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Mandate, objectives and rules of procedure for the Scientific Advisory Groups (SAGs) and Ad-Hoc Expert Groups (AHEGs)

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1. Legal basis

Article 56(2) of Regulation (EC) No 726/2004 provides that the Committee for Medicinal Products for Human Use (hereinafter "the Committee") may establish scientific advisory groups (hereinafter "SAGs") in connection with the evaluation of specific types of medicinal products or treatments, to which the Committee may delegate certain tasks associated with drawing up the scientific opinions. When establishing SAGs, Article 61(8) of Regulation (EC) No 726/2004 provides that the Committee shall in its rules of procedure lay down procedures relating to SAGs.

Article 62(1) of Regulation (EC) No 726/2004 provides that when consulting SAGs, the Committee shall forward to them the draft assessment report(s) drawn up by the rapporteur or the co-rapporteur. The opinion issued by the scientific advisory group shall be forwarded to the chairman of the relevant Committee in such a way as to ensure that the applicable deadlines are met.

Article 62(1) of Regulation (EC) No 726/2004 also provides that the Applicant may request that the Committee consults a SAG in connection with the re-examination of their opinions.

Article 78(2) of Regulation (EC) No 726/2004 provides that SAGs shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health care professionals' associations.

Article 80 of Regulation (EC) No 726/2004 provides that the internal rules and procedures of the Agency, its committees and its working groups shall be made available to the public at the Agency and on the internet.

2. General considerations

The Committee consults SAGs to deliver answers on scientific/technical matters related to medicinal products under evaluation at the European Medicines Agency (hereinafter "EMA").

SAGs will be convened at the request of the Committee. The need for such meetings should be identified as early as possible in the evaluation process.

When the issues refer to a therapeutic area for which no SAG is established, the advice of additional available expertise will be requested in the form of consultation of an ad hoc expert group (hereinafter "AHEG") meeting.

This document sets out the rules for the operation of SAGs and AHEGs.

3. Mandate and objectives

SAGs/AHEGs are established by the Committee to answer, on a consultative basis, the Committee's specific questions in the context of the evaluation of a medicinal product or any other scientific issue relevant to the work of the Committee.

SAGs operate in a complementary manner to the Committee's working parties by bringing additional expertise in specific domains to complement, where appropriate, the evaluation of medicinal products in the context of regulatory procedures at EU level.

SAGs/AHEGs report back to the Committee which, while taking into account the position expressed by the SAG/AHEG, remains responsible for its final opinion.

SAGs/AHEGs can also be consulted on scientific questions by other committees within EMA and their working parties.

The established SAGs cover the following fields:

- **Scientific advisory group on Cardiovascular issues, diabetes and obesity**: any clinical aspects of cardiovascular issues, diabetes and obesity;
- **Scientific advisory group on Neurology**: any clinical aspects in the field of neurology;
- **Scientific advisory group on Oncology**: any clinical aspects of oncology and haematological malignancies;
- **Scientific advisory group on Vaccines and Therapies for Infectious diseases**: any clinical aspects of vaccines and of fungal, bacterial and/or parasitic diseases and infections;
- **Scientific advisory group on Immune and inflammatory diseases**: any clinical aspects in the field of clinical immunology (immunodeficiencies, autoimmune diseases, transplant and allergies), pulmonology and dermatology;

The scope of SAGs includes, but may not be limited to, clinical aspects and/or clinical trials methodology and biostatistics.

4. Composition and rules of participation

SAGs/AHEGs are composed of members selected according to their specific scientific expertise in the field of the SAG/AHEG.

4.1. SAG composition

SAGs consist of a core panel of members who are appointed by the Committee for a 3-year mandate, on the basis of nominations by Committee members or by EMA, from the European experts list referred to in the second subparagraph of Article 62(2) of Regulation (EC) No 726/2004, and taking into account expression of interests received from the public call launched by EMA at time of establishment and/or renewal of the SAG.

In case a core member resigns from the SAG, a replacement of the member will be considered by the Committee and, where applicable, will be appointed for the remainder of the duration of the SAG mandate.

The number of appointed core members may vary per therapeutic SAG. The core membership of each SAG is available on EMA's website.

SAGs may include additional members who may be called upon to participate, as appropriate, in specific meetings. Patient and consumer experts may also be appointed by the Committee to participate in SAG meetings either as core or additional members. When appointed, they participate in an individual capacity.

The EMA secretariat may also contact relevant academia, healthcare professional organisations and learned societies for potential candidates to participate as additional SAG members, for appointment by the Committee. When appointed, they participate in an individual capacity.

4.2. AHEG composition

The members of the AHEG will be appointed by the Committee for a specific meeting on the basis of nominations by Committee members or by EMA, in accordance with the expertise required.

Patient and consumer experts may be appointed by the Committee to participate in AHEG meetings. EMA secretariat may also contact relevant academia, healthcare professional organisations and learned societies for potential candidates to participate as AHEG members, for appointment by the Committee.

4.3. SAG/AHEG rules of participation

Non-EEA affiliated experts may be appointed by the Committee to participate as AHEG members or as additional SAG members only, as appropriate. Non-EEA affiliated experts cannot be appointed as SAG core members.

Members of EMA's committees and working parties, concerned (co-)rapporteurs, assessors from NCAs, visiting experts and regulators from non-EEA countries under confidentiality agreement with EMA may participate as observers.

Experts involved in the evaluation of a regulatory procedure at EU level subject to a SAG/AHEG meeting, members of any EMA Scientific committees, their working parties and EMA staff are not eligible to become SAG/AHEG members.

The Committee is solely responsible for identifying the required expertise and for adopting the final list of experts invited to the SAG/AHEG meeting.

5. Meeting frequency

The SAG/AHEG will meet at the request of the Committee.

6. Duration of the activity of SAGs/AHEGs

SAGs are established for a 3-year period which can be renewed or not renewed by the Committee. The mandate and continuity of each SAG will be confirmed by the Committee at time of renewal.

AHEGs are constituted on an ad-hoc basis for a specific medicinal product in the context of a regulatory procedure.

7. Rules of procedure

7.1. Responsibilities of chairperson and vice-chairperson

The chairperson will be responsible for the efficient conduct of the work of the SAG/AHEG and shall, in particular, be responsible for the following tasks:

- propose to the Committee (additional) experts to a SAG/AHEG meeting, as appropriate;
- prepare the SAG/AHEG meeting, with support of the EMA secretariat;
- ensure, together with the EMA secretariat, that the mandate and rules of procedure are respected;
- ensure, together with the EMA secretariat, that at the beginning of each meeting any potential conflicts of interest are declared;
- assume responsibility for the conduct and running of the meeting;
- ensure that the Committee questions for the SAG/AHEG and any additional topics in the agenda are discussed;

- before the end of each meeting, summarise the conclusions of the SAG/AHEG on each question raised by the Committee for inclusion in the SAG/AHEG answers document to the Committee. These conclusions will form the basis for the debriefing to the applicant/marketing authorisation holder (hereinafter "MAH");
- ensure that the conclusions are adequately reflected in the SAG/AHEG answers document;
- in case consensus cannot be reached, ensure that all the views expressed by the SAG/AHEG members are reflected in the SAG/AHEG answers document;
- provide feedback from the SAG/AHEG discussions including divergent views to the Committee plenary meeting, when requested.

The vice-chairperson, where appointed, will deputise for the chairperson in their absence in all above-mentioned responsibilities.

In a situation where both chairperson and vice-chairperson are unable to attend a specific meeting, another core member of the SAG will act as chairperson for said meeting chosen from among and by the core members of the SAG.

7.2. Chairing of SAG/AHEG meetings

7.2.1. Election of SAG chairperson

SAGs shall elect, from amongst its core members, a chairperson for endorsement by the Committee. A vice-chairperson may also be elected for endorsement by the Committee if the group considers it appropriate.

The election of the chairperson and, if applicable, the vice-chairperson shall be by absolute majority of the core members of the SAG, i.e. favourable votes from more than half of the total number of SAG core members and by secret ballot.

If absolute majority is not reached, the candidate(s) with the lowest number of favourable votes shall withdraw. If there is a tie amongst the candidates with the lowest number of votes, all tied candidates are eliminated, and a further voting round is organised with the remaining candidate(s) only. In the case of a tie when only two candidates remain, a new voting round is organised with these two remaining candidates. If, during the new round, the candidate with the highest number of votes does not get an absolute majority, a further voting round is organised with this candidate only. If there is only one (remaining) candidate, they need favourable votes from more than half of the total number of SAG core members, to be elected chairperson or vice-chairperson, as the case may be. If the remaining candidate(s) do(es) not get an absolute majority, the election is annulled, and a new election is convened for the next scheduled meeting of the SAG following the same procedure as stated in this paragraph. The Committee thereafter endorses the chairperson and, if applicable, the vice-chairperson.

In the event of resignation of the chairperson, the vice-chairperson, if appointed, shall take the chair until a new chairperson has been elected.

The chairperson and, if applicable, the vice-chairperson of the SAG shall be elected for a term of three years, which may be renewed once. Regardless of the time of election, the chairperson and, if applicable, the vice-chairperson shall be appointed for the remaining term of the SAG should this be shorter than 3 years.

7.2.2. Appointment of AHEG chairperson

In case of AHEG meetings, the chairperson will be chosen from among and by the experts appointed for the meeting.

7.3. Responsibilities of EMA secretariat

Under the authority of the executive director, the EMA secretariat shall provide technical, scientific and administrative support to the SAG/AHEG. This includes:

- propose to the Committee (additional) experts to a SAG/AHEG meeting, as appropriate;
- organise the meeting of the SAG/AHEG and ensure timely preparation and follow-up to the meeting;
- ensure that all members have a valid declaration of interest (including confidentiality undertaking) and that these are evaluated prior to the meeting in accordance with Policy 0044;
- ensure scientific and regulatory consistency of the recommendations from the SAG/AHEG in cooperation with the chairperson;
- prepare the SAG/AHEG answers document for the Committee in consultation with the chairperson and share the SAG/AHEG answers document for review with the SAG/AHEG members;
- contribute, together with the SAG/AHEG chairperson, to the debriefing meetings with the applicant/MAH;
- provide feedback from the SAG/AHEG discussions including divergent views to the plenary Committee meeting, when requested;

7.4. Organisation of meetings and reporting arrangements

The SAG/AHEG will meet virtually unless otherwise agreed. In case of in-person meetings, members who are prevented from participating in person, can participate through a remote connection.

The meetings will be held in English and the outcome of the SAG/AHEG meeting will be a SAG/AHEG answers document. Provided that SAG/AHEG members have a valid declaration of interest (including confidentiality undertaking) and are eligible for participation to the meeting, in accordance with the rules set out in Policy 0044, the EMA secretariat will circulate to the SAG/AHEG members, in advance of the meeting, the relevant documents for the meeting, including the questions to the SAG/AHEG and the relevant assessment reports drawn up by the (co-)rapporteurs.

The questions to the SAG/AHEG, list of documents shared with the SAG/AHEG members and the names of participating SAG/AHEG members will be made available to the applicant/MAH in advance of the SAG/AHEG meeting.

The Committee's rapporteur and co-rapporteur and, where applicable, rapporteurs from other committee(s) or working party(ies)/groups will be invited to attend the SAG/AHEG meeting and may be asked by the chairperson to present the background to the specific Committee's questions. They may also provide additional information or ask additional clarifications to the SAG/AHEG members.

The (co-)rapporteurs of the concerned committee(s) may be supported by one or more of their assessors.

The applicant/MAH will be invited to provide an oral explanation in front of the SAG/AHEG and will be allowed to attend the (co-)rapporteur's presentations and answer any questions by the SAG/AHEG members.

The SAG/AHEG shall neither conduct discussions, deliberations nor reach any formal decisions in the presence of the applicant/MAH or any third party.

The SAG/AHEG chairperson will ensure that the SAG/AHEG discusses and provides an answer to each of the Committees questions.

A debriefing meeting will be held after the end of the meeting to inform the applicant/MAH on the outcome of the discussions. The debriefing meeting will only focus on the outcome of the SAG/AHEG discussions and will not be the forum for any regulatory discussions, including on subsequent steps in the procedure.

The chairperson, supported by the EMA secretariat, will be responsible for finalising the SAG/AHEG answers document taking into account, where appropriate, comments received from SAG/AHEG members. The SAG/AHEG answers document will be shared with the applicant/MAH concerned.

The SAG/AHEG answers document will be presented by the chairperson of the SAG/AHEG or by the EMA secretariat at a subsequent Committee meeting, including any divergent views, if applicable.

When issues were raised by other EMA's committee(s) or working party(ies), the SAG/AHEG chairperson or the EMA secretariat will, in addition to reporting to the Committee, also report to the other committee(s) or WPs concerned.

The SAG/AHEG answers document will be part of the assessment report and, where applicable, be published as part of the public assessment report.

7.5. Guarantees of independence

EMA's policy on the handling of competing interests of scientific committees' members and experts (Policy 0044) applies to all SAG and AHEG chairperson and members.

SAG/AHEG members and any other experts attending SAG/AHEG meetings shall declare at the beginning of each meeting any specific interests which could be prejudicial to their independence with respect to the points of the agenda. This will be documented in the SAG/AHEG answers document.

Any incomplete and/or incorrect declarations of interests as well as any disclosure of confidential information will be handled according to the European Medicines Agency breach of trust procedure for competing interest of and disclosure of confidential information by scientific committees' members and experts.

7.6. Code of conduct

SAGs/AHEG members and all other attendees to their meetings and activities shall abide by the principles set out in the EMA Code of Conduct.

7.7. General provisions

SAG/AHEG members and chairpersons as well as 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[1].

When participating in meetings or other fora on behalf of the Committee, SAG/AHEG members shall get prior agreement from the Committee and ensure that the views expressed are those of the Committee. When they are not participating on behalf of the Committee, they shall make clear that the views expressed are their own, in compliance with EMA Policy 0029.

When preparing a scientific publication related to EMA activities, SAG/AHEG members shall comply with EMA Policy 0015.

[1] Article 76 of Regulation 726/2004.