EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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ENCePP Secretariat

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Mandate, Objectives and Rules of Procedure for the ENCePP Plenary

1. General Considerations

The European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCePP) is a European Medicines Agency (EMA)-led initiative that brings together expertise and resources in pharmacoepidemiology and pharmacovigilance across Europe. ENCePP is aimed at further strengthening the monitoring of the benefit:risk balance of medicinal products. This will be achieved by facilitating the conduct of high quality, multi-centre, independent post-authorisation studies with a focus on observational research. ENCePP develops methodological standards and governance principles and provides a platform for collaboration.

ENCePP is comprised of representatives from research centres and networks that have joined the network referred to as 'ENCePP partners'. Participation in ENCePP and all related activities is done on a voluntary basis.

ENCePP partners are encouraged to publish the following statement on their websites (publication of the statement is linked to the use of the ENCePP logo in publications, presentations etc.):

> *We are a partner centre of the ENCePP scientific network which is coordinated by the European Medicines Agency. We are dedicated to excellence in research by adhering to the ENCePP Guide on Methodological Standards and promoting scientific independence and transparency. We register studies in the EU PAS Register, a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies.*

2. Mandate and Objectives

2.1. Purpose

All discussions shall remain non-product specific. The main purposes of ENCePP are:

- to provide a platform for the exchange of scientific and operational information and for collaboration between the participating centres and networks, i.e.:

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  - exchange information and experience in the conduct of research in pharmacoepidemiology
  - in the spirit of the ENCePP partnership, each ENCePP centre is expected to actively work within each calendar year on at least one study which is registered with the EU PAS Register
  - discuss and elaborate standards and best practices for research
  - share best practice and support capacity building
  - foster further collaboration between partners
  - provide advice to the EMA on scientific and operational aspects on pharmacoepidemiology and pharmacovigilance on an ad hoc basis
  - provide a forum for discussion of scientific issues at the forefront of pharmacoepidemiology and pharmacovigilance
  - disseminate information on research funding opportunities
- to provide a forum to elaborate proposals to the ENCePP Steering Group;
- to provide a forum for the election of representatives to the ENCePP Steering Group.

2.2. Interaction between the Plenary and the ENCePP Steering Group

The Deputy Chairperson of the Steering Group makes a report to each ENCePP Plenary meeting, and the Plenary may submit suggestions pertinent to the network's activities for consideration by the Steering Group.

The Steering Group will determine whether to consult the ENCePP Plenary on particular issues and will determine the form and method of consultation. Such consultation might involve - but is not restricted to - plenary meetings of ENCePP.

2.3. International Co-operation

Observer participation from non-EU organisations/regulators is encouraged to foster international collaboration and harmonisation.

3. Composition and Rules of Participation

3.1. Composition

ENCePP partners join the network by adding their own information directly to the ENCePP Research Resources Database.

In line with the aims of increasing capacity to conduct research and fostering collaboration, the network considers population of the 'Registry of Data Sources' as crucial. Adding a data source to the ENCePP 'Registry of Data Sources' of itself does not equate to joining the network and becoming an ENCePP partner. However, an individual or group that adds a data source can become a partner by additionally adding themselves as a centre or network, if appropriate.

In addition:

- Representatives from other stakeholders identified by the EMA may attend the ENCePP Plenary meetings. These may include: EMA scientific committees, working parties and groups, the European Commission and other EU agencies, National Competent Authorities, learned societies and other organisations and centres.

- The industry observer on the Steering Group may attend the Plenary.
- Observers from European Union Accession Countries have standing invitations to attend the meeting.
- Observers from non-EU regulatory agencies may attend by invitation from the EMA (see “2.3. International Co-operation”).

3.2. Rules of Participation

Pre-registration requests will be sent to all “main contacts” (as indicated by the centres in the ENCePP Resources Database), asking for nomination of the person who shall receive an invitation to the ENCePP Plenary meeting. Consequently, official invitations will be sent directly to the nominated invitee.

Only representatives from non-for-profit organisations will be reimbursed. Subject to the availability of necessary funds, reimbursement of travel expenses will be granted to a limited number of representatives confirming their attendance at the plenary on a first-come, first-served basis. Only one representative per research centre or network will be eligible for reimbursement. If a centre appears in the ENCePP Resources Database both as a research centre and a maintainer of a data source, it will only be considered for reimbursement once.

ENCePP partners not eligible for reimbursement, and additional representatives from a reimbursable centre or network, may attend the ENCePP Plenary meeting at their own expense.

Representatives from the European Commission, other EU agencies, non-EU regulatory agencies and industry shall not be reimbursed.

4. Meeting Frequency

The ENCePP Plenary shall meet at least once per year. The date(s) of the meeting(s) shall be announced at the beginning of each calendar year on the ENCePP website. In addition, extraordinary meetings may be organised.

5. Rules of Procedure

5.1. ENCePP Secretariat

The ENCePP Secretariat organises and supports the ENCePP Plenary meeting. This includes the following:

- Ensure timely circulation of pre-registration information and dispatch of invitations to the appointed invitees;
- Prepare the meeting agendas in consultation with the ENCePP Steering Group;
- Prepare and co-ordinate the Plenary meeting in consultation with the Steering Group;
- Ensure timely circulation of meeting documents;
- Provide support during the meetings;
- Prepare the minutes of the meetings;
- Ensure, if appropriate, that the rules of the election process for the ENCePP Steering Group are adhered to.

The Executive Director of the EMA and members of the EMA Secretariat may attend all meetings of the ENCePP Plenary.

5.2. Organisation of ENCePP Plenaries and Reporting Arrangements

- The ENCePP Plenary shall meet in London.
- The Secretariat of the ENCePP Plenary is provided by the EMA (ENCePP Secretariat).
- The meeting will be chaired by the EMA.
- The meetings will last one day.
- The meetings will be held and minuted in English, without interpretation.
- The draft agenda for each meeting shall be published on the ENCePP website by the ENCePP Secretariat at least 2 weeks before the meeting.
- The Deputy Chairperson of the ENCePP Steering Group and the Chairperson of each ENCePP Working Group (or a nominated replacement) will make a report to each ENCePP Plenary meeting. The terms of reference and mandate of the ENCePP Steering Group shall be reviewed regularly, taking into account any recommendation from the Steering Group for modifications.

5.3. Election of Steering Group Members

See document Mandate of the ENCePP Steering Group, Item 5. “Selecting Members”.

5.4. Working Groups

The ENCePP Steering Group may establish working groups or ad hoc task forces including at least one Steering Group sponsor and refer to them any matter in the Steering Group’s mandate. Volunteers will be invited from the Plenary.

Maximum membership from the ENCePP Plenary per working group shall be limited. Members shall meet regularly in line with work plan deliverables. Subject to the availability of necessary funds, these meetings will be either face-to-face, virtual (Adobe Connect) or by teleconference. Which members are invited to face-to-face meetings will depend on responsibilities and deliverables assigned within the working group. Reimbursement of travel expenses will be granted to a limited number of representatives from non-for-profit organisations.

Membership in Working Groups implies a commitment to participate actively in the development of deliverables according to the adopted work plan. In cases where a working group member is unable to attend a meeting, he or she may nominate a replacement from the same ENCePP centre or network.

To allow new members to participate and in light of busy schedules, existing members shall be requested to periodically express their commitment to continue active participation. Individuals wishing to join a working group or contribute to particular deliverables should express their interest to the ENCePP Secretariat. The ENCePP Secretariat in consensus with the Working Group Chair may propose new members to ensure progress of work plan deliverables.

Working Group Chairs shall be appointed by consensus from amongst the members of the working group.

Working Group Chairs shall provide regular reports on the working groups’ activities to the ENCePP Steering Group in line with work-plan deliverables. These will be published on the ENCePP website.

5.5. Special Interest Groups

ENCePP fosters the development of internal networks ("Special Interest Groups") based around a shared interest in particular topics. The topics of these special interest groups shall be based on suggestions from the ENCePP community, but subject to agreement by the ENCePP Steering Group.

Special interest groups shall have no maximum membership and be open to interested representatives from any ENCePP centre or network. They shall meet regularly either by teleconference or virtual means (Adobe Connect). Face-to-face meetings may be organised in the margins of ENCePP Plenary meetings.

Special interest group Chairs shall report on their group's activities to the ENCePP Steering Group.

5.6. Participation of Experts in Meetings

When appropriate, additional experts in specific scientific or technical fields may be invited to attend and present at ENCePP Plenary meetings. These experts will be selected by the ENCePP Secretariat taking account of suggestions from the Plenary and in consultation with the ENCePP Steering Group.

5.7. Consultations and Contacts with Interested Parties

Pharmaceutical industry, healthcare professionals, patients/consumers or other interested parties will have the opportunity to comment in writing during public consultation of documents. Results of such consultations will be presented to the ENCePP Plenary and be made public.

Additional collaboration with interested parties will be notified to the ENCePP Plenary and undertaken as considered appropriate, depending on the issue being raised, and in consultation with the ENCePP Steering Group.