ENCePP WEBINAR PROGRAMME 19 March 2019

Chair: Xavier Kurz, European Medicines Agency

14.00-14.05 Introduction (Xavier Kurz)

14.05-14.45 Update on ENCePP activities and plan for next year (each 5-10 minutes highlight)

- Working Group 1: Alejandro Arana (Chair Working Group 1)
- Working Group 2: Rosa Gini (Steering Group Sponsor Working Group 2)
- Working Group 3: Gianluca Trifirò (Chair Working Group 3)
- Special Interest Group (SIG) on Measuring the Impact of Pharmacovigilance Activities: Agnes Kant (Chair SIG Impact)
- Steering Group: Olaf Klungel (Elected member of Steering Group)

14.45-15.00 Discussion on the update

15.00-15.10 EMA Business Continuity Phase IV: update; election of the new Steering Group (Xavier Kurz)

15.10-15.25 Discussion

15.25-15.30 Wrap up (Olaf Klungel)

- WG1 summary, see <u>slides</u>; Xavier Kurz provided an outlook on organising revision 8 of the ENCePP Methods Guide in 2020 (skipping the revision in 2019).
- WG2 summary, see <u>slides</u>; the way forward outlined in a recent publication about Revision 4 of the ENCePP
 Code of Conduct in *Pharmacoepidemiology and Drug Safety* (<u>doi.org/10.1002/pds.4763</u>) will serve as basis for
 new WG2 deliverables; moreover, a commentary is planned to be submitted to BMJ.
- SIG Impact summary, see <u>slides</u>; current SIG mandate is fulfilled but group will be maintained and expanded with input from ISoP members (call for expressions of interest to join the SIG are ongoing) and the mandate will be revised accordingly (impact of pharmacovigilance, collaboration with ISoP SIG Medication Errors).
- WG3 summary, see <u>slides</u>; commentary on strategies for conduct of multi-database studies under preparation for submission to BMJ; review of multi-database studies in the EU PAS Register ongoing, researchers from 10 partner institutions collaborate on this activity.
- SG summary, see slides; main focus should be the dissemination of Revision 4 of the ENCePP Code of Conduct and ways to promote its implementation; consider revision of the Code's Annex 4 on data sharing in line with Revision 4; focus on access to Eastern and Central EU databases (Steering Group has approached respective data source providers), follow up to further expand the ENCePP network; possible presentation of the SIG Impact work at the ISoP Annual Meeting 2019 (to be confirmed); activities will be continued through informal network meetings until EMA support to ENCePP is fully restored.
- Business Continuity Phase (BCP): Xavier Kurz reminded all partners that until September 2019 no EMA
 administrative or meeting support to ENCePP activities can be expected; this may change after review of the
 BCP; at this stage, the next plenary meeting is expected in 2020; in the meanwhile EMA participates as observer
 to informal network activities and respective deliverables maintained by ENCePP partners; output of informal
 activities during BCP will provide basis for a new work plan.