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SCIENCE MEDICINES HEALTH

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ENCePP Secretariat

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Meeting Report - 10th ENCePP Plenary Meeting

11 October 2012 – chaired by Peter Arlett

Meeting Agenda:

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
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1. General Matters

1.1. Welcome and introductory remarks

Peter Arlett welcomed the delegates, in particular those attending their first plenary, including representatives from four new partners that had joined ENCePP recently. He also welcomed observers from Croatia, Serbia, Macedonia and Kosovo, as well as from the European Federation of Pharmaceutical Industries and Associations (EFPIA).

He announced that the first meeting of the ENCePP HTA (Health Technology Assessment) Task Force would be taking place in the form of a breakout session during the morning. The aim of this short meeting would be to agree a high-level mandate and a Chair.

1.2. Adoption of agenda

The agenda was adopted without changes.

2. Report from the Steering Group & Working Groups

2.1. Report from ENCePP SG

In the absence of Nicola Magrini, Deputy Chair of the ENCePP Steering Group, Stella Blackburn presented on the following topics:

- Key deliverables - draft ENCePP Work Plan 2013-2014
- ENCePP HTA task force
- ENCePP guidance on data integration of pooling of studies
- Revision to plenary mandate regarding use of the ENCePP logo and annual registration of studies
- ENCePP contribution to draft scientific research agenda of possible future public private partnership that follows IMI
- ENCePP plenary dates 2013

In conclusion, the Chair reiterated that the list of key deliverables from the new draft work plan presented an orientation as to the network's priorities over next two years. He highlighted the revised plenary mandate, which now includes a statement that ENCePP partners are encouraged to publish, together with the ENCePP logo, on their websites. A further update to the mandate captures the expectation that each ENCePP centre actively works on registering at least one study each year in the ENCePP E-Register (*aka* the EU PAS Register).

It was agreed that the changes to the mandate would be circulated to all partners for information, including guidance on where the ENCePP logo can be downloaded.

2.2. Reports from ENCePP Working Group Chairs

Meetings of all three current working groups had taken place during the afternoon preceding the Plenary meeting. Each of the Working Group Chairs provided updates on the activities of their respective group.

WG1 – Research Standards and Guidances

Alejandro Arana, Chair of WG1, started his report by thanking all members of the working group for their input and encouraged anybody interested in joining the group to submit an expression of interest to the ENCePP Secretariat.

He informed the Plenary that the working group would soon be launching revision 2 of the *Guide on Methodological Standards in Pharmacoepidemiology*. It is planned that the revision will be open for public comments, but will also include chapter review by authors and expert review of selected chapters. Further development of the methods section and development of new sections on vaccines, pharmacogenetics and comparative effectiveness research is planned.

The working group is planning to launch a survey on the Guide to gain further insight on its use, and collect feedback on which other topics might be useful for inclusion. Ad hoc suggestions from the plenary included guidelines on risk minimisation measures and guidelines on survey methodologies.

He also mentioned that WG1 has been charged with exploring the merits of accreditation for ENCePP centres. During the next work plan period the working group would be looking into the need and possible benefits of an ENCePP accreditation system.

WG2 – Independence and Transparency

Helen Dolk, Chair of WG2, gave a report of the meeting which had taken place during the previous day.

She started by reminding everybody that the role of the group had shifted to enhancing and monitoring the use of the ENCePP Study Seal and the ENCePP E-Register. The statistics clearly show that both are currently under-used and WG2 has discussed ways of addressing this. One proposal is to circulate a questionnaire to ENCePP partners in an effort to identify why the uptake of these facilities is slow. A further proposal is to produce and update regularly a list of ENCePP centres indicating the number of ENCePP registered studies and of Study Seal applications per centre. In an effort to encourage use of the ENCePP Study Seal concept, the working group is also considering preparation of a similar list also indicating the number of ENCePP studies performed on behalf of pharmaceutical companies. In addition it is proposed to approach major medical journals asking them to publish an article about the ENCePP Study Seal.

The working group has had further discussions regarding the creation of template contracts, but has decided that it won't progress this further as it was considered impractical and considering that the ENCePP Code of Conduct already contains a standard statement of compliance which can be put into contracts.

Two new guidance documents relating separately to the EU PAS Register and the ENCePP Study Seal have been developed and will be published on the ENCePP website shortly.

Finally, in the spirit of transparency and promotion of independent studies, WG2 is proposing to have a link on the ENCePP website to existing regular publications of signals and safety concerns from EMA.

In conclusion, Helen invited ENCePP partners to comment on the group's work and encouraged anybody interested in joining WG2 to send their expression of interest to the ENCePP Secretariat.

WG3 – Data sources and multi-source studies

Although the Chair of WG3, Miriam Sturkenboom, had lead the WG meeting the previous day, she was unable to attend the plenary meeting. Kevin Blake provided a report on her behalf.

He reminded the plenary of the key deliverables of the working group, one of which was the revision of the processes to add a data source on-line to the ENCePP Database of Research Resources. To this end, he confirmed that the Terms and Conditions had been clarified and amended to allow third parties to add a data source. Furthermore, the online data questionnaire has been streamlined to facilitate entries with much fewer mandatory questions.

Data privacy surveys were conducted earlier in the year among the EU Member States via the PhVWP and among ENCePP partners in parallel and both were met with a very good response. WG3 is in the process of compiling and interpreting the responses, and the plenary will be kept updated on any developments.

Finally, in relation to data pooling methodologies the working group has conducted a survey of research coordinators of EMA/European Commission publicly funded multi-country studies. Responses are being compiled in an effort to identify current best practice. It is envisaged that this information will form the basis for future guidance on data pooling.

3. Implementation of PV legislation in practice

3.1. Post-authorisation safety studies and the EU PAS Register

Xavier Kurz presented slides including the following topics:

- PASS: definition and objectives
- Obligations and recommendations
- The EU PAS Register
- Guidance for PASS protocol submission

He highlighted the fact that the EU PAS Register would be developed as an upgrade of the existing ENCePP E-Register. A decision has not yet been made as to whether the EU PAS Register will continue to be hosted on the ENCePP website, and any potential implications on other existing ENCePP databases are being considered by EMA.

The presentation also contained an overview of obligations and requirements relating to reporting and transparency requirements arising from the new pharmacovigilance legislation and associated good pharmacovigilance practice (GVP). Xavier presented on the guidance for PASS protocol submission, which aims at promoting existing standards and good practice. He stressed that the GVP takes into account existing recognised templates and guidances from other sources, including ISPE.

It was agreed that the slide set would be circulated by email to all ENCePP partners for information.

3.2. ADR Reporting

Following her presentation on this subject at the recent ICPE conference in Barcelona, Susana Perez-Gutthann presented on the GVP study adverse drug reaction reporting requirements from an academic/service provider perspective.

4. IMI Joint Undertaking

Hugh Laverty, Senior Scientific Project Manager at Innovative Medicines Initiative Joint Undertaking (IMI JU), presented on 'Boosting Drug Development through Public-Private Partnerships: The IMI Model' providing an overview of the IMI key concepts and project application processes. The presentation included a closer look at on-going projects and guidance on proposals for Call 8 topics which will be launched in November 2012.

He presented on the future of public-private partnerships under Horizon 2020 where innovative health research will be based on experience from IMI. He stressed that both the European Commission and EFPIA are very committed to future public-private partnerships.

In conclusion, he encouraged ENCePP centres to submit proposals for additions to the scientific research agenda directly to EFPIA where such proposals are welcomed.

5. Methodologies

5.1. Special Populations – Pregnancy

The afternoon session of the plenary meeting was set aside to focus on scientific methodological issues. The chosen subject of the session was 'Special Populations – Pregnancy'. The invited speakers were:

- ✓ Miia Artama (Finnish Cancer Registry / National Institute for Health and Welfare – Drugs and Pregnancy Research)
- ✓ Lolkje de Jong-van den Berg (University of Groningen, Department of PharmacoEpidemiology and PharmacoEconomics)
- ✓ Corinne de Vries (University of Bath - Department of Pharmacy & Pharmacology)

Maternal medication and pregnancy outcomes

Miia Artama presented on the topic of *maternal medication and chronic diseases during pregnancy and pregnancy outcomes – Finnish national database*.

Different study designs for signal detection and signal evaluations in pregnancy

Lolkje de Jong-van den Berg presented on the topic of *different study designs for signal detection and evaluation in pregnancy*.

EUROmediCAT: first results from an FP7 programme to evaluate medicines in pregnancy

Corinne de Vries presented on the topic *EUROmediCAT: developing a European reproductive pharmacovigilance system. First results from an FP7 programme to evaluate medicines in pregnancy*.

5.2. Discussion

During the ensuing discussion delegates expressed their interest in working together more and sharing information (e.g. study plans, data, signal evaluation) on the subject of pregnancy, possibly in the form of a special interest group within ENCePP.

6. Feedback from breakout session: ENCePP HTA Task Force

The inaugural meeting of the ENCePP Health Technology Assessment (HTA) Task Force had taken place during the morning. Ana Hidalgo (EMA) reported to the Plenary that it had been a very productive meeting of a very experienced group of people. She was further able to announce that Professor Marlene Sinclair of University of Ulster had agreed to be Chair of the Task Force. Support is also being provided by Nicholas Moore who has agreed to act as the ENCePP Steering Group Sponsor, and who participated in the meeting via teleconference. The first action for the new task force will be to draft a more detailed mandate than the high-level one adopted in the meeting. It was agreed that the group would work mainly via TC, and that it would try to meet once a month, starting from November 2012. Support from the European Medicines Agency will be provided by Luis Prieto.

The Chair thanked all participants for their support and wished the Task Force every success in progressing its work over the next months. He also emphasised the importance of enriching the task force with additional representatives of HTA bodies.

7. Summary of discussions & next steps

In summarising the meeting, the Chair again thanked all delegates for their support and particularly the presenters for their contribution to the meeting.

He highlighted the challenges lying ahead in terms of the ENCePP work plan for the next couple of years.

Finally, he reminded everybody that the next plenary will be taking place on 18 June 2013.