EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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ENCePP Secretariat

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

The ENCePP Seal – Concept and Application

Concept

Upholding high standards throughout the research process of studies in pharmacoepidemiology and pharmacovigilance based on the principles of scientific independence, transparency and robust methodologies is at the core of the ENCePP initiative. The Code specifically aims to avoid financial, commercial or institutional interests of the study funder and potential personal interests of researchers that could influence the study results in any particular direction. To recognise studies following these ENCePP core principles the ENCePP Seal has been introduced.

Fig. 1: The ENCePP Seal

Studies bearing the ENCePP Seal (Fig. 1) are performed taking into account the relevant methodological research standards described in the ENCePP Guide on Methodological Standards in Pharmacoepidemiology and conducted in line with the rules and requirements for independent and transparent research laid down in the ENCePP Code of Conduct and in established international guidelines such as the World Medical Association Declaration of Helsinki and the European Code of Conduct for Research Integrity.

The ENCePP Seal publicly identifies studies in the EU PAS Register that adhere to the entirety of the Code's provisions. Reference to the Seal is encouraged in publications arising from the study.

Studies conducted in accordance with the following principles may qualify for the ENCePP Seal:

- The study's primary purpose is to generate data of potential scientific or public health importance and not to promote the sale of a medicinal product;
- The the design of the research shall aim at minimising any potential bias;
- The highest possible level of transparency regarding the use of methodological standards in the study protocol;

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- The contractual arrangements between investigators and the study funder clearly define the research assignment and address critical areas of interaction, remuneration, feasibility assessment, protocol agreement, study registration, data analysis and publication of results;
- Remuneration is only granted as specified in the research contract and independent of a particular study result;
- The study is registered in the EU PAS Register prior to its start, thereby making publicly available information on the research process;
- The study results (synopsis or manuscript) are published in the EU PAS Register in line with agreed timelines.

Conditions

ANY pharmacoepidemiological and pharmacovigilance study may qualify for the ENCePP Seal if ALL of the following conditions are met and the respective provisions are implemented:

1. The (primary) lead investigator belongs to an entity that is included in the ENCePP Inventory of Research Centres[1].
2. The study is registered in the EU PAS Register[2] together with the full protocol[3] prior to study start.
3. The (primary) lead investigator makes the following documentation of commitment to adhere to the provisions of the ENCePP Code of Conduct prior to study start publicly available in the EU PAS Register:
    a. Signed Checklist of the ENCePP Code of Conduct (Annex 2)
    b. Signed Declaration on compliance with the ENCePP Code of Conduct (Annex 3)
    c. Signed ENCePP checklist for Study Protocols
    d. Signed Declaration of Interests (Annex 5)
4. The (primary) lead investigator publishes the research results in the EU PAS Register.

Researchers that follow the provisions of the ENCePP Code of Conduct in its entirety are encouraged to consider applying for the ENCePP Seal if the above conditions are met.

How to apply for the ENCePP Seal

Please refer to the detailed step-by-step guide how to obtain the ENCePP Seal which is available on the ENCePP website (see step-by-step guide section 3).

To confirm a commitment to comply with the provisions of the Code, the (primary) lead investigator of the study must **print**, **complete** and **sign** the **documents listed under point 3 of the conditions** above.

[1] The ENCePP Inventory of Research Centres forms part of the ENCePP Database of Research Resources and can be accessed at http://www.encepp.eu/encepp/resourcesDatabase.jsp.
[2] The European Union electronic Register of Post-Authorisation Studies (EU PAS Register) is the publicly available register of non-interventional post-authorisation studies (PAS) referred to in Good Pharmacovigilance Practices (GVP) which can be accessed at http://www.encepp.eu/encepp_studies/indexRegister.shtml.
[3] The original version of the full study protocol, i.e. the version at the time of study start, together with the final version shall be made publicly available, without delay after the final study report is available. However, the (primary) lead investigator may decide to publish the protocol at an earlier point in time if he so wishes and provided that the study funder agrees.

An electronic copy (PDF) of these signed documents must be **emailed to the ENCePP Secretariat prior to study start** and the study must be **registered in the EU PAS Register** together with the full protocol.

Once the application is accepted by the ENCePP Secretariat the declaration and the checklist will be made publicly available in the EU PAS Register and the ENCePP Seal will be displayed next to the study title as a symbol for adherence to the Code.

Breach of declaration of compliance with the Code

The (primary) lead investigator should inform the ENCePP Secretariat if the study deviates from and/or no longer fulfills the criteria for the ENCePP Seal. Any failure to comply with the entirety of the provisions of the Code may be considered a breach of the declaration (Annex 3) and relevant documentation, and the ENCePP Seal will be removed from the EU PAS Register.

Point of reference

The ENCePP Secretariat is the point of reference for the (primary) lead investigator and funder for enquiries about the conditions for the ENCePP Seal and the practical implementation of the Code's provisions.

Contact

ENCePP Secretariat
Email: ENCePP_Secretariat@ema.europa.eu