Reviewer’s report

Title: Safety and tolerability of sitagliptin in clinical studies: A pooled analysis of data from 10,246 patients with type 2 diabetes

Version: 1 Date: 8 March 2010

Reviewer: Guillermo Di Girolamo

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Minor Essential Revisions:

1. The question posed by the authors is well defined and methods are appropriate and well described. The information in clearly relevant. Nevertheless, regarding methods, we would need to know more on the characteristics of the included studies: are they all “international multicentric studies”? Are the authors also collecting information from local studies? Are these results collected from all the controlled trials the sponsor carried out during the stated period? (if not, state in a deeper manner the inclusion criteria for the 19 studies entered into analysis). Some of them are published, other presented just as abstract to congresses. Is that correct?

2. Hypoglycemia is an adverse event of main interest. But hypoglycemia definition may vary among different studies. What was the definition of hypoglycemia for the 19 selected studies? (please include in methods). Was this definition homogeneous among studies?

3. Were the adverse events frequencies (at least for those of main interest) homogeneous among studies? (even when it is a pool analysis, among studies heterogeneity could be of interest, at least for most important events).

4. Pancreatitis is another event of importance. Even when authors state: “the analysis of reports of pancreatitis, an additional gastrointestinal event of recent interest, is presented elsewhere”, some data could be of importance. Had the authors access to amylase and / or lipase values to detect their modification?. If not, please state this as a limitation.

5. Also studies duration is a limitation for some of the events considered into this analysis: e.g. some neoplasias. As far as we understand, the longer trial lasted for two years. Please state this into “study limitations”.

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 declare that I have no competing interests' below.