Vice-Presidency was ensured by Professor Werner Knöss, Head of Department Complementary and Alternative Medicines and Traditional Medicines of the German Medicines Board. No conflicts of interest were declared.

The following issues were discussed:

**Outcomes of the hearing**

A hearing was organised with the following associations: AESGP (The Association of the European Self-Medication Industry), ECCH (European Central Council of Homeopaths), ECH (Committee for Homeopathy), ECHAMP (European Coalition on Homeopathic and Anthroposophic Medicinal Products), EFHPA (European Federation of Homeopathic Patients’ Association), ESCAMP (European Scientific Cooperative on Anthroposophic Medicinal Products), IAAP (International Association of Anthroposophic Pharmacists Goetheanum Medical Section), IAVH (International Association of Veterinary Homeopathy), IVAA (International Federation of Anthroposophical Medical Associations).

The hearing was very fruitful and was an excellent opportunity to improve the communication between the HMPWG and the stakeholders.

The main concerns raised by the associations were:
- The lack of availability of Homeopathic Medicinal Products in Europe and the policy of ‘no substitution’ between homeopathic medicinal products. Physicians and patients need all the remedies in all potencies and also the so called "small remedies" which do not interest industry, due to low market potential.
- The unattractive mutual recognition and decentralised procedures due to divergent implementation, interpretation and enforcement policy of these procedures in the Member States. Need of a best practice guide related to MRP/DCP for homeopathic medicinal products.
- The lack of transparency of the HMA website (no list of HMPWG members, no intermediate versions of documents …)
- The lack of consideration by the HMPWG of homeopathic medicinal products subject to article 16 of the Directive 2001/83/EC, as amended.
- The need of a new regulatory body for the HMPWG.

**Minutes of the 17th meeting in Dublin**

The minutes were adopted. The implementation of the actions, as decided by the 17th meeting, were presented.
- Expectations from the HMA Management Group about the HMPWG

The HMPWG had the great honour to welcome Professor Thomas Heberer, representative of the HMA Management Group and the current mentor of the HMPWG. Professor Thomas Heberer made a presentation on the HMA Management Group’s expectations regarding collaboration on Homeopathic Medicinal Products issues in Europe. He highlighted the fact that the HMPWG’s mandate was interdisciplinary pertaining to both “human and veterinary use” and that henceforth, it should be made clear in HMPWG documents whether it is intended to use the documents for human use, veterinary use or for both. Professor Thomas Heberer added that the CMDv should officially comment on documents of veterinary interest prepared by the HMPWG, before the public commenting phase. The CMDh should be informed about the publication of relevant documents. The conclusion was that, in addition to what is laid down in the Rules of Procedure, the HMPWG was invited to present information and to address issues of interest at the annual meetings of the HMA and to present expectations to the HMA.

- HMPWG expectations

The HMPWG chair addressed the expectations of the HMPWG to Professor Thomas Heberer, in particular:
- Better recognition of the HMPWG by the HMA and by the other working groups of the HMA.
- To raise awareness in the HMA of all MS with regard to the HMPWG.
- Better support by the HMA for the organization of the meetings and to HMPWG participants.
- Improvement of publication of documents on the HMA HMPWG website.

- HMPWG priorities

The HMPWG established its priorities for 2014 on the items of Homeopathic Use, First Safe Dilution, Viral Safety, Harmonization of terms used in Homeopathy, Facilitation of the mutual recognition procedure and decentralised procedure in order to improve availability of products in the European Union.

- HMPWG organization

Documents for public consultation
The templates for submission of comments and the template for overview of comments have been adopted by written procedure and are now published on the HMA website. Consequently, these two templates are now to be used systematically by the stakeholders commenting on HMPWG documents and by the rapporteur of the HMPWG in drafting an overview of the comments.

- Homeopathic Use

List of stocks
The chair of the Homeopathic Use subgroup gave an overview of the work performed. The second list of stocks whose homeopathic use is justified, a new version of the preamble and the answer to the stakeholders after the public consultation of the first list were adopted by written procedure. Consequently the second list of stocks whose homeopathic use is justified is currently published for public consultation. A third list will be proposed and discussed.
Specific requirements for homeopathic veterinary medicinal products
A presentation was made, comparing the requirements set out in article 18 of the Directive 2001/82/EC, relating to homeopathic veterinary medicinal products, to the requirements set out in article 15 of the Directive 2004/27/EC relating to homeopathic medicinal products for human use.

Mandate of the Homeopathic Use subgroup
The mandate was adopted for publication on the website.

Besides, the Homeopathic Use Subgroup will examine the specificities of the assessment of the homeopathic use of products manufactured with a stock from animal origin and the feasibility of performing provings on homeopathic medicinal products in accordance with the Clinical trials Directive 2001/20/EC.

- **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 1-5 Document was adopted for public publication on the HMA website.

- **List of terms used in Homeopathy**

The rapporteur presented the detailed overview of the comments from the stakeholders. The overview was intensively discussed. A new version of the document will be established.

- **Viral safety**

The update of the document “Point to consider on Safety of Homeopathic Medicinal Products from Biological origin” was deferred because the rapporteur could not attend the meeting.

- **Legislation**

**Paediatric regulation**

The possible application of the EC regulation 1901/2006 on medicinal products to homeopathic medicinal products registered under article 16 of the Directive 2001/83 EC should be thoroughly examined.

**Survey on the excipients in the label and package leaflet of homeopathic medicinal product**

An overview was made on the outcome of the survey. The presence of certain excipients are mentioned on the label and where appropriate on the package leaflet of homeopathic medicinal products in most of the Member States.

**Mutual recognition procedure and Decentralized procedure**

A presentation highlighting the different interpretations on the European level of the mandatory character of the mutual recognition procedure and Decentralized procedure was made.

- **Quality assessment on microbial quality of stocks**

A presentation was made on the application of the Ph.Eur. microbial limits to homeopathic preparations, products and stocks.

The presence of Prof. Heberer was highly appreciated by HMPWG members. The chair thanked all participants for their attendance and contributions and expressed her gratitude on behalf of the HMPWG to Germany for inviting the HMPWG and the interested parties, for the warm welcome and the excellent organization of the hearing and of the meeting.