EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

6 July 2016
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ENCePP Secretariat

Minutes - ENCePP Steering Group Meeting

20 June 2016, 09.30 to 16.30, chaired by Peter Arlett

List of participants	
Present:	Morten Andersen, Peter Arlett, Marieke de Bruin, Corinne de Vries, Dinah Duarte, Pierre Engel, David Haerry, Maria Teresa Herdeiro, Thomas MacDonald, Nicholas Moore, Susana Perez-Gutthann, Nawab Qizilbash, Patrice Verpillat Principal Adviser to the SG: Xavier Kurz Statistical Adviser to the SG: Jim Slattery ENCePP Secretariat: Cristina Sandu, Dagmar Vogl Others: Agnes Kant, Chair of ENCePP SIG 'Impact' (partly, via TC), Daniel Morales (EMA), Alison Cave (EMA), Zahra Hanaizi (EMA), Jordi Llinares Garcia (EMA)
Apologies:	Hans-Georg Eichler, Yola Moride

1. Welcome & Adoption of draft agenda

The Chair briefly introduced the day's agenda which was adopted without change.

2. ENCePP Work Plan

2.1. Progress report – ENCePP Work Plan 2015-2016

With the mandate of the work plan 2015-2016 coming to an end, Xavier Kurz presented an overview on the progress of the current work plan, including a list of deliverables to be carried over to 2017.

The presentation also included a report on the status of the upgrade of the EU PAS Register. The Steering Group (SG) was informed that the 1st wave upgrade is scheduled to take place in July 2016 and will include improved searching and data management functionalities, enhanced database performance and allow for regulatory compliance monitoring; a 2nd wave upgrade is planned in Q4 2016.

The Steering Group strongly welcomed the proposed enhancements to the EU PAS Register. The SG cautioned that the full acceptance of the Register by journal editors and in terms of referencing of registered studies by PRAC should be further clarified. The SG also raised questions about whether users would be able to complete the data fields on regulatory status of studies.

For action:

- ENCePP Secretariat to circulate to SG members for comment the explanatory text relating to the new data field 'RMP study category'.
- ENCePP Secretariat to investigate how to optimise the status and use of the EU PAS Register.

2.2. Steering Group proposals for ENCePP Work plan 2017-2019

The new work plan will be aligned in duration with the mandate of the new Steering Group and will cover a three year period. SG members were invited to make proposals for topics that they would like to see covered during the next work plan mandate. During an initial brainstorming the following topics emerged to be of interest to the group and it was agreed that they would be taken into consideration when drafting the new work plan:

- Funding of studies post Horizon 2020
- Impact of new data protection rules
- Impact of new clinical trials regulation

It was confirmed that further discussions with the Steering Group on the new work plan will be taking place.

In this context the Chair also reminded the group that the mandate of the current Steering Group will be coming to an end in 2016, and that SG elections will be taking place at the November plenary.

For action:

- ENCePP Secretariat to circulate relevant information on the SG election process and term of service.

2.3. Mandate of joint Enpr-EMA - ENCePP working group on paediatric pharmacovigilance (Revision 1)

Xavier Kurz introduced the revised mandate of the joint Enpr-EMA – ENCePP working group which has been amended to include the group's contribution to the revision of the new module of the Good Pharmacovigilance Practices (GVP) on paediatric pharmacovigilance. He informed the SG that a request for expression of interest had been sent to the ENCePP members of the joint working group to re-confirm their interest in the group's work.

Revision 1 of the mandate of the joint Enpr-EMA - ENCePP working group on paediatric pharmacovigilance was adopted by the Steering Group.

For action:

- ENCePP Secretariat to circulate the adopted mandate to WG members and to publish the revised mandate on the ENCePP website.

2.4. WG1 mandate (Revision 3)

The mandate of the working group on research standards and guidances (WG1) has been amended to include reference to needs of regulatory and HTA decision-making in its overall mandate.

Revision 3 of the WG1 mandate was adopted by the Steering Group.

For action:

- ENCePP Secretariat to circulate the adopted mandate to WG members and to publish the revised mandate on the ENCePP website.

2.5. ENCePP Checklist for Study Protocols (Revision 3)

Xavier Kurz introduced the revised checklist for study protocols which now includes reference to sections, rather than page numbers of protocols, and a change to section 6.4 relating to HTA endpoints. In addition, the wording of the checklist has been improved and some questions re-arranged to appear in a more logical order. The revised checklist is to be published in parallel with the latest revision of the ENCePP Methods Guide (early July 2016).

SG members were invited to provide additional editorial comments within one week.

For action:

- ENCePP Secretariat to circulate draft Revision 3 of the ENCePP Checklist for Study Protocols to SG members for written adoption.
- Following adoption, ENCePP Secretariat to publish new version on the ENCePP website and inform stakeholders.

2.6. Update on Revision 5 of ENCePP Methods Guide

The annual review of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology is complete, and publication of Revision 5 is planned for early July. Daniel Morales briefly highlighted the main changes following this latest revision which includes a number of new sections and a new chapter on *Using data from social media and electronic devices as a data source*.

It was agreed that draft Revision 5 would be circulated to the Steering Group for information and comments.

For action:

- ENCePP Secretariat to circulate draft Revision 5 of the ENCePP Methods Guide to SG members for comment and written adoption.
- Following adoption, ENCePP Secretariat to publish new version on the ENCePP website and inform stakeholders.

3. Update on issues discussed at previous meeting

3.1. Funding mechanisms for PAS

Xavier Kurz presented the ADVANCE project draft governance models saying that the objective of the ADVANCE project was to develop governance models in the European environment to support and expand collaborative utilisation and integration of vaccine real life data across countries. The aim of today's discussion would be to discuss the relevance to ENCePP of the different governance models for public-private interactions elaborated in the context of the ADVANCE project.

In particular, the SG discussed the application of the ADVANCE models to the two funding proposals presented at the 2015 Plenary, i.e. a third party peer review model, and a proposal on research funding for medication safety in pregnancy.

Overall, the model 'Selection by External Organisation' to facilitate industry funding emerged as the preferred option by the SG, although it was acknowledged that other options could also provide robust governance.

Peter Arlett said that it is of utmost importance that any system put in place needs to be robust and sustainable. To move this forward, it is proposed to first reach out to stakeholders to get their feedback on the proposal before proceeding with any formal selection process for involvement of an external organisation. He also cautioned that a number of legal questions would have to be clarified before proceeding further.

In terms of a proposal to ring-fence funding for research in medication safety in pregnancy, it was agreed that the topic of 'infrastructure funding' would be brought up in the EMA discussions with stakeholders planned in the context of the third party peer review model. It is further proposed to draft a specific business case for consideration of this topic under post Horizon 2020 funding by the European Commission.

For action:

- EMA to clarify legal aspects relating to the funding model 'Selection by external organisation' and initiate contact with stakeholders.
- ENCePP Pregnancy SIG to consider drafting business case for post Horizion 2020 funding.

3.2. ENCePP Special Interest Group (SIG) on Impact of pharmacovigilance activities

Following agreement at the SG meeting in December 2015, the ENCePP SIG on Impact of pharmacovigilance activities was established in March 2016 and has been meeting monthly via TC.

Agnes Kant, Chair of the ENCePP SIG on Impact, joined the meeting via TC to introduce the group's draft mandate and detailed work plan.

It was clarified that the objective of the ENCePP SIG is to provide recommendations to the PRAC Interest Group (IG) on Impact, and that the ENCePP SIG's focus will be on more methodology aspects with a broader scientific scope, rather than the regulatory focus of the PRAC group. Nevertheless, it is important that the two groups' work is complementary and overlap should be avoided. The mandates and work programmes of both groups therefore need to be aligned optimally.

It was agreed that the mandate and work plan of the ENCePP SIG on Impact of pharmacovigilance activities will be adopted by written procedure following one final round of review vis-à-vis the PRAC IG mandate.

For action:

- ENCePP Secretariat to liaise with Chairs of ENCePP SIG and PRAC IG regarding final alignment of the two groups' mandates and work plans.
- ENCePP Secretariat to circulate the SIG's mandate and work plan to the Steering Group for written adoption.
- ENCePP Secretariat to publish adopted mandate on the ENCePP website.

4. ENCePP Plenary 22 November 2016

The Steering Group members were invited to propose topics for the agenda of this year's ENCePP Plenary meeting.

The suggestions included:

- Report from PRAC on how pharmacoepidemiology studies have made a difference to regulation
- Impact of pharmacovigilance activities
- Feedback from registries workshop
- New clinical trials regulation
- New data protection regulation
- Assessment of medicines – how is benefit/risk decided?
- Update on PAES guidance

- General reflection on ENCePP (impact of ENCePP to date, successes, going forward)
- EU PAS Register upgrade
- Reminder to ENCePP partners that journal editors are in agreement with sharing findings with regulators prior to publication

5. ENCePP delivering to the lifecycle of medicines

The EMA is working to build capacity for better use of real-world evidence to support innovation, to support authorisation of medicines for patients, benefit-risk monitoring and regulatory decision-making. The aim of this session therefore was to discuss the potential role of ENCePP in such initiatives.

The session included presentations on the role of innovation/RWE, a reflection on optimisation of ENCePP support to committees (in particular PRAC and COMP), and on EMA work to support medicines development (including the PRIME initiative).

The SG agreed that the centres participating in ENCePP, as well as the data sources, were higly relevant to generating evidence from real-world use of medicines and that ENCePP could therefore contribute significantly to such evidence generation. The SG noted that epidemiological methods were already applied through the product lifecycle including identifying unmet medical needs, disease prevalence, background rates for adverse reactions, effectiveness of standard care and paediatric use, as well as the more familiar uses in evaluating the risks and benefits of marketed medicines.

The SG recommended that enhancing the ENCePP role through the lifecycle be included in the next work plan and that this could include liaison with the different EMA committees, HTA use of evidence, review of the profile of ENCePP partners, as well as, the ENCePP data sources.

For action:

- ENCePP Secretariat to circulate to all ENCePP partners information relating to the Agency's PRIME initiative.
- ENCePP Secretariat to include lifecycle of medicines in the next work plan.
- ENCePP Secretariat to consider the practical steps needed to optimise ENCePP delivering throughout the lifecycle.

6. Issues raised / A.O.B.

None.

7. Summary of discussions & next steps

The Chair summarised the discussions and thanked all participants for their contributions to a very productive meeting. The Steering Group was reminded that the next face-to-face meeting will be taking place in October 2016, with the exact date still to be confirmed.