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

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EMEA meeting with interested parties and research centres on ENCePP

(European Network of Centres for Pharmacoepidemiology and Pharmacovigilance)

Summary of the Outcome of the Working Groups

WG 1: *Roles and Organisation of Centres in ENCePP*

Chair: Xavier Kurz

- The concept of having a rather rigid structure of predefined (therapeutic/database) subnetworks and of pre-established Coordinating Centres was abandoned. Instead a "flexible" approach was preferred:
  - Establishment of centre collaboration on an "ad-hoc" basis depending on the research question.
  - Call for tender for a new project to be answered by the ENCePP centres (however, it was noted that such a procedure is time-consuming).
  - Subsequently selection of a Coordinating Centre.
  - Coordinating Centres might also be nominated for a certain period of time for long-term purposes.
  - It was suggested to create a protected internet platform for the above process.
- Since a major role for ENCePP would be the development, promotion and dissemination of Ph'Epi standards and methods, it was suggested to create a methodological/scientific subnetwork, which could also advise on the study protocol.
- In addition to the generation of new data, another major objective of ENCePP would be to identify existing data sources within the member states of the EU and to coordinate these data sources in a comprehensive registry. It was suggested to contact the national competent authorities in this respect.
- A list of selection criteria for the ENCePP centres was proposed, which could be used for a quality check in the future:
  - Experience and competence (to be assessed using a peer review system)
  - Publication and on-going research
  - Available resources (human resources, expertise)
  - Independence from industry

  It was agreed that a programme of quality assurance should be envisaged in the future.

WG 2: *Principles and Code of Conduct for ENCePP*

Chair: Ingemar Persson

- As a general principle, it was agreed that any Ph'Epi research within ENCePP is to be carried out with full *transparency* and according to best scientific standards. A common Code of Practice addressing all relevant steps in the research process has been suggested in order to ensure maximum scientific *independence*. Moreover, patient data privacy and confidentiality issues should be addressed.
- A standard funding/business contract template should further strengthen independent research. The contract should define a set of principle rights and duties:
  - Right of ENCePP centres to publish

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- Maximum time period for the sponsor of a study to comment on the report before publishing
- Application of international authorship guidelines
- Ownership of research data
- Responsibility to fulfil regulatory requirements
- Conditions of withdrawal/termination of funding

- Further to the above, the following suggestions have been made to enhance scientific independence and transparency:
  - Online publication of the research project, e.g. the final study protocol
  - Rules defining/limiting the nature and the extent to which the sponsor of a study is involved
  - Establishment of a register of initiated and concluded Ph'V studies
- In order to strengthen the general scientific quality of Ph'V studies performed within ENCePP, a set of quality criteria should be established. Regardless, the ISPE Guidance for Good Ph'Epi Practice should be applied throughout. Further suggestions in order to raise research quality included:
  - Endorsement or peer review of study protocols supported/advised by Scientific Advisory Committee
  - Online publication of full study reports (maybe linking to the study register and to the respective journal papers)
  - Transparency of process to identify priority research questions to be publicly funded.
- It was noted that an ENCePP-accredited research process and contract could help to increase the credibility of the centres and their research, thus facilitating the recruitment of study patients.

WG 3: *Functional organisation of the network I: Health Care Databases and Registries*

Chair: Jim Slattery

- The creation of a database of data sources was generally supported. However, it was noted that well-established lists of data sources are available and should be used. Also, specialised databases, e.g. for rare diseases should be included. It was agreed that a questionnaire should be designed to allow for the identification of appropriate data sources.
- A list of minimum criteria for event-history databases was defined:
  - Ongoing data collection
  - Prospective definition
  - Automation in data collection
  - Minimum size
  - Ease of accessibility
  - A core set of data elements
  - Clear rules of coding
  - other quality criteria to be further defined
- The concept of a standing Coordinating Centre for all databases was unanimously rejected. Instead, the establishment of ad-hoc Coordinating Centres depending on the research question was preferred. Given a common and straightforward policy for the election procedure, this should not delay the conduct of a study.
- In order to facilitate the combination of data from different databases, a common protocol should be applied for studies addressing the same question in different data sets. The idea of a common coding system, however, was rejected in view of the well-established existing systems. Furthermore, the concern was raised that the release of patient-related data from one country to the other could be legally restricted.
- It was found that ENCePP centres should be free to perform also purely scientific studies within ENCePP, i.e. by using the ENCePP infrastructure and achievements.

WG 4: *Functional organisation of the network II: Therapeutic Areas*

Chair: Eric Abadie, Panos Tsintis

- Organising the network into several therapeutic areas was unanimously rejected in favour of a more flexible approach. Centres should be able to form collaborations on their own in order to answer a research question.
- It was agreed that ENCePP centres should be free to carry out research within or outside the ENCePP rules and scope. However, studies performed within ENCePP would have to meet the agreed standards and business rules.
- An administrative and scientific Governance body should be established. Possible tasks of this body could be to formulate research questions, to prepare calls for tender and to approve/refuse proposals. The Governance body could serve as the entry point to ENCePP for study sponsors.
- In an attempt to define the role of the EMEA, it was proposed that the EMEA should be responsible for the ENCePP Secretariat. Furthermore, the EMEA should help to identify priority research questions.
- As a major task, the existing list of ENCePP centres has to be updated in order to generate a comprehensive, transparent and searchable Inventory, preferably electronically and publicly available, thus facilitating collaborations between the centres. It was suggested to develop and distribute a 2nd questionnaire in order to obtain the required details for such an inventory.

WG 5: *Quality Assessment and Assurance within and by ENCePP*

Chair: Saad Shakir

- It was agreed that there is a need for quality standards for ENCePP. However, before generating new standards applicable to ENCePP it was agreed to look into existing and published stantards (e.g. ISPE's Guidance for Good Ph'Epi Practice, GCP, CONSORT statement, etc) and establish which could be applicable to ENCePP. It was felt that there was a need to establish a Working Group to progress on this topic.
- Quality criteria and standards should apply to
  - centres
  - studies/methodologies
  - data

  and should be both of a general and a specialised nature.
- It was felt that at this early stage of the project, no accreditation system should be enforced taking into account the diverse nature of the scientific work to be undertaken and of the centres to be included in ENCePP. Instead, there was a strong preference for a system of self-assessment of the centres followed by a peer-review process through an ENCePP body.
- ENCePP activities should be overseen by a Governance body. This body should be responsible for initially establishing the network and the subsequently maintenance. In addition, a Scientific Committee should be created to assess and advise on study protocols and any other scientific issue.
- It was agreed that there is the need for training of less experienced Ph'Epi centres.