



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Working Group 2 – independence and transparency

Report of activities and next steps

ENCePP Plenary, 1 December 2023

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An agency of the European Union





Working Group 2 – mandate and members

16 August 2022
EMA/196490/2011 Rev.3



European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

Mandate of ENCePP Working Group 2

Independence and transparency

Chair: Rosa Gini

Code of Conduct

- Assess the need to supplement the Code of Conduct with additional tools to support good governance of pharmacoepidemiological research.
- Further elaborate some of the provisions already included in the Code of Conduct, e.g. by developing specific guidance, policies or sample/template contracts.
- Explore ways to better monitor implementation of the Code of Conduct for ENCePP Seal studies.
- Support the use of the Code of Conduct.
- Support registration of studies in the EU PAS Register.

EU PAS Register and ENCePP databases

- Support EMA in the further development of the EU PAS Register and ENCePP databases.
- Provide recommendations for business requirements to ENCePP Steering Group and EMA.

Members

Rosa Gini, Morten Andersen, Helen Dolk, Stephen Evans, Xavier Fournie, Agnes Kant, Iryna Vlasenko, Martin Daumer, Foteini Dermiki, Alexia Mpikou, Lia Gutiérrez, Christos Kontogiorgis, Elena Petelos, Evangelia E. Ntzani, Nicolas Deltour, Luca Giraldi (EMA)



Workplan 2023-2025

Actions to promote and support compliance with the ENCePP Code of Conduct in pharmacoepidemiology research contributing to regulatory decisions

Promotion

- Teaching material to facilitate compliance
- Inclusion in EU PAS Register of explicit fields
- Revision/update of checklists for the ENCePP Seal
- Public presentations (EMA Committees, national regulators, research funders)



Activities 2023

- Added two questions to the new EU PAS Register (1) Who is the (primary) lead investigator of this study? (2) Is this study performed in line with the ENCePP Code of Conduct?
- Revised checklist (to be finalised with EMA feedback)
- Discussion with EMA on whether compliance with the ENCePP Code of Conduct could exempt investigators from being considered in the EMA Conflict of Interest Policy EMA/196298/2022 – was deemed impossible
- Dissemination: see next slide



Launch of podcast series 'Conduct Your Study'

- **Conduct your study**, *Conversations about conflict of interests and the ENCePP Code of Conduct on scientific independence and transparency*
- First episode: **Barbara Mintzes** (Professor of evidence-based pharmaceutical policy, University of Sidney) will discuss her studies on conflict of interest, and why the Code of Conduct can help
- Second episode: **Anton Pottegård** (Professor in Clinical Pharmacology, Pharmacy and Environmental Medicine, University of Southern Denmark) will discuss his experience and perspective
- Five episodes are planned for 2023: **stay tuned!!!**