European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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REPORT OF THE ENCEPP SCIENTIFIC CONVENTION
"EU HEALTH CARE DATABASES FOR PAN-EU PHARMACOEPIDEMIOLOGICAL RESEARCH"
25 NOVEMBER 2008, 14h00 – 18h30
Chairperson: Noël Wathion, Chair of panel discussion: Miriam Sturkenboom

Present: see participants' list

Minutes: Stefanie Prilla

AGENDA

1. General Issues
1.1. Welcome and introductory remarks (T. Lönngren)
1.2. Adoption of Agenda
1.3. Update on EMEA Pharmacovigilance Activities

2. ENCePP: Update on latest developments
2.1. ENCePP Overview – development and current status (H. Fitt)
2.2. ENCePP Working Groups (WG): Status Report 2008 (Chairs of the WGs: G. Calvo Rojas, H. Dolk, M. Sturkenboom, M. Teeling)

3. Session on EU Data Sources and Pan-EU Research (Chair: Miriam Sturkenboom)
3.1. Introduction: ENCePP – Pharmacovigilance needs and opportunities (B. Leufkens)
3.2. Introduction of speakers
3.3. Presentations by T. Van Staa, J. Askling, S. Shakir, C. de Vries, M. Sturkenboom, H. Kieler
3.4. Panel discussion

4. Close of the meeting

1. Executive Summary

The meeting started with a brief overview of the developments and achievements within ENCePP since the General Assembly in April 2008. Specifically, a web platform for ENCePP is being developed and the draft web page was presented. In addition, the work of the 4 ENCePP Working Groups (WG) was summarised by the WGs' chairpersons.
The main part of the meeting was dedicated to a session with 6 speakers presenting on the needs and challenges of the use of data sources for EU-wide drug safety research and areas where collaborative research in Europe is needed or has been realised.The talks were followed by a panel discussion.

2. Minutes of the Meeting

The Executive Director of the EMEA, T. Lönngren, welcomed the participants, thanked everyone for the achievements to date, highlighted a number of future challenges and invited the scientific community to work together towards improving the safe use of drugs in Europe.

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The audience consisted of representatives of the main stakeholders of ENCePP including academia, other (commercial) reseach organisations, data providers, pan-EU networks and registries, regulators, learned societies, and patients' and health care providers' organisations.

ENCePP Developments and Achievements

During 2008 ENCePP has grown to 86 partner organisations located in 21 European countries (Switzerland, Greece and Romania are the latest to be represented).

The ENCePP Secretariat (encepp_secretariat@emea.europa.eu) has been formalised as the contact point for the partners and other interested parties. The last member of the ENCePP Implementation Advisory Group (ENCIAG) has been appointed: Yola Moride, representing the International Society of Pharmacoepidemiology (ISPE). ENCIAG now has a full membership of 11 members.

Of note, a web page for ENCePP is under construction, displaying information on the mission, structure and work of the network. Links to relevant sites, news and announcements will be included at a later stage.

The chairpersons of the 4 ENCePP Working Groups presented interim status reports of the progress in their respective WGs, and gave an outlook of the next steps and deadlines. The main deliverables expected of the Working Groups are:

- Development of a set of guidance & standards
- Development of an ENCePP Code of Conduct
- Establishment of a Registry of post-authorisation studies
- Establishment of an Inventory of EU data sources
- Establishment of an Inventory of research centres in ENCePP

These will be further developed and finalised in 2009 and 2010.
The guidance documents, Code of Conduct, etc, will be shared with the public and relevant EMEA Committees, working groups and working parties like the Committee for Medicinal Products for Human Use (CHMP), the CHMP Pharmacovigilance Working Party, the EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) and the EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG).

Talk Session on EU Data Sources and Pan-EU Research

Six representatives/members of the ENCePP network were invited to give talks on database and collaborative research, methodologies for combining data throughout Europe, and areas for collaborative approaches or where pan-EU collaboration has been undertaken.

H. Leufkens introduced the session with a brief presentation on 3 current safety concerns regulators face [bisphosphonates and stress fractures, monoclonal antibodies and peripheral multifocal leukoencephalopathy (PML), and antipsychotics and increased mortality in the elderly], which he used to highlight the needs/opportunities for collaboration in post-authorisation surveillance and Pharmacovigilance research. He reminded the audience that Pharmacoepidemiology research should also attempt to identify benefits of medicinal products, so that the focus should be to balance both risks and benefits.

The talk session and the subsequent panel discussion were chaired by M. Sturkenboom. The following topics were addressed:

- One database, two answers; ten databases, million answers - Challenges in conducting multi-database studies (T. Van Staa)
- Biologics in inflammatory disease - a novel European network for pharmacovigilance and pharmacoepidemiology (J. Askling)
- How does Modified PEM support risk management (S. Shakir)
- Using a primary care database to evaluate drug safety in pregnancy: possibilities and limitations (C. de Vries)
- Ongoing EU collaborations and work models to do cross database or cross country studies (M. Sturkenboom)
- NorPEN – the Nordic Pharmacoepidemiological Network for knowledge exchange, research and research training (H. Kieler)

The presentations are annexed to this report.

Generally, the heterogeneity of the national data sources, methods, and regulations were recognised as a huge challenge for collaborative and multi-national research in Europe. At the same time, however, the variability was also seen as a unique strength. Methods should be used and further developed to combine data where necessary as well as recommendations (e.g. to use the same coding system), but research should in principle remain independent.

Panel Discussion

The panel consisted of the six speakers:

- Johan Askling, Karolinska Institute, SE
- Corinne de Vries, University of Bath, UK
- Helle Kieler, Karolinska Institute, SE
- Saad Shakir, Drug Safety Research Unit (DSRU), UK
- Miriam Sturkenboom, University of Rotterdam, NL
- Tjeerd Van Staa, General Practice Research database (GPRD), UK

The panellists were asked where they see the main benefits but also drawbacks of a network such as ENCePP in light of their specific activities.

The panellists unanimously found that the main benfit of participating in ENCePP is the obvious advantage of increased collaboration between the partners and the opportunity to promote multi-national research. At the same time, the heterogeneitity and different methodological approaches throughout Europe could be a major challenge for pan-EU research.

The main concern of some panellists was that through ENCePP, Pharmcoepidemiological research could become overregulated by guidances, SOPs etc. According to some panellists, the network should not aim at creating numerous guidance documents but rather help to organise, streamline and complement existing guidance, whilst at the same time leaving the freedom and flexibility to the researchers to deviate from the guidelines and use different approaches when justified.

3. Conclusion

The scientific talks reflected current valid approaches to pan-EU research using EU data sources and addressed areas where further improvement is needed. The meeting was an effective means to allow the exchange of scientific experience and opinions and to promote a unifying spirit within the scientific community. In the light of the perceived success of this 1st ENCePP Scientific Convention, it is foreseen to organise a similar meeting during the second half of 2009.

Annexes:

- List of Participants

- Presentations