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

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2ND ENCEPP MEETING WITH CENTRES AT THE EMEA
(European Network of Centres for Pharmacoepidemiology and Pharmacovigilance)

MEETING REPORT

18 April 2008, 9.30 – 17.10h

Chairperson: Thomas Lönngren

AGENDA

1.	**INTRODUCTION**	9.30 – 9.45 (15')
1.1	Welcome and introductory remarks *(Thomas Lönngren)*	
2.	**ENCEPP: ACHIEVEMENTS & ROLE IN THE EU PHV SYSTEM**	9.45 – 10.25 (40')
2.1	Summary of the outcome of the 1st Meeting in 2007 & Achievements in 2007/2008 *(Stefanie Prilla)*	
2.2	The ENCePP Implementation Advisory Group *(Ingemar Persson, Tjeerd van Staa)*	
1.1	Risk Management Plans and ENCePP *(Stella Blackburn)*	
2.3	Questions & Discussion	
3.	**PRIORITY ACTIONS AND FUNDING OPTIONS IN 2008**	10.25 – 12.15 (110')
3.1	Priority Actions for 2008/2009 *(Henry Fitt)*	
3.2	Funding options for ENCePP: The Innovative Medicines Initiative (IMI), an opportunity to fund some ENCePP activities *(Noël Wathion, Henry Fitt)*	
3.3	Questions & Discussion	
Coffee Break: 10.45 – 11.05		
Lunch break: 12.15 – 13.00		
4.	**INTRODUCTION TO THE WORKING GROUPS**	13.00 – 13.15 (15')
4.1	Introduction of the 4 Working Groups	
5.	**WORKING GROUPS**	13.15 – 15.50 (155')
	(Participants join one of 4 Working Groups)	
5.1	**WG 1:** Research standards and PV and PE guidances	
5.2	**WG 2:** Independence and Transparency	
5.3	**WG 3:** Register of EU data sources and methodological approaches for multi-source studies	
5.4	**WG 4:** Comprehensive Inventory of EU PV & PE research resources (centres) in ENCePP	
Coffee Break: 15.50 – 16.10		

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6.	**SUMMARY OF THE DISCUSSIONS OF THE WORKING GROUPS** *(Room 2A)*	16.10 – 17.00 (50')
6.1	Presentation of the main outcomes	
6.2	Next steps	
6.3	Questions & Discussion	
7.	**CONCLUSION AND CLOSING REMARKS** *(Thomas Lönngren)*	17.00 – 17.10 (10')

1. EXECUTIVE SUMMARY

This was the 2nd meeting of ENCePP partners and interested parties held at the EMEA. The purpose of the meeting was to report on the progress in the development of the network, discuss further steps and establish 4 ENCePP Working Groups to develop the main areas addressed by the network.

More than 60 representatives of EU research organisations and other stakeholders including the Committee for Medicinal Products for Human Use (CHMP), the CHMP Pharmacovigilance Working Party, learned societies [International Society of Pharmacovigilance (ISoP), International Society for Pharmacoepidemiology (ISPE), European Federation for Pharmaceutical Sciences (EUFEPS)], National Competent Authorities (DK, IT, UK), patients' organisations (EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations, PCWP), health care professionals (EMEA Human Scientific Committees' Working Party with Healthcare professionals' organisations, HCPWG), and Industry (European Federation of Pharmaceutical Industries, EFPIA) were represented. A list of participants is annexed to this report.

The morning session was dedicated to presenting the achievements and future plans for ENCePP. The ENCePP Implementation Advisory Group (ENCIAG) was introduced to the ENCePP partners and the possible benefit of ENCePP for the EU Risk Management System was outlined. In addition, funding possibilities for ENCePP were addressed. In the afternoon, participants joined one of 4 Working Groups where more detailed discussions took place.

Of note, throughout the meeting, participants emphasised their support of the ENCePP project and confirmed their willingness to participate in and commit to a joint network of pharmacovigilance (PV) and pharmacoepidemiology (PE) research in the EU. ENCePP, as a comprehensive pan-European collaboration of the existing PE and PV resources is regarded as a unique opportunity to strengthen the EU scientific community in this field.

2. PLENARY DISCUSSIONS

The plenary session in the morning consisted of presentations on the latest developments, current and planned activities for the near future pertaining to ENCePP. The presentations were followed by discussions.

The following main topics were addressed:

- The ENCePP Implementation Advisory Group (ENCIAG).
  ENCIAG is an interim body of experts including representatives of academia, the national competent authorities (NCAs), EMEA, CHMP, PhVWP and learned societies, to assist the EMEA in establishing ENCePP (*see Annex 3 for a list of names of the ENCIAG members and Annex 4 for the Mandate of ENCIAG*). A permanent Steering Group will eventually replace ENCIAG.
- The amended Working Model for ENCePP, which is based on the centres' wish for a more flexible, non-bureaucratic structure of the network.
  Central to the proposed model for ENCePP is a comprehensive and detailed Inventory of EU research centres and existing networks with expertise in PE & PV and/or pertinent databases, registries and other relevant data sources. The EMEA will allocate dedicated people resources to the project in the form of the ENCePP Secretariat. In its task of managing and promoting the network the EMEA will initially be supported by ENCIAG for an interim period of time and subsequently by a permanent Steering Group. *(see also annexed Model flow chart*)

- Efforts of EMEA to ensure the financing of the project, including the possibility of creating an "EMEA fund" for observational studies on emerging risks related to the use of medicines.
- In the context of the financing of PE & PV research in the EU, the Innovative Medicines Initiative (IMI) was introduced and EMEA announced the intention to establish a Public Consortium to address call no. 6 of the *Draft Scientific Priorities for the IMI JU 2008* / *IMI Call Topics 2008* "Strengthening the monitoring of benefit/risk". Discussions on this topic are described in detail under 2.1.

Furthermore, participants were informed that in 2008, two IT projects were initiated at the EMEA to create a web site for ENCePP and an electronic Inventory of the available research resources in the EU. In addition, ENCIAG has discussed a draft Implementation Strategy for the network.

The presentations were followed by an active discussion. It was agreed that the area of pharmacoepidemiological research, especially observational studies, needs to be harmonised and strengthened at EU level to enhance the acceptance and significance of data derived from such studies for pharmacovigilance purposes. In this respect, the EMEA mentioned some of the legislative proposals in the field of non-interventional studies put forward by the European Commission in a recent public consultation exercise.

Through ENCePP, scientists, regulators and other stakeholders could work together, whilst maintaining their independence.

However, it was recognised that the remits of ENCePP need to be further defined. The patients' representative emphasised the challenge and importance of translating new safety information into effective public communication. Due consideration should be given to including a representative from the patient organisations in the future ENCePP Steering Group.

2.1 IMI call topic "Strengthening the monitoring of benefit/risk"

The Innovative Medicines Initiative Joint Undertaking (IMI JU) is a public-private partnership recently established to support numerous research projects, published as Calls for interest, in order to facilitate the development of medicines. One such Call regards research in the field of PV and PE and is entitled "Strengthening the monitoring of benefit/risk".

EMEA informed the ENCePP partners of its intention to establish and lead a Public Consortium to answer the above-mentioned Call. It was announced that EMEA would contact the ENCePP members after the publication of the 1st Call to ask for their interest, willingness and capability to contribute to the Consortium. The final Consortium should consist of partners representing regulatory authorities, academia, non-EFPIA companies, especially small and medium sized enterprises (SMEs), and further partners including patient organisations.

In the following discussion, a number of issues were raised and discussed. However, it was pointed out that due to the fact that the IMI 1st Call and the rules and conditions for participation had not been published at the time of the meeting, not all questions could be addressed.

– The involvement of Pharmaceutical Industry could jeopardise the independence of the public consortium partners. The EMEA explained it was well aware of this issue and that it would seek reassurances from IMI that Industry would not lead those aspects of the project regarded as most sensitive. Another aspect identified as requiring further clarification was the nature of the "in-kind" contribution from Industry to the project.

– Another point of discussion was the number of partners (e.g. academic centres, SMEs, etc) in the Consortium.

  - The EMEA stated that whilst it would like to involve all ENCePP partners in the Public Consortium, it would have to await the publication of the Rules for participation in IMI to see if there was a limit to the number of members in a Consortium. Moreover, the EMEA would have to ensure, and demonstrate to the peer review body, that it was leading a balanced and manageable consortium capable of addressing all the expected deliverables of the Call. A two-tier Consortium was briefly discussed, where a limited number of centres would act as subproject leaders or coordinators and the remaining would assist in research

activities as appropriate given that not all ENCePP centres have the capacity and/or willingness to substantially contribute to the consortium. Another possible option could be a two step approach with a small number of core partners forming the initial consortium, which could then be enlarged at a later stage. The EMEA said it would further investigate these alternatives.

- Some centres were unhappy with the idea of regulatory bodies leading/participating in consortia, since this would limit the number of participating academic centres. However, it was pointed out that some regulatory agencies hold large amounts of data on spontaneous adverse drug reactions in their databases and would therefore be as relevant as, if not more, than some academic institutions. Moreover, the idea behind the IMI initiative is clearly to involve all stakeholders, including regulatory agencies.

– A further point of discussion was whether an institution should be able to participate in different consortia and different research projects. The EMEA mentioned that it considered it acceptable for institutions to participate in several consortia as long as they addressed different calls, i.e. as long as the consortia were not in direct competition, as otherwise this would represent a clear conflict of interests.

Finally, the EMEA stressed that it would continue to drive the ENCePP project with its current, and hopefully extended, membership regardless of the outcome of the application to this IMI Call.

3. ENCEPP WORKING GROUPS

Further to the outcome of the 1st ENCePP meeting and to suggestions form the ENCIAG, the following 4 Working Groups were established during the meeting to progress the main items on the ENCePP agenda (see table below).

WG 1	WG 2	WG 3	WG 4
ENCePP standards and guidances	Independence and Transparency	Registry of EU data sources and methodological approaches for multi-source studies	Inventory of EU PV & PE research centres in ENCePP

The Working Groups were asked to discuss and agree their mandate and to organise their future work including the frequency of further meetings. Reports of all future meetings and discussions of the Working Groups will be circulated to the ENCePP partners.

(*Minutes of the 1st Meeting of the 4 Working Groups are annexed to this meeting report.*)

Annexes:

1. List of participants
2. Minutes of the Working Groups
3. List of ENCIAG members
4. Mandate of ENCIAG