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OPEN PEER REVIEW

Cost-Utility Analysis of Mirabegron Compared to Solifenacin in the Treatment of Overactive Bladder (OAB) in Iran

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About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

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1 Original submission

1 comment · 7 Jul 2023

Associate Editor

MINOR REVISION 7 Jul 2023

- In line 37 (in the Background section), what's the meaning of OB? Is it OAB? If not, please use the whole word before using its abbreviation.
- In line 49 (in the Background section), IDL means "Iran Drug List," not "Iranian Drug List."
- Considering the explanation of 5 disease states in the manuscript, there is no need to have these and other explanations below Figure 1.
- Why do you use Tolterodine data when your research is about Mirabegron and Solifenacin?
- Please provide the reference for the willingness-to-pay (WTP) threshold in Iran.
- It's better to have references below the tables and figures.
- Please show the complete calculation of the 5-year cost per subject for both Solifenacin and Mirabegron. Considering the data in Table 5, it seems that there is a mistake in the cost calculation.
- There is no need to have such an explanation below Figures 2, 3 and 4.
- In lines 240-241, what's the reference for this claim: "The FDO found the economic analysis to be well constructed, transparent, and accurate and that the primary base case was robust to parameter uncertainty."?
- In the Abstract, you claim the following: "Transition probabilities were based on published trials, clinical judgments, and expert opinion." Please provide evidence for these claims in your manuscript.
- Are clinical practices for managing OAB in Iran the same as those in other parts of the world? What's the physician's attitude in this regard?
- Please explain the source of the price of Mirabegron in Iran in 2018-2019. Considering that there was no local manufacturer for this product and it could be supplied only with per-prescription importation permission issued by IFDA, and that it's not allowed to use subsidized currency for this type of importation (per prescription), why do you use a conversion rate of 42000 IRR in this manner? This problem also exists when converting the price of locally manufactured Solifenacin into USD because the total price of this product is not affected by USD. Only the imported API portion is affected by USD.

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Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear Editor,

Many thanks for your letter and the opportunity to revise the manuscript entitled “Cost-utility Analysis of Mirabegron Compared with Solifenacin in the Treatment of Overactive Bladder (OAB) in Iran.” in the Iranian Journal of Pharmaceutical Research. We read all the comments and applied them point by point, as follows:

Row	Original comments of the reviewer	Reply by the author(s)	Changes are done on the section, or line
1	In line 37 (in Background section), what's the meaning of OB? Is it OAB? If not, please use the whole word before using its abbreviation.	Thank you for your comment, we meant OAB & it has been corrected.	Line 37
2	In line 49 (in Background section), IDL means "Iran Drug List" not "Iranian Drug List"	Thanks, it has been corrected.	Line 49
3	Considering the explanation of 5 disease states in the manuscript, there is no need to have these and other explanation below the Figure 1.	Thank you for this comment; the explanations in Figure 1 have been deleted.	Figure 1
4	Why do you use Tolterodine data when your research is about Mirabegron and Solifenacin?	In our model, Tolterodine was the second-line medication for the patients not responding to the first-line medication (Mirabegron or Solifenacin) for any reason.	General
5	Please use the reference for the willingness-to-pay (WTP) threshold in Iran.	Thanks for your valuable comment. The reference of the WTP threshold was added in the Materials and Methods model output section.	Line 144
6	Please show the complete calculation of 5-year cost per subject for both Solifenacin and Mirabegron. Considering the data in Table 5, it seems that there is a mistake in cost calculation.	Thanks for your comment. The calculation was done using our model in TreeAge Pro 2020 software, the unit price of drugs and services used in the model is depicted in table 5, costs of items like Botulinum Toxin A injection, Sacral Neuromodulation, and Bladder augmentation surgery were calculated based on the probabilities (Table 1); finally, the cost per cycle (1 month) for each item was calculated and summed up according to the 5-year time horizon of the model.	General
7	There is no need to have such explanation below Figures 2, 3 and 4.	Thanks for your comment; it was corrected accordingly.	Figure 3 and 4
8	In line 240-241, what's the reference of such claim (The FDO found the economic analysis to be well constructed, transparent, and accurate and that the primary base case was robust to parameter uncertainty.)?	Thank you for your valuable comment. The report was presented to the pharmacoeconomics committee of the FDO by the authors of this article, accordingly, Mirabegron molecule entered the Iran's Drug	Line 238-241 has been deleted

		List. However, since we do not have any certificates as reference, this sentence was eliminated from the article script.	
9	In Abstract you claim that (Transition probabilities were based on published trials, clinical judgments, and expert opinion.). Please have the evidences for these claims in your manuscript.	Thanks for your professional comment. We have referenced the mentioned clinical trials in the method section.	References number 25-29
10	Are clinical practices in managing OAB in Iran as same as other part of the worlds? What's the physician's attitude in this regard?	Thank you for your comment. In Iran, the adopted guideline for treating OAB is from American Urological Association (AUA/SUFU guidelines). Clinical practices for managing OAB can differ between Iran and other parts of the world. This can be influenced by factors like the structure of Iran's healthcare system, research and guidelines used to treat OAB, available medical resources, healthcare policies, and cultural preferences. Various factors, including medical training, access to current research and guidelines, patient preferences, and the local healthcare context, can influence physicians' attitudes toward managing OAB. It would be valuable to investigate the specific attitudes of Iranian physicians toward OAB management through surveys or interviews.	General
11	Please explain the source of price of Mirabegron in Iran in 2018-2019. Considering that there was no local manufacturer for this product and it could supply just based on per prescription importation permission issued by IFDA, and it's not allowed to use subsidized currency for such importation type (per prescription), why do you use 42000 IRR conversion rate in this manner? This problem exist for conversion the Solifenacin local manufactured price into USD. Because total price of this product is not affected by	Thank you for your comment. All the calculations in this article were initially done in Rials; then, the prices were exchanged to USD (divided by 42000) to be understandable internationally. The unit prices of all the medical resources used in this article were extracted from the price list published and available online by the FDO.	General

USD. Just imported API part is affected by USD.		

2 Revision 1

0 comments

No public comments in this round.