CLINTON HEALTH ACCESS INITIATIVE

Shaping Markets for Social Impact

A Guidebook

Acknowledgments

The Global Markets Team at the Clinton Health Access Initiative (CHAI) extends our deepest gratitude to all those who contributed to the creation of this resource.

We are especially grateful to the Renaissance Philanthropy—whose generous support has made the publication of this work possible.

We acknowledge the invaluable contributions of our CHAI colleagues across our programs, 30+ country teams, and PCQRA team, as well as individuals in partner organizations whose dedication, expertise, and insights have supported our work. Your efforts have been instrumental in advancing our shared mission.

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INTRODUCTION:

Shaping markets for social impact

For over 20 years, the Clinton Health Access Initiative (CHAI) has honed a comprehensive, practical approach to market shaping in global health. The approach has achieved dramatic health outcomes while creating commercially sustainable opportunities for industry. Pioneered during the AIDS crisis, this approach has since been applied to many pressing global health challenges and is being explored in other sectors. To date, CHAI has negotiated over 150 market shaping agreements, which have generated many billions of dollars in savings for health systems and touched hundreds of millions of lives.

This guidebook provides an overview of CHAI's approach to addressing large-scale, complex problems and practical steps for others who want to apply the model to their work.

Who is this guidebook for?

This guidebook will be most useful to leaders who are exploring innovative ways to address large-scale, complex problems and can help these leaders support market shaping interventions on a global scale (Part 1). It will also support practitioners who want to apply a tested and refined framework to accelerate their impact (Part 2).

A new market shaping model emerges out of the AIDS crisis

In the early 2000s, close to two million people died from AIDS-related illnesses every year—yet less than 10 percent of people living with HIV were on treatment in low- and middle-income countries. The foremost experts at the time said that treating the disease in these regions was impossible, as HIV drugs were too expensive, and it was too complicated to establish the systems of care necessary to treat AIDS.

However, as South African President Nelson Mandela and former US President Bill Clinton closed the 2002 International AIDS Conference in Barcelona and stepped off the stage, Mandela turned to Clinton and asked him for a favor. Could he help get treatment for people living with HIV? Later that summer, the Clinton HIV/AIDS Initiative, or CHAI, launched in answer to Mandela's question (it would later re-brand to the Clinton Health Access Initiative as its remit grew beyond HIV/AIDS). This is how CHAI was founded, rooted in the belief that no one, no matter where they live, should die because they cannot access treatment.

The organization tackled the AIDS crisis by reshaping the HIV drug market. Many governments could not afford to buy drugs and tests in the quantities essential to treat the millions of people in need in their countries. CHAI conducted the first-ever market shaping initiative in global health, working on both the demand- and supply-side of the problem. We partnered with governments and other key actors to create and aggregate funded demand for HIV drugs while also working to guarantee that high enough volumes of products would be purchased so manufacturers could provide treatment at lower costs while remaining profitable. The model was ambitious and completely new. It identified novel ways to dramatically increase the number of patients treated by lowering prices and building long-term viable businesses for companies.

It worked. CHAI's pioneering market shaping work—negotiating significant drug price reductions and designing and implementing powerful market shaping interventions such as volume guarantees and product development incentives—together with critical efforts from other leading partners, accelerated generic market entry and dramatically reduced the price of HIV drugs. The annual cost of

treatment plummeted from US$10,000 in 2002 to under US$40 today—enabling over 20 million people in lower-income regions to access top-quality HIV medicines.

Since then, we have applied the lessons learned during the AIDS crisis to many other health areas which has led to CHAI's transformational impact—billions of dollars in health systems' savings and hundreds of millsions of lives touched—through our more than 150 negotiated market shaping agreements.[1]

CHAI's market shaping: the origin story

As President Clinton, our co-founder Ira Magaziner, and their team struck out on a new mission to help address the global HIV/AIDS pandemic, they examined the landscape. They identified an emerging issue: the huge cost of getting antiretroviral drugs (ARVs) to patients in Africa and other low-income regions. So, CHAI took on the economics of it all.

The effort started small. The Prime Minister of the Bahamas invited CHAI into the country. CHAI always works at the invitation of our host government. An economic analysis showed that while the government was already using generic ARVs, they were buying the drugs through a distributor at a considerable mark-up. They could save substantial money by dealing directly with the manufacturers. CHAI helped the Bahamas negotiate a deal directly with the ARV manufacturers that cut the price by 87 percent. This would not be the last the world saw of CHAI's new model.

With the Bahamas success story as inspiration, CHAI got bolder. We helped shape both the supply and demand side of the market to ensure that sufficient volumes were in place to allow manufacturers to provide the drugs at lower costs while remaining profitable. ARVs shifted from a high-cost, low-volume business to a lower-margin, high-volume market where lots-more-people-get-AIDS-drugs-and-the-company-still-makes-money model.

The story came full circle on September 25, 2025, when CHAI—together with partners Unitaid, Wits RHI, and Dr. Reddy's Laboratories—announced a landmark agreement to rapidly make lenacapavir, a nearly 100 percent effective twice-yearly injection for HIV prevention, available to 120 low- and middle-income countries at just US$40[2] per patient per year.

This breakthrough has the potential to transform HIV prevention. As President Bill Clinton remarked that day, *"this partnership marks a remarkable breakthrough and a fundamental shift in what's possible for HIV prevention, [...] not only confronting the epidemic but helping give the world a genuine chance to end it."*

The challenge now is to build on this momentum—ignite the ecosystem and ensure this innovation reaches those who need it most—so that its promise becomes reality.

As CHAI's CEO Dr. Neil Buddy Shah also stated: *"for too long, low-income countries have waited years for access to breakthrough medicines. This...is a new model for how innovation reaches those who need it most."*

Taking a holistic approach

What distinguishes CHAI's approach is the pragmatic and comprehensive manner with which it orchestrates the entire market ecosystem, placing equal weight on both demand- and supply-side considerations and actors. A focus restricted to securing pricing deals with manufacturers, often leads to overall failure because it ignores production economics and, importantly, demand-side realities, both at the global level and in local contexts.

In the fight against AIDS, for instance, CHAI negotiated lower prices with manufacturers and pooled demand and guaranteed volumes from governments. At the same time, we helped create an environment that enabled product introduction and uptake in many countries. By partnering with health ministries to establish treatment protocols, set up diagnostic labs, create efficient supply chains, and train health workers to administer the drugs, we ensured these now affordable medicines could reach people living with or at risk for HIV. That holistic

1 Based on savings reported upon completion of the 2012-2018 DFID market shaping grant and then FCDO's SHAPE grant plus 3DSHAPE
2 The current price of lenacapavir in the US is ~$28,000 per person per year.

approach is key to CHAI's market shaping success. It is a model that has delivered extraordinary impact and laid the current access landscape's foundation.

Today, as global health is experiencing a moment of unprecedented challenge and change, the center of gravity for financing essential health commodities is shifting from bilateral and multilateral global donors to national government budgets. In this context, market shaping —the strategic alignment of supply and demand to ensure equitable, sustainable access to affordable, high-quality products— becomes even more critical. The business (and art) of shaping and transforming markets must adapt to respond to the rapidly evolving global health ecosystem. If we are to, collectively, preserve and extend past access gains and increase sustainable, affordable and equitable access to health products in line with national governments' current stated health care priorities, we must further accelerate the impact of global health institutions' continued investments and, importantly, effectively support the transition from donor-funded access to increasing domestically financed access. Harnessing the power of market shaping to achieve both goals is how CHAI believes we can meet the moment.

Part 1

CHAPTER 1:

Reshaping global health markets, a framework for change

Over the last two decades, market shaping in global health has dramatically increased access to life-saving products by driving down the costs of procuring medicines and diagnostics.

To understand when market shaping should be used and which tool or intervention—financial or not—can help achieve the desired outcome, CHAI developed its Market Shaping Framework. The Framework provides a roadmap for creating sustainable marketplaces for high-quality health products.

In this chapter, we outline the origins of market shaping in global health and then distill CHAI's approach to reshaping markets and driving transformational impact.

1.1 Origins of market shaping in global health

The theory and practice of market shaping asserts that markets—the interactions between a sector's buyers and sellers—play a critical role in determining the availability and affordability of products and services. By strategically intervening in these markets, it is possible to dramatically reduce costs and therefore prices and increase access to these products and services. This fosters better health outcomes and creates sustainable marketplaces.

Market shaping in global health originated as a strategy to address inefficiencies in the supply and demand of essential health products, especially in low- and middle-income countries (LMICs). The concept gained momentum in the early 2000s, alongside the rise of large-scale global health funding initiatives such as Gavi, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), and Unitaid. A major objective of these institutions was to improve access to effective products to diagnose and treat infectious diseases such as malaria, tuberculosis, HIV, and modern contraceptives.

CHAI's innovation was figuring out how to leverage the pools of funds created through institutional buyers to aggregate demand among procurers and government buyers and dramatically reduce the price of products by conducting effective market shaping interventions. Our early 2000s work, which, for the first time in a decade, made effective HIV treatment (drug) prices affordable to populations in LMICs, showcased how strategic negotiations, bulk purchasing, and galvanizing the ecosystem could overcome barriers like high prices and limited access. This approach not only made life-saving drugs more affordable but also demonstrated to manufacturers that there was a commercially viable market for these products in LMICs, encouraging more competition and innovation.

Over the last two decades, CHAI has developed a holistic, pragmatic approach, informed by real-world observations and needs, that builds win-win partnerships between buyers and sellers and encourages the development and commercialization of health products tailored for LMIC markets. Critically, the most vulnerable populations also win by gaining more access to high-quality health products.

1.2 Activist organizations: a critical innovation in market shaping

One of the most critical innovations in market shaping is empowering a highly effective "activist

organization"[3] that is respected by all relevant stakeholders and has the necessary expertise to help orchestrate partners towards achieving a common goal. The critical work performed by the activist organization enables market shaping to work on both the supply- and demand-sides. It includes hard, behind-the-scenes work that is essential for coordinating players across the entire market ecosystem: governments, suppliers, buyers, procurement agents, regulators, opinion leaders, and more. This relentless organizing, informing, influencing, and dot-connecting speeds up market shifts by processing key steps that would otherwise happen slowly, piecemeal, or not at all.

Activist organizations must have the expertise to put into play a wide range of possible interventions, financial and/or non-financial, and support demand-side implementation with extensive technical skills and market reach. In parallel, it requires the ability to integrate each ecosystem actors' requirements or needs, without which market shaping is unlikely to deliver on the promise of a paradigm shift.

Within the global health space, CHAI has often played such a role.

CHAI's approach is built on deep, active, and ongoing engagement with both the private sector and public health systems. We leverage our operations in over 35 LMICs, and our close partnerships with national, state, and local governments to strengthen public health infrastructure. Ensuring that governments are leading the implementation of the strategy enables the rapid uptake of new health products following price reductions achieved through market shaping deals. CHAI's success is also driven by our diverse capabilities and skillsets, including market analytics, business forecasting and modeling; product development and tech transfer know-how; business and manufacturing expertise, and negotiation skills.

To conduct comprehensive market shaping and drive concrete results, it is important for activist organizations to build a team with an "activist stance" and the right expertise, able to work equally on the demand and supply side of the market. This need for activist organizations to work skillfully across the supply and demand side requires them to have the following expertise.

- **Robust market analytics, forecasting capabilities, and importantly, business expertise:** the organization needs both a deep understanding of the market dynamics in LIMCs as well as executive-level industry expertise. Due to the lack of data and limited market visibility, to understand how to be successful in LIMC markets and forecast and generate demand, including how to trigger the funding to meet that demand, an organization needs to have a long-standing broad footprint in the region, and have a history of active engagement and partnering in these markets. Additionally, industry expertise is key. CHAI's team of seasoned industry experts and market analysts have the credibility needed to engage the industry at the decision-maker level whilst also working with humility, creativity, and a sense of urgency, at the service of governments to ensure that patients' and end-users' needs are met. This has enabled us to earn the trust of our partner governments.
- **Customized supply/business modeling capabilities:** once a detailed understanding of the market contexts and dynamics at play is established, then CHAI applies business and technical expertise to design business models that leverage tools and analysis, and identify appropriate market shaping interventions. These interventions span across the continuum from product development (COGS analysis, API optimization, regulatory strategy, etc.) and manufacturing (cost structure assessment, manufacturing process optimization, etc.), to commercialization (licensing/tech transfer, IP, strategic distribution partnerships, etc.), ensuring that these models will both facilitate viable and sustainable returns for manufacturers while also fully addressing the public health needs in an affordable and sustainable manner.

3 The "activist organization" role can be conducted by one organization or, if the circumstances warrant it, by a small group of activist organizations united by a shared goal.

- **Negotiation/deal-making skills:** CHAI has honed its negotiation skills over more than 150 access agreements with industry. Many companies have been "repeat customers," attesting to CHAI's ability to achieve public health goals while also generating highly valued commercial opportunities for industry. Market shaping often requires a portfolio of interconnected agreements, each addressing one or more barriers to access. The ensemble of agreements, their orchestration and coordinated execution is what delivers impact. A team of skilled negotiators, with significant business expertise, is essential to land transformational market shaping deals.
- **Ecosystem alignment and orchestration skills:** the activist organization must serve as a trusted catalyst that problem solves holistically, and serves no other interest than to address the identified, unmet, public health need. That has always been a CHAI strength. Other ecosystem actors—such as ministries of health, procurers, funders and companies—each have, or may be perceived as having, their own interests and view of a global health problem that may be restricted by their own jurisdiction, scope and/or priorities. Without an informed and trusted catalyst with an activist approach to orchestrating market interventions, the diverse actors in the marketplace may not align on the comprehensive interventions needed. Without these actors working in concert, no deal can truly succeed in achieving transformational global health outcomes.

Not all market shaping initiatives in global health have been successful, of course. Most commonly, this has been because partners focused too much on a specific financial intervention and not enough on the painstaking work of actively guiding collaboration among key actors to build alignment, generate demand for a product, and prepare to bridge from a catalytic program to a mature, self-sustaining market. Again and again, we have found that markets get stuck or develop deeply unhealthy dynamics in the absence of hands-on stewardship.

1.3 Key pillars of CHAI's approach

As CHAI has worked over the last two decades to hone a strategic approach to shaping markets, our goal has been rooted in accelerating the uptake of high-quality medicines, vaccines, and diagnostics in LMICs. Our approach to achieving this goal includes several time-tested strategies that we continue to iterate on.

Coordinating and negotiating with a complex mix of buyers and sellers

Our approach helps solve complex global health challenges by optimizing interactions between buyers and sellers, often through a portfolio of agreements negotiated across the buyers,[4] sellers, and other key actors. In global public health, the key actors are not limited to buyers (e.g., procurers) and sellers (e.g., product manufacturers), but include various other actors such as governments, donors, implementing partners, and civil society groups, whose interests often vary widely. Further, the "buyer functions" are often played by multiple actors within the global health ecosystem, adding another layer of complexity. Active orchestration of these key actors is what drives market shaping results.

Solving both supply- and demand-side problems

Our approach focuses on solving all the various demand and supply-side challenges that prevent effective access to essential health products. Beyond pricing (supply-side barrier), which is often an important factor but very rarely the only factor preventing access, other important obstacles may include regulatory or policy barriers (demand-side barriers). For instance, even if a product is made affordable, it may face market entry delays if regulatory approvals are stalled. A comprehensive market shaping strategy that addresses both

4 It is important to note that in global health, buyers are not necessarily the patients, end-users, or the program that chooses and decides to use a particular product; more often than not, the buyers are global procurers, governments, donors and/or other entities or a combination of actors. The patients, end-users and advocates are usually categorized as "civil society".

demand and supply challenges is critical to overcoming these roadblocks.

On the supply side, we collaborate with drug, diagnostics, and device manufacturers to develop viable business strategies for delivering products effectively and sustainably to LMICs. In practice, this requires our teams to identify products (existing or new, or optimally a pipeline of both) that are well suited to LMIC contexts, and then define development, licensing, regulatory, pricing, and/or commercialization opportunities for these products.

On the demand side, CHAI works with governments, healthcare providers, advocacy groups, and others to drive awareness and generate demand for the products, facilitating a smooth, accelerated market entry and scale-up. This includes helping shape normative, regulatory guidelines and policy (at the global and country levels), facilitating medical education and training for clinical staff, supporting ministries of health to design and implement product introduction and scale programs, and supporting advocacy groups to drive product awareness and demand.

Leveraging financial tools to support a paradigm shift

At times, orchestrating these supply and demand-related interventions is enough to create the conditions needed for market growth and cost savings.

However, specific financial tools are often necessary to reduce risks for buyers and sellers alike. These tools can range from volume guarantees and product development incentives to subsidies and working capital facilities. These tools work best together as part of a comprehensive strategy that addresses both supply and demand challenges. We will explore these financial tools further in Part 1, Chapter 2, section 4 of this guidebook and we provide a more in-depth look at the volume guarantee and other tools in Part 2.

Being a trusted partner

What sets CHAI apart in global health market shaping is our ability to bridge government, industry, and civil society to create sustainable solutions tailored to real-world challenges.

Our deep understanding of healthcare as a business—from product development and manufacturing to commercialization—means we engage with industry at the highest levels to negotiate deals that benefit both patients and companies. This expertise, unique for a global health organization, is driven by a team of seasoned professionals who understand the economics of healthcare and can drive impactful agreements.

Another key differentiator is our longstanding, trusted partnerships with governments. CHAI works closely with public health systems in over 35 countries, with most staff based in the countries where we work. This local presence fosters deep trust and a shared sense of urgency, making CHAI a credible and effective strategic partner. Our government-led approach ensures that the solutions we create are sustainable and scalable, empowering local health systems to drive long-term improvements beyond donor involvement.

Finally, our work as an ecosystem catalyst sets CHAI apart. We don't just align buyers and sellers; we bring together funders, governments, civil society, and industry, choreographing their roles to address both supply and demand barriers. By understanding and integrating each player's needs, CHAI delivers holistic solutions that transform health outcomes for millions.

1.4 The right enabling environment to conduct successful market shaping

Based on CHAI's active engagement with health ecosystems, and deep analysis of various products and production systems over the last 20 years, we have developed a list of factors that we believe work in combination to create the conditions for successful market shaping in global health:

1. **Market opportunity**: This means an ability to (a) increase a product's use by five-to-10-fold, (b) create a pathway to significantly reduce the product's Cost of Goods Sold (COGS), and (c) aggregate and predict demand for that product.

2. **Ecosystem catalyst**: A credible activist organization with the expertise to work on both the supply and demand sides of the market must be in play to orchestrate the different components of the market shaping strategy and the ecosystem of actors.
3. **Visible long-term stream of public sector product procurement funding**: A flow of money is needed to support a portfolio of market shaping interventions and sustain the gains over time.
4. **Political pressure**: Key actors must be actively aligned behind the product and advocating for its introduction into the market.

These factors do not operate independently and are best viewed as a high-level screening tool to gauge the feasibility and risk associated with market shaping interventions. In the largest and most impactful market shaping interventions CHAI has been involved in, all five factors played a positive enabling role.

However, for an activist organization/ecosystem catalyst, a visible long-term flow of public money and the ability to aggregate demand are likely the most important factors that create the opportunity for market shaping.

The factors listed under "market opportunity" help create a positive setting for supplier negotiations. When present, they motivate manufacturers to discuss how best to capture a market growth opportunity. CHAI also proactively explores strategies to lower product COGS[5] and total supply chain costs. If our analysis demonstrates a sustainable pathway to lower costs and prices, we initiate discussions with manufacturers to understand their current costs and the scope to enter into an agreement (an access program partnership or volume guarantees, for example) that could lower these overall product and system costs. Our aim is always to achieve "mutual benefits": increased access for the people we serve and, commercial viability and sustainability for manufacturers.

1.5 DIADS: CHAI's innovative market shaping framework

Over more than 20 years of learning and iterating on how to best shape markets, CHAI has developed a robust market shaping framework that we now call DIADS. Like the word "dyad"—which served as inspiration for our framework's name—our approach revolves around the need for simultaneous strategic focus on **two** equally important parts: supply and demand. The DIADS approach stresses the importance of looking across both sides (or halves) of the market to understand how to best design interventions that will shape it in the most impactful way.

Through this guide, we are sharing our DIADS framework in the hope that it will be useful to leaders who want to design and carry out market shaping interventions on a global scale; and those who would like to apply a tested and refined framework to accelerate the delivery of results.

We delve into the details of the framework in the following sections and provide a much more detailed and nuanced view in Part 2 of this guidebook. But, to understand the framework at the highest level, we present the five core steps here.

CHAI's DIADS market shaping framework:

1. **D**ecide if market failure exists
2. **I**dentify barriers and conditions that, if addressed, can create a competitive and sustainable market
3. **A**ctivate the market with activist organizations who align the ecosystem and orchestrate market shaping interventions
4. **D**etermine if a financial tool is needed
5. **S**cale and grow demand for the product

5 The acronym COGS stands for Cost of Goods Sold.

CHAPTER 2:

Unpacking the DIADS market shaping framework

In this section, we elaborate upon each of the steps of the DIADS market shaping framework, as they relate to our experience in global health.

2.1 D: Decide if market failure exists

Seek direct guidance from key actors to fully understand the unmet need.

It's not uncommon in LMIC healthcare settings to see donor-supplied health products, tech solutions, or tools sitting in storage facilities or on shelves, remaining tragically unused. Often, this occurs when well-meaning organizations provide what seem like effective solutions to problems without understanding the market characteristics and dynamics at play.

What works in a high-income healthcare setting often will not work in an LMIC setting. Many of the countries CHAI serves experience significant challenges with basic amenities and services such as reliable access to clean water or electricity, or repair and maintenance services for critical technology. These deficiencies complicate and slow patients' access to the healthcare system and services. Understanding the market failure(s) or problem statement from the perspective of those we serve is critical. To drive impact, the design of effective market shaping strategies and interventions must be rooted in a deep understanding of the context-specific needs and circumstances of the countries, governments, and end-users we serve.

2.2 I: Identify barriers and conditions

Thoroughly identify all barriers and preconditions to access, whether existing or anticipated

A single remaining barrier or precondition left unaddressed can often lead to failure or sub-optimal outcomes.

Figure 1 provides a non-exhaustive overview of potential barriers and preconditions within the global health space to give the reader a sense of their diversity. To be comprehensive, we look at the Key Market Dynamics as they relate to R&D, normative and regulatory issues, manufacturing and commercialization, procurement & supply management, and introduction, scale, and sustainability. Barriers and preconditions across these five categories will certainly differ for other sectors, but the high-level categories will likely be somewhat similar.

2.3 A: Activate the market

Enhance engagement across the ecosystem of actors relevant to the problem statement: identify and align all levers, formal and informal.

CHAI's approach to comprehensive market shaping utilizes its global- and country-level expertise to map out all of the actors who serve as levers within the relevant ecosystem, whether formal (those who have formal authority over certain aspects of the market such as regulators, procurers, among others) or informal (those who do not have formal authority but exert influence within the ecosystem such as patient associations, advocacy groups, etc.). CHAI then engages each actor to understand their role, in order to help address the barriers and preconditions identified.

To do so, we engage multiple partners and actors on various levels across the ecosystem, both on the supply- and demand-side. We listen closely to their specific needs and challenges to frame the problem statement and propose market shaping interventions in a way that gains buy-in.

Empowering an activist organization: engagement across the ecosystem of actors is not easy. It is time-consuming and takes significant expertise,

Figure 1: Overview of key barriers and preconditions in global health across five market dynamics

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

but is necessary to achieve transformational goals. We call this the activist approach, and, as detailed above, it needs to be led by a trusted activist organization with the right expertise, reputation, and relationships. An activist approach is critical as certain actors with similar goals may otherwise compete to the point of undermining fruitful collective action, namely the market shaping goals. Often, it is only through such activist engagement that it becomes possible to frame market shaping solutions and coordinate action in a way that aligns actors' interests, active participation, and activities. Generating transformational impact is only possible when the collective—the ensemble of key actors within an ecosystem—agrees on shared goals and a shared market shaping strategy.

Identifying the market shaping interventions to best address barriers and preconditions: once the mapping of barriers and preconditions is completed and insights from broad ecosystem engagement have been captured, attention should turn to identifying the appropriate intervention or set of interventions to address them.

CHAI has developed a menu of market shaping interventions tailored to the global health field, along the product continuum. For other sectors, the menu of interventions will need to be tailored accordingly. Coordinating and sequencing interventions is the key to accelerated outcomes, resulting in rapid market transformation and impact. Below we detail interventions to shape the Key Market Dynamics in the five categories.

Research & development

One of the considerations within the R&D realm involves the magnitude of time and/or investment involved in developing a product relative to the rate at which the market evolves, particularly in cases where innovation cycles are accelerating or likely to accelerate. The market shaper will often need to assess product development risk considering uncertainty or changing circumstances and the potential benefits. They must also consider an intervention's ability to de-risk product development accordingly.

Regulatory & normative

CHAI is globally recognized for its work supporting manufacturers to design innovative regulatory strategies that significantly expedite regulatory reviews. This leads to product approvals and market authorizations, which enables quality-assured health products get to the market faster. Commercial benefits derived from CHAI's regulatory support represent high value for companies and, as such, play an enormous role in CHAI's ability to lower costs for high-quality health products.

Figure 2: Key market dynamics during research and development

RESEARCH & DEVELOPMENT		
INTERVENTION	**DESCRIPTION**	**IMPLEMENTATION TIMEFRAME**
Target Product Profile Issuance	Convene stakeholders to define and publish lists of desired product characteristics, use cases, target populations, etc.	1-2 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 healthcare 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 subjects	3+ years
Implementation Research	Test innovations in real-world health settings to bring what works to scale	1-3 years

Figure 3: Key market dynamics during regulatory and normative strategies

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

Manufacturing & commercialization

Several parts of CHAI's cross-cutting expertise come into play as we typically deploy a range of interventions at this stage. We work to identify new lower-cost manufacturers, or support innovator access strategies, often supporting licensing and technology transfers to generic manufacturers. Our technical experts support these manufacturers through the technology transfer process while also tailoring the product or product presentation (packaging, etc.) for LMIC markets. We also help accelerate product development timelines and position the manufacturer to achieve quality-assurance through their regulatory filing strategies. Our manufacturing and process chemistry experts work with suppliers to identify opportunities to optimize production, lowering costs.

We provide product commercialization expertise, design strategic commercialization partnerships, and facilitate product introduction and scale.

By leveraging our robust market analysis and forecasting capabilities we provide to the ecosystem of actors, including the manufacturers with enhanced visibility into the market, we enable more informed decision-making and supply/risk management. This also gives manufacturers an increased level of predictability, which helps them better manage their production lines, costs, and lead times.

Our market shaping experts leverage the demand forecasts, cost of goods analysis, and dynamic production cost analysis, among others, to design business models and negotiate mutually beneficial access agreements that center on a committed access price, production capacity, dedicated capacity for LMIC markets, and other access terms. These agreements aim to serve the needs of the populations within the broadest geography possible to ensure equitable access while also ensuring the opportunity is commercially viable and sustainable for the manufacturers.

Figure 4: Key market dynamics during manufacture and commercialization

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

Procurement & supply management

To achieve lower costs for health products, CHAI's analytical teams help enhance market visibility and predictability. We provide robust demand forecasting specifically to manufacturers and work to consolidate or aggregate demand volumes. This results in larger, more predictable procurement orders. This also enables manufacturers to realize economies of scale. All of this leads to reduced production costs that translate to lower pricing for buyers and end users. Aggregating demand or pooling procurement funding or volumes are fundamental tools in the market shaping portfolio of interventions as we work to achieve affordable prices for health products in LMICs.

CHAI technical teams also support optimization and efficiency to unlock any obstacles to procuring and delivering high-quality health products. Our global and in-country teams work together to conduct market analytics and forecasting to provide buyers, procurers, supply chain actors, and other relevant actors with better market visibility and enable more informed procurement, tender, and supply chain-related decisions, thus minimizing risks.

2.4 D: Determine if a financial tool is needed

Market shaping does not always entail the use of a financial tool. They can be risky, and there is often a high transaction cost associated with their implementation. However, at times, a financial instrument is the key to unlocking an opportunity and/or catalyzing a specific desired outcome. Before deciding if developing a new financial tool is appropriate, there are several steps in Part 2 of this guidebook that you should work through.

In this section, we detail some of the most interesting financial tools that CHAI has put into practice over the years.

- **Prizes** provide financial rewards to product developers for achieving a pre-defined R&D milestone(s). The aim is to generate R&D investment in a new area or specific product class where there may be stagnation,

Figure 5: Key market dynamics during procurement and supply management

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

a lack of awareness, low-volume markets, or other bottlenecks impeding progress.

- **Development incentive grants** provide milestone-based payments to a supplier to pursue agreed upon R&D, regulatory, and/or commercial activities. These grants are effective in combination with technical assistance and pricing commitments to incentivize the accelerated development or launch of high-priority products while ensuring favorable access terms in advance.
- **Advance market commitments** involve donors committing to purchase or subsidize a minimum volume of products that meet a target product profile at an agreed-upon price once developed. This approach helps to offset the financial risk taken by developing R&D, especially for products with uncertain demand that require intensive, upfront investment.
- **Product subsidies** offer a fixed per-unit subsidy for a predefined period or quantity implemented at any point in the distribution chain. It is critical that subsidies are catalytic, i.e., that they are not a temporary market distortion following which prices will revert to their original level.
- **Volume guarantees** typically consist of a supplier's commitment to a lower price in return for a sales volume guarantee over a period of time (generally three to five years). The guarantor agrees to compensate the supplier for any sales shortfall. This type of agreement can address issues related to market visibility and demand risk, reduce prices, and accelerate the uptake of a product that falls into a "high price/low volume" market trap.
- **Procurement guarantees** are a promise to an intermediate buyer to ensure that customer payment will be received on time and in full. The guarantor takes on the risk of default. Procurement guarantees offset the risk of procurers entering longer-term or fixed purchase contracts in advance of receiving funds needed from the intended recipients.
- **Payment guarantees** are provided to a seller (e.g., supplier, service provider, etc.) to ensure customer payment will be received on time in full. The guarantor assumes the risk of default. This offsets the risk assumed by sellers as they manufacture products and incur costs on the basis of committed demand, particularly in new markets or with buyers that are perceived to carry higher levels of payment risk.
- **Working capital facilities** are low-cost loans provided to suppliers, procurers, wholesalers, and distributors to cover operational expenses/liquidity needs. As a debt-based tool, these facilities require upfront funding. They enable commercial partners to better manage day-to-day operations and can be structured in exchange for favorable terms that improve access to goods. This tool can help alleviate inventory risk for private sector actors, supporting them in maintaining higher stock levels and thereby enhancing product availability and supply security.
- **Impact investment** is financing provided to companies that aim to achieve social impact and financial return through debt, equity, or mixed instruments. Impact investments lower the cost of the capital needed to support product development and commercial activities to help enable reduced end-user pricing.
- **Regulatory incentives** are rewards for developing products for specific patient populations. They might include priority review vouchers, filing fee waivers, and tax credits. The FDA and other national regulatory authorities may offer these to encourage the development of new products (typically drugs) for a set of pre-defined neglected health areas.

Within a comprehensive market shaping strategy, the intervention(s), whether financial or not, must be well-coordinated, well-sequenced, and support a widespread execution to drive the desired transformational impact.

2.5 S: Scale and grow demand for the product

A market shaping deal is meaningless unless the negotiated product gets into the hands of the individuals who need it in a timely manner. CHAI, therefore, exerts tremendous effort to ensure that the health product in question reaches the people we serve. Leveraging our footprint in 35 countries and strong relationships with ministries of health and public health systems, we enable effective product introduction and scale while providing assurances of delivery to the last mile.

Demand generation activities are critical to any market shaping strategy and an essential element in negotiating with manufacturers to lower costs. It is by generating demand, aggregating volumes where possible, and triggering procurement funding that a market opportunity is created to the benefit of the manufacturer(s) in exchange for an affordable, quality-assured product tailored to meet the needs of LMIC populations.

Figure 6: Key market dynamics during introduction, scale, and sustainability

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 healthcare worker training 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

CHAPTER 3:

Measuring a comprehensive market shaping strategy's success

CHAI measures its market shaping success based on the health impact our work delivers: lives saved, improved health outcomes, and value for money.

At the request of our donors, to demonstrate value for money, we compare the health benefits achieved against the financial investments made by funding organizations, showing that more people can access better health products for the same or lower cost, as a result of market shaping. This has meant, in most cases, that retroactively examining the incremental savings generated and number of people having access to a health product, relative to a projected counterfactual account for price, leads to volume changes (level of access) in the absence of the market shaping intervention(s).

As market shaping evolves, we are continuously looking to improve how we measure the impact of our interventions, including enhancing our ability to better assess the cost effectiveness of market shaping.

CHAPTER 4:

Case studies: CHAI market shaping in action

To demonstrate how comprehensive market shaping strategies have been designed and executed and how the impact of such strategies has been measured, this section reviews select case studies of CHAI's comprehensive market shaping work.

4.1 TLD (Tenofovir, Lamivudine, and Dolutegravir)

The TLD market shaping strategy and execution required a concerted multi-partner effort, including LMIC governments, Unitaid, UK DFID (now UK FCDO), the Global Fund, PEPFAR, the Gates Foundation, and CHAI, among others, where each partner played an essential role. Some partners focused their resources and investments on the critical demand-side work, whilst others focused on equally important supply-side work. The key was the coordination of the partners and ensemble of various efforts required to catalyze the introduction of the best available HIV treatment to LMICs. This global success story in access to medicines is detailed below.

Notable accomplishments

- First time a new, more effective single pill, once-daily regimen, was offered in LMICs for a price lower than the product it was replacing.
- Enabled governments to achieve two often-conflicting priorities simultaneously:
  - Offering better treatment options to people living with HIV (PLHIV), and,
  - Reducing overall treatment costs to make limited budgets go further.
- Breakthrough pricing agreement in 2017 led to the introduction of TLD at US$75, a superior product at 17% savings compared to the previous standard of care of US$90.
- Today, TLD pricing has been further reduced to US$37per patient per year; this is a result of expanded access to this product and the high number of patients reached via concerted demand generation efforts, which has enabled manufacturers to achieve important economies of scale and drive further price reductions.
- Enabled rapid scale-up in more than 90 countries that had access to the negotiated price, representing over 90 percent of people in LMICs living with HIV.

- Partnership with, and tireless advocacy by, communities of people living with HIV was a powerful lever.
- **1B+ packs of TLD** distributed from 2018 to 2023. **In 2023, there were more than 23 million people in generic accessible LMICs on a DTG-based regimen.**
- US$1B+ estimated in global program savings.

Why was this product of interest for market shaping?

For PLHIV in LMICs this was a highly desirable new product. TLD isa superior drug. It suppresses the virus more quickly and does so effectively, with significantly fewer side effects providing a higher quality of life.

In addition to improving quality of life for millions of people living with HIV, the widespread use of TLD reduces the cost of HIV treatment, expanding impact.

Market overview

Any change in product mix becomes a massive undertaking, with over 19 million PLHIV in LMICs using HIV treatment drugs every day in 2017 (and almost 28 million on treatment in 2023). The purpose of the market intervention was to shift the LMIC market from the existing triple combination drug to TLD. Bringing about a shift to TLD was risky because generic firms were already selling over 100 million packs of the competitor's triple-combination product in 2017. Its costs had declined by 40 percent in the previous five years. It was already established within the health system. Meanwhile, generic firms were planning to launch TLD at 25 percent above the cost of this competitor's product to recover startup costs for producing a new drug. These circumstances were not setting up the market for a shift towards the superior TLD formulation.

Funding for HIV treatment often falls short of need. Most country programs could not accept an increase in treatment cost that might lead to fewer PLHIV receiving care. Many LMICs wanted to transition HIV treatment standards to include TLD, yet the price of the product was too high to commit to orders and a significant investment in new product rollout.

The deal

Two deals were signed one with Mylan and one with Aurobindo, which were important in assuaging concerns related to supply security. In September 2017, Mylan and Aurobindo entered into a four-year volume guarantee with the Gates Foundation that set the price for the launch of TLD at US$75 per person per year in 92 LMICs. CHAI and the Gates Foundation negotiated this volume guarantee deal in which Mylan and Aurobindo agreed to maintain sufficient capacity to serve four million PLHIV and to gradually reduce the price of TLD over the term of the agreement. The Gates Foundation agreed to cover any shortfall in demand.

Ecosystem orchestration

The agreement involved funding from the Gates Foundation, but its success resulted from coordinated efforts between a consortium of partners that CHAI helped orchestrate: donors (Unitaid, the Gates Foundation, UK DFID (now UK FCDO), global procurers (The Global Fund, USAID; partners WHO, UNAIDS), suppliers (Mylan, Aurobindo, and ViiV), national governments (including South Africa, Kenya, and others), and PLHIV advocacy groups.

The Gates Foundation guaranteed the volume commitment to secure the supply-side engagement, combined with a demand generation investment. Other donors like Unitaid and UK DFID (now UK FCDO) focused their funding on supporting successful demand-generation and introduction in-country.

Community perspective

A key lever to driving demand in the PLHIV was supporting activism from grassroots organizations. "Since the day I switched to DTG my overall health has greatly improved, and the drug has improved my quality of life," said one of the first people to use the new treatment in Kenya. "I feel reenergized; my moods are even better now. I hope that policymakers and leaders will embrace and adopt Dolutegravir since it has been shown to be superior to many ARVs currently in our clinics. We need DTG now more than ever in Africa."

4.2 Long-acting reversible contraceptive implants

The long-acting reversible contraceptive implants market shaping efforts were orchestrated by CHAI and involved various partners, from LMIC governments to donors such as UK DFID (now UK FCDO) and the Gates Foundation, among others, to a number of other partners including global procurers and implementing partners. These aligned efforts conducted both on the demand and supply-side successfully catalyzed the rapid scale-up of long-acting reversible contraceptive implants in LMICs, serving a significant unmet demand-side need and leading to more than US$450 million in savings.

Unmet need

Access to modern methods of contraception empowers families with essential reproductive health choices. Of the widely available family planning methods, three- and five-year contraceptive implants are among the most highly effective at preventing pregnancy and are well-suited to meet the needs of many women and health systems in LMICs. Despite the efficacy, quality, and availability of implants, evidence from demographic and health surveys showed a significant unmet demand for this method.

Trigger to shape the market for LARCs

In 2012, the United Kingdom requested CHAI's assistance to support ongoing discussions with implant manufacturers and explore opportunity for a price reduction. CHAI's initial analysis indicated that the cost of producing implants was much lower than the selling price for these products at the time, with Bayer selling Jadelle for US$18/unit and Merck selling Implanon for US$16.50/unit. These findings suggested that price reductions could potentially be achieved with appropriate market shaping interventions.

Understanding the barriers

Discussions with major manufacturers, buyers, and implementing partners in LMICs not only helped CHAI determine the scope for reducing prices and expanding the uptake of contraceptive implants but also identified the following barriers.

- Usage was low due to high upfront costs, frequent and prolonged stock outs, and shortages of trained healthcare workers to insert and remove implants.
- The market was in a counter-productive cycle of procurement of low volumes and unpredictable demand leading to high prices and low investment in capacity and innovation.
- Ministries of health and partners could not purchase additional implants due to the high prices.

A deep dive into the market dynamics

To take on this global challenge, CHAI worked with partners to conduct analyses to forecast implant demand and confirm the market's growth potential. The analysis found that the global implant demand could reach approximately nine million units/year by 2015, potentially expanding to 11 million by 2020. In fact, demand reached 13.5 million by 2020.

Production costs were not optimized for a variety of reasons: uncoordinated and uncertain ordering patterns, various labeling and packaging configurations, and underutilization of available capacity. In discussions with manufacturers, CHAI then identified steps that could be taken by procurers and funders to reduce overall costs based on a potential volume increase. Standardization of product packaging requirements and coordinated procurement were identified as key steps toward manufacturer production cost optimization and price reductions.

The deal

In concert with partner demand generation investments, CHAI worked with the Gates Foundation on a volume guarantee mechanism to achieve significant price reductions for the implant products. The following activities were critical to the execution of the implants market shaping strategy:

- Engaged various donors to participate in the volume guarantee partnership.
- Identified guarantors to provide financial backing to the volume guarantee via sharing of risk with the Gates Foundation.
- Negotiated a volume guarantee-based price reduction agreement with manufacturers. An agreement was negotiated with both Bayer and Merck to reduce prices to US$8.50/unit in return for commitments to purchase certain volume levels over a period of six years. Bayer agreed to the VG deal in mid-2012; Merck agreed in early 2013.
- Key demand-generation investments were supported by another group of donors. These were critical to achieve the committed volumes.
- Aligning the ecosystem of partners.

In Q3 2012, the price of Jadelle (Bayer) was reduced from US$18/unit down to US$8.50/unit. In 2013, Implanon (Merck) pricing was reduced from US$16.50/unit down to US$8.50/unit. These agreements delivered procurement savings exceeding US$450 million over the six years of the agreement, freeing up funding that enabled LMIC governments to increase their service delivery and capacity. This made implants one of the most cost-effective methods of contraception available.

Additional impact

After the deal announcements Bayer and Merck, along with their respective guarantors, procurers, donors, and implementing partners came together to establish the Implant Access Program. This group helped manage issues expediently, support target markets to increase access and grow demand. It also ensured that a consistent supply of implants would be available to meet the demand for all 69 countries prioritized by Family Planning 2020, a global partnership to expand access to family planning information, services, and supplies.

The Implant Access Program forecasted that the program would avert more than 31 million unintended pregnancies over the years of the agreement and avert over 414,000 child deaths and 41,000 maternal deaths. The pricing deal created a virtuous cycle of reinforcing country-level demand and donor funding commitment, ultimately allowing the market to reach and exceed the forecasted potential.

Over the program's first two years, the market volumes exceeded the guaranteed volume threshold agreed upon in the VG, and expanded the range of available contraceptive options beyond short-acting methods and helped meet the growing demand for long-acting contraception in LMICs.

Later, in 2015, CHAI worked alongside other partners, including FHI360, to support another company, Shanghai Dahua Pharmaceuticals Co Ltd, to develop and bring to market a generic contraceptive implant product at a lower cost of US$6.90 per unit, ensuring stable supply security and continuous competitive pressure to maintain the access pricing for all implants. The deal volumes were met every year of the guarantee, the price was maintained beyond the

end of the guarantee, and procurement volumes increased during each of the six years.

On the demand side, additional countries requested CHAI's support to increase access to implants and family planning more broadly. Working alongside partners, CHAI continued to provide support to accelerate scale-up in countries already accessing the deals and supported the scale-up of Levoplant, the new product manufactured by Shanghai Dahua Pharmaceutical once it entered the market.

4.3 Hepatitis C therapeutics

Another example that illustrates the multi-faceted nature of comprehensive market shaping is the effort to improve health outcomes for people living with hepatitis C virus (HCV) in LMICs. The HCV market story offers both caution and hope. Rwanda's success proved that elimination is achievable when leadership, financing, and affordability converge. Yet, the collapse of the 2023 pricing deal warns that without a clear focus on generating sustainable demand, even the best negotiated prices cannot scale and maintain access.

Background

In 2015, over 70 million people were living with chronic HCV, more than 80 percent of whom were living in LMICs. With 400,000 deaths and 1.8 million new infections each year, access to testing and treatment remained scarce, and care was largely confined to the private sector.

Before 2013, treatment relied on injectable interferon and oral ribavirin—costing over US$3,000 per course, with severe side effects and cure rates below 50 percent—making it unviable for LMIC health systems. The approval of all-oral, highly effective direct-acting antivirals (DAAs) transformed this landscape. Sofosbuvir (SOF) and daclatasvir (DCV) offered a simple, 12-week oral regimen with cure rates above 95 percent, eliminating the need for injections or cold-chain storage.

Yet major barriers persisted: DAAs were not yet included in WHO or national guidelines, lacked regulatory approval, and remained under patent, keeping prices near US$750 per course—far beyond most LMIC budgets. Limited funding, weak clinical capacity, and low awareness further constrained uptake.

In 2014, Gilead Sciences licensed Indian generic manufacturers to supply sofosbuvir (SOF) to 91 LMICs—covering over half the global infected population. Yet without a coordinated market-shaping approach inclusive of financing and demand creation investments at the national level, access remained limited.

These conditions highlighted the need for a comprehensive approach linking affordable supply with country-led implementation, laying the groundwork for CHAI's efforts to catalyze access, strengthen public delivery models, and demonstrate that elimination was achievable.

Building an affordable market by increasing demand

In 2016, CHAI launched the HCV Quick Start Program in partnership with Duke University and Bristol Myers Squibb to demonstrate that HCV could be diagnosed and cured through public sector–led programs in LMICs. The initiative focused on addressing both supply- and demand-side barriers simultaneously.

On the supply side, CHAI first negotiated with Bristol Myers Squibb to license daclatasvir (DCV) through the Medicines Patent Pool to allow for accelerated generic entry. 1.5 million donated doses were also secured to catalyze the ecosystem and accelerate market entry. Concurrently, CHAI worked alongside the generic licensees to develop and register affordable formulations of sofosbuvir (SOF) and DCV, achieving substantial cost reductions. Diagnostic prices were also negotiated downward to enable testing scale-up.

On the demand side, CHAI worked with WHO and ministries of health to develop national guidelines, integrate HCV care into existing health programs, train clinical providers, strengthen monitoring systems, and initiate treatment programs in seven countries. These early efforts proved that a simplified public health approach could achieve high cure rates at dramatically lower costs.

Aligning supply and demand: Rwanda's breakthrough

In 2018, Rwanda made history as the first country in sub-Saharan Africa to launch a national HCV elimination program. With an estimated four percent of its population living with chronic HCV, the Rwandan Ministry of Health committed to treat 112,000 patients between 2019 and 2024—backed by strong political will, domestic financing, and strategic partnerships.

To enable this vision, CHAI helped the government negotiate a landmark US$60 price for a 12-week WHO-prequalified sofosbuvir/daclatasvir (SOF/DCV) treatment course—bringing the total cost per cure, including diagnostics, to under US$80. This breakthrough set a new global benchmark and enabled rapid price reductions worldwide: the Global Fund adopted an US$80 procurement price, Nasarawa State in Nigeria secured the same US$60 deal, and Indonesia achieved an 85 percent price cut. And set the stage for a new global pricing agreement.

Rwanda's success showed the power of aligning supply, financing, and delivery capacity. The government mobilized over US$5 million in domestic funds, integrated HCV care into existing HIV and primary health platforms and rapidly scaled national services.

Key results included:

- 1,500 healthcare workers trained;
- Expanded hepatitis C care to over 500 facilities;
- 7 million people screened; and
- Over 60,000 patients treated, with cure rates above 95 percent.

Rwanda proved that elimination was not just aspirational—but achievable. By combining political leadership, domestic investment, and affordable access, it established a model for elimination of HCV that continues to inspire global efforts.

The 2023 global pricing agreement: lessons from a broken market

Building on Rwanda's success, CHAI and The Hepatitis Fund (THF) sought to extend this access pricing globally. In 2023, we partnered with two leading generic suppliers—Viatris and Hetero—to establish a global ceiling price of US$60 per treatment course for all LMICs.

To operationalize this, THF committed to a soft volume guarantee equivalent to 16,000 treatment courses to catalyze procurement. The deal enabled any government or global buyer, including the Global Fund, to access treatment at the same low

price. This was intended to unlock demand and market stability.

However, even though the global pricing agreement had generated breakthrough pricing for a product with a 95% cure rate, the HCV market shaping strategy ultimately failed to deliver on its promise due to demand-side failures, including:

- **Funding gaps**: anticipated commitments made, including during a resource mobilization conference organized for that purpose, did not materialize, preventing fulfillment of the volume guarantee.
- **Fragmented procurement**: key procurers were unable or unwilling to align processes, reducing the ability to aggregate demand and obstructing demand visibility.
- **Supplier disincentives**: with low uptake and limited orders, and lack of ecosystem commitment, manufacturers deprioritized HCV production relative to higher-volume products, to ensure business viability and continuity.
- **Operational limitations**: the global deal required country-level coordination and advocacy to drive uptake, but resources for this were insufficient.

By late 2024, both Viatris and Hetero had withdrawn. This demonstrated fundamental lessons. First, one needs an effective mechanism to catalyze and coordinate the ecosystem. But critically one also needs appropriate demand generation investments to ensure predictable and sustainable demand. Finally, without financing and market stewardship, affordable supply cannot be scaled and sustained. So, despite achieving the lowest-ever WHO-prequalified curative treatment price, price alone does not guarantee access.

The contrasting outcomes of Rwanda's successful coordinated approach and the global market shaping approach revealed a core lesson in market shaping: affordability alone cannot sustain access. Rwanda proved that when government leadership, ecosystem coordination, financing, and delivery capacity align, affordable pricing can translate into concrete, significant population-level impact. In contrast, the collapse of the global pricing deal underscores the need to pair supply-side achievements with robust demand generation, predictable financing, ecosystem alignment and integration of HCV services into broader health systems to sustain progress toward elimination.

CHAPTER 5:

Conclusions

For market shaping to be successful—and truly transformative—it must be orchestrated by an organization willing to act as an activist convener, applying a comprehensive approach that brings equal focus to both supply- and demand-side interventions. It must also catalyze the full ecosystem of actors needed to drive results. CHAI's 20-year track record of delivering paradigm-shifting progress in global health demonstrates the power of such principled, end-to-end market shaping.

This model delivered extraordinary impact over the last two decades, laying the foundation for today's access landscape. Its core principles are more relevant than ever. In donor-financed markets, where CHAI continues to work alongside global health institutions to shape markets, driving dramatic price reductions and expanding access to lifesaving commodities through centralized procurement, volume aggregation and targeted use of tools like product development technical assistance and incentives as well as volume guarantees, among others. At the same time, as market context become increasingly complex, fragmented and cost-sensitive, CHAI is innovating, developing evolved market shaping strategies comprising new integrated, sustainable models for financing and delivering health products, rooted in these core principles, to support national governments expand equitable access even as they take on domestically a far greater share of their country's procurement of health commodities. Yet, even as the tectonic plates shift, the measure of success remains constant: how many lives have been saved or significantly improved as a result of market shaping.

The impact of CHAI's market shaping work, past and present, is clear. It is reflected not only in global market shifts, but most importantly in the millions of people in LMICs who are alive today—and the many more whose quality of life has dramatically improved—because essential diagnostics and medicines were made available, affordable, equitably accessible through market shaping. That is, and will always remain, the truest measure of success.

This raises two important questions: how can market shaping be more widely applied across sectors? And why has its use remained concentrated in global health, despite its demonstrated power?

While there are notable success stories—particularly in global health—much of the potential of market shaping remains unrealized. As detailed in this guidebook, comprehensive market shaping can have transformative impact in addressing complex, market-based challenges across sectors far beyond health.

In global health, some of the most effective market shaping interventions have occurred in markets where products already existed but had not yet reached scale. These actions—ranging from catalyzing product reformulation to securing sustainable price reductions—have enabled rapid adoption of better technologies and delivered substantial improvements in health outcomes. With funding often scarce, stakeholders have prioritized interventions that maximize both impact and value for money—further reinforcing market shaping as a smart, efficient strategy.

As complex global challenges across sectors persist, the need for powerful, cost-efficient tools to reshape markets has never been more urgent. Comprehensive market shaping—as outlined in this guidebook—can play a pivotal role in accelerating the high-cost transitions underway in a diverse set of industries, from heavy manufacturing to technology-driven sectors. And as CHAI continues to innovate and advance market shaping to respond to the changing tides, we will publish details on how the model evolves.

While breakthrough solutions already exist or are rapidly emerging, their deployment is too often constrained by assumptions about long-term costs, market readiness, or feasibility—assumptions

that are frequently outdated or incorrect. Market shaping can help unlock the pathways to scale and affordability, just as it has done in health, ensuring that essential innovations reach the markets and people who need them most.

History shows that what once seemed impossible—from affordable AIDS and malaria treatments to low-cost vaccines, prevention products, diagnostics, semiconductors, and optical communications—can become reality through deliberate, collaborative, market shaping interventions. Millions of lives attest to what happens when affordability and access barriers are dismantled.

We should not allow skepticism to deter organizations, funders, and investors from applying these proven tools to other complex global problems.

Part 2

A practitioner's guide to designing and executing key financial market shaping interventions

CHAPTER 1:

Delving into the CHAI's DIADS market shaping framework

Part 2 of this guidebook is specifically for practitioners who would like to apply a tested and refined market shaping framework to accelerate the delivery of results.

We delve much further into the details of CHAI's framework in the following sections, and for an even more nuanced view, we provide a step-by-step approach to negotiating a volume guarantee (VG).

CHAI's DIADS market shaping framework

CHAI has developed a robust market shaping framework that we call DIADS. Like the word "dyad"—which inspired our framework's name—our approach revolves around the simultaneous strategic focus on two equally important parts: supply and demand. The DIADS approach stresses that an activist organization needs to be playing a catalyst role. It must work across both sides of the market to understand how to best design interventions—non-financial and financial—that will shape it in the most impactful way, while aligning the ecosystem of actors towards a shared goal.

1. **D**ecide if market failure exists
2. **I**dentify barriers and conditions that, if addressed, can create a competitive and sustainable market
3. **A**ctivate the market with activist organizations who align the ecosystem and orchestrate market shaping interventions
4. **D**etermine if a financial tool is needed
5. **S**cale and grow demand for the product

Unpacking the framework

Figure 7 and Figure 8 represent the framework at a glance. In this section, we delve into the details of the 5 components of the framework and provide nuances in the context of our global health experience in summary, the following are the main activities that must occur sequentially to yield results.

Figure 7

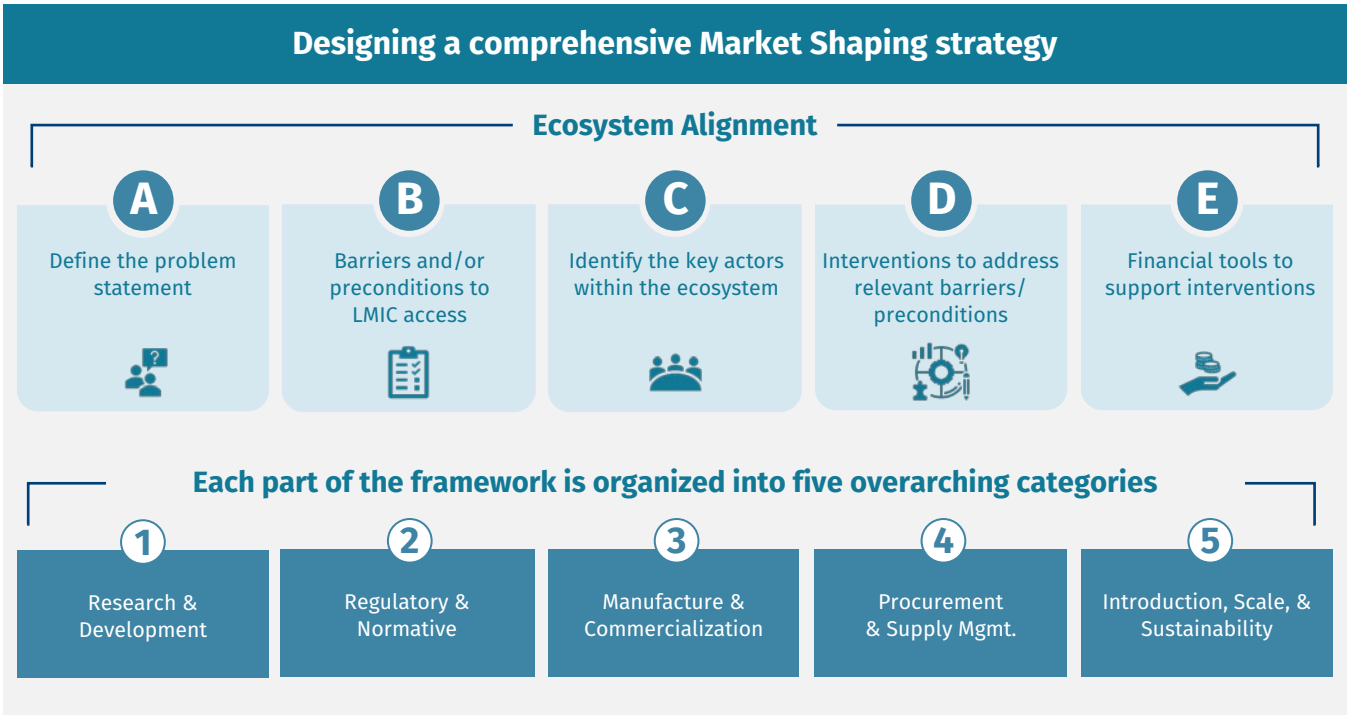


Figure 8

How to use the Market Shaping Framework	
Step 0	**DEFINE THE PUBLIC HEALTH PROBLEM THAT NEEDS TO BE SOLVED** Seek direct guidance from the end users to fully understand the unmet need.
Step 1	**MAP OUT EXISTING AND ANTICIPATED BARRIERS/PRECONDITIONS TO ACCESS FOR THE PRODUCT/SERVICE** Thoroughly identify all barriers and preconditions to access, whether existing or anticipated
Step 2	**IDENTIFY AND ALIGN THE KEY ACTORS WITHIN THE ECOSYSTEM** Enhance visibility and engagement across the ecosystem relevant to the problem statement, identifying and aligning all levers, formal and informal.
Step 3	**IDENTIFY THE INTERVENTIONS THAT CAN ADDRESS THE BARRIERS/PRECONDITIONS FOR THE PRODUCT/SERVICE** There may be a need to engage in one or multiple stages of the continuum, based on the barriers and preconditions identified
Step 4	**DETERMINE WHETHER A FINANCIAL TOOL IS CRITICAL TO SUCCESSFULLY IMPLEMENT THE INTERVENTIONS**

1.1 D: Decide if market failure exists

Seek direct guidance from key actors to fully understand the problem that needs to be solved, the unmet need, leveraging on-the-ground & global market intelligence.

It's not uncommon in LMIC healthcare settings to see donor-supplied health products, tech solutions, or tools sitting in storage facilities or on shelves, remaining tragically unused. Often, this occurs when well-meaning organizations provided what seemed like effective solutions to problems without understanding the market characteristics and dynamics at play. What works in a high-income healthcare setting often will not work in an LMIC setting. Many countries CHAI serves experience significant challenges with basic amenities and services such as reliable access to clean water or electricity, or repair and maintenance services for critical technology. These deficiencies complicate and slow patients' access to the healthcare system and services. Understanding the market failure (s) and problem statement from the perspective of those we serve is critical. To drive impact, the design of effective market shaping strategies and interventions must be rooted in a deep understanding of the context-specific needs and circumstances of the countries, governments and end-users we serve.

CHAI has established trusted relationships with government partners, and patient user groups over our more than two decades of service to them. Earning their trust took time, a demonstration of genuine commitment to sustainable solutions, and consistent delivery of measurable results. We also have established trust-based relationships with pharmaceutical and diagnostics companies. We actively cultivate these relationships and make every effort to understand their business, enabling CHAI to engage with them directly and quickly when needed and seek their partnership in developing and commercializing prioritized products.

CHAI services unmet needs, market-based opportunities, inefficiencies within health systems, and bottlenecks to access by providing support to

Questions to Consider:

- Does the identified product align with priorities of the key actor(s) in the ecosystem? In global health this would include governments, for example.
- What is the position of other relevant actors/levers within the space?
- To what extent can the product or service address the problem?

our country partners at a variety of touchpoints. Our team of clinicians supports and learns from in-country doctors, nurses, community health workers, and civil society.[6] This is one of the ways we identify unmet needs. Our team of pharmaceutical experts learn from public and private pharmacies which products are being sought by end users, whether they are being used appropriately, and how much patients can pay for certain types of tests and treatments. This is one of the ways we surface market opportunities. Our analysts work with or within ministries of health, alongside local program managers to understand procurement and supply obstacles, how current processes work, and how they may be streamlined and enhanced. This is one of the ways we determine inefficiencies within health systems. CHAI's regulatory and policy experts engage both at county and global levels to better understand how to accelerate product approval in specific country settings. This is one of the ways we identify bottlenecks to access. Together, our country teams, where the majority of CHAI staff reside, and our global cross-cutting teams gain valuable insights directly from the countries we serve as well as from relevant global stakeholders, enabling CHAI to define the problem statement accurately. This is key to designing the right market shaping interventions.

Another important consideration in many of our program areas is the involvement of civil society leaders to better understand user preferences, gather consensus around specific needs, issues and products and drive awareness. Understanding public opinion, and the social and cultural environment

6 Civil society represents patients, end-users, and advocates.

surrounding certain diseases and/or health areas are critical as it can influence how a public health problem is defined in a country, how the solution is designed, and importantly, how to drive or thwart demand for a certain solution.

Beyond this, CHAI actively participates in global health forums and engages with thought leaders across various disease and program areas to discuss the latest product innovations, clinical studies, and findings in the ever-evolving field of global public health. This may lead to newly discovered public health problems that require a solution, or new innovations that drive new or expanded opportunities to better serve LMIC populations and address their specific needs. Once the intelligence has been gathered, the goal is to integrate insights from the ground with input at the global level to define the problem or opportunity and take the next step toward designing an appropriate market shaping strategy to drive transformational impact.

1.2 I: Identify barriers and conditions

Questions to Consider:

- Which barriers are directly affecting the market for the product or service in question? To what degree?
- Are there foreseeable future challenges or barriers that should be prepared for?

Thoroughly identify all barriers and preconditions to access the product and/or service, whether existing or anticipated.

A single remaining barrier or condition, left unaddressed, can often lead to failure or sub-optimal outcomes.

Figure 9 provides a non-exhaustive overview of potential barriers and preconditions within the global health space to give the reader a sense of their diversity. These barriers and preconditions will certainly differ for other sectors, but the high-level categories are likely to be somewhat similar.

1.3 A: Activate the market

Questions to Consider:

- Are there demand-side parties beyond the obvious?
  - Multiple tiers of government?
  - Private sector providers and customers?
  - Civil society organizers or activists?
- Are there supply-side parties beyond the obvious?
- Who controls each aspect of the supply chain? What are their needs?
- Are there overarching governing bodies or multilateral organizations offering relevant guidance and recommendations?

Actively engage across the ecosystem of actors relevant to the problem statement and identify and align all levers, formal and informal, to successfully orchestrate market shaping interventions.

Ecosystem alignment: CHAI's approach to comprehensive market shaping utilizes its global- and country-level expertise to map out all of the actors who serve as levers within the relevant ecosystem, whether formal (those who have formal authority over certain aspects of the market such as regulators, procurers, among others) or informal (those who do not have formal authority but exert influence within the ecosystem such as patient associations, advocacy groups, etc.), and then engage them to understand what role each of those actors could play to help address the barriers and preconditions identified.

To do so, we actively engage with multiple partners and actors on various levels across the ecosystem, both on the supply and demand side, to understand their roles, goals, and interests. We listen closely to their specific needs and challenges to frame the problem statement and propose market shaping interventions in a way that gains buy-in. Engagement across the ecosystem of actors is not easy. It is time-consuming and takes significant expertise, but it is necessary to achieve transformational goals. We call this the activist approach. An activist approach is critical as certain actors with similar goals may

otherwise compete with each other to the point of undermining fruitful collective action, namely the market shaping goals. Often, it is only through such activist engagement that it becomes possible to frame market shaping solutions and coordinate action in a way that will align actors' interests and active participation and ensure aligned activities. Generating transformational impact is only possible when the collective—the ensemble of key actors within an ecosystem—agrees on shared goals and a shared market shaping strategy.

Identify and conduct market interventions that can most effectively address the barriers/conditions. There may be a need to engage at one or multiple stages of the product continuum, from development to delivery, based on the barriers and conditions identified.

Questions to Consider:

- Will **ALL** current and future critical barriers and preconditions be addressed by an intervention or suite of interventions? Most market shaping strategies involve multiple interventions.

Once barriers and conditions have been mapped and insights from broad ecosystem engagement have been captured, attention should turn to identifying the appropriate intervention or set of interventions to address them. CHAI has developed a menu of market shaping interventions along the product continuum tailored to the global health field. The menu of interventions will need

Figure 9: Overview of potential barriers and preconditions in global health, highlighting their diversity and broader relevance across sectors

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

to be tailored for other sectors. Coordinating and sequencing interventions is the key to accelerated outcomes, resulting in rapid market transformation and impact.

Research & development

Many interventions at this stage are suited to CHAI's capabilities, while others are best deployed in partnership with, or entirely independently by technical experts. Such is the case with clinical studies. CHAI's convening power can be useful in forming collaborations to launch clinical trials with research institutions, which could then be appropriate to support regulatory filings. One of the considerations within the R&D realm involves the magnitude of time and/or investment involved in developing a product relative to the rate at which the market evolves, particularly in cases where innovation cycles are accelerating or likely to accelerate. The market shaper will need to assess product development risk, considering uncertainty or changing circumstances and the potential benefits, and think through an intervention's ability to de-risk product development accordingly.

Figure 10: Key interventions to enhance research and development efficiency

RESEARCH & DEVELOPMENT		
INTERVENTION	**DESCRIPTION**	**IMPLEMENTATION TIMEFRAME**
Target Product Profile Issuance	Convene stakeholders to define and publish lists of desired product characteristics, use cases, target populations, etc.	1-2 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 healthcare 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 subjects	3+ years
Implementation Research	Test innovations in real-world health settings to bring what works to scale	1-3 years

Regulatory & normative

CHAI is globally recognized for its work supporting manufacturers to design innovative regulatory strategies that significantly expedite regulatory reviews. This leads to product approvals and market authorizations, enabling quality-assured health products to reach markets faster. Commercial benefits derived from CHAI's regulatory support represent high value for companies and play an enormous role in CHAI's ability to lower costs for high-quality health products. CHAI recognizes the importance of advising on a company's portfolio and the need to develop fit-for-purpose strategies around a targeted product or Stock Keeping Unit (SKU).[7]

CHAI's clinical and in-country teams also work to support the inclusion of target products into relevant global and local guidelines, formularies and essential medicines lists (EMLs), as this is a key factor in generating demand for the product.

Figure 11: Key interventions to enhance regulatory and normative timeline efficiency

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

7 Stock Keeping Unit or SKU is a unique alphanumeric code assigned to each product or variant within a company's portfolio or inventory.

Manufacturing & commercialization

Several of CHAI's cross-cutting experts come into play as we typically deploy a range of interventions at this stage. We work to identify new lower-cost manufacturers and support mechanisms such as the Medicines Patent Pool (MPP) or direct voluntary licensing, where the innovator licenses a product to specific generic companies to accelerate the LMIC market entry of more affordable high-quality health products. In some cases, we support innovator access strategies.

Our technical experts support manufacturers through the technology transfer process, tailor the product or product presentation (packaging, etc.) for LMIC markets, accelerate product development timelines, and position the manufacturers to achieve quality-assurance through their regulatory filing strategies as noted above.

Our manufacturing and process chemistry experts work with suppliers to identify opportunities to optimize production and, therefore, lower costs. We provide product commercialization expertise and design strategic commercialization partnerships to accelerate time to market and facilitate product introduction and scale. By leveraging our robust market analysis and forecasting capabilities, we provide the ecosystem of actors, including the manufacturers, with enhanced visibility into the market. This enables more informed decision-making and supply and risk management, while also providing manufacturers with an increased level of predictability, helping them to better manage their production lines, lead times, and production costs. Our market shaping experts leverage the demand forecasts, cost of goods analysis, and dynamic production cost analysis, among others, to design business models and negotiate mutually beneficial access agreements that center on a committed access price, production capacity, dedicated capacity for LMIC markets, and other access terms. These agreements aim to serve the needs of the populations within the broadest geography possible to ensure equitable access, whilst also ensuring that the opportunity is commercially viable and sustainable for manufacturers.

Figure 12: Key interventions to enhance manufacture and commercialization efficiency

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

Procurement & supply management

To achieve lower costs for health products, CHAI's analytical teams help enhance market visibility and predictability by providing robust demand forecasting specifically to manufacturers. They also work to consolidate or aggregate demand volumes, resulting in larger, more predictable procurement orders and enabling manufacturers to realize economies of scale. This then leads to reduced production costs that translate into lower pricing for buyers and end users. Aggregating demand or pooling procurement funding or volumes are fundamental tools in the market shaping portfolio of interventions as we work to achieve affordable prices for health products in LMICs.

CHAI technical teams also support procurement, tender, and supply chain optimization and efficiency to unlock obstacles to the procurement and delivery of high-quality health products. Our global and in-country teams also work together to conduct market analytics and forecasting to provide buyers, procurers, supply chain actors, and other relevant actors with better market visibility and enable more informed procurement, tender, and supply chain-related decisions, thus minimizing risk.

Figure 13: Key interventions to enhance procurement and supply management efficiency

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

1.4 D: Decide if a financial tool is needed

Determine if a financial tool is critical to successfully implement the market shaping interventions, and if so, which one is best suited to achieve the shared goal.

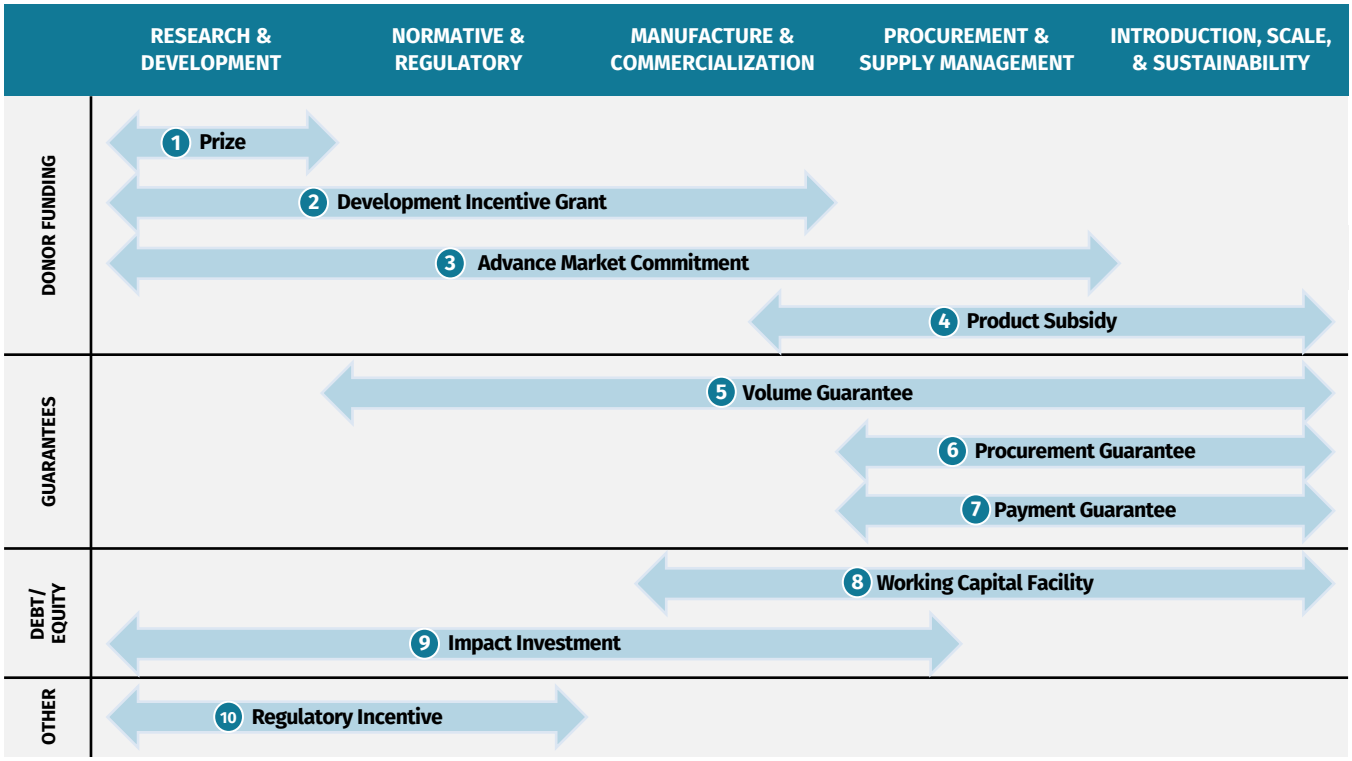
Financial tools can be risky, and there is often a high transaction cost associated with their implementation. By drawing a complete, exhaustive map of the obstacles and requirements that prevent end-users from accessing a product, you may uncover opportunities to improve access that don't require additional financial investment. However, a financial instrument is sometimes the key to unlocking an opportunity and/or catalyzing a specific desired outcome. The following conditions should be satisfied, and materials be in place prior to proceeding with financial tool development and execution:

- A **compelling case for the product/service** in direct user impact, lives saved, and/or savings, 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 for procurement of the product/service and**

Consider:

- If a financial tool is critical to moving forward, develop a shortlist of options based on the sequencing/timing of utilizing the tool or set of tools and the type/magnitude of financing required.

Figure 14: Financing and incentives across the product lifecycle



technical assistance needed to address any other critical barriers/preconditions

- **Sufficient lead time** and resources to conduct due diligence and execute the agreement

Various tools may be available across the product continuum if these conditions are met. CHAI has found that some tools deliver far higher value and more sustainable impact than others.

Prizes provide financial rewards to product developers for achieving a pre-defined R&D milestone(s). The aim is to generate R&D investment in a new area or specific product class where there may be stagnation, a lack of awareness, low-volume markets, or other bottlenecks impeding progress. For the prize to succeed, characteristics of the target solution should be clearly defined and, ideally, demand for the target solution should be ascertained with reasonable confidence.

Prizes that are small in scale will likely not solve major unmet market needs. However, if we consider larger prizes in combination with other tools such as a VG, this could perhaps, collectively serve as an evolving AMC—signaling that innovation is still needed even in the context of the deployment of a VG. A VG in this context would likely have a very different risk profile than the VGs' discussed below and would need to be sequenced appropriately to address some of the risks.

Development incentive grants provide milestone-based payments to a supplier to pursue agreed-upon R&D, regulatory, and/or commercial activities. These grants are effective in combination with technical assistance and pricing commitments to incentivize the accelerated development or launch of high-priority products while ensuring favorable access terms in advance (access price, dedicated LMIC supply, quality assurance, supply quantities, etc.). This is an intervention that CHAI leverages often and can be designed to serve a similar purpose as small prize schemes but with notable advantages.

With an **advanced market commitment**, donors commit to purchasing or subsidizing a minimum volume of products that meet a target product profile at an agreed-upon price once developed. This approach helps to offset the financial risk taken by developing R&D, especially for products with uncertain demand that require intensive, upfront investment. AMCs can be difficult to design and often require very substantial funding to create appropriate incentives, typically hundreds of millions of dollars. It would be interesting to consider creatively designing AMCs to optimize cost.

AMCs, however, and other tools such as VGs do not obviate the need for a large demand-side investment to be made in tandem. This ensures that a product developed and registered via a prize or development incentive mechanism is actually procured, ultimately delivered to targeted recipients, and achieves the desired benefits.

Arguably, AMCs can act similarly to the way VGs do in health areas where bilateral or multilateral agencies provide large, predictable funding (e.g., GFATM and PEPFAR in the context of HIV). However, the absence of stable programmatic demand can increase the risk that AMC-related procurement does not reach the intended end-users post-purchase, underpinning the need for significant demand-side investment to ensure an AMC's success.

Product subsidies offer a fixed per-unit subsidy for a predefined period or quantity implemented at any point in the distribution chain. It is critical that subsidies be catalytic, i.e., that they are not a temporary market distortion following which prices will revert to their original level.

A product subsidy can include short-term donations for "catalytic procurement." This tool reduces product costs to catalyze adoption and uptake in target markets (or via target channels) while also accelerating product commercialization at the manufacturer level post-approval. It can also support and validate demand generation activities, and accelerate timelines to achieving longer-term, sustainable lower prices.

Typically, a **volume guarantee** consists of a supplier's commitment to a lower price in return for a sales volume guarantee over generally three to five years; the guarantor agrees to compensate the supplier for any sales shortfall. This type of agreement can address market visibility and demand risk issues, reduce prices, and accelerate

the uptake of a product that falls into a "high price/low volume" market trap. By increasing production capacity, VGs also improve the sustainability and security of supply and, thereby, lower costs due to scale efficiencies. They can be attractive to donors and/or investors because of their inherent leverage: if well designed and executed, committed sales volumes are realized (or mostly realized) by buyers within the market and, therefore, the guarantor's financial outlay is minimal. For example, they are not required to buy the product. Like other financial instruments, though, the VG alone is inadequate to achieve broad market shaping goals; it must be combined with investments to generate and scale demand for the product. Without a nuanced understanding of the demand side of the market and appropriately designed demand-side interventions, the VG is unlikely to meet the desired outcome and impact.

The VG is a signature CHAI intervention. It is a tool that can also galvanize the ecosystem of actors in support of shared market shaping goals. We elaborate more deeply on this financial instrument in Chapter 3 of this guidebook.

Procurement guarantees are a promise to an intermediate buyer to ensure that customer payment will be received on time and in full. The guarantor takes on the risk of default. Procurement guarantees offset the risk of procurers entering longer-term or fixed purchase contracts in advance of receiving funds needed from the intended recipients. This scenario is particularly common in global health where procurers such as UNICEF and the Global Fund function as intermediary procurers on behalf of LMIC public health programs. Again, as financial outlay from the guarantor is conditional upon default, it can be an attractive option for donors.

Payment guarantees are provided to a seller (e.g., supplier, service provider, etc.) to ensure customer payment will be received on time in full; the guarantor assumes the risk of default. This offsets the risk assumed by sellers as they manufacture products and incur costs based on committed demand, particularly in new markets or with buyers that are perceived to carry higher levels of payment risk.

Working capital facilities are low-cost loans provided to suppliers, procurers, wholesalers, and distributors to cover operational expenses/liquidity needs. As a debt-based tool, these facilities require upfront funding, unlike other market shaping tools described above. They enable commercial partners to better manage day-to-day operations and can be structured in exchange for favorable terms that improve access to goods. This tool can help alleviate inventory risk for private sector actors, supporting them in maintaining higher stock levels and thereby enhancing product availability and supply security.

Impact investment is financing provided to companies that aim to achieve social impact and financial return in the form of debt, equity, or mixed instruments. Impact investments lower the cost of the capital needed to support product development and commercial activities to help enable reduced end-user pricing.

Finally, **regulatory incentives** are rewards for developing products for specific patient populations. They might include priority review vouchers, filing fee waivers, tax credits, etc. The FDA and other national regulatory authorities may offer these to encourage the development of new products (typically drugs) for a set of pre-defined neglected health areas.

Within a comprehensive market shaping strategy, the intervention or portfolio of interventions, whether financial or not, must be well coordinated and sequenced, in support of a widespread execution to drive the desired transformational impact.

1.5 S: Scale and grow demand for the product

A market shaping deal is meaningless unless the negotiated product gets into the hands of the individuals who need and want them in a timely manner. CHAI, therefore, exerts tremendous effort, to ensure that the targeted and/or negotiated health product reaches the people we serve. Leveraging our footprint in 35 countries and strong relationships with ministries of health and public health systems, we enable effective product introduction and scale and provide assurances of delivery to the last mile. Demand generation activities, which can include infrastructure strengthening to improve service delivery, technical assistance (TA) for product introduction and scale, workforce training, and awareness campaigns, among others, are critical to any market shaping strategy and an essential element in the negotiation with manufacturers to lower the cost of a health product. It is by generating demand, aggregating volumes where possible, and triggering procurement funding that a market opportunity is created to the benefit of the manufacturer(s), in exchange for an affordable, quality-assured product tailored to meet the needs of LMIC populations.

As part of the ecosystem alignment, our country partners are called upon to lead the formal or informal structures supporting the product's introduction and scale, including mobilizing the necessary funding to procure the product to meet demand. This requires accurate demand forecasting, procurement planning and stock monitoring, which CHAI supports, working alongside government partners.

Figure 15: Key interventions to enhance introduction, scale, and sustainability efficiency

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 healthcare worker training 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

CHAPTER 2:

The enabling environment must be right to conduct successful market shaping

Based on CHAI's active engagement with health ecosystems, and deep analysis of various products and production systems over the last 20 years, we have developed a list of factors that we believe work in combination to create the conditions for successful market shaping in global health:

1. **Market opportunity:** this means an ability to (a) increase a product's use by five-to-10-fold, (b) create a pathway to significantly reduce the product's Cost of Goods Sold (COGS), and (c) aggregate and predict demand for that product.
2. **Ecosystem catalyst:** a credible organization, with an activist approach and the expertise to work on both the supply and demand sides of the market, must be in play to orchestrate the different components of the market shaping strategy and the ecosystem of actors.
3. **Visible long-term stream of public sector product procurement funding:** a flow of money is needed to support a portfolio of market shaping interventions and sustain the gains over time.
4. **Political pressure:** key actors must be actively aligned behind the product and advocating for its introduction into the market.

These factors do not operate independently of each other and are best viewed as a high-level screening tool to gauge the feasibility and risk associated with market shaping interventions. In the largest and most impactful market shaping interventions CHAI has been involved in, all five factors played a positive enabling role.

However, an activist ecosystem catalyst, visible long-term flow of public money and the ability to aggregate demand are likely the most important factors creating market shaping opportunities.

The factors listed under "market opportunity" help create a positive setting for supplier negotiations. When present, they motivate manufacturers to discuss how best to capture a market growth opportunity. CHAI also proactively explores strategies to lower product COGS[8] and total supply chain costs. If our analysis demonstrates a sustainable pathway to lower costs and prices, we initiate discussions with manufacturers to understand their current costs and the scope to enter into an agreement (an access program partnership or volume guarantees, for example) that could lower these overall product and system costs. Our aim is always to achieve "mutual benefits:" increased access for the people we serve and, commercial viability and sustainability for manufacturers.

8 The acronym COGS stands for Cost of Goods Sold.

CHAPTER 3:

How to source, structure, and implement market shaping agreements, using the volume guarantee as an example

The volume guarantee (VG) is an important financial tool, but it is only one of many tools within a portfolio of market shaping interventions available to the market shaping practitioner. With such tools, ensuring parallel investments to create and/or grow demand is always also needed.

Yet, despite the importance of considering the full suite of market shaping interventions, CHAI is often asked specifically about financial tools and incentives that can be used to shape markets. In the sections below, we will walk through the process of sourcing, developing, and executing a comprehensive market shaping deal using volume guarantees as a case study. The VG is perhaps the most complex of the various financial tools used in market shaping interventions and, therefore, allows us to cover all of the process steps and skills needed to be successful.

3.1 Skills and resources

The capabilities and relationships needed to do comprehensive market shaping, and here in this annex defined more specifically as being able to support the deployment of VGs include expertise in Cost of Goods (COGS), product development and manufacturing, regulatory affairs, commercialization, demand forecasting, and negotiation, as well as the ability to collaborate effectively with major donors, procurers, and global and country level policymakers.

CHAI's approach to comprehensive market shaping has evolved to a finely tuned coordination and collaboration mechanism across the organization and with several key ecosystem actors to originate, develop, and execute various deal opportunities. The capabilities needed to do comprehensive market shaping do not sit within a single team at CHAI or other organizations, but are spread across several functions, geographies, and content areas.

Take the TLD VG as an example,[9] which was referred to chapter 4 in Part 1 of this guidebook; this was a deal led by CHAI lead and funded by the Gates Foundation in collaboration with other key stakeholders, including UNAIDS, Unitaid, The Global Fund, and USAID. Our internal "deal team" consisted of representatives from several teams across the organization:

- **HIV Team**, which established TLD as a CHAI strategic priority and led our interactions with major donors;
- **Market Intelligence Team**, which developed the demand forecast;
- **Product Costing Team**, which developed the cost of goods sold (COGS) model;
- **Regulatory Team**, which led discussions with the WHO and USFDA;
- **South Africa, Kenya, Nigeria, and Uganda Country Teams**, which represented the early adopter "anchor" countries and worked to bring governments on board; and
- **Global Markets Team**, which was the primary interface with the guarantors and manufacturers and supported term sheet development and due diligence.

9 New high-quality antiretroviral therapy to be launched in South Africa, Kenya and over 90 low- and middle-income countries at reduced price Negotiated pricing agreements have lowered costs and will improve access to quality treatment for people living with HIV https://www.unaids.org/sites/default/files/20170921_PR_TLD_en.pdf

At the Gates Foundation, resources from the HIV Program Team, Strategic Investment Fund, and the legal department worked in parallel to model the impact of this new product on clinical outcomes in LMICs and the feasibility and impact of accelerating the rollout.

Other deals have had similar setups. This "compartmentalization" helps us feel confident in the overall soundness of our deal hypotheses, as key outputs are arrived at independently and via specialized teams. This also helps ensure we adequately balance and navigate the interests of the various stakeholder groups (key ecosystem actors)—e.g., governments, donors, procurers, financiers—as we advance the work but work in tandem to ensure that ultimate goals are aligned and accelerated.

The configuration of actors working to achieve discrete market shaping outcomes can take many forms. Many have nearly always started as confidential collaborations between CHAI and the guarantor (e.g., Gates Foundation, MedAccess, etc.) or as fully guarantor-led propositions (without CHAI involvement), with the circle of partners gradually expanding as the deal nears the finish line.

A precise sequencing of activities and stakeholder interactions is required to conclude VG deals, which benefits from a smaller core team in the earliest stages. Broadening the partner circle before validating the rough contours of a deal risks prematurely raising program expectations regarding price or availability, compromising the guarantor's ability to negotiate effectively, and increasing transaction costs, especially given the high proportion of opportunities that do not progress within the pipeline.

Additionally, market shaping practitioners must be sensitive to the roles played by procurers, regulators, and normative agencies, which must adhere to impartial and transparent processes that do not favor specific companies and should, therefore be kept at an appropriate distance from core deal activities.

While it is undoubtedly helpful to have broadly agreed upon "access" goals within a given disease area or geographic region, which may include specific targets regarding launch timing, pricing, and supply of priority health products, there are aspects of market shaping that must operate behind closed doors to maximize impact, with key activities led by a smaller group of partners, in some cases the guarantor alone.

3.2 Sources of funding

For a VG to be successful, a guarantor is needed. Governments and philanthropic organizations have created and funded global health guarantors to improve health outcomes in LMICs. Active guarantors operating in the global health sector include SIDA, which is backed by the Swedish government; MedAccess, which is backed by the UK government through British International Investment, the Gates Foundation's Strategic Investment Fund, and the Children's Investment Fund Foundation, among others.

In 2018, CHAI and MedAccess—the Credit Facility for Access to Medicines ("CFAM") at the time—launched a new partnership centered on identifying and advancing high-impact VG propositions to help MedAccess deploy its US$200 million in a way that would best serve LMIC patients and programs. MedAccess was a new organization and the first standalone VG "provider." Core to the initial business strategy was establishing a set of procedures and parameters to govern the pipeline process from start to finish—to enable the small team to efficiently (and concurrently) screen dozens of market shaping opportunities each year while moving a select few forward for further due diligence and potential investment committee (IC) approval.

The skills required at different points in the process vary widely (e.g., from basic desk research in early stages to stakeholder influence and negotiation in later stages). Given that a typical VG proposition is two to three years in the making,[10] a stage-gated approach, flexible staffing model, and diverse team

10 Timelines can vary widely. A minimum of 18 months is generally required to advance an opportunity through the full MedAccess process (including supplier negotiations, due diligence, and partner engagement); however, we have seen deals take up to several years depending on clinical development and regulatory timelines. A VG for a new drug class, vaccine, or diagnostic technology will usually take much longer to conclude than a VG for a product which brings improvements (or a steep price discount) to the existing LMIC standard of care.

Figure 16: Volume Guarantee (VG) Deal Process: Stages from Scanning to Execution

	Stage 1 Scanning	Stage 2 Scoping	Stage 3 Alignment	Stage 4 Diligence	Stage 5 Negotiation	Stage 6 Execution
Average no. of products at any time	100+	10+	5+	3	2	
Objective	Research commodities for which market shaping may improve access	Identify promising VG opportunities	Outline potential deal structure and investment case	Perform deal due diligence	Finalize deal parameters	Implement deal
Method	Stakeholder discussions, secondary research	Evaluate ideas against suitability and prioritization criteria	Advance research; preliminary partner engagement	Continue partner engagement and alignment; initiate negotiations	Finalize negotiations with suppliers and other partners	
Output	Database	Scoping Memo	Screening Paper	Due Diligence & Risk Model	Final Term Sheet	VG Agreement

were critical, allowing MedAccess to complete 10 guarantees within its first five years.

The pipeline process that MedAccess adopted and continues to follow, and one that CHAI has incorporated into its comprehensive market shaping work, includes three broadly defined phases:

- Deal origination
- Deal development
- Deal execution

In the sections that follow, we describe some of the key considerations and activities for each phase, many of which will be applicable to a broader set of market shaping interventions, including those beyond the global health sector.

3.3 Deal origination

There are many answers to the question, "where does a deal come from?"—commonly referred to as the "origination" phase within a guarantor's pipeline. In the case of VGs, which are deployed to achieve lower prices or increase supply, we can match sourcing strategies to typical use cases:[11]

1. **Accelerating introduction of a previously unused product class in resource-limited settings**

   Target profile: products used as part of the "standard of care" in high-income countries, for which a realistic pathway to price reduction exists,[12] and whose introduction in LMICs could help close major prevention, diagnosis, or treatment gaps and improve health outcomes.

   Sources: clinical guidelines and formularies in high-income countries for diseases that impact both high-income countries and LMICs.

   Examples: a) integrase inhibitor-based first-line antiretroviral regimens (VGs with Mylan and Aurobindo); b) long-acting reversible contraceptive implants (VGs with Bayer and Merck).

2. **Accelerating uptake of an existing product or product class in resource-limited settings**

   Target profile: products already recommended for use in resource-limited settings and

11 These use cases are neither comprehensive nor mutually exclusive

12 E.g., via generic licensing, tiered pricing strategies, product modifications, etc.

deemed essential for meeting government or donor program objectives, whose high price and/or constrained supply presents a barrier to country-level adoption and scale-up.

Sources: prevention, screening, diagnosis, and/or treatment targets in global and country-level disease-specific strategic frameworks matched against observed uptake to date.

Examples: c) viral load testing for infectious disease (VG with Hologic); d) HIV self-tests (VG with Wondfo); e) dual nets (VG with BASF).

3. **Achieving savings for governments, procurers, & donors that can be redeployed elsewhere**

   Target profile: products or product classes comprising a significant portion of total expenditure within major purchaser portfolios, for which price reduction may be possible.

   Sources: procurement data of major global or country-level buyers (e.g., GFATM, GHSC-PSM).

   Examples: f) pentavalent vaccines (VG with BioE).

The above methods can be employed when a guarantor or similar entity is building a pipeline from scratch. However, we've also seen deal opportunities arise organically. For example, a policymaker might signal that a price reduction could enable the recommendation or elevation of a new product class within clinical guidelines due to improved cost-effectiveness. Furthermore, a government might indicate that a lower price for a new product would allow for meaningful acceleration of introduction and scale-up for key patient populations. Finally, a supplier might suggest that better visibility regarding future sales volumes would allow for significant price reductions previously thought to be untenable. The above scenarios all represent realistic starting points for deal origination. For this reason, it's crucial for guarantors and their partners to maintain close working relationships with key global health actors.

Guarantors rely upon additional criteria to further screen and prioritize deal opportunities. In 2020, CHAI and MedAccess developed a VG prioritization framework, which served as a basis for advancing opportunities within the pipeline. The framework includes five dimensions each scored as "low", "medium," or "high" for a given product or product class:

1. **Public health impact potential**

   Definition: will the product contribute to a meaningful improvement in disease management for target populations compared to the current standard of care?

   Rationale: VG transactions can be time and resource-intensive with millions of dollars at risk; they should be deployed sparingly, ideally for the highest-impact opportunities.[13]

2. **Suitability of VG instrument**

   Definition: are pricing or supply availability the primary barriers (current or anticipated) to access for the product in LMICs?

   Rationale: VGs are meant to address specific issues. While other barriers can be present, we want to avoid scenarios where reduced price/ increased supply does not lead to greater access.

3. **Extent of normative alignment and guideline inclusion**

   Definition: is the current or future role of the product within LMIC care models and clinical algorithms widely agreed upon? Do we expect the product to be included in the appropriate guidelines?

   Rationale: this relates to impact and risk. If the role of the product is still uncertain (potentially with evidence gaps), it may be premature to consider a VG.

4. **Level of purchaser consolidation**

13 Each guarantor will have its own development impact framework. MedAccess evaluates opportunities in terms of lives changed, money saved, and markets shaped (e.g., increasing competition or supply security)

Definition: how concentrated is procurement of the product across LMIC buyers (e.g., global procurers, governments, hospitals, pharmacies, etc.)?

Rationale: the rule of thumb has been that over 70 percent of procurement volumes should sit with no more than three entities; the higher the level of fragmentation, the higher the level of risk.

5. **Strategic fit with guarantor and implementing partner priorities and capabilities**

   Definition: does the product fall within established partner programs, and are there synergies with other investments in the portfolio?

   Rationale: the likelihood of success for a VG will be higher in disease areas where guarantors and their partners have ongoing, funded initiatives.

The above criteria are not meant to be definitive but provide an early steer as to relative levels of impact and risk across identified opportunities. For products with mostly high ratings, additional desk research and expert interviews are conducted to further build the fact base and pressure test core assumptions. Areas of focus include the target product profile (technical, clinical, etc.), current and future positioning within global guidelines, regulatory pathways, key donor and purchaser perspectives, total addressable market, supplier landscape, including an early look at market access strategies, production capacity, and COGS. This data is used to develop a quick "back of the envelop" assessment of impact in terms of patients reached and money saved. As the opportunity becomes clearer, a deal hypothesis emerges, i.e., whether a VG of a certain magnitude is a feasible and suitable solution for current or anticipated barriers to access.

3.4 Deal development

The next phase in the process for high-potential VG propositions is known as deal development. During this phase, a deal team is formed to actively advance the opportunity. This includes opening negotiations with target counterparties, conducting initial due diligence, and beginning to cultivate the coalition of partners to create the enabling environment for the deal's success. Guarantors will form both internal deal teams, responsible for guiding the opportunity through the IC process, as well as joint deal teams with market shaping partners, who can leverage their extended networks and expertise to supplement in-house capabilities.

Deal development is the stage at which supplier engagement kicks off in full. There is no one-size-fits-all approach to this process, as much will depend on:

a) whether there are multiple suppliers with products eligible for consideration within the same product category,

b) whether the guarantor has a preexisting relationship with the relevant supplier(s), and

c) whether the supplier(s) have participated in previous market shaping initiatives and have empowered "access" teams with the ability to drive commercial decision-making for relevant global health markets and products.

Consideration a) is paramount. If multiple suppliers with products perceived to be equally competitive are currently or soon-to-be in play, a more formal supplier engagement process, such as a targeted EOI or RFP, may be warranted. This is essential for two reasons. First, suppliers will have varying capabilities, cost structures, and strategic priorities, which may or may not include increasing market share within the LMIC segment. Given multiple possible VG configurations (e.g., VGs with several suppliers, potentially with different deal terms), a standardized approach to supplier evaluation ensures that all options are thoroughly considered and that the deal team selects the option that maximizes potential impact and minimizes risk. Second, as additional partners join the initiative, including potential co-guarantors, they will want assurances that a fair and objective process was followed, rather than working with only one supplier from the outset and that the process considers

supplier diversification and promoting appropriate competition, once the market is established.

If some of the supplier's products are already well established in LMIC markets and the company has previously engaged in market shaping programs, a more direct and strategic approach may be feasible. Arranging for a once or twice-per-year briefing with the supplier's senior management on "current challenges in public health for LMICs" creates an opportunity for strategic discussions as to how current or near-to-market products could be adapted for use cases in LMICs. This approach allows for an informal discussion about potential opportunities where a VG might effectively address barriers to access and get input from the company on the factors they believe are limiting sales.

One of the most pressing priorities for the deal team is to establish a price-volume matrix early in the process. As described in section 3.5.1 below, this table summarizes the guaranteed quantities and ceiling prices for each annual period as agreed to by the guarantor and the supplier and represents the beating heart of the VG deal. Reaching initial alignment on these terms is an iterative process, requiring multiple rounds of negotiation between the deal team and supplier counterparties. And in case no alignment is possible, it's better to reach this conclusion sooner rather than later and pivot to alternative market shaping strategies.

On the deal team side, the starting point often involves the following question: what degree of price reduction for this product would meaningfully change the slope of the uptake curve? This curve is essentially governed by the rate at which public health programs in high-burden countries choose to adopt or substitute the product within their clinical guidelines—a decision informed by both total cost and cost-effectiveness considerations. Determining this price threshold can vary in complexity depending on the degree of global donor support and coordination within a given disease area.[14] At a minimum, it requires multiple conversations with key opinion leaders and decision-makers in target geographies, especially those pegged to be high-volume early adopters.

The other key input at this stage in the process is the cost analysis. This topic is explored in more detail in section 3.5.1 below. The deal team can use this analysis to determine whether the VG is even feasible without exceptional cost reduction measures[15] or help set the anchor price for the opening bid by adopting a "COGS plus" approach. The range of possible options for the ceiling price in the price-volume matrix is then bounded on the lower end by assumed COGS, which may shift if the counterparty is willing to share its actual costs, and on the higher end—the deal team's reservation price—by the lowest price reduction that still achieves sufficient incremental uptake to meet the guarantor's development impact objectives. In cases where COGS are especially sensitive to economies of scale, it may be possible to propose a series of gradually decreasing ceiling prices across annual periods, similar to the approach taken for the TLD deal, referred to in chapter 4 of the guide. It is also important to note that although CHAI works to achieve an access price that triggers demand, one of our main tenets is to ensure the deal is commercially viable and sustainable for manufacturers, or else they will exit the market quickly, which serves no one.

Finally, the deal team should have a preliminary idea of how much volume could be guaranteed under different pricing scenarios. While there will be plenty of time to refine and validate the demand forecast (see section 3.5.2), the team should already have a sense of the shortlist of high-volume countries likely to adopt the product (and the associated "total addressable market" for each country), the timeline for product registration, adoption, and introduction, the rate of uptake among target populations, and the extent to which the previous categories are price sensitive. Conservative assumptions should be used at this stage to reflect the level of market risk associated with the deal. If the deal progresses, a more formal assessment will be made of the company track record in the target markets, degree

14 E.g., PEPFAR will take a decision globally as to whether to add a new drug to its formulary (based partly on cost considerations) and will then promote updates to local guidelines and treatment programs via its country programs

15 In cases where a VG does not appear feasible due to high COGS, the deal team can propose a broader collaboration that includes cost reduction strategies; additional partners may need to approached depending on financing needs

of purchaser fragmentation, level of competition, and regulatory complexity.

With the annual VG price and volume targets in hand, the deal team can open more formal discussions with target counterparties, presenting either a standalone ceiling price proposal and asking the supplier to respond with the guaranteed quantity that would be necessary to meet this price or a full price-volume matrix, if the team believes it's sensible to already anchor the supplier to the lower end of its forecast.[16,17]

Three other terms should be introduced at this time to ensure that the scope of the price-volume matrix is clear to all parties. The first is the list of Eligible Countries—countries for which the ceiling price would apply and whose purchase volumes would count towards the guaranteed quantities. The second is the list of Eligible Purchasers—buyers for whom the ceiling price would apply and whose purchase volumes would count towards the guaranteed quantities.[18] Last is the Incoterm associated with the ceiling price, which specifies whether the buyer or seller is responsible for paying and managing the shipment, insurance, customs clearance, etc., and can contribute to significant price swings given the high costs associated with freight and logistics.[19,20]

It is rare for a supplier to accept the first price-volume matrix presented.[21] Counteroffers generally include a combination of the following requests: higher ceiling price, higher total guaranteed quantity, guaranteed quantities shifted from later years to earlier years, longer deal duration, and specific countries exempted from either ceiling price or counting towards guaranteed quantities.[22] The deal team will need to revisit its model to determine the implications of these modifications for risk and impact and identify where there may be room for compromise.

Some of these scenarios are easier to navigate than others. For instance, if the supplier agrees to the ceiling price as is but requests higher volumes, a workable price-volume matrix is likely achievable—it may just take some time to get there. The deal team will need to perform routine country-level due diligence to validate its base case estimates and may need to conduct scoping in additional countries and/or determine whether extra resources can be made available to fund adoption and uptake activities beyond what's already planned, depending on the difference in volumes between the parties. However, aligning on a price-volume matrix may be impossible if the supplier counters with either a higher ceiling price, a higher total guaranteed quantity, or a ceiling price exceeding the deal team's reservation price.

Differences with respect to ceiling prices are particularly difficult to resolve due to price sensitivity uncertainty in LMICs. While the deal team can feel confident that a certain discount versus the current standard of care will generate a minimum demand in target markets, the impact of a price above this threshold will be difficult to quantify. Conversely, making concessions with respect to volumes is generally easier, given the number of options the deal team has for both managing risk via the term sheet (see below) or seeking to bolster

16 E.g., if the deal team is already sensing it will have limited room to maneuver on volumes, or if the deal team has reason to believe that the supplier's volume proposal will be an order of magnitude higher than what is possible

17 Likewise, if an EOI or RFP process has been run instead, the deal team can screen and prioritize initial proposals based on its price and volume targets

18 Across the VGs completed to date, "eligible purchasers" has represented global procurers, governments, and NGOs purchasing products on behalf of public sector patients in the eligible countries.

19 See here for more information on Incoterms. A separate but related consideration is the extent to which private sector distributors will be involved in product delivery and charge a mark-up. Where this is the case, the term sheet should indicate whether the ceiling price includes or excludes distributor fees.

20 A fourth term is the product definition ("Product"). This is straightforward for most VGs, although in the case of diagnostics or devices that involve a service component (e.g., installation, training, maintenance, etc.), it will require more attention given the impact of these after-sales components on price.

21 If they do, it's fair to question whether they fully understand the VG instrument and proposed partnership model

22 A supplier may ask for a country to be exempted from the deal if it has an existing contract in place or has invested in market access activities and sees a pathway for getting there without the VG

demand generation efforts. The specific context will be crucial, but the sooner the deal team can establish and communicate its red lines to the supplier, the sooner both sides can determine whether a deal is possible.

Drafting the term sheet

Assuming the negotiation advances, several additional provisions are important to introduce during the deal development stage, which, when combined with price, volume, and eligibility considerations, form the foundation of the draft term sheet (link here). These include:

1. **Qualified order:** the Qualified Order provision further specifies whether and when a purchase order is eligible to receive the ceiling price and be counted towards the guaranteed minimum quantities (beyond the Eligible Country and Eligible Purchaser conditions introduced previously). These terms are generally negotiated by the supplier and may include a) a minimum order quantity clause, that any single order must meet or exceed a predefined quantity, b) a minimum lead time clause, that any order provides for a minimum number of days between purchase order confirmation and fulfillment, and c) a maximum shelf-life remaining upon deliver requirement, defined as either a percentage or in number of months. These conditions are essential for the supplier to be able to manage its commercial operations and are communicated to all eligible purchases upon finalization of the VG agreement.
2. **Shortfall payment:** the "shortfall" section of the term sheet describes what happens if sales volumes associated with qualified orders fall short of the guaranteed quantity in an annual period. Perhaps most importantly, the guarantor and supplier will need to agree on the shortfall price—the price per unit that will be used to calculate the total shortfall payment amount owed to the supplier. Historically, the ceiling price has been used as the shortfall price. More recently, guarantors have negotiated lower shortfall prices, calculated as the sum of fixed cost and reasonable margin per unit (with variable costs removed),[23] reducing the overall gross exposure.
3. **Excess sales:** also known as the "carry forward" provision, excess sales describes what happens if sales volumes associated with qualified orders exceed the guaranteed quantity in a year. This can range from an unlimited rollover of excess quantities from one annual period to the next, thereby reducing the guaranteed quantity for that annual period by the cumulative rolled-over amount (the most favorable variant for the guarantor) to a capped carry forward arrangement or one in which excess quantities are used to offset non-adjacent annual periods or spread equally across all remaining periods. Whatever its final form, this is an essential clause for the guarantors, given the variability in purchase orders year to year.
4. **Conditions precedent:** conditions precedent (CPs) describe the key requirements that must be satisfied for VG "effectiveness" (i.e., for the first annual period to begin). This section of the term sheet includes three components: 1) the earliest date the VG can become effective (if the CPs are met), 2) the CPs themselves, and 3) the latest date the VG can become effective (after which point the guarantor can terminate the agreement). In global health, the CPs include normative conditions (e.g., specifying that the product must receive a clinical endorsement by the WHO) and regulatory conditions (e.g., specifying that the product must receive WHO prequalification, SRA, and NRA approvals). Other commercial conditions can also be included (e.g., specifying that the first qualifying purchase order for the product must be received). Similar to excess sales, the conditions precedent are key provisions the guarantor can use to manage risk.
5. **Product registration:** finally, the product registration section establishes a timeline

23 The justification being that the guarantor should not have to compensate the supplier at the full ceiling price, given that the supplier is not obligated to manufacture the shortfall quantity

and prioritization for country-level regulatory approvals. this will be one of the supplier's core obligations over the course of the vg – obtaining (and maintaining) approval from national regulatory authorities in eligible countries, a prerequisite for introduction and usage of the product. An effective approach has been to "tier" eligible countries (e.g., category A, category B, etc.), according to perceived level of urgency, with fixed filing deadlines for each tier (the understanding being that the supplier cannot practically advance this work in dozens of countries concurrently). Category A will include the projected high-volume, early adopter countries and will often have a CP built around it (i.e., that the product needs to be approved in all or some proportion of category A eligible countries for the VG to come into effect). For the other tiers, the supplier's failure to submit for and/or obtain approval by the stated deadline can be a cause for reductions to the guaranteed quantity for a given annual period. Product registration provisions are important not only for managing risk but also for maximizing impact, given the tendency for suppliers to deprioritize market access activities in low-volume LMICs.

Reaching alignment on a draft term sheet typically takes between six-12 months on average, as it requires several iterations and rounds of negotiation. It should also be understood that while the price-volume matrix will be considered mostly settled at a certain point (at the latest by the close of deal development), other key terms may continue to evolve as the deal team advances due diligence and proposes additional modifications and risk-mitigation measures.

Due diligence and partner alignment

We briefly turn our attention to due diligence and partner alignment, both of which are critical at this stage in the process. In parallel to supplier negotiations, the team should begin engaging the relevant global health stakeholders to pressure-test assumptions that have underpinned the deal hypothesis and demand forecast and advocate for increased prioritization of and funding for VG-linked (or dependent) initiatives among donors, governments, and other partners.

Based on the specific deal context and VG "use case" described above, exploratory topics may include:

1. **Clinical guidelines and recommendations:** if the product is not already recommended in WHO clinical guidelines globally and within high-priority anchor countries, what are the processes by which these decisions are made, and what is the potential timing and likelihood of achieving the desired results?
2. **Purchase and supply decisions:** if and when the product is recommended for use in high-priority countries, how will purchase and supply decisions be made and funded? This will govern introduction timing, rate of uptake, and the specific product selected if there are multiple, non-interchangeable options available.
3. **Procurement process:** assuming purchase orders are anticipated to be placed, how will procurement processes work for the high-volume buyers? It's essential to understand the general criteria and weighting that inform how volumes are indicatively allocated to each supplier.
4. **Country-level implementation:** what activities are required for integrating the product within existing clinical practice at the country level? Importantly, will new service delivery platforms be required? What about complementary product needs (e.g., companion diagnostics)? How much will all this cost?
5. **Donor and partner interventions**: how heavily are donors and other partners planning to intervene and/or invest to accelerate the rate of adoption and uptake within target geographies and populations? What other market shaping initiatives are already planned or underway?

To answer these questions, a range of partner discussions will need to be held, and the team should prioritize visits to the handful of anchor countries that will make or break the deal.

Throughout this process, the deal team should be making a distinction between the findings that are "fixed" (e.g., a set regulatory process, a short-term funding envelope, existing stock levels of the current standard of care product, etc.) and those that are "flexible" (e.g., key opinion leader perspectives on new product benefits, level of donor prioritization, etc.). The question then becomes, for those findings that are flexible, which are the most relevant for the risk vs. impact profile of the deal, and which are the most amenable to team leverage and influence? For the remainder of the deal development phase, the team will gradually shift its stakeholder engagement from fact-checking to advocacy and partnership to enhance the chances of VG success.

3.5 Deeper dive into tools and techniques for negotiating prices and volumes

There are four common challenges that practitioners encounter when working on VGs or similar market shaping interventions:

1. Setting the right price for the product over the life of the deal strikes a balance between access goals and economic sustainability.
2. Determining what volumes to guarantee or underwrite by developing detailed market forecasts and understanding the rate at which different country programs can scale usage.
3. Developing a framework for assessing the guarantor's risk in underwriting the agreement. What is the methodology and data needed to estimate the probability of a call on the guarantee? How can this information be best presented to the Investment Committee? What levels of risk can be supported, and what are the costs?
4. Working to build stakeholder alignment. The global public health ecosystem supports a complex mix of multi-lateral institutional, programmatic, and national public health priorities. To be successful, the market shaping intervention needs the support of this ecosystem.

The following section presents a deep dive into each of these topics and provides guidance on analytical tools and techniques, case study materials, and references to other resources.

3.5.1 Setting the right price

Over the years CHAI has earned a reputation with stakeholders as hard bargainers over the price of health commodities. As a mission-driven organization that aims to save lives, we are aware that lower prices usually mean that more people can receive lifesaving drugs, vaccines, or diagnostic tests. To be sustainable, however, pricing agreements must take account of the company's costs and how those costs are likely to evolve over time.

Experience has shown that companies are hesitant to share detailed cost data and may not know what their costs will be if the volume of sales and production increases substantially. The market shaping practitioner will need capabilities to understand overall costs, production costs, and supply chains, and use this information to develop successful price negotiation strategies. The following will be essential in establishing the right price. For a deep dive on setting the right price, click here. The topics covered in this deep dive include:

- Creating the Price Volume Matrix
- Techniques for Estimating Production Costs
- Analysis of COGS for Small Molecule Drugs Produced at Generic Firms
- Modeling API Costs
- Pricing Negotiations with Innovator Firms
- Reducing COGS and Selling Prices by Transferring IP or Licensing
- Pricing Negotiations of Diagnostic Products

3.5.2 Setting the right volume

In LMIC markets, data for healthcare products is not routinely available or reliable. Public health system and consumer expenditure data may be difficult or costly to obtain, and future demand is either unknown or highly dependent on institutional actors, WHO guidelines, funding of multilateral institutions, regulatory action, and other political factors. Given this reality, how do you decide what volume of products can be absorbed and how will

this match up with available funding? If there are guarantees involved, what risk should the supplier versus the guarantor take as the market develops over a three-to-six-year period? For a deep dive on demand forecasting, click here. The topics covered in this deep dive include:

- Drivers of Product Demand: Treatment Guidelines, Funding, and Regulatory Status
- Country Modeling and Tipping Point Events

3.5.3 Managing risk

Large scale market shaping programs like VGs have been possible in public health because third-party guarantors have emerged that are willing to assume financial risk on behalf of suppliers or purchasers in exchange for provisions that will generate impact. These risks are often classified as funding risk, adoption risk, and allocation risk.

Global health guarantors have relatively standardized frameworks to characterize, quantify, and mitigate financial risk. The linked materials describe the general approach global health guarantors have defined to characterize, quantify, and mitigate financial risks associated with these transactions. It is critical for guarantors to set out a clear approach to managing financial risk in any investment strategy and to regularly re-examine and re-calibrate risk management policies and practices. For a deep dive on managing risk, click here. The topics covered in this deep dive include:

- Who are the Guarantors?
- Quantum of Risk
- Type of Risk
- Funding Risk, Adoption Risk, Allocation Risk
- Quantification of Risk
- Mitigation of Risk
- Contractual Protections

3.6 Achieving ecosystem alignment

In many LMICs, the national health system and multilateral donors account for 70 percent or more of the expenditure on health commodities. As such, market shaping interventions must be designed via stakeholder consultations, institutional bargaining, and consensus decision-making; aligning and catalyzing the ecosystem is a critical success factor as many actors will play important roles in achieving the market shaping goals.

These institutional factors create a need for "quarterbacking" a deal rather than just hoping that the ecosystem of actors will respond to new incentives. In product categories where comprehensive market shaping has been most successful, product availability and pricing are informed by the WHO policies and guidelines, funding availability, and donor priorities.

This raises the question of what tools can be created to achieve alignment among stakeholders and what forums are needed for these discussions. For a deep dive on stakeholder alignment, click here. The topics covered in this deep dive include:

- Creating the Deal Concept Note
- Start with the Public Health Problem
- Decide what Stakeholders and Forums are Appropriate for Discussion
- Creating Forums for Alignment

CHAPTER 4:

Deeper dive on other key types of market shaping interventions

Beyond volume guarantees, which we have discussed at length in Part 2, Chapter 3, there are other market shaping tools that have generated strong global health impact. In this section, we focus on five tools that CHAI has utilized in the past to great results: Product Development Incentive Programs (PDIPs), buydowns, procurement guarantees, licensing, and science-based cost optimization.

It is important to underline that multiple market shaping interventions and instruments, such as these next five tools and the VG, can be combined and utilized either sequentially or in parallel, within a comprehensive market shaping strategy. In global health, CHAI has often combined financial tools along with demand-side market shaping interventions to achieve transformational global public health goals.

4.1 Product development incentive programs (PDIPs)

PDIPs can be a powerful and surprisingly low-cost market shaping tool. A PDIP combines milestone payments to offset product development costs, technical assistance, regulatory strategy, and ceiling price agreements into a "package deal." The goal of these programs is to accelerate time to market and reduce the commercialization risk for drugs needed urgently in LMIC. Competitive RFPs are released to select one or two companies capable of developing and commercializing the target product within a demanding timeline.

Turning again to HIV, we use a case study on pediatric HIV products to illustrate how PDIPs can be a powerful market shaping tool. In high-income countries, mother-to-child HIV transmission has been largely eliminated, leaving little need for and no market for pediatric HIV treatments. Even though over 95 percent of infants and children living with HIV are in LMICs, innovator companies that develop HIV drugs for adults do not typically launch their own product's pediatric versions.[24] Rather, innovators receive an incentive for developing pediatric products—extension/exclusivity period on their adult products, which can make it very lucrative—they tend to develop and commercialize pediatric products but do not market these products in LMICs due to a perceived lack of return on investment. For pediatric DTG, for example, ViiV developed and commercialized the product in the US and the EU but licensed the product for LMIC.

Unitaid, working with CHAI and other partners, has repeatedly provided funding for the PDIP market shaping intervention. In 2013, CHAI began this work by forming a partnership with ViiV, Matrix, and Aurobindo to develop a flavored dispersible pediatric dosage form of abacavir combined with 3TC. With the launch of integrase inhibitors in 2015, CHAI again worked with ViiV, Viatris, and Mcleods to develop, register, and commercialize a pediatric version of dolutegravir (DTG), and several years later, a combination product of abacavir, lamivudine, and dolutegravir (ALD). CHAI's strategic regulatory work has been found to accelerate regulatory approvals significantly.[25] The DTG pediatric was followed by work on pediatric darunavir/ritonavir in partnership with Laurus labs; it is still under FDA review, thus not yet complete.

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24 Milic, C., & Milic, C. (2024, June 30). 2023 HIV Market Report: The state of the HIV market in low- and middle-income countries. Clinton Health Access Initiative. https://www.clintonhealthaccess.org/report/2023-hiv-market-report-the-state-of-hiv-market-in-low-and-middle-income-countries/

25 https://www.clintonhealthaccess.org/wp-content/uploads/2023/06/Pediatric-DTG-Case-Study_Mar-2023.pdf

The overall cost of these programs, including costs incurred by CHAI, generic firms, and the innovator firm were in the range of US$8-$12 million per product. Incentives paid to generic firms to offset product development costs were tied to achieving key milestones and ranged from US$1.5 - $2.5 million in total per product.

This PDIP approach was used to successfully commercialize four important pediatric HIV products over the past 10 years. These new products were specifically designed for children by addressing obstacles to adherence that included developing a pediatric-friendly dosage form and palatability. The payback on PDIP investments in terms of lives saved and procurement savings are considerable. As part of the "package deal" for the development of pediatric DTG, CHAI negotiated a price in advance of the product launch, which represented 75 percent savings compared to pediatric standard of care at the time.[26] The PDIP program for pediatric DTG is expected to yield savings between US$60-$260 million over 2021-2026.

The PDIP approach has also been successful in reducing time to market. CHAI and ViiV worked together to develop an innovative regulatory strategy that was agreed by the FDA and allowed for concurrent review of the generic and innovator products by the US FDA. This enabled the fastest-ever regulatory approval of a generic HIV medication for adults or children, with the FDA giving tentative approval for Viatris' generic product just five months after the FDA approval for ViiV's innovator product. This reducing what was historically an eight to 10-year gap between the availability of adult and pediatric products.

The success of the PDIP approach underlines the power of collaboration within the ecosystem, here specifically between customers, regulators, buyers, and producers.

4.2 Buydown agreements

A buydown agreement is a market shaping intervention where a donor or a group of donors pays a lump sum (or can be a per-unit amount) to offset a product's production costs in return for a ceiling price agreement that significantly reduces the price charged to a defined group of buyers. Buydowns are used to bridge the unit costs of producing a product at low volumes with the costs that can be achieved at high volumes. The calculation of the payment is determined after an in-depth analysis undertaken with the company of the direct and indirect costs incurred under several volume scenarios.

The first example of a product buydown agreement in global health was a deal negotiated with Cepheid by the Gates Foundation, CHAI, Unitaid, USAID, and PEPFAR in 2012. The agreement set a new ceiling price for the Cepheid GeneXpert MTB/RIF diagnostic test. The product was initially introduced in 2010 for US$16.86 per cartridge. The health system in South Africa was the largest potential customer for the Cepheid TB test but had rejected the price offered, so uptake was at a standstill. Large buyers were seeking a price below US$10 per test to commit to the implementation of the Cepheid point-of-care test system to screen for TB.

To resolve the impasse, Cepheid participated with CHAI in a detailed COGS analysis. The data revealed that at low volumes, the fixed manufacturing overhead costs were a relatively high percentage of total costs. These fixed costs become much less significant in comparison to variable materials, labor, and distribution costs as volumes increase from three to five to 10 million units per year.

To solve the cost recovery problem and achieve a ceiling price agreement satisfactory to major buyers and funders, the partners paid US$11.1 million to Cepheid over three years to "buy down" or compensate for sales revenue that would not be received at the proposed ceiling price of US$9.98 per cartridge. Cepheid agreed to hold the price constant

26 https://www.clintonhealthaccess.org/wp-content/uploads/2023/06/Pediatric-DTG-Case-Study_Mar-2023.pdf

Figure 17: Total Manufacturing Overhead Costs at Selected Volumes

Components:

Supervisors
Management
Quality Control
Engineering Support
Maintenance
Facility Costs
IT Costs
Excess Capacity

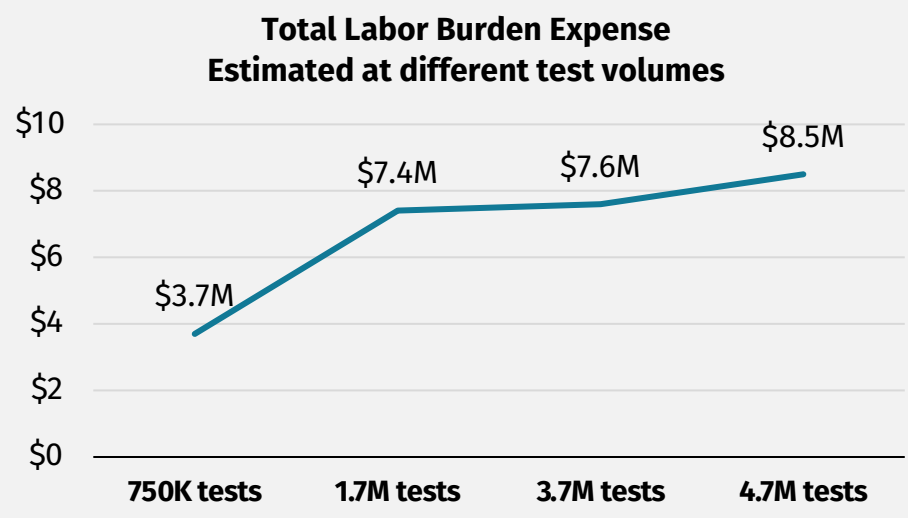
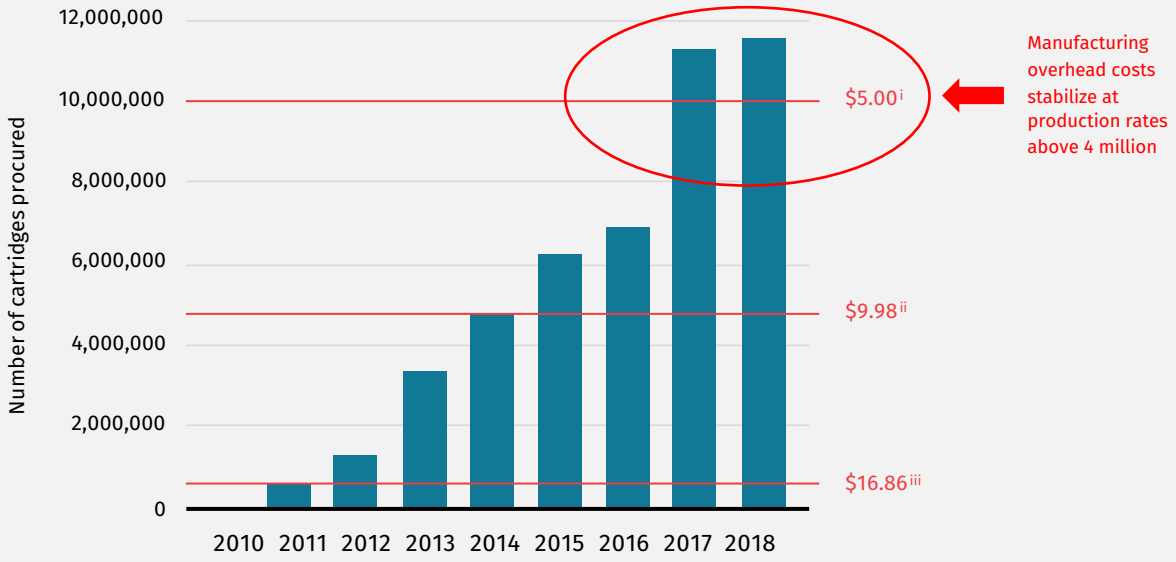


Figure 18: Annual Volumes of GeneXpert TB tests Procured by LMICs, 2010-2018. Source: Link



i $5 is the Time for $5 target price based on estimated COGS and annual volumes over 10 million
ii $9.98 is the buy-down price for volumes over 4.7 million
iii $16.86 is the FIND-negotiated price for volumes over 600,000

for ten years and apply it to orders from all public sector purchasers in 145 countries through 2022.[27]

This buydown agreement is a good example of the "tipping point" aspect of pricing in LMICs. During the five years after the deal sales exploded, from less than two million tests in 2012 to over 10 million tests five years later. The buydown agreement reduced the price of the Cepheid test by US$6.88, resulting in savings of over US$150 million for the donors that had funded the deal and were funding the procurement of TB tests.

The Gates Foundation initiated another buydown in 2017 with OraSure Technologies, Inc. for their OraQuick HIV self-test (HIVST), a critical tool to expand access to discreet HIV testing. The OraQuick HIVST was seen as an important tool for helping to increase the number of people who know their HIV status, particularly in regions with high stigma surrounding the disease. However, the self-test kits were not widely used because the price was too high.

The buydown from the Gates Foundation brought the price of the OraQuick test to US$2.00 per kit (ex-works) in fifty LMICs for a period of four years.[28] This initiative complemented extensive investments in demand generation by other donors and is credited with creating the market for millions of HIVSTs to be used in LMICs.[29] While the two types of investments helped create the market for HIVST, OraQuick retained an advantage as other suppliers found it difficult to launch self-test products at such a low price.[30] The risk of market distortion demonstrates the importance of planning for a sustainable exit to the market shaping intervention. By 2022, the market dynamics had improved, other interventions had come into play, resulting in 6 producers supplying self-tests at prices ranging from US$1[31] to US$3 EXW.[32]

4.3 Procurement guarantees

A procurement guarantee enables buyers to aggregate demand, reduce prices, and ensure stability of supply by purchasing directly on behalf of LMIC public health programs. These guarantees are needed when buyers are prevented by statute or policy from placing firm orders with suppliers or shipping orders to partner governments until they have received payment; examples include UNICEF and the Global Fund.

With a guarantee in place, UNICEF or another procurer can purchase supplies and ship them to countries in advance of receiving payment. If governments or donors ultimately default on their payments or the purchaser has secured supplies that are unsellable (either because sufficient demand does not exist or willingness to pay falls short of the acquisition cost), then the guarantor would compensate the procurer.

The first use of a large-scale procurement guarantee was the Vaccine Independence Initiative (VII), established in 1991 and managed by UNCIEF Supply Division.[33] Under the VII, countries utilize their own domestic resources to procure health-related supplies. The guarantee provided to UNICEF helps countries bridge temporary short-term funding gaps, which might otherwise lead to supply shortages and stock-outs. Each country has a ceiling that sets the maximum amount which may be owed to UNICEF at any given point. Countries have thirty days to repay VII once the products are received and invoiced. If a country defaults on its payment, it jeopardizes its

27 The Cepheid buy down agreement: Evaluation and implications for the future | Document | U.S. Agency for International Development. (n.d.). U.S. Agency For International Development. https://www.usaid.gov/document/cepheid-buy-down-agreement-evaluation-and-implications-future

28 Expanding HIV self-testing in Africa - Unitaid. (2023, July 28). Unitaid. https://unitaid.org/project/self-testing-africa-star/#en

29 Meyer-Rath, G., Jamieson, L., & Pillay, Y. (2023). What will it take for an injectable ARV to change the face of the HIV epidemic in high-prevalence countries? Considerations regarding drug costs and operations. Journal of the International AIDS Society, 26(S2). https://doi.org/10.1002/jia2.26106

30 Expanding HIV self-testing in Africa - Unitaid. (2023, July 28). Unitaid. https://unitaid.org/project/self-testing-africa-star/#en

31 The $1 price was achieved with a related VG.

32 EXW stands for Ex Works, an Incoterm whereby the buyer of a shipped product pays for the goods when they are delivered to a specified location.

33 The Vaccine Independence Initiative. (n.d.). UNICEF Supply Division. https://www.unicef.org/supply/vaccine-independence-initiative

future participation in VII and the supply procured through VII may stop until payment is made.

As of 2023, VII had US$150 million in capital with contributions from BMGF, Gavi, the US Fund for UNICEF, and others.[34] Its scope has expanded from vaccines to include medicines, bed nets, nutrition products, and cold chain equipment.[35] Between 2015-2019, VII facilitated the on-time delivery of 565 million doses of vaccines, 100,000 cartons of ready-to-use therapeutic foods, and 400,000 packs of ARVs.[36]

In 2020, the Gates Foundation and MedAccess committed US$50 million each as part of their COVID-19 response, which enabled UNICEF to provide LMICs with US$313 million in pre-financing commitments for COVID-19 supplies.[37] This facility enabled UNICEF to buy COVID-19 tests and other essential health products on very favorable terms. Given the flexibility that VII provides, it is anticipated that the fund will continue to grow.

Risk management on procurement guarantees.

Global health guarantors have executed fewer procurement guarantees than VGs, and the risk assessment approach must be "bespoke" for each deal. Most procurement guarantees are intermediated to some extent, i.e. the procurer is authorized to assume risk against a third-party guarantee, per the negotiated provisions, though the level of intermediation can vary between agreements. For instance, a guarantor may deem that a particular procurer has sufficient track record and operating procedures to offer prepayments or VGs to suppliers or to pre-finance orders from eligible purchasers, up to a certain value. Alternatively, guarantors may ask that every transaction conducted against a guarantee come to their investment committee for prior authorization. Even in the latter scenario, the sourcing and execution of the individual transactions falls to the procurer, not the guarantor.

Given the intermediated nature of these deals, guarantors must assess the transaction-level default risk—the likelihood that the transactions being backed by the guarantee will result in a pay-out—and any operational risks related to the people, processes, and mandate of the procurer.

Transaction-level default risk - *What is the nature of financial risk at the individual transaction level? What is the counterparty's track record of losses? Will the counterparty be engaging in higher- or lower-risk transactions going forward?*

Across procurement guarantees applied in the global health sector to date, transaction-level financial risks have included:

- **Prepayments to suppliers:** demand does not materialize to cover purchased quantity OR market price decreases force onward sale at a price below acquisition cost (partial or full quantity loss at acquisition cost or at weighted average market price – acquisition cost).
- **Volume guarantees to suppliers:** similar to a direct VG, the primary risk is that demand does not materialize to cover the guaranteed quantity (partial or full loss at contracted ceiling price or shortfall fee).
- **Prefinancing to purchasers:** counterparty orders and ships product based on commitments from funders—typically government payors or donors—to transfer payment upon delivery; default arises if the funder is ultimately unable to pay for goods (partial or full loss at cost of product and logistics).

34 New funding will allow countries to secure sustainable vaccine supplies and reach children more quickly - UNICEF. (n.d.). https://www.unicef.org/press-releases/new-funding-will-allow-countries-secure-sustainable-vaccine-supplies-and-reach

35 Strengthening domestic resources to deliver life-saving commodities. (n.d.). UNICEF Supply Division. https://www.unicef.org/supply/stories/strengthening-domestic-resources-deliver-life-saving-commodities

36 Strengthening domestic resources to deliver life-saving commodities. (n.d.). UNICEF Supply Division. https://www.unicef.org/supply/stories/strengthening-domestic-resources-deliver-life-saving-commodities

37 Mobilizing finance for infectious disease prevention, detection, and response: learning brief and case study analysis | MarketLinks. (2024, January 17). Marketlinks. https://www.marketlinks.org/resources/mobilizing-finance-infectious-disease-prevention-detection-and-response-learning-brief

Once the broad structure of the procurement guarantee has been defined, deal teams can determine the relative exposure the guarantor has to each of the types of financial risk outlined above, and which product classes and funders may generate the greatest risk of a pay-out.

Where available, the track record of defaults and information on the transaction pipeline/projections can be helpful to contextualize the risk that a guarantor will be undertaking.

- **Operational risks:** given the intermediated nature of procurement guarantees, guarantors must assess the people, policies, and procedures that will govern implementation of the guarantee within the procurer's organization. While operational risks are difficult to quantify, they are nevertheless critical for guarantors to understand, accept, and potentially mitigate.
- **Strategic alignment:** guarantors must understand the broad mission of the procurer and the vision for the team(s) responsible for administering and implementing the guarantee. From an impact perspective, there must be alignment on the objectives of the guarantee and the eligible territories and products. From a financial risk perspective, guarantors must be comfortable with the counterparty's broad approach to transaction origination, risk assessment, and risk mitigation.
- **People:** guarantors must also understand which employees are responsible for implementing the guarantee and how they interface with the rest of the organization and key partners. Guarantors must ultimately feel comfortable with both the origination skills of key staff and their approach to risk-taking against the guarantee.
- **Systems:** guarantors may ask to review policies and procedures related to the implementation of the guarantee and related functions within the procurement organization. For example, if the guarantor expects to be exposed to prefinancing of orders paid by national governments, then deal teams may ask the procurer for details on how orders are solicited and confirmed and how the procurer determines the availability of funds and ability to complete payment.

4.4 Licensing

Many of the most successful market shaping interventions for pharmaceutical products have involved collaborative licensing agreements between innovator and generic pharmaceutical firms. Licensing enables additional manufacturers to produce and sell on-patent products within defined territories and may involve a tech transfer and/or royalty. Licensing can enhance the global supply of medications, reduce treatment gaps, and improve health equity.

Gilead has leveraged voluntary licenses as a tool on numerous occasions. The company was one of the early successful innovators in producing anti-retroviral drugs to treat HIV, winning about 50 percent of the global market by 2006. Over the previous five years Gilead had experimented with a variety of approaches to expand access to TDF in LMICs, including donations, tiered pricing, and not-for-profit pricing but with poor results. Less than 50,000 of the over five million potential patients in LMICs had received the drug. Gilead's "not for profit" pricing proved far too expensive for governments and donors in LMICs despite the price being a 95 percent discount to the US price.[38]

In September of 2006, Gilead announced that it had signed licensing agreements with eight Indian firms to produce generic versions of its blockbuster product TDF.[39] Gilead was the first of the innovative pharma companies to carefully analyze what was needed to expand the number of people that could

38 Gilead will license tenofovir to Indian companies; Merck to take Atripla to Africa. (2006, July 26). aidsmap.com. https://www.aidsmap.com/news/jul-2006/gilead-will-license-tenofovir-indian-companies-merck-take-atripla-africa

39 https://www.gilead.com/news/news-details/2006/gilead-announces-licensing-agreements-with-eight-india-based-companies-for-manufacturing-and-distribution-of-generic-versions-of-viread-in-the-developing-world

benefit from their drugs and then to systematically adjust its strategy based on results.[40]

On production costs, Gilead recognized that dedicating very large amounts of their TDF manufacturing capacity in Puerto Rico to serve a not-for-profit market that had 20 times more patients than the for-profit segment would not be in their shareholder's best interest, but getting TDF to patients in LMICs would be. In licensing the product, Gilead had determined that generic firms could sell TDF for 30-50 percent less than Gilead's not-for-profit price.

Gilead's licensing strategy for TDF was extremely bold and was counter to conventional wisdom. Innovator companies had refused to license their most profitable products for use in LMIC for years based on five "concerns":

1. **Reimportation**: generic products would be imported into the US and Europe by unscrupulous distributors and undermine pricing in the core markets.
2. **Adverse events**: generic drugs prescribed in LMICs would produce adverse events not seen in the more closely supervised medical practice systems in rich countries, but these adverse events would be recognized by the FDA and other regulators and possibly undermine the original marketing authorization.
3. **Leakage of technology**: sharing the know-how for producing blockbuster drugs would enable generic firms to compete more effectively with innovators and gradually undermine the innovators competitive advantage.
4. **Counterfeiting**: allowing sale of licensed products in LMICs would also encourage widespread counterfeiting of these important products and this would undermine the overall value of the medicine and the brand.
5. **Generic firms would not honor licensed territory agreements**: generics firms would start to sell into middle- and upper-income markets. Legal action would be fruitless as courts in India would favor local companies over international firms.

These "concerns," however, had very limited evidence and Gilead's continued willingness to license profitable products proved the conventional wisdom to be completely false. By 2023, after granting over thirty-five licenses to the full portfolio of HIV and HCV products, 2023 Gilead remained the profit and market share leader in both sectors.

4.5 Science-based cost optimization

For small molecule drugs, the cost of active pharmaceutical ingredient (API) is the major factor driving finished product costs. When cost savings from scale effects and yield improvement are not enough, it may be necessary to consider additional options involving new synthetic routes and approaches to producing raw materials. CHAI has supported science-based cost optimization over a number of years using its own staff and through academic partnerships.

For the past 15 years, TDF has been the backbone of most fixed-dose combination anti-viral medications for management of HIV. Given the massive amounts of TDF used and the long-term importance of this compound, CHAI's analysis identified opportunities for lower-cost sources of raw materials and chemical intermediates and changes in the manufacturing processes.

When the first generic supplier of TDF entered the market in 2006, a year's course of the drug cost about US$210 per patient. The chemical synthesis for the API was a three-step process with an overall yield of 13 percent. The team at CHAI used their knowledge of process chemistry to improve the yield by over 80 percent and published their improvements in a paper.[41] CHAI also worked to secure more reliable supplies for starting materials,

40 Alton, G., Samuel, C., & Reddi, A. (2022). Providing access to high-quality, low-cost medicines across low and middle-income countries (LMICs), working with governments and generic manufacturers around the globe - A business case. Antiviral Therapy, 27(2), 135965352110686. https://doi.org/10.1177/13596535211068617

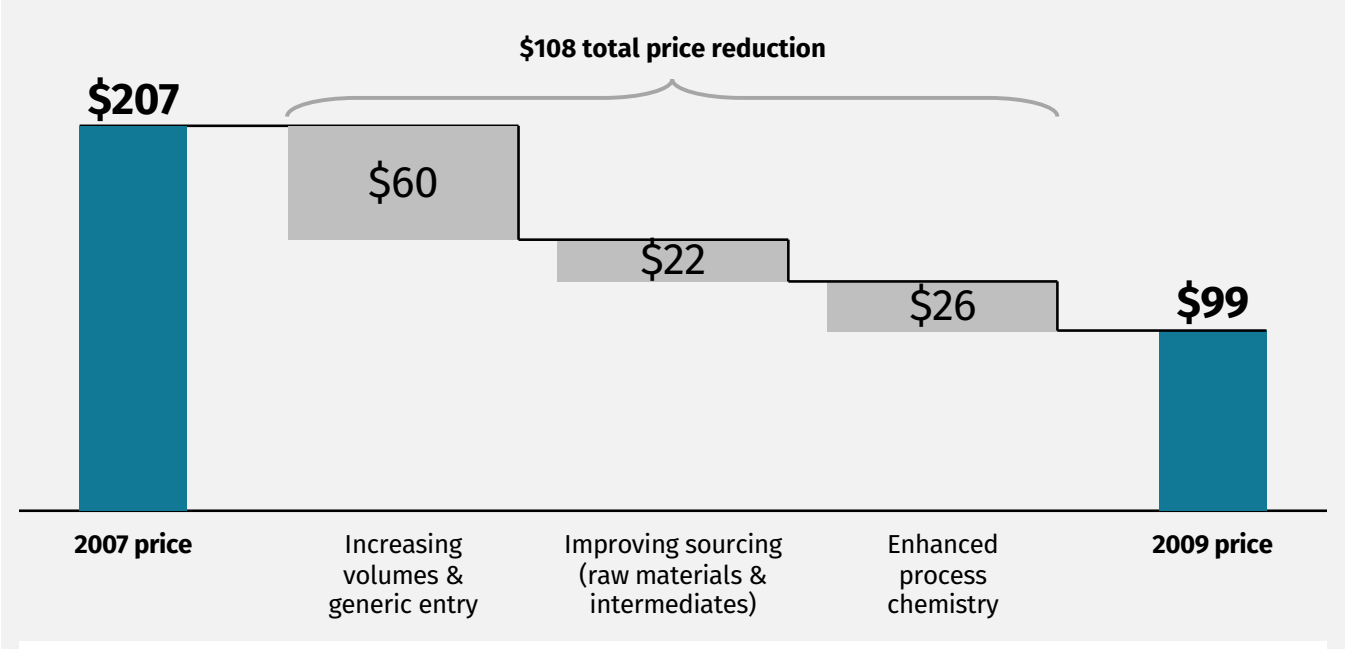
41 https://cen.acs.org/articles/88/i39/Tenofovir-Developing-World.html

including quality magnesium tert-butoxide, which has "been a big help in TDF manufacture."[42]

Four starting materials accounted for ~45 percent of the manufacturing cost. CHAI identified new, lower-cost manufacturers of these materials and coordinated their adoption by generic manufacturers. CHAI's process chemistry work identified inefficiencies in two of the TDF manufacturing steps. With financial support from the BMGF, CHAI chemists investigated improvements internally and, in cooperation with external organizations, were able to improve efficiency by 50 percent. The net effect of these efforts was a 45 percent reduction in the COGS for TDF over a three-to-five-year period.[43]

"This work illustrates the importance of lowering production costs through insightful process chemistry improvements," commented Robert Singer, a process chemist with Pfizer. "These process improvements are particularly important for bringing this medicine to the Third World at an affordable cost."[44]

Figure 19: Tenofovir price reduction, 2007-2009 (price per patient per year, PPPY)



42 Halford, B. (2011, October 27). Tenofovir for the developing world. Chemical & Engineering News. https://cen.acs.org/articles/88/i39/Tenofovir-Developing-World.html

43 Ripin, D. H. B., Teager, D. S., Fortunak, J., Basha, S. M., Bivins, N., Boddy, C. N., Byrn, S., Catlin, K. K., Houghton, S. R., Jagadeesh, S. T., Kumar, K. A., Melton, J., Muneer, S., Rao, L. N., Rao, R. V., Ray, P. C., Reddy, N. G., Reddy, R. M., Shekar, K. C., . . . Williams, A. (2010). Process improvements for the manufacture of tenofovir disoproxil fumarate at commercial scale. Organic Process Research & Development, 14(5), 1194–1201. https://doi.org/10.1021/op1001337

44 Halford, B. (2011, October 27). Tenofovir for the developing world. Chemical & Engineering News. https://cen.acs.org/articles/88/i39/Tenofovir-Developing-World.html

Annex

ANNEX 1:

CHAI's first deal: Bringing ARVs to low- and middle-income countries (LMICs)

By Ira C. Magaziner, co-founder of the Clinton Health Access Initiative

In 2002, AIDS was raging throughout Africa and beginning to have a significant impact on many countries in Asia and the Caribbean. Despite the awareness and attention of the global health community, millions of people were dying from AIDS in these countries each year, even though the drugs and systems of care to treat HIV/AIDS existed in wealthier nations.

In January 2002, President Clinton and I started what we then called the Clinton HIV/AIDS Initiative (whose name we changed to the Clinton Health Access Initiative when we expanded into other areas of Global Health in 2005). Our aim was to scale up AIDS care and treatment in low- and middle-income countries where the epidemic was most severe.

After talking with AIDS experts in the United States and preparing an analysis of the problem in early 2002, we attended the global AIDS conference in Barcelona that summer where President Clinton and former President Nelson Mandela had been asked to give keynote speeches. We took the opportunity while at the conference to meet with several government leaders from Africa and the Caribbean to discuss the AIDS crisis in their countries.

Leaders with whom we spoke said that what they needed most was assistance in creating the systems in their central governments and throughout their countries to scale up effective AIDS care and treatment, and they wanted to set this up in a way that would eventually enable them to run their systems without depending on outside support.

We started by partnering with selected governments in Africa and the Caribbean and put people on the ground in these countries to work with governments on developing the human and physical infrastructure necessary for diagnosing and treating people for AIDS.

However, the prices of drugs and tests were prohibitively expensive. While some pharmaceutical companies offered lower prices or donations in limited quantities, it was not enough. The average price in most developing countries, even for generic ARV drugs, was US$600 per person per year. The price of annual tests added another US$100 or more per person. In countries where the average per capita income was only US$400 per person per year, this was unaffordable.

The market shaping approach: dynamic cost analysis and deal-making

The "market shaping" approach to reducing costs and prices and accelerating the availability of new products to a market originated in private sector work that I did while at BCG in the late 1970s and at my own firms Telesis and SJS in the 1980s. This work was also informed by the total quality manufacturing movement (TQM) that applied principles developed by Japanese manufacturers globally.

I was confident about this based on work that I had done in the private sector to develop dynamic cost analysis and total quality management procurement during the 1980s and on the dramatic cost and price reductions I had seen (and in some cases had worked on) in various industries.

Theoretical tools like the experience curve and Moore's law in the semiconductor industry predicted that with increasing experience and scale the cost of new products could decline continuously. During my business career in the late 1970s and 1980s I observed this in work that I did with Corning Inc. on optical fiber and photonic components for telecommunications and new compositions of glass that enabled flat screen televisions and touch pads in hand-held devices. I also observed it in work with General Electric on microwave ovens and with several semiconductor and chemical companies.

Achieving dramatically lower costs involves cooperation among suppliers and customers, working with companies throughout the value chain and dynamic cost analysis with companies throughout the supply chain. Ultimately, however, it also involves negotiating sets of deals that are necessary to cause companies to make the investments necessary to increase production and reduce costs.

Dynamic cost analysis is a key element to the success of the CHAI approach to market shaping. The role that this plays is crucial to lowering costs and prices and yet it is poorly understood.

To carry out this analysis, CHAI negotiated non-disclosure agreements (NDAs) with pharmaceutical, diagnostics and vaccine companies and their raw materials and intermediate products suppliers that allowed us to gain access to private cost data and to manufacturing and finance managers at the companies.

It is typical for purchasing organizations to enlist an accounting or consulting firm to vet the cost of production of a product to verify that a manufacturer is not making an excessive profit on the product they are producing. This “static” cost analysis can be accurate but yet miss the potential to dramatically reduce costs and therefore prices by the use of various market or supply chain interventions. We used our access to company manufacturing and cost systems to do dynamic cost analysis that analyzed ways we could shape the market to allow companies to lower costs.

The production of a drug usually involves the combining of different chemical materials that may be heated in vats, mixed together with other materials in tanks, purified, dried and then made into capsules. The direct labor to produce products is usually relatively small. Indirect costs such as material handling, inspection and quality control, maintenance, utilities and so forth are typically much larger. The yields at each process step are also important (the amount of material that must be thrown away or re-manufactured). If a vat or machine is used to make multiple products, then there can be down time where they are being cleaned to remove all residue of one product before running a different product.

If a manufacturer knows that it will have large predictable orders that allow it to run dedicated machinery at high capacity utilization consistently, it can install larger capacity machinery and tanks with automated materials handling between production stations and automated inspection which lowers direct labor costs and material handling costs and results in less inspection costs and much better yields.

Further, the production of a drug usually involves the procurement of multiple specialty chemicals which are combined and used to produce an API (active pharmaceutical ingredient). This active pharmaceutical ingredient is then combined with excipients and other materials in a production process to produce the final drug. Each specialty chemical has its own set of economics. If the chemical is produced in small batches with uneven order patterns, it can be very expensive. If it can be produced in larger predictable quantities, then specialty chemical suppliers can use dedicated large scale continuous processes that can reduce their costs by 70 or 80 percent. Since the optimum scale for different chemical intermediates may be different, the negotiation of specific deals with each company and the balancing of inventories can be very important to overall product cost.

Similarly, standardization of packaging requirements across customers and standardization of product specifications as well as simpler more predictable tendering rules across numerous customers can help manufacturers to lower their costs of production and their marketing and distribution costs. These lower costs can result in lower prices while still preserving profits so that companies can invest in product improvements and new generations of drug development.

A volume guarantee with predictable steady offtake provided to the final product manufacturer can help underpin the various deals that are necessary as companies at all stages of manufacturing from specialty chemical suppliers to API manufacturers to final product manufacturers can be assured that if they invest in large scale, dedicated, continuous equipment, it will be fully utilized. Putting together this chain of deals was essential to our initial AIDS drug and diagnostics negotiations and to subsequent deals.

Ultimately, working with manufacturers to do dynamic cost analysis to show what costs could be, striking deals at different levels of the supply chain to enable the dynamic lowering of costs at each level, and organizing the market to higher volume steady demand and standardization are the key factors to lower costs and prices. And, in some cases the provision of the volume guarantees cements the deals.

The expertise to work with companies to do this dynamic cost analysis and do the necessary deals was essential in enabling us to cut costs dramatically for AIDS drugs by over 75% and diagnostics by 90% in the first deals and then to continue to cut costs and prices by large percentages across more than 150 different agreements over the years.

We started our work in Mozambique, Rwanda, Ethiopia, Tanzania, Kenya and several Caribbean nations. We soon expanded to South Africa, China, and India. Eventually we set up offices in almost 40 countries

After we announced our first deal with Cipla, Aspen, Ranbaxy, Hetero and Matrix, we turned our attention to diagnostic testing for HIV patients. Interestingly, we found that Beckton-Dickinson from the US and Roche from Europe were willing to work with us. We successfully concluded our first AIDS diagnostic deals about six months after the AIDS drug deals. Watch Ira Magaziner's interview at The Atlantic Meets the Pacific in 2012.

In these first round of agreements, we lowered the prices of AIDS drugs to treat someone for a year from over $600 per year to $139 per year and we lowered the price of diagnostics from around $100 per year to under $10 per year. As we continued our work overtime with subsequent generations of drugs and tests, we now have better drugs and diagnostics at less than half these costs.[1,2,3]

With our success in lowering the prices of AIDS drugs and diagnostics to lower- and middle-income countries, the Bill and Melinda Gates Foundation (BMGF) and other donors asked if we would expand our market shaping work to malaria and tuberculosis (TB) products. We then expanded to vaccines, maternal and child health, sexual and reproductive health, and beyond. At the same time, we expanded the number of countries and country teams where we worked so that we could help more people. Doing this also allowed us to aggregate larger markets to attract manufacturers to work with us.

Putting it all together at CHAI

The keys to our success can be found in the type of people we hired. We hired people with business experience in doing dynamic cost analysis and in negotiating deals. We established country teams mainly of local nationals with business experience and experience working with governments. We deployed a combination of medical people with experience treating AIDS and people with business and management experience who could help governments develop the management systems necessary to run the care and treatment systems. For the former capabilities, we partnered with groups at US universities like Harvard, Columbia, UCSF, and the University of Washington that had AIDS medical experts that worked in the developing world and then we recruited and hired people with the business and management experience to work directly for us.

We understood that setting up clinics run by NGOs would not scale to meet the demands of the AIDS crisis. We needed to partner with governments who ran the health systems in most developing countries and help them develop the skills and infrastructure to scale-up care and treatment in mainstream health systems in the country.

At the time, many of the NGOs in the AIDS space questioned why we were hiring businesspeople who knew nothing about AIDS. But they soon understood that the ability to work with governments, to help establish management systems on the ground and the ability to do the analysis and create the deals

1 Times, N. Y. (2004, April 6). Plan to bring generic AIDS drugs to poor nations. The New York Times. https://www.nytimes.com/2004/04/06/health/plan-to-bring-generic-aids-drugs-to-poor-nations.html

2 Clinton Foundation, Global Fund, World Bank, UNICEF extend Low-Cost Generic AIDS drug prices to more than 100 countries - KFF Health News. (2004, April 6). KFF Health News. https://kffhealthnews.org/morning-breakout/dr00023059/

3 Magazine, B. B. M. F. (2006, September 18). The power of philanthropy - September 18, 2006.

with companies globally were all essential to scaling up care and treatment.

The businesspeople we hired included seasoned professionals who had run businesses and who could convince senior executives at major pharmaceutical and diagnostics companies that we understood their businesses. It was essential that we hired not just analysts, but also people who knew how to negotiate deals.

This is an important point: those doing market shaping must be good negotiators who can create the web of deals to bring about a final result. These deals can often involve moving companies outside of their comfort zones and current practices, and so the people leading negotiations must be able to gain the confidence of senior managers at companies. They also must be able to persuade senior managers that there is a significant enough market that will emerge to justify the investments and the efforts necessary to increase scale and decrease costs.

This combination of having people on the ground who could work on the demand side with governments and help them develop the infrastructure to scale-up care and treatment alongside seasoned executives who could work with companies to assist them to expand capacity and lower costs and prices throughout the supply chain was unique in global health.

VGs and credit enhancements are valuable tools for market shaping, but they are not at the core of market shaping. The fundamental work of market shaping is bringing suppliers and customers to work together, involving companies throughout the supply chain of a product, doing the dynamic cost analysis at every level of the supply chain, helping negotiate the web of deals necessary to lower costs and prices of a product and developing the markets. Sometimes putting this all together is sufficient to trigger the scale-up and price lowering goals. Sometimes, a VG and other credit enhancements can help make the deals work.

Western governments that set up programs to provide advanced market commitments are often frustrated because individual companies on their own usually lack the motivation and bandwidth to perform the analysis throughout the supply chain and the time to put together all the deals necessary. As a result, uptake on the financial incentives is infrequent, and incentives provided to individual companies do not bring transformative results. Successful market shaping requires working with multiple companies under non-disclosure agreements to reshape the whole supply chain.

ANNEX 2:

CHAI resources and public goods

CHAI Market Reports

Topic/ Disease Area	Available Market Reports
Diabetes	2021
Malaria	2021, 2022, 2023
HIV	2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025 ARV Market Reports: 2014, 2015, 2016, 2017
Hepatitis	2017, 2020, 2021, 2022 HCV, 2022 HBV, 2023
Family Planning	2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025
Assistive Products	2024, 2025

CHAI market shaping framework

Click here for access to CHAI Market Shaping Framework.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