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Inspections, Human Medicines Pharmacovigilance & Committees Division

Mandate, objectives and rules of procedure for HMPC temporary working parties and drafting groups

1. General considerations

In accordance with Article 56(2) of Regulation (EC) No 726/2004, the HMPC may establish standing and temporary working parties (WPs).

According to the HMPC Rules of Procedure (EMA/HMPC/139800/2004 Rev.2), when required in order to prepare proposals on specific topics, the Committee or the working parties may convene drafting groups (DGs) constituted by members or alternates of the Committee, members of the working parties or experts involved in the scientific evaluation, as appropriate.

2. Mandate and objectives

Temporary WPs/DGs are convened by the HMPC in order to carry out specific tasks related to their respective fields according to the following mandate:

- preparation, review and update of guidelines/concept papers,
- contribution to product-related assessment following specific HMPC request,
- preparation of specific positions/Q&As following specific HMPC request,
- interaction with stakeholders under supervision of HMPC,
- European and International cooperation under supervision of HMPC,
- training of assessors,
- contribution to other Committee's needs,
- liaison with other EMA working parties on specific matters relating to (traditional) herbal medicinal products under supervision of HMPC,
- contribution to Scientific Advice Working Party activities upon request under supervision of HMPC,
- accountable to HMPC for all activities.

The tasks identified by the HMPC should be included in the work plan of each WP/DG to be adopted by the HMPC. The work plan shall be regularly reviewed (at least annually) in the light of WP's/DG's performance and updated as necessary with the agreement of the HMPC.

3. Composition and rules of participation

WPs and DGs should be composed of assessors from or associated to national competent authorities with specific expertise in the area of interest.

It is recommended that relevant number of the WPs'/DG's members should be senior assessors with accredited experience. One of the senior assessors should act as a Chair. It is highly desirable that at least one HMPC member or alternate should be part of each WP/DG.

There should be a maximum of 10 members per WP/DG; however by exception more than 10 may be permitted by HMPC and EMA.

DGs composition could be limited to very few members as agreed by the HMPC.

The nominations for WPs and DGs will be adopted by the HMPC in accordance with the membership profile previously agreed and following proposals from HMPC members and alternates and EMA Secretariat.

Specific requirements on the composition of each WP/DG require adoption by HMPC (i.e. inclusion of members from other WPs/DGs or Committees).

Additional experts may be invited for particular topics for which specific expertise is required and these should be appointed by the HMPC and they will be reimbursed by EMA. If such a topic (e.g. guideline) involves paediatric patients and no paediatrician is member of the WP/DG, at least one additional expert should be appointed by the PDCO.

Additional assessors, who have been proposed by individual national competent authorities and agreed by the HMPC could participate as observers, however, there will not be reimbursement by the EMA. Their participation aims to ensure information exchange within the European regulatory network. However, observers cannot act as Rapporteurs for drafting guidelines or other guidance documents.

Observers from the European Commission, other EU Agencies, non-EEA Regulatory bodies or international institutions may participate with the agreement of the HMPC. Specific confidentiality rules will apply.

Membership of a WP or DG implies a commitment to participate actively in the work and to attend the meetings and tele/videoconferences regularly. If a member does not participate in 3 consecutive meetings without reasonable justification, EMA Secretariat may ask HMPC, in consultation with the WP or DG Chairperson, to reconfirm his/her membership or to nominate a new one.

4. Meeting frequency

The maximum number of face-to-face meetings per year will be 2 with a maximum of 2 days each.

Additional meetings will require specific approval from the HMPC and EMA.

One of the main characteristics of the regular work of the WPs and DGs should be based in the use of IT facilities in order to improve efficiency and minimising costs. Use of tools such as tele/videoconference (including web sharing) should ensure the ability of WPs/DGs to hold dynamic discussions, keeping assessors properly involved and replying to HMPC requests in a timely basis.

5. Duration of activity

Temporary WPs and DGs are constituted for the period of time needed to complete tasks committed by the HMPC. Continuity of each Temporary WP and DG should be confirmed by the HMPC at least once a year at the time of the adoption of the annual work plan.

Temporary WPs and DGs can be put on hold and/or their composition modified at any time depending on the ongoing needs.

Chairpersons will be nominated for a term of 3 years, which may be renewed once, in case that the WP/DG is required for a longer period of time. No time limit is proposed for the term of WP/DG members, however in case of continuing activities (re)nominations should take place every 3 years.

6. Rules of procedure

6.1. Responsibilities of the WP/DG Chairperson and WP Vice-Chairperson(s)

The Chairperson is responsible for the scientific conduct of the business of the WP/DG in efficient manner and shall in particular:

- plan the work of the WP/DG together with the EMA Secretariat,
- ensure, together with the EMA Secretariat, that the rules of procedure are respected,
- ensure that at the beginning of each meeting any potential competing interest is declared,
- aim to achieve consensus on issues discussed by the WP/DG,
- ensure, together with the EMA Secretariat, the regulatory and scientific consistency of the recommendations,
- coordinate together with the EMA secretariat the work with that of the other relevant WPs, DGs and Committees,
- report on the activities of the WP/DG to the HMPC.

The WP Vice-Chairperson will deputise for the Chairperson in his/her absence in all above mentioned responsibilities and functions.

6.2. Election/nomination of WP/DG Chairperson and WP vice Chairperson(s)

The WP/DG Chairperson and WP Vice-Chairperson shall be appointed by the HMPC for a term of 3 years, which may be renewed once, in case that the WP/DG is required for a longer period of time.

Nominations should be submitted in writing to the EMA secretariat no later than the start of the Committee meeting at which election of the working party Chairperson 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 Chairperson and the Vice-Chairperson, where appropriate, shall follow the same procedure as that for the election of the Chairperson of Committee as stated in Article 3, paragraphs 1 to 4, of the Rules of Procedure of the HMPC.

6.3. Organisation of meetings and reporting arrangements

Meetings refer to both face to face and tele/videoconference meetings. The face to face meetings shall take place at the Agency. The dates of meetings are decided on an annual basis. The meetings will be held and minuted in English.

The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMA Secretariat, in consultation with the Chairperson, at least 7 calendar days before the meeting. Agenda and Table of conclusions/minutes of the meetings should be circulated for information to the HMPC.

When considered appropriate by the WP/DG, oral presentations by companies, expert groups, representatives of professional bodies, patients associations or other interested parties can be made during a meeting on matters directly related to the activities of the WP/DG, following prior agreement of the HMPC. The WP/DG shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.

WPs and DGs report to HMPC.

6.4. Guarantees of independence

The members of the WPs and DGs, other assessors, experts or observers 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. The specific provisions for handling declaration of interests and confidentiality undertakings are as defined in the EMA Policy on the Handling of Declarations of Interests for Scientific Committees' Members and Experts, adopted by the Management Board (in the current version).

When a member is unable to participate in a meeting or part of the meeting, due to competing interest, he/she must inform the Secretariat in advance.

All attendees of WPs and DGs meetings shall declare at the beginning of each meeting any specific interest, 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 meeting.

6.5. Code of conduct

Members of the WPs and DGs and all other attendees to their meetings shall abide by the principles set out in the European Medicines Agency Code of Conduct.

7. Agency secretariat

Under the authority of the Executive Director, the Agency secretariat shall provide technical, scientific and administrative support to the WPs and DGs. This includes the following:

- provide technical and scientific support to Rapporteurs/Co-ordinators and other members,
- provide legal, regulatory and scientific support,
- prepare and co-ordinate the work of the WP/DG in consultation with the Chairperson,
- organise meetings as described in 6.3 ensuring timely circulation of meeting documents to an agreed list of recipients,

- responsible for the coordination of WP/DG with regard to planning, producing guidelines and reporting on progress /deviations from plans,
- facilitate the necessary contacts between the WP/DG, the Committees and other concerned WPs/DGs or scientific advisory groups,
- facilitate the necessary contacts and co-ordination between the WP/DG and the HMPC,
- contribute to the overall quality and assurance of scientific and regulatory consistency of the documents/recommendations of the WP/DG in co-operation with the Chairperson,
- prepare the agenda, Table of conclusions/minutes of the meetings in consultation with the Chairperson,
- communicate when necessary any Committees recommendations relevant to the WP/DG to interested parties,
- contribute to the identification of assessors and experts.

The Executive Director of the Agency and staff members of the Agency may attend all meetings.

8. General provisions

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

When participating in international or other fora on behalf of the EMA/HMPC, members shall ensure that the views expressed are those of the EMA/HMPC. It is noted that such participation requires prior agreement by the EMA/HMPC.

When participating in international or other fora not specifically on behalf of the EMA/HMPC, members shall make clear that the views expressed are their own views and not those of the EMA/HMPC.