

## **Heads of Medicines Agencies Homeopathic Medicinal Products Working Group (HMPWG)**

### **Rules of Procedure adopted at HMA meeting in Lisbon, July 10, 2007**

Whereas EU legislation governing homeopathic medicinal products has been in place since 1992 with the publication of Council Directives 92/73 EC and 92/74 EC

Whereas with the implementation of the review of the EU pharmaceutical legislation, the need to find a harmonized approach to the interpretation of the legislation on homeopathic medicinal products has increased significantly

Whereas in chapter 2 Article 13, 14, 15 and 16 of Directive 2001/83/EC, as amended by Directive 2004/27/EC, and in chapter 2 Article 16, 17, 18, 19 and 20 of Directive 2001/82/EC, as amended by Directive 2004/28/EC, there are laid down specific provisions applicable to the procedure for licensing of homeopathic medicinal products

Whereas the registration procedure according to Article 14 of Council Directive 2001/83/EC, as amended, respectively according to Article 17 of Council Directive 2001/82/EC, as amended, is established in all Member States

Whereas a homeopathic medicinal product registered according to Article 14 of Directive 2001/83/EC as amended, respectively according to Article 17 of Council Directive 2001/82/EC, as amended, has access to mutual recognition procedures (MR-/DC-Procedure)

The following Rules of Procedure of the Heads of Medicines Agencies Homeopathic Medicinal Products Working Group have been approved by the Heads of Medicines Agencies:

#### **ARTICLE 1 – Mandate**

The HMPWG shall

- create a forum for exchange of regulatory and scientific expertise regarding the assessment of the quality and safety of homeopathic medicinal products for human and veterinary use in the Member States;
- provide guidance on the assessment of homeopathic medicinal products on request from Competent Authorities;
- provide guidance for applicants on the registration of homeopathic medicinal products;

- establish one common dossier template for applications for the registration (Article 14 of Directive 2001/83/EC, as amended) of homeopathic medicinal products in the EU, in co-operation with the Notice to Applicants Group;
- provide advice and expertise on request of the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human (CMD(h)) and Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMD(v)) on procedural, regulatory and scientific issues arising from the mutual recognition and decentralised procedures applicable to homeopathic medicinal products;
- facilitate the resolution of procedural, regulatory and scientific issues arising from variation procedures pertaining to homeopathic medicinal products;
- support the drafting of a list of safe dilution grades for homeopathic medicinal products;
- address regulatory and scientific issues concerning homeopathic medicinal products on request by the European Commission, the CMD(h), the CMD(v), the Heads of Medicines Agencies and the EDQM;
- draft rules of procedure for approval by the Heads of Medicines Agencies;
- prepare guidance documents which will be presented to the Heads of Medicines Agencies for publication on their website.

## **ARTICLE 2 – Composition of HMA-HMPWG**

1. Each EU/EEA medicines agency (NCA) may nominate one member and an alternate for a term of three years, which may be renewed.
2. The members and alternates should be from the national competent authorities and have adequate regulatory and/or scientific expertise. They also should have sufficient delegated authority to express the views of their regulatory authority's intention to implement the final outcome.
3. When a member of the HMPWG is not able to attend, the alternate may attend in his/her place.
4. Representatives of the European Commission and EMEA are invited to attend all meetings of the HMPWG.
5. In addition, observers from EDQM, the EFTA countries and WHO may participate for relevant subjects on special invitation.
6. Nominations of a member and an alternate should be submitted to the Chairperson and the Vice-chairperson. The Vice-chairperson is responsible to consolidate a list of members and alternates and to forward this list to the Chairperson, to each member and alternate of the HMPWG and to the HMA permanent secretariat.

### **ARTICLE 3 – Chair of HMA-HMPWG**

1. The Chairperson of the HMPWG shall be elected by and from amongst its members for a term of three years.

Every nomination, together with short a curriculum vitae of the candidate, should be submitted to the Chairperson of the meeting no later than 7 days prior to the HMPWG meeting at which the election is to take place.

The Vice-Chairperson is always the member of the Member State which is organizing the meeting, i.e. normally the presidency of the day.

2. The election of the Chairperson shall be by absolute majority of the members or alternates entitled to vote and by secret ballot. At each round, the candidate(s) with the lowest number of favourable votes shall withdraw. If an absolute majority vote is not obtained when only two candidates remain, further rounds of voting will be organized with the two remaining candidates, if it is considered that an absolute majority vote may be achieved. If an absolute majority vote for one of the candidates is not considered feasible a further voting is held with the candidate who has received the highest number of votes in the latest round only. This candidate is elected Chairperson if he/she receives a majority of votes.

3. After the election of the Chairperson, the Member State which appointed him/her will appoint a new member to replace the Chairperson as a member of the HMPWG. From the date of this appointment, the Chairperson shall lose his/her vote. This provision also applies to the Vice-Chairperson whenever he/she takes the chair and replaces the Chairperson. His/her vote will be assigned to the alternate of his/her delegation attending the meeting.

### **ARTICLE 4 – Role of Chairperson and Vice-Chairperson**

1. The Chairperson and Vice-Chairperson will be responsible for the efficient conduct of the activities of the HMPWG. The Chairperson has, in particular, the following responsibilities in collaboration with the Vice-Chairperson:

- a) to monitor and promote compliance with the rules of procedure;
- b) to convene the meetings of the HMPWG;
- c) to ensure that any potential conflict of interests is declared before any particular item is discussed by the HMPWG;
- d) to manage the business of the agenda by:
  - giving the floor to all participants equitably, taking into account time constraints,
  - formulating questions and proposals,
  - summing up discussions,
  - bringing all items to a conclusion;
- e) to strive for a consensus. If a consensus can not be achieved, to consider the option of voting in agreement with the participants;
- f) to ensure consistency of agreements;

- g) to ensure that the best possible advice is given by the HMPWG to other parties;
- h) to submit a written report to the Heads of Medicines Agencies after each meeting;
- i) to ensure the follow up of the decisions taken during the meetings;
- j) to circulate all documents to members, alternates and representatives who may make comments within a specified time period.

2. The Vice-Chairperson will replace the Chairperson of the HMPWG in his/her absence and support the Chairperson. The HMPWG may give more detailed instructions of the duties of the Vice-Chairperson.

3. In case of resignation of the Chairperson, the Vice-Chairperson shall take the chair until a new election is convened.

#### **ARTICLE 5 – Participation of Experts**

1. When necessary, the HMPWG or the members/alternates of the HMPWG may avail themselves of the services of other experts. The names of these experts shall be notified to the Chairperson and the Vice-Chairperson before the meeting which they are due to attend.

2. When experts accompanying members/alternates of the HMPWG cannot adequately cover a specific field of expertise, the HMPWG itself may request the contribution of other experts.

#### **ARTICLE 6 - Meetings**

1. Normally, the HMPWG should meet twice a year.

2. Normally, meetings should be planned and organised by the presidency of the day (according to Article 4 in collaboration with the Chairperson). Every year in May, the Chairperson shall contact the presidencies of the next year to get information whether a meeting of the HMPWG is intended. If one presidency of the next year does not intend to organise a meeting of the HMPWG, the Chairperson shall look for an alternative.

3. All participants shall cover their own expenses for travel and accommodation.

4. A first invitation and a first draft agenda – as a result of the previous meeting – should be circulated two months in advance of the next meeting.

5. The updated draft agenda for every regular meeting shall be agreed upon in advance of the meeting. It is recommended that the Chairperson/Vice-Chairperson shall circulate a draft agenda together with all relating documents.

## **ARTICLE 7 - Agreements**

1. Whenever possible, agreements on guidance documents, standard operating procedures (SOP), recommendations, procedural or regulatory practices or position statements of the HMPWG shall be adopted by consensus. In the absence of consensus they are deemed to be adopted if supported by a majority of the members of the HMPWG.
2. Each member of the HMPWG or alternate attending instead shall have one vote.
3. All agreements to be adopted by the HMPWG shall be reached when at least the majority of the members are present.
4. In the absence of consensus or a majority position of the Members States represented, the discussion is deemed inconclusive and hence the group can not publish any statements.
5. Documents and advice formulated by the HMPWG should be referred to the Heads of Medicines Agencies for approval. HMA should also be consulted in matters which are resource-related, concerns policy or have a considerable national impact.

## **ARTICLE 8 – Written procedure**

1. Between two meetings of the HMPWG, the Chairperson/Vice-Chairperson can submit draft documents to the HMPWG where the plenary agreed to adoption of the specified documents by written procedure.
2. Such written procedures should be restricted to measures deemed necessary by the Chairperson/Vice-Chairperson, for example the adoption of draft documents previously discussed by the HMPWG.
3. A full report on the outcome of the written procedure should be made at the following meeting.
4. In case of serious objections, the Chairperson will decide whether the written procedure should be suspended and the adoption of the draft statement postponed to the next meeting of the HMPWG.

## **ARTICLE 9 – Sub-working groups**

1. When necessary, the HMPWG may decide to create ad-hoc temporary working groups (defined as sub-working groups). Such working groups should not duplicate the work of other working parties already established.

2. Members of a sub-working group and a sub-working group chairperson/rapporteur to the HMPWG will be appointed by the HMPWG during the meeting. They should preferably be members/alternates of the HMPWG but may include other experts. National competent authorities could also propose a non-member/alternate of HMPWG as a member or a chairperson of a sub-working group.
3. The HMPWG shall adopt the mandate and objectives of each sub-working group and the duration of their activity.
4. The draft agenda of each meeting of any sub-working group shall be circulated in advance. The chairperson must ensure that any potential conflict of interest is declared before the particular item is discussed.
5. The written minutes will be circulated to all HMPWG members/alternates as soon as possible and no later than the next scheduled sub-working group meeting.
6. Reports are presented at the following HMPWG meeting by the sub-working group chairperson/rapporteur. The sub-working-group chairperson/rapporteur may delegate this task to another member of the sub-working group.

#### **ARTICLE 10 – Circulation of documents**

1. A draft agenda and other documents shall be circulated in due time before each meeting – preferably four weeks in advance of the meeting.
2. Documents shall be dated in order to distinguish versions.
3. Items to be put on the agenda should be sent to the Chairperson at the latest four weeks ahead of the meeting. Items received later than this shall be included or not at the discretion of the Chairperson/Vice-Chairperson.
4. Draft minutes and a table of decisions for each meeting shall be produced and circulated within three weeks after the meeting.

#### **ARTICLE 11 – Entry into force**

The Rules of Procedure or any amendment to them shall enter into force after receiving approval by the Heads of Medicines Agencies following recommendation of the HMPWG.



**Approval by HMA:**  
**Date of entry into force:**