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

2ND ENCEPP MEETING WITH CENTRES AT THE EMEA

MINUTES OF WORKING GROUP 1:
Research standards and PhV and PhEpi guidances

18 April 2008

Chairperson: Gonzalo Calvo Rojas

Doc. Date: 11 August 2008
Doc. Ref: EMEA/279618/2008

Present:
Jane Apperley
Rabi Bajrami
Ulf Bergman
Gonzalo Calvo Rojas (*Chair*)
Jesper Hallas
Milena Jadrijevic-Mladar Takac
Xavier Kurz (*EMEA*)
Hubert G. Leufkens (*ENCIAG*)
Herve Le Louet
Lila Mayahi
Nicholas Moore (*ENCIAG*)
Yola Moride
John Parkinson
Consuelo Pedros
Susana Perez-Gutthann
Bukky Omojola (*EMEA*)
Robert Van der Stichele

Apologies: Ketevan Pachkoria

Minutes: Xavier Kurz

1. List of questions

The following questions were presented for discussion to the working group:

1. Does the Working Group agree with its proposed mandate ?
2. Are there additional topics which need to be included ?
3. Are there topics which overlap with other groups ?
4. How would the WG suggest prioritising the topics ?
5. How will the topics be addressed ?
6. Are there any possible conflicts of interest which might preclude a topic from being included in the IMI proposal ?
7. How will the work of the WG be organised in the future:
    - Chair and co-chair
    - Members willing to further participate
    - How will the group communicate?
    - Dates for next meeting

The discussion mainly focussed on questions 1 to 5. Question 6 was not addressed. Question 7 was only briefly discussed due to lack of time.

2. Proposed mandate for WG1

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- Identify areas in the field of PhV and PhEpi for which research standards are needed
- In co-operation with learned societies: Identify and develop standards and guidances as appropriate according to the network's needs
- In co-operation with learned societies: Implement existing standards
- Explore the merits of developing a (self-)accreditation system
- Short-term: Develop training programs
- Input to the design of the EMEA web page

3. Introduction

Gonzalo Calvo-Rojas (Chair) initiated the meeting with a Tour de Table and a presentation of the objectives of the meeting. These objectives were:

- To agree on the WG1 objectives
- Structure and functioning
- Define outcomes and deliverables
- Timelines and meetings schedule

He also presented the questions asked to WG1.

X. Kurz made introductory remarks and indicated that each Working Group is expected to have a minimum continuity of 2 years. Participants in WG1 will be invited to continue working on a voluntary basis but no decision about future participation was required at this stage. Each WG could operate independently from the plenary ENCePP meetings and from the other WGs. A meeting of each WG is planned at EMEA in 2008 and the date may be chosen independently. A second meeting may be possible according to the organisation or not of a plenary meeting.

4. Outcome of the discussion

4.1. General comments

- There is a need to have very clear ENCePP standards and accreditation criteria. However, the WG should not "reinvent the wheel" and repeat recommendations/standards that are already in textbooks. For example, the WG should not address general standards in the field of pharmacovigilance and pharmacoepidemiology, which already exist. On the other hand, there should be a specification of "ENCePP standards" (which may be based on existing standards), which the centres participating to the network should adhere to. It is therefore suggested to rename WG1 as follows: "**ENCePP research standards and guidances**".
- There is a need to include drug utilisation studies
- Consideration should be given to address the quality of data in addition to quality of study design and conduct.
- It will be very important to communicate and disseminate ENCePP standards at an early stage
- Quality standards should be defined in terms of operational standards, eg. by defining the different activities needed to be performed for ensuring high-quality studies. This could take the form of a check list of the different aspects that need to be followed, and these operational criteria would be amenable to auditing/inspection.
- The first step is therefore to identify standards that are needed, and to develop the missing ones.
- Consideration should be given to defining standards for peer reviewers.
- Consideration should be given to recommending disclosure of conflicts of interest in terms of transparency regarding use of data sources (e.g. when a researcher received free access to a database).

4.2. Recommendations

The following revised title and mandate of the WG are proposed:

Revised title

WG1. "ENCePP research standards and guidances"

Revised mandate

1. Identify areas in which standards (quality, operational, methodology, ethics, publication, communication, etc.) relevant for ENCePP activities are needed.
2. Develop standards and guidances as appropriate according to network's requirements
3. Disseminate and promote implementation of new and existing standards
4. Explore the merits of developing an accreditation system and its methodologies
5. Identify the training needs for the implementation of the ENCePP standards
6. Dissemination including input to the design of the ENCePP web page

The objectives of this working group are to improve the quality of ENCePP activities and will be carried-out in cooperation with the relevant learned societies.

4.3. Prioritisation of tasks

The first three tasks were considered the highest priority. Dissemination and promotion should not be dissociated from the development of ENCePP standards.

4.4. Deliverables

Two subgroups will be initially created, with the following deliverables:

1. Development of set of operational research standards to be applied by all centres participating to ENCePP; this set of standards will cover ENCePP activities related to the development, conduct, analysis and reporting of PE studies; it may be used in the future as a starting point for quality assurance and possible centre accreditation.

2. Compilation of existing recommendations and guidelines for pharmacoepidemiological studies, with a short description and an assessment of relevance, scientific quality, applicability throughout Europe, and usefulness for ENCePP.

4.5. Organisation of work

If possible, the next meeting should be organised before summer.

- It was proposed that Bert Leufkens will chair the sub-WG1 regarding the identification of the standards needed for ENCePP activities. The WG will also include Jane Apperley, Robert Vanderstichele, Herve Le Louet, Gonzalo Calvo-Rojas, Brian Ewards, Xavier Kurz.
- Susana Perez-Gutthann was proposed to chair sub-WG2 on existing recommendations and guidelines; Jesper Hallas, Ulf Bergmann, Consuelo Pedrós, Yola Moride, and Nicholas Moore volunteered to be included.
- Other participants may confirm their preference at a later stage.

ANNEX – Amended Mandate of ENCePP Working Group 1

Working Group 1

Scope	***ENCePP research standards and guidances***
Chair: **Rapporteur(s):** **ENCIAG:**	Gonzalo Calvo Rojas Xavier Kurz Nicholas Moore, Bert Leufkens
Mandate	▪ Identify areas in which standards (quality, operational, methodology, ethics, publication, communication, etc.) relevant for ENCePP activities are needed. ▪ Develop standards and guidances as appropriate according to network's requirements ▪ Disseminate and promote implementation of new and existing standards ▪ Explore the merits of developing an accreditation system and its methodologies ▪ Identify the training needs for the implementation of the ENCePP standards ▪ Dissemination including input to the design of the ENCePP-EMEA web page The objectives of this working group are to improve the quality of ENCePP activities and will be carried-out in cooperation with the relevant learned societies.