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European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Report - 12th ENCePP Plenary Meeting

12 November 2013 - chaired by Henry Fitt (AM) & Peter Arlett (PM)

Meeting Agenda:

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1. General Matters

The Chair welcomed all delegates, including observers from Bosnia and Herzegovina, Macedonia, Serbia and India. He also extended a welcome to observers from the European Network for Health Technology Assessment (EUnetHTA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

He announced that an informal meeting of the Special Interest Group 'Pregnancy' would be taking place over lunch.

The agenda was adopted without changes.

2. Report from the Steering Group & Working Groups

2.1. Report from the ENCePP Steering Group

On behalf of the Deputy Chair, Susana Perez-Gutthann presented the report from the Steering Group. Her report included the key achievements of the network over the past two years from the perspective of the outgoing Steering Group. Statistics on the EU PAS Register/ENCePP E-Register were also provided, highlighting a substantial increase in the number of studies registered. The delegates were also informed of the main changes to the ENCePP Steering Group and Plenary mandates. These include that in 2014 and the foreseeable future the available meeting budget would be used towards funding one annual plenary meeting with a shift in funding towards face-to-face working group meetings.

2.2. Updates from the ENCePP Working Group Chairs

Four of the five current working groups met during the afternoon preceding the Plenary meeting. Each of the WG chairs provided a brief report focussing on key developments since the last Plenary, the status of ongoing work and next steps.

WG1 – Research Standards and Guidances

Alejandro Arana started by saying that work on Revision 3 of the Guide on Methodological Standards in Pharmacoepidemiology would be launched soon. For this next revision two new topics are under development – firstly on the use of genetic data in pharmacoepidemiological studies, and secondly paediatric pharmacoepidemiological studies. A new chapter on 'drug utilisation studies' is also under consideration. He further explained that the working group has been discussing ways to enhance presentation of available information in the Guide.

Alejandro Arana further stated that, following discussions at Steering Group level, the working group was awaiting feedback from ISoP on the need for additional pharmacovigilance guidance to be included in the existing Guide on Methodological Standards.

Regarding an accreditation system for ENCePP centres the working group is proposing not to introduce a separate system, but instead to include new fields in the ENCePP Resources database which would allow partners to be transparent by entering information about existing accreditations and quality assurance.

WG2 – Independence and Transparency

Laura Yates informed the Plenary that the working group has agreed in principle the draft 3rd revision of the ENCePP Code of Conduct, which incorporates previous plenary discussions, clarity around the concept of scientific independence, and takes on board issues/changes received from stakeholders since the last revision of the Code. As a next step, the draft revision will be circulated to all WG2 members for final comment. In a further effort to improve the uptake of the ENCePP study seal and

the registration of studies in the ENCePP E-Register/EU PAS Register, the relevant text of the ENCePP website has been revised for simplification and clarification. As a next step, the draft text will be checked for consistency and the website will be updated.

Laura further noted that a link has been placed on the ENCePP website to the listing of PRAC recommendations on safety signals which are published monthly on the EMA website. Working Group 2 is seeking feedback from ENCePP partners on whether they would like to see additional explanatory text included on the website, but also whether they would consider additional methods of alerting ENCePP partners about safety signals as useful.

In conclusion, Laura reminded the Plenary that a survey on the uptake of the ENCePP study seal and registration of studies in the ENCePP E-Register by ENCePP centres is currently under development. This survey is aimed at helping to identify the reasons contributing to the sup-optimal uptake and will be circulated prior to the next plenary meeting.

WG3 – Data Sources and Multi-source Studies

On behalf of the WG Chair Miriam Sturkenboom, Kevin Blake informed the Plenary that the working group would be meeting the following week via TC. He highlighted as the major WG output during the period since the previous plenary meeting the publication of the results of the survey of Member States on national data protection legislation on the ENCePP website.

He further explained that the working group's activities relating to the revision of the EU data protection rules have been put on hold for the moment pending the finalisation of the legislative process through the EU Parliament and Council of Ministers. The next European Parliament discussions are indicated as due to take place in March 2014, and the Plenary will be kept informed about any developments.

Progress has also been made in drafting a paper for publication on the results of the survey of researchers conducting publicly funded research which will be finalised at the next TC of the group as a mature draft for circulation to the researchers involved for their comment.

WG Health Technology Assessment (HTA)

Marlene Sinclair started by saying that the working group had agreed on a revised mandate and work plan with a renewed focus on capacity building. The focus will be on mapping existing resources within ENCePP to conduct studies that potentially support the requirements of both medicines regulators and HTA bodies. In the first instance this will involve a detailed survey of ENCePP to identify experience in conducting studies that have already supported HTA, to identify needs of centres to enhance capacity to undertake such studies and to reflect available resources in an update of the ENCePP database of resources.

She added that the recent ISPOR conference featured a poster and a workshop communicating on ENCePP and the HTA working group which were well received. The poster and the presentations from the workshop will be published on the ENCePP website.

François Meyer, co-chair of the group, added that a call for expression of interest had gone out to EUnetHTA institutions following the revised mandate/work plan. Discussions are ongoing re. how interested parties might engage with the ENCePP group and provide input to its activities.

WG Data Integration

Nawab Qizilbash informed the plenary that the working group has started writing and presented a list of milestones and timelines for the development of the guide for the conduct of meta-analyses of completed controlled observational studies of harm. The plan is to present a pre-final draft of the guide to the Steering Group and Plenary by June 2014.

He further confirmed that the development of a guide for the conduct of collaborative multi-database studies to assess harm has been put on hold for the time being.

In response to a query from the plenary, Nawab confirmed that the group was aware of what has been produced in this area by the Cochrane group and that no overlap has been identified. Furthermore, one of the WG members is also a member of CIOMS and there appears to be no overlap with that group's output either.

3. Proposal for Industry Dialogue

On behalf of the Steering Group, Morten Andersen presented a summary of the follow-up discussions by the SG to the meeting with industry held in May 2013, and a proposal for further ENCePP dialogue with the pharmaceutical industry.

In this context Henry Fitt added that the discussions at Steering Group level had focussed on the uptake of ENCePP outputs by industry including the ENCePP Study Seal. Whilst the ENCePP guidance on methodologies has been very well received and the feedback from industry has been positive, the uptake on the use of the Code of Conduct and ENCePP Study Seal concept has been sub-optimal to date. The idea is to engage more with industry in the context of the next review of the Code in an effort to clarify some of its details. The SG felt that it was important to put any proposal for further dialogue to the plenary to seek its views.

During the ensuing discussion the principle of further engaging with industry was questioned by some delegates who felt that the aim of the network was to support EMA and to conduct transparent and independent research as academics.

Whilst acknowledging this, it was highlighted that industry is being requested by regulators to conduct studies. Industry, in turn, has a need for resources and expertise in conducting these studies. Industry is a key part of the established system and engagement in a dialogue is therefore useful for everybody and should facilitate promotion of the ENCePP principles of transparency and independence. The ENCePP mandate is to strengthen research, and there is a need to move forward with all stakeholders for the benefit of public health.

Laurent Auclert (EFPIA observer) added that 'industry' is a broad concept, and whilst the big pharma companies have their own in-house expertise and facilities to do research, he can see an important role for ENCePP to be developed in particular for studies needed by SMEs and generic drug manufacturers. The dialogue should therefore also include these types of companies.

Summarising the discussions, the Chair said that ENCePP dialogue with industry to improve the uptake of ENCePP principles should be further explored. Whilst it is acknowledged that there are sensitivities, the original ENCePP principles shall not be challenged by future dialogue. The dialogue with industry should continue without damaging the ENCePP network of excellence that has delivered so much for public health in recent years. It is proposed to collect further views from the plenary on dialogue with industry and present a way forward at the next plenary meeting.

4. Election of ENCePP partners to the Steering Group

Thomas Goedecke presented slides explaining the procedure for election of ENCePP partners to the Steering Group.

This introduction was followed by a secret ballot as a result of which the following six candidates were elected to the Steering Group 2014-2016 (in alphabetical order):

- Morten Andersen, Karolinska Institutet, Sweden
- Pierre Engel, Quintiles/Outcome, France
- Teresa Herdeiro, Secção Autónoma de Ciências da Saúde (SACS), Universidade de Aveiro, Portugal

- Tom MacDonald, Medicines Monitoring Unit (MEMO) and Hypertension Research Centre (HRC), University of Dundee, UK
- Susana Perez-Gutthann, RTI Health Solutions, Spain
- Nawab Qizilbash, Oxon Epidemiology Ltd., Spain

The Chair welcomed the new SG which will serve a three year mandate.

5. Request for collaboration

Nilima Kshirsagar from the Indian Council of Medical Research (ICMR) / Department of Health Research, Government of India, presented a proposal for a pharmacoepidemiological programme at the ICMR. The proposal is to set up a network of pharmacoepidemiology research in India, and feedback and collaboration is sought from the ENCePP network.

It was agreed that the contact details of Dr Kshirsagar would be circulated to all ENCePP partners who may contact her directly.

6. Session on Methodology – Pharmacogenomics

Marisa Papaluca of the European Medicines Agency provided the introductory remarks for the session on pharmacogenomics. Her intervention included definitions and information on the EMA Pharmacogenomics Working Party. She also highlighted the EMA guidance on Pharmacogenomics in pharmacovigilance which is about to be published for public consultation. ENCePP partners will be informed of the release and Marisa urged ENCePP partners to send in any comments they might have.

These introductory remarks were followed by three presentations:

- Pharmacogenomics – A Clinical Perspective

  Munir Pirmohamed is Professor at the Molecular and Clinical Pharmacology Department at the University of Liverpool and NHS Chair of Pharmacogenetics.

- Pharmacogenomic methods – An Epidemiological Perspective

  Olaf Klungel is Associate Professor at the division of Pharmacoepidemiology & Clinical Pharmacology at the University of Utrecht.

- Pharmacogenomics, an important step in the quest for biomarkers of drug response

  Bruno Stricker is Professor of pharmacoepidemiology at the Department of Epidemiology of the Erasmus University Medical School.

The presentations (available via the above hyperlinks) were followed by a rich discussion which showed keen interest in this topic.

The Chair summarised the session by highlighting the existing links between ENCePP and pharmacogenomics, including proposed WG1 work on the methodological interface between pharmacoepidemiology and pharmacogenomics.

It was agreed that the topic of further bridging pharmacoepidemiology and pharmacogenomics - e.g. via the establishment of a special interest group - would be taken to the Steering Group for further discussion.

7. IMI – future calls

Hugh Laverty, Senior Scientific Project Manager at the Innovative Medicines Initiative (IMI) presented on the current status and future IMI calls, and particularly highlighted the recently published indicative topics of Call 11 which is scheduled for launch on 13th December 2013. In this context it was agreed that the draft call would be circulated to all ENCePP partners for information.

He also informed on IMI 2 which is going through the legislative process and may be launched as early as April 2014. One of the proposed new features of IMI 2 is the broadening of scope of companies that can get involved to include non-pharma enterprises.

The new scientific research agenda is open for public consultation, and he urged ENCePP partners to comment on the proposals.

In conclusion, he encouraged all potential applicants to approach him directly or IMI in general, prior to submission of an application. IMI is dedicated to supporting the process in any way possible and will be able to provide advice in order for a solid research proposal maximising the chances of success for securing funding. Links to the ongoing consultation and the next call will be circulated by the ENCePP Secretariat.

8. A.O.B.

None.