Author's response to reviews

Title: New Highly Active Antiretroviral drugs and generic drugs for the treatment of HIV infection: a budget impact analysis on the Italian National Health Service

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Author's response to reviews: see over
Dear editor,

Me and my co-authors would like to thank you for the opportunity to answer to the points raised by the reviewers. We hope we have been able to provide you with satisfactory responses.

Yours sincerely,

Umberto Restelli

Reviewer’s report:

I think the methodology of this paper is greatly improved and the model structure is fine. Also, there is now a reference for the expected price reduction due to generic entry, which was another important point I raised. However, there are a few other points I would still question.

Major Revision:

1. Market share data are not transparent. If I understood correctly, the current market shares of drugs were estimated based on “expert opinion”. That is not robust enough to warrant publication in a peer reviewed journal. I want to differentiate between two sources of market share data, there is the current share and there is the future trend. I appreciate the difficulty of estimating future trends in market shares and I think it would be okay to use expert opinion to inform future trends. But current shares should be based on currently available information, not opinion. I would suggest three alternative methods to inform current shares, a) use market share information from recognized vendors that collect such data such as IMS Health, b) review the literature to see if this data is published for Italy in another publication, c) conduct a chart or electronic medical records review of a cohort of HIV-infected patients in a local setting and then generalize these local findings to the national setting. Option a) would be my preference, but I am not sure if that is a feasible option for the authors. Options b) and c) do have some limitations, but they are far better than just using expert opinion.

Current market shares are based on data provided by Lombardy Region, as reprocessed by the HIV/AIDS group of technical experts from the regional database.

The data concerning annual market share of each therapy are calculated starting from published data from Lombardy Region. The use of these data at a national level, as reported in the conclusions, is a conservative approach, since Lombardy Region has been able to control the per capita costs of HIV positive patients through the implementation of a clinical pathways, and therefore the savings due to the use of generic drugs could be higher, considering less virtuous regions.

Minor Revisions:
1. Cost inputs are not transparent. I raised this in the first review, it was not addressed. For each drug included in Table 1, the branded price and the assumed generic price should be listed in Euros. This should be an easy fix.

We added a table (Table 2) as suggested by the reviewer.

2. I suggested to include language on the bioavailability of branded versus generic HIV drugs as there is some literature to suggest pharmacokinetic differences. This point was not addressed. These differences may not be clinically meaningful, but it should be listed as a limitation of the analysis that the authors assume that the generic versions are lower priced perfect substitutes for the brand, although it is theoretically possible that they may not be perfect clinical substitutes.

However the topic raised by the reviewer is of interest, considering the objective of the article we don’t think it would be appropriate to stress this topic within the article.