Reviewer's report

Title: Using clinical trial data and linked administrative health data to reduce adverse events associated with the uptake of newly released drugs by older Australians: a model process

Version: 3 Date: 25 February 2011

Reviewer: Ugo Moretti

Reviewer's report:

The comment I made to the last version of the paper is still valid. I don't see how the method presented by the Authors could be helpful in the identification of new adverse reactions.

It has been stated that clinical trial information and the linked morbidity and medication data have been copmapred to assess which patients are at risk of an adverse event. In relation to the example presented in the paper I don't understand what data presented by the Authors suggest the cardiovascular toxicity of rofecoxib. We only know that patients with cardiovascular diseases have not been included in premarketing RCT of rofecoxib even if patients with osteoarthrosis often have a cardiovascular problem. This consideration does not automatically lead to the conclusion that rofecoxib can give cardiovascular toxicity.

Caution in the use

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I have no competing interests