

# **PDPs ROLE IN COUNTRY DECISION MAKING INTERVIEW GUIDE**

## Introduction

Product Development Partnerships (PDPs) are focused on developing health products suitable for use in low income settings. Ensuring access – that these products reach those who need them most – will not be easy. To support this effort, a PDP Access Steering Committee (including representatives from Aeras, Concept, DNDi, FIND, iOWH, IPM, IVCC, MMV, MVI, PDVI, and TB Alliance) has commissioned a series of discussion papers on discrete topics relevant to new product access. Preliminary findings from these draft discussion papers will be presented in a meeting in July.

The questions listed below are to support the discussion paper on Country Decision Making. During the interviews it will be important to capture what PDPs are doing, why they are taking that approach, what lessons can be learned, and what improvements might be made. For country and donor stakeholders, it will be most important to understand what approaches by PDPs would best synergize with country and donor efforts. There will be differences in strategy between modalities (vaccines, drugs, diagnostics, and insecticides) and diseases; they should be noted. Based on these differences, the aim of the papers is not to be prescriptive but to set out the range of possibilities.

## QUESTIONS TO PDPs AND DONORS

- 1) Preliminary question: What does your PDP / organization feel it means for a country to “prepare” for adoption of a new product?
- 2) Building country-based consensus around the public sector decision on adoption of a new technology: basic models and strategies
  - a) What approach has your PDP / organization taken to support country decision making?
  - b) What country-based activities by a PDP are required, what are their benefits, and at what time should they be conducted relative to the year of regulatory approval?
  - c) What adoption-related activities can a PDP realistically expect a country to participate in prior to Phase III results?
  - d) How has your PDP validated its processes (or how should PDPs validate their processes) from a country perspective?
- 3) Prioritizing countries and strategies for establishing a local presence
  - a) How many countries should/can a PDP engage directly in decision-making dialogue, e.g., via in-person representation and engagement?
  - b) On what basis should these countries be chosen?
  - c) What are the costs and benefits of a PDP country office?
  - d) What new activities does it allow, and what is the added value of these activities?

- 4) Generating data to inform decision-making
  - a) What is the PDP role in activities to directly obtain information supporting decision-making, such as burden of disease or knowledge attitude practice studies, and/or effectiveness, pilot or demonstration studies? [probe if necessary: Does it fund (or co-fund), provide research staff/expertise, or just bring together others?]
  - b) For a PDP launching a single product, how many countries should they (or can they realistically) engage directly in conducting studies as identified above?
  - c) What are best practices for conducting studies to inform decision-making for new products in low income settings? Are there projects or documents that reflect these best practices?
  
- 5) The role of PDPs relative to other actors
  - a) How should PDPs fit in with contributions from country programs, multilaterals (e.g., WHO), local researchers, NGOs and Pharma companies?
  - b) Who are the appropriate partners for a PDP in country to support the data generation or decision-making process?
  - c) What is the best way to identify them and develop partnerships/collaborations with them?
  - d) What role does the PDP play relative to WHO's normative role?
  - e) What is the ideal balance of PDP effort between engagement of country-based decision makers (who then devise country-led funding solutions; e.g., national budget or GFATM applications) and global decision makers (who may earmark particular funds for roll-out, e.g., UNITAID or GAVI, and thus drive local decisions)?
  - f) Will the number of products being developed by PDPs in the near future overwhelm the capacity for countries to make informed decisions? What can PDPs, countries multilaterals and other actors do to address this potential problem?
  
- 6) Wrap-up
  - a) What individuals outside of PDPs could offer the best insight into these questions? [probe: from endemic countries, pharma, multilaterals, and bilaterals]
  - b) Is there anything else that you think we should consider in formulating PDP strategy to support country decision making?

## QUESTIONS TO COUNTRY STAKEHOLDERS

- 1) Context and definitions
  - a) What has been your experience with country decision making, specifically around the introduction of new health products?
  - b) What, if any, interaction have you had with PDPs?
  - c) In your opinion, what does it mean for a country to “prepare” for adoption of a new product? What country-based activities are required, what are their benefits, and at what time should they be conducted relative to the year of regulatory approval?
  - d) Are there any adoption-related activities that countries can pursue prior to Phase III results?
  
- 2) The role of PDPs relative to other actors

- a) What can PDPs do to facilitate country-led decision making? What are the benefits of these PDP activities, and at what time should they be conducted relative to the year of regulatory approval?
  - b) How should PDPs fit in with contributions from country programs, multilaterals (e.g., WHO), local researchers, NGOs and Pharma companies?
  - c) Do PDPs have a role in activities to directly obtain information supporting decision-making, such as burden of disease or knowledge attitude practice (KAP) studies, and/or effectiveness, pilot or demonstration studies? [probe if necessary: Does it fund (or co-fund), provide research staff/expertise, or just bring together others?]
  - d) Who are the appropriate partners for a PDP in country to support the data generation or decision-making process?
  - e) What role does the PDP play relative to WHO's normative role?
  - f) Will the number of products being developed by PDPs in the near future overwhelm the capacity for countries to make informed decisions? What can PDPs, countries multilaterals and other actors do to address this potential problem?
- 3) Wrap-up
- a) Is there anything else that you think we should consider in formulating PDP strategy to support country decision making?