Reviewer's report

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

Version: 1 Date: 12 February 2011

Reviewer: Julie Milstien

Reviewer's report:

Discretionary Revisions
1. Introduction, para 2, suggest to add a sentence on NITAGS
2. Introduction, para 3, PDPs have NOT products health products but have catalyzed their development
3. Section How PDPs fit, para 1, Might be useful to reference WHO-Gates LMIC study on this. See R4D report to SAGE Nov 2010 on WHO SAGE website
4. Section How PDPs fit, Basis in research, add CT approval; ethics committees, NRAs, SAEs.
5. Table 1. Add risk benefit analysis or CE studies; add role for PDP capacity building; add regulatory status of countries as it is not clear that countries will be equipped to make regulatory decisions: includes in-country marketing authorization, PMS activities, CT oversight, capacity building at all levels. SO FAR MOST PDPS HAVE NOT DONE A VERY GOOD JOB OF CAPACITY BUILDING AND THAT IS A SCANDAL!
6. I am not clear on difference between tables 1 and 2 and suggest to consolidate.
7. Section Geographic, Prioritizing countries: Add importance of country activities on overall regulatory strategy
8. Somewhere there is a need to mention the essential role for PDPs to market products even if there is a commercial partner
9. Table 4, Add regulatory support (NRAs). What about GAVI for vaccines for poorer countries?

Minor revisions
1. Inconsistent terminology: for example in abstract you have said Phase 4, and in Table Phase IV
2. Under Geography, Role, para 2, AMC is Advance Market Commitment, not advanced
3. Under Geography, Role, para 3, Haemophilis influenzae, not influenza
4. Table 4, disadvantages for WHO, substitute "not enough staff and restricted funding"
5. Under Specific PDP models, Countries para 2, last sentence, As of Sept 2010
- relevance? Clarify or suggest to delete
6. Under Engagement, para 1, suggest to start sentence with "We describe 3 PDPs..."
7. Reference 35, suggest to find complete reference on GAVI website and add it.

**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