



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Press release

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# European Medicines Agency and European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCePP) launch 'ENCePP studies'

New seal identifies transparent, independent and methodical studies on risk and benefit of medicines.

On 8 June 2010 the European Medicines Agency and the European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCePP) launched 'ENCePP studies'. Building on the foundations of the ENCePP network of Excellence, 'ENCePP studies' is a seal for EU-based, benefit/risk or risk studies that are carried out in compliance with the ENCePP code of conduct for independence and transparency and its methodological research standards and are entered into a publicly available electronic register before their start.

Investigators who apply to conduct an ENCePP study commit to a maximum level of transparency with respect to relevant information regarding their investigation. This includes publication of study findings regardless of their positive or negative results and making public relevant information on the study protocol before the study commences.

The seal 'ENCePP studies' is a confirmation for the public that the study was conducted in adherence to the ENCePP research and methodological principles and will increase trust in the robustness of the findings.

'ENCePP studies' is an important milestone for ENCePP, the European network of excellence in the fields of pharmacoepidemiology and pharmacovigilance. It builds on some of the network's main achievements since 2007, specifically the adoption of an ENCePP Code of Conduct and the development of a checklist of methodological standards for ENCePP study protocols.

The ENCePP Code of Conduct is a set of rules and principles to ensure transparency and promote scientific independence. The Code is voluntary and lays down rights and obligations between investigators and study funders detailing their responsibilities in the conduct of studies. It covers aspects such as the development of the study protocol, the conduct of the study, data ownership, and access to data and publication of the results. In order to facilitate compliance with the transparency requirement outlined in the Code, the Agency is developing an electronic-register of studies, which will



provide a publicly accessible resource for the registration and consultation of pharmacoepidemiological and pharmacovigilance studies.

The checklist of methodological standards for ENCePP study protocols is aimed at stimulating researchers to address important epidemiological principles when designing a pharmacoepidemiological study and writing a study protocol. Adherence to these principles will promote transparency regarding methodologies used in pharmacoepidemiological studies performed in the EU. It will also increase awareness of new developments in science and methodology in the field of pharmacoepidemiology.

## Notes

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1. The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP) is a project led by the European Medicines Agency intended to further strengthen the postauthorisation monitoring of medicinal products in Europe by facilitating the conduct of multi-centre, independent, post-authorisation studies focusing on risk and on benefit/risk. The network involves research and medical-care centres, healthcare databases, electronic registries and existing networks.
2. More information on the work of ENCePP including ENCePP Studies can be found at <http://www.encepp.eu>
3. The ENCePP Code of Conduct can be found at [http://www.encepp.eu/documents/encepp\\_studies/ENCEPP%20Code%20of%20Conduct\\_20100507.pdf](http://www.encepp.eu/documents/encepp_studies/ENCEPP%20Code%20of%20Conduct_20100507.pdf)
4. The Checklist of Methodological Standards for ENCePP Study Protocols can be found at : [http://www.encepp.eu/documents/encepp\\_studies/Checklist%20of%20methodological%20standards%20for%20ENCEPP%20Studies0.doc](http://www.encepp.eu/documents/encepp_studies/Checklist%20of%20methodological%20standards%20for%20ENCEPP%20Studies0.doc)
5. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: [www.ema.europa.eu](http://www.ema.europa.eu)

## Contact our press officers

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