EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Declaration on compliance with the ENCePP Code of Conduct for ENCePP Studies[1]

The (primary) lead investigator and a person authorised to sign on behalf of the coordinating study entity hereby declare for the purpose of conducting the study Impact of risk minimisation in patients treated with rosiglitazone-containing products

- to follow the rules and principles for the independent and transparent conduct of pharmacoepidemiological and pharmacovigilance studies of the ENCePP Code of Conduct adopted on 12 / 9 / 2010;
- to inform the ENCePP Secretariat, without delay, of any change or decision to change that constitutes a deviation from the provisions of this Code.

It is of note that the (primary) lead investigator and the person authorised to sign on behalf of the coordinating study entity may be identical.

Name of (primary) lead investigator:
Professor Henrik Toft Sørensen, MD, PhD, MSc
Date: 14 / 1 / 2011 (xx/yy/zzzz)
Stamp (if applicable) and signature:

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Name of the coordinating study entity: Department of Clinical Epidemiology, Aarhus University Hospital
Address:
Olof Palmes Alle 43-45
DK-8200 Aarhus N Denmark
Name of person authorised to sign on behalf of the coordinating study entity [if different from (primary) lead investigator]:

Date: / / (xx/yy/zzzz)
Stamp (if applicable) and signature:

The (primary) lead investigator should also complete, sign and date the Checklist of the ENCePP Code of Conduct for ENCePP Studies.

The agency is unable to accept electronic signatures and will not accept photocopies of the completed declaration and checklist.

[1] Complete the declaration on screen, then print, stamp (if applicable) and sign.