EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 October 2010
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European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Minutes ENCePP Steering Group Vitero meeting

16 September 2010, 14.00-16.00 – Chaired by Peter Arlett

List of Participants	
Present:	Peter Arlett (PA), Corinne de Vries (CdV), Hans-Georg Eichler (HE), Henry Fitt (HF), Joan-Ramon Laporte (JRL), Hubert Leufkens (HL), Jytte Lyngvig (JL), Yola Moride (YM), Ingemar Persson (IP), June Munro Raine (JMR), Miriam Sturkenboom (MS), Giuseppe Traversa (GT) *EFPIA Observer*: Valerie Simmons *ENCePP SG Advisors*: Xavier Kurz (XK), Jim Slattery (JS) *ENCePP Secretariat*: Kevin Blake (KB), Rocio Fernandez Fresquet (RFF), Stefanie Prilla (SP), Camilla Smeraldi (CS)
Apologies:	Stella Blackburn, David Haerry, Nicholas Moore

Item	Preliminary draft agenda	Initials	Mins
1.	**Adoption of draft agenda**	PA	5
2.	**Matters arising / Feedback from Partners Forum**	All	10
3.	**ENCePP Studies**		
	3.1 Status update: e-Register of Studies	CS/RF	15
	3.2 Outcome of written procedure: Data access	HF/SP	
4.	**SG Priority Items**		
	4.1 Dialogue with Medical Journals		
	➢ List of journals and issues to be raised	HF	10
	4.2 Performance & success measures		
	➢ List of metrics to be used for the impact evaluation of ENCePP	KB	10
5.	**ENCePP Work Plan**		
	5.1 List of deliverables 2011	CS	10
	5.2 For discussion and further definition:		
	➢ a. ENCePP Communication Strategy	All	35
	➢ b. Interface between ENCePP and Regulators		
	5.3 ENCePP Working Groups:	CS	15
	➢ Allocation of SG rapporteurs		

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Item	Preliminary draft agenda	Initials	Mins
6.	**Summary of discussions & next steps**	PA	5
7.	**A.O.B**	All	5

1. Adoption of draft agenda

The draft agenda was adopted.

2. Matters arising / Feedback from Partners Forum

The SG requested an update on the status of the applications for the ENCePP Study Seal. The SG heard that one application has been received so far and that after review of the submitted documentation the study was deemed appropriate to be awarded with the ENCePP Seal. While the electronic register of studies is being finalised, the data entry form for the study, the protocol and all relevant documents will be made public in accordance with the interim solution previously agreed by the SG. The EMA is also considering issuing a dedicated press release on the EMA website to communicate achievement of this important milestone.

3. ENCePP Studies

3.1 Status update: e-Register of Studies

The SG was presented with an update on the status of the IT project for the development of the electronic register of studies. The deployment of the database by the IT project team is scheduled for 27 September. After this date the electronic register will be ready to go live.

In order to make sure that the database will be fully operational once it is released to the general public it is envisaged to run a pilot phase in the month of October during which the database will be populated by the EMA Staff to test the data entry and submission tool, to test the automated acceptance/rejection tool and more in general to get feedback from users. Members of the SG were also invited to volunteer for this pilot phase.

At the end of the pilot phase the e-Register of Studies will be formally presented to the public during the next ENCePP plenary meeting in November and at the ENCePP Infoday that will be held on 26 November.

3.2 Outcome of written procedure: Data access

The SG noted that on 12 September 2010 a revision of the Code of Conduct and an implementation guidance to clarify the conditions of providing access to study data were adopted through written procedure by a majority of members.

The updated version of the ENCePP Code of Conduct and the implementing rules on access to data will now be published on the ENCePP website and will be formally presented to the next ENCePP plenary in November 2010.

While acknowledging that these newly adopted rules should answer the concerns raised by some of the centres/networks during the last plenary meeting the SG was also of the opinion that further elaboration on this topic is warranted at the time of the review of the Code of Conduct that will take place one year after its adoption. In this respect, the SG also noted a discussion paper that had been circulated by G Traversa to the members of the SG and agreed that the points raised in this document as regards to access to investigational data set would also deserve further discussion.

4. SG Priority Items

4.1 Dialogue with Medical Journals

The advice of the SG was sought on a proposed list of points to be discussed with Editors of Medical Journals. The SG agreed with the proposed points for discussion and suggested engaging in a dialogue with the British Medical Journal as a priority.

The SG also was of the opinion that the New England Journal of Medicines and the Journal of American Medical Association should also be contacted. It was however suggested to re-open discussion on the ENCePP and Sentinel initiatives with the FDA before approaching these two journals. To this end, P Arlett informed the SG about his planned mission to the FDA at the end of this month.

4.2 Performance & success measures

The SG considered a paper prepared by K Blake with the aim of gathering some ideas to be used for a possible impact analysis of ENCePP.

Overall the SG agreed with the idea of evaluating the impact of ENCePP as outlined in the paper presented although it was acknowledged the difficulty of finding parameters that could be easily measured. It was felt that additional qualitative evaluations including a structured interview with stakeholders could be helpful in measuring the success of the initiative, while quantitative metrics (such as number of applications, visits to the website, etc) could be readily used to produce annual statistics.

The document was presented to the SG to receive an immediate feedback: as a next step, written comments from individual members will be collected through a further re-circulation of the document.

5. ENCePP Work Plan 2011

5.1 List of deliverables for 2011

A list of possible deliverables to be included in the ENCePP Work Plan 2011 was presented to the SG to receive an immediate feedback. Further to the comments received and the discussion at point 5.2.a and 5.2.b a revised version will be prepared and re-circulated to the SG for agreement.

The SG agreed with the proposed list of deliverables for 2011, although it was noted that it would be an ambitious work plan to be fulfilled.

5.2.a ENCePP Communication Strategy

Further to the initial discussion at the previous Steering Group meeting in May 2010, this topic was brought back to the agenda for formal decision on the establishment of a dedicated Working Group on Communication. Some points for discussion provided by D Haerry to the Secretariat in advance to this meeting were noted.

The SG was of the opinion that, at this stage, the development of a communication strategy for ENCePP should be focussed on the dissemination of this initiative to a wider audience. The SG members encouraged progress on the dialogue with medical journals and suggested raising awareness on the status of the project with CHMP and PhVWP. To this end updates on the progress of ENCePP will be scheduled at future CHMP and PhVWP meetings.

Concerning the role of ENCePP as regards communication of study results and more generally of risk of medicines, it was felt that this could possibly generate conflicting situations with the role and the responsibilities of the Regulatory bodies. In this respect it was noted that a number of initiatives are

currently ongoing aimed at improving communication in pharmacovigilance and therefore caution should be exercised to avoid conflict or duplication of efforts in this field.

As regards internal communication between ENCePP partners, it was highlighted that a dedicated forum has been set up on the ENCePP website but that so far this has not been widely used. More effort should be put in enhancing the contents of the Partners' forum and in facilitating its use as an important resource for the exchange of information among the members of the ENCePP community.

In conclusion, the SG felt that activation of a dedicated working group on communication at this stage would be premature, but that further discussion on this topic should continue at the next face to face meeting of the Steering Group.

5.2.b Interface between ENCePP and Regulators

The need to define the role of ENCePP as regards its interaction with Regulators, also in light of the changes that will be introduced by the new Pharmacovigilance legislation, had been identified as a priority item to be discussed by the Steering Group.

The views of the representatives of Regulatory bodies in the Steering Group were noted, in particular their call for timely availability of data that may have an impact on decision making processes. It was felt that on some occasions data were not disclosed in a timely fashion for the fear of affecting their publication in medical journals. On the other hand, representatives from Academic centres in the Steering Group advocated the right for researchers to allow some time for a peer review of the data before sharing them with Regulatory authorities. Additionally, the trend in recent years for Regulators to interact directly with researchers rather than via Marketing Authorisation Holder(s) for matters arising from data published in the scientific literature was acknowledged.

The SG supported the development of a guidance (or "best practice consensus") on the interaction with Regulators for those cases in which researchers have findings of public health relevance. The guidance should clarify the status of "regulatory" publication of the findings in contrast to the publication in scientific literature, the fact that one does not preclude the other (the link to the dialogue with journal editors was noted).

Lastly, the SG agreed that further consideration would be valuable on the possibility for Regulatory authorities to undertake commissioned work or conduct research using in-house data sources.

The guidance document to be developed will be included in the list of deliverables for the 2011 Work Plan and contact will be made with Working Group 2 to seek their involvement on this topic.

5.3 ENCePP Working Groups:

Due to time pressure, this agenda item was postponed for discussion at the next SG meeting.

6. Summary of discussions & next steps

Action Points arising from the discussions:

- ENCePP Secretariat to organise an additional VITERO meeting or teleconference to prepare for the next plenary meeting;
- Members of the SG to volunteer for the pilot phase of the electronic register of studies;
- ENCePP Secretariat to re-circulate document on impact analysis for written comments;
- ENCePP Secretariat to re-circulate table of deliverables for Work Plan 2011 for written comments;
- Progress updates on the status of ENCePP to be scheduled at future CHMP and PhVWP meetings;

Next meetings:

- Vitero meeting: 21 October 2010, 13h00-14h-00
- ENCePP Plenary meeting: 18 November 2010
- ENCePP Infoday: 26 November 2010
- Vitero meeting: 2 December 2010, 14h00 – 16h00