



## Minutes - ENCePP Steering Group Teleconference

28 February 2018, 15.00-17.00 UK time

### List of participants

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

## 1. Welcome & Adoption of draft agenda

The action points from the previous meeting (face-to-face meeting 13/10/2017) were reviewed. It was confirmed that all points had already been addressed or will be addressed during this teleconference.

The agenda was adopted without change.

## 2. ENCePP Code of Conduct – Rev. 4

On behalf of Working Group Independence and Transparency (WG2) Rosa Gini presented slides summarising the main issues arising from stakeholder comments during the targeted consultation of EFPIA, EUCROF, ADVANCE, ISPE and ISoP, and how these had been addressed in the final draft revision of the Code (as agreed by WG2).

The Steering Group (SG) was invited to submit final comments on draft revision 4 of the Code by 9 March 2018. To this end, the ENCePP Secretariat would circulate to the SG the full list of comments received during the stakeholder consultation, including how these had been addressed.



A final version of Revision 4 of the Code should be available by 16 March at the latest and will then be circulated to the SG for endorsement in writing.

It was agreed that no further consultation of WG2 would be required, unless major issues are identified by the SG.

Tom MacDonald agreed to make available the University of Dundee's interpretation of the role and responsibilities of a 'study sponsor' versus 'study funder', the term referred to in the Code.

The Steering Group agreed that the ENCePP website should be updated following endorsement and in line with the revised Code.

Furthermore, the SG supported the publication of the revised Code in a peer-reviewed journal, focusing on the background and objectives of the revision and the main changes, and describing the differences between the ENCePP and ADVANCE Codes.

### **3. Benefit/risk effect tables**

Following on from his presentation to the ENCePP Plenary in November 2017, Hans Hillege introduced a pilot project on the use of Addis-2 (Aggregate Data Drug Information System) in B/R analysis which is being sponsored by the Committee for Medicinal Products for Human Use (CHMP).

The Steering Group discussed how ENCePP could potentially contribute to the pilot and how to optimise interaction with the CHMP group launching this initiative.

The SG unanimously supported the proposal of setting up a ENCePP Special Interest Group (SIG) which could be established based on the model of the existing 'SIG Impact' which provides methodological support to the PRAC Interest group on measuring the impact of pharmacovigilance activities.

To this end, the ENCePP Secretariat will liaise directly with Hans Hillege to agree the potential objectives of the group and next steps. A call for expressions of interest to ENCePP members could be launched after the definition of the mandate of the SIG. Some members of the Steering group already expressed an interest in becoming members.

### **4. ENCePP Guide on Methodological Standards – Rev. 7**

The Steering Group was informed of the imminent launch of the annual revision of the ENCePP Methods Guide, with the aim of publishing Revision 7 in July 2018.

The main objective is to revise existing sections with new available guidance and publications. In the context of this year's revision a new topic on 'Impact Research' will be added to the Guide. This is currently under preparation by the ENCePP SIG 'Impact' and will be handed over to Working Group Research Standards and Guidances (WG1) for incorporation into the Guide, and following consultation of the PRAC Interest Group on Impact in March.

The SG members were invited to inform the ENCePP Secretariat in case of interest in contributing to the revision of existing chapters, or to propose new topics considered missing from the current guidance. Any proposal for new topics will be submitted to WG1 for consideration.

Rosa Gini suggested that the ENCePP Guide is lacking guidance on the topic of risk stratification; she was invited to submit a short proposal in writing with additional background information.

### **5. ISPE mid-year meeting 2019**

Further to the discussions at its meeting in October 2017, the SG re-confirmed its support of an endorsement by ENCePP of the Midyear Meeting of the International Society for Pharmacoepidemiology taking place in Rome during April 2019.

A decision on the extent of the endorsement and practical aspects will be made once more details are available from the programme committee.

Xavier Kurz stated that the availability of EMA staff will be limited due to the relocation of the Agency which will be taking place around the same time as the conference.

## **6. Update from I SoP**

Hervé Le Louet informed the SG of the progress made to date with the I SoP roadmap on strengthening pharmacovigilance. To support his discussions with the I SoP Executive Committee, it was proposed to submit a letter from the ENCePP SG Chairs to the I SoP president highlighting the importance of the topic. The ENCePP Secretariat will liaise with Tom MacDonald regarding the content of the letter.

## **7. Action points**

- Steering Group members to submit final comments on draft revision 4 of the ENCePP Code of Conduct by 9 March 2018.
- Tom MacDonald to make available the University of Dundee's interpretation of the role and responsibilities of a 'study sponsor'.
- ENCePP Secretariat to update ENCePP website following endorsement and in line with the revised Code.
- Thomas Goedecke in collaboration with WG2 to progress drafting of article on the revised Code for publication in a peer-reviewed journal.
- ENCePP Secretariat to liaise with Hans Hillege regarding objectives of the possible ENCePP SIG on effect tables for benefit-risk assessment of medicines.
- Rosa Gini to submit a brief proposal for inclusion of the new topic 'risk stratification' in the next revision of the ENCePP Methods Guide for consideration by WG1.
- ENCePP Secretariat, in cooperation with Tom MacDonald, to draft a letter to I SoP President in support of developing a roadmap on strengthening pharmacovigilance.