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 September 2018, 13.30-15.30 UK time

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

1. Welcome & Adoption of draft agenda

The action points from the previous meeting (19/07/2018) were reviewed, and the draft agenda adopted with the addition of one AOB item:

- Update from Working Group 3 (Data sources and multi-source studies)

2. Benefit/Risk tool

It was noted that no comments have been received from the Steering Group (SG) following the presentation and demo of the benefit/risk tool at the meeting on 19 July 2018.

3. Pharmacovigilance activities and ISoP

A teleconference between the ENCePP Steering Group and Sten Olsson, President of ISoP, took place on 12 September 2018. The meeting was organised to discuss suggestions from ISoP for the planning of future pharmacovigilance activities to be recommended by the ENCePP Steering Group. These suggestions have been developed in consultation with ISoP Advisory Board.

The SG agreed the following actions relating to the individual suggestions:

1. Development of a set of pharmacovigilance indicators allowing assessment of functionality of pharmacovigilance systems on a national and health facility level

It should be considered that definition of indicators at health care facility level is a national responsibility with limited influence from EMA/ENCePP.

Members of the SG highlighted the important role health care systems should have to implement efficient pharmacovigilance systems. Every health care system has a duty of care in this respect but this duty of care is often ignored and there is currently no system to monitor it. It was also mentioned that there are many stakeholders involved and any action to improve pharmacovigilance at health care sytems level would be very complex.

However, the SG considers that ISoP involvement in the ENCePP SIG 'Impact' would be useful as the ENCePP SIG may evaluate processes in pharmacovigilance. The ENCePP Secretariat will propose to ISoP the text of a call for expressions of interest for ISoP members to join the ENCePP SIG virtual group and share the mandate.

ISoP will be invited to submit suggestions for a revised mandate of the SIG; proposal for a revised mandate will require adoption by the ENCePP Steering Group.

The SG supports the proposal to organise a joint session on PhV impact measures at a future ISoP meeting.

2. Development of basic requirements for pharmacovigilance systems in private healthcare facilities

The SG considered this topic was linked to the previous one pharmacovigilance in health care systems and acknowledged that there is little possibility for contribution from ENCePP, as this is a matter of the competent authorities in each country, and it is not in EMA's legal mandate to provide recommendations or accreditation for private health care facilities.

3. Development of methodologies and guidelines allowing continuous monitoring of hospitalised patients

ISoP will be invited to provide comments on the reflection paper on methodological aspects of the use of patient registries for regulatory purposes. The paper is due to be published soon by the EMA task force on registries.

4. Broadening pharmacovigilance activities

a) Address lack of patient adherence

The SG agreed that a link between the EMA activities on medication errors and the ISoP SIG on medication errors could be useful. The ENCePP Secretariat will liaise with the ISoP SIG for upcoming initiatives on medication errors.

b) Active monitoring systems

It was agreed that ISoP should be consulted for input during the next revision of the ENCePP Methods Guide in relation to the section on monitoring.

A further suggestion is to create a strong collaboration between ENCePP and ISoP with respect to the use of data sources other than spontaneous reporting (e.g. electronic medical records and claims databases) for drug safety signal detection. In this context it was suggested that a definition of the term 'active monitoring' would be useful. Further discussions should take place with Gianluca Trifiro/ENCePP WG3 on how this suggestion may be taken forward.

5. Developing harmonised pharmacovigilance curricula for introduction in universities throughout the EU

The SG strongly supports the proposal from ISoP that a major shift in the curricula for healthcare professionals is required to include proper training on pharmacovigilance principles and to remind them that they have duty of care relating to the monitoring of safety of medicines. The need for lobbying of regulators at national level was suggested.

The core competencies developed by ISoP have fed into the curriculum of the Eu2P project, where some ENCePP SG members are involved. Although ENCePP's focus is not on teaching, the SG feels that the network can provide guidance and methodologies which should be part of any curricula.

It was further suggest that individual ENCePP members should be encouraged promote and stimulate pharmacovigilance principles in their curricula. To this end it is proposed to include a relevant reference in the next revision of the 'Key messages for communication on ENCePP' (see agenda item 5.2).

4. ENCePP 10th Anniversary session at ICPE

Xavier Kurz gave a brief update on the ENCePP session at ICPE which was well attended and featured an interesting presentation on the status of pharmacoepidemiology in Eastern European countries given by Jiri Vleck, which had been shared with the SG.

The presentation highlighted the low level of training and expertise, lack of requirements from national authorities to involve PhEpi experts and lack of access to data. The SG was invited to reflect on how ENCePP might help to improve this situation.

It was suggested that there is a big scope for cooperation at academic level. Support is particularly needed in the area of outcomes research, and the SG considers it most useful to start contacting the individuals from eight countries identified by Jiri Vleck (listed on the first slide of his presentation), who already have relevant experience, in order to identify priorities and possible actions most useful to engage Eastern European countries.

In terms of facilitating access to data, it was agreed to engage with known databases in those countries to see how ENCePP might me of assistance.

Olaf Klungel, Tom MacDonald and Daniel Morales confirmed their support to this initiative.

5. ENCePP activities October 2018 onwards

5.1. EMA proposals for BCP period

A slide set had been circulated to the SG in advance of the meeting explaining the temporary reduction of activities of working parties and working groups and guideline development from October 2018 onwards. Xavier Kurz stressed that this reduction of activities is not specific to ENCePP, but applies to most EMA activities.

In view of these measures, and the fact that there will be no ENCePP meetings in the near future, the ongoing and outstanding activities from the ENCePP work plan have been reviewed. The proposed actions relating to these activities were presented to the Steering Group for agreement.

In terms of the annual revision of the ENCePP Methods Guide it was agreed to assess the need for a revision in September 2019 for publication in early 2020. If considered unnecessary at that stage, the next revision of the Guide will be launched in early 2020 with a view to publication in July 2020.

Rosa Gini queried the possibility of holding regular meetings of the SG and working groups during the BCP period without support from the ENCePP Secretariat, and at the groups' own initiative.

The suggestion was welcomed in the spirit of continuity during BCP period. It was proposed to organise a meeting at the end of the BCP period to discuss and formalise the outcomes of these informal meetings and to agree on an action plan, as appropriate.

5.2. Review of 'Key messages for communication on ENCePP'

Thomas Goedecke informed the SG that it is considered appropriate to revise the key messages for communication on ENCePP following the latest revision (Rev4) of the ENCePP Code of Conduct.

The Steering Group agreed on the importance of having a uniform message and supported the revision of key messages in line with the latest revision of the Code.

Furthermore, a reference to the promotion and stimulation of pharmacovigilance principles shall be included (see agenda item 3.5.).

It was agreed that the ENCePP Secretariat would circulate to the SG a proposal for written comments and adoption.

6. AOB

Working Group 3 activities update

Rosa Gini informed the SG that meetings of the two sub-groups have been taking place this week. WG3 has identified a need for clarification on the chapter of the ENCePP Methods Guide on the different strategies in Europe for the conduct of multi-database studies. The group intends to publish a relevant commentary within the next couple of months.

7. Action points

- ENCePP Secretariat to provide an update to ISoP with agreed actions on suggestions received from ISoP.
- ENCePP Secretariat to circulate to the SG a proposal for revised 'Key messages for communication on ENCePP' for written comments and adoption.
- ENCePP Secretariat to organise a TC with the individuals from eight Easter European countries identified by Jiri Vleck, including Olaf Klungel, Tom MacDonald and Daniel Morales.