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"The payer's perspective: Accelerating LA HIV prevention products from R&D to programs: Opportunities and challenges"

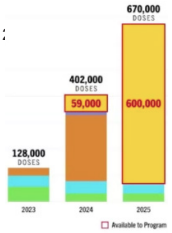
PEPFAR supports a multi-product HIV prevention platform

Programmatic context.

- Choice is encouraged.
  - ◊ QD oral PrEP, QM DPV ring, Q2M CAB-LA (Recent roll out) are currently available.
  - ◊ Q6M LEN is promising (PURPOSE 1 and 2 results).
- There are many challenges, even with choice.
  - ◊ Economic feasibility and licensing are major bottlenecks for LAI introduction in LMICs.
  - ◊ Ministry/government concerns include: Price, Generic licensing, and Local registration.
- USAID and PEPFAR objective.
  - ◊ Convene global stakeholders to set favorable programmatic, policy, regulatory, and market conditions for program roll out of LAIs for HIV.

Long timelines (Approval to programs) in LMICs are unacceptable.

- CAB for PrEP roll out in nine countries.
  - ◊ Choice studies, Pilot projects, and "Real" programs (i.e., Procure & deliver to certain countries).
- **Very limited CAB for program procurement.**
  - ◊ Allocation of non-commercial CAB supply for PrEP in LMICs, 2
    - * 955K of 1.2M doses are for program procurement.
      280K from PEPFAR to date (Orange)
      659K anticipated from ViiV (Yellow).
    - * 245K doses are committed to studies (Green and Blue).
  - ◊ 600K doses in 2025 means ~100K people on CAB-LA.
- **Significant start up delay**.
  - ◊ DCEs indicate LAI preference, but system preparedness takes time (i.e., Transition from QD oral to Q2M injection).



Lessons learned

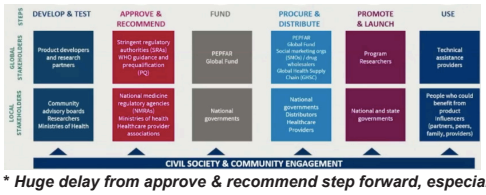
Engage early. Each step from R&D to program implementation has multiple components.

1. Harness research networks to advance R&D.
   Initial work with product developers.
2. Optimize products to meet PEPFAR program needs.
   Ensure product acceptability (Fund DCEs and patient preference studies).
3. Prime enabling environments to accelerate introduction.
   Fund AVAC to work with our community networks; policy and communication programs, and countries.
4. Maximize program integration and impact.
   Program roll out and data collection to assess numbers and impact.
   Impact of HIV prevention is disappointing.

USAID dynamic "end-to-end" model

Coordinated efforts to accelerate the timeline – How?

- Individual parties are doing well, but partnership is needed.
  PEPFAR buying power does not always translate to convening power.



**** Huge delay from approve & recommend step forward, especially for HIV products.***

Product introduction and access program challenges.

- Each element listed is funded.

Policy, Plans, & Costing	Supply Chain & Market Development	Service Delivery	Uptake & Effective Use	Monitoring & Evaluation	Cross-cutting Contributions
Global/national guidance Implementation plans National strategies	Market shaping Demand forecasting Private sector Bottlenecks	Research collabs Implementation research DSD Provider training	End-user engagement Demand generation CQI	Resistance surveillance Routine M&E Data-informed approaches	Evidence/resources Global collabs Capacity building Civil society engagement

- We are investigating various service delivery channels for LAIs.
  - ◊ ***There is government push back on pharmacy & CHW options***, even for testing.
  - ◊ Our experience with medical male circumcision program roll out (i.e., Government negotiation & staff shifting) may help overcome ministry-level/policy constraints.
- Acceptability; Feasibility & deliverability; Affordability; & Sustainability.
  - ◊ Developing a product that stays in the market goes beyond safety & efficacy.
  - ◊ Special emphasis on sustainability and capacity building. PEPFAR aims to hand over programs.
  - ◊ Our framework to support R&D is based on 20y of experience.
    - * Technology Accelerator hub. Support new R&D/Prioritize products.
    - * Design 2 Delivery (D2D) hub. Incorporate stakeholder and end-user feedback.
    - * Capacity strengthening engagement and mentorship(CaSE) hub. Build research partnerships and use R&D capacity in Africa for sustainability.
    - * Business market dynamics and commercialization hub (BACH). Develop the business case for program success.
    - * Clinical trials hub. Design and conduct early clinical trials (P0-P3) in US and Africa.

How to work with industry partners on new products.

- Touch points from R&D to roll out. Gilead and LEN example.

R&D (Research demand; Equity; Establish value proposition)	• Engaged with Gilead on product affordability 3y ago. • Helped prepare clinical trial sites (Community engagement, policy, etc). • Funded a qualitative sub-study on end-user preferences.
Manufacturing (Early engagement; Design for scalability; Local links)	• Identified potential manufacturers with the capability before clinical trials.
Price negotiation & demand estimation (Demand vs need; Real cost vs innovator margin)	• ***We have not coordinated on this at all.***
Pre-market regulatory approvals (National/International; TA to expedite approval)	• Capacity strengthening around local registration.
Facilitate generic access (Early agreement; Support policy to expedite transition; TA/capacity building to meet quality standards)	• PEPFAR is planning to put a lot of investment in this area.
Financial support for the transition (Incentives to originators for generic licensing; Fund initiatives to lower scaling costs for generics)	• We have a history of financing the initial manufacturing for generics (Family planning space), especially when they don't have volume numbers.
Policy & advocacy (Policy negotiation with governments to facilitate market entry; Advocate for regulatory harmonization)	• Engage directly and indirectly with industry and ministry partners.

Towards a high-level donor commitment model.

- Potential market shaping interventions to support product roll out.
  - ◊ Timeline. Engage stakeholders for a 1-2y timeline for increased demand.
  - ◊ Procurement. Provide a volume guarantee.
  - ◊ Supplier Engagement. Identify suppliers and finance equipment &/or regulatory fees.
  - ◊ Demand Forecasting. Own/lead continuous forecasting analysis to reduce supplier risk.
  - ◊ Demand Generation. Promote/subsidize adoption & wide-scale demand generation to increase uptake.
  - ◊ Market Information. Generate additional reporting requirements and systems for participating countries.
- Firm donor commitment is often a political decision.
  - ◊ Leadership changes introduce complexity.
  - ◊ Ministry decisions are based on total program cost, not simply COGs vs price.

Success is possible with concerted efforts.

- Global ARV demand pooling (PEPFAR, Global Fund, and SA) resulted in a 47% reduction in TLD cost over 5y.
- DTG generic licensing. Timeline to reach LMICs <4y. 2013 FDA approval; 2014 Generic licensing (ViiV/MPP); 2016 Tentative FDA approval of first generic version; 2017 First shipment to LMIC.
- Optimize Consortium is a good overall model. We need global partnership; One agency, funder, or country cannot do it alone.

Takeaways

- LA ARVs are a promising opportunity, but past timelines are too long.
- Early engagement with private sector partners with recurring opportunities for R&D of new technologies can accelerate program implementation.
- Originator vs generic perspective. Originators bear significant R&D, regulatory, and SG&A costs, whereas COGs is the dominant force for generics.
- COGs is one component of product price. COGs and price are highly sensitive to product volume and location of manufacture.
- Facilitators for LA PrEP introduction: Reliable & sustainable supply; Steady demand increase; Balanced procurement price; Regulatory policy; Program timelines.
- Donor-driven economic motivations can stimulate private sector innovations and potential investments in generic manufacturing.
- LA ARVs are viable product options if programmed at large scale.