



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press release

European Medicines Agency awards first 'ENCEPP study' seal for post-marketing study

New seal awarded to transparent, independent observational study in patients with chronic obstructive pulmonary disease.

The European Medicine Agency and the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP) have awarded the first 'ENCEPP study' seal to an observational study investigating the "long-term outcomes and adverse events of therapy with inhaled corticosteroids, long-acting beta-2-agonists and anticholinergic drugs in hospitalised patients with Chronic Obstructive Pulmonary Disease (COPD)".

The objective of this cohort study is to compare the long-term effectiveness and the side-effects of these inhaled medicines used in COPD patients. It will analyse data of some 40,000 subjects available in health information systems in three Italian regions. The study is coordinated by the Department of Epidemiology, Lazio Regional Health Service. The final study report is expected in June 2013.

The seal 'ENCEPP study' is a confirmation for patients, healthcare professionals and the public that the study was conducted in adherence to the ENCePP research and methodological principles. 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 results regardless of their positive or negative findings and making public relevant information on the study protocol before the study commences. ENCePP studies are entered in a publicly available electronic register before their start.

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP) is a project developed by the European Medicines Agency (EMA) with the pharmacoepidemiology research community to contribute to the protection of public health. It aims to strengthen the post-authorisation monitoring of medicines by facilitating the conduct of multi-centre, independent and scientifically robust studies focusing on safety and the balance of benefits and risks.

Notes

1. More information about ENCePP is available here: www.encepp.eu.



2. The study log can be found here: http://www.encepp.eu/encepp_studies/index.html
3. The register of ENCePP studies will be published on the ENCePP website before the end of the year.
4. 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

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