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Patient Health Protection

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

ENCePP Work Plan 2010

(European Network for Centres of Pharmacoepidemiology and Pharmacovigilance)

As adopted by the ENCePP SG on 19 March 2010

This Work Plan defines the objectives and milestones for the year 2010 in the context of the implementation of the ENCePP network, as well as the means of achieving these objectives in a timely manner. The Work Plan seeks to organise the work of the main active bodies of ENCePP, namely the ENCePP Secretariat, the ENCePP Steering Group and the ENCePP Working Groups against the background of the *ENCePP Implementation Strategy* and the European Medicines Agency Work Programme for 2010.

1. Background and current status

In 2009 a number of milestones were achieved towards the further development and implementation of the ENCePP network:

- Launch of public consultation on draft Code of Conduct for Independence and Transparency (16 November 2009)
- Launch of public consultation on draft Methodological Research Standards that lay down key elements and principles for the conduct of "European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Studies" (November 2009)
- Endorsement and publication of Mandate of the ENCePP Steering Group
- Endorsement and publication of Mandate of the ENCePP Plenary
- ENCePP Plenary meetings on 18 September and 11 December 2009
- Establishment of the ENCePP Steering Group, including the election of the ENCePP members to the ENCePP Steering Group at the Plenary meeting on 11 December 2009

For numerous reasons – notably the bulk of work coinciding with the H1N1 pandemic and the re-structuring of the Agency – progress on the very ambitious work programme 2009 has fallen slightly behind schedule. The following deliverables from the WP09 will be carried over to 2010:

- Launch of publicly available database of research centres and networks
- Launch of database of data sources
- Creation of database that can be populated with post-authorisation studies
- Fully functional web page (Members' Forum, FAQs, Contact Form)
- Survey of PASS 2007-2008

2. Main goal and objectives

To have in place by the end of the year a high quality, self-sustainable network in the field of independent post-authorisation monitoring of medicinal products in the EU.

To promote ENCePP as a resource and increase its usage internationally.

Essential deliverables:

- Final Code of Conduct (following public consultation)
- Final Checklist of Methodological Research Standards (following public consultation)
- Guide on the use of Methodological Standards and Guidelines
- ENCePP e-Inventory of Research Resources (centres, networks, data sources)
- Database for post-authorisation studies
- Consolidation of the ENCePP Steering Group: inaugural meeting in February 2010, followed by at least three more meetings during 2010
- Development of a Members' forum on ENCePP web page
- Promotional events, including
  - ENCePP Info Day
  - Participation in international conferences, symposia

Other deliverables:

- 2 Plenary meetings in 2010 (June and November)
- Continue contact with FDA (Sentinel) and Health Canada/Sante Canada (DSEN) to exchange information and consider complementarity with their respective initiatives

3. Resources and possible constraints

In order to achieve the objectives as described above, the active bodies of ENCePP will need to work together and exchange information and results as appropriate.

The ENCePP Secretariat will ensure a smooth flow of information, organise meetings and provide assistance to the Working Groups and the ENCePP Steering Group. Senior Agency staff will serve

as Rapporteurs to the Working Groups and will, together with the respective chair, ensure adequate progress. In order to guarantee that the deliverables as indicated in this Work Plan are achieved in due time, the Agency will need to make available sufficient resources.

The four ENCePP Working Groups - consisting of ~ 10 volunteers from centres participating in ENCePP - will work according to their agreed mandates and prioritised activities assisted by the ENCePP Secretariat.

The ENCePP SG will meet on a regular basis (at least quarterly) to oversee the delivery of the outcome of the ENCePP Working Groups and provide expert advice to the European Medicines Agency.

The Agency has budgeted for a number of meetings including meetings of the Working Groups, Steering Group, and Plenary Meetings of ENCePP.

The contribution of the Agency IT Department is crucial to the development and implementation of the web page and electronic tools including the databases for the research resources and for post-authorisation studies.

4. Strategy and action plan

- **Populate Inventory of research resources: research centres and networks.**
- **Populate Inventory of research resources: data sources for PEpi and PV research.**
- **Populate database for post-authorisation studies. Link to study protocol and publication of study results.**
- **Finalise the Code of Conduct and MRS Checklist.**
  - Adoption by ENCePP SG
  - Adoption by ENCePP Plenary
- **Further strengthen the networking facilities of ENCePP promoting exchange of information and experiences and collaboration between the participating centres.**
  - ENCePP Plenary meetings on 8 June 2010 and 18 November 2010: At these meetings, representatives of the ENCePP centres and other stakeholders will have the opportunity to meet face-to-face, to get to know each other and to exchange and explore possible collaborations.
  - Further development of the ENCePP web page (Q&A document, electronic contact form, members-only forum)
- **Promotion of Pharmacovigilance and Pharmacoepidemiology research in the EU.**
  - Publicise relevant funding opportunities through European funding schemes like the European Commission's Framework Programme (FP) and the Innovative Medicines Initiative (IMI)
  - Support the EMA funding of drug safety studies:
    - Promote the EMA funding of drug safety studies through the ENCePP network
- **Promote ENCePP as a resource internationally and increase its usage.**
  - Participation in international conferences, symposia, workshops (development of ENCePP leaflet, posters)

- Promotion of ENCePP at national level, particularly in new Member States
- Organisation of ENCePP Info Day
- Promotion of Code of Conduct and MRS Checklist during sessions at CHMP and PhVWP plenary meetings