EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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ENCePP Secretariat

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

ENCePP Plenary meeting rules

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 by facilitating the conduct of high quality, multi-centre, independent non-interventional studies. 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 EMA-HMA catalogues of data sources and non-interventional studies, a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies.*

2. Mandate and objectives of the ENCePP Plenary

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 and pharmacovigilance
- 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.

2.2. Interaction between the Plenary and the ENCePP Steering Group

The co-chairs of the Steering Group report back on the activities at 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 determines whether to consult the ENCePP Plenary on particular issues and will decides about the form and method of consultation.

2.3. International co-operation

Limited participation from non-EU organisations/regulators to the ENCePP Steering Group is encouraged to foster international collaboration and convergence.

3. Composition and rules of participation

3.1. Composition

The following participants might attend the Plenary:

- ENCePP partners who joined the network
- ENCePP Steering Group members
- EMA staff members

In addition:

- Representatives from other stakeholders identified by the EMA, e.g., EMA scientific committees, working parties and groups, the European Commission and other EU agencies, National Competent Authorities, learned societies
- Additional experts in specific scientific or technical fields - these experts can be selected by the ENCePP Secretariat taking into account suggestions from the ENCePP Steering Group
- Representatives from European Union Accession Countries
- Representatives from non-EU regulatory agencies (see "2.3. International Co-operation")

3.2. Rules of participation

A call for expression of interest is sent to all "main contacts" of the ENCePP partners (institutions and networks that joined ENCePP) available in the EMA-HMA catalogues, asking for nomination of the person (themselves or others from the institution/network) who shall receive an invitation to attend the ENCePP Plenary meeting virtually or in person. Consequently, official invitations are sent directly to the nominated invitees.

Only representatives from non-for-profit organisations can be reimbursed. Subject to the availability of necessary funds, reimbursement of travel and hotel expenses can be granted to a limited number of representatives on a first-come, first-served basis, but also, considering a good balance of stakeholders. Only one representative per research centre or network might be reimbursed.

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. 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 call for expression of interest to the network
- Prepare the meeting agendas in consultation with the ENCePP SG
- Prepare and co-ordinate the Plenary meeting in consultation with the SG
- Dispatch invitations to appointed invitees
- Ensure timely circulation of meeting documents (if necessary ahead of the meeting)
- Provide support during the meeting
- Prepare the report after the meeting

5.2. Organisation of ENCePP Plenaries and Reporting Arrangements

The ENCePP Plenary can be either virtual or hybrid meeting. In case of face-to-face attendance, the location of the meeting is Amsterdam. The meeting lasts maximum one day.

The Secretariat of the ENCePP Plenary is provided by the EMA (ENCePP Secretariat). The meeting is chaired by the ENCePP SG co-chairs.

The draft agenda for the meeting shall be published on the ENCePP website by the ENCePP Secretariat before the meeting. All documents (including meeting minutes) are prepared in English, without interpretation.

The co-chairs of the ENCePP SG and the chairperson of each ENCePP Working Group (or a nominated replacement) shall report activities back at each ENCePP Plenary meeting. The terms of reference and mandate of the ENCePP SG shall be reviewed regularly, taking into account any recommendation from the SG for modifications.