



25 September 2013
EMA/572593/2013
ENCePP Secretariat

Minutes - ENCePP Steering Group Meeting (Teleconference)

17 September 2013, 14.30-16.30 – chaired by Peter Arlett

List of Participants	
Present:	Peter Arlett (PAR), Stella Blackburn (SB), Alfonso Carvajal (AC), Henry Fitt (HF), Miriam Sturkenboom (MS), Morten Andersen (MA), Nicola Magrini (NM), Hubert Leufkens (HL), Susana Perez-Gutthann (SP), Yola Moride (YM) <i>EFPIA Observer:</i> Laurent Auclert (LA) <i>ENCePP Secretariat:</i> Kevin Blake (KB), Thomas Goedecke (TG), Eeva Rossi (ER) <i>EMA:</i> Jim Slattery (JS)
Apologies:	Ana Corrêa Nunes, David Haerry, June Raine, Marcus Müllner, Nicholas Moore, Xavier Kurz

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1. Welcome & Adoption of draft Agenda

PAR welcomed everyone to the ENCePP Steering Group meeting.

The draft agenda was adopted without changes.

1.1 EMA Reorganisation

PAR informed the SG that the EMA reorganisation was announced on the EMA website on 16 September 2013. These changes do not have any impact on the communication with the ENCePP Secretariat.

2. Proposal for join EnprEMA-ENCePP paediatric pharmacovigilance WG

KB presented the background to the proposal for a joint EnprEMA – ENCePP WG on paediatric pharmacovigilance which had originated with the establishment of an EnprEMA WG on the subject. In line with the number of representatives of EnprEMA in the WG, it is proposed that there would be 3 – 4 representatives of ENCePP to join a combined group.

The SG was supportive of the proposal and also agreed on the draft high-level mandate of the joint WG, which will be focussed on the revision of the paediatric pharmacovigilance guideline and a chapter for the ENCePP Guide on Methodological Standards.

It was decided that a call would be circulated among ENCePP for expressions of interest to join the WG with statements of motivation supported by evidence of relevant expertise.

3. Follow-up: Meeting with industry associations

3.1 Recommendations arising from discussions with industry representatives

3.2 ENCePP-industry working group/discussion forum/ENCePP DIA Info Day

KB summarised the report from the meeting which took place 22 May 2013 highlighting the conclusions.

General observations from the SG:

HL raised the issue how industry in-house pharmacoepidemiological expertise could be recognised, particularly in publications and SPG pointed out that the Code's concept of independence should rather be guarded and work should focus on how industry could better contribute to this concept of independence. AC commented that some part of the industry may not see the need to collaborate with ENCePP given their own in-house expertise and that the number of ENCePP seal applications is generally not a good measure of industry collaboration, therefore specific KPIs may be considered.

SG feed-back on the specific proposals:

1. Need to further engage with industry and establishment of a joint ENCePP-industry forum (explore utility of the network for industry)

- The group supported a joint ENCePP-industry platform for dialogue and considered it necessary that a first kick-off meeting should take place exploring how to progress the dialogue
 - The group also requested a draft proposal for industry engagement to be consulted at the next plenary. This proposal will feed into further discussions with industry and development of a joint work plan.
2. Role of ENCePP SG observer from industry (EPFIA)
 - SG supported to continue EPFIA observer status after the kick-off meeting has taken place, the role of the observer could be further reviewed
 3. Review the Code and ENCePP Study Seal concept
 - While clearly indicating that the key pillars of transparency and independency must remain, SG supported a review of the Code and considered it paramount to get input from all ENCePP partners on this revision, as well as input from industry.
 - In this context also a review of the contents of the ENCePP website with focus on industry needs was supported
 - As mid-term initiative the SG also supported training in the form of a workshop or information day for industry
 - LA agreed to seek written feed-back from industry on needs for clarification before the kick-off meeting

4. ENCePP Plenary 12 November 2013

The first draft of the proposed agenda was discussed and the SG was supportive with the following amendments:

- The updates from the WG Chairs are to be streamlined to keep within the allocated timeframe. It is proposed that each Chair in their presentation has 3 slides highlighting (1) key developments since the last Plenary (2) status of on-going work and next steps (3) where the WG needs input from the Plenary.
- It was considered that the time allocated at Plenary meetings to the election of ENCePP partners to the SG needs to be reduced. To this end, in the longer term it is proposed for consideration by the Plenary at the November meeting that the mandate of the SG be extended from the current 2 year to a 3 year term, in line with other existing mandates at EMA. In the more immediate term, it was agreed that statements of motivation of candidates would be circulated in writing before the Plenary instead of presentations on the day. The call for candidates is to be circulated soon.
- Further feedback on the meeting with industry and a draft work plan for industry engagement is to be added to the agenda.
- The session on methodology relating to pharmacogenomics is to be extended to include additional speakers.

5. A.O.B

N/A.