EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

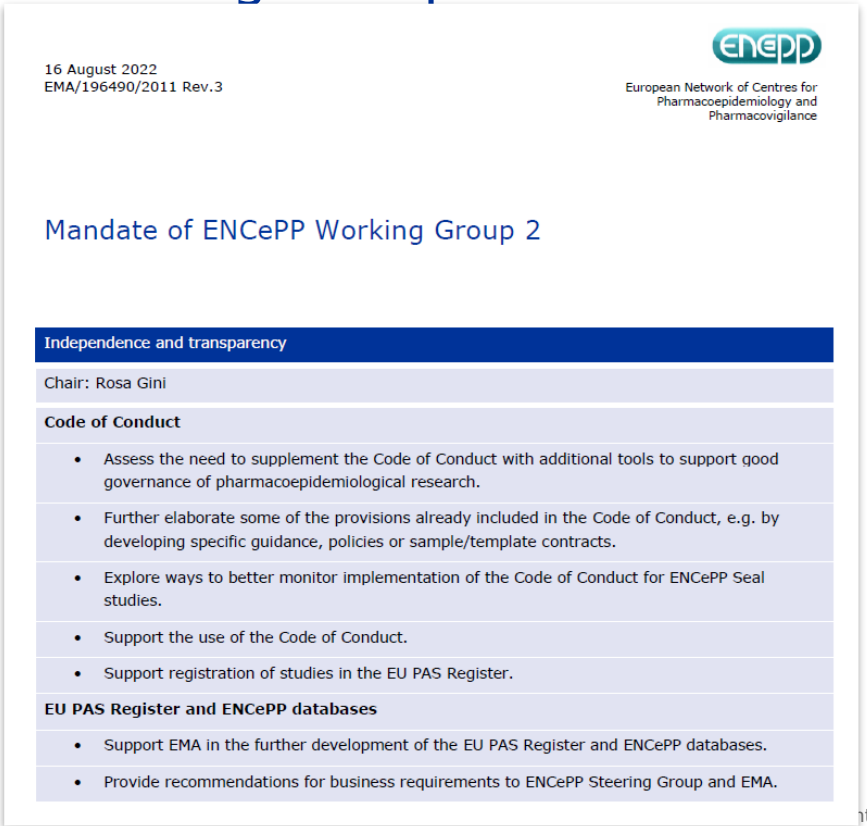
Working Group 2 – independence and transparency

Report of activities and next steps

ENCePP Plenary, 30 November 2022

Rosa Gini, ARS Toscana

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, Lia Gutiérrez, Christos Kontogiorgis, Elena Petelos, Evangelia E. Ntzani, Nicolas Deltour,

Luca Giraldi (EMA)

Comparison between the ENCePP CoC and the new EMA CoI policy

- On April 2022, the European Medicines Agency issued a document EMA/196298/2022 "Note on evaluation of potential conflicts of interests in studies funded by EMA under framework contracts awarded following open procedure ref. EMA/2020/46/TDA"
- Upon mandate of the Steering Group, WG2 analysed and compared the two documents (see included annex) and concluded with a recommendation to the Agency to clarify in a statement that

principal investigators and investigators of post authorisation observational studies compliant with the ENCePP Code of Conduct and whose institutions receive grant or other funding from a pharmaceutical company for the conduct of such studies will be waived from restriction in the involvement into EMA-funded studies on the same product

New questions in the EU PAS Register

As part of the revision of the EU PAS Register, the WG2 requested that two questions are added

- Who is the (primary) lead investigator of this study? (name, affiliation, email address)
- (mandatory) Does the (primary) lead investigator attest that this study is compliant with the ENCePP code of conduct, in its current version? (yes/no)

SHARING scoping review

The SHARING scoping review aims to characterise different possible levels of transparency in the execution of pharmacoepi studies on existing data sources, as a base to create a framework on this topic. A hierarchy of transparency is foreseen

- actionable access to the raw data underlying the study
- sharing programming code, transparently mapped to the statistical analysis plan, and actionable on simulated datasets
- availability of a 'sandbox' environment where the action of the software is reproduced may indicate a level of transparency

The principal investigator is **Elena Petelos**

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)

Investigation on barriers to compliance with the ENCePP Code of Conduct and application to the ENCePP Seal