EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

11 June 2013
EMA/306851/2013
ENCePP Secretariat

Minutes - ENCePP Steering Group Meeting

22 May 2013, 09.30 to 13.00 – chaired by Peter Arlett

List of participants	
Present:	Morten Andersen (MA), Peter Arlett (PAR), Stella Blackburn (SB), Alfonso Carvajal (AC), Ana Corrêa Nunes (ACN), Henry Fitt (HF), Nicholas Moore (NM), Yola Moride (YM – via TC), June Munro Raine (JMR), Susana Perez-Gutthann (SPG) *EFPIA Observer*: Laurent Auclert (LA) *EMA Advisers to the Steering Group*: Xavier Kurz (XK), Jim Slattery (JS) *ENCePP WG Chairs (via TC):* Alejandro Arana (WG1), Laura Yates (WG2) *EMA*: Ana Hidalgo-Simon, Luis Prieto, Corinne de Vries *ENCePP Secretariat*: Kevin Blake, Thomas Goedecke, Dagmar Vogl, Eeva Rossi
Apologies:	David Haerry, Hubert Leufkens, Marcus Müllner, Nicola Magrini

Meeting Agenda

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 8668
E-mail encepp_secretariat@ema.europa.eu **Website** www.encepp.eu

1. Welcome & Adoption of draft agenda

The Chair welcomed the Steering Group to the meeting which mainly focussed on a progress review of the current ENCePP work plan. The meeting also served to prepare for the meeting with industry associations during the afternoon session.

The proposed agenda was adopted without any changes.

2. Report from the Working Groups

2.1. WG1 Progress Update

Alejandro Arana provided a summary of activities by Working Group 1 'Research Standards and Guidances' since the beginning of the year.

- Following the adoption of the revised ENCePP Checklist for Study Protocols the new version (Revision 2) was published on the ENCePP website in January. This revision aligns the Checklist with the recommendation that the Checklist be included as an annex to study protocols included in the Good pharmacovigilance practices (GVP) module VIII on post-authorisation safety studies (PASS).
- Currently, the Working Group (WG) is reviewing the ENCePP Guide on Methodological Standards in Pharmacoepidemiology. The new version will also include new sections on vaccines and comparative effectiveness research (CER). Regular WG meetings are taking place with a view to finalising the draft revision of the guide in time for the ENCePP Plenary meeting in June.
- Discussion on the accreditation of centres is ongoing including lessons learned from the example of the paediatric network Enpr-EMA which operates a system of self-accreditation for its members.
- SPG highlighted that there is potential overlap between the work of WG1, WG3 and the Drafting Group (DG) on data integration. It would be prudent to identify potential overlap and coordinate the work by these three groups in order to avoid any duplication. The Steering Group therefore requested the ENCePP Secretariat and relevant WG/DG Chairs to closely monitor all data integration activities within ENCePP to avoid potential duplication of output. To this end, the Chair of the DG (Nawab Qizilbash) has agreed to brief WG3 on any progress made at its face to face meeting in June.

2.2. WG2 Progress Update

Laura Yates - who recently took over as Chair of Working Group 2 'Independence and Transparency' - started by acknowledging the large amount of work that had been achieved during the Chairmanship of Helen Dolk who retired from her role earlier this year, but remains an active member of the WG.

- One of WG2's major deliverables will be the revision of the ENCePP Code of Conduct. The group has also been charged with drafting an action plan to better monitor the compliance of ENCePP seal studies with the Code. Work has started on this and a draft document is in progress.

- Furthermore, WG2 will be looking at the uptake of the ENCePP Study Seal; to this end, a letter to scientific medical journal editors has been drafted for discussion by the Steering Group (see item 3.4.). The aim is to approach editors about the Code and its function and to try and get their input on how the awareness and uptake might be increased. The WG also intends to launch a survey of ENCePP partners to better understand the barriers to the uptake of the ENCePP study seal. The survey results will feed into the revision of the Code. It was also agreed that the full responses to the industry survey would be made available to WG2, as the comments made would be pertinent to the group's work on the uptake of the ENCePP study seal.
- Finally, Laura explained that the special interest group (SIG) 'Pregnancy' that had been proposed at the last ENCePP Plenary in November 2012 had developed from WG2 since a number of WG members happen to be specialists in pregnancy research. The draft mandate of the SIG has been tabled for discussion by the Steering Group (see item 3.3.).

For action:

- ENCePP Secretariat to circulate responses to the industry survey to WG2

2.3. WG3 Progress Update

Miriam Sturkenboom gave a summary of most recent activities of WG3 'Data sources and multi-source studies'.

- She outlined that the focus of the group is on multicentre/multinational studies utilising existing data sources. A survey of multi-source studies has been conducted, and the responses will form the basis of a paper outlining the current state of the art in utilising multiple data sources. She cautioned that it is premature at this stage to develop specific guidelines on this topic.
- A large amount of heterogeneous information was collected following a request to all Member States via the Pharmacovigilance Working Party (PhVWP) asking for information relating to national data privacy legal requirements when sharing and pooling data. The EMA legal team has been analysing the information, but it has recently been decided that no further effort should go into analysis at this stage due to the revision of the General Data Protection Regulation potentially making these requirements redundant. Instead the focus will be to continue to monitor very closely the progress of the EU data protection rules currently under development. However, the information collected through the survey should be made publicly available in a structured way through the ENCePP website.

JMR suggested that the 'UK information governance review' – so-called Caldecott review - might be relevant for the work of WG3. It was agreed that she would make a copy of the document available to the ENCePP Secretariat for circulation to the working group.

For action:

- ENCePP Secretariat to circulate *UK information governance review* to WG3
- ENCePP Secretariat, on behalf of WG3, to publish MS survey results on the ENCePP website

2.4. WG HTA Progress Update

On behalf of its Chair Marlene Sinclair, Ana Hidalgo Simon provided an update on the activities of the ENCePP Working Group on Health Technology Assessment.

There is a great deal of interest in HTA and following a call for expressions of interest among ENCePP partners, the WG has been set up consisting of 13 members, plus its Chair, and a Co-Chair representing EUnetHTA. The group meets regularly, and one of its first outputs was a response to the European Commission public consultation on post-authorisation efficacy studies in February 2013. Currently ongoing are discussions on the general mandate of the group and defining the focus of its activities.

- The WG has completed a compilation of HTA activities and expertise of its members, and has reviewed lessons learned from the development of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology.
- The development of methodological guidance for studies in HTA will be another major output and is ongoing.
- During a recent meeting it was agreed that the group would draft a working document aiming at bridging the gap between HTA and medicines regulation regarding additional evidence generation. In this context it has become clear that more information on EUnetHTA activities is needed. This will be provided via the group's co-chair François Meyer.
- In his role as Steering Group sponsor of the HTA working group, NM added that the most challenging part from the outset was to understand the interface of HTA and ENCePP. He explained that, while HTA looks at assessing existing data, ENCePP is about generating data. The problem is to define the activities of the ENCePP WG and how it can support regulation and HTA through methods.
- It was confirmed that the HTA working group had been consulted in the review of the new chapter on comparative effectiveness research (CER) of the ENCePP Methodological Guide.

In conclusion, the Steering Group agreed that it will be absolutely critical to be clear on the objectives and mission of the ENCePP working group, in order to position it vis-à-vis other European initiatives in this field.

For action:

- WG mandate to be revised on completion of the bridging analysis, as necessary

3. ENCePP Work Plan 2013-2014

3.1. Progress Report Work Plan 2013-2014

The Steering Group reviewed the work plan 2013-2014 and progress made so far. KB confirmed that the delivery of the work plan was broadly on track, with one deliverable being slightly delayed.

3.2. Assignment of SG sponsors for individual deliverables

The SG members were asked to review the SG sponsorship of individual key deliverables from the work plan, as proposed by the ENCePP Secretariat. In this context PAR reminded everyone that

the sponsorship of a deliverable translates to engaging with a particular working group and its outputs.

There were no objections from the SG members present at the meeting to any of the proposals.

SPG volunteered to be co-sponsor with MS for the deliverable 'Map current practice for multi-source PhEpi studies, including methodological approaches'.

For action:

- ENCePP Secretariat to liaise with absent SG members to get their agreement to the proposed sponsorships and update work plan as necessary

3.3. Mandate of Special Interest Group (SIG) 'Drug Safety in Pregnancy'

Corinne de Vries (CdV), who will be leading the SIG from within EMA, introduced the mandate which had been drafted in cooperation with WG2. She explained that there is a very active group on this subject already within ISPE, and any overlap should be avoided. Furthermore, there is ongoing activity on drug safety in pregnancy within the EMA.

The Steering Group made a number of comments which will be incorporated into the revised draft mandate. The name of the group was confirmed as a 'SIG', and not 'SIN' (special interest network), as previously proposed. The revised mandate will be circulated to the SG for adoption by written procedure.

It was agreed that potential candidates would be approached over the next couple of weeks with a view to chairing the group. A first meeting of the SIG will be organised during the coffee break of the ENCePP plenary meeting on 18 June.

For action:

- EMA lead (CdV) to revise SIG mandate; ENCePP Secretariat to circulate revised mandate to SG for adoption
- EMA lead (CdV) to contact potential Chairs for the group
- Initial SIG meeting to be held during morning coffee break at ENCePP Plenary on 18/06/2013

3.4. Letter to Journal Editors

Helen Dolk in collaboration with WG2 has drafted a letter to journal editors in an effort to raise the profile of the ENCePP Code of Conduct.

Overall, the SG remains supportive of this initiative, but expressed some concerns that the contents ought to find the right balance between promoting the Code of Conduct and promoting the ENCePP study seal. It should recognise that the principles of the Code are universally applicable, whereas the seal only open to ENCePP Centres.

During the discussion on this subject matter some Steering Group members voiced their concern over the current wording of the Code which is perceived to be too ENCePP-seal-focussed. MA suggested that WG2 should consider a clear stepped approach in the next revision to highlight the universal applicability of the Code.

The Steering Group agreed that the letter needs re-orientation, and rather than focus exclusively on the importance of the Code, the message should be broadened and emphasize transparency, i.e. the registration of studies in the e-Register.

The drafting group in WG2 (Helen Dolk, Laura Yates, Thomas Goedecke) is now charged with finalising the letter taking into account the points expressed by the Steering Group. The letter will then be circulated to the SG for adoption by written procedure.

KB also asked the Steering Group to keep in mind that the alignment of the e-Register to the WHO ICPT platform is in hand in relation to the update to the EU PAS register, and that accreditation by WHO would be recognised by ICMJE.

For action:

- WG2 drafting group to finalise letter to journal editors taking into account the SG comments
- ENCePP Secretariat to circulate finalised draft letter to SG for adoption by written procedure

4. ENCePP Plenary 18 June 2013

4.1. Draft Agenda

The preliminary draft agenda for the ENCePP plenary was agreed by the Steering Group, and the discussion focussed on defining objectives for the various agenda items.

LA agreed to give a report to the Plenary from the ENCePP meeting with industry associations. He stressed that the ENCePP initiative to enhance the interface with industry is very welcome and important work still needs to be done to improve the collaboration.

SPG proposed to include more information on the agenda, e.g. objectives, weblinks to documents, etc. This proposal was welcomed by other SG members.

For action:

- ENCePP Secretariat to amend the draft Plenary agenda and publish on ENCePP website

4.2. Next SG election

As laid down in the SG mandate, in the event of an elected SG member resigning during his/her tenure, a call for nominations for election for the vacated position should be held. Following Corinne de Vries' resignation earlier this year this would mean that an election to replace her should be held at the plenary meeting in June.

Seeing that the tenure of the current Steering Group expires at the end of the year and a SG election is already scheduled for the plenary meeting in November, it is proposed to hold off the election to find a replacement for C. de Vries until the November plenary.

The Steering Group agreed to this proposal.

5. ENCePP Best Evidence Supporting EMA Committees

5.1. Experience so far

KB presented slides outlining various examples of best evidence support provided by ENCePP to EMA Committees to date. This would orientate on a presentation on this subject at the next ENCePP Plenary meeting. PA also informed the SG that, in due course, it is planned to write an article on this topic for publication in a scientific journal.

JMR proposed to provide a broader picture of examples of major safety reviews in recent past, and also to focus on ENCePP's contribution to transparency.

MS cautioned that, although there is great willingness from ENCePP partners to provide information feeding into best evidence, partners may not be willing to give this information necessarily for free. She urges EMA to find means for further funding of these activities.

For action:

- KB to revise slides for presentation at the ENCePP plenary meeting

6. Meeting with industry associations

6.1. Agenda & Preparation for meeting with industry representatives

The Steering Group reviewed the draft agenda for its meeting with industry representatives scheduled for the afternoon.

The discussion focussed on the objectives of the meeting and it was agreed that the outcome should be a list of action points and recommendations, which would ultimately feed into the development of a set of ENCePP tools for use by industry as governance models.

LA confirmed that there is broad industry support for such tools.

7. A.O.B / Issues raised

None.