Reviewer's report

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

Version: 3
Date: 5 June 2015

Reviewer: Andreas Kuznik

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.

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.

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.
**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests