

Format for ANSWERING REVIEWERS



January 24, 2014

Dear Editor,

Please find enclosed the edited manuscript in Word format (file name: 7974-review.doc).

Title: New and Emerging Diabetes Mellitus Drug Therapies

Author: Charmaine Rochester, Oluwaranti Akiyode

Name of Journal: *World Journal of Diabetes*

ESPS Manuscript NO: 7974

The manuscript has been improved according to the suggestions of reviewers:

1 Format has been updated

2 Revision has been made according to the suggestions of the reviewer

(1) A short running title of less than 6 words should be provided.

Response: The running title has been added with 5 words (Emerging Diabetes Mellitus Drug Therapies)

(2) The format of this section should be like this: **Author contributions:** Wang CL and Liang L contributed equally to this work; Wang CL, Liang L, Fu JF, Zou CC, Hong F and Wu XM designed research; Wang CL, Zou CC, Hong F and Wu XM performed research; Xue Jz and Lu JR contributed new reagents/analytic tools; Wang CL, Liang L and Fu JF analyzed data; and Wang CL, Liang L and Fu JF wrote the paper.

Response: This was changed in the Author contribution section to: Rochester CD and Akiyode O both contributed to the conception of the document, drafting the outline, reviewing research articles and the writing of the paper. The drug classes were divided between the two authors Both Akiyode O and Rochester CD reviewed the final paper for grammar, clarity, consistency and accuracy. They both revised the document critically to ensure important intellectual content. Both authors would give final approval of the version to be published.

(3) Only one corresponding address should be provided. Author names should be given first, then author title, affiliation, the complete name of institution, city, postcode, province, country, and email. Thank you!

Response: This was added in the correspondence address section. Charmaine D. Rochester, PharmD, CDE, BCPS, BCACP, University of Maryland School of Pharmacy, Department of Pharmacy Practice and Science, 20 North Pine Street, Baltimore, MD 21201. United States. crochest@rx.umaryland.edu.

(4) Telephone and fax should consist of +, country number, district number and telephone or fax

number, e.g. Telephone: +86-10-59080039, Fax: +86-10-59080039.

Response: This has been corrected. **TEL:** +1-410-706-4336 **FAX:** +1-410-706-5906

(5). Core Tip: Please write a summary of less than 100 words to outline the most innovative and important arguments and core contents in your paper to attract readers.

Response: This is included in the document (99 words): Type 2 diabetes mellitus is a metabolic disorder of deranged fat, protein and carbohydrate metabolism resulting in hyperglycemia. Limited efficacy, adverse effects, cost, contraindications, renal dosage adjustments, inflexible dosing schedules and weight gain significantly limit the use of currently available anti-hyperglycemic agents. In the past, drug researchers targeted defects of pancreatic β -cell failure and insulin resistance, but more recent attention has shifted to other contributing factors. This article reviews new and emerging diabetes classes, including the sodium-glucose cotransporter-2 inhibitors, 11β -hydroxysteroid dehydrogenase type 1 inhibitors, glycogen phosphorylase inhibitors, protein tyrosine phosphatase 1B inhibitors, G protein-coupled receptor agonists, and glucokinase activators.

(6) All the references should appear in proper order, e.g., 1.2.3... Please revise

Response: This has been corrected throughout the document

(7) Please put the reference numbers in square brackets in superscript at the end of citation content or after the cited author's name. Please check across the text.

Response: This was completed throughout the document

(8) Please define it when the abbreviation is first appear, Please check across the text.

Response: CDC was defined as Centers for Disease Control and Prevention in text

(9) [My comment: updated the current FDA information – change this sentence] Dapagliflozin was approved in Europe, Australia, Brazil, Mexico and New Zealand as Forxiga®, but the FDA initially delayed its approval as there were concerns of increased breast and bladder cancer in patients taking the drug compared to placebo.^[19] The FDA has since accepted a New Drug Application for dapagliflozin with additional clinical trials data, and they have issued a new Prescription Drug User Fee Act goal date of January 11, 2014 to make a decision regarding approval.^[20]

Response: This has been changed to the following since new information has since been released. Dapagliflozin was approved in Europe, Australia, Brazil, Mexico and New Zealand as Forxiga®, but the FDA initially delayed its approval as there were concerns of increased breast and bladder cancer in patients taking the drug compared to placebo.^[19] In January 2014, the FDA approved dapagliflozin as Farxiga® with six postmarketing studies including a cardiovascular outcomes trial (CVOT) to evaluate the cardiovascular risk in patients with high cardiovascular disease risk and the evaluation of bladder cancer risk in patients enrolled in the CVOT.^[20]

(10) [My comment] Change the reference 20 to the new information

Response: The reference (20) has also been replaced from **Nainggolan L.** FDA accepts NDA resubmission of diabetes drug dapagliflozin. Available at:

<http://www.medscape.com/viewarticle/808480>. Accessed December 4, 2013.

Changed to: (20). **Food and Drug Administration:** FDA News Release. FDA approves Farxiga to treat type 2 diabetes Available at:

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm380829.htm> Accessed

January 24, 2014.

3 References and typesetting were corrected

Thank you again for publishing our manuscript in the *World Journal of Diabetes*.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Charmaine Rochester".

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