



The European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCEPP)

Mandate of the ENCePP Steering Group (SG)

1. Role of the Steering Group	2
2. Specific Tasks and Duties	2
3. Steering Group Membership	2
3.1. Roles required.....	2
3.2. Composition	2
3.3. Ex-officio members.....	3
4. Rules of Procedure	3
4.1. Methods of work.....	3
4.2. Channels of Communication.....	3
4.3. Consultation Process.....	4
4.4. Review of terms of reference and mandate.....	4
4.5. Conflicts of interest and code of conduct	4
4.6. Remuneration of expenses and time	4
5. Selecting Members	5
5.1. Nomination of ENCePP representatives.....	5
5.2. Election Process	5
5.3. Term of Service.....	5



1. Role of the Steering Group

The 'ENCePP Steering Group' was established to assist the European Medicines Agency (EMA) in the implementation of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). It defines and safeguards the objectives and principles of ENCePP and decides on operational tasks of the network. The Steering Group is the highest authority of ENCePP and thus its final decision making body. It acts as adjudicator in case of discrepancies or complaints in the context of the ENCePP network.

2. Specific Tasks and Duties

Specifically, the tasks of the Steering Group include, but are not limited to, the following:

- Identification of the network's priority actions
- Approval of the network's Work Programme
- Oversight of the network's activities
- Adjudicator in case of discrepancies or complaints in the context of the ENCePP network
- Ongoing review of the ENCePP working model and working group structure, and assistance to the EMA in making any necessary revisions
- Champion and promote ENCePP as appropriate
- Contribute to the ongoing analysis aimed at measuring the impact of ENCePP on current research practices and on regulatory activities

3. Steering Group Membership

3.1. Roles required

The Steering Group shall consist of 16 members, including the Chair who will be a representative from the EMA, and deputy Chair who will be one of the ENCePP partner representatives elected to the Steering Group. The ENCePP Secretariat will fulfil the role of the Steering Group secretariat. The responsibilities of the Steering Group Chair include convening meetings, preparing the agenda and ensuring that meetings are properly conducted. The deputy Chair takes the role of the Chair when the Chair is not present. The Steering Group secretariat co-ordinates and records all Steering Group-related activities including distributing the agenda, attending the meetings, logging declared Conflicts of Interest and preparing minutes of the Steering Group's meetings.

3.2. Composition

The composition of the Steering Group should provide a good balance of expertise (e.g. regulatory, conduct of pharmacoepidemiological studies, patients, healthcare professionals, ethical issues). It shall consist of:

- 6 representatives from ENCePP partners (including deputy Chair)
- 3 representatives from EMA (including Chair)
- 1 representative from the Heads of Medicines Agencies

- 1 representative from the Committee for Medicinal Products for Human Use
- 1 representative from the Committee for Orphan Medicinal Products
- 1 representative from the Pharmacovigilance Risk Assessment Committee
- 1 representative from the EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations
- 1 representative from the International Society for Pharmacoepidemiology (ISPE)
- 1 representative from the International Society of Pharmacovigilance (ISoP)

3.3. Ex-officio members

The Steering Group shall include two ex-officio members with observer status: 1 from an international regulatory agency, and 1 representative from the pharmaceutical industry (EFPIA – European Federation of Pharmaceutical Industries and Associations).

4. Rules of Procedure

4.1. Methods of work

- Membership of the Steering Group implies a commitment to attend its meetings regularly and to participate actively in its work. In cases where a member is unable to attend a meeting, he or she may not nominate a replacement.
- The Steering Group shall meet at least 4 times per year. The chair is responsible for convening meetings. The chair may convene additional meetings.
- A minimum attendance (quorum) of 11 members (i.e. two thirds) is mandatory for any decision making to take place.
- Meetings will be either face-to-face, virtual [*Adobe Connect*] or by teleconference.
- The Steering Group secretariat is responsible for ensuring that the agenda of the meeting and supporting documentation is made available to the members in good time before meetings.
- Business will be conducted by careful and considered deliberation leading to consensus where possible. Where consensus is not achieved recommendations shall be decided by majority vote of members voting on the question. In the case of a tied vote the person acting as Chair shall be entitled to a casting vote.
- The Steering Group may decide to ask parties who are not members of the Steering Group to participate in a meeting so that they can provide relevant information, material or knowledge to the Steering Group. These co-opted experts may be representatives from non-EU regulators, learned societies, or experts with a relevant background (e.g. legal, scientific, ethical, etc).
- The Steering Group may establish working groups and refer to them any matter in the Steering Group's mandate. Each working group shall include at least one Steering Group sponsor and any number of co-opted ENCePP partners.

4.2. Channels of Communication

The Steering Group secretariat reports within 2 weeks of each Steering Group meeting to the ENCePP partners.

The Steering Group Deputy Chair makes a report to each ENCePP plenary meeting.

4.3. Consultation Process

The Steering Group will determine whether to consult the ENCePP network on particular issues, and if it decides to consult, will determine the form and method of consultation. Consultation might involve, but is not restricted to, plenary meetings of ENCePP, focus groups, questionnaires and surveys, workshops or web-based public consultation.

The Steering Group may consider for discussion proposals submitted by the ENCePP Plenary.

4.4. Review of terms of reference and mandate

The ENCePP Plenary shall review the terms of reference and mandate of the Steering Group at least every 3 years, taking into account any recommendation from the Steering Group for modifications. The Steering Group may at any time ask the Plenary to consider a recommendation for changes to its terms of reference and mandate.

4.5. Conflicts of interest and code of conduct

Individual Steering Group members will be included in the EMA's Experts Database, following official nomination by the Executive Director (or responsible EMA Manager under delegation from the Executive Director).

The individual Steering Group members shall undertake to act in the interest of the network. Before the start of the first meeting they shall make a declaration of their interests (to be renewed annually or when a new conflict arises) and should not have undeclared conflicting commitments or responsibilities, which could affect their impartiality. At the beginning of each meeting, they shall declare any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda and these shall be recorded in the minutes. Based on the information provided by the Steering Group member, the ENCePP Secretariat will evaluate whether a declared interest constitutes a conflict.

Furthermore, at the beginning of their mandate, members of the Steering Group shall sign a confidentiality undertaking and shall treat all information and documents indicated as confidential, to which they acquire access as a result of their participation in ENCePP activities, under conditions of strict confidentiality and discretion. This does not apply to confidential information which:

- is, at the time of communication, in the public domain;
- after the communication, is placed in the public domain by publication or otherwise;
- is obtained from a Third Party not in breach of any obligation of confidentiality; or
- is known by the recipient Third Party prior to the date of the communication.

When participating in fora and mentioning either ENCePP or their SG role or status, Steering Group members shall make clear that the views expressed are their own views and not necessarily those of ENCePP.

4.6. Remuneration of expenses and time

Meetings of the Steering Group are convened at the EMA premises in London, travel (from Europe) and accommodation expenses incurred in connection with this meeting will be reimbursed together with a

daily allowance to cover meals and all local transport (including return transport from the airport), according to the existing EMA rules.

5. Selecting Members

5.1. Nomination of ENCePP representatives

The ENCePP partners shall be informed about the election no later than 4 weeks before the meeting at which members will be elected. A description of the role and functions of the Steering Group and the rules of the election procedure shall be provided no later than 1 month prior to the election.

Applications for Steering Group membership should be submitted in writing to the ENCePP Secretariat no later than one week before the date of the ENCePP plenary meeting at which the election is to take place.

At the time of application, candidates shall submit a brief résumé, including the motivation for standing, in support of their candidature. The ENCePP Secretariat shall circulate the list of candidates and their résumés in advance of the ENCePP plenary meeting at which the election is to take place.

Candidates may stand for election in absentia.

5.2. Election Process

Candidates elected from ENCePP to the Steering Group will be elected by and from amongst ENCePP partners during ENCePP plenary meetings.

Each ENCePP centre present at the plenary meeting is eligible to vote and can vote for six candidates. If more than one representative of an individual ENCePP centre is present at the meeting, the centre may only submit one ballot paper.

In cases when the ENCePP centre is not represented at a plenary meeting the proxy may be given to another ENCePP centre that will vote on its behalf. This needs to be notified to the ENCePP Secretariat in writing no later than one week before the meeting.

The election of the ENCePP Steering Group members shall be based on a simple majority vote and shall be performed by secret ballot. The six representatives receiving most votes will be chosen. In case of a tie another round of voting may be necessary.

A maximum of 2 incumbents may be re-elected to the Steering Group.

5.3. Term of Service

Members of the Steering Group shall be elected to serve a term of three years.

Terms shall begin at the close of the meeting at which they are elected.

Representatives of EMA, the relevant stakeholders as identified by the EMA, and the ex-officio members are appointed by their respective organisations for the duration of the term of service of the Steering Group (three years), and may be renewed.

The deputy Chair shall be elected at the inaugural meeting of the Steering Group, based on a simple majority vote.

In the event of an elected Steering Group member resigning during his tenure, a call for nominations for election for the vacated position will be held.