



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



European Network of Centres for  
Pharmacoepidemiology and  
Pharmacovigilance

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# 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 to bring together expertise and research resources in the fields of pharmacoepidemiology and pharmacovigilance across Europe. The aim of ENCePP is to further strengthen the post-authorisation monitoring of medicinal products in Europe by facilitating the conduct of high quality, multi-centre, independent post-authorisation studies focusing on safety and benefit:risk balance. ENCePP shall continue to develop standards, provide information resources, foster capacity-building and provide a platform for collaboration in pharmacoepidemiology and pharmacovigilance research in Europe.

The ENCePP Plenary 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.

## 2. Mandate and Objectives

### 2.1. Purpose

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

- to provide a platform for the exchange of scientific and operational information and for collaboration between the participating centres and networks, i.e.:
  - exchange information and experience in the conduct of research in pharmacoepidemiology
  - 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 for adoption.

The Steering Group will determine whether to consult the ENCePP Plenary on particular issues, and if it decides to consult, 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***

The ENCePP Plenary is composed of ENCePP partners. ENCePP partners join ENCePP by adding their own information directly to the ENCePP Research Resources Database via the ENCePP web-portal.

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.
- A representative from industry (EFPIA) may attend the meeting as an observer.
- 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 "c. 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.

Subject to the availability of necessary funds, reimbursement of travel expenses will be granted to the first 55 non-for-profit organisations confirming their attendance at the plenary. 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 (EFPIA) shall not be reimbursed.

## **4. Meeting Frequency**

The ENCePP Plenary shall meet at least once per year. The dates of the meetings shall be included in the ENCePP Work Plan and 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 is composed of EMA staff and shall provide support to the ENCePP Plenary. 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 organisational 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 normally last one day.
- The meetings will be held and minuted in English, without interpretation.
- The draft agenda for each meeting shall be circulated by the ENCePP Secretariat normally 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 at least every two years, 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 member and refer to them any matter in the Steering Group's mandate. Volunteers will be invited from the Plenary.

### ***5.5. 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.

### ***5.6. 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.