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

Rules of Procedure

adopted at HMA meeting in Dublin 30/01/2013, as amended by HMPWG at the 23rd meeting in Utrecht 14-15/04/2016

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, safety and homeopathic use 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 EMA as well as observers from EDQM, WHO and Switzerland are invited to attend all meetings of the HMPWG.

5. A veterinary representative (CMDv contact point) is invited to attend all HMPWG meetings.

6. Nominations of a member and an alternate should be submitted to the Chairperson and the Vice-chairperson. It is the responsibility of the Vice-chairperson 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 a short 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 holding the current EU Presidency (hereinafter referred to as 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 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.

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

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 circulate a draft agenda of the meeting together with all relating documents in advance of the meeting;
    c) to convene the meetings of the HMPWG;
    d) to ensure that any potential conflict of interests is declared before any particular item is discussed by the HMPWG;
    e) 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;
    f) to strive for a consensus. If a consensus can not be achieved, to consider the option of voting in agreement with the participants who are entitled to vote;
    g) to ensure consistency of agreements;
    h) to ensure that the best possible advice is given by the HMPWG to other parties;
    i) to submit a written report adopted by the HMPWG by written procedure to the Heads of Medicines Agencies after each meeting for publication on the HMA website
    j) to ensure the follow up of the decisions taken during the meetings;
    k) 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.

ARTICLE 5 – Participation and purpose 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.

3. The CMDv should nominate a veterinarian representative for 3 years as the contact point between the CMDv and the HMPWG. The CMDv should officially inform the HMPWG of the nomination. The veterinarian representative should give expertise in the veterinary field to the HMPWG. The HMPWG veterinarian representative may suggest to forward a specific document to the CMDv. The HMPWG Chair should inform the CMDv Chair that the CMDv is invited to comment on the HMPWG document of veterinary interest within a specified time period. The CMDv contact point should submit the document to all CMDv members and forward an overview of the CMDv comments with their rationale to the HMPWG, at least one month before the next HMPWG meeting. Similarly, when a CMDv document concerns homeopathic veterinary medicinal products, the CMDv contact point should inform the HMPWG members in order to ensure consistency of agreements between the CMDv and the HMPWG.

ARTICLE 6 - Meetings

1. The HMPWG meetings shall be scheduled twice a year and should be hosted by the Presidency of the day.

2. Every year in May, the Chairperson shall contact the presidencies of the next year to ascertain as to whether a meeting of the HMPWG is planned. If one presidency of the next year is unable to organize a meeting of the HMPWG, the Chairperson, in collaboration with HMA, shall look for other alternatives by taking into account all EU Member states, Switzerland, as well as organizations and institutions involved in meetings as participants or observers.

3. The Host country shall provide practical and logistical assistance to HMPWG members as well as staff support during the meeting. Activities of the Host country include all the necessary organizational support before, during and after the meeting, including drafting and circulating the minutes, as defined in Article 10.

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

5. If the Presidency of the day is not able to host a meeting, the organizational activities connected to the meeting shall be carried out by the interim secretariat created in sufficient time before the meeting is held. The interim secretariat shall be created on a volunteer basis, or failing that, it shall consist of three members nominated by the previous, current and forthcoming Presidency. The creation of an interim secretariat is the responsibility of the Chairperson and the Vice-chairperson.

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 cannot 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 for a period of 3 years. 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.

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ARTICLE 10 – Circulation of documents

1. First invitation and first draft agenda - as a result of a previous meeting, should be circulated two months in advance of the next meeting. Final version of 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 shall be produced and circulated within two months and a table of decisions for each meeting shall be produced and circulated within one month 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 MG: 07-06-2016
Date of entry into force: 07-06-2016