



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

Mandate of the ENCePP Steering Group (SG)

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1. Role of the Steering Group

The 'ENCePP Steering Group' was established in 2010 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;
- Ongoing review of the ENCePP working model and working group structure, and assistance to the EMA in making any necessary revisions;
- Contribute to the ongoing analysis aimed at measuring the impact of ENCePP on current research practices and on regulatory activities;
- Adjudication in case of discrepancies or complaints in the context of the ENCePP network;
- Promotion of ENCePP as appropriate.

3. Steering Group Membership

3.1. Roles required

The Steering Group shall consist of 17 members, including a co-chair who will represent the EMA, and a co-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 co-chairs include convening meetings, preparing the agenda and chairing meeting ensuring that meetings are properly conducted. The ENCePP 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 co-chair)
- 3 representatives from EMA (including co-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)
- 1 representative from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)

3.3. Ex-officio members

The Steering Group shall include ex-officio members with observer status:

- From international regulatory agencies (e.g., U.S. Food and Drug Administration (FDA), Health Canada)
- Representatives from the pharmaceutical industry (EFPIA – European Federation of Pharmaceutical Industries and Associations – 1 observer and 1 deputy observer)

4. Rules of Procedure

4.1. Methods of work

- a) Membership of the Steering Group implies a commitment to attend the meetings of the Steering Group and to actively participate in discussions during meetings and in the different activities and deliverables.
- b) The Steering Group shall meet at least 2 times per year. The co-chairs are responsible for convening meetings. The co-chairs may convene additional meetings of the full Steering Group or working subgroups as needed.
- c) Meetings will be either face-to-face or virtual.
- d) The ENCePP Secretariat will circulate the agenda of the meeting and the supporting documents before the meetings.
- e) 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 co-chairs shall be entitled to a casting vote.
- f) 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.).
- g) The Steering Group may establish working groups and refer to them any matter relevant to 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 ENCePP Secretariat reports within 2 weeks of each Steering Group meeting to the ENCePP partners.

The Steering Group co-chairs report on ENCePP SG activities to each ENCePP plenary meeting.

4.3. Consultation Process

The Steering Group will determine whether to consult the ENCePP network on particular matters, 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 co-chairs may take the initiative for such consultations.

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

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 interests¹ (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.

¹ [European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts](#)

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 for face-to-face meetings

When the meetings of the Steering Group are convened at the EMA premises in Amsterdam, 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 8 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 4 weeks 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.

In case the ENCePP Plenary is held virtually, the election is organised electronically ahead of the plenary meeting or on the day of the plenary by using an electronic voting system.

5.2. Election Process

In case of face-to-face meetings, 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.

In case of virtual plenary meetings, the election is held before the meeting electronically or on the day by using an electronic voting system.

5.3. Term of Service

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

Terms shall begin at 1 January of the following year.

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 co-chair from the ENCePP partners 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.