EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Mandate, objectives and rules of procedure for the CHMP Safety Working Party (SWP)

1. General considerations

According to the Committee for Medicinal Products for Human Use (CHMP) rules of procedure, 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 of applications, or drafting of guidelines to the relevant working parties. The tasks identified by the Committee should be included in the work plan of each working party to be adopted by the CHMP.

The Safety Working Party (SWP) is therefore established to provide recommendations to the Committee on all matters relating directly or indirectly to non-clinical safety aspects and to perform the tasks described under section 2.

2. Mandate and objectives

The SWP is established to provide recommendations to the Committee on all matters relating directly or indirectly to non-clinical safety aspects including, but not limited to the tasks defined below:

- Support to dossier evaluation on non-clinical safety related matters at the request of the CHMP;
- At the request of the CHMP, provision of scientific advice on general and product specific matters related to non-clinical safety aspects;
- Contribution to the Advices produced by the Scientific Advice Working Party of the CHMP;
- Assessment of non-clinical safety findings raised post authorisation at the request of the CHMP;
- Preparation, review and update of guidelines;
- Setting up of drafting groups (see point 6.4.);
- Liaison with other working parties on non-clinical safety related matters;
- Focus and catalyst for training on non-clinical safety assessments to develop a common approach for the evaluation of non-clinical documentation;

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- On request, advice, through the CHMP, to other Committees and working parties/working groups on non-clinical safety related matters;
- Advice, through the CHMP, to the European Commission on non-clinical safety related issues;
- Liaison with interested parties (see point 6.9.);
- International cooperation on non-clinical safety related matters;
- Contribution to non-clinical safety related workshops and training.

3. Composition and rules of participation

The SWP is composed of experts selected from the European experts list according to their specific expertise.

All members of the CHMP are invited to nominate 1 expert to be member of the SWP (one member per Member State).

The final composition shall be agreed by CHMP.

Membership of a working party implies a commitment to participate actively in the work of that working party and to attend the meetings of the working party regularly.

A member may nominate an alternate to participate in those exceptional cases where he/she is unable to attend a meeting.

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

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

Members from other Committees and/or their working parties may participate with the agreement of the chairperson and EMA.

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

Observers from accession countries and Mutual Recognition Agreement (MRA) partners may have standing invitations to participate in certain working parties' meetings.

Specific confidentiality rules will apply to observers.

CHMP members are encouraged to take an active role in the activities of the SWP.

4. Meeting frequency

The SWP shall meet up to 11 times per year (virtually or face-to-face) in accordance with the adopted work plan. The dates of the meetings shall be included in the work plan of the SWP.

Drafting Group meetings may be convened on specific topics approximately 3 times a year per topic or in the margins of plenary meetings to complement the written procedure.

5. Duration of activity (in the case of temporary working parties)

Not applicable.

6. Rules of procedure

6.1. Responsibilities of chairperson and vice-chairperson(s)

The chairperson, and in his/her absence the vice-chairperson(s), is responsible for the efficient conduct of the business of the working party and shall in particular:

- Plan the work of the SWP 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 SWP;
- Aim to achieve consensus on issues discussed by the SWP;
- Decide in exceptional cases, when a vote is necessary;
- Ensure, together with the SWP and the EMA Secretariat, the regulatory and scientific consistency of the SWP's recommendations;
- Co-ordinate together with the EMA Secretariat the work of the SWP with that of other relevant working parties of the Agency;
- Report on the activities of the SWP to the CHMP or other working party as appropriate.

The vice-chairperson(s) will deputise for the chairperson when the latter is unable to chair either all or part of the working party meeting. On such occasions the chairperson will seek the agreement of the vice-chairperson(s) as early as possible, prior to the meeting and the EMA Secretariat shall be informed immediately.

6.2. Election of chairperson and vice-chairperson(s)

The chairperson and vice-chairperson(s) of the SWP shall be elected by the members of the CHMP for a term of three years, which may be renewed once. A Committee member, an alternate or a member of the SWP may be elected by the Committee to fulfil this responsibility. Regardless of the time of election of the chairperson, he/she shall be appointed for a term of three years. This appointment may be renewed once.

Nominations should be submitted in writing to the EMA secretariat no later than the start of the CHMP meeting at which election of 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(s), where appropriate, shall follow the same procedure as that for the election of the chairperson and vice-chairperson of the CHMP as stated in Article 3, paragraphs 1 to 6, of the Rules of Procedure of the CHMP.

6.3. Organisation of meetings and reporting arrangements

- The SWP shall meet regularly at the Agency.
- The dates of meetings are decided on an annual basis in consultation with the SWP and the CHMP.
- The meetings will be held and minuted in English.
- The draft agenda for every meeting shall be circulated, together with the related documents, by the EMA Secretariat, in consultation with the chairperson, at least 14 calendar days before the meeting.
- When a member of the SWP is unable to participate in a meeting, part of meeting, or discussion topic due to a conflict of interest, he/she must inform the Secretariat in advance in writing.
- The SWP may identify and propose topics for its consideration. Any proposal for a guideline, providing adequate justification, shall be transmitted to the CHMP for endorsement and shall be preceded by a concept paper to be endorsed by the CHMP.
- Any recommendation from the working party shall be transmitted to the relevant Committee for adoption.
- When considered appropriate by the SWP, oral presentations by companies can be made during working party meetings on matters directly related to the activities of the working party, following agreement of the CHMP.
- The SWP shall prepare an annual work plan for adoption by the CHMP, which shall include topics identified in accordance with point 6 above and any specific tasks identified by the Committee. The work plan shall be regularly reviewed and updated as necessary with the agreement of the CHMP.
- Agenda and minutes of the meetings of the SWP should be circulated to the CHMP.
- The chairperson will be invited to attend plenary Committee meetings to report on the activities of the SWP and ensure liaison with the work of the CHMP.
- The mandate of the SWP shall be agreed by the CHMP. It shall be reviewed, at least at the start of each new term of the committee.

6.4. Drafting groups

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

Drafting groups will report to the SWP in direct line.

6.5. Participation of experts in meetings

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

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

6.6. Guarantees of independence

The members of the SWP 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 interests. The Declarations of Interests of the SWP's members and alternates shall be made available on the Agency's website.

Members of the working party 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 made available to the public.

The specific provisions for handling Declarations of Interests and confidentiality undertakings as defined in the European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (EMA/626261/2014) are applicable to members of the SWP and experts participating in SWP activities.

6.7. Code of conduct

Members of the SWP and experts participating in EMA's activities shall abide by the principles set out in the 'EMA Code of Conduct' (EMA/385894/2012).

6.8. EMA Secretariat

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

- Provide technical and scientific support to rapporteurs and other members of the SWP;
- Provide legal, regulatory and scientific support to the SWP;
- Prepare and co-ordinate the work of the SWP in consultation with the chairperson(s);
- Ensure, if appropriate, that the timelines laid down by EU legislation for the adoption of the opinions are complied with;
- Organise meetings of the SWP ensuring timely circulation of meeting documents;
- Facilitate the necessary contacts between the SWP, CHMP and other concerned working parties and/or scientific advisory groups;
- Ensure adequate co-ordination of the work carried out within the SWP, the EMA scientific committees and other concerned working parties and/or scientific advisory groups;
- Contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents/recommendations of the SWP in cooperation with the chairperson or vice-chairperson, as appropriate;
- Prepare the agenda, table of actions and minutes of the SWP meetings in consultation with the chairperson(s);
- Communicate when necessary any Committee recommendations relevant to the SWP to interested parties;
- Contribute to the identification of experts.

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

6.9. Contacts with interested parties

Where relevant, the SWP will establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations, health-care professionals' associations or other interested parties.

Draft guidelines and general regulatory developments will be subject to public consultation of all interested parties (industry, health care professionals, patients/consumers or other).

When considered appropriate by the SWP, oral presentations by interested parties can be made during working party meetings in earlier stages of development of guidelines. The SWP may also meet with interested parties to discuss general matters or specific scientific issues with the agreement of the CHMP and under specific conditions to be agreed by the CHMP.

In any case, the SWP shall neither conduct any deliberations nor reach any formal decisions in the presence of interested parties.

Before any consultation session, interested party representatives and SWP 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 SWP chairperson and circulated by the EMA Secretariat.

6.10. General Provisions

The members of the SWP 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 CHMP, members shall ensure that the views expressed are those of the CHMP.

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