EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP

Proposal for revision of ENCePP and Steering Group mandates

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ENCePP Plenary meeting – 01 December 2023

Context

Time to finalise the revision of the ENCePP and SG mandates

- Not revised since many years -> after about 15 years, adaptation to the current environment is needed
  - The catalogues (EU PAS Register and ENCePP Resource Database) will not remain part of the ENCePP mandate after the migration to the EMA website early next year
  - Task forces mentioned but not used over the last years
  - More democratic rules for the SG election
  - …

ENCePP mandate

Proposed changes

Need for *slight* mandate revision

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP®) is a network coordinated by the European Medicines Agency (EMA). The members of this network (the ENCePP partners) are public and private institutions ~~and contract and research organisations (CRO)~~ involved in research in pharmacoepidemiology and pharmacovigilance. Research interests ~~are not restricted to the safety of medicines but may~~ include disease epidemiology, ~~and~~ drug utilisation, and the benefits (effectiveness) and risks (safety) of medicines. Participation to ENCePP is voluntary.

ENCePP aims to strengthen the monitoring of the benefit-risk balance of medicinal products in Europe by:

- Bringing together expertise and resources in pharmacoepidemiology and pharmacovigilance across Europe and providing a platform for collaborations;
- Facilitating the conduct of high quality, multi-centre, independent ~~post-authorisation~~ non-interventional studies (~~PAS~~NIS using RWD)~~ with a focus on observational research~~;
- Developing and maintaining methodological standards and governance principles for research in pharmacovigilance and pharmacoepidemiology.

Need for *slight* mandate revision

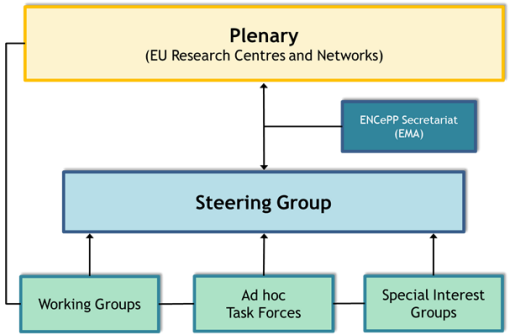
ENCePP provides a unique opportunity for collaboration to improve pharmacoepidemiological research and post-authorisation safety surveillance (benefit-risk assessment) of medicinal products and medical devices in Europe through access to a network of resources working in a transparent and independent manner and support to conduct joint non-interventional studies. ~~Individual centres and networks that are registered in ENCePP may be contacted directly or by submitting a request to the ENCePP Secretariat to place an announcement in the ENCePP partners forum.~~

What has ENCePP achieved?

- Need to adapt wording to reflect changes
  - ENCePP Database of Research Resources -> EMA/HMA catalogue of RWD sources
  - EU PAS register -> EMA/HMA catalogue of Non-Interventional Studies
  - Moving from an annual to a regular update of the ENCePP Guide on methodological standards in pharmacoepidemiology
  - Not only refer to the role of ENCePP during COVID-19 but also other recent health emergencies
  - Introduce DARWIN EU and pharmacogenomics

Special Interest Groups (SIGs)

- Only one currently active (Pregnancy)
- SIGs could be more often leverage to deal with specific topics of interest
  - A call for interest could be sent to the network to further engage with (new) members and better animate the network, which would include clear mandate and timelines, and be in close liaison with the MWP
  - Similarly, ENCePP special interest groups are in place to lead and advise the ENCePP Steering Group, where applicable, on future activities of ENCePP to enable a better focus and progress discussions on topic-related issues, thus expediting the generation of specific outputs



ENCePP Steering Group mandate

Proposed changes

Steering Group Membership

- Has expanded from 17 (previous version) to 22
  - Additional representatives from the Methodology Working Party (MWP), the European Commission (EC), the European Centre for Disease Prevention and Control (ECDC), and international regulatory agencies (Health Canada and U.S. Food and Drug Administration)
  - Industry representative to be more inclusive of all pharma associations
- All SG representatives will have the same role
  - Deletion of the “ex-officio members”

Steering Group Method of Work

- Membership of the SG implies a commitment to attend the meetings of the SG (at least 50% of the meetings organised yearly)
- The SG may establish working groups and special interest groups

Steering Group Election Process

- Composition of the SG
  - The composition of the ENCePP SG should provide a good balance of expertise. To ensure some degree of representativeness at the ENCePP SG, a quota of seats per membership category is applied. Even if each ENCePP Partner will be able to vote for the 6 members to be elected, two third of the seats (4 out of 6) will be reserved for public institutions - universities, hospitals, government agencies, charities / national and international networks, and one third (2 out of 6) for CRO & consultants / data sources
- Re-election
  - A maximum of 3 (instead of 2) incumbents may be re-elected to the Steering Group
- Possibility to hold the election electronically (before the meeting) not only in case of virtual but also hybrid plenary meeting

Thank you for your attention

Further information

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