EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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ENCePP Secretariat

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Minutes - ENCePP Steering Group Adobe Connect meeting

6 July 2012, 13.00-15.00 – Chaired by Peter Arlett

List of Participants	
Present:	Morten Andersen (MA), Peter Arlett (PAR), Alfonso Carvajal (AC), Ana Corrêa Nunes (ACN), Corinne de Vries (CdV), Henry Fitt (HF), David Haerry (DH), Nicola Magrini (NMa), Susana Perez-Gutthann (SPG), June Raine (JR), Miriam Sturkenboom (MS) *ENCePP SG Advisors*: Jim Slattery (JS), Xavier Kurz (XK) *EFPIA Observer:* Laurent Auclert (LA) *ENCePP Secretariat*: Kevin Blake (KB), Thomas Goedecke (TG), Eeva Rossi (ER), Dagmar Vogl (DV) *EMA*: Ana Hidalgo-Simon (AHS), Luis Prieto (LP) *ENCePP WG3:* Nawab Qizilbash (*partly – via TC)*
Apologies:	H. Leufkens, M. Müllner, Y. Moride, S. Blackburn, N. Moore

Item	Draft agenda
1.	**Adoption of draft agenda**
2.	**Matters arising** 2.1 Meeting between SG and industry
3.	**ENCePP Guide on data integration & pooling of studies** 3.1 Data Integration Concept Paper
4.	**GVP on post-authorisation studies and the ENCePP Register** 4.1 Update on the requirements for post-authorisation studies / The EU PAS register
5.	**Promotion of ENCePP: proposal from Working Group 2** 5.1 Statement for publication of ENCePP centres' websites linked to use of the ENCePP logo 5.2 Commitment of 1 study/year for ENCePP partners
6.	**SG Mandate** 6.1 Adoption of Revision 2

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Item	Draft agenda
7.	**Special Interest Groups** 7.1 Revised SIG discussion paper
8.	**ENCePP HTA Task Force** 8.1 Outcome of ENCePP HTA survey 8.2 Mandate of the Task Force
9.	**A.O.B**

1. Adoption of draft agenda

The agenda was adopted without changes.

2. Matters arising

2.1. Meeting between SG and industry

PAR raised for discussion the proposal of organising a dedicated meeting with industry leaders in an effort to increase awareness of the expert capacity that the ENCePP network can offer.

The SG members agreed that a focussed meeting to convey to industry the principles of ENCePP (particularly regarding transparency and standards) would be helpful.

It is therefore proposed to set up a meeting between the ENCePP Steering Group (SG) and different industry associations.

Action

- ENCePP Secretariat to look into possible dates during autumn 2012 to organise a meeting between ENCePP SG and industry associations.

3. ENCePP Guide on data integration & pooling of studies

3.1. Data Integration Concept Paper

Nawab Qizilbash (NQ), member of Working Group 3 and author of the 'Data Integration Concept Paper', joined this part of the discussions via TC.

During the previous SG meeting on 21 March 2012 it had been agreed that a concept paper setting out the purpose and scope of developing further guidance on data integration and information would be drafted. The document drafted by NQ had been reviewed and agreed by Working Group 3 prior to submission to the Steering Group, and includes proposed next steps.

The SG agreed with the proposal of assembling a drafting group and identifying potential work streams and work stream leaders. The scientific next steps, as proposed in the concept paper, include an assessment of the current situation, devising a structure of the guideline for each type of data integration, consideration of checklists for different types of data integration, and agreement on the methodology for developing the guideline.

The development of the guideline will be hosted by Working Group 3, in light of ongoing initiatives by WG3 in defining current practices including methodological and data protection aspects of data

integration. It was also agreed that WG1 would input, including at SG Sponsor level, and broader representation from other groups including CIOMS X, Cochrane and maybe PRAC would be sought.

Action

- WG3 to establish drafting group for 'ENCePP Guide on Data Integration and Pooling of Studies'.

4. GVP on post-authorisation studies and the ENCePP Register

4.1. Update on the requirements for post-authorisation studies / The EU PAS Register

XK highlighted key aspects of the Good Vigilance Practice (GVP) Module VIII - Post-authorisation safety studies (PASS) that came into force on 2 July 2012 including requirements for protocols and abstracts and provisions for transparency.

XK detailed that the European Medicines Agency shall maintain an EU electronic register for post-authorisation studies (EU PAS Register) which shall be accessible via the European medicines web-portal. Building on the development of the ENCePP E-Register by Working Group 2, and the subsequent experience of the Agency in maintaining the E-Register, it is now proposed that the ENCePP E-Register will serve as the EU PAS Register to meet regulatory requirements in relation to non-interventional post-authorisation studies. For this purpose it will be necessary to upgrade the current E-Register and make a small number of changes to meet the requirements foreseen in the new Pharmacovigilance legislation, whilst the guiding principles shall remain transparency and independence.

There was broad support from the Steering Group for the proposal. It was also agreed to provide a focussed presentation on the GVP registration requirements for PASS at the next Plenary meeting.

Action

- ENCePP Secretariat to include a presentation on the GVP registration requirements for PASS on the agenda for the Plenary meeting on 11 October 2012.

5. Promotion of ENCePP: proposal from Working Group 2

5.1. Statement for publication on ENCePP centres' websites linked to use of the ENCePP logo

TG presented two proposals from Working Group 2 aimed at promoting ENCePP which include statements referring to the ENCePP principles which ENCePP partners could put on their websites. In addition, it is proposed to make available the ENCePP logo in the ENCePP partners' forum for download to accompany the website statement; the logo may also be used in presentations. The proposal also foresees that the use of both the statement in connection with the ENCePP logo is linked to the commitment to register at least one study per year in the E-Register.

The Steering Group was broadly supportive of the idea of having the statement linked with the use of the ENCePP logo but would like to see the word 'excellence' incorporated in the statement with some minor amendments in the middle paragraph.

The exact statement wording will be finalised through written procedure based on the revised version circulated by the Secretariat.

5.2. Commitment of 1 study/year for ENCePP partners

Working Group 2 is also proposing to link the use of the website statement and ENCePP logo to a commitment to register at least one study per year in the ENCePP Register of studies/EU PAS Register.

The Steering Group is supportive of a proposal to register at least one study per year in the E-Register which should only be a commitment if ENCePP partners intend to use the statement and the logo.

In conclusion, it was agreed that the ENCePP Secretariat would reword the statement, taking into account the comments made by the SG, and to circulate the statement and revised Plenary mandate (changes consequent to the statement policy) for adoption by written procedure.

Action

- ENCePP Secretariat to revise the partner website statement reflecting the SG comments, and to circulate the revised Plenary mandate for adoption by written procedure.

6. SG Mandate

6.1. Adoption of Revision 2

DV summarised the proposed revision of the Steering Group mandate to include provisions relating to impact analysis and the re-election of incumbents to the Steering Group, plus some small editorial changes.

The Steering Group adopted revision 2 of the Steering Group mandate.

Action

- ENCePP Secretariat to publish revision 2 of the SG mandate on the ENCePP website.

7. Special Interest Groups

7.1. Revised SIG discussion paper

KB presented the revised paper on special interest groups (SIGs) which was updated in line with discussions at the Steering Group meeting in March 2012 and the Plenary meeting on 3 May 2012.

Whilst the Steering Group was generally supportive of the proposal to establish sub-networks, the concept of SIGs based rigidly on therapeutic areas was not fully supported. It was agreed that the focus of such groups should be on EU-added value and based on drug utilisation, new groups of products and/or outcomes, as well as, potentially, on therapeutic areas. While it was agreed the overall aim of these groups would be to share information, develop strategic networks, develop methodologies, further collaborate and establish consortia, how these groups might be implemented in practice was not finalised.

The Steering Group therefore agreed that the ENCePP partners should be encouraged to submit suggestions for SIG topics on an ongoing basis which will then be presented to the Steering Group for endorsement and support.

Action

- ENCePP Secretariat to broadly encourage ENCePP partners to submit suggestions for sub-network topics including at Plenary meetings and through the Partners Forum.

8. ENCePP HTA Task Force

8.1. Outcome of ENCePP HTA survey

LP reported on the outcome of the recent HTA survey of ENCePP partners. The overall response rate of 42% has been very encouraging including a number of respondents who indicated their interest in joining a task force in a leading role.

8.2. Mandate of Task Force

It was agreed that a meeting of the partners that expressed interest in leading the task force should be organised. This initial meeting will serve to work out organisational details and to discuss the mandate and leadership of the group. Participation from HTA bodies is desirable, and EUnetHTA will be formally approached to take an active role in this new task force.

Action

- ENCePP Secretariat to approach EUnetHTA and organise inaugural meeting of task force.

9. AOB

None.

Next meeting: 14 September 2012 (possibly combined with Journal Editors workshop)