European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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ENCePP Work Plan 2009

(European Network for Centres of Pharmacoepidemiology and Pharmacovigilance)

I. MAIN GOAL AND OBJECTIVES

The aim is to have in place by the end of the year an **operational network system** that would allow the conduct of **"ENCePP studies"**[1]

Specifically, the main objectives for 2009 are to take the necessary steps and further develop the core aspects of ENCePP to achieve the goal for 2009 as specified above:

Essential deliverables for a functional ENCePP network

- a Checklist of operational research standards covering the core elements and methodological aspects in Pharmacoepidemiology and Pharmacovigilance research
- the Code of Conduct (CoC) setting out rules and requirements for investigators and sponsors/funders when planning/conducting/reporting ENCePP studies in order to achieve a maximum level of transparency and scientific independence in the research process
- establish a Database and start populating it with (i) data sources that can be used for Pharmacoepidemiology and Pharmacovigilance research and (ii) research centres participating in ENCePP. The Inventories shall be made publicly available to facilitate access for possible sponsors/funders of Pharmacoepidemiology and Pharmacovigilance research
- create a Database that can be populated with post-authorisation studies
- agree the mandate, tenure, etc to enable the appointment of the ENCePP Steering Group (to replace the interim governance body ENCIAG)

Other deliverables in the field of Drug Safety Research

- further strengthen the networking facilities of ENCePP and promote exchange of information, experiences and collaboration between the participating centres
- promotion of Pharmacovigilance and Pharmacoepidemiology research in the EU

[1] *Post-authorisation studies* performed according to relevant operational research standards as agreed by ENCePP and in line with the rules on transparency and *independence* as laid down in the *ENCePP Code of Conduct* may be referred to as **"ENCePP study"**. To qualify as **ENCePP study**, [the principle *investigator* or] at least one of the main *investigators* of a study team needs to belong to an entity participating in ENCePP

II. STRATEGY AND ACTION PLAN

The activities, milestones and timelines to achieve the objectives for 2009 are outlined below.

Generate a set of operational research standards covering the core elements and methodological aspects in Pharmacoepidemiology and Pharmacovigilance research

- Together with the Working Group *Research Standards & Guidance* develop a Checklist of Operational Research Standards to be applied to study protocols in order to confirm that essential methodological aspects have been addressed and that the study follows relevant guidance/complies to relevant standards, where applicable, as agreed within ENCePP. The Checklist will be based on the review of selected examples of Pharmacoepidemiological studies and of available guidelines performed by the Working Group.

Finalise the Code of Conduct setting out rules and requirements for investigators and sponsors/funders when planning/conducting/reporting ENCePP studies

- Together with the Working Group *Transparency and Independence* prepare a draft Code of Conduct (CoC) according to previous discussions in the group and the existing backbone document. The CoC should be endorsed by the wider ENCePP membership.
- Launch a public consultation, specifically addressing Industry associations, learned societies, etc.
- Based on the CoC, prepare a Checklist to be applied to studies in order to assess whether these meet the criteria of an "ENCePP study" with regard to independence and transparency.

Establish a Resource Database and initiate its population with (i) data sources that can be used for Pharmacoepidemiology and Pharmacovigilance research and (ii) research centres participating in ENCePP.

- Together with the Working Groups *Data sources and multi-source studies* and *Research centres* identify the data fields and functionalities of the database both for data sources and research centres.
- Together with the EMEA IT Department, establish the Database including a data entry form and a search function allowing the identification of suitable research resources by possible sponsors/funders of studies.

Create a Database that can be populated with post-authorisation studies

- Together with the Working Group *Transparency and Independence* define the data fields for the Registry, which initially should only cover ENCePP studies (non-interventional as well as interventional), taking into account the structure of the EudraCT Database.
- Together with the EMEA IT Department, establish the electronic Database including a data entry form.
- Finalise survey of post-authorisation safety studies (PASS) requested by CHMP between 2007 and 2008. The survey, once completed, should help to estimate the need for these types of studies from a regulatory point of view.

Appointment of the ENCePP Steering Group (to replace the interim governance body ENCIAG)

- Draft a Mandate including terms of reference, specific tasks, rules for the interaction with the CHMP (and PhVWP), details regarding the size, composition and tenure etc.
- Agree on an election procedure to democratically elect the members representing the ENCePP centres in accordance with the ENCePP Implementation Strategy.

The respective current status of the aforementioned Deliverables will be presented to the ENCePP community at the Plenary Meeting in Sept 2009 and at the 2nd ENCePP Meeting in Dec 2009.

The meetings will also serve to adopt relevant documents:

Plenary Meeting on 18 Sept 2009:
- final draft Code of Conduct for public consultation
- Checklist of Operational Research Standards
- Mandate and Election Procedure for Steering Group

ENCePP meeting in Dec 2009:
- final Code of Conduct
- Checklist on Independence & Transparency Rules

In addition, it is anticipated that the members representing the ENCePP centres in the Steering Group will be elected at the meeting in Dec 2009.

Further strengthen the networking facilities of ENCePP and promoting exchange of information and experiences and collaboration between the participating centres

- ENCePP Plenary Meeting (PM) on 18 Sept 2008: At this meeting, representatives of the ENCePP centres and other stakeholders will have the opportunity to meet face-to-face, to get to know each other and to exchange and explore possible collaborations.
- Development of a common format for ENCePP communications. This will include the development of templates for reports, presentations etc including the ENCePP logo and contact details.
- Further development of the ENCePP web page: In order to provide network related information to interested parties, the ENCePP Secretariat will develop a Link/Publication Policy covering any information, links and publications placed on the webpage. In addition, a Q&A document, an electronic contact form for external queries and a separate members-only section should be developed, the latter to also serve as a scientific forum.
- 2nd ENCePP Meeting in Dec 2009: This meeting will either be another Plenary Meeting to allow for the adoption of crucial documents and the election of the ENCePP members of the Steering Group or the Scientific Convention including a session on ENCePP organisation. In order to further strengthen the interaction between the participants an abstract book/poster session introducing the participants and their centres will be promoted.

Promotion of Pharmacovigilance and Pharmacoepidemiology research in the EU

- **Publicise relevant funding opportunities through European funding schemes like the European Commission's Framework Programme (FP) and the Innovative Medicines Initiative (IMI)**
  - Organisation of an information session on the 4th Call of the 7th Framework Programme in the margins of the ENCePP Plenary in September 2009.
  - Provide information on relevant calls which might be of interest to centres participating in ENCePP.