EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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ENCePP Secretariat

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Minutes - ENCePP Steering Group Teleconference

19 July 2018, 10.00-12.00 UK time

Chair: Xavier Kurz & Tom MacDonald

List of participants	
Present	Marieke De Bruin, Dinah Duarte, Vera Ehrenstein, Rosa Gini, Teresa Herdeiro, Hans Hillege, Xavier Kurz, Tom MacDonald, Gianluca Trifirò, Patrice Verpillat Statistical Adviser to the SG: Jim Slattery EMA: Alexandra Pacurariu, Gianmario Candore ENCePP Secretariat: Thomas Goedecke, Eeva Rossi, Dagmar Vogl
Apologies	Kathi Apostolidis, Peter Arlett, Hans-Georg Eichler, Giampiero Mazzaglia, Corinne de Vries, Olaf Klungel, Yola Moride, Hervé Le Louet

1. Welcome & Adoption of draft agenda

The agenda was adopted with the addition of two AOB items:

- Update from Working Group 3 relating to ongoing work on models for multi-database pharmacoepidemiology studies (Gianluca Trifirò)
- ENCePP activities October 2018 onwards (Xavier Kurz)

The list of open action points from previous meetings was reviewed.

2. Benefit/Risk tool

Hans Hillege explained that the use of benefit/risk tables has become the norm in the review of products in the Committee for Medicinal Products for Human Use (CHMP). He presented a recent example - including an online demonstration of the tool - to show to the Steering Group (SG) the practical application of this tool in a regulatory context.

The Steering Group members were invited to share their thoughts on how this tool might impact on pharmacoepidemiology studies and how ENCePP may contribute to developing this methodology further.

It was agreed that any comments and/or suggestions should be submitted to the ENCePP Secretariat in writing for discussion at the next SG meeting.

To this end, Hans Hillege agreed to share the link to the online application with the Steering Group.

3. ENCePP Code of Conduct publication

Thomas Goedecke and Rosa Gini presented a summary of the recent stakeholder survey on the ENCePP Code of Conduct. They explained that the aim of the survey was to evaluate how the latest version of the Code (revision 4 published in March 2018) is understood and applied in practice by individuals in five different stakeholder groups.

In terms of next steps the survey findings are to be included in a journal article on the ENCePP Code, with focus on the most positive findings (usefulness, clarity, trust), issues with interpretation or practical implementation of provisions, and relevance in the context of other guidelines (ISPE GPP, ADVANCE, ICMJE). The draft manuscript will be shared with the SG prior to publication. In addition, a full survey report will be registered in the EU PAS Register and submitted as a 'short report' to *Pharmacoepidemiology and Drug Safety*.

The SG members were invited to reflect on possible further dissemination methods for the Code. The ENCePP Secretariat is proposing to make available on the ENCePP website a poster and info sheet presenting the key principles of the Code in context of revision 4. One further suggestion was to share the Code with scientific societies. To this end SG members were invited to forward the names of suitable contacts to the ENCePP Secretariat. A translation of the Code – or at least a summary of its main aspects - into different languages may also be considered.

Patrice Verpillat suggested to measure the impact of the revised Code in terms of the practical application to studies performed. It was suggested that investigators should be encouraged to cross-reference the Code in the study protocol and publication of results where applicable. A Working Group 2 proposal for measuring the impact of the revised Code is to be discussed at a future SG meeting.

4. ENCePP Guide on Methodological Standards

The SG members were informed that the latest revision of the ENCePP Methods Guide was published on 13 July 2018. Revision 7 of the Guide includes 33 authors and 544 references. The previous version (Revision 6) had around 4,300 views on average per month, plus 890 downloads.

In addition to a couple of new chapters the next revision of the Guide will include a reference to the methods guide on registries due to be finalised in 2019.

5. A.O.B

5.1. Pharmacovigilance activities and ISoP: update on contact with ISoP President

It was confirmed that a TC between the ENCePP Steering Group and representatives from ISoP will be taking place on 12 September 2018. The topic of discussion will be collaboration between the two networks.

5.2. Priorities beyond 2019

Due to time constraints this topic was postponed to the next SG meeting.

5.3. Update from Working Group 3

Gianluca Trifirò provided a brief progress update on work done in the context of the concept paper on 'Models for multi-database pharmacoepidemiology studies'. He confirmed that responsible individuals have been assigned to each agreed task, and that collaborative work will start shortly.

A further progress update is anticipated by November 2018.

5.4. ENCePP activities October 2018 onwards

Xavier Kurz announced that in the context of the EMA's relocation to Amsterdam the next phase of the Agency's business continuity plan will come into effect on 1 October 2018. This phase will include suspension of a number of EMA activities, including all planned workshops and meetings, except those that are product-related. This decision has an impact on ENCePP related activities, and both the ENCePP plenary meeting scheduled for 20 November 2018 and the face-to-face meeting of the Steering Group on 19th November 2018 will have to be cancelled. The Steering Group teleconferences scheduled for 12 and 25 September 2018 will take place as planned.

Routine ENCePP activities not requiring EMA organisational meeting support or guidance work will not be affected. All product-related interactions with ENCePP partners will continue as and when requested by the Pharmacovigilance Risk Assessment Committee (PRAC).

These measures are temporary and expected to affect ENCePP activities also in 2019. The ENCePP Secretariat will explore alternative measures to support ENCePP's networking activities for discussion at the Steering Group teleconference in September 2018.

6. Action points

- SG members to submit their comments and/or suggestions relating to the benefit/risk tool to the ENCePP Secretariat in writing for discussion at the next SG meeting.
- ENCePP Secretariat to circulate to the SG the link to the online b/r application.
- WG2 to discuss and submit proposal for measuring impact of the revised Code on studies performed.
- ENCePP Secretariat to circulate details on temporary suspension of ENCePP activities.