European Medicines Agency

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

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# ENCePP Plenary Meeting

**18 September 2009, 09.30 – 16.30**
**Room 2A**
***Chairperson: Noël Wathion (morning) / Peter Arlett (afternoon)***

## Meeting Report

**Agenda:**

1. General Issues
1.1 Welcome and introductory remarks
1.2 Adoption of Agenda
2. ENCePP: Update on the latest Developments
ENCePP Overview – Work programme 2009 & current status
3. Documents for Discussion and Endorsement by Plenary
3.1 ENCePP Seal – Definition of ENCePP Study
3.1.1 Checklist of operational research standards
3.1.2 Independence & transparency: Draft Code of Conduct for public consultation & Draft Checklist
3.2 Mandate and Election Procedure for ENCePP Steering Group
3.3 Mandate, Objectives and Rules of Procedure for the ENCePP Plenary
4. Presentation and Discussion of Documents by Plenary
4.1 Mock-Up of database of research resources
4.1.1 Data fields & applications for
- data sets used for PEpi and PV research
- research centres participating in ENCePP

4.2 Register for post-authorisation studies
5. Presentation and Discussion (including coffee break 20 minutes)
5.1 Presentation by European Commission/RTD: *FP7 – 4th Call in the field of Drug Safety Research*
5.2 Vaccine Vigilance / H1N1 Pandemic Surveillance
6. Presentation
ENCePP Activities: Outlook Q4/2009 & 2010
Close of the Meeting

**Summary of Discussions**

## 1. GENERAL ISSUES

### 1.1 Welcome and introductory remarks

The Executive Director of the EMEA, Thomas Lönngren, welcomed all participants to the first ENCePP Plenary of 2009, followed by a welcome by Noël Wathion, Chairperson of the morning session.

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The Chairperson was able to welcome a number of ENCePP centres who had recently joined the network and were attending the Plenary for the first time and who were asked to briefly introduce themselves. Present were also a number of visitors who had attended the H1N1 vaccines pharmacovigilance strategy meeting which had taken place at the EMEA during the previous day.

**1.2 Adoption of Agenda**
The draft agenda was adopted without changes.

## 2. ENCEPP: UPDATE ON THE LATEST DEVELOPMENTS

Henry Fitt gave a short overview presentation detailing the 2009 ENCePP work programme and its current status.

## 3. DOCUMENTS FOR DISCUSSION AND ENDORSEMENT BY PLENARY

### 3.1 ENCePP Seal – Definition of ENCePP Study

Ingemar Persson, member of ENCIAG and WG2 Subgroup "Registry for non-interventional studies", gave a short presentation on the ENCePP Study Seal. During the following Q&A session concerns were raised in relation to the retrospective application of the seal. It was agreed that the responsible Working Group will be looking at this in more detail and report on the issue at the December Plenary.

*3.1.1 Checklist of operational research standards*
Xavier Kurz and Bert Leufkens gave a presentation on the draft Checklist of Operational Research Standards, which was developed by WG1 Subgroup "Operational Research Standards" and which is intended as an attachment to the PV & PE Guidelines still to be developed by the Working Group.
During the discussion comments were made mainly in relation to sections1, 7 and 10 of the existing draft checklist. The Plenary was invited to submit any additional comments in writing until 2 October 2009. All comments will be reviewed prior to an external consultation and report of the Working Group to the Plenary at the meeting in December 2009.

*3.1.2 Independence & transparency: Draft Code of Conduct for public consultation & Draft Checklist*
Stefanie Prilla and Helen Dolk, Chairperson of WG2 Subgroup "ENCePP Code of Conduct", updated the Plenary on the scope, principle and main goal of the working group and introduced the main elements of the current draft document.

The presentation was followed by a lively discussion on different areas of the Code including the definition of Conflict of Interests, with a particular view to investigators from the pharmaceutical industry, and the proposal to include a chapter on ethical issues.

All comments will be taken into consideration and implemented as appropriate. The Plenary was invited to submit any additional comments in writing within the next couple of weeks following the meeting. The new draft document will be presented to ENCIAG prior to launching a public consultation during November 2009. It is intended to have the final draft endorsed by the ENCePP Plenary during the meeting on 11 December 2009.

### 3.2 Mandate and Election Procedure for ENCePP Steering Group

Henry Fitt gave a presentation on the main elements of the Mandate and Election Procedure for the ENCePP Steering Group. The full draft document had been circulated to all ENCePP partners and meeting participants prior to the Plenary meeting.

The comments following the presentation focused mainly on term limitation, representation of expertise and the voting procedure (proxy vote, single transferable vote, online voting). Noël Wathion confirmed that all comments will be taken into consideration, but stressed that the document is currently still undergoing checks by the EMEA legal team.

It was confirmed that candidates for the Steering Group that are physically not present during the Plenary meeting at which the election is taking place can still stand for election in absentia.

### 3.3 Mandate, Objectives and Rules of Procedure for the ENCePP Plenary

Henry Fitt gave a presentation on the main elements of the mandate of the ENCePP Plenary, the full text of which had been made available to ENCePP centres and meeting participants prior to the meeting.

Following a suggestion by Bert Leufkens, and given the fact that the Chairs of the SG and the Plenary will both be representatives from EMEA, it was agreed to amend the text to say that the SG Vice-Chair will report to the Plenary.

As with the Mandate of the ENCePP Steering Group, this document is still undergoing legal checks.

## 4. PRESENTATION AND DISCUSSION OF DOCUMENTS BY PLENARY

### 4.1 Mock-Up of database of research resources

Stefanie Prilla presented a mock-up of the ENCePP Research Resources Database which is currently under development by the EMEA IT team. The database will undergo an iterative development process, including online user testing. It is intended to present and launch the database at the 2nd ENCePP Plenary on 11 December 2009.

*4.1.1 Data fields & applications for data sets used for PEpi and PV research*
Miriam Sturkenboom, Chairperson of WG3: EU data sources and methodological approaches for multi-source studies, presented on the background and work achieved so far. Jim Slattery continued by presenting the different sections of the draft questionnaire.

Although the draft questionnaire had already been circulated to ENCePP centres for consultation, the Plenary was invited to submit any further comments.

It was agreed that the Working Group will look again at the question of how to capture the completeness of data and whether further quality markers are needed in addition to the list of publications involving the respective data source.

*4.1.2 Data fields & applications for research centres participating in ENCePP*
Mary Teeling, Chairperson of WG4: EU PhV & PhEpi research centres in ENCePP, presented an overview of the WG's mandate, objectives, scope and milestones. She also introduced the different sections of the current draft questionnaire, followed by a short Q&A session.

### 4.2 Register for post-authorisation studies

Nick Halsey gave a short presentation on the progress of the Working Group so far. The registry of PASS will have a broad scope which will capture non-interventional studies, but will also be inclusive of Clinical Trials. The registry will not be exclusive to studies with the ENCePP Seal.

As the work needs to be progressed soon, a meeting of the Drafting Group of PASS studies will be organised as soon as possible (i.e. early October 2009), input from the Code of Conduct Working Group would be desirable.

## 5. PRESENTATION AND DISCUSSION

### 5.1 Presentation by European Commission/RTD

Fergal Donnelly, representative from the Research Directorate-General of the European Commission, gave a presentation on Adverse Drug Reaction Research in the framework of the FP7 research

programme. This was followed by a short Q&A session. A point stressed by F. Donnelly was the lack of consortium members from new MSs in successful proposals. The EC would like to improve this.

**5.2 Vaccine Vigilance / H1N1 Pandemic Surveillance**

Xavier Kurz reported on the outcome of the H1N1 vaccines pharmacovigilance strategy meeting which took place at the EMEA on 17 September 2009.

The following discussion focused on the establishment of possible consortia, their scope and funding. Representatives from ECDC gave an update on activities and particulars of the VAESCO consortium which aims to provide epidemiological follow-up of safety signals for pandemic vaccines. Many ENCePP centres are already part of VAESCO, and although only restricted funding is available at present, anyone interested in joining the existing consortium is asked to contact ECDC for more information.

The Plenary agreed that collaboration was needed and that it was important to share as much information and data as possible. It was therefore decided that EMEA will re-circulate the survey of ongoing activities in vaccine vigilance to all ENCePP centres. Furthermore, EMEA will look into whether a collaboration or consortium could add value and what forms of funding might be available. The outcome of this investigation will be communicated to the ENCePP community by e-mail.

Since antivirals were not part of the discussion at the pharmacovigilance strategy meeting, the respective pharmacovigilance strategy will be circulated to ENCePP centres.

**6. PRESENTATION**

Henry Fitt gave a short overview of ENCePP Outlook and Highlights Q4/2009 & 2010:

- The next ENCePP Plenary will take place on 11 December 2009. The elections of the ENCePP Steering Group are scheduled to take place during this meeting.
- The public consultation on the ENCePP Code of Conduct will be launched in November 2009.
- A decision will be made soon on holding a "ENCePP Scientific Debate" immediately following the ICPE Meeting in Brighton (August 2010).
- The EMEA has launched a Call for Expressions of Interest for Drug Safety Studies which will remain open for applications until April 2012.

**Conclusions**

Peter Arlett, the Chair of the afternoon session, thanked all meeting participants and summarised that ENCePP has moved from a period of brainstorming two years ago to a period of delivering results. There is expectation the network will start conducting and delivering ENCePP studies in 2010.

It was noted that not many representatives from new Member States were present at the meeting which is something that should be addressed. Bearing in mind the similarly low representation of new MSs addressed in FP-funded projects, it was agreed an effort should be made to involve new countries, especially those from Eastern Europe, in PhEpi initiatives.

Corinne de Vries reminded everybody that the ICPE meeting will take place on 19-22 August 2010.

**Action Points arising from the Discussions**

- WG2 to clarify possible retrospective application of ENCePP Study Seal.
- WG1 Subgroup "Operational Research Standards" to take into consideration comments received on draft checklist. Revised checklist to be published on ENCePP web page for consultation. Presentation of final checklist at December Plenary.
- WG2 Subgroup "ENCePP Code of Conduct" to take comments on draft CoC into consideration; presentation of final draft CoC to ENCIAG prior to launch of public

consultation in November 2009. Endorsement of final draft CoC by ENCePP at December Plenary.

- Mandate and Election Procedure for ENCePP Steering Group: to come into force following consideration of comments made and conclusion of EMEA legal checks.
- Mandate of the ENCePP Plenary: to come into force following conclusion of EMEA legal checks.
- WG3 "EU data sources and methodological approaches for multi-source studies" to clarify the question of completeness of data and quality markers.
- Drafting Group of PASS studies to meet as soon as possible.
- EMEA to re-circulate the survey of ongoing activities in vaccine vigilance to all ENCePP centres. EMEA to explore whether a collaboration or consortium could add value and what forms of funding might be available and communicate outcome to ENCePP centres. Antivirals information to be circulated to ENCePP centres.
- EMEA to decide on holding a "ENCePP Scientific Debate" adjacent to the ICPE Meeting in Brighton (August 2010).

Annexes:
- List of Participants
- Presentations