Reviewer's report

Title: Adoption of New Health Products in Low and Middle Income Settings: How Product Development Partnerships Can Support Country Decision Making

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Reviewer: Michael R Reich

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The authors have responded to my earlier comments on the original manuscript, and the revisions are generally acceptable. The comments below are only for their review and consideration, as discretionary comments.

I still think that the presentation of the “process category” of how decisions are made in countries (page 3) is not sufficiently well developed. The idea is that someone (not specified) identifies and convenes a group of stakeholders “who have the mandate and resources to identify and review evidence.” Which institutions are responsible for making these decisions? Is this model of the process based on a review of what happens in countries? Is this the general way that technology introduction decisions are made? Or is this what the authors think should be done? Is this located in the Ministry of Health? Ministry of Commerce? Agency on Technology Assessment? The specific disease control program? The discussion in the next paragraph (pages 3-4) provides some examples where there were “unclear or non-existent procedures or bodies to consider regimen change [for TB].” I still think it is not clear what a PDP can do (or should do) when the institutions or procedures for making decisions are not well developed. How does a PDP “support country decision making” when there is not a clear locus for making decisions, when there are conflicting interests, no clear institutional mandate or criteria? What does it mean to “catalyze the establishment of decision-making structures or processes” (page 6)? The revision describes “generating data and bringing the data to the attention of country stakeholders” as part of this “catalyzing” effort (page 6); does this work? If so, under which conditions?

Just a note: PDPs may not have “direct profit motives” (page 6) but they do have strong organizational interests that they want to protect and advance (including the goal of promoting the usage of their technology). These interests should and do influence what PDPs decide to do both in product development and product introduction in countries. It might be helpful to have some discussion of the motivation for PDPs to get involved in support of country decision making.

The authors changed the description of what PDPs have done to support country decision making to use the word “examples” (page 13). But the title for the section still calls them “models”, which has some normative implications. Do they still view the different categories as models?
The activities conducted by the Global Alliance for TB Drug Development (page 14) sound like the kinds of market analysis that a private company would do before entering a new market. It is not entirely clear how these activities “support country decision making.” I do see how they would support PDP decision making (which markets, which products, which stakeholders to interact with). Do the authors see the activities of PDPs as fundamentally different from what a private company would do? Or do they see a difference only in primary motivation?

The evaluation of “support” for country decision making is more complex than presented by the authors (page 17), although they do admit “significant challenges.” The kind of evaluation should differ for the kind of support activity (background information, process and people, evidence base). The authors state, “Usage outcomes noted in this paper can reasonably be assumed to correlate positively with impact and provide indirect evidence of the work from PDPs.” This contradicts what the authors say in the previous paragraph, and indicates that the authors believe that the main purpose of “support” is to promote “usage” (or uptake). In this view, “support” is an instrument to achieve an end, “usage”. But what if “support” results in a country decision not to adopt the technology? Is that success for the country and failure for the PDP? Can support still be effective if a country decides not to adopt the technology?

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.