European Medicines Agency

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MANDATE, OBJECTIVES AND RULES OF PROCEDURE FOR THE ENCEPP PLENARY

I. GENERAL CONSIDERATIONS

The European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCePP) is a European Medicines Agency (EMEA)-led initiative to bring together the available expertise and research experience in the fields of pharmacoepidemiology and pharmacovigilance located across Europe in a Network of Excellence, comprising research and medical-care centres, healthcare databases, electronic registries and existing networks. 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 develop standards, provide information resources, foster capacity building and provide a platform for collaboration in pharmacoepidemiology and pharmacovigilance in Europe.

The Plenary of ENCePP is the meeting of representatives from research centres and data providers that are included in the ENCePP database of resources.

II. MANDATE AND OBJECTIVES

a. Purpose

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

- to provide a platform for the exchange of scientific and operational information as well as experiences and collaboration between the participating centres and networks, i.e.:
  - exchange of information and experience in the conduct of research in pharmacoepidemiology
  - discuss and elaborate standards and best practices for research
  - sharing best practice and support capacity building
  - foster further collaboration between partners
  - provide advice to the EMEA 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
  - dissemination of 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.

b. Interaction between the Plenary and the ENCePP Steering Group

The Vice-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.

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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.

c. International Co-operation

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

III. COMPOSITION AND RULES OF PARTICIPATION

a. Composition

The ENCePP Plenary is composed of representatives from research centres and data providers that are included in the ENCePP database of resources. It is the responsibility of the research centres and data providers to populate the ENCePP database of resources with their own information via an electronic data entry form.

- Representatives from other stakeholders identified by the EMEA may attend the ENCePP Plenary meetings. These may include: EMEA 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 EMEA (see "c. International Co-operation").

b. Rules of Participation

Pre-registration requests will be sent to all "main contacts" (as indicated by the centres in the ENCePP database of resources), 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 80 non-for-profit organisations confirming their attendance at the plenary. Only one representative per research centre or data provider will be eligible for reimbursement. If a centre appears in the ENCePP database of resources both as a research centre and a database provider, it will only be considered for reimbursement once.

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

IV. MEETING FREQUENCY

The ENCePP Plenary shall be held 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.

V. RULES OF PROCEDURE

a. ENCePP Secretariat

The ENCePP Secretariat is composed of EMEA 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 EMEA and members of the EMEA Secretariat may attend all meetings of the ENCePP Plenary.

b. Organisation of ENCePP Plenaries and Reporting Arrangements

- The ENCePP Plenary shall meet in London.
- The Secretariat of the ENCePP Plenary is provided by the EMEA (ENCePP Secretariat).
- The meeting will be chaired by the EMEA.
- 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 Vice-Chairperson of the ENCePP Steering Group will be invited to 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.

c. Election of Steering Group Members

See document *Mandate of the ENCePP Steering Group*, Item 5. "Selecting Members".

d. Working Groups

The ENCePP Steering Group may establish working groups including at least one or more of its members and refer to them any matter in the Steering Group's mandate. It may co-opt other ENCePP centres onto such working groups. Volunteers will be invited from the Plenary.

e. 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, in consultation with the ENCePP Steering Group.

f. 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.