EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Minutes of ENCePP Steering Group Vitero/TC meeting

19 May 2011, 14.00-16.00 – Chaired by Peter Arlett

List of Participants	
Present:	Peter Arlett (PA), Stella Blackburn (SB), Corinne de Vries (CdV), Hans-Georg Eichler (HGE – *partly*), Joan-Ramon Laporte (JRL), Hubert Leufkens (HL), Jytte Lyngvig (JL), Ingemar Persson (IP), Yola Moride (YM), Nicholas Moore (NM), June Raine (JR), Miriam Sturkenboom (MS), Giuseppe Traversa (GT) *ENCePP Secretariat*: Kevin Blake (KB), Eeva Rossi (ER), Camilla Smeraldi (CS), Dagmar Vogl (DV) *EMA*: Stefanie Prilla (SP)
Apologies:	David Haerry, Henry Fitt, Valerie Simmons (Observer)

Item	Draft agenda
1.	**Adoption of draft agenda**
2.	**Matters arising** 2.1 🗎 Industry ENCePP Centres (N Moore) 2.2 🗎 Policy for ENCePP Announcements (H Leufkens) 🗎 *Draft ENCePP Linking Policy* 2.3 Use of partners forum for industry announcements
3.	**ENCePP Survey** 3.1 🗎 Feedback on Survey Results and action points
4.	**ENCePP Work Plan 2011-12** 4.1 Interaction with regulatory decision-making • Strategy for PhEpi to support regulatory decision-making (oral update) • 🗎 *Options for funding mechanisms of post-authorisation studies linked to medicines regulation* 4.2 Impact Analysis • 🗎 **Adoption** of *Concept paper on the proposed strategy for the impact evaluation of ENCePP* 4.3 Oral update: ENCePP response to the EC public consultation on the revision of the Clinical Trials Directive
5.	**Journalist Workshop 29 June 2011**

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 8416
E-mail encepp_secretariat@ema.europa.eu **Website** www.encepp.eu

Item	Draft agenda
	5.1 Oral update on workshop preparations Draft Agenda
6.	**Access to Data** 6.1 Outcome of task force meetings
7.	**Data protection:** 7.1 Oral report: Outcome of meeting with DG Justice
8.	**ENCePP Plenary meeting 30 June 2011** 8.1 Draft agenda 8.2 Working groups meeting on 1 July 2011
9.	**Upcoming Events** 9.1 2nd ENCePP Info Day 7 November 2011: Draft Agenda 9.2 PharmSciFair Prague 16 June 2011: Speaker Opportunity
10.	**Summary of discussions & next steps**
11.	**A.O.B**

1. Adoption of draft agenda

The draft agenda was adopted without changes.

2. Matters arising

2.1. Industry ENCePP Centres

NM raised the question of the possibility of having ENCePP studies done within a pharmaceutical company, by a specific entity within the company that meets all the provisions in the ENCePP Code of Conduct.

PA clarified that it is currently not foreseen for industry to be able to join ENCePP. However, he highlighted the fact that this does not stop centres within industry from conducting commissioned studies and from registering their studies in the ENCePP e-register of studies. Furthermore, industry can still largely adhere to the principles of the Code of Conduct and follow the methodological guidance developed by ENCePP even without applying for the ENCePP study seal. It should also be made clear that use of ENCePP for commissioned research is not a regulatory requirement and that there are no plans for it to be so.

The Steering Group (SG) gave broad support to this intervention. CdV stressed the fact that the concept of an industry ENCePP centre would go against the principles of ENCePP's inception.

The SG acknowledged that some aspects of the concept of 'ENCePP centre' might need to be re-visited in the near future.

2.2. Policy for ENCePP Announcements

The ENCePP Secretariat has drafted a 'linking policy' for the ENCePP website with a view to complementing the existing EMA privacy policy and to establish a policy/guidance relating to links to third-party websites and the announcement of third party activities on the ENCePP website. Once adopted and approved by the EMA legal department, this policy will be published on the ENCePP website. SG members are requested to provide their comments on the draft policy in writing.

The main principle of the policy is that the ENCePP Secretariat will only accept requests for links and announcements with relevance to PhEpi and PhV that are of non-commercial nature. For this purpose a new section will be created on the ENCePP website for third party announcements.

In response to a query by CdV it was clarified that announcements by the ENCePP Secretariat will continue to be published in the Partners' Forum, the 'news'-section of the website, or circulated via email to ENCePP partners. However, the ENCePP Secretariat will look into ways of how to best keep ENCePP partners up-to-date and informed of developments, while keeping email messages to a minimum. A possible solution would be to use more the partners' forum (e.g. for communications related to the activities of the Working Groups, for announcements, etc.) although it is acknowledged that at the moment this tool is not exploited as fully as it could be.

2.3. Use of partners forum for industry announcements

SB was recently approached about the possibility of industry posting announcements, e.g. on the need for a study, in the ENCePP Partners' Forum. The SG agreed in principle to facilitating such requests. In practice, such requests would be addressed to the ENCePP Secretariat which will place the announcement, including relevant contact details, in the forum.

A detailed process of how to deal with such requests will be elaborated and communicated to industry.

3. ENCePP Survey

CS introduced the summary of responses to the recent ENCePP Plenary survey. A number of action points had arisen for which agreement was being sought from the SG:

Q1 – Motivation behind joining ENCePP:

The results of the survey show that active involvement of partners in some of the ENCePP activities increases their satisfaction with the network. The current work plan identifies a number of topics that should be dealt with by the network in collaboration with working groups and ad hoc task forces. A call for volunteers to join the existing working groups has been closed recently. Meetings of the three existing working groups have been scheduled in the margins of the next ENCePP Plenary meeting.

The SG agreed that in order to involve partners actively, the working groups need to be activated and group discussions should be encouraged.

Q2 - Priorities for ENCePP:

The majority of respondents considered that conduct of non-interventional studies and methodological guidance as two priority issues for ENCePP. While issues relating to funding of studies were also flagged as important, the responses clearly indicate that ENCePP partners do not consider the presentation of research results as a priority for ENCePP.

The SG took note of this clear indication of preferences by ENCePP partners which will be taken into consideration in future planning of ENCePP activities. The SG also agreed that the networking and communication are clearly very important aspects for the Plenary. It was suggested to obtain feedback from the Plenary on the interaction with industry.

Q3 - ENCePP Plenary Meetings:

The responses highlighted that the three aspects considered most relevant to the ENCePP partners are facilitating collaboration & networking between research centres, methodological aspects of research and information on funding opportunities. Again, it appears that partners do not expect the ENCePP Plenary to be a forum for the presentation of scientific results or discuss specific drug issues.

The SG took note of this clear indication of preferences by ENCePP partners which will be taken into consideration in the planning of future ENCePP Plenary meetings.

Q4 - Research topics to be included in public funding programmes

In response to this question more than 40 different topics were suggested by the ENCePP partners, ranging from purely methodological topics to specific adverse reactions of interest, special populations or safety of particular drugs or classes of drugs.

The SG agreed that the topics should be grouped and then presented to the Plenary on 30 June. Since this information was gathered anonymously, discussions should take place with ENCePP partners first on how to make best use of this information and agree on the next steps.

Q5 - Contribution of ENCePP partners to the ENCePP Plenary

In response to this question a number of proposals were received, ranging from suggestions of methodological topics to examples of collaborations between centres and results of research conducted.

The SG agreed to take some of the proposals into consideration already for the June 2011 Plenary agenda, while others will be carried over to future Plenary meetings.

4. ENCePP Work Plan 2011-2012

4.1. Interaction with regulatory decision-making

PA informed the group that there are a number of initiatives ongoing and efforts are being made to try and rationalise all these initiatives into one strategy that brings together best evidence for regulatory decision-making. This strategy will be one overarching document that aims to link into the committees under the new Pharmacovigilance legislation, ENCePP and the role of regulators as researchers. Furthermore, it is proposed that the existing draft document on options for funding mechanisms of post-authorisation studies linked to medicines regulation will become an annex to the overall strategy.

The SG expressed their broad support for this initiative and stressed that it will be a challenge to get this strategy right and a lot of hard work will be needed to do so, but that ENCePP was an ideal platform for the development of such a strategy.

PA voiced the intention to closely involve the ENCePP Steering Group in the development of the strategy. In response all SG members pledged their unanimous support and direct involvement.

PA thanked the SG for their interest and confirmed that the skeleton of the document will be circulated in the next two months for review. As a first step, the SG will be asked to reflect on the scope of the issues to be developed, including the suggestions for annexes.

4.2. Impact Analysis

KB briefly summarised the document “Concept paper on the proposed strategy for the impact evaluation of ENCePP”. Following several rounds of consultations with the SG, it was agreed that, although it would ultimately be difficult to directly capture the impact of ENCePP, the strategy will incorporate outcome measures including quantitative metrics, qualitative evaluation and counterfactual analysis.

The strategy was adopted by the Steering Group.

4.3. ENCePP response to the EC public consultation on the revision of the Clinical Trials Directive

KB informed the Steering Group that an ENCePP response to the EC public consultation on the revision of the Clinical Trials Directive had been submitted on 13 May 2011. The response had been elaborated by a dedicated ENCePP task force on non-interventional trials.

The SG agreed that the submitted response should be published on the ENCePP website, together with an article giving information on the background of the debate and different views expressed during the consultation on this topic with ENCePP partners.

Furthermore it was agreed to circulate the response widely, including regulatory committees, and journals. JYL agreed to distribute the document to the Clinical Trials Faciliation Group and Heads of Medicines Agencies via the European Risk Management Strategy.

5. Journalist Workshop 29 June 2011

CS informed the SG that the Journalist workshop has been confirmed for 29 June 2011. The event is being organised with support from the EMA press office. Participating journalists will be supplied with an information package on ENCePP in advance and no formal presentations are planned during the meeting, the focus will rather be on discussion with questions and answers. The 2-hour workshop will provide the possibility for journalists to join via the web.

The SG were invited to comment on the preliminary draft agenda by Thursday, 26 May.

During the following discussion a number of additional potential contacts were named by the SG who will be invited to the workshop. A number of topics were raised for discussion with the journalists (e.g. views on journal's approach to non-ENCePP studies, how can editors contribute to the success of ENCePP?). It was agreed that the information package provided to editors prior to the meeting will include the ENCePP Code of Conduct and checklists.

All Steering Group members and working group chairs are invited to participate in the workshop. MS agreed to attend the workshop in person and report to the Plenary on its outcome the following day.

6. Access to Data

SP gave an update on the outcome of the recent task force meetings chaired by Helen Dolk. The task force has met twice in the past two months in order to discuss and revise the access to data provisions in the Code of Conduct as well as the separate implementation guidance on access to data. She highlighted the main points agreed by the task force which have been implemented in both documents. A lot of progress has been made and broad consensus reached on the current text.

The next step will be to circulate the revisions to the task force for final endorsement prior to submission to the SG for adoption. It is anticipated that the access to data provisions will feed into the general revision of the Code and will not be adopted separately.

The SG agreed that a dedicated discussion on this topic will be necessary, and it was suggested to make use of the fact that most SG members will be at the EMA for the journalist workshop on 29th June. The ENCePP Secretariat will look into organising a short SG meeting following the workshop.

On behalf of the SG, PA expressed his thanks to the task force, and in particular to the Chair, for the work done.

7. Data Protection

Following the submission of an ENCePP response to the consultation on the approach to personal data protection in the EU, a joint delegation representing EMA, ENCePP and ECDC recently visited the responsible Head of Unit at DG Justice at the European Commission.

CdV, who was a member of the delegation, gave a short oral report on the outcome of the meeting. The meeting was very positive and took place in a very open and collaborative manner. The delegation was invited to submit proposals and examples of current practice. These were submitted jointly during the first week of May.

In summary, PA again thanked CdV and MS for their substantive input to this initiative which could potentially feed into changes to the Data Protection Directive.

8. ENCePP Plenary Meeting 30 June 2011

The SG are asked to provide their final comments on the preliminary draft agenda by the end of next week (Friday, 27 May 2011), when it will be circulated to the Plenary.

Furthermore, it was confirmed that working group meetings will be taking place in the margins of the Plenary meeting. WG1 will likely meet for a working lunch on the day of the Plenary meeting, with its sole agenda item being the appointment of a new Chair. WG2 and WG3 will meet during the morning of 1st July to discuss their mandate and next steps.

9. Upcoming Events

9.1. 2nd ENCePP Info Day 7 November 2011

CS reminded the SG members of the date of the Info Day and that volunteers are being sought for involvement in the various sessions. The ENCePP Secretariat will re-circulate the draft programme.

9.2. PharmSciFair Prague 16 June 2011

KB informed the SG that an ENCePP session will be taking place during the upcoming PharmSciFair event, and one slot is still available for which a presenter is being sought. The ENCePP Secretariat will circulate a call for expressions of interest including all relevant details.

10. Summary of discussions & next steps

Action Points arising from the discussions:

- SG members to provide their comments on the draft linking policy for the ENCePP website.
- ENCePP Secretariat to explore ways of how to best keep ENCePP partners up-to-date and informed of developments, while keeping email messages to a minimum.
- ENCePP Secretariat to elaborate a detailed process of how to deal with requests from industry for placing announcements in the Partners' Forum.
- ENCePP Secretariat to add to the Plenary agenda a discussion item on next steps regarding suggested research topics gathered from Plenary survey.
- ENCePP Secretariat to publish on the ENCePP website an article on the consultation process and the response to the EC public consultation on the revision of the Clinical Trials Directive. Response to be circulated more widely to Committees, journals etc.

- SG to provide comments on the preliminary draft agenda for the Journalist Workshop.
- ENCePP Secretariat to add 'feedback from the Journalist Workshop' to the Plenary agenda.
- If feasible, ENCePP Secretariat to organise a short SG meeting following the workshop on 29 June to discuss the revision of the Code of Conduct and implementing rules on access to data.
- SG to provide final comments on the preliminary draft agenda for the ENCePP Plenary by Friday, 27 May.
- ENCePP Secretariat to circulate draft programme for 2nd ENCePP Information Day.
- ENCePP Secretariat to circulate call for a volunteer to present on ENCePP at PharmSciFair.

11. AOB

CS informed the meeting that she will be leaving the Agency on 1st July 2011 to take up a new post with the European Food Safety Agency in Parma. Her successor in the ENCePP Secretariat is yet to be named.

For the SG, PA thanked Camilla for her dedicated work on behalf of the ENCePP network and wished her all the best for the future.

Next meetings:

- Face-to-face meeting: 29 June 2011 (tbc)
- Face-to-face meeting: 21 October 2011