



To: The Heads of Medicinal Agencies

November 30, 2004

Re: Homeopathic Medicinal Products Working Group (HMPWG)

## **Executive Summary.**

The Heads of Agencies are invited to endorse the continuation and consolidation of the activities of the HoA Working Group for Homeopathic Medicinal Products. Therefore a proposal for the mandate of this Group has been drafted.

It is proposed that the activities of the WG be supportive of the Mutual Recognition Coordination Group and be coordinated by the Heads of Medicines Agencies (HMA). The establishment of a permanent HoA Working Group of experts for Homeopathic Medicinal Products is proposed in order to harmonise the assessment of homeopathic products and create a network of assessors to facilitate cooperation in National and Mutual Recognition Procedures. The Heads of Agencies are invited to endorse the proposed mandate and operating procedures of the WG.

## **Introduction.**

EU legislation governing homeopathic medicinal products for human use has been in place since 1992 with the publication of Council Directive 92/73/EC. To support the implementation of this Directive and subsequent EU legislation an informal Competent Authorities (CA) group was formed in 1999. This group of experts from national competent authorities has acted under the auspices of the Heads of Agencies since the year 2000 and rules of procedures have been implemented under Portuguese and Swedish Presidencies. The Group is composed of one or two representatives from each Member State as well as representatives of the European Commission and the European Pharmacopoeia (EDQM). This Group meets biannually, in a Member State on a post presidency basis.

The Group has been concerned primarily with national procedures relating to homeopathic medicinal products, seeking to harmonise the approach of the Member States in their assessment of homeopathic medicinal products.

With the finalisation and implementation of the review of the EU pharmaceutical legislation, the need to find a harmonised approach to the interpretation of the legislation on homeopathic medicinal products has increased significantly. A registration procedure according to Article 14 of Council Directive 2001/83/EC, as amended by Directive 2004/27/EC, will be mandatory in all Member States by October 2005. Homeopathic medicinal products registered according to Article 14 of Directive 2004/27/EC will have access to mutual recognition procedures. There will be the option for an extension of the simplified registration scheme for homeopathic medicinal products to categories of homeopathic products that are currently excluded, (e.g. concentrations higher than  $10^{-4}$ ), using the Comitology procedure.

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#### **Achievements of the informal Group 1999-2004.**

The current Group has worked very effectively since its inception and has developed proposals for guidance documents as listed. These guidance documents deal with issues specific to homeopathic medicinal products, which are not adequately covered by existing EU Notice to Applicants and other EU regulatory documents:

- Good Practice for Meetings document /Rules of Procedures– under the presidency of Portugal and Sweden – 2000-2001
- General Quality aspects related to homeopathic medicinal products in co-operation with EDQM - 2000
- Points to Consider on the Safety of Homeopathic Medicinal Products for human and veterinary use from biological origin – 2002
- Draft Common Technical Document for homeopathic medicinal products (Modules 1, 2 and 3) – 2003-2004

In addition consultation has started on the following:

- EU List of “Safe Dilutions for homeopathic medicinal products.”
- Proposition for a Decision Tree for the safety assessment of non-biological homeopathic products and a criteria table of safe dilutions
- Proposal for a GMP annex for the manufacturing of homeopathic medicinal products was also discussed during some CA's meetings.

#### **Limitation of current informal status of the CA's group for homeopathic medicinal products.**

After 5 years of cooperation there is a need to describe the mandate and activities of the group for homeopathic medicinal products. Furthermore it is important to be transparent on the status and activities of this group.

Such a mechanism is essential in order to support the harmonised implementation of the new provisions of the amended Directive 2001/83/EC with respect to homeopathic medicinal products by the Member States. Indeed, transparency and a harmonised interpretation of the legislation is specifically needed for homeopathic medicinal products, because of variations in national experiences and traditions in Member States are much greater than for most other medicinal products. Consistency of standards, assessments and good quality decision-making across the EU are in the interest of public health and a prerequisite for implementation of the legislation.

For publication of Guidelines and other information the Heads of Agencies website is most appropriate.

#### **Proposal.**

In order to facilitate harmonisation in the assessment of homeopathic products and cooperation in National and Mutual Recognition Procedures the establishment of a permanent HoA Working Group of experts for Homeopathic Medicinal Products is proposed.

#### **Support and Resources.**

The WG is currently supported by the national competent authorities, by the contribution of national experts. It is proposed that this continue. Organisational support is sought from the Secretariat of the Heads of Medicines Agencies (HMA). Competent authorities are expected to organise a meeting of the WG, during the respective countries EU presidency.

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## **Operation of proposed WG.**

### Meetings.

The WG will hold two regular meetings per year. One during each presidency hosted by the presidency of the day. Additional meetings may be agreed with the HMA MG. The Working Group may decide to hold drafting group meetings among some members in order to prepare documents.

### Participants.

Each Member State as well as the EU Commission, the EMEA, EDQM and the EEA countries may nominate one representative to attend

### **Mandate:**

1. To create a forum for exchange of regulatory and scientific expertise regarding the assessment of the quality and safety of homeopathic medicinal products in the Member States;
2. On request from Competent Authorities, to provide guidance on the assessment of homeopathic medicinal products;
3. To provide guidance for applicants on the registration of homeopathic medicinal products;
4. To establish one common dossier template for applications for the registration (Art 14 of CD 2001/83/EC) of homeopathic medicinal products in the EU, in co-operation with the Notice to Applicants Group;
5. To provide advice and expertise, on request of the Coordination Group on procedural, regulatory and scientific issues arising from the mutual recognition and decentralised procedures applicable to homeopathic medicinal products;
6. To facilitate the resolution of procedural, regulatory and scientific issues arising from variation procedures pertaining to homeopathic medicinal products;
7. To support the drafting of a list of safe dilution grades for homeopathic products referred to in article 14 (1) of Directive 2001/83/EC
8. To address regulatory and scientific issues concerning homeopathic medicinal products on request by the European Commission, the Coordination Group, the HoA and the EDQM;
9. The WG shall draft rules of procedure for approval by HoA;
10. Guidance documents, prepared by the Working Group, will be presented to the HoA Group for approval and publication on the HoA website;

### **Recommendation.**

The Heads of Medicines Agencies endorse the mandate and the operating procedures of the permanent Homeopathic Medicinal Products Working Group (HMPWG).

Yours Sincerely,

Gwen Glasgow,  
Irish Medicines Board, Ireland.

Emiel van Galen  
CBG-MEB, the Netherlands

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