Reviewer’s report

Title: Cost-effectiveness of insulin degludec versus insulin glargine U100 in adults with type 1 and type 2 diabetes mellitus in Bulgaria

Version: 0 Date: 01 Oct 2019

Reviewer: Yukihiro Fujita

Reviewer's report:

Please include all comments for the authors in this box rather than uploading your report as an attachment. Please only upload as attachments annotated versions of manuscripts, graphs, supporting materials or other aspects of your report which cannot be included in a text format.

Please overwrite this text when adding your comments to the authors.

The reviewer thanks for this opportunity to review the article 'Cost-effectiveness of insulin degludec versus insulin glargine U100 in adults with type 1 and type 2 diabetes mellitus in Bulgaria' submitted to BMC Endocrine Disorders.

The topic is important and practical in real world health care for insulin therapy. However the reviewer has some concerns in the current article for publication.

1) This study is the comparison of costs and effectiveness between two insulin analogues. If these comparisons are performed by 'employees of one company', the study should be carefully conducted in randomized head to head, double-blind trial, especially when hypoglycaemic events are determined. Otherwise bias can not be eliminated.

2) The authors described there are more hypoglycaemic events in Bulgaria in discussion, but they used data of hypoglycaemia from multinational Phase3b trials. In contrast, Insulin doses were taken from daily insulin doses used in clinical practice in Bulgaria. The reviewer believes that the authors should use data of hypoglycaemia collected in Bulgaria. If not, the reviewer feels no consistency in the results.

3) Degludec is allowed, but the biosimilar is not allowed to inject anytime in a day. In HRQoL, the authors gave 'Flexibility Utility gain' as 0.006 to Degludec. The authors gave advantage to Degludec based on only one study performed elsewhere. (Boye et al. [40]). If the authors intended to give the gain, they must cite multiple studies to justify the value of the gain.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes
**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Yes

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable

**Declaration of competing interests**
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.
I declare that I have no competing interests.

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal