Reviewer's report

Title: Efficacy of omalizumab (Xolair) in patients with moderate to severe asthma in Taiwan: a retrospective, population-based database cohort study

Version: 2 Date: 30 August 2015

Reviewer: David Price

Reviewer's report:

I am delighted to see real-life national data from Taiwan being used to evaluate the true value of therapy in practice but I believe some re-analysis is required before this can be published.

Major compulsory decisions

1. There is a major bias introduced by selecting successful patients i.e. those who continued omalizumab for 4 months or more after initiation, especially when the drug could only be continued after 3 months in successful people. Therefore we are examining the effect of omalizumab in those in whom it was successful. Such circular arguments are to be avoided in research. Therefore we need to understand what happened to all patients initiated i.e. an ITT analysis. A re-analysis is required to include all patients initiated on omalizumab.

2. Ideally there would be a control group - i.e. a matched cohort not receiving omalizumab who are equally severe. The reasons for not doing this need complete explanation in methods and the impact needs discussion. With full explanation I believe this should be acceptable.

Level of interest: An article of importance in its field

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 spoken, undertaken research and been on advisory boards for Novartis who sell omalizumab in many parts of the world.