Author's response to reviews

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

Authors:

David Semel (david.semel@pfizer.com)
T. Kevin Murphy (t.kevin.murphy@pfizer.com)
Gergana Zlateva (gergana.zlateva@pfizer.com)
Raymond Cheung (raymond.y.cheung@pfizer.com)
Birol Emir (birol.emir@pfizer.com)

Version: 2 Date: 3 June 2010

Author's response to reviews: see over
Dear Editors,

On behalf of my coauthors, I am pleased to resubmit the manuscript entitled “Evaluation of the safety and efficacy of pregabalin in older patients with neuropathic pain: results from a pooled analysis of 11 clinical studies” for consideration for publication in *BMC Family Practice*. We have revised the manuscript to address your concerns. Responses to your concerns and a detailed list of revisions that were made to the manuscript are provided on the next page.

We hope you find the revisions we have made to address the editors’ concerns acceptable and that the revised manuscript is suitable for publication in *BMC Family Practice*.

Sincerely,

David Semel
Response to Editors’ Comments:

Could you please outline in your manuscript why you chose this approach rather than performing a systematic review and meta-analysis. Essentially, we would like you to state your response from your previous email in the manuscript. We feel that this is sufficient justification to proceed and we believe that stating this in your manuscript could prevent reviewers from questioning your approach.

Authors’ response: The rationale for our approach for this post hoc analysis has been added to the Methods section under a new subhead Clinical Study Selection (pages 5-6). Briefly, the goal of the current post hoc analysis was to break down efficacy and safety data using specific age cut-offs and these data would have been difficult, if not impossible, to obtain from summary statistics from published reports. Access to patient-level data from a rich database of Pfizer Inc., clinical studies of pregabalin in patients with DPN and/or PHN provided us with the flexibility to perform this analysis.

Additionally, we would like you to provide more methodological detail including where you selected these studies from, what criteria you used to select the 11 RCTs, whether any were excluded, and what exclusion criteria were applied. We also ask that you state that all of the studies were funded by Pfizer.

Authors’ response: A more detailed description of the criteria and selection process for the clinical studies included in the analysis has been added the Methods section under subhead Clinical Study Selection (pages 5-6). We have detailed which criteria led to the exclusion of some studies and the number of studies excluded. We have added statements indicating that all studies were sponsored/funded by Pfizer throughout the Methods Section under the subheads Clinical Study Selection (pages 5-6) and Post hoc Analysis (page 6). Furthermore, the Acknowledgements section contains the disclosure that this post hoc analysis and all clinical studies were funded by Pfizer Inc. This statement was in the Acknowledgements of the initial manuscript submission.

Finally, we ask that you clarify why the unreported studies were not reported and whether the data from the unreported studies are available to the public for our reviewers or any other researchers who may wish to repeat your study.

Authors’ response: Studies 1008-030 and 1008-040 were completed prior to the establishment of a corporate policy requiring publication of all clinical trials for marketed products and their publication was, therefore, dependent on the priorities of Pfizer colleagues involved at the time. Results of these 2 studies have been summarized in a review article (Dworkin RH, et al: *Prog Neurother Neuropsychopharmacol* 2008, 3:167-187) and in a European Public Assessment Report Scientific Discussion posted at the European Medicines Agency Web site.
Additionally, a synopsis of study 1008-040 has been posted at the PhRMA Clinical Study Results Web site (http://www.clinicalstudyresults.org/documents/company-study_1952_0.pdf). The review article and EMEA and PhRMA summaries have been added as citations for these 2 clinical studies in the Methods section under the subhead Post hoc Analysis (page 6).