Foundations of Market Shaping

Fundamental concepts and best practices for successful global health market shaping

February 2024

Table of Contents

Acknowledgments

Developing Foundations of Market Shaping (FMS) was a collaborative effort that would not have been possible without the support of and contributions from many members of the global health market shaping community. We are grateful for the dedication of these partners, who put significant time and energy into making sure this resource captures market shaping practitioners' latest thinking and provides clarity on foundational aspects of the discipline.

FMS is part of the Bill & Melinda Gates Foundation-funded Market Ecosystem Thought Leadership (META) initiative to strengthen the market shaping community of practice, and we at Linksbridge are thankful for the opportunity to spearhead this effort. Special thanks to Gaurvika Nayyar and Ian Thornton at the foundation for their invaluable vision and support on the creation of FMS.

We also deeply appreciate the significant contributions of the META Advisory Council, a dedicated group of market shaping leaders who helped envision, develop, and champion this resource. The META Market Shaping Network also provided important feedback and insights that helped guide the direction of FMS. Thank you to these groups for providing conceptual guidance and applied examples for this document. Lastly, we would like to thank CHAI for their close coordination on the META effort and for their work to update the CHAI Market Shaping Framework, which provides a valuable compilation of current market shaping interventions and financial tools and is shared in FMS.

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Executive summary

The field of market shaping for global health has seen significant evolution and impact over the past decades as practitioners work to close gaps between commercial interests and health needs. While advancement in the market shaping practice and ecosystem has spurred progress, it has also contributed to a proliferation of approaches and varied understanding of fundamental principles, which has hampered collaboration. This presents opportunities to build greater alignment across the expanded ecosystem.

To continue progressing, it's imperative that practitioners work from a shared foundational understanding of core concepts and strategies. With this objective in mind, Foundations of Market Shaping (FMS) explores key aspects of the market shaping practice: definitions, characteristics of healthy markets, widely accepted best practices, and practical guidance for intervention planning and execution.

Actors intervene in markets to improve health outcomes by closing market gaps between commercial drivers and societal needs for equitable access to essential health products. The fundamental characterization of a market shaping intervention is that it alters the dynamics or incentives between buyers and suppliers in a way that improves market health. Market intervention is a powerful tool and one that poses risk for unintended consequences. It is not always the most appropriate course of action, including in situations where the need for a new product is not well established or when funding is unavailable to support product purchasing. As such, opportunities for market intervention should be scrutinized and selected judiciously.

FMS synthesizes a set of 12 best practices (see below) that can help ensure that interventions avoid unintended consequences, create shared value for all parties involved, and meet their predetermined targets.

As actors begin to design, plan, and execute market interventions, they should make sure they clearly understand factors that may make market shaping easier or more challenging: aspects of their market shaping operating environment, including established partner coordination and decision-making processes, and factors inherent to the market's structure, such as delivery homogeneity and demand predictability. The process of market strategy design and intervention implementation includes seven essential steps which, when followed with FMS's 12 best practices in mind, can help market shapers execute more effective interventions. Effective intervention processes start with understanding local stakeholders' decisions, competing priorities, and health program needs. The remaining steps encompass conducting various analytical assessments, aligning on clearly defined targets, selecting the most appropriate interventions, and evaluating the results and impact of the interventions.

Discrete market interventions should align with an overarching market shaping strategy with defined targets, objectives, and responsibilities. Each market situation and its gaps are unique, and strategies and interventions must be designed to fit the specific situation. Part 4 of FMS (Interventions playbook) provides explanations and examples of common interventions used in each product phase—from development through delivery—and financial tools that can be used in a variety of product stages.

As a point-in-time synthesis of practitioners' latest thinking in a continuously growing discipline, FMS represents one step in an ongoing effort to better organize, connect, and develop the market shaping community of practice. Global health market shaping has seen incredible achievements and experienced various unintended consequences as the practice has developed, and its sustainability and future success hinges on our ability to align on definitions, document best practices, and learn from past mistakes.

Market shaping best practices

Fundamentals for success

1. A genuine market shaping opportunity exists
2. Market shaping actors understand the true need and potential demand for a product

Ensuring sustainable, mutual value

3. Accurate, impartial, symmetric market information enables informed decision-making by all
4. Differentiated risk and resource positions form the basis of mutually valuable agreements
5. Compared to other options, the intervention creates sustainable, positive, and mutual value for end-users, buyers, and sellers

Effective execution

6. Individual interventions align with an overarching market shaping strategy based on strong market analytics
7. Actors working to shape a market follow an agreed-upon value chain that focuses on mutual success in accomplishing the market shaping strategy
8. Intervention teams have i) empowered, strong leadership, ii) discipline and clear structure, and iii) the necessary skills to succeed

Impact achievement

9. Interventions are tracked all the way to impact, with course corrections made as appropriate
10. A named owner manages implementation and impact measurement

Transparency with partners

11. Global health actors engage all relevant stakeholders before, during, and after intervention execution
12. Global health actors share information about interventions, including their successes and challenges

Introduction

Market shaping for global health has evolved over the past several decades into a critical component of access to medicines in low- and middle-income countries (LMICs). Market shaping efforts have helped reduce the cost of pentavalent, pneumococcal, and rotavirus vaccines by nearly a third over the last decade.[1] Competitive tenders among generics pharmaceutical manufacturers for organized, aggregated demand have reduced the cost of first-line HIV treatments to less than $45 per year.[2] Various market shaping efforts including product development support and WHO prequalification helped accelerate access to next-generation mosquito nets for tens of millions of people—averting nearly 12 million malaria cases.[3] While a growing variety of actors and an improved understanding of market shaping have made it more impactful over time, its rapid evolution has also generated confusion, opacity, and contradictory interpretations of fundamental concepts and best practices.

As markets[4] are varied and diverse, so too is the market shaping practice: a uniform approach to the latter is neither realistic nor desirable. However, greater alignment and shared guidance on foundational elements of market shaping could make collective efforts more efficient and impactful. To that end, Foundations of Market Shaping (FMS) aims to synthesize practitioners' latest thinking—building on previous seminal works such as the USAID Market Shaping Primer—to offer definitions of healthy

[1] Global Vaccine Market Model
[2] Global Fund press release
[3] MedAccess: Next-generation mosquito nets
[4] For the purposes of this document, a "market" refers to the transaction between a buyer and supplier for a group of related products, usually defined by their target health area (e.g., tuberculosis or malaria) and the product category (e.g., drugs or vaccines).

markets and market shaping practices, provide practical guidance on intervention planning and implementation, and outline generally agreed upon best practices. Because the market shaping field is growing and evolving, FMS represents one step in an ongoing effort to better organize, connect, and develop the market shaping community of practice.

FMS's primary goal is to offer experienced market shaping actors a set of definitions, principles, and best practices across areas in the field where understanding may vary. Its secondary purpose is to demystify market shaping and provide frameworks and tools for newer members of the community. With these goals in mind, a variety of actors may find this resource helpful, but it is targeted toward those involved in planning and executing large-scale global and regional market interventions.

A number of critical areas of improvement for the market shaping practice fall outside of the scope of FMS and should be a priority of future efforts. For example, it will be important to document and provide technical guidance for critical skills, such as building market intelligence, conducting market analyses, and designing interventions. Future resources should also dive deeper into market shaping approaches, actors, and tools involved at the subnational or local level, as they can differ from those used in global-level market shaping. Market shortcomings at all levels—from local to global or from research and development to final-mile delivery—must be addressed to ensure broad, equitable access to critical health products for people in LMICs.

This document is divided into four parts

Market shaping overview: Presents context, definitions, and goals

Critical concepts and best practices: Summarizes the core considerations required for successful interventions

Effective intervention planning and execution: Describes features of the operating environment and market that impact execution; discusses essential steps for effective market shaping efforts

Interventions playbook: Offers a playbook of intervention types and real-world examples of market shaping activities

PART 1 Market shaping overview

This section aims to provide guidance on the definitions and boundaries of market shaping by placing it in the context of other efforts to improve access to critical health products. It begins by distinguishing the problem, intervention, and intended outcome:

Problem: What problem does market shaping specifically aim to solve?

Intervention: How do practitioners differentiate market shaping activities and opportunities versus other related activities?

Outcome: What are the target outcomes and goals of market shaping?

Problem statement: Market shortcoming

Intervention is required when a market shortcoming, deficiency, or distortion compromises health outcomes. Prevailing market dynamics between buyers and suppliers may inhibit access to desired or essential health products or services, resulting in suboptimal health outcomes.

Market shortcomings particularly plague global health markets for several reasons, including information asymmetry between buyers and suppliers, unequal resource distribution, a complex mix of tiered buyers and suppliers, and a lack of innovation drivers.

Market shortcoming examples

Next-generation mosquito nets: Growing resistance among mosquitoes to pyrethroids—the main insecticide class used in standard insecticide-treated nets—hindered progress in preventing the spread of malaria. Uptake of next-generation nets that address this issue was expected to be slow due to several market-related barriers, including cost, adoption uncertainty, and slow prioritization.[5]

Antimicrobial resistance: Despite the growing threat of antibiotic resistance, incentives for pharmaceutical companies to develop and market new antibiotics are weak. The R&D pipeline for new antimicrobial therapies has stagnated due to scientific challenges, high uncertainty, and low revenues. Furthermore, while several push mechanisms incentivizing the initial phases of R&D have been put in place, few pull incentives have been implemented to help correct market shortcomings.[6]

HIV viral load testing: HIV viral load testing is needed to ensure treatment is effective and viral suppression achieved. The market had many buyers but few sellers—two dominant suppliers in Africa offered HIV viral load testing at a wide range of prices—meaning that product and service procurement was fragmented, leading to opaque pricing.[7] Other market challenges included technical complexity, difficulties with sample transport, and quality control issues.

HIV self-tests: Current HIV testing strategies were not effectively reaching priority populations, who often face stigma from seeking testing, treatment, or prevention services. WHO recommends countries implement HIV self-testing as a part of HIV testing services, and while several prequalified self-tests have been available since 2016, they have historically been more expensive than other tests offered in health facilities.[8]

[5] MedAccess: Next-generation mosquito nets
[6] OECD, WHO, FAO and OIE report
[7] MedAccess: Viral load testing
[8] MedAccess: HIV self-test

Intervention: Identifying genuine market shaping opportunities

It is important to understand and identify situations where market shaping is the best intervention to improve access. While offering potential for significant impact, market shaping can also have unintended consequences and sustainability challenges. Opportunities for market intervention should be scrutinized and selected judiciously.

Market shaping practitioners should be aware of "red flags" indicating that market intervention may not be the most appropriate course of action, including:

- The need for a new intervention is not well established or supported by country demand
- Funding is unavailable to support product purchasing
- Poor access to health products is related to execution challenges or budgetary constraints
- A healthy market already exists that is supported by local governments and donor funding
- The situation involves emergency response or humanitarian crises

Market shaping is just one approach global health actors use to improve access to critical health products. Defining and achieving optimal product access is complex and multifactorial—a result of numerous systems working together (Figure 1), including:

- Disease control and global health programs
- Healthcare infrastructure and personnel
- Supply chain and product delivery systems
- Policy and normative guidance
- Regulatory systems
- Clinical research and development
- Markets and market dynamics

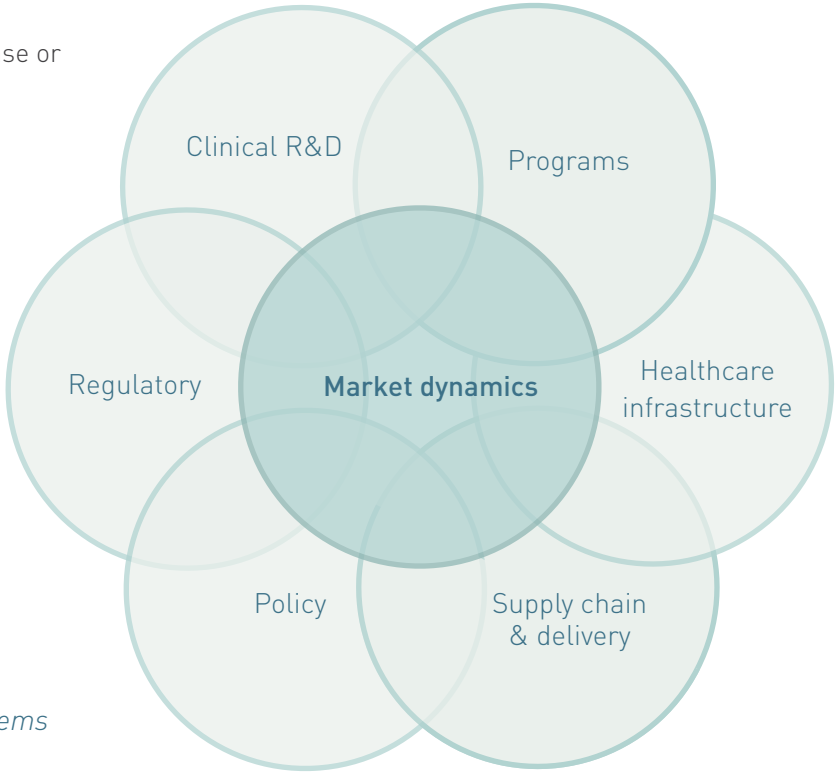

Figure 1: Factors in several overlapping systems can affect product access.

Interventions in these related systems can address access issues, and changes in any of them can impact markets. For example, disease control program priorities like cervical cancer elimination targets can boost demand for HPV vaccines. Lack of trade finance instruments for distributors can create supply chain risks that result in higher prices or reduced product availability for end users. Disparate, cumbersome regulatory processes can disincentivize suppliers to register their products in countries, particularly if there is a lack of clear market intelligence to understand the risk-benefit tradeoff. Policy and normative guidance on the most cost-effective methods to achieve health goals can clarify products' demand trajectory in a way that de-risks or incentivizes supplier investment.

Within all of this, it can be difficult to assess the scope and boundaries of market shaping relative to other interventions. Rather than having a clear divide, market shaping activities and interventions in other systems often intertwine. The fundamental characterization of a market shaping intervention is that it alters the dynamics or incentives between buyers and suppliers in a way that improves market health. Ultimately, these dynamics are shaped by the collection of systems (e.g., policy, regulatory, and delivery infrastructure) in which they operate. Therefore, market shapers must monitor, assess, and align changes across all systems to improve market health. Considering and working within this broader "markets perspective" is essential for designing and implementing successful interventions that help close gaps between global health needs and commercial incentives. Each intervention should fit within an overarching strategy that anticipates future market states and drives toward a sustainable healthy market. Depending on the market, actors should be prepared to make long-term commitments to achieve these goals.

Outcome: healthy markets

The ultimate goal of market shaping is to improve people's health by increasing their access to critical health products—something that can be achieved by improving the health and resilience of markets. A healthier market is one in which suppliers are incentivized to equitably respond to users' needs in a sustainable and resilient fashion, and buyers are incentivized to integrate the product into health systems.

Ways of measuring market health may differ slightly depending on the market. Practitioners working in the same markets should align on market health assessment tools, metrics, and frameworks so they can agree on priorities, set objectives, and measure progress. Core attributes of healthy markets span demand- and supply-side factors, both of which also overlap with various other market attributes, including price and innovation (Figure 2).[9]

[9] Gavi healthy markets framework; USAID Market Shaping primer; SEMA healthy markets framework

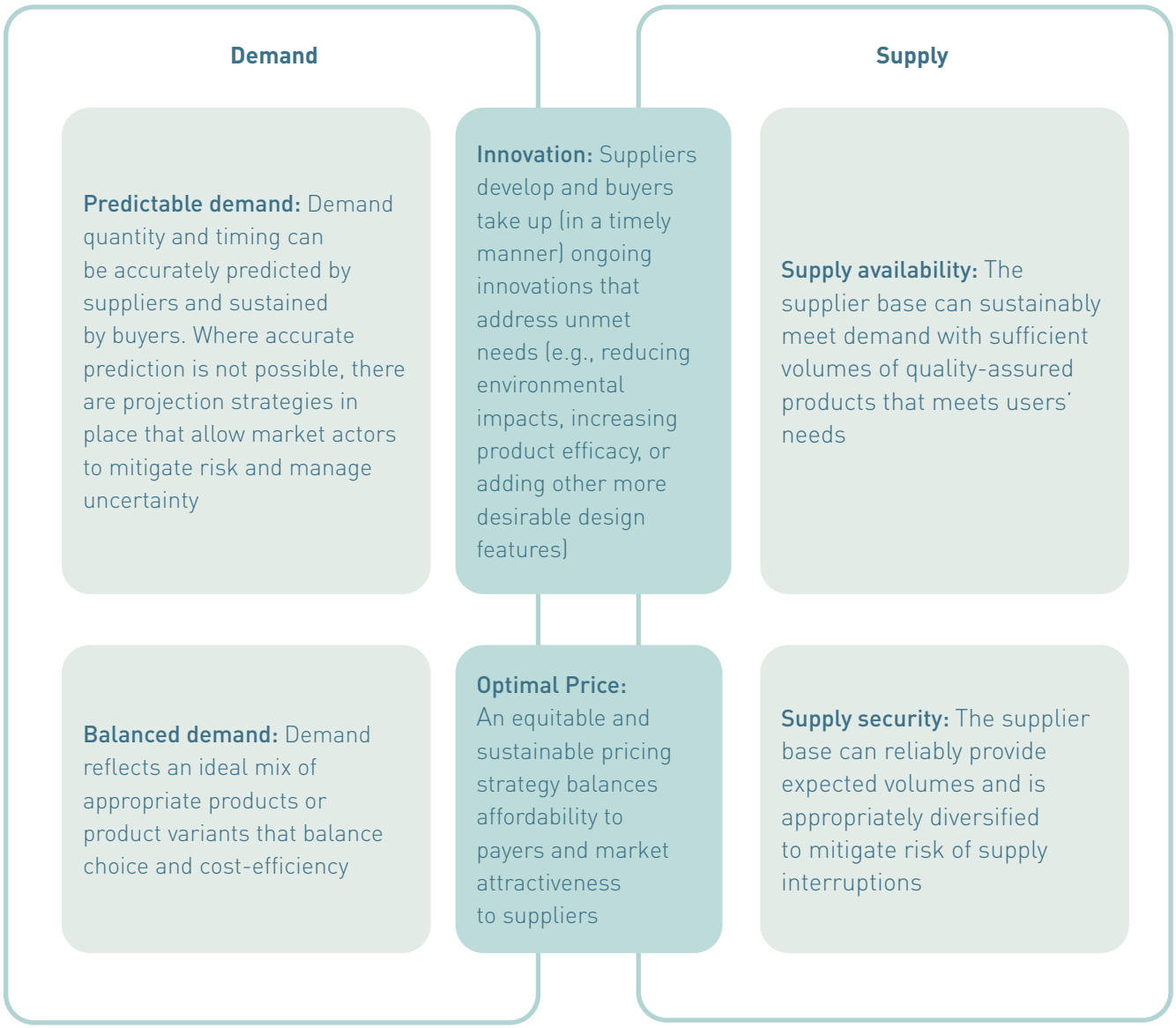

Figure 2: Common attributes of healthy markets span demand- and supply-side factors.

PART 2 Critical concepts and best practices

This section summarizes guidance for achieving the best possible market shaping results. These market shaping best practices fall into five topic areas:

Fundamentals for success: What positions interventions to add required value and avoid unintended consequences?

Ensuring sustainable, mutual value: What determines whether interventions can survive market conditions and achieve impact?

Effective execution: How should global health entities manage interventions from inception through the remainder of their lifecycles?

Impact achievement: What is required for meeting target outcomes and monitoring and evaluating success?

Transparency with partners: How can global health actors use mutual review to scrutinize ideas, align on needed market interventions, and collectively learn from their experiences?

Fundamentals for success

1. **A genuine market shaping opportunity exists.** There must be a true market shortcoming, deficiency, or distortion to address—meaning the prevailing buyer-supplier dynamics fall short of an optimal efficiency point that maximizes welfare gains. For example, there might be a barrier to entry by an LMIC manufacturer, reticence by an incumbent to supply due to uncertain demand, or payment risks, among other issues.

2. **Market shaping actors understand the true need and potential demand for a product**, based on evidence and strong analytics. In other words, country unmet demand—also called the serviceable obtainable market[10] —for a product is already established, the product is superior to an existing commodity, or there is proven potential consumer demand. Market shapers should take care to prove demand if the product is based on a new technology or if demand is otherwise unclear. The Discerning Demand publication by USAID's Center for Innovation and Impact provides more detail on this fundamental concept.

[10] Nepomnyashchiy, L. "Discerning Demand: A Guide to Scale-Driven Product Development and Introduction." Center for Innovation and Impact, USAID. May 2023.

Ensuring sustainable, mutual value

3 **Accurate, impartial, symmetric market information enables informed decision-making by all.** All parties involved in an intervention must have access to and understand market information related to the intervention. Suppliers should accurately understand potential demand and not overestimate other market profits needed to make an intervention viable. Global health actors must understand the wider supply landscape to ensure they select the best partners.

4 **Differentiated risk and resource positions form the basis of mutually valuable agreements.** Interventions work best when entities knowingly trade factors under their control for risks they cannot control. A buyer with known demand backed by guaranteed payment can offer this certainty to a supplier who would be willing to expand production capacity at a market-beating lower price.

5 **Compared to other options, the intervention creates sustainable, positive, and mutual value for end-users, buyers, and sellers.** An intervention that is strong for a buyer and weak for a supplier will not last. An intervention that appears too good to be true likely is. For example, market shapers should be cautious if the buyer or supplier does not understand true production costs. Global health actors should avoid pursuing fragile interventions in which small economic changes could readily undermine the business case for the buyer, supplier, or both.

Effective execution

6 **Individual interventions align with an overarching market shaping strategy based on strong market analytics.** While potentially difficult within complex stakeholder environments, improving market health most often requires a set of interventions combined into a coherent strategy. As much as possible, each intervention should complement and build upon others in the strategy. For example, the terms of new deals should be broadly consistent with comparable prior global access agreements. A sweeter arrangement—such as setting a lower price—seemingly needed for momentary advantage risks setting a precedent for future interventions that could reduce market sustainability and resilience.

7 **Actors working to shape a market follow an agreed-upon value chain that focuses on mutual success in accomplishing the market shaping strategy.** Partners should identify shared goals and then define roles, responsibilities, and decision-making processes that enable informed and coordinated progress based on each organization's expertise. Shared success must be more valuable than institutional priorities. Undercoordinated efforts can easily and unintentionally work at cross-purposes.

8 **Intervention teams have i) empowered, strong leadership, ii) discipline and clear structure, and iii) the necessary skills to succeed.** Multidisciplinary intervention teams should have a single named leader empowered to manage the intervention from inception through delivery. The team should include the full complement of experience and skills needed for the intervention to succeed, which could include technical, financial, industry, legal, analytical, and project management skills.

Impact achievement

9 **Interventions are tracked all the way to impact, with course corrections made as appropriate.** Intervention plans should outline impact measurement in detail, addressing it in project setup and funding timelines. Too many interventions assume intended consequences will be achieved, without planning for specific measurement and evaluation over time. The agreement itself should not be the endpoint; instead, market shaping actors should monitor progress until market and health goals are achieved.

10 **A named owner manages implementation and impact measurement.** No intervention owner should move on from an arrangement until a new manager takes over responsibilities or impact is achieved and the intervention is closed. An unmonitored intervention is at high risk of not achieving its intended outcomes.

Transparency with partners

11 **Global health actors engage all relevant stakeholders before, during, and after intervention execution.** A global health actor can rarely act safely in isolation from other actors. Therefore, early engagement of all relevant stakeholders in an intervention or market strategy is essential. Inviting critique and objections may help avoid a misstep. These critical concepts can serve as a tool to analyze the merits of proposed interventions and resolve institutional differences in an evidence-based way.

12 **Global health actors share information about interventions, including their successes and challenges.** Global health actors learn from and improve on collective approaches if they are honest about successes and challenges. Embedding transparency into contracts, with fewer items under non-disclosure agreements, could help inform knowledge exchange. While it is pleasing to tout successes, failures can provide more insights, but only if other actors can readily access this information.

PART 3 Effective intervention planning and execution

This section provides practical guidance on how to develop and execute market shaping strategies and interventions. Certain factors can make market shaping easier or more challenging—including aspects of actors' operating environment and features of the market itself—and it is important to understand these at the outset of intervention planning. Part 3 outlines these factors, provides tools for recognizing and assessing them, and discusses how each can affect market shaping strategies. Then, it lays out essential steps for designing and implementing successful market interventions.

Operating environment enablers

Aspects of market shapers' operating environments can impact their effectiveness in shaping markets. The "Six C's" of an enabling market shaping institutional ecosystem are outlined in Table 1.

Actors should consider the enabling or limiting factors within their operating environments and how these will impact different market shaping strategies. For example, if an assessment of the Six C's reveals insufficient data or weak coordination structures,

Table 1: The Six C's of a market shaper's operating environment.

Operating environment enablers (Six C's)	Illustrative ideal state
1 Consolidated, quality, reliable data	• Availability of systematically collected, high-quality market intelligence for relevant stakeholders, reducing information asymmetry and enabling a comprehensive understanding of the market
2 Capable and complementary partners	• Diverse skill sets and representation of regulatory and policy institutions, civil society, and industry experience • Actors play to their institutional strengths across the value chain • Disciplined action, e.g., actor accountability

3 Coordination and alignment between market actors	• Agreed roles and responsibilities between actors within and across sectors
	• Willingness to welcome new entrants and prioritize common mission over individual mandates
	• Inter-agency tensions are minimized and mitigated
	• Agreed market shaping standards and practices, including:
	  • Approaches to assess market health
	  • Market priorities and strategies within sectors
	  • Global access and market sustainability standards across sectors

4 Capital and influence	• Access to capital, financial ability, or influence to intervene in markets • Predictable long-term funding is available to purchase products
5 Commitment time horizon	• Actors with long-term commitments to markets
6 Cross-learning	• Cross-learning between actors within and across sectors

actors could invest in those elements to improve the impact of future interventions. These investments could include developing partner coordination tools and processes, publicly sharing intervention details and impacts, and transparently sharing market data.

A key aspect of the operating environment for market shapers is coordinating with partners. The market shaping ecosystem now comprises dozens of organizations, in addition to national governments and industry players. While this evolution has spurred progress, it has also resulted in an expanded field of practitioners with considerable overlap and varying levels of capabilities, making it challenging for actors to meet their mandates and market shaping objectives. Figure 3 provides a high-level overview of major roles actors can play and their typical level of engagement across the product lifecycle (i.e., from R&D to procurement to delivery).

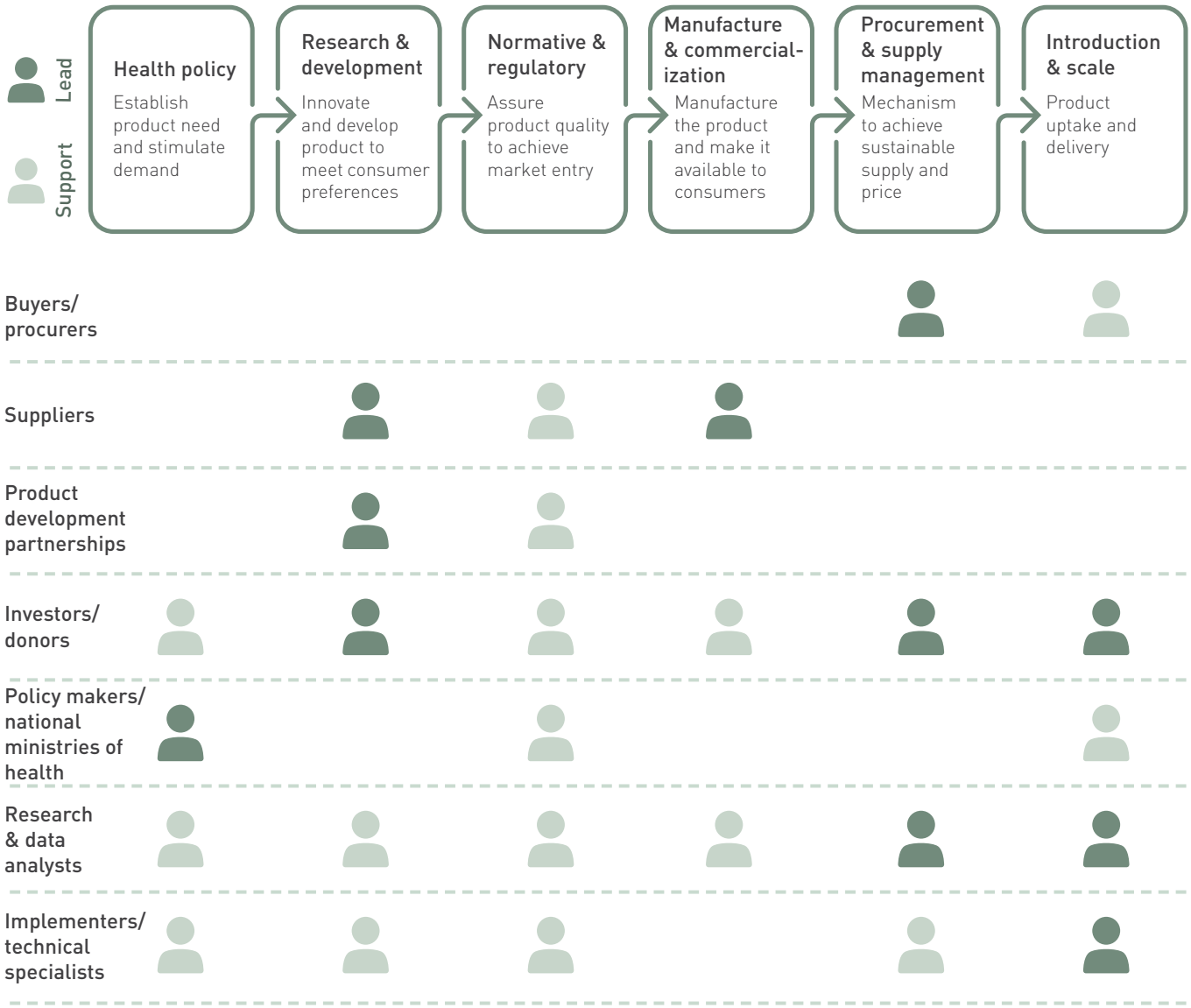

Figure 3: Types of actors involved in market shaping and their respective areas of focus and levels of engagement. This figure is illustrative and not exhaustive.

Market archetypes

Based on the characteristics of the product, target health area, or more fundamental aspects of a given market structure, markets can have inherent features that significantly impact strategies for shaping them. For example, due to manufacturing complexity, vaccines will generally have fewer suppliers than drugs. A highly novel technology, such as Wolbachia replacement technology or drone delivery, will have a less clear regulatory and policy pathway than an established platform. Products targeting diseases with high outbreak potential, such as chikungunya virus, will inherently have less predictable demand. Markets set up with global financing and procurement mechanisms that service a large portion of the global market will have more consolidated buying power and more predictable demand.

Major market features to consider include:

- Level of supplier consolidation
- Level of buyer consolidation
- Level of financing consolidation
- Clarity of policy pathway
- Clarity of regulatory pathway
- Homogeneity of delivery
- Demand volume
- Demand predictability

Prominent combinations of these market features make up market archetypes, which include, but are not limited to:

- Highly consolidated, predictable demand markets (e.g., Gavi-supported routine vaccines)
- Partially buyer-consolidated markets (e.g., drugs and diagnostics markets for tuberculosis [TB], HIV, and malaria)
- Fragmented markets (e.g., maternal, neonatal, and child health devices)
- Consumer markets (e.g., oral rehydration solution)
- Novel technology markets (e.g., Wolbachia replacement technology)
- Low-volume, volatile-demand markets (e.g., chikungunya virus vaccine)

Understanding the underlying market features or archetype is an important preliminary step. It provides insights into the challenges actors may face and options for strategies or approaches that may have been successful in similar market contexts.

Essential steps for effective market intervention

Before beginning to think about interventions, actors should ensure they have a well-developed understanding of their operating environment strengths and weaknesses (Six C's) and the general archetype of the market in question. This context should inform the market shaping strategy and intervention design. The multistep process for developing and carrying out a market shaping strategy begins with engaging local stakeholders, such as national governments, to understand competing priorities and program needs (Figure 4). Once these are articulated, the next steps entail a strong analytics-led process that includes: repeatedly assessing market health, diagnosing the drivers of market shortcomings, agreeing on targets, aligning on interventions, and coordinating actors' work to implement and monitor impact. Identifying appropriate actors for an intervention is not always straightforward and may vary depending on factors including market characteristics and intervention type.

Essential steps for market shaping strategy design

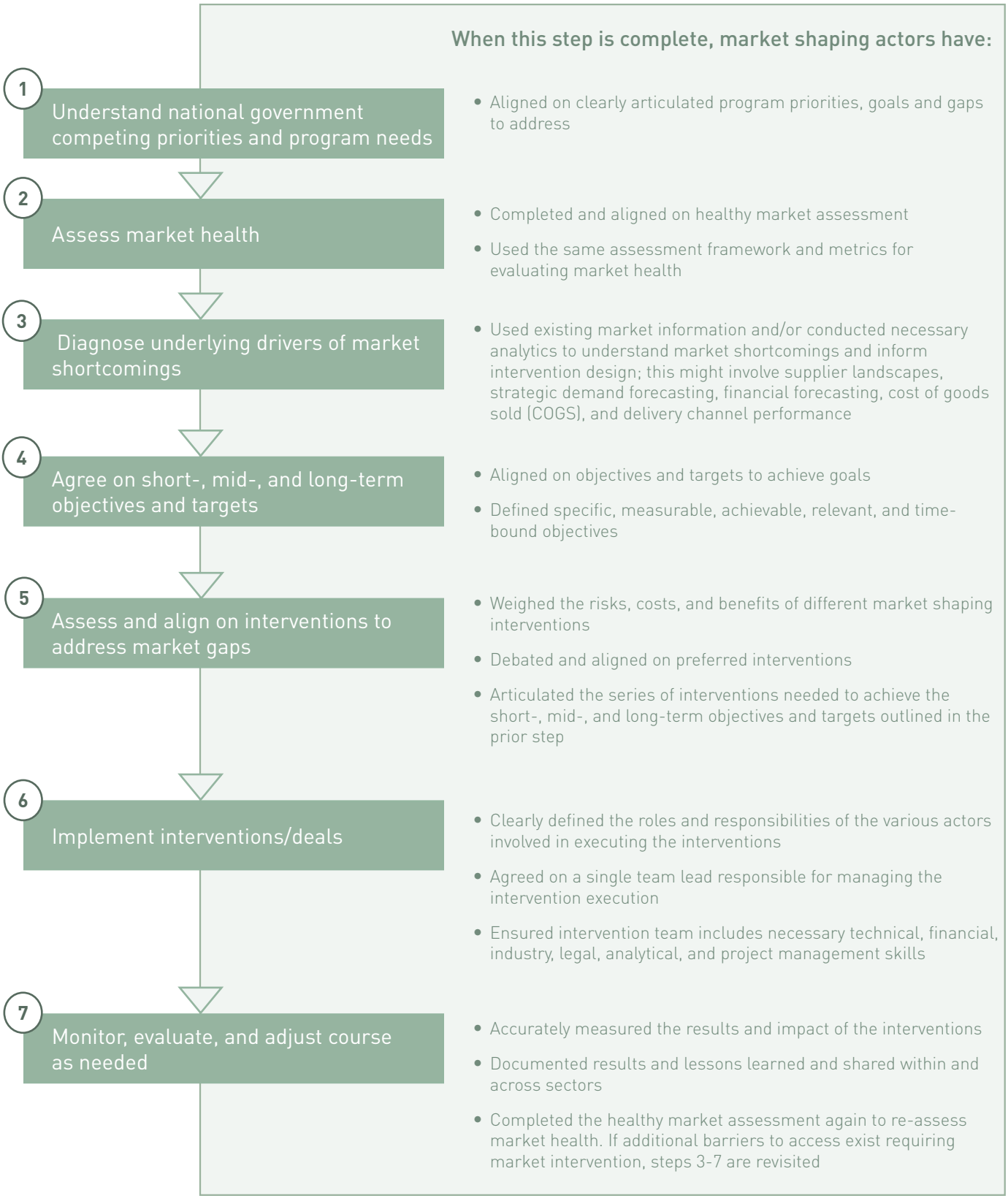

Figure 4: Steps for effective market shaping intervention design.

While all market shaping interventions need clear decision-making pathways, deals with commercial entities—often pharmaceutical suppliers—require even more stringent structure and discipline to avoid unintended consequences. The exact structure and process may vary based on the situation and actors involved, but well-executed deals often contain similar core attributes. As an example of one approach, a simplified version of how the Bill & Melinda Gates Foundation executes vaccine supply investments is illustrated below.

Steps to execute a Bill & Melinda Gates Foundation vaccine supply investment

1. Confirm demand forecast, carry out supply analysis (e.g., COGS and capacity assessment), and complete suitable market analysis to identify the problem a market shaping intervention could solve
2. Assemble deal team and agree on roles and responsibilities. Every deal team must have: a single named deal team lead, stakeholder representation, a negotiating lead, a project manager, and an analyst
3. Confirm expenditure responsibility requirements to verify that the investment meets foundation legal requirements for charitable purpose
4. Complete supplier options analysis to identify and select preferred suppliers
5. Brief internal directors and external partners on status
6. Complete investment options analysis and select the preferred investment
7. Complete technical, financial, and legal due diligence to investigate supplier's capabilities and financial health
8. Create investment business case and draft investment term sheet that describes the business terms for moving forward, implements necessary financial and legal risk mitigations, and provides a target for the negotiation lead
9. After carrying out supplier negotiations, update internal directors and external partners before finalizing term sheet
10. Complete investment application and proceed with supplier, third party, and foundation approvals
11. Execute and announce investment and continue to monitor implementation and impact of the deal for its entirety, making adjustments as needed

PART 4 Interventions playbook

This section outlines various types of market shaping interventions and financial tools that can be combined into a coherent market shaping strategy to help address access barriers for a product or service.

Global health markets vary widely in their complexity, market shaping challenges, partner ecosystem, and programmatic goals. Rarely can a single intervention successfully address a market shortcoming on its own—instead, interventions typically occur simultaneously and, if organized well as part of a larger strategy, in a complementary manner. Two real-world examples below illustrate this point.

From CHAI's Market Shaping Framework[11], the following pages outline common interventions used in each phase of product development and delivery as well as financial tools that can be used in a variety of product stages. Importantly, the timeframes provided indicate the approximate length of time to complete the specific intervention type, not the length of time to achieve desired outcomes.

Examples of market strategies consisting of multiple interventions

Next-generation mosquito nets: Market shapers increased access to dual-active-ingredient bed nets through various complementary interventions.

1. Product development support from the Innovative Vector Control Consortium (IVCC)
2. A volume guarantee provided by MedAccess and the Bill & Melinda Gates Foundation to BASF in exchange for increased production volumes of its product and reduced prices
3. A time-limited co-payment mechanism and consolidated procurement for 21 countries through the New Nets Project, led by IVCC and co-funded by Unitaid and the Global Fund
4. A clinical trial and implementation pilots (co-funded by Unitaid and the Global Fund) to drive adoption and support a WHO recommendation
5. WHO prequalification of BASF's next-gen net in 2018, paving the way for purchase of the product by international procurers for low-income countries
6. A purchase agreement from the Global Fund, which used its new financing facility to secure sustainable prices for a dual-active-ingredient net from the market's second entrant, Vestergaard

HIV self-tests: A wide range of market shaping interventions were needed to meet a targeted $1 price point for HIV self-tests, expand access, and improve market health.

1. Landscape and market analyses to provide evidence necessary to create a market for self-testing
2. A 2017 volume guarantee from the Bill & Melinda Gates Foundation to OraSure, enabling the company to provide its test for $2
3. Unitaid-supported policy adoption, introduction pilots, product evaluations, and additional pricing agreements with Abbott and Mylan for their tests
4. Investments from the Children's Investment Fund Foundation to support development of OraSure's lower-cost test and, in partnership with the Global Fund, scale up access to self-tests in several African countries
5. Other implementation support, including help expediting registration, validation, and field evaluations and pilots
6. A volume guarantee from CHAI and MedAccess to Wondfo to secure a $1 price point for its self-test product

[11] CHAI Market Shaping Framework

Research & development interventions

Target Product Profile (TPP) issuance: Convene stakeholders to define and publish list of desired product characteristics, use cases, target populations, etc. *Timeline: 1-3 years*

New product development: Develop new products to meet TPP, serve new populations, or satisfy other context-specific conditions (e.g., pediatric formulations, fixed-dose combinations, etc.); may require new R&D partnerships. *Timeline: 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.). *Timeline: 3+ years*

Label expansion: Pursue new indications for approved product via additional clinical trials. *Timeline: 3+ years*

Clinical studies: Assess safety and efficacy of health interventions using human volunteers. *Timeline: 3+ years*

Implementation research: Test innovations in real-world health settings to bring what works to scale. *Timeline: 1-3 years*

Example: New product development

In 2014, Cepheid, FIND, and Rutgers New Jersey Medical School launched a collaboration to develop Xpert MTB/RIF Ultra, a next-generation test for TB.[12] With support from the U.S. National Institutes of Allergy and Infectious Diseases, the partners set out to develop a diagnostic with increased sensitivity to aid in detection of patients with smear-negative TB.

The test launched in 2017, aiming to reach millions of people annually who fail to receive TB testing or treatment.[13]

[12] FIND press release
[13] FIND press release

Regulatory & normative interventions

Regulatory submission: Provide product-specific regulatory support to suppliers to accelerate dossier submission and review process with respect to WHO and other regulatory authorities. *Timeline: 1-3 years*

Regulatory strategy: Employ innovative approaches within existing regulatory authority's pathways to enable and/or accelerate review of new product/ product class. *Timeline: 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. *Timeline: 1-3 years*

Guidelines inclusion: Support processes for inclusion of new products in guidelines, formularies, and essential medicines lists (e.g., conduct health technology assessments, facilitate guidelines review process, disseminate guidelines, etc.). *Timeline: 1-3 years*

Manufacture & commercialization interventions[14]

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). *Timeline: variable*

Strategic sourcing: Improve sourcing of high-quality active pharmaceutical ingredients, raw materials, and component parts through bulk, direct, and/or local purchasing to reduce overall product cost. *Timeline: <1 year*

Manufacturing optimization: Identify opportunities to optimize product manufacturing, including via process chemistry, factory automation, packaging redesign, etc. *Timeline: <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. *Timeline: 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.). *Timeline: <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. *Timeline: <1 year*

Price analysis & negotiation: Conduct COGS, cost-effectiveness, and other pricing analyses to determine target price range. Negotiate and publicize preferential pricing that is applicable to target countries and buyers. *Timeline: <1 year*

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

Example: Licensing agreements

In 2022, Aspen Pharmacare secured funding to support its partnership with Serum Institute of India (SII) to manufacture, market, and distribute four Aspen-branded routine vaccines in Africa.[15] CEPI and the Bill & Melinda Gates Foundation each pledged $15 million to support SII's tech transfer of pneumococcal, rotavirus, polyvalent meningococcal, and hexavalent vaccines.

Aspen also aimed to use the funds to help sustain regional vaccine manufacturing capacity for future outbreak response.

GSK, PATH, and Bharat Biotech (BBIL) in 2021 signed a product transfer agreement to help ensure long-term supply of the RTS,S malaria vaccine.[16]

The agreement transferred manufacturing of the RTS,S antigen and granted all rights to the malaria vaccine to BBIL, while GSK said it would continue to produce and supply the shot's AS01E adjuvant.

Example: Demand forecasting

In 2016, Unitaid published a demand forecast for rapid diagnostic tests, artemisinin-based combination therapies, and artemisinin monotherapies.[17] The report estimated rising demand for malaria diagnostics and treatments, despite sharp declines in malaria prevalence worldwide.

[15] CEPI press release
[16] GSK press release
[17] Unitaid press release

Procurement & supply management interventions

Demand visibility: Improve forecasting capabilities to enable procurers to enter longer-term, higher-volume, and/or fixed-volume contracts (at country or global level). *Timeline: <1 year*

Pooled procurement: Establish a centralized procurement mechanism to consolidate demand/funding across multiple buyers (including sub-national buyers) to reduce transaction costs/increase leverage. *Timeline: variable*

Coordinated supply planning: Facilitate inter-procurer coordination and data sharing to increase overall market visibility and manage supply security (e.g., antiretroviral procurement working group, coordinated supply planning group, etc.). *Timeline: <1 year*

Variant optimization: Align key buyers and end-users on standardized product packaging, inserts, sizes, colors, etc., to generate manufacturing efficiencies and cost savings. *Timeline: <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. *Timeline: 1-3 years*

Product bundling: Combine procurement of interdependent products from the same or multiple suppliers to reduce prices and maximize patient impact. *Timeline: 1-3 years*

Tender optimization: Promote best practices in implementing tenders/request for proposals (e.g., supplier eligibility, award criteria, timing & duration, reference prices, indicative/minimum volumes, quality assurance, contracting process, etc.). *Timeline: <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. *Timeline: <1 year*

Example: Pooled procurement

In 2014, The Global Fund launched a new agreement for purchasing HIV medication aiming to save close to $100 million over two years—savings equivalent to providing antiretroviral drugs to an additional 400,000 people over the same timeframe.[18] As part of the initiative, the Global Fund entered into agreements with eight suppliers; three of the agreements represented long-term strategic partnerships.

First established in 2009, the Global Fund's pooled procurement mechanism enables the organization to aggregate order volumes from participating country programs to leverage market spend. It aims to secure quality-assured products, get better value for money, reduce lead times for critical health products, and contribute to sustainable markets for core life-saving products.

Example: Coordinated supply planning

In 2022, Bayer Foundation and Africa Medical Supplies Platform (AMSP) teamed up to expand access to Covid-19 vaccines and medical supplies in Africa.[19] The Bayer Foundation's one-year grant aimed to support AMSP expansion by leveraging bulk purchasing power to secure critical medical supplies for the continent and stabilize prices.

[18] Global Fund press release
[19] Bayer Foundation press release

Introduction, scale, & sustainability interventions

Forecasting & quantification: Aggregate on-the-ground data and insights to inform supply planning, procurement, financing, and/or new product introduction strategies. *Timeline: <1 year*

Stock monitoring optimization: Establish/update stock monitoring tools, ordering forms, and patient management systems to include new products/services, manage transitions, reduce frequency of stockouts, and measure outcomes. *Timeline: 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). *Timeline: variable*

Workforce capacity strengthening & optimization: Improve provision of care by conducting healthcare worker trainings related to new product/service; may require updating policies (e.g., task-shifting) and training curricula. *Timeline: 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. *Timeline: 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. *Timeline: <1 year*

Financial tools

Prize: Provide financial reward to innovator for achieving a predefined R&D outcome. Used to generate R&D investment in a new area/specific product class. Characteristics of the ideal solution should be clearly defined.

Development incentive grant: Upfront and/or milestone-based payments provided to supplier to pursue agreed-upon R&D, regulatory, and/or commercial activities. Used to incentivize accelerated development/launch of high-priority products. Supplier must commit to favorable access terms and conditions.

Advance market commitment: Donors commit to purchasing a minimum volume of products that meet a TPP at an agreed-upon price once developed. Used to offset R&D risk, especially for products with uncertain demand that require intensive upfront investment.

Product subsidy: Fixed per unit subsidy for predefined period or quantity implemented at any point in distribution chain; includes short-term donations (e.g., "catalytic procurement").[20] Used to reduce product costs to catalyze adoption and uptake in target markets (or via target channels) and accelerate timelines to achieve longer-term, sustainably lower prices.

Volume guarantee: Supplier agrees to lower price in return for sales volume guarantee. Guarantor agrees to compensate supplier for any shortfall. Used to accelerate uptake of a product that falls into the "high price/low volume" trap or improve supply security by increasing production capacity.

[20] "Catalytic procurement" can include the specific commitment to purchase validation batches, which accelerates commercialization and market entry of a new product.

Example: Volume guarantee

MedAccess provided a volume guarantee to Wondfo in 2022 for the China-based diagnostics specialist's WHO-prequalified HIV self-test.[21] The CHAI-facilitated deal ensured that public-sector purchasers in 140 LMICs could buy the fingerstick blood test for under $1. MedAccess estimated that the deal would contribute to an additional 8.1 million people tested for HIV and 131,000 additional people starting treatment.

Pfizer, the Bill & Melinda Gates Foundation, and the Children's Investment Fund Foundation have reached several deals in the last decade to increase access to Pfizer's Sayana Press injectable contraceptive. The partners' initial collaboration in 2014, which covered 69 of the world's poorest countries, allowed qualified purchasers to buy the product for $1 per dose.[22] By the end of 2016, 6.4 million units of Sayana Press had been shipped to 20 developing countries, potentially reaching over 1.5 million women.[23]

In 2017, the partners reached a multi-year deal to lower the price of Sayana Press by 15%.[24] The volume guarantee ensured that qualified purchasers could buy the product for $0.85 per dose through 2022. The partners expanded the deal again in 2023, pledging to deliver over 320 million doses of Sayana Press in 92 countries through 2030.[25]

In 2022, a deal between Viatris, MedAccess, and the TB Alliance cut the price of tuberculosis drug pretomanid by 34%.[26] Under the MedAccess-backed volume guarantee, the ceiling price fell to $240 per six-month treatment course.

MedAccess projected that the guarantee would enable an additional 36,000 people to be treated and would help avert 31,000 adverse events that require hospitalization or cause disability. The deal was expected to save governments and global procurers $15.6 million.

[21] MedAccess: HIV self-test
[22-24] Pfizer press release
[25] Bill & Melinda Gates Foundation press release
[26] MedAccess press release

Procurement guarantee: Guarantee facility provided to intermediate buyer (e.g., procurer) to ensure customer payment will be received on time in full. Guarantor assumes risk of default. Used to offset risk of procurers entering longer-term and/or fixed purchase contracts in advance of receiving funds from intended recipients.

Payment guarantee: Guarantee facility provided to seller (supplier, service provider, etc.) to ensure customer payment will be received on time in full. Guarantor assumes risk of default. Used to offset risk of sellers agreeing to new or longer-term contracts in markets or with buyers that are perceived to carry higher levels of risk.

Working capital facility: Low-cost loans for operating expenditures provided to suppliers, procurers, wholesalers, distributors, etc. with liquidity needs.[27] Used to enable commercial partner to better manage day-to-day operations—can be provided in exchange for favorable access terms and conditions.

Impact investment: Financing provided to companies that aim to achieve both social impact and financial return in the form of debt, equity, or mixed instruments.[28] Used to lower the cost of capital needed to support product development/commercial activities to help enable reduced end-user pricing.

Regulatory Incentive: Rewards for developing products for specific patient populations, including priority review vouchers, filing fee waivers, tax credits, etc. Used to encourage the development of new products (typically drugs) for a set of predefined neglected health areas.

[27, 28] "Loan guarantees" can be employed as part of the debt-based instruments listed above to further reduce the cost of capital to the private-sector entity.

Example: Development incentive grant

LG Chem announced in 2019 that it had received a $33.4 million grant from the Bill & Melinda Gates Foundation to develop an inactivated polio-containing, whole cell pertussis-based hexavalent vaccine candidate for children.[29] The company pledged to supply the vaccine to UNICEF and other organizations.

Example: Advance market commitment

The Gavi board in 2023 approved the African Vaccine Manufacturing Accelerator (AVMA), a new financing mechanism aimed at establishing a sustainable vaccine manufacturing industry in Africa.[30] With up to $1 billion available over the next 10 years, AVMA aims to help offset high initial costs of production via two types of incentives: milestone payments and accelerator payments (paid as a per-dose "top-up").

Example: Procurement guarantee

In 2021, the Bill & Melinda Gates Foundation and the Swedish International Development Cooperation Agency provided UNICEF with a $150 million financial guarantee to help the organization procure Covid-19 vaccines and other health-related supplies for LMICs.[31] Effective through 2025, the financing aims to allow UNICEF to place orders with manufacturers without requiring that countries pay for the products in advance.

Example: Working capital facility

In 2021, CEPI provided Dynavax with a forgivable loan—recoverable upon product sales—of up to $99 million to support the at-risk manufacture of the company's CpG 1018 vaccine adjuvant for CEPI-funded Covid-19 vaccine development programs.[32] CEPI anticipated that vaccine developers using the adjuvant produced under the agreement would make vaccine output available for procurement through COVAX.

[29] DCVMN press release
[30] Gavi press release
[31] Bill & Melinda Gates Foundation press release
[32] CEPI press release

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