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

Reviewer's report:

This paper has the title of “Adoption of New Health Products in Low and Middle Income Settings: How Product Development Partnerships Can Support Country Decision Making”. The paper is mostly written from the perspective of the PDPs, however, and not from the perspective of the countries. In other words, the paper seems to be mostly about what Product Development Partnerships (PDPs) can do to encourage countries to adopt the new health products that are being developed by the PDPs, and not so much about what PDPs can do to develop the capacity of countries to make independent decisions about health products more generally. Here are my suggestions about revisions:

1) The paper provides what it calls a “simplified framework” to describe country decision making (in the section on “How PDPs fit into country decision making”). The description should provide references to the academic literature on country decisions about technology adoption. In my view, the framework is too simplified and needs some expansion and analysis, supported by references from the literature. What kinds of decisions need to be taken by countries (safety, efficacy, tariffs, financing, registration, licensing, procurement, distribution, etc)? Where are those decisions located within a country? Within which government agencies? The paper needs a better description of the problems confronted by low and middle income countries regarding the flow of new health products. This would be similar to a problem statement. Do countries have problems making these decisions, and if so, what kinds of problems, and why?

2) The paper identifies ways that PDPs can “support” countries in making decisions about new health products (see table on “Country decision making activities”). What does “support” really mean? What kinds of “support” can PDPs provide to help countries address the problems in decision making (presented in point #1 above). This is related to the broader issue of building the capacity of countries to make their own decisions. It is not clear whether the paper seeks to analyze how countries can build up the capacity of their own institutions to make decisions. It would be helpful if the authors could clarify this point and then identify how PDPs can assist in capacity building for the assessment of new health products. The literature on capacity-building for health institutions and decision making in developing countries could be discussed and cited. More specifically, in Table 1, how were the “country activities” selected?

3) Some of the “support” activities (presented in Table 2, for example) seem to
be advocacy efforts on the part of the PDP to persuade decision makers to adopt the health product developed by the PDP. In other words, the PDP is an interested party in the decisions under consideration in this paper. But those interests of the PDP are not discussed directly in the paper. Advocacy for the adoption of a particular product is not the same as assistance to develop a country’s capacity to make its own independent decisions about health technologies. This point needs to be directly addressed and discussed. The paper needs to clarify whether it is promoting “capacity building for countries” or “product advocacy of PDP technologies.” If the authors believe that these two points are the same, then that point should be presented and supported. To some degree, the authors recognize the limitation of PDPs in “country-level implementation,” as discussed in the last paragraph of the conclusion. This paragraph, and its implications, could be expanded.

4) The section of the paper on “Specific PDP models for supporting country decision making activities” provides five different “approaches to facilitating country decision making.” It is not clear how the case studies presented here were selected; the authors should explain how they were selected and whether they can be generalized. In addition, it is not clear how the five approaches here relate to the activities presented in Tables 1 and 2. Do these approaches build country capacity to make decisions? If so, in what ways?

**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.