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EMA/HMPC/358825/2005 Rev.4
Committee on Herbal Medicinal Products (HMPC)

Mandate, objectives and rules of procedure for the HMPC Working Party on Community Monographs and Community List (MLWP)

1. General considerations

According to the HMPC Rules of Procedure (EMA/HMPC/139800/2004 Rev.3), the Committee may consult its working parties on any scientific issue related to their specific fields of expertise. The Committee may also delegate certain tasks associated with the scientific evaluation or drafting of guidelines to the relevant working parties. The tasks identified by the Committee should be included in the work programme of each working party to be adopted by the HMPC.

The Working Party on Community Monographs and Community List (MLWP) is therefore established as a standing working party, to provide recommendations to the Committee on all matters relating directly or indirectly to the establishment of Community herbal monographs and the Community 'list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'. In addition, the MLWP is responsible for developing guidance relating to well-established use and traditional-use applications and to perform the tasks described under section 2.

2. Mandate and objectives

The MLWP provides recommendations to the Committee in relation to the issues listed below:

- Establishment and revision as appropriate of Community herbal monographs.
- Establishment and revision as appropriate of entries to the Community 'list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'.
- Preparation, review and update of relevant guidelines.
- At the request of the HMPC, provision of scientific advice on matters related to clinical and non-clinical safety and efficacy aspects of (traditional) herbal medicinal products.
- At the request of the HMPC, contributing to prepare an opinion of the HMPC on clinical and non-clinical aspects of (traditional) herbal medicinal products.

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- On request, provide advice, through the HMPC, on questions relating to clinical and non-clinical aspects of (traditional) herbal medicinal products to Member States, the EMA scientific committees and the European Commission.
- Liaison with other EMA working parties on clinical and non-clinical matters relating to (traditional) herbal medicinal products.
- Setting up of drafting groups (see section 5. Rules of Procedure, point 5.4).
- Liaison with interested parties to the HMPC (see section 5. Rules of Procedure, point 5.9).
- Contribution to workshops and training relating to the tasks of the MLWP.

3. Composition and rules of participation

The MLWP is composed of experts selected from the European Experts list according to their specific expertise and a Chair.

The final composition shall be agreed by the HMPC.

Membership of a working party implies a commitment to attend the meetings of the working party regularly and to participate actively in the work of that working party e.g. to be Rapporteur for at least one topic per calendar year.

A member may nominate a replacement to participate in those exceptional cases where he or she is unable to attend a meeting.

If a member does not participate in 3 consecutive meetings or does not contribute actively, the chair of the WP will bring this to the attention of the HMPC that will decide on a replacement

Members who want to bring additional experts should notify the EMA Secretariat in advance to the meeting, subject to the agreement of the chair.

Meeting documentation will be distributed to an agreed list of recipients drawn up by the EMA with the agreement of the Chair.

Observers from non-EEA countries may participate with the agreement of the EMA.

Observers from EU accession candidate countries and Mutual Recognition Agreements[1] (MRA) partners may participate with the agreement of the HMPC.

Confidentiality rules will apply to all participants.

HMPC members are encouraged to take an active role in the activities of the MLWP.

4. Meeting frequency

The MLWP shall meet at least 6 times per year in accordance with the adopted annual work programme. The dates of the meetings shall be included in the work programme of the MLWP.

Drafting Group meetings may be convened in the margins of the MLWP plenary meetings on specific topics or in order to complement a written procedure.

[1] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000248.jsp&mid=WC0b01ac058005f8ac

5. Rules of procedure

5.1. Responsibilities of Chair and Vice-Chair

1. The Chair, or in his/her absence the Vice-Chair, is responsible for the efficient conduct of the business of the MLWP and shall in particular:

- Plan the work of the MLWP together with the EMA Secretariat.
- Monitor, together with the EMA Secretariat, that the rules of procedure are respected.
- Ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the MLWP.
- Aim to achieve consensus on issues discussed by the MLWP.
- Decide in exceptional cases, when a vote is necessary. Only MLWP members can vote. The MLWP opinion or recommendation will be adopted if supported by a simple majority of the members of the working party (i.e. favourable votes by at least half of the number of MLWP members present at the time of the vote plus one). It is the duty of the MLWP Chair to alert the HMPC of scientific divergences pertinent to the opinion or recommendation upon which a vote took place, in particular when there is a close vote.
- Ensure, together with the MLWP and the EMA Secretariat, the regulatory and scientific consistency of the MLWP's recommendations.
- Co-ordinate together with the EMA Secretariat the work of the MLWP with that of the other relevant working parties of the Agency.
- Report on the activities of the MLWP to the HMPC, other scientific committees, other working parties or scientific advisory groups as appropriate.

2. The Vice-Chair will deputise for the Chair when the latter is unable to chair either all or part of the MLWP meeting. On such occasions the Chair will seek the agreement of the Vice-Chair as early as possible, prior to the meeting and the EMA Secretariat shall be informed immediately.

5.2. Election of Chair and Vice-Chair

The Chair and Vice-Chair of the MLWP shall be elected by the members of the HMPC for a term of three years, which may be renewed once. A Committee member, an alternate or a member of the MLWP may be elected by the Committee to fulfil this responsibility.

Nominations should be submitted in writing to the EMA Secretariat no later than the start of the Committee meeting at which election of the MLWP Chair is to take place.

Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.

The election of the Chair and the Vice-Chair shall follow the same procedure as that for the election of the Chair of Committee as stated in Article 3, paragraphs 1 to 4, of the Rules of Procedure of the HMPC.

5.3. Organisation of meetings and reporting arrangements

1. The MLWP shall meet regularly at the Agency.
2. The dates of meetings are decided on an annual basis in consultation with the MLWP and the HMPC.
3. The meetings will be held and minuted in English.
4. The draft agenda for every meeting shall be circulated by the EMA Secretariat, in consultation with the Chair, at least 14 calendar days before the meeting. The related documents shall be circulated at least 7 calendar days before the meeting.
5. When a Member of the MLWP is unable to participate to a meeting, part of meeting, or a specific discussion topic due to conflict of interest, he/she must inform the EMA Secretariat in advance. Such declarations will be recorded in the minutes of the respective meeting.
6. The MLWP may identify and propose topics for its consideration. Any proposal for a guideline, providing adequate justification, shall be transmitted to the HMPC for endorsement and shall be preceded by a concept paper to be endorsed by the HMPC.
7. Any recommendation from the MLWP shall be transmitted to the HMPC for adoption.
8. The MLWP shall prepare an annual work programme for adoption by the HMPC, which shall include topics identified in accordance with point 6 above and any specific tasks identified by the Committee. The work programme shall be regularly reviewed and updated as necessary with the agreement of the HMPC. The annual work programme shall be published on the EMA website.
9. Agenda, table of conclusions and minutes of the meetings of the MLWP should be circulated to the HMPC.
10. The Chair will be invited to attend plenary meetings to report on the activities of the MLWP and ensure liaison with the work of the HMPC.
11. The mandate of the MLWP shall be agreed by the HMPC. It shall be reviewed, at least at the start of each new term of the Committee.

5.4. Drafting groups

When further consideration is required in order to prepare proposals on specific topics the MLWP may convene drafting groups constituted of members of the MLWP or experts, as appropriate.

The drafting group will report to the MLWP directly.

5.5. Participation of experts in meetings

1. When necessary, the MLWP may avail itself of the services of experts in specific scientific or technical fields. Such experts shall have proven experience in the assessment of herbal medicinal products or in their field of expertise and be included in the European experts list. Where appropriate members from patient organisations or health-care professionals may act as experts.

2. The names of these experts shall be notified to the EMA Secretariat before the meeting that they are due to attend.

5.6. Guarantees of independence

1. The members of the MLWP and experts referred to above shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests that could relate to the pharmaceutical industry shall be entered in a register held by the Agency, which is accessible to the public, on request at the Agency's office.
2. Members of the MLWP and experts attending these meetings shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be recorded in the minutes of the MLWP meeting.
3. The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the European Medicines Agency Policy on the handling of conflicts of interests of Scientific Committee members and experts adopted by the Management Board (EMA/513078/2010) are applicable to members of the MLWP and experts participating in the scientific activities of the MLWP.

5.7. Code of conduct

Members of the MLWP and experts participating in the EMA's activities shall abide by the principles set out in the 'EMA Code of Conduct' (EMEA/6470/03/2368)[2].

5.8. EMA Secretariat

1. Under the authority of the Executive Director, the EMA Secretariat shall provide technical, scientific and administrative support to the MLWP. This includes the following:

- Provide technical and scientific support to Rapporteurs, and other members of the MLWP;
- Provide legal, regulatory and scientific support to the MLWP;
- Prepare and co-ordinate the work of the MLWP in consultation with the Chair or Vice-Chair, as appropriate;
- Ensure, if appropriate, that the periods laid down by EU legislation for the adoption of the opinions or recommendations are complied with;
- Organise meetings of the MLWP ensuring, together with the respective Rapporteurs, timely circulation of meeting documents;
- Facilitate the necessary contacts between the MLWP and the HMPC;
- Ensure adequate co-ordination of the work carried out within the MLWP, the EMA scientific committees and their working parties and/or scientific advisory groups in consultation with the respective Chairs;

[2] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004924.pdf

- Contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents/recommendations of the MLWP in cooperation with the Chair or Vice-Chair, as appropriate;
- Prepare the agenda, table of conclusions and minutes of the meetings of the MLWP in consultation with the Chair or Vice-Chair, as appropriate;
- Communicate when necessary any HMPC recommendations relevant to the MLWP to interested parties;
- Contribute to the identification of experts.

2. The Executive Director of the Agency, members of the EMA Secretariat, and representatives of the European Commission, may attend all meetings of the MLWP.

5.9. Contacts with interested parties

1. Where relevant, the MLWP will establish contacts, on an advisory basis, with parties concerned with the use of herbal medicinal products, in particular patient organisations and health-care professionals' associations or other interested parties.
2. Community herbal monographs, entries to the Community 'list of substances, preparations and combinations thereof for use in traditional herbal medicinal products' and guidelines will be subject to public consultation of all interested parties (pharmaceutical industry, health-care professionals, patients/consumers, their representing organisations or any other interested party).
3. When considered appropriate by the MLWP, oral presentations by interested parties can be made during MLWP meetings. The MLWP may also meet with interested parties to discuss general matters or specific scientific issues with the agreement of the HMPC and under specific conditions to be agreed by the HMPC.
4. In any case, the MLWP shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.
5. Before any consultation session, interested party representatives and MLWP members will communicate to the EMA Secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the MLWP Chair and circulation by the EMA Secretariat.

5.10. General Provisions

The members of the MLWP as well as observers and all experts shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by professional secrecy.

When participating in international or other fora on behalf of the HMPC and the MLWP, members shall ensure that the views expressed are those of the HMPC and of the MLWP. They shall follow the Policy[3] on scientific publication and representation for EMA scientific committees and their members (EMA/231477/2005 Rev.1).

[3] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004627.pdf

When participating in international or other fora not specifically on behalf of the HMPC or the MLWP, members shall make clear that the views expressed are their own views and not those of the HMPC nor of the MLWP.