EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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ENCePP Secretariat

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Report - 16th ENCePP Plenary Meeting

21 November 2017 – chaired by: Xavier Kurz & Tom MacDonald

1. Welcome and adoption of agenda

Xavier Kurz welcomed delegates, including observers from EFPIA, PMDA Japan and Health Canada (via TC) to this meeting of the ENCePP plenary which marked the tenth anniversary of the network.

2. ENCePP Anniversary 2007-2017

Marking the occasion of the 10 year anniversary of ENCePP, Susana Perez-Gutthann, the Deputy Chair of the previous Steering Group, gave a presentation briefly outlining the history of ENCePP, including some important milestones achieved and ENCePP's chief outputs over the years in terms of methodological guidance and governance principles. She touched on ENCePP's contribution to regulatory decision-making and regulatory science and concluded with a list of key areas of focus agreed by the Steering Group for the short to mid-term. She mentioned that a manuscript authored by the ENCePP Steering Group on the subject of the 10 year anniversary has been submitted to PDS Open Access, and highlighted that the anniversary leaflet titled '*ENCePP: 10 years of collaboration to strengthen the monitoring of benefits and risks of medicines in Europe*' is available for download on the ENCePP website.

3. Report from Steering Group

In his role as the Deputy Chair, Tom MacDonald presented a report from ENCePP Steering Group, highlighting milestones achieved since the last meeting and providing brief updates from Working Groups and Special Interest Groups. His presentation also included some statistics relating to the EU PAS Register and the ENCePP Methods Guide.

He invited ENCePP partners interested in joining any of the existing working groups or wishing to contribute to particular work plan deliverables to express their interest to the ENCePP Secretariat.

4. Framework of collaboration between EMA and Academia

In March 2017 the EMA Management Board adopted a framework for collaboration between EMA and academia. Isabelle Moulon, Senior Adviser on Stakeholder Engagement at EMA, presented the framework, highlighting the agreed action plan. Delegates were invited to express their views on how they think ENCePP might participate in the framework, and to identify action plan items of particular interest.

ENCePP partners agreed that the lack of public funding for pharmacoepidemiology and pharmacovigilance research is of particular concern to centres. The mechanism of identifying areas of public health concern under the old FP7 programme was mentioned as an example of good practice, as was the Italian funding system.

It was suggested to add the topic of funding as a matter of concern to the existing action plan. Furthermore, it was agreed that the framework for academia would be further discussed at Steering Group level and that all ENCePP partners would be invited to provide their feedback in writing.

In conclusion, attention was drawn to the contact point for academia at EMA which is: academia@ema.europa.eu

5. Models for multi-database studies

The reactivated Working Group 3 (data sources and multisource studies) met during the afternoon preceding the plenary meeting and the newly appointed Chair of the group - Gianluca Trifirò – gave an update on the discussions that had taken place, in particular on the draft concept paper on 'Models for multi-database pharmacoepidemiologic studies'.

His presentation informed on the outline and aim of the concept paper on multi-database studies, and provided an update on the work already in progress in terms of information retrieval, definition of dimensions and identification of research scenarios. Gianluca presented a draft questionnaire which will be circulated to all ENCePP partners to elicit information on types of regulatory decisions that can profit from evidence generated by multi-database studies. His presentation concluded with a list of next steps which includes amongst others two surveys, a systematic review and analysis of studies available in the EU PAS Register.

To help achieve this ambitious work plan ENCePP partners interested in contributing are invited to join one of the three subgroups that will be set up to address the planned tasks.

It is planned to present some preliminary results by February 2018.

6. ENCePP Code of Conduct – Revision 4

On behalf of Working Group 2 (Independence and Transparency) Thomas Goedecke and Rosa Gini provided a summary of the ongoing discussions regarding the proposed revision of the ENCePP Code of Conduct, including an overview of the proposed amendments. They explained that the objectives of Revision 4 are three-fold:

- Definition and clarification on the practical implementation of 'scientific independence'
- Procedures related to the ENCePP Seal application are to be moved to a separate document
- Improve operability of the Code

Their presentation was complemented by interventions from three different stakeholder groups:

1. Perspectives from academia (Laura Yates)
2. Perspectives from industry (Patrice Verpillat)
3. Perspectives from Contract Research Organisations (CRO) (Xavier Fournie, Giovanni Fiori)

A very useful discussion took place following these presentations with a number of pertinent comments which will be taken into consideration for the revision of the Code.

In terms of next steps it was agreed that the current draft revision of the Code would be circulated to all ENCePP partners whose agreement in principle is sought to the proposed clarifications on scientific independence and to separating Seal-related procedures into a new document whilst maintaining the Seal concept and conditions on a voluntary basis.

Feedback received will be considered by the working group before finalising the revision. A decision on whether to launch a public consultation on the revised Code is under consideration. Target date for adoption of the revised Code is Q1 2018.

7. Promoting ENCePP at national level

Following discussions at the most recent Steering Group meeting, the ENCePP Italian Chapter was invited to present the Italian network of ENCePP centres to the plenary. The Steering Group considered that the establishment of similar models might be of interest to other countries with a view to promoting networking and collaboration.

To this end, Ursula Kirchmayer provided an introduction to the Italian chapter of ENCePP centres providing specific examples of how this cooperation has proven to be very successful in promoting regulatory science and improving education and training in Italy.

Delegates were reminded that similar networks may facilitate engagement of centres as well as the implementation of ENCePP principles at national level.

8. Benefit-risk assessment

Hans Hillege, CHMP representative on ENCePP Steering Group, introduced the table of effects in benefit-risk assessments which is part of the new CHMP Benefit-Risk Assessment template. His presentation included background information and specific examples of benefit-risk assessments.

9. EMA Patient registries initiative

Xavier Kurz presented the EMA Patient Registry Initiative which was launched in September 2015 with the aim of strengthening the contribution of patient registries to the benefit-risk evaluation of medicines. He talked about achievements to date, in particular the two disease registry workshops on cystic fibrosis and multiple-sclerosis which took place earlier this year and which resulted in a number of actions points for the various stakeholder groups.

He also highlighted the fact that the ENCePP resources database is being utilised for the creation of the 'EMA inventory of registries' which is aimed at facilitating interaction between stakeholders. To this end, patient registries are proactively being invited to add their details in the ENCePP database.

10. Update on Brexit-related issues

Noël Wathion, Chair of EMA's 'Operations and relocation preparedness (ORP) task force', confirmed that the Agency will have left London by April 2019. The decision to relocate the Agency to Amsterdam is considered a good one in the interest of maintaining business continuity, but he also warned that the location decision marks the official start of a challenging joint relocation project that will have to be delivered within extremely tight timelines.

In response to concerns expressed by the network, he stated that it is very much in the Agency's interest to maintain access to UK expertise in post-authorisation studies even after Brexit. How this might be achieved will be subject to further debate, and the Agency hopes to have clarity on this issue as soon as possible. At this point in time it is impossible to make any commitments as regards the future status of the UK vis-à-vis the Agency, but it is hoped that by autumn 2018 a much clearer picture regarding the future relationship will have emerged.

In conclusion he stated that EMA has initiated a business continuity plan to ensure that necessary resources are available for Brexit preparedness. It may be necessary to scale back certain activities, including ENCePP.