EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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ENCePP Secretariat

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Meeting Report - 9th ENCePP Plenary Meeting

3 May 2012 – chaired by Peter Arlett

Meeting Agenda:

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1. General Matters

1.1. Welcome and introductory remarks

Hans-Georg Eichler, Senior Medical Officer of the European Medicines Agency (EMA), welcomed the delegates with a short introduction to the day's programme. He extended a particular welcome and thank-you to Mr Iiro Eerola from the Health Directorate of the European Commission's Research Directorate-General for providing the Plenary with an update on adverse drug reaction research in FP7.

The Chair continued by welcoming all delegates, particularly new ENCePP partners, and delegates attending their first Plenary meeting. He extended a welcome to observers from Macedonia and Serbia, as well as the National Institute for Health and Clinical Excellence (NICE), and the Haute Autorité de Santé, both representing the European Network for Health Technology Assessment (EUnetHTA).

1.2. Adoption of agenda

The agenda was adopted without any changes.

2. Report from the Steering Group & Working Groups

2.1. Report from ENCePP SG

Nicola Magrini, the newly elected Deputy Chair of the ENCePP Steering Group (SG), provided a slide presentation, focusing on the outcome of the first meeting of the new Steering Group which had taken place in March 2012.

2.2. Reports from ENCePP Working Group Chairs

WG1 – Research Standards and Guidances

The Chair of WG1 (Alejandro Arana) provided feedback from the working group meeting which had taken place the previous day. The group is working on finalising the first revision of the *Guide on Methodological Standards in Pharmacoepidemiology.* Following a public call for comments and an expert review more than 100 comments had been received which were now being taken into consideration for Revision 1 of the Guide, to be adopted by the Steering Group in July 2012.

In conclusion, Peter Arlett informed the Plenary that the number of hits on the Guide on the ENCePP website had reached nearly 6000 between January and April 2012 which gives an indication of the interest in the document.

WG2 – Independence and Transparency

A meeting of the working group had been scheduled for the day following the Plenary. In the absence of the WG Chair (Helen Dolk), Thomas Goedecke provided a reminder of the WG's deliverables to be discussed at the meeting.

The first priority of the discussions will be the promotion of use of the ENCePP Code of Conduct and registration of studies, and the exploration of possible avenues for reaching these goals. The second priority will be raising awareness of the Code in scientific journals, followed by the elaboration of a strategy to promote independent studies.

WG3 – Data sources and multi-source studies

In the absence of the WG Chair (Miriam Sturkenboom), Kevin Blake reported on the outcome of the meeting which had taken place during the previous afternoon.

He outlined a number of ongoing initiatives focusing on facilitating the conduct of multi-source studies and aspects of data integration and data protection. A major action point is increasing representation in the ENCePP registry of data sources, as despite an appeal at the last Plenary meeting for centres to register the data sources that they work with, the numbers in the database are still considered well below the actual number of existing data sources.. The Working Group has reviewed the website and the information requested to add a data source to the ENCePP Registry. The Working Group will shortly circulate a survey among the EU Member States via the PhVWP and the ENCePP Plenary relating to data protection.

3. Networks & Networking

3.1. Astro-lab project

Eric van Ganse introduced the FP7-funded Astro-lab project which aims at investigating the safety of therapy in asthma, with a focus on adherence. The main objective of the project is to compare in real-life settings the rates of serious adverse events (SAEs) in children and adults treated with LABAs (alone or in combination with inhaled corticosteroids - ICS) to the rates observed in persons treated with ICS alone, following adjustment for severity.

He concluded his presentation with a number of very interesting key messages based on his experience in setting up a research network. The list includes:

- Before the application:
    - Identify the right persons (science)
    - Identify the right 'mix' (public/private)
    - Identify the right 'writers' of the project
    - Identify the right 'reasoning': innovative, reasonable risk-taking, improving knowledge base, tackling key issues
    - Verify acceptability/political and scientific correctness
    - Lobby
- After the application:
    - Expect the unexpected
    - Do not take risks
    - Prioritise
    - Disentangle the big project into a large number of small projects

In the ensuing discussion it was emphasised that full time operational support is a major success factor for any research project.

3.2. The Psonet collaboration

Luigi Naldi presented slides on Psonet which is a European network of independent psoriasis registries used in post-marketing surveillance studies aimed at monitoring the effectiveness and safety of systemic agents, including biological and any new medications in the treatment of psoriasis.

His presentation included a detailed description of the network structure and work methods, funding of the network and a number of very interesting organisational and analytical challenges and lessons learned.

The ensuing discussion highlighted the challenges of data privacy/informed consent for sharing data from individual registries at the level of the network. It was proposed that Working Group 1 keep this issue in mind for future discussions relating to the Guide on Methodological Standards in Pharmacoepidemiology.

3.3. Suggestions for Optimising ENCePP

Building on the two previous presentations, and to encourage discussion on how the existing network might be optimised, Kevin Blake summarised a number of challenges and opportunities to achieve optimisation in the context of the ENCePP work plan period 2013-2014.

The ensuing discussion highlighted a number of suggestions on how to optimise ENCePP:

- In an effort to promote ENCePP and make the network more visible, it was proposed to increase interaction with learned societies (ISPE, ISoP, EACPT), through the organisation of joint sessions at their annual meetings. In connection with this initiative, Gonzalo Calvo-Rojas issued an invitation to have an ENCePP presentation at the European Association for Clinical Pharmacology & Therapeutics Annual Meeting which will take place in August 2013 in Geneva. A further suggestion was to encourage ENCePP partners to refer to ENCePP and include the ENCePP logo in their presentations at international events.
- The importance of drug utilisation patterns for pharmacoepidemiological research was highlighted. It was agreed that the Steering Group would look into drug utilisation as an area of special interest within ENCePP. The ESAC project and EuroDURG were named as possible helpful collaborators.
- An effort will be made to better link ENCePP to other existing resources and networks within EMA to further optimise the interface between ENCePP and the core medicines regulatory process (e.g. paediatric network and geriatric expert group).
- ENCePP should encourage the collection of new data, especially pharmacogenetic data, to further research into the effectiveness and safety of drugs through novel biomarkers. Iiro Eerola of DG RTD intervened at this point to confirm that genomes and biomarkers research was currently part of the IMI funding programme.
- It was agreed that introducing networking around therapeutic areas would require careful consideration and further discussion at the level of the Steering Group. Sub-networking based on methodologies was agreed as a useful way forward. As a next step the ENCePP Secretariat will survey interest amongst ENCePP partners including asking partners to express half a dozen keywords of interest. This would facilitate the creation of task forces following a bottom-up approach.

4. A Changing Landscape for PhV and PhEpi

4.1. Proposed new legislation on data protection

Alessandro Spina, EMA Data Protection Officer, presented the Plenary with an update on the European Commission proposals to reform the EU data protection rules with particular reference to health data and its secondary use for research purposes. The implementation of the new legislation is currently envisaged for 2016, and would be followed by implementing acts on more operational aspects.

On request of the Plenary it was agreed that ENCePP – via the Steering Group - would be kept informed on the progress of this issue and that ENCePP partners would be provided with a list of key players involved in the legislative process. During the WG3 meeting which had taken place the previous day, it had been agreed to very closely follow the relevant delegated acts and further legislation, and provide an expert opinion when necessary. Another major outcome from the discussions at the WG was the challenges faced with keeping data anonymised vis-à-vis developing

technology. In order to obtain a better overview, it was agreed the proposed WG3 survey of ENCePP partners would ask specifically what mechanisms are in place to keep data anonymised.

The Plenary was unanimous in its view that researchers' views should be heard in the legislative process and joint action would be extremely useful. Responding to this call, Alessandro Spina agreed that it is of utmost importance that expert feedback be provided as soon as possible.

4.2. Good Vigilance Practice: post-authorisation studies

Annalisa Rubino presented slides putting into context the new PhV legislation, focusing in particular on the PASS module of the Good Vigilance Practice (GVP) guidance for the implementation of the new legislation, which has recently undergone a public consultation.

Peter Arlett highlighted that the new rules are only binding for the pharmaceutical industry, and not for purely academic studies. ENCePP principles are core to the guidance, with references to the ENCePP Guide on Methodological Standards in Pharmacoepidemiology, to the ENCePP Code of Conduct, and the ENCePP electronic register of studies. Furthermore, it will be a requirement for imposed company-sponsored studies that the analytical dataset be traceable for inspection by regulators. In summary, the GVP builds on all principles that have come out of ENCePP over the last couple of years and will, ultimately, raise the standard of data quality.

It was agreed to provide ENCePP partners in June 2012 with a summary of the implications for ongoing studies and adverse reaction reporting, including implications for expedited adverse reaction reporting.

Finally, in response to discussion on the issue among the Plenary, it was pointed out that, as recently stated by EMA's Executive Director, the Agency intends to develop a mechanism to conduct meta-analysis on individual patient data from company studies.

4.3. Adverse drug reaction research in FP7

Iiro Eerola, Scientific Project Officer in DG Research presented an overview of adverse drug reaction research in the FP7 Health Theme, as published in the Health Directorate's Orientation paper.

He particularly highlighted three research proposals received from EMA which may be included in the next call. The final call for proposals will be available in July 2012. He also mentioned important timelines and very useful advice for applicants to the call and stressed the EC requirement of SME participation in FP-funded research.

In conclusion, he informed the Plenary that the next framework programme for research and innovation will be entitled 'Horizon 2020' - details of which are still under development.

4.4. HTA & ENCePP

Luis Prieto presented on the subject of 'Health Technology Assessment (HTA) & integration in Pharmacoepidemiology'. He concluded his presentation proposing for discussion by the Plenary the establishment of a HTA task force, and announcing the launch of an ENCePP/HTA survey.

The two observers from EUNetHTA expressed their full support to the establishment of a HTA task force within ENCePP. Given the commonalities between medicines regulation and HTA it was considered in everybody's interest to cooperate further.

The Plenary endorsed the establishment of the HTA task force, including a survey aiming at collecting information on the experience of centres in the area of HTA. The survey will also be used as a call for expressions of interest to lead the task force.

5. Methodology

5.1. EHR4CR Project – Electronic Health Records for Clinical Research

Dipak Kalra introduced EHR4CR, an IMI-funded project whose objective it is to promote the wide scale research use of EHRs including to accelerate regulated clinical trials across Europe.

It was agreed that a link to the project's website will be added to the ENCePP website.

5.2. Case-population strategy in Pharmacovigilance

Due to lack of time it was agreed that this topic will be presented at the next Plenary meeting (11 October 2012).

5.3. Open discussion

Susana Perez-Gutthann highlighted a number of key methodological issues with the use of electronic healthcare data which were further discussed by the Plenary.

6. Summary of discussions & next steps

Henry Fitt concluded the meeting on behalf of the Chair by summarising the discussions and agreed action points.

He thanked all delegates and observers for their participation in a very fruitful meeting and confirmed that the meeting report and presentations will be placed on the ENCePP website.

He confirmed that for organisational reasons the date for the 2nd 2012 Plenary meeting had had to be changed and will now be taking place on Thursday, 11 October 2012. As a consequence, working group meetings will also be affected by this change.