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ENCePP

The European Network of Centres for Pharmacoepidemiology & Pharmacovigilance

Mandate of the ENCePP Implementation Advisory Group (ENCIAG)

I. Role and responsibilities

The interim 'ENCePP Implementation Advisory Group' has been established in order to expedite and facilitate the launch of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). The work of the group shall be directed towards the development of a robust infrastructure for ENCePP taking into account the general needs of networks of a size and miscellaneous membership such as ENCePP's, as well as the specific requirements of ENCePP pertaining to pharmacovigilance and pharmacoepidemiology. In essence, the group shall help the EMEA to further define the objectives and principles of ENCePP and to elaborate an efficient working model for the network. The group shall meet on a regular basis to appropriately address the needs of the ENCePP project, including writing proposals on the scope, mandate, implementation strategy and other strategic documents pertinent to the activities of the network. Furthermore, the group shall also serve as a scientific forum and give scientific guidance to the EMEA. On occasion, the EMEA may request members of the group to represent the network.

The role of ENCIAG will be taken over by a permanent Steering Group in due time.

II. Guarantees of independence and confidentiality

The individual ENCIAG members shall undertake to act in the interest of the network and in an independent manner. In principle, they shall make a declaration of their financial interests (to be renewed annually) and should not have direct interests in the pharmaceutical industry or any other undeclared conflicting commitments or responsibilities that could affect their impartiality. At the beginning of each meeting, they shall declare any specific interests that could be considered to be prejudicial to their independence with respect to the points of the agenda. Furthermore, members of ENCIAG shall sign a confidentiality undertaking and shall treat all information and documents to which they acquire access as a result of their participation in ENCIAG activities under conditions of strict confidentiality and discretion. Any external communication should be in line with standard EMEA procedures.

III. Specific tasks and duties

Specifically, the tasks of this group will include, but are not limited to, the following:

- To assist the EMEA in finalising the currently proposed ENCePP working model, based on the structure, the objectives and the deliverables of the network
- To draft the mandates of the ENCePP Working Groups (WGs) in line with the current proposed ENCePP working model, and to oversee the delivery of the outcome of the ENCePP WGs
- To advise the EMEA on how best to address any proposals/expressions of interest in response to calls for interest of funding programmes (e.g. IMI and FP7) in the field of pharmacovigilance or pharmacoepidemiology in the context of ENCePP
- To champion and promote the ENCePP project as appropriate
- To advise the EMEA on an appropriate communication strategy for ENCePP
- To take the necessary steps to facilitate the establishment of a permanent ENCePP Steering Group.