CHAI Market Shaping Framework

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Overview

Over two decades, CHAI has worked in concert with partners & governments to create sustainable marketplaces for health commodities — Accelerating market introduction, ensuring affordability, & enhancing supply security to increase equitable access.

CHAI's market shaping work has traditionally supported the following objectives:

1. **Accelerating development,** registration, adoption, & scale-up of life-saving products
2. Achieving appropriate and **sustainable access pricing**
3. **Generating demand** among governments & end users
4. **Ensuring functionality** of key medical equipment
5. Enhancing **supply security**
6. **Improving product quality** to meet internationally recognized standards

In 2020, we sat down to document our approach, to share lessons learned and promote best practice within the market shaping community. The framework that follows is the result of these efforts. We hope our partners find it useful when developing new market shaping strategies for high-impact health interventions in low- and middle-income countries.

Framework at a glance

A

Barriers and/or preconditions to LMIC access

B

Interventions to address relevant barriers/preconditions

C

Financial tools to support interventions

Each part of the framework is organized into five overarching categories

1. Research & Development
2. Regulatory & Normative
3. Manufacture & Commercialization
4. Procurement & Supply Mgmt.
5. Introduction, Scale, & Sustainability

How to use this framework

Step 0	**DEFINE THE PUBLIC HEALTH PROBLEM THAT NEEDS TO BE SOLVED** Develop a clear understanding of the public health problem you are trying to solve, whether it aligns with government priorities, and the extent to which the product or service can address the problem.
Step 1	**MAP OUT ALL EXISTING AND ANTICIPATED BARRIERS/PRECONDITIONS TO ACCESS FOR THE PRODUCT/SERVICE** Review the list in Part A and identify all which are applicable to the product or service in question.
Step 2	**IDENTIFY THE INTERVENTIONS THAT CAN ADDRESS THE BARRIERS/PRECONDITIONS FOR THE PRODUCT/SERVICE** Based on the results from Step 2, review the interventions listed in the corresponding slides in Part B to determine which are well suited to address the relevant barriers and/or preconditions. Ensure that all critical barriers and preconditions are covered by the selected interventions.
Step 3	**DETERMINE WHETHER A FINANCIAL TOOL IS CRITICAL TO SUCCESSFULLY IMPLEMENT THE INTERVENTIONS** In some cases, financial tools may be needed to augment the selected interventions. Review the financial tools in Part C and develop a short list of options based on when each financial tool should be used and the type/magnitude of financing required.

Part A: Barriers and/or preconditions to product or service access (1/2)

A

Barriers and/or preconditions to LMIC access

B

Interventions to address relevant barriers/preconditions

C

Financial tools to support interventions

Part A of the framework should be used for products/services with clear potential for public health impact and existing or anticipated access challenges in LMICs.

Part A will help answer the following question:

What are the key barriers and/or preconditions to access for a health product or service that need to be addressed?

Part A: Barriers and/or preconditions to product or service access (2/2)

RESEARCH & DEVELOPMENT	NORMATIVE & REGULATORY	MANUFACTURE & COMMERCIALIZATION	PROCUREMENT & SUPPLY MANAGEMENT	INTRODUCTION, SCALE, & SUSTAINABILITY
❑ No consensus on target product profile (TPP) ❑ Lack of optimally designed product for relevant patient populations ❑ Insufficient evidence for product approval and/or adoption	❑ Lack of clear regulatory pathway for product class ❑ Lack of WHO pre-qualification (PQ) for target product ❑ Lack of stringent regulatory authority (SRA) approval for target product ❑ Lack of national regulatory authority (NRA) approval or waiver for target product ❑ Product not included or recommended in WHO guidelines or essential medicines list (EML) ❑ Product not included or recommended in focal countries' medicines lists or clinical guidelines	❑ Manufacturing/sales restricted by intellectual property provisions ❑ Limited supplier footprint/interest in serving key markets ❑ Limited production capacity and/or long lead times ❑ Price too high to be considered cost effective or adopted in guidelines ❑ Lack of clarity on target price for relevant market	❑ Insufficient/unsustainable financing for procurement ❑ Fragmented and/or irregular procurement ❑ Limited visibility into demand ❑ Inefficient supply chain & distribution networks ❑ Supplier(s) do not satisfy conditions to participate in the tender/request for proposal (RfP)	❑ Lack of awareness or willingness to use product or service ❑ Insufficient/unsustainable financing for introduction activities and/or added service delivery costs ❑ Limited interest/political will, due to competing priorities ❑ Complementary products or services unavailable ❑ Healthcare workforce lacks necessary mandate, training, and/or capacity ❑ Required infrastructure is unavailable or insufficient ❑ Limited delivery channels/access points ❑ High out-of-pocket (OOP) costs to end-user

Note: Lists are non-exhaustive and non-chronological; categorization is illustrative only. Barriers are meant to be observable and do not speak to potential root causes.

Part B: Interventions to address relevant barriers/preconditions (1/6)

A

Barriers and/or preconditions to LMIC access

B

Interventions to address relevant barriers/preconditions

C

Financial tools to support interventions

The subsequent five slides provide a menu of interventions which are relevant to barriers/preconditions falling under the corresponding category in Part A.

Part B will help answer the following question:

Which intervention(s) can help address the identified barriers and/or preconditions to access?

Part B: Interventions to address relevant barriers/preconditions (2/6)

RESEARCH & DEVELOPMENT		
INTERVENTION	**DESCRIPTION**	**IMPLEMENTATION TIMEFRAME**
Target Product Profile Issuance	Convene stakeholders to define and publish list of desired product characteristics, use cases, target populations, etc.	1-3 years
New Product Development	Develop new products to meet TPP, serve new populations, or satisfy other context-specific conditions (e.g., pediatric formulations, fixed-dose combinations, etc.); may require new R&D partnerships	3+ years
Product Redesign	Improve design of existing products for LMIC settings (e.g., to improve durability, to address infrastructure gaps, to reduce health care worker (HCW)/patient training requirements, etc.)	3+ years
Label Expansion	Pursue new indications for approved product via additional clinical studies	3+ years
Clinical Studies	Assess safety and efficacy of health interventions using human volunteers	3+ years
Implementation Research	Test innovations in real-world health settings to bring what works to scale	1-3 years

Note: Intervention list is non-exhaustive. Timeframes above are intervention-specific and do not represent the full length of time required for achieving desired market/access outcome.

Part B: Interventions to address relevant barriers/preconditions (3/6)

REGULATORY & NORMATIVE		
INTERVENTION	**DESCRIPTION**	**IMPLEMENTATION TIMEFRAME**
Regulatory Submissions	Provide product-specific regulatory support to suppliers to accelerate dossier submission & review process with respect to WHO, SRAs, and/or NRAs	1-3 years
Regulatory Strategy	Employ innovative approaches within existing WHO, SRA, and/or NRAs regulatory pathways to enable and/or accelerate review of new product/product class	1-3 years
Simplified Registration	Leverage simplified registration pathways (e.g., WHO Regulatory Reliance, WHO-CRP, WHO-SRA-CRP, regional harmonization, etc.) to accelerate product reviews in target geographies	1-3 years
Guidelines Inclusion	Support processes for inclusion of new products in guidelines, formularies, and EMLs (e.g., conduct health technology assessments, facilitate guidelines review process, disseminate guidelines, etc.)	1-3 years

Note: Intervention list is non-exhaustive. Timeframes above are intervention-specific and do not represent the full length of time required for achieving desired market/access outcome.

Part B: Interventions to address relevant barriers/preconditions (4/6)

MANUFACTURE & COMMERCIALIZATION		
INTERVENTION	**DESCRIPTION**	**IMPLEMENTATION TIMEFRAME**
Licensing Agreements	Enable additional manufacturers to produce and sell on-patent products within a defined territory through voluntary licenses (with tech transfer and/or royalty as applicable)	Variable
Strategic Sourcing	Improve sourcing of high-quality active pharmaceutical ingredients (API), raw materials, and component parts through bulk, direct, and/or local purchasing to reduce overall product cost	<1 year
Manufacturing Optimization	Identify opportunities to optimize product manufacturing, including via process chemistry, factory automation, packaging redesign, etc.	<1 year
New Supplier Entry	Support entry of additional suppliers within existing product class to increase total production capacity, diversify supplier base, exert downward pricing pressure, etc.	1-3 years
Commercialization Partnerships	Facilitate agreement of new commercialization partnerships to introduce products in LMICs (via links between manufacturers, distribution partners, in-country service providers, etc.)	<1 year
Demand Forecasting	Aggregate on-the-ground data and insights to determine total addressable market, price elasticity of demand, and other market characteristics, to support supplier negotiations and commercial planning	<1 year
Price Analysis & Negotiation	Conduct cost of goods sold (COGS), cost-effectiveness, and other pricing analyses to determine target price range; negotiate and publicize preferential pricing that is applicable to target countries & buyers	<1 year

Implementation of many of the above interventions may require additional R&D and regulatory work to ensure appropriate quality standards are met.

Note: Intervention list is non-exhaustive. Timeframes above are intervention-specific and do not represent the full length of time required for achieving desired market/access outcome.

Part B: Interventions to address relevant barriers/preconditions (5/6)

PROCUREMENT & SUPPLY MANAGEMENT		
INTERVENTION	**DESCRIPTION**	**IMPLEMENTATION TIMEFRAME**
Demand Visibility	Improve forecasting capabilities to enable procurers to enter longer-term, higher-volume, and/or fixed volume contracts (at country or global level)	<1 year
Pooled Procurement	Establish centralized procurement mechanism to consolidate demand/funding across multiple buyers (including sub-national buyers) to reduce transaction costs/increase leverage	Variable
Coordinated Supply Planning	Facilitate inter-procurer coordination and data sharing to increase overall market visibility and manage supply security (e.g., ARV Procurement Working Group, Coordinated Supply Planning Group, etc.)	<1 year
Variant Optimization	Align key buyers and end users on standardized product packaging, inserts, size, colors, etc. to generate manufacturing efficiencies and cost savings	<1 year
All-Inclusive Procurement	Expand scope of procurement to include all relevant related products and services (e.g., training, maintenance, etc.) to reduce costs, streamline budgeting, and/or ensure longer-term functionality	1-3 years
Product Bundling	Combine procurement of interdependent products from the same or multiple suppliers to reduce prices, streamline procurement and supply management, and maximize patient impact	1-3 years
Tender Optimization	Promote best practices in implementing tenders/RfPs (e.g., supplier eligibility, award criteria, timing & duration, indicative/minimum volumes, quality policy, contracting process, etc.)	<1 year
Supply Chain Optimization	Align with global standards, including from other industries, to generate more efficient, transparent, and cost-effective supply chains/distribution systems	<1 year

Note: Intervention list is non-exhaustive. Timeframes above are intervention-specific and do not represent the full length of time required for achieving desired market/access outcome.

Part B: Interventions to address relevant barriers/preconditions (6/6)

INTRODUCTION, SCALE, & SUSTAINABILITY		
INTERVENTION	**DESCRIPTION**	**IMPLEMENTATION TIMEFRAME**
Forecasting & Quantification	Aggregate on-the-ground data and insights to inform supply planning, procurement, financing, and/or new product introduction strategies	<1 year
Stock Monitoring Optimization	Establish/update stock monitoring tools, ordering forms, and patient management systems to include new products, manage transitions, reduce frequency of stockouts, and measure outcomes	1-3 years
Infrastructure Strengthening	Implement infrastructure improvements at health facility level to improve service delivery and/or enable new product/service introduction (e.g., installing cold-chain equipment)	Variable
Workforce Capacity Strengthening & Optimization	Improve provision of care by conducting health care worker trainings related to new product/service; may require updating policies (e.g., task-shifting) and training curricula	1-3 years
Health Financing & Resource Mobilization	Seek inclusion of new health intervention under domestic and/or donor financing mechanisms to pool volumes, improve predictability of demand, negotiate prices, and/or regulate markups	3+ years
End-User Awareness Campaigns	Generate demand for the product/service among end-users via awareness and educational campaigns to ensure patient knowledge and adherence	<1 year

Note: Intervention list is non-exhaustive. Timeframes above are intervention-specific and do not represent the full length of time required for achieving desired market/access outcome.

Part C: Financial tools to support interventions (1/4)

A

Barriers and/or preconditions to LMIC access

B

Interventions to address relevant barriers/preconditions

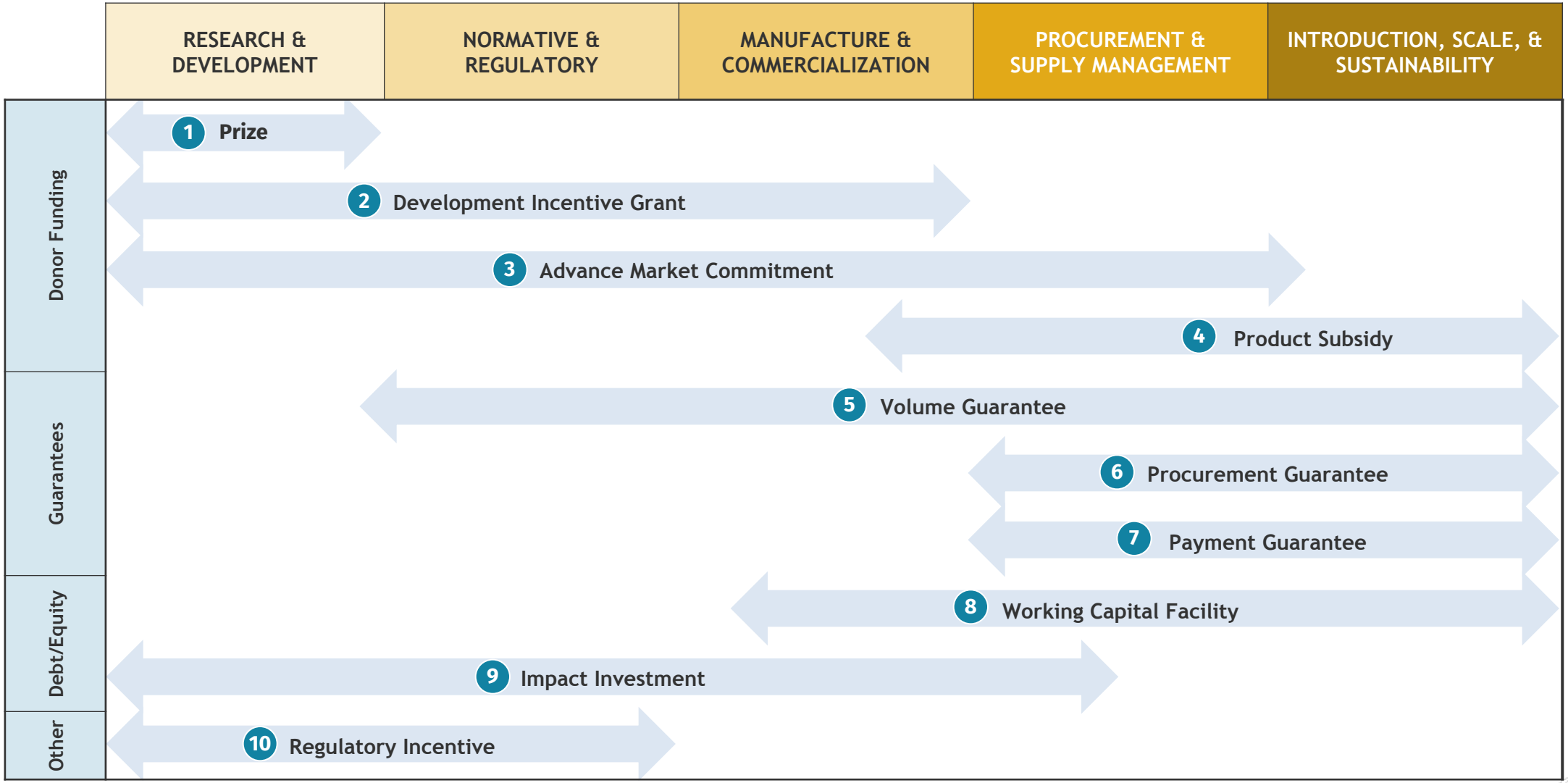
C

Financial tools to support interventions

In some cases, the interventions selected in Part B may require or can be further enhanced via deployment of one or more financial tools.

Part C will help answer the following question:
Which financial tools, if viable, could increase the likelihood of intervention success?

Part C: Financial tools to support interventions (2/4)



Part C: Financial tools to support interventions (3/4)

TOOL	1 PRIZE	2 DEVELOPMENT INCENTIVE GRANT	3 ADVANCE MARKET COMMITMENT	4 PRODUCT SUBSIDY	5 VOLUME GUARANTEE
DESCRIPTION	Provide financial reward to product developer for achieving a pre-defined R&D outcome.	Upfront and/or milestone-based payments provided to supplier to pursue agreed upon R&D, regulatory, and/or commercial activities.	Donors commit to purchasing a minimum volume of products that meet a TPP at an agreed-upon price once developed.	Fixed per unit subsidy for predefined period or quantity implemented at any point in distribution chain; includes short term donations (e.g., "catalytic procurement").	Supplier agrees to lower price in return for sales volume guarantee; guarantor agrees to compensate supplier for any shortfall.
USE CASES	Generate R&D investment in a new area/specific product class. Characteristics of the ideal solution should be clearly defined.	Incentivize accelerated development/ launch of high priority products; supplier must commit to favorable access terms in advance.	Offset R&D risk, especially for products with uncertain demand that require intensive, upfront investment.	Reduce product costs to catalyze adoption & uptake in target markets (or via target channels) and accelerate timelines to achieving longer-term, sustainably lower prices.	Accelerate uptake of a product that falls into the "high price/low volume" trap or improve supply security by increasing production capacity.
FUNDING TYPE	Donor (Conditional)	Donor (Conditional)	Donor (Conditional)	Donor	Guarantee
UPFRONT FUNDING REQUIRED	No	Varies	No	Varies	No
EXAMPLE PARTNERS	USAID, Grand Challenges Canada, XPRIZE, UBS Optimus Foundation	BMGF, USAID, CIFF, Unitaid	BMGF, USAID, Gavi, FCDO, Norad, World Bank	BMGF, CIFF, Unitaid	BMGF, MedAccess, CIFF, Norad

Note: "Catalytic procurement" can include the specific commitment to purchase validation batches, which accelerates commercialization and market entry of a new product

Part C: Financial tools to support interventions (4/4)

TOOL	6 PROCUREMENT GUARANTEE	7 PAYMENT GUARANTEE	8 WORKING CAPITAL FACILITY	9 IMPACT INVESTMENT	10 REGULATORY INCENTIVE
DESCRIPTION	Guarantee facility provided to intermediate buyer (e.g., procurer) to ensure customer payment will be received on time in full; guarantor assumes risk of default.	Guarantee facility provided to seller (supplier, service provider, etc.) to ensure customer payment will be received on time in full; guarantor assumes risk of default.	Low-cost loans for operating expenditures provided to suppliers, procurers, wholesalers, distributors, etc. with liquidity needs.	Financing provided to companies that aim to achieve social impact and financial return in the form of debt, equity, or mixed instruments.	Rewards for developing products for specific patient populations, including priority review vouchers, filing fee waivers, tax credits, etc.
USE CASES	Offset risk of procurers entering longer-term and/or fixed purchase contracts in advance of receiving funds from intended recipients.	Offset risk of sellers agreeing to new or longer-term contracts in markets or with buyers that are perceived to carry higher levels of risk.	Enable commercial partner to better manage day-to-day operations; can be provided in exchange for favorable access terms and conditions.	Lower the cost of capital needed to support product development/ commercial activities to help enable reduced end-user pricing.	Encourage the development of new products (typically drugs) for a set of pre-defined neglected health areas.
FUNDING TYPE	Guarantee	Guarantee	Debt	Debt / Equity	Other
UPFRONT FUNDING REQUIRED	No	No	Yes	Yes	No
EXAMPLE PARTNERS	BMGF, MedAccess, Sida, USAID, JICA	BMGF, World Bank, MedAccess, Rockefeller, European Investment Bank	BMGF, MedAccess, BII	Acumen, Global Innovation Fund, Adjuvant Capital, TEAM Fund, DFC	FDA, other NRAs

Note: “Loan guarantees” can be employed as part of the debt-based instruments listed above to further reduce the cost of capital to the private sector entity

When is the use of a financial tool appropriate?

Financial tools can be risky, and there is often a high transaction cost associated with their implementation. Ideally, the following conditions should be satisfied and materials in place prior to proceeding with deal development and execution:

- ✓ A compelling case for the product/service in direct patient impact and/or value-for-money terms
- ✓ A robust forecast for the product/service that factors in the price elasticity of demand
- ✓ A credible hypothesis for how the financial tool(s) and other interventions will address key supply and demand side barriers, versus the counterfactual, without jeopardizing broader, longer-term market health
- ✓ Identification of potential financing partner(s) based on target financial tool, forecasted deal size, risk profile, programmatic priorities, and timelines
- ✓ The availability of (or a plan to secure) funding/TA to address any other critical barriers/preconditions
- ✓ Sufficient lead time/resources to conduct due diligence and execute the agreement

Key considerations for global access agreements

When negotiating access agreements, the following considerations should be prioritized to maximize impact, mitigate risk, and minimize the need for further interventions/tools:

CEILING PRICE	• Is the target ceiling price low enough to accelerate uptake in high burden countries? • Will the ceiling price be maintained at the end of the agreement? Is there room for further price reduction? • Can the scope of the agreement be expanded to include related services and/or manage downstream costs?
COUNTRY ELIGIBILITY	• How broad is the deal in terms of LMIC inclusion? What % of patients in need will be covered globally? • Has the agreement been designed with the requirements & procurement systems of key purchasers in mind?
REGULATORY FILINGS	• To what extent is the supplier obligated to pursue accelerated regulatory filling in priority countries? • What terms can be included to help ensure timely regulatory filings in lower volume countries? • Are there protections in the agreement in case of quality issues or loss of regulatory approval?
SUPPLY SECURITY	• Are there mechanisms to ensure the supplier builds and maintains sufficient production capacity for LMICs? • Are there mechanisms to ensure the supplier participates in relevant RfPs & achieves reasonable lead times?
REPORTING	• Does the agreement include strict supplier reporting requirements & KPIs? • How will health impact & procurement savings linked to the agreement be measured?

Note: These considerations are relevant for all ceiling price/access agreements, including those that do not rely on financial tools or outside capital.

Case study: Viral load testing services (2018)

Public Health Issue

Viral load testing is needed to ensure effective diagnosis and management of HIV, HCV, HBV, and HPV. But access in LMICs has been limited. A handful of suppliers offered testing platforms and assays in LMICs, but several key barriers needed to be addressed to maximize their impact.

~BARRIERS/PRECONDITIONS~

- **Price too high** given upfront equipment costs & substantial after sales service requirements
- **Lack of clarity on target price** given hidden costs and nonuniformity in contracting
- **Irregular procurement** of reagents & consumables led to frequent stockouts
- **Lack of service & maintenance** resulted in high levels of equipment downtime

~INTERVENTIONS~

- **All-inclusive procurement** includes all supplies & services needed to generate a test result & enables price comparison across suppliers & countries by removing hidden costs
- **Price negotiation** to establish Hologic all-inclusive ceiling price at $12 per patient test
- **New supplier entry** to introduce Hologic's Panther platform in LMICs to spur competition

~FINANCIAL TOOLS~

- **Volume guarantee** to Hologic to offset risks associated with new market entry and switch to innovative all-inclusive pricing

Outcomes To-Date

Since 2018, the agreement has enabled 932k individuals to access viral load testing services on the Hologic platform and has saved donors and procurers nearly $45m in direct procurement costs.

Source: https://medaccess.org/wp-content/uploads/2023/07/2022-Annual-Review.pdf

Case study: 3HP for TB prevention (2021)

Public Health Issue

TB prevention therapy is essential to combatting the TB epidemic, but uptake has traditionally been poor. The 3HP regimen offered significant programmatic benefits versus the existing standard of care. However, several key barriers needed to be addressed for 3HP to be introduced and scaled-up in LMICs.

~BARRIERS/PRECONDITIONS~

- **Lack of optimally designed product** which only existed as a multiple product regimen
- **Limited production capacity** given single supplier on the market
- **Price too high** to be considered cost effective or to be eligible for PEPFAR funding
- **Limited interest/political will** to scale 3HP due to competing priorities in TB programs

~INTERVENTIONS~

- **New product development & supplier entry** to introduce Macleods' fixed-dose combination product and to increase supply security
- **Demand forecasting** to understand buyers' price sensitivity & demonstrate potential demand at a reduced target price
- **Price analysis & negotiation** to establish cost-effective pricing & enable PEPFAR adoption

~FINANCIAL TOOLS~

- **Development incentive grant** to offset Macleods' development & commercialization costs needed for cost-effective market entry
- **Volume guarantee** to extend launch price & mandate further price reductions to support sustained product procurement
- **Product subsidy/donation** to launch 3HP in countries where inclusion in routine donor procurement was on a longer timeline

Outcomes To-Date

Since 2021, the agreement has led to an additional 419k TB prevention therapy courses completed, averting an estimated 106k hospitalizations, and generating $22m in direct procurement savings.

Source: https://medaccess.org/wp-content/uploads/2023/07/2022-Annual-Review.pdf

Appendix: Additional resources

Global health market shaping frameworks:

- USAID, Healthy Markets for Global Health: A Market Shaping Primer (link)
- GAVI, Healthy Markets Framework (link)
- The Global Fund, Market Shaping Strategy (link)

Examples of financial tool application:

- USAID and DFID Creating Hope in Conflict Grand Challenge Prize (link)
- Gavi COVAX Advanced Market Commitment (link)
- BMGF subsidy of OraQuick HIVST (link)
- MedAccess Volume Guarantee with Hologic (link)
- Malaria No More, the US DFC, and others launch the Open Doors African Private Healthcare Initiative (link)
- Adjuvant Capital investment in Evofem Biosciences to support R&D of a new family planning method (link)
- FDA issues priority review vouchers for rare pediatric disease products (link)

Please contact Colin Brown with any questions or to request the ppt. version of the slides at cbrown@clintonhealthaccess.org

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