Reviewer's report

Title: The global pediatric antiretroviral market: analyses of product availability and utilization reveal challenges for development of pediatric formulations and HIV/AIDS treatment in children

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Reviewer: Ashwin Vasan

Reviewer's report:

This is a very solid article that highlights some of the key inconsistencies in the development of pediatric FDC antiretrovirals and their subsequent uptake. The data demonstrates that although much advocacy has occurred around incentivizing manufacturers to invest more capital into the R&D of pediatric ARVs in suitable formulations - resulting in the formation of a pull mechanism like UNITAID, for example - uptake of improved formulation pediatric ARVs is still relatively low and procurement agents and funders alike (outside of UNITAID) continue to rely on outdated older formulations. This is a concerning phenomenon, and one that is of importance, as those of us in the field who work on procurement and pricing of ARVs often assume that the mere availability of appropriate (in price and formulation) ARVs should be sufficient to change procurement patterns, which is not reflected in this data. Instead, the authors highlight an important information gap which results in continued irrationality of the downstream pediatric ARV market, despite shifts in the market incentive structures for companies to tailor development of peds ARVs more suitable for developing country markets. It is clear - and a problem that the authors rightly forewarn the reader of - that continued irrational procurement practices for peds ARVs, thereby deflating an otherwise effective market, could potentially un-do the hard work that resulted in increased investment into formulations previously believed to be economically unsuitable for mass production. It is also true that this continued contraction pressure on the market for new peds ARV formulations, due to continued reliance on older drugs, will disincentivize other producers from entering this field, and is suggested in this data by paucity of producers that have actually entered into the production of peds FDCs and other appropriate peds formulations. My only critique is that I believe the authors should make this point - that we threaten the enterprise of innovation around peds ARVs by continued outdated procurement practices - much more clearly and up front in the paper (conclusions, etc).

- Major Compulsory Revisions
  None

- Minor Essential Revisions
  None
- Discretionary Revisions

See above comments.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**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'