EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

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ENCePP Secretariat

Minutes - ENCePP Steering Group Meeting

17 October 2014, 09.30 – 16.30, chaired by Peter Arlett

List of participants	
Present:	Morten Andersen (MA)*, Peter Arlett (PAR), Ana Corrêa Nunes (ACN), Corinne de Vries (CdV), Pierre Engel (PE), Henry Fitt (HF), David Haerry (DH), Teresa Herdeiro (TH), Hubert Leufkens (HL)* [partly], Susana Perez-Gutthann (SPG), Nawab Qizilbash (NQ)* EFPIA observer: Patrice Verpillat Principal Adviser to ENCePP SG: Xavier Kurz Statistical Adviser to ENCePP SG: Jim Slattery [partly] Secretariat: Kevin Blake, Thomas Goedecke, Eeva Rossi, Dagmar Vogl, Veronica Tudor (EMA trainee) **via Adobe Connect and teleconference*
Apologies:	Marieke de Bruin, Nicholas Moore, Tom McDonald, Viola Macolić Šarinić, Yola Moride

Meeting agenda:

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1. Welcome & Adoption of draft agenda

The Chair welcomed the Steering Group (SG) to its first meeting in the new EMA building, and extended a warm welcome to Patrice Verpillat who has replaced Laurent Auclert as the EFPIA observer on the Steering Group.

The agenda was adopted without changes.

2. Topics to consider for Work Plan 2015-2016

2.1. Gap Analysis on additional Risk Minimisation Measures

NQ presented slides outlining the results of the work undertaken by a subgroup of the Steering Group, on a gap analysis regarding the monitoring of risk minimisation measures and proposing the establishment of an ENCePP working group. The proposed mandate of this group would be to lead a systematic approach to describing trends in the nature, implementation, and methods of additional risk minimisation measures, and to complement, enhance and integrate activities performed within EMA and other groups or initiatives.

CdV suggested that while this was important work and there was immense potential within the network, the current proposal was overambitious and would need to be more focussed to identify gaps where ENCePP resources could be used most effectively. This was supported by the other SG members.

In closing it was agreed that it was premature to set up a new working group at this stage and the task force under the lead of NQ was charged with further refining its proposal to focus on methodology and criteria for success. A possible presentation on this topic to the plenary was considered useful.

For action:

- Task force (NQ) to further refine proposal for work on risk minimisation methods and to define clear objectives.

2.2. Registries

XK provided a brief summary of EMA internal discussions on a possible future strategy on registries. He outlined the current situation with the aim of initiating a discussion on how ENCePP might support any EMA strategy. He stated that the ENCePP network could be a very useful source of information, where existing data sources might fill a gap in information and knowledge in the post-authorisation phase and highlighted that establishing methods and rules and data elements could serve as standard core elements of registries, thereby increasing the quality, comparability and utility of data collected.

He asked the Steering Group for its opinion on whether it could envisage a role for ENCePP in areas of identification and evaluation of existing data sources.

The Steering Group members voiced their support for this work. It was highlighted that a number of centres registered in the ENCePP Resources Database state they have existing registries, and it could be a matter of identifying any source of potentially useful information including structures, governance, rules etc.

ACN highlighted the particular need of good registries in the area of orphan drugs.

In conclusion it was agreed that a deliverable would be included in the new ENCePP work plan in relation to the methodological aspects of this task. Further discussions at SG level on more practical aspects of the task shall take place at a future meeting.

For action:

- ENCePP involvement in any EMA strategy on registries to be anchored in new work plan.
- Steering Group to discuss further aspects of the task at a future meeting.

2.3. Future directions for HTA WG

KB informed the SG that a survey of ENCePP centres was launched earlier this year to gauge to what extent centres have experience in conducting research that could support HTA bodies, by identifying experience with specific health outcomes endpoints. The survey also served to identify potential training needs. Whilst the overall response rate was modest (35 out of 147), this needs to be seen in the context of the network being originally focussed on mainly pharmacovigilance and pharmacoepidemiology. The centres that responded are likely to be those with interest and experience and while this picture may not be representative of all ENCePP centres, the results have confirmed that a proportion of centres within ENCePP are conducting research with HTA outcomes. The results are therefore an index of current ENCePP capacity and will be helpful in defining approaches to building on this, including training.

The SG was asked for an orientation as to how the group should be taken forward given the deliverables in the current workplan which were focussed on capacity have been achieved.

The SG agreed that it would be relatively easy to propose amendments to the ENCePP resources database to allow for an inclusion of HTA experience of centres, but any expansion in the scope of ENCePP would need to be reflected upon and communicated clearly.

The Steering Group acknowledged that some good work has been done by the HTA WG to date; the group could be further enriched with more representatives with HTA experience. The SG therefore recommends that the make-up of the WG be reconsidered, and its format be changed into a Special Interest Group (SIG). Inclusion of a relevant deliverable in the new ENCePP work plan continuing with the existing mandate of capacity building and being a consultative group on methods/guidance was supported.

For action:

- HTA working group to be enriched with further expertise in research supporting HTA.

2.4. Review of Working Groups

KB reminded the Steering Group that – in the interest of time - written progress reports from the Chairs of all Working Groups had been circulated prior to the meeting for information. These reports will ultimately be published on the ENCePP website together with the minutes of this meeting.

He highlighted the proposal that no deliverables for WG3 (Data sources and multi-source studies) will be included in the new work plan. This is based on the fact that the WG had, in line with its mandate, completed its activities in relation to multi-national and multi-source pharmacoepidemiological studies and in increasing the representation of data sources in the resources database. One remaining deliverable relates to the revision of the EU data protection rules where the legislative process is ongoing. The legislative process will continue to be monitored at Agency level. A task force approach

based around the current WG3 may be adopted if and when expert input to implementing technical guidelines on health data/research is considered appropriate by the Steering Group.

It was also noted that the WG on Data Integration would wrap up after the publication of the guide and the need for more guidance on multi-source studies would be further considered by the Steering Group at that stage.

SPG said that whilst she found the written reports very useful, she was concerned that WG Chairs should also continue to have an opportunity to address the Steering Group directly. It was confirmed that WG Chairs have been asked to report on specific deliverables of their respective WGs at the upcoming plenary meeting.

For action:

- ENCePP Secretariat to publish reports from WG Chairs on ENCePP website.
- Presence of WG Chairs vis-à-vis Plenary to be optimised.

3. ENCePP Work Plan 2015-2016

KB presented slides outlining the proposed objectives and deliverables for the next two years. He explained that the current proposal is high-level and, once agreed, would be taken back to the WGs for further discussion and to work out the finer details including milestones and timelines. This introduction was followed by extensive and engaged discussion, and the Steering Group agreed support for the following high-level objectives:

- It was agreed that a more systematic approach to the interface between EMA/Committees and ENCePP should be developed including completion of declaration of conflicts of interest where appropriate to support decision-making (to allow greater use of expertise within ENCePP).
- Efforts being made in defining clear mechanisms to support product life-cycle through epidemiology, including drug development would need to be put in the context of an extension of the scope of ENCePP including review of the network's mandate if this is considered necessary. This would require careful reflection as while the experience with the HTA survey confirmed some members of the network might have specific interests e.g. in outcomes that support HTA, these might not be of interest to the network as a whole.
- Finalisation of a stand-alone ENCePP communications strategy with an emphasis on involving empowering the network in communication activities.
- Review of the ENCePP Code of Conduct in line with stakeholder requirements for good governance including consideration of the need for additional tools separate to the ENCePP Study Seal concept to support the principles of transparency, independence and methodological excellence.
- Updating the ENCePP E-Register/EU PAS Register in line with legislative developments and stakeholder requirements. This was emphasised as being of critical practical importance to the network and although an EMA responsibility it will be included in the work plan accordingly.
- Exploring how ENCePP might fit with the EMA regulatory training strategy which is under development. This might involve ENCePP being trained or doing training. The need to avoid overlap with ongoing initiatives including EU2P was highlighted.
- Ongoing review of existing ENCePP methodological guidances, including consideration of additional chapters in the methods guide where considered appropriate for WG1.

Concluding the discussions KB stressed that the work plan is a dynamic document and may be amended during its validity if considered necessary.

For action:

- ENCePP Secretariat to amend the draft work plan based on SG discussions.
- Agreed deliverables to be presented to ENCePP plenary.

4. ENCePP Draft Communication Strategy

Following on from previous high-level discussion by the Steering Group HF presented an outline of the proposed communication strategy for further consideration. He elaborated that the proposed strategy will focus on the four ENCePP pillars, namely transparency, methods, capacity and independence, and on highlighting how ENCePP tools help to apply these. He explained that initially the SG is requested to consider the proposed key messages, priority target groups and communication channels. The next step would be to agree a more detailed communication plan, including main initiatives, key events, milestones, simple ways to measure impact, etc.

The Steering Group agreed that it will be of utmost importance to convey a positive message and to explain the importance of independence, transparency and scientific robustness. The network's key focus on researchers coming together to try and solve common problems should be highlighted. Furthermore, ENCePP partners should be conduits for communication about the network, and they should be encouraged to communicate about ENCePP in different fora. The necessary tools e.g. standards slides, statements, logos are to be made available by EMA.

From an industry perspective, PV cautioned that the advantages of working with ENCePP should be emphasized. He suggested that it would be helpful to provide positive examples how ENCePP has helped. Finally, the SG emphasized that the utility of ENCePP beyond drug safety studies should be made clear.

For action:

- HF to revise draft communication strategy based on SG discussions.
- Single summary slide on key messages to be presented to Plenary.

5. Issues raised / A.O.B.

5.1. Lessons learned on the design of PASS since July 2012

PE presented the outcome of a study on the experience of PRAC review and lessons learned on the design of PASS under the new PhV legislation. The intention is to present this work at the upcoming ICPE conference, and to submit a manuscript for publication in a scientific journal.

The Steering Group considered the study results of great interest to stakeholders and fully supported the publication of the material, with the caveat that reference to possible limitations be included in the publication.

It was agreed that PE would present the study also to the plenary meeting on 25th November 2014. He was invited to circulate bullet points in advance of the meeting to the Steering Group for information and to further liaise with the ENCePP Secretariat and EMA colleagues on the appropriate caveats to be highlighted for interpretation of the results.

5.2. A.O.B.

NM's proposals for standards for advisory boards and an ENCePP advisory board were raised in the context of the discussion of the work-plan. It was agreed that further clarification on the proposal was needed, before any decisions could be made on progressing. It was agreed that clarification would be sought from NM.

For action:

- NM to be contacted to clarify proposals and next steps.