

The PDP Reach: How Far Should PDPs Extend?

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Current Role of Access within PDPs

- **Access imbedded in work of organization**
 - R&D, BD, Executive follow access principles
 - Focus of the Access Teams
- **Access informs product development**
 - How access considerations are incorporated into development of new product
 - How access informs target product profiles (TPP)
 - Consider: Mechanisms for mapping user requirements & Timing – before Phase 3, know the market
- **Access facilitates timely uptake**
 - Think through all the needs and facilitate potential roadblocks: fewer surprises
 - Catalyze/Leverage other partners
 - Fill gaps



PDP Role in Post-Licensure

- **Prioritize activities at country level**
 - Financing - the biggest hurdle?
 - Regulatory
 - Policy change
 - Pricing
 - Distribution/sales
 - Patient/provider education
- **Define Objectives: How far should we go?**

SRA
regulatory
approval

WHOPQ

WHO
“endorsement”
of the product

Regulatory or
policy approval
at country level

Product
purchase

The last mile



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Partners

- **Are the partners in place to take the rest on?**
 - Partners with offices: e.g. MVI has PATH, others have...?
 - Manufacturers: relationships with regulatory, distribution, sometimes govt relations
 - Technical assistance providers in disease areas, supply chain management
 - WHO
 - National programs
- **Are these sufficient or are there gaps?**
- **Input from countries and WHO needed!**



Defining Our Mandate:

What is appropriate PDP Role Post-Licensure?

- **Do we have the expertise?**
 - Better to highlight the relevant gaps and advocate for others to take action?
- **What successful balancing is currently happening?**
 - Lessons learned from those on the market now
- **How can we be clearer about what we are doing?**
 - Is any of us covering the last mile?
 - If the worry is about cost, perhaps we need to define what costs we expect to have at implementation stage
 - Input from donors needed!

