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SCIENCE MEDICINES HEALTH

What has ENCePP achieved and what is next

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Outline

- What have been important achievements of ENCePP?
- Why is a new ENCePP mandate needed?
- Elements of a new ENCePP mandate

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

- Improvements needed in the communication and dissemination of ENCePP outputs and the promotion of educational activities
- Dissemination and integration of ENCePP method recommendations to national medicines agencies
- 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
- 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.
- In 2020, adoption by the EC of a Digital Strategy and an Artificial Intelligence White Paper.

Why is a new ENCePP mandate needed?

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

- 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 tools could be increased by addressing more needs of learned societies and other organisations like ISPE, ISoP, ISPOR, HTA bodies, payers, disease registry networks

Elements of a new ENCePP mandate

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The elements of the new mandate will be at the core of the ENCePP mission to strengthen the monitoring of the benefit-risk balance of medicinal products in Europe

- Access to data
  - Supporting the identification and access to high quality data relevant for research and regulatory decision-making on the benefits and risks of medicines
- Methods and governance
  - Developing and maintaining methodological standards and governance principles for research in pharmacoepidemiology and pharmacovigilance
- High quality studies
  - Bringing together capacity and expertise across Europe facilitating the conduct of high quality, multi-centre post-authorisation studies
- Excellence for public health emergencies
  - Providing a network of excellence in pharmacoepidemiology that can be leveraged

Note: 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

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Access to data

- Support data discoverability
  - Identification of adequate data sources in Europe in different fields of medicines evaluation
  - Development and visualisation of a standard set of metadata describing data sources and providing a clear understanding of their characteristics
- Contribute to the development of a data quality framework
  - Provide researchers with adequate and high-quality information on data sources
- Promote FAIR principles
  - Promote the use of Findable, Accessible, Interoperable and Reusable data

Methods and governance

- Guidance to support implementation of good methodological and governance principles
  - Continuously updating existing guidance on best practice in pharmacoepidemiological and pharmacovigilance research (ENCePP Guide on Methodological Standards in Pharmacoepidemiology, ENCePP Checklist for Study protocols, ENCePP Code of Conduct)
  - Developing new guidance as necessary
- Collaboration
  - Strengthening collaborations with existing ENCePP stakeholders and interact with new networks (DARWIN EU, coordinated registry networks,…) to develop and promote use of good methodological and governance principles in their specific fields of research
- Strengthen recommendations on analytic methods on multi-database studies
  - As a follow-up to work performed by ENCePP WG3

High quality studies

- Leverage expertise needed for the analysis and interpretation of observational research
  - Strengthening use of methods such as genetic epidemiology or artificial intelligence by reaching out to centres with expertise in these domains
- Support the upgrade of the EU PAS Register
  - To facilitate access to high-quality studies and their protocols through improved field definitions and search functions, addressing stakeholders' needs for information
- Promote use of best practice guidance
  - For the design, conduct and analysis of studies in pharmacoepidemiology and pharmacovigilance
- Support the provision of training curricula in pharmacoepidemiology
  - Including the development of training on new methods as needed, in collaboration with ISPE

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Excellence for public health emergencies

- Increase the capacity for rapid studies in case of public health emergencies
  - Develop tools, processes and 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 gives orientation, defines and safeguards the objectives and principles of ENCePP and decides on operational tasks of the network

The ENCePP Working Groups (WG) and Special Interest Groups (SIG) are of a temporary nature in line with the continued development and objective of the network

There are currently three active WGs and one active SIG

- 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

New WGs and SIGs may be established as appropriate

Any questions?

Further information

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