



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 April 2013
EMA/HMPC/139800/2004 Rev.3
Committee on Herbal Medicinal Products (HMPC)

HMPC Rules of procedure

Article 55 of Parliament and Council Regulation (EC) No 726/2004 of 30 April 2004 establishes the European Medicines Agency with the responsibility for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

Competence of the Committee on Herbal Medicinal Products (Committee), being part of the Agency, in relation to the marketing authorisation and the traditional-use registration of herbal medicinal products, are laid down in:

- Regulation (EC) No 726/2004 and
- Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004, amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Appropriate co-ordination between this Committee and the Committee for Medicinal Products for Human Use and other scientific committees of the Agency will be ensured through a procedure developed by the EMA namely the 'EMEA Policy on appropriate coordination between the scientific committees of the Agency' (EMA/124704/2005 Rev.1).

Since the Committee is part of the Agency, the Integrated Quality Management System, endorsed by the Agency Management Board on 11 March 2004, applies to the Committee and its working parties.

Each national competent authority shall monitor the level and independence of the evaluation carried out and facilitate the activities of nominated members and experts. Member States shall refrain from giving Committee members and experts any instruction, which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.



Having regard to Parliament and Council Directive 2001/83/EC, as amended, on the Community Code relating to medicinal products for human use;

Having regard to the EEA Joint Committee Decision No 74/1999 of 28 May 1999 regarding the participation of the EEA-EFTA states in the work of the EMA;

The Committee adopts the following rules of procedure:

Composition

Article 1

1. The Committee consists of one member appointed by each of the EU Member States, for a term of three years, which may be renewed, and a chair.
2. The Committee shall also include one member appointed by each of the EEA-EFTA States, for a term of three years, which may be renewed.
3. The Committee, in order to complement its expertise, may appoint up to five co-opted members chosen on the basis of their specific scientific competence, among the experts nominated by Members States or the Agency. Co-opted members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.

Responsibilities of Chair and Vice-Chair

Article 2

1. The Chair, and in his absence the Vice-Chair, is responsible for the efficient conduct of the business of the Committee and shall in particular:
 - plan the work of the Committee meetings 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 Committee;
 - decide when a vote is necessary;
 - ensure, together with the Committee and the Secretariat, the regulatory and scientific consistency of the Committee's opinions and recommendations;
 - ensure that scientific grounds are adequately reflected in the Committee opinions;
 - co-ordinate together with the EMA Secretariat the work of this Committee with that of the other Committees of the Agency and other bodies established under EU law.
2. The Vice-Chair will deputise for the Chair when the latter is unable to chair either all or part of any meeting related to the Committee. 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.
3. If the Vice-Chair takes the chair, his/her place and vote will be assigned to his/her alternate.

Election of Chair and Vice-Chair

Article 3

1. The Chair and Vice-Chair of the Committee shall be elected by and from amongst its members for a term of three years, which may be renewed once.
2. Nominations for Chair and Vice-Chair should be submitted in writing to the EMA Secretariat no later than the start of the Committee's meeting at which the election is to take place.
3. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.
4. The election of the Chair and the Vice-Chair shall be by absolute majority of the Members (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one) and by secret ballot. At each round, the candidate(s) with the lowest number of favourable votes shall withdraw. In the case of a tie in the decisive round, another round is organised with two remaining candidates. If, at the decisive round, the candidate with the highest number of votes does not get an absolute majority, a further voting is organised with this candidate only, where he/she needs favourable votes by at least half of the total number of Committee members eligible to vote plus one, to be elected Chair or Vice-Chair, as the case may be.
5. After the election of the Chair, the Member State who appointed him or her will designate a new member to replace the Chair as a member of the Committee. From the date of this appointment, the Chair shall lose his/her vote.
6. In the event of resignation of the Chair, the Vice-Chair shall take the chair until a new election is convened.
7. The members appointed by the EEA-EFTA States may not vote nor be elected Chair or Vice-Chair of the Committee.

Appointment of co-opted members

Article 4

1. Members shall decide if co-opted members should be appointed and shall agree on their profile and number. The Committee shall also agree on the procedure for the selection of co-opted members.
2. The Committee shall take the necessary steps to identify and appoint any such co-opted members forthwith.
3. The members and alternates appointed by the EEA-EFTA States may not vote nor be elected co-opted members.

Alternates to nominated Committee members

Article 5

1. Each member of the Committee referred to under Article 1, paragraphs 1 and 2 shall have an alternate appointed by their Member State or EEA-EFTA State for a term of three years, which may be renewed.
2. Alternates shall represent and vote for the nominated member in the absence of the member when he/she is not in attendance at the meeting. They may act as rapporteurs at any time. At the request of the member, the alternate may respond on behalf of the member in case of written procedures or any request for urgent advice from members between meetings.
3. Alternates may not be elected as Chair or Vice-Chair of the Committee.

Rapporteur, Co-Rapporteur and Assessment Team

Article 6

1. For any scientific evaluation in respect of a procedure a rapporteur shall be appointed from amongst the members of the Committee or alternates. The role of the rapporteur is to perform the scientific evaluation and to prepare a report to the Committee according to the timetable agreed for the respective procedure, taking into account any timeframe laid down in the relevant legislation.

For scientific issues such as drafting Community herbal monographs, Community list entries and guidelines, a rapporteur may be appointed from amongst the members of the Committee, alternates or experts included in the EMA expert Database.

The appointment of the rapporteur shall be made on the basis of objective criteria which will allow the use of the best available expertise in the EU on the relevant scientific area.

2. When appropriate, the rapporteur can be supported by one or more co-rapporteur(s), as agreed by the Committee. Co-rapporteur(s) shall be appointed from amongst the members of the Committee or alternates or experts and shall prepare a critique of the rapporteur's report or prepare a separate report at the discretion of the Committee. In addition, the Committee may at any time ask for a peer review of any critical issues by the appropriate Committee's working party.

3. The rapporteur, and when appropriate, co-rapporteur(s) choose(s) amongst the experts included in the European experts list available at the EMA, those who will form his/her/their assessment team. He/she/they notify his/her/their choice to the EMA prior to the start of the scientific evaluation in respect of a procedure. Members of the Committee or alternates and experts shall rely on the scientific evaluation and resources made available by national competent authorities and the EMA.

4. For scientific evaluations in respect of a procedure, meetings may be organised between rapporteurs or co-rapporteurs with applicants or marketing authorisation/registration holders. Whenever such meetings take place, minutes of all contacts shall be made available to the rapporteur, co-rapporteur and the EMA Secretariat. Contacts by other members and alternates with applicants and marketing authorisation/registration holders are not considered appropriate

and should be avoided during assessment procedures. Should such contacts take place, these shall be reported to the rapporteur and co-rapporteur and to the EMA.

5. Rapporteurs may establish contacts on an advisory basis, with representatives of patient organisations and health-care professionals' associations relevant to the therapeutic field of the concerned scientific evaluation. Any such contacts should be organised in liaison with the EMA Secretariat with the prior agreement of the Committee. The rapporteur should provide a report on the outcome of such contacts to the Committee.

6. The format and quality of scientific evaluation reports should be determined and judged by the Committee.

Scientific opinions and recommendations

Article 7

1. The quorum required for the adoption of scientific opinions or recommendations by the Committee shall be reached when two thirds of the total members of the Committee eligible to vote are present. The votes shall be positive or negative (unless the provision concerning the conflicts of interest is applied).

2. Whenever possible, scientific opinions or recommendations of the Committee shall be taken by consensus. If such a consensus cannot be reached, the scientific opinion or recommendation will be adopted if supported by an absolute majority of the members of the Committee (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one).

3. The divergent positions of and the names of the members expressing the divergent positions in the scientific evaluation shall be mentioned in the opinion of the Committee, and where relevant, in the minutes of the Committee. Members having divergent positions shall provide them in writing by the close of the meeting, stating clearly the reasons on which they are based. They will be appended to the opinion. The reasons for the divergent opinions shall be publicly available together with the document made publicly available where appropriate.

4. The members from the EEA-EFTA States may not vote but their positions shall be stated separately in the opinion, where relevant, in the minutes of the Committee and in case of divergent opinions these positions shall be appended to the Committee's opinion. Their position is not counted in reaching the Committee's opinion.

5. In the event of no absolute majority position, the Committee's opinion is deemed to be negative.

Procedure for urgent adoption of opinions/recommendations

Article 8

1. In some instances, it may be necessary to take an urgent decision with regard to pharmacovigilance, serious concerns on public health or quality defects of herbal medicinal products. This may be done by:

Adoption of an opinion/recommendation during the course of a scheduled meeting (using an accelerated timeframe if necessary), when the need for adoption of the urgent opinion/recommendation/agreement on course of action has been identified during the course of the meeting (or within 48 hours before the meeting);

The convening of an extraordinary meeting, if considered necessary and if feasible to organise within the necessary short timeframe. This meeting should take place in the presence of a quorum allowing the Committee to adopt an opinion i.e. when at least two thirds of the members are available to participate. A separate full report of this meeting, formally recording the adoption of the opinion/recommendation should be prepared;

Written procedure in accordance with Article 9.

2. The decision on the need for the adoption of an urgent opinion/recommendation outside of a scheduled Committee meeting will be taken by the EMA Secretariat in discussion with the Committee Chair and Vice-Chair.

Written procedure

Article 9

1. Draft opinions and recommendations can, after approval of the Chair, be submitted by the EMA Secretariat to the Committee for adoption by written procedure. However, such written procedures should be restricted to measures required to be taken between scheduled meetings.

2. Draft opinions or recommendations are addressed to members of the Committee, who may raise objections within a specified time period, to be established in agreement with the Chair. The Secretariat shall present a full report on the outcome of the written procedure at the following meeting of the Committee.

3. In the case of major and justified objections, the Chair decides whether the written procedure should be suspended and the adoption of the draft opinion or recommendation postponed to the next meeting of the Committee.

Re-examination of opinions

Article 10

1. For the implementation of the procedures for the re-examination of opinions mentioned in Article 62(1) of Regulation (EC) No 726/2004, in Article 32(4) of Directive 2001/83/EC, as amended, a different rapporteur and where previously appointed, (a) different co-rapporteur(s) from those appointed for the initial evaluation, will be appointed to assess the grounds for the re-examination of opinions. This re-examination shall be made by using the best endeavours to ensure an examination, independent from the first opinion.

2. The re-examination may deal only with the points of the opinion initially identified by the applicant and is based only on the scientific data available when the Committee adopted the initial opinion. The Committee shall request the advice of additional available expertise.

Organisation of meetings

Article 11

1. The Committee shall meet regularly at the Agency. The meeting shall be convened by the Executive Director or his/her representative after consultation with the Chair.
2. The dates of meetings are decided on an annual basis in consultation with the Committee. In exceptional circumstances and on motivated grounds agreed with the Chair an extraordinary meeting may be convened at short notice.
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. Relating documents shall be circulated at least 7 calendar days before the meeting. This draft agenda shall enable the Committee to perform its duties. The draft table of decisions and draft minutes for every meeting shall be circulated respectively 5 and a further 15 working days after the meeting.

Once adopted agendas and minutes of the Committee's meetings shall be made publicly available at pre-defined time points.
5. When a Member of the Committee 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 Secretariat in advance. Such declarations will be recorded in the minutes of the respective meeting.

Hearings - Oral Explanations

Article 12

1. The Committee shall invite an applicant or marketing authorisation/registration holder to provide oral explanations in connection with an evaluation procedure where requested by the applicant or marketing authorisation/registration holder, unless urgent measures need to be adopted for reasons of public health. The Committee may also invite on its own initiative an applicant or marketing authorisation/registration holder to provide oral explanations in connection with a marketing authorisation/registration procedure. Oral explanations may also be provided by the applicant or marketing authorisation/registration holder to working parties when the Committee has delegated tasks associated with the scientific evaluation to a working party.
2. The Committee may also invite on its own initiative or may consider a request of any other relevant third party for a hearing in connection with a scientific evaluation. With the agreement of the Committee, hearings may also be provided by any other relevant third party in connection with a scientific evaluation to working parties.
3. Oral explanations/hearings shall be indicated clearly in the draft agenda of the meeting. The scientific argumentation on which a presentation will be based as well as details (names and responsibilities) of the participants shall be sent to the members of the Committee or working party in advance.
4. The Committee or working party shall not make any conclusions during these presentations in the presence of the company representatives or the third parties.

5. In all cases the applicant or marketing authorisation/registration holder is informed of the trend at HMPC level at the end of the scientific discussion ahead of any formal vote to conclude the evaluation process.

Coordination with other scientific committees and working parties

Article 13

1. The Committee shall adhere to the procedure developed by the EMA to ensure an appropriate coordination between the scientific committees of the Agency as laid down in Article 64(2) (d) of Regulation (EC) No 726/2004, namely the European Medicines Agency Policy on appropriate coordination between the scientific committees of the Agency (EMA/124704/2005 Rev.1).
2. When a medicinal product containing a herbal substance is referred to the Committee for Medicinal Products for Human Use, the Committee on Herbal Medicinal Products shall be requested to give an opinion on the herbal substance, where appropriate. Appropriate coordination with the Committee for Medicinal Products for Human Use will be ensured by the above-mentioned procedure.
3. Each scientific committee shall seek collaboration with working parties and scientific advisory groups of other scientific committees in accordance with the EMA procedure, in order to maximise the operation of the various bodies making up the Agency with a view to developing the best possible scientific opinion/recommendation.

Working parties

Article 14

1. The Committee may establish standing working parties.
2. Temporary working parties may also be established when work of a temporary or ad hoc nature is required such as preparation of proposals on a specific scientific topic, preparation of responses to specific questions raised by the Committee, drafting of new guidelines or revision of existing ones in relation to specific scientific fields.
3. Working parties are composed of experts selected from the European experts list according to their specific expertise.
4. The mandate and objectives of each working party shall be published; the document shall include its composition and meeting frequency and in the case of temporary working parties, also the duration of their activity. The Committee shall review the mandate and objectives of each standing working party at least every three years. Those of the temporary working parties should be reviewed either at the end of the period for which they have been created or after three years, whichever comes first.

Where amendments are introduced in the mandate of any working party the Committee shall consider if the composition of the working party should be re-visited in order to ensure that scientific experience is available to execute the respective mandate.

The work programmes of each working party shall be reviewed at least annually and will be made publicly available.

5. Whenever considered appropriate the Committee shall consult its working parties on any scientific issue related to their specific fields of expertise. The Committee may also delegate certain tasks associated with a 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 Committee.

6. The working parties may identify and propose topics for consideration by the Committee. Any proposal for a guideline, providing adequate justification, shall be transmitted to the Committee for endorsement and shall be preceded by a concept paper to be endorsed by the Committee.

7. The recommendation from the working parties shall be transmitted to the Committee for adoption.

8. The Chair of a working party shall be elected by the members of the Committee for a term of three years, which may be renewed. A Committee member, an alternate or a member of the working party may be elected by the Committee to fulfil this responsibility. The Chair will be invited to attend plenary Committee meetings to report on the activities on the working party and ensure liaison with the work of the Committee.

9. A Vice-Chair may be elected by the Committee if the working party considers it appropriate.

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

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

12. The election of the Chair and the Vice-Chair, where appropriate, 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 these Rules of Procedure.

13. Agenda, table of conclusions and minutes of the meetings of the working parties should be circulated to the Committee.

14. The Committee shall together with the Secretariat put in place measures to ensure that there is coordination of work and exchange of information between the standing, temporary working parties and drafting groups as appropriate.

Drafting Groups

Article 15

1. When further consideration is required in order to prepare proposals on specific topics the Committee or the working parties may convene drafting groups constituted by members or alternates of the Committee, members of the working parties or experts involved in the scientific evaluation, as appropriate.

2. The same rules provided in Article 14 for working parties apply also by analogy to drafting groups, with the exception of points 1, 2, 4, 5, and 13.

3. At the request of the Committee, the mandate and objectives of drafting groups may be published; the document shall include its composition and meeting frequency.

Where amendments are introduced in the mandate of a drafting group, the Committee shall consider if the composition of this drafting group should be re-visited in order to ensure that scientific experience is available to execute the respective mandate.

The work programme of each drafting group shall be reviewed at least annually; it may be made publicly available.

4. Agenda and meeting report of the meetings of the drafting groups should be circulated to the Committee.

Participation of Experts in meetings

Article 16

1. When necessary, the Committee and its working parties may avail themselves of the services of experts in specific scientific or technical fields. Such experts shall have proven experience in the evaluation of herbal medicinal products or in their field of expertise and be included in the European experts list.

2. Members of the Committee may be accompanied by the experts mentioned in paragraph 1 (at their own expense). The names of these experts shall be notified to the EMA Secretariat before the meeting, which they are due to attend.

Guarantees of independence

Article 17

1. The names of the members and alternates of the Committee shall be made public. When each appointment is published, the professional qualifications of each member and alternate shall be specified.

2. The members of the Committee and alternates, members of working parties and experts mentioned in various articles of the present Rules of Procedure, 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, which 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. In addition, the Declarations of Interest of the members and alternates of the Committee shall be made available on the Agency's website.

3. Members of the Committee and alternates, members of working parties (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 Committee's meeting.

4. 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 Committee, working parties and experts participating in the scientific activities of the Agency.

5. The members of the Committee or working parties shall not accept from the Member States any instructions incompatible with the tasks incumbent upon them within the Agency. It is essential for these tasks to remain strictly scientific in nature.

Code of conduct

Article 18

Members of the Committee, working parties and experts participating in the EMA's activities shall abide by the principles set out in the EMA Code of Conduct¹ (EMEA/6470/03/2368).

Call for expression of interest

Article 19

The performance of scientific services for which there are several potential providers may result in a call for an expression of interest, if the scientific and technical context allows, and if it is compatible with the tasks of the Agency, in particular the need to provide a high level of public health protection.

EMA Secretariat

Article 20

1. Under the authority of the Executive Director, the EMA Secretariat shall provide technical, scientific and administrative support to the Committee and its working parties with a view to the performance of its duties. This includes the following:

- Provide technical and scientific support to the Committee and its working parties;
- Provide legal and regulatory support to the Committee and its working parties;
- Prepare and communicate relevant public information related to the activities of the Committee such as press releases, public statements, Q&A documents after consultation of the Committee, where appropriate;
- Ensure that the periods laid down by EU legislation for the adoption of the opinions are complied with;
- Organise meetings of the Committee and its working parties ensuring, together with the respective rapporteurs, timely circulation of meeting documents;
- Ensure adequate co-ordination of the work carried out within this Committee, its working parties and its drafting groups and between them, in consultation with the respective Chair;
- Ensure scientific and regulatory consistency of the opinions/recommendations of the Committee in co-operation with the Chair or Vice-Chair, as appropriate;

¹ http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC50004924.pdf

- Co-ordinate together with the Chair the work of the Committee with that of the other committees of the Agency and other bodies established under EU law;
 - Organise, when necessary, joint meetings with other scientific committees of the Agency;
 - Prepare the minutes of the meetings of the Committee and its working parties in consultation with the Chair;
 - Communicate to interested parties relevant recommendations of the Committee;
 - Communicate the views of the Committee in international fora.
2. The Executive Director of the Agency, members of the EMA Secretariat, and representatives of the European Commission, may attend all meetings of the Committee and its working parties.

Contacts with interested parties

Article 21

1. The Committee and its working parties 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. The Committee may agree to invite representatives of such interested parties to address a plenary meeting.
2. Concept papers, draft guidelines and general regulatory developments will be subject to public consultation of all interested parties (industry, healthcare professionals, patients/consumers or other).
3. When considered appropriate by the Committee, oral presentations by interested parties can be made during working party meetings in earlier stages of development of guidelines. The working parties may also meet with interested parties to discuss general matters or specific scientific issues with the agreement of the Committee and under specific conditions to be agreed by the Committee.
4. In any case, the Committee and its working parties 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 Committee 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 Committee Chair and circulation by the EMA Secretariat.

Observers

Article 22

1. At the initiative of the European Commission and in agreement with the Management Board, the Committee may admit representatives of international organisations with interests in the harmonisation of regulations applicable to herbal medicinal products as observers at the Committee and working parties' meetings or meetings arranged for this purpose to discuss topics of common interest. The conditions for participation shall be determined beforehand by the European Commission.

2. For the purposes of regulatory cooperation, and particularly within the framework of mutual recognition agreements, visiting experts or other representatives from non-EEA regulatory authorities may also participate as observers to the Committee and its working parties. Participation shall be agreed with the respective Chair in advance of the meeting.
3. The observers shall be bound by the rules of confidentiality mentioned in Article 17.

General Provisions

Article 23

For tasks incumbent on the Agency, other than those of evaluation, the Committee may propose that the Agency has recourse to rapporteurs within the meaning of Article 6 paragraph 1 or to experts within the meaning of Article 16.

Article 24

The Committee may, if they consider it appropriate, seek guidance on important questions of a general scientific or ethical nature.

Article 25

The members of the Committee, working parties 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 for a on behalf of the HMPC, members shall ensure that the views expressed are those of the HMPC. They shall follow the Policy² on scientific publication and representation for EMA scientific committees and their members (EMA/231477/2005 Rev.1).

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

Article 26

The decision to adopt or to amend these rules of procedure shall be taken by an absolute majority of the members of the Committee (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one).

Article 27

The rules of procedure or any amendment to them will be made publicly available.

² http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004627.pdf

Adopted by the Committee on 12 November 2004

Revision 1 adopted by the Committee on 8 May 2007

Revision 2 adopted by the Committee on 6 November 2008

Revision 3 adopted by the Committee on 1 April 2013

Date of entry into force of Revision 3: 1 April 2013