



6 December 2011
EMA/951938/2011
ENCePP Secretariat

Meeting Report – 8th ENCePP Plenary Meeting

23 November 2011 – chaired by Peter Arlett

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1. General Matters

1.1. Welcome and introductory remarks

The meeting was opened by Noël Wathion, Head of Unit Patient Health Protection, who welcomed all delegates to the 8th ENCePP plenary, including representatives from 6 new centres that have recently joined the network. A warm welcome was also extended to observers from Croatia, Macedonia and Serbia, an observer from the Healthcare Professionals Working Group, and a representative from Health Canada.

This was followed by a welcome from Guido Rasi, the new Executive Director of the European Medicines Agency (EMA). Mr Rasi said that he was aware of the importance of ENCePP and its achievements and that he was very supportive of this initiative. He will be following the developments closely and made particular reference to further establishing a clear interface between ENCePP and regulators, and with HTA bodies. In closing, he thanked the outgoing Steering Group for all the work done and wished the Plenary a fruitful meeting.

With this the Chairmanship was handed over to Peter Arlett for the remainder of the day.

1.2. Adoption of agenda

The draft agenda was adopted without changes, but the Plenary was informed that item 6 would be taken before lunch, on request by JR Laporte.

The Chair made a number of announcements:

- The 2nd ENCePP Info Day took place on 7 November; the day had been a success with lots of interest from industry.
- The Plenary was reminded that the ENCePP Secretariat no longer circulates announcements by email, but these will be posted to the partners' forum instead. In order not to miss any important announcements, partners may subscribe to certain topics which will trigger automatic notifications to their Inbox. This is of particular importance in view of the recently adopted 'Third Party Announcement Policy' which allows interested parties to request the posting of notices in the partners-only forum.
- The 'ENCePP Linking Policy' was adopted earlier this month, and a notice board section has been launched on the ENCePP website. This potential networking opportunity includes four different topics; requests for posting announcements in this section should be submitted to the ENCePP Secretariat.
- Presentations from this meeting will be published on the ENCePP website, together with the meeting report. No handouts will be provided.

2. Report from the Steering Group & Working Groups

2.1. Reflections of outgoing ENCePP Steering Group

Ingemar Persson, Vice Chair of the outgoing Steering Group, gave a [presentation reflecting on the work done over the past two years](#).

He concluded by extending his best wishes from the outgoing Steering Group to the new group taking up its mandate from today.

Peter Arlett highlighted that there are a number of key challenges which will need to be addressed by the new Steering Group, not least the interface with regulatory decision-making, new data protection legislation and the definition of non-interventional trials.

In response to a question from the Plenary on the usefulness of SOPs on research methodology and how ENCePP's work could be fully embedded into routine practices it was explained that the *ENCePP Guide on Methodological Standards in Pharmacoepidemiology* provides a practical tool for researchers. In fact, the *Guide* has been very influential in the drafting of the regulatory guidance for post-authorisation safety studies which is likely to go to public consultation early next year.

2.2. Reports from ENCePP Working Group Chairs

WG1 – Research Standards and Guidances

Alejandro Arana, Chair of WG1 since August 2011, started by thanking all members of the working group for their efforts in developing the *Guide*, which was adopted in May 2011. He outlined that the group's main task is to decide how to make the *Guide* a living document and how to improve it. Three actions are envisaged:

1. Key opinion leaders on topics/chapters to be identified and asked for review;
2. Consultation with scientific societies;
3. Putting in place a review process which will allow ENCePP partners to make comments on the document through the use of an interactive tool; a sub-committee will be set up to review any comments made.

A meeting of WG1 will take place on the day following the Plenary.

WG2 – Independence and Transparency

On behalf of the WG Chair (Helen Dolk) Stefanie Prilla explained that over the past 12 months the working group had focused on the review of the ENCePP Code of Conduct. She expressed her gratitude to the members of the working group for their time and valuable input that led to the successful conclusion of the 2nd revision of the Code which was adopted in November 2011. This represents a major milestone and issues which were considered major barriers for applying for an ENCePP seal have been addressed in this revision.

Stefanie provided a [summary of the main amendments](#) which also include a new Declaration of Interests form for ENCePP studies. The revised Code, including a summary of changes, will be circulated to all ENCePP partners, and published on the ENCePP website within the next days.

Peter Arlett reiterated that the Code is absolutely central to what ENCePP has set out to achieve and as such sets a very high standard. This may have been part of the reason why the number of ENCePP seal applications has been below expected in the first year. However, he is confident that these latest changes will lay to rest the main concerns relating to the complexities of access to data and make it easier to conduct publicly-funded studies ENCePP studies.

A meeting of WG2 will take place on the day following the Plenary.

WG3 – Data sources and multi-source studies

Miriam Sturkenboom, Chair of WG3, reported back from the meeting of the group which had taken place the previous day. The main topics of the discussions were the conduct of multicentre (or multi data source) studies and how to increase the number of data sources in the ENCePP database of research resources. A number of concrete proposals to solicit additional input have been identified and

will be taken forward. An appeal was made to all ENCePP centres to provide the ENCePP Secretariat with details of data sources used for pharmacoepidemiological studies in the recent past.

2.3. Feedback from PML Workshop

Henry Fitt gave a [presentation](#) on the PML (Progressive Multifocal Leukoencephalopathy) workshop which had taken place at the Agency in July 2011.

Following the presentation it was agreed to poll ENCePP centres active in the area of PML research to gauge interest in setting up a special interest group.

2.4. Feedback from Rare Diseases Workshop

Giuseppe Traversa and Stella Blackburn presented [slides](#) providing feedback from the Rare Diseases Workshop which took place at the Agency on 4 October 2011.

3. Election of ENCePP Partners to the Steering Group

Thomas Goedecke presented [slides](#) introducing the revised mandate of the Steering Group and explaining the election procedure.

Peter Arlett clarified that three members of the outgoing Steering Group had put forward their candidature for re-election. Although this was very welcome in the interest of continuity, it had been agreed that only a maximum of two candidates standing for re-election would be eligible to be voted in. In case all three of the existing members were to be voted onto the SG, only the two receiving the most votes would actually be elected.

Following these clarifications all 13 candidates were invited to introduce themselves and motivate their candidature. Candidates unable to attend the meeting in person were given the opportunity to do so via TC.

The introductions were followed by a secret ballot. The following six ENCePP partners were elected to the Steering Group 2012-2013 (in alphabetical order):

1. Morten Andersen, Karolinska Institutet, Centre for Pharmacoepidemiology/Department of Medicine, Sweden
2. Alfonso Carvajal, Universidad de Valladolid, Spain
3. Corinne de Vries, Department of Pharmacy & Pharmacology, University of Bath, UK
4. Nicola Magrini, CeVEAS Centre for the Evaluation of the Effectiveness of Health Care, Italy
5. Susana Perez-Gutthann, RTI Health Solutions, Spain
6. Miriam Sturkenboom, Erasmus Medical Centre, Netherlands

4. Session on Methodology

4.1. Meta-analysis and pooling of data

Nawab Qizilbash – in conjunction with Miriam Sturkenboom - presented on the need for meta-analysis, pooling and systematic reviews in safety, and the collaborative prospective pooling of epidemiological data. He concluded his [presentation](#) by putting forward two proposals for discussion by the Plenary,

one being a methodological guidelines document for meta-analysis, and the other a 'structure' for data integration (including a mechanism to engage ENCePP centres when a systematic review was needed).

The presentations stimulated a lot of debate and highlighted a number of issues, underlining the need for further consideration of methodological guidance. Expertise, access to data and resources are all important points in this respect. Planning is very important, and the new pharmacovigilance legislation will allow to plan reviews in the future.

It was agreed that the topic of developing guidance for meta-analysis and pooling of data would be taken to the Steering Group for further discussion.

5. Session on Special Populations - *the Elderly*

5.1. Highlights from informal PhVWP

June Raine, representative of the Pharmacovigilance Working Party on the ENCePP Steering Group, presented [slides](#) providing feedback on recent working party discussions relating to the public health impact of ADRs in the elderly.

5.2. The EMA geriatric medicines strategy

Francesca Cerreta gave a [presentation](#) introducing the EMA geriatric medicines strategy to the Plenary. She closed by announcing two key dates, one being the EC open day on the call for proposals for Active and Healthy Ageing Public Health Programme in Brussels on 14 December 2011, and the other being the EMA Geriatric Medicine Workshop scheduled for 22-23 March 2012.

5.3. Cross-national survey of ADRs in the elderly

Following on from his presentation at the June Plenary, Ulf Bergman provided an update on the proposal for a cross-national survey of ADRs in the elderly.

It was agreed that the ENCePP Secretariat would issue a call for expressions of interest with a view to setting up a task force to take this proposal forward and work out a suitable methodology.

6. Introduction to Platform of Training Opportunities

6.1. Demo of PROTECT-EU2P training platform

Joan-Ramon Laporte presented [slides](#) introducing the interactive training platform developed in the context of the PROTECT and EU2P projects.

He confirmed that there are no restrictions as to who can apply for the offers advertised and encouraged all ENCePP centres to distribute the information further and to populate the database with training opportunities. A link to this database has been included in the ENCePP website.

7. Summary of discussions & next steps

Peter Arlett closed the meeting by thanking the outgoing Steering Group for the hard work and expertise that have been put into ENCePP over the past two years. He thanked those who had put themselves forward for election to the Steering Group and welcomed the newly elected Steering Group members, who will be facing a challenging work plan.

8. A.O.B

None.