Reviewer’s report

Title: Evaluation of the safety and efficacy of pregabalin in older patients with neuropathic pain: results from a pooled analysis of 11 clinical studies

Version: 2 Date: 3 July 2010

Reviewer: Sebastian Straube

Reviewer’s report:

The study by Semel et al. is an important contribution: the paper is well written, methodologically sound, analyses a unique data set, and addresses an important clinical question.

Discretionary Revisions

I have some suggestions that in my opinion would make this strong paper even stronger. The suggestions are Discretionary Revisions because the paper is already data rich and the suggested analyses may or may not be possible with the data in the authors’ database.

1) In addition to presenting the mean changes in pain and sleep interference scores by age and treatment groups, would it be possible to include data corresponding to the benchmarks for interpreting changes in chronic pain clinical trial outcomes as they were recommended by the IMMPACT group (Dworkin et al., J Pain. 2008 Feb;9(2):105-21.)? The IMMPACT group defined 'moderately important' and 'substantial' changes as a >/= 30% decrease in pain scores and a >/= 50% decrease, respectively. These levels of improvement also correspond to Patient Global Impression of Change levels of 'much improved' and 'very much improved', respectively. Do the available data allow calculation of the number of patients achieving IMMPACT benchmarks in the various treatment and age groups?

2) In addition to presenting data for individual adverse events, would it be possible to present data for the categories ‘number of patients with any adverse event’ and ‘number of patients with any serious adverse event’? This would allow ready comparison between pregabalin doses and age groups with regard to overall adverse events.

3) In the Methods section please provide references after this sentence "Several of the studies excluded patients who had previously failed to respond to gabapentin at dosages #1200 mg/day for the treatment of DPN or PHN.“ It would be interesting to know how many of the studies used enriched enrolment.

Level of interest: An article of outstanding merit and interest 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 declare that I have no competing interests.