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Perspectives of from the CHAI

"Collaborative, future-focused development is critical for sustainable LA product access in LMICs."

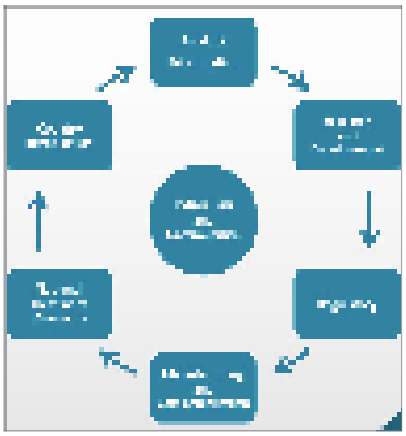
CHAI is committed to delivering access to care in LMICs

Broad-acting mission.

- Save lives and reduce the burden of disease in LMICs.
- Sustainably strengthen government and private health systems in the countries where we work.

Product access requires collaboration across the continuum of care.

- Complex technical, logistical, cultural, and financial processes are inherent in the discovery, development, and introduction lifecycle.
- Well-designed product access programs can unlock the potential of emerging markets, meet public health goals, and become commercially viable.
- Success requires: Assembling the talent, passion and commitment of diverse individuals; Maintaining coordination and alignment for years; Being proactive, purposeful, transparent, and respectful.
- ***CHAI is active, engaged, and willing to partner with like-minded groups.***



Key considerations for product access

The goal is to minimize or eliminate barriers at each stage:

Often via planning ahead and collaborating with groups that have the skill and knowledge.

Research and development.

- Barriers: No consensus on **TPP**; Lack of optimally designed product for **relevant patient populations**; Weak **IP** estate management; **Insufficient evidence** for approval & adoption.
- Interventions: Issue a **TPP**; New product development; **Global approach** to IP management; **Clinical studies** (with the right patients and volunteers); **Implementation research**.
- Partners: Academia; Donors, Industry, Ministries, NGOs, NTP, Patients, SRAs, WHO.

Normative and regulatory.

- Barriers: Lack of a **clear regulatory pathway** for product class; Lack of WHO pre-qualification for target product; Lack of **NRA** approval or waiver for target product; Product not included or recommended in **WHO guidelines** or essential medicines list (EML) or in focal **countries' EML or clinical guidelines**.
- Interventions: **Development of regulatory strategy**; Simplified registration; Dossier submission; Guidelines submission.
- Partners: Academia, Donors, Industry, Ministries, NGOs, NTP, Patients, SRAs, WHO.
- We must leverage accelerated regulatory pathways (Plan early and work with FDA on novel approaches).
  - CHAI was able to shorten the time to pediatric approval (<2y vs average adult approval of 8-10y).

Manufacture and commercialization.

- Barriers: Manufacturing/sales restricted by **IP** provisions; Limited supplier **footprint or interest** in serving key markets; Limited production **capacity** or long lead times; Price too high to be considered cost-effective or adopted in guidelines; Lack of clarity on **target price** for the relevant market.
- Interventions: **Demand forecasting**; Licensing agreements; Strategic sourcing; New supplier entry; Manufacturing optimization; **Commercialization partnerships**; Price analysis and negotiation.
- Partners: Donors, Industry, Ministries, NGOs, NTP, Patients, SRAs, WHO.
- Need to ensure common ground across many parties (TPP established).

- What is the accessible market? What is the value to the nation, patient, and business? ***To be sustainable, someone needs to make it, someone needs to make money on it, patients need to take it, and patients need to be monitored.***

Procurement and supply management.

- Barriers: Insufficient or unsustainable **financing** for procurement; Fragmented or irregular procurement; Limited visibility into **demand**; Insufficient supply chain and **distribution** network; Supplier does not satisfy conditions to participate in the **tender or RFP**.
- Interventions: **Demand visibility**; **Coordinated supply planning**; Pooled procurement; variant optimization; All-inclusive procurement; Product bundling; Tender optimization; Supply chain optimization.
- Partners: Donors, Industry, Ministries, NGOs, NTP, Patients.
- Need to facilitate common ground across agendas (Ministries of Health, Budget, and Finance; NRAs; and different countries).
  - Finding common ground ensures political will to roll out a new product and necessary care, including diagnostics, training, and public awareness.
  - Coordination is very country-specific, even for things like packaging.

Introduction and scale.

- Barriers: Lack of **awareness** or willingness to use product or service; Insufficient or unsustainable **financing for introduction activities**; Limited interest or **political will**; **Complementary** products or **services** not available; **Healthcare workforce** lacks necessary mandate, training, or capacity; Required **infrastructure** is insufficient; Limited delivery channels/access points; High out of pocket **costs** to end-user.
- Interventions: **Forecasting and quantification**; Stock monitoring options; **Infrastructure strengthening**; **Workforce capacity strengthening**; Resource mobilization; End-user awareness campaigns.
- Need to begin activities years before generic dossier submission.
  - Secure funding and work with ministries, patient advocates, and groups that issue guidelines.
  - Build a business case to convince ministries that the transition is worth the effort. This includes a lot of in-country work to ensure demand (Market-shaping, enhancing infrastructure).
- Example: pDTG for children living with HIV.

  - **Global and national partnerships** accelerated adoption and introduction of a product that transformed care in a relatively small population of children.
    WHO, PEPFAR, EGPAF, the Global Fund, Unitaid, and CHAI published a joint statement in December 2022.
  - **Work with local agencies** ensured operational research (implemented by local staff) was customized to the patient population they are serving:
    Nigeria, Benin, and Uganda: CHAI-supported research initiatives focused on patient/caregiver satisfaction, side effects, VL, adherence, and other indicators.
    Kenya, Zimbabwe, and Malawi: Demonstrated enhanced monitoring can be done within existing data and pharmacovigilance systems.