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SCIENCE MEDICINES HEALTH

Draft proposal for revised ENCePP mandate

Presented by Xavier Kurz, on behalf of ENCePP Steering Group

Background

- Hand-over document prepared by current ENCePP Steering Group for the new ENCePP SG (2021-2023)
- Several rounds of discussions and teleconferences
- Background document to be used by new ENCePP SG to define new ENCePP SG and prioritise ENCePP activities
- Document to be circulated and published on ENCePP website

Outline of document

- **Current mandate of the ENCePP network**
- **What have been important achievements of ENCePP?**
- **Why is a new ENCePP mandate needed?**
  - Aspects not fully achieved
  - New challenges and opportunities
  - Addressing the needs of ENCePP stakeholders
- **Elements of a new ENCePP mandate**
  - Mission of ENCePP
  - How is the mission of ENCePP implemented
    - METHODS AND GOVERNANCE
    - ACCESS TO DATA
    - HIGH-QUALITY STUDIES
    - EXCELLENCE FOR PUBLIC HEALTH EMERGENCIES

What have been important achievements of ENCePP?

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- **ENCePP Guide on methodological standards in pharmacoepidemiology:** reference for guidance and training on best practice in pharmacoepidemiology and complementing regulatory guidance
- **Updated Code of Conduct:** best practice in the relationship between investigators and study funders, irrespective of source of funding; key reference for the conduct of studies
- ENCePP Working groups address **methodological challenges on specific topics and methods not covered by other groups,** e.g. methods to measure impact of pharmacovigilance
- **Access to large pool and network of experts** in pharmacoepidemiology and pharmacovigilance across Europe providing support to regulatory evaluations
- **Access to a large number of clinical or administrative electronic health care databases** available in Europe through their identification in a public inventory
- Through the public register of post-authorisation studies (EU PAS Register), ENCePP increases the **transparency of observational post-authorisation studies** and the availability and accessibility of post-authoristion evidence on medicines
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Why is a new ENCePP mandate needed?

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1) Aspects not fully achieved

- Difficulties to achieve effective collaborations between ENCePP centres on large research projects and multicentre studies- competitive environment for leadership, funds and publications for academic institutions → additional mechanisms needed for collaboration?
- Improvements needed in the communication and dissemination of ENCePP outputs and the promotion of educational activities.
- Collaboration between the ENCePP network, as a source for methodological recommendations, and national medicines agencies to be improved.
- Improvements and clarifications needed in the EU PAS Register and the ENCePP resources database; expansion of the scope and utility of these databases requiring an effective collaboration with a wider potential users' community

Why is a new ENCePP mandate needed?

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2) New challenges and opportunities

- The research environment is changing: new data sources and new approaches for their use, new fields of research like artificial intelligence, increased expectations on transparency of studies, need to strengthen availability of expertise in some domains like pharmacogenomics, stakeholders' needs
- Need for methodological standards and high-quality evidence supporting COVID-19 related regulatory decisions
- HMA-EMA Joint Big Data Task Force report's proposal to establish a sustainable platform to access and analyse healthcare data from across the EU
- In 2020, adoption by the EC of a Digital Strategy and an Artificial Intelligence White Paper.
- End of 2021, legislation to create a 'European Health Data Space': ENCePP to be ready to both support this development and leverage the anticipated increase in healthcare data use it should bring.

Why is a new ENCePP mandate needed?

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2) Addressing the needs of ENCePP stakeholders (stakeholders' perspectives)

- Patients and health care professionals to be recognized as both contributors and end-users of activities developed by ENCePP on methods and governance
- Guidance on the accessibility and suitability of specific type of data sources for regulatory purpose; improvement of the quality and availability of RWE adequate for regulatory decision making.
- Industry to be seen as partner for studies (not only study funders), bringing expertise and experience, while safeguarding researchers' independence; emphasis on scientific collaboration between the network and industry.
- Scope and usefulness of ENCePP could be increased by better adapting ENCePP tools to the needs of learned societies and other organisations like ISPE, ISPOR, ISoP, HTA bodies, payers, disease registry networks

Elements of a new ENCePP mandate

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Mission of ENCePP

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

- Developing and maintaining methodological standards and governance principles for research in pharmacoepidemiology and pharmacovigilance (METHODS AND GOVERNANCE)
- Supporting the identification and access to high quality data relevant for research and regulatory decision-making on the benefits and risks of medicines (ACCESS TO DATA)
- Bringing together capacity and expertise in pharmacoepidemiology and pharmacovigilance across Europe facilitating the conduct of high quality, multi-centre post-authorisation studies with a focus on observational research (HIGH QUALITY STUDIES)
- Providing a network of excellence in pharmacoepidemiology that can be leveraged in public health emergencies (EXCELLENCE FOR PUBLIC HEALTH EMERGENCIES)

ENCePP does not perform regulatory activities related to specific substances, medicinal products, or classes of product and does not provide a forum for the assessment of their benefits and risks.

Elements of a new ENCePP mandate

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METHODS AND GOVERNANCE

- To continuously update existing guidance on best practice in pharmacoepidemiological and pharmacovigilance research and develop new guidance as necessary to support implementation of good methodological and governance principles.
- To strengthen collaborations with existing ENCePP stakeholders and interact with new networks, such the Darwin EU community, the Big Data stakeholder forum or coordinated registry networks, to develop and promote use of good methodological and governance principles in their specific fields of research.
- To promote use of FAIR Principles (Findable, Accessible, Interoperable and Reusable data).

Elements of a new ENCePP mandate

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ACCESS TO DATA

- To support data discoverability through :
  - the identification of fit-for-purpose data sources in Europe in different fields of medicines evaluation,
  - the development and visualisation of a standard set of metadata describing data sources and providing a clear understanding of their reliability and quality.
- To contribute to the development of a data quality framework providing researchers with adequate and high-quality information on data sources
- As a follow-up to work performed by ENCePP WG3, to strengthen recommendations on analytic methods to be used for different formats and scopes of databases.

Elements of a new ENCePP mandate

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HIGH QUALITY STUDIES

- To leverage expertise needed for the analysis and interpretation of observational research; strengthening use of methods such as genetic epidemiology or artificial intelligence (AI).
- To promote use of best practice guidance in pharmacoepidemiology for the design, conduct and analysis of studies in pharmacoepidemiology and pharmacovigilance.
- To support the upgrading of the ENCePP Resources databases to provide information on expertise and capacity of ENCePP centres in PE and PhV
- To support the upgrading of the EU PAS Register to facilitate access to high-quality studies and their protocols through improved field definitions and search functions.
- To support the provision of training curricula in pharmacoepidemiology and the development of training on new methods as needed, in collaboration with ISPE

Elements of a new ENCePP mandate

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EXCELLENCE FOR PUBLIC HEALTH EMERGENCIES

To develop the tools and processes to increase the capacity for rapid studies in case of public health emergencies by establishing mechanisms for rapid leverage of expertise, guidance development, study design, data source identification, access and analysis, and pooling of results

Organisation of work

The ENCePP Steering Group defines and safeguards the objectives and principles of ENCePP and decides on operational tasks of the network T

The ENCePP working groups and SIGs New working groups may also be established as appropriate. There are currently three active working groups and one active Special interest group:

- WG1: Working Group Research Standards and Guidance
- WG2: Working Group Independence and Transparency
- WG3: Working Group Data sources and multi-source studies
- SIG: Measuring the Impact of Pharmacovigilance Activities
- SIG: Drug Safety in Pregnancy

Any questions?

Further information

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