



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 divergences and complaints within the ENCePP network.

2. Specific Tasks and Duties

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

- Development and approval of the network's Work Plan, including identification of priority actions ;
- Oversight of the network's activities;
- Ongoing review of the ENCePP working model and working group structure and mandate, and assistance to the EMA in making any necessary revisions;
- Contribution to the ongoing analysis aimed at measuring the impact of ENCePP on current research practices and on regulatory activities;
- Adjudication in case of divergences or complaints within the ENCePP network;
- Promotion of ENCePP as appropriate.

3. Steering Group Membership

3.1. Roles required

The Steering Group shall consist of 27 members, including a co-chair representing the EMA, and a co-chair representing the ENCePP partners and elected to the Steering Group. The ENCePP Secretariat fulfils 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 coordinates 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 (including but not limited to regulatory, conduct of pharmacoepidemiological studies, patients, healthcare professionals, ethical issues). It shall consist of:

- Up to 10 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 (CHMP)
- 1 representative from the Committee for Orphan Medicinal Products (COMP)
- 1 representative from the Pharmacovigilance Risk Assessment Committee (PRAC)

- 1 representative from the EMA Patients and Consumers Working Party (PCWP)
- 1 representative from the Methodology Working Party (MWP)
- 1 representative from European HTA bodies
- 1 representative from the European Commission (EC)
- 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)
- 1 representative from the pharmaceutical industry
- Representatives from international regulatory agencies (1 for the U.S. Food and Drug Administration (FDA), and 1 for Health Canada)

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 (at least 50% of the annual meetings) and to actively participate in discussions during meetings and in the different activities and deliverables of the Work Plan.
- b) The Steering Group shall meet at least twice per year. The co-chairs are responsible for convening meetings. The co-chairs may convene additional meetings of the Steering Group as needed.
- c) Meetings will be either face-to-face or virtual.
- d) The ENCePP Secretariat circulates the agenda of the meeting and the supporting documents before the meetings (ideally, a week before the meeting date).
- e) Business is 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 special interest groups, and refer to them for any matter relevant to the Steering Group's mandate and Work Plan. Each working group and special interest 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 3 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 determines whether to consult the ENCePP network on particular matters, and if it decides to consult, determines 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 the mandate

The ENCePP Plenary shall review the 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 mandate.

4.5. Conflicts of interest

The Steering Group members shall undertake to act in the interest of the network, bearing in mind any specific interests which could be considered to be prejudicial to their independence with respect to the agenda of the meetings and the overall ENCePP Work Plan.

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 are reimbursed together with a daily allowance to cover meals and local transport (including return transport from the airport), according to the existing EMA rules.

5. Steering Group Membership

5.1. Election process

The ENCePP Secretariat will inform the ENCePP partners about the election before the end of each mandate of the Steering Group, together with a description of the role and functions of the Steering Group and the rules of the election procedure.

Applications for membership should be submitted in writing to the ENCePP Secretariat according to the indicated timelines. Applicants shall submit a brief résumé, including their motivation for standing, in support of their application.

The election is organised via an electronic survey.

Each ENCePP centre is eligible to vote and can vote for up to ten candidates. Only one application per centre is accepted. Applicants must be registered in the [HMA-EMA Catalogues](#) as ENCePP Partners.

The composition of the ENCePP Steering Group should provide a good balance of expertise. To ensure some degree of representativeness, a quota of seats per membership category is applied. Even if each

ENCePP Partner will be able to vote for the 10 members to be elected, two third of the seats (7 out of 10) will be reserved for public institutions - universities, hospitals, government agencies, charities / national and international networks - and one third (3 out of 10) for CROs & consultants / data sources.

The election of the ENCePP Steering Group members is based on a simple majority vote. The ten representatives receiving most votes will be selected, taking into account the above quota rules. In case of a tie another round of voting may be necessary.

A maximum of 4 incumbents may be re-elected to the Steering Group at each mandate.

Only members of EU centres can apply. Applications after deadline will not be accepted.

The composition of the new Steering Group is announced during the ENCePP Plenary meeting.

5.2. Term of Service

Members of the Steering Group are elected to serve a term of three years. The terms begin at 1 January of the following year.

Representatives of EMA, the relevant stakeholders as identified by the EMA, and other 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 representing the ENCePP partners shall be elected at the kick-off meeting of the new Steering Group, following expression of interest and 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.

5.3. Co-chairs of the Steering Group

The Steering Group has two co-chairs, representing EMA and the ENCePP partners, respectively.

- The EMA co-chair is a staff member of the EMA, nominated by the EMA Secretariat.
- The ENCePP partner co-chair is selected amongst the elected representatives from ENCePP partners (n=10) on the Steering Group. The candidates should apply by sending an expression of interest to the ENCePP Secretariat before the first meeting of the new term. In case several Steering Group members express interest, a formal vote will take place. All SG members have one equal vote. If there is equality of votes, a new vote is proposed. If there is only one candidate, the Steering Group members shall confirm that they agree on the nomination.