Author’s response to reviews

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

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Author’s response to reviews:

Dear Editor in Chief,

On behalf of my co-authors, please find below the point-by-point response to the editorial comments.

Editor Comments:
The authors have addressed all the concerns of the reviewer.

Editorial Comments:
1 - Any manuscript submitted to a BioMed Central journal must be original and the manuscript, or substantial parts of it, must not be under consideration by any other journal. We note that the current submission contains textual overlap with other previously published works. Please re-write these sentences and phrases in your own words to ensure no overlap. If there is overlap in the Methods section, please ensure that you summarize the methods and cite the source.
We recommend the authors use an anti-plagiarism software, such as turnitin or other freely available ones, to assess the overlap and aim to reduce it.

There is considerable overlap with:
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Response

In line with your request, we have shortened the methods section considerably, and referred back to earlier publications around this model, i.e. the above-mentioned Lallic et al, 2018,1 which were already quoted in the manuscript. These changes concern line 118 and the subsections “Cost of Hypoglycaemia” (lines 163ff) and “Utility Data” (lines 168f).

We have also modified a sentence that appeared to be identical (around indirect costs, in the introduction, line 53), but have not implemented any other changes to the text. Any remaining similarities in wording with Lallic et al appeared very limited. Furthermore, as outlined in our cover letter, the submitted work is based on an existing model, which has been published previously.1-4 We feel that country-specific data for Bulgaria are a valuable addition to the body of evidence, offering specific local information to Bulgarian decision-makers, as well as demonstrating the wider applicability and validity of the previously published model results.1-4 In view of the fact that the analysis is based on an economic model, which has been used to estimate the cost-effectiveness of insulin degludec in other countries (analyses which have also been published), it is challenging to use entirely different wording. The terminology and phrasing available to describe economic models is limited, if the meaning, which has to be precise, is to be maintained.

2 - Research involving human subjects (including human material or human data) that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (https://nam01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.wma.net%2Fen %2F30publications%2F10policies%2F10policies%2Findex.html&data=02%7C01%7Cbmoore %40teamdrg.com %7Cadd6dc73d564b99219708d768f17484%7C5d6495b15cd44a4fa6ddf1f5f3bf58831%7C0%7C0%7 C637093258578511422%26amp;data=1%2B0jRztEyCdcOlfENGHO46JO5h74OKyUZ2VeB4lpXSc %3D%26amp;reserved=0). A statement to this effect must appear in the ‘Ethics approval and consent to participate’ section of the Declarations of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.

If the need for ethics approval were waived, then please clearly state this, including the name of the ethics committee that provided the exemption, together with the reasons for the waiver, or a reference to the relevant legislation.

Response

As stated in the manuscript, this article does not contain any studies with human participants or animals performed by any of the authors, and ethics approval is not applicable.

3 - For all research involving human subjects, informed consent to participate in the study should be obtained from participants (or their parent or guardian in the case of children under 16) and a statement to this effect should appear in the ‘Ethics approval and consent to participate’ section of the Declarations including whether the consent was written. When reporting on such studies, individual patient data should not be made available unless consent for publication has also been obtained.

If the need for informed consent has been waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this with details, including the name of the Board or a reference to the relevant legislation in the ‘Ethics approval and consent to participate’ section of the Declarations.

Response

As stated in the manuscript, this article does not contain any studies with human participants or animals performed by any of the authors, and informed consent is not applicable.
4 - If you wish to acknowledge someone by their name in the Acknowledgements, please ensure you have obtained permission from them to do so.
Response
We can confirm that permission has been obtained.

5 - At this stage, please upload your proofread manuscript as a single, final, clean version that does not contain any tracked changes, comments, highlights, strikethrough or text in different colours. All relevant tables and figures should also be clean versions. Figures (and additional files) should remain uploaded as separate files. Should you wish to respond to these revision requests, please include the information in the designated input box only.
Response
A clean version of the document has been uploaded and the responses to the revision requests have been included in the designated input box.

Yours faithfully,

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References