EPID Research

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From	To
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Reference: "Pan European Multi-Database Bladder Cancer Risk Characterisation Study": the ENCePP Seal

To whom it may concern,

The Medicinal Products of Human Use (CHMP) of the European Medicines Agency (EMA) has requested Takeda Global Research & Development Centre Europe Ltd (Takeda) to conduct a post-authorisation safety study (PASS) on pioglitazone use and occurrence of bladder cancer.

The study protocol, includes a statement that the study will be submitted for ENCePP Seal of Approval. The ENCePP Seal requires making the study data from each dataset as well as the pooled dataset available to 3rd parties. The investigators (including research partners EPID Research, PHARMO, CPRD and Karolinska Institutet) of the study fully support the transparency principle of observational research, but are not able to commit to making the data available to 3rd parties at this time. Local governance of the use of the datasets for medical research purposes does not permit the investigators to provide the data to 3rd parties. As members of the ENCePP I myself and another study investigator (Helle Kieler) are bringing this issue back to ENCePP for further consideration and discussion on how investigators can meet the criteria of sharing data to 3rd parties.

For the reasons mentioned the investigators agreed not to apply for the ENCePP Seal but only to register the study in ENCePP E-Register of Studies.

For the Study group,

Pasi Korhonen (PhD, Adj. prof. biostatistics)
Principal investigator

Co-Investigators	
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