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HEALTHY MARKETS FOR GLOBAL HEALTH: A Market Shaping Primer



Fall 2014

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This *Market Shaping Primer* shares guidance gleaned from the field on the role market shaping can play in advancing the goals and objectives of global health. It seeks to synthesize these key principles into a flexible framework that can inform future market shaping interventions across health sectors. Questions and comments are welcome and can be directed to the USAID leads for this primer, Amy Lin and Joe Wilson.

For contact information and to download the latest version of the Market Shaping Primer and the complementary Guide to Introduction and Scale of Global Health Innovations, please visit www.usaid.gov/cii.

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Acknowledgements

A tremendous amount of work has gone into this report to capture, analyze, and authenticate the collective knowledge presented herein, and we are incredibly grateful to the many who gave so much of their time and expertise along the way. Special thanks go to CII's Director **Wendy Taylor**, **Prashant Yadav** at the University of Michigan's William Davidson Institute, **Laura Kopczak** at MIT-Zaragoza, and **Susie Nazzaro** and **Andrew Jones** at the Bill & Melinda Gates Foundation for their invaluable role in the creation of this report.

In addition, we express our deep appreciation to the following individuals who have made significant contributions to the Primer and to whom we owe a great deal.

Adam Sabow (McKinsey)	Francisco Blanco (UNICEF)	Melissa Malhame (GAVI)
Allyala Nandakumar (USAID)	Hema Srinivasan (CHAI)	Michael Conway (McKinsey)
Amelia Pittman (USAID)	James Droop (DFID)	Orin Levine (Gates Foundation)
Amie Batson (PATH)	Jennifer Wray (USAID)	Priya Sharma (USAID)
Amy Meyers (CHAI)	Jessica Fast (CHAI)	Robyn Iqbal (Gates Foundation)
Anban Pillay (Dept. of Health, South Africa)	Joel Kuritsky (USAID)	Shanelle Hall (UNICEF)
Andrew Storey (CHAI)	John Crowley (USAID)	Shristi Gupta (McKinsey)
Anita Deshpande (RHSC)	John Skibiak (RHSC)	Susan Mitchell (Abt Associates)
Blair Hanewall (Gates Foundation)	Jonathan Weiss (UNICEF)	Tony Boni (USAID)
Brenda Waning (UNITAID)	Julie Wallace (USAID)	Tony Lee (McKinsey)
Chrisan Thuraisingham (R4D)	Kanika Bahl (R4D)	Vicky Hausman (Dalberg)
Christine Årdal (Norad)	Knut Jønsrud (Norad)	Vinesh Kapil (USAID)
David Milestone (USAID)	Larry Barat (USAID)	Wilson Mok (GAVI)
David Ripin (CHAI)	Maria Miralles (USAID)	Wouter Deelder (Dalberg)
	Mark Rilling (USAID)	Ya'ir Aizenman (Dalberg)

The market shaping sector is a rapidly evolving field, and this primer is a synthesis of unique perspectives and approaches that, taken together, present our view of the current state of the practice. We hope it will be valuable in examining potential market shaping opportunities in new product markets.

– **Amy Lin and Joe Wilson, USAID Center for Accelerating Innovation and Impact**

Foreword

USAID and the global health community are fully committed to realizing the once unimaginable goals of ending preventable child and maternal deaths and achieving an AIDS-free generation, but we cannot do it alone. To continue bending the curve, we need to leverage the capabilities and resources of the public, private, and nonprofit sectors to harness innovation and break down barriers to progress. USAID and the global health community can do more than operate within challenging and developing healthcare markets; we can work together to help shape them in ways that save lives.

Global market shaping can accelerate progress toward increasing access to and use of life-saving commodities. Whether by halving the cost of antiretroviral drugs for children with HIV, helping deliver malaria treatment to far-flung places, or increasing women's access to contraceptive implants, market shaping is addressing previously insurmountable market barriers at scale. As these challenges are addressed, the market shaping field requires additional coordination and leadership to uncover potentially transformational solutions.

This Market Shaping Primer aims to present the state of the practice by identifying noteworthy achievements across products and markets. By taking inventory of successful market shaping interventions and assessing commonalities, it presents a high-level roadmap and an opportunity to further the discussion over how market shaping can advance global health goals. While coordination among stakeholders is important, we recognize there is no one-size-fits-all approach to market shaping. Some interventions, such as vaccine procurement, may operate solely within the public sector to increase programmatic effectiveness or improve value-for-money in a tight budgetary environment. Others will drive market efficiency and value for the end-user by cultivating a vibrant and competitive private sector market. In either case, the product price may be reduced or volumes stabilized, but these changes affect both current and potential buyers and suppliers.

It is precisely because so many different actors operate in healthcare markets that market shaping needs to be carefully thought through. Ideally, every intervention would create “win-win” solutions, but typically the actions of one part of the health sector, or even of a single organization, will have both positive and negative ripple effects. The depiction of donors “meddling” in developing country markets is of course antithetical to the actual vision for anyone considering a market shaping intervention, so it is critical to consider potential unintended consequences and to monitor all results closely.

On balance, we believe the benefits can outweigh the risks, and the success of organizations pioneering this approach across global health speaks to the possibilities. We view this as a timely opportunity for our community – donors, implementers, and developing country governments alike – to identify commonalities in how we approach markets to strengthen ongoing collaborations. While it may take time to develop a common direction that fits the structures, constraints, and mandates of both countries and the vast range of organizations operating within their markets, this primer seeks to facilitate a dialogue and inform the ongoing development of market shaping strategies.

This primer is intended for global health decision-makers and technical health experts who want to explore how market shaping can be applied to improve global health outcomes. These practitioners may sit in federal ministries of health or finance, implementing or advisory organizations, or donor or procurement agencies. Manufacturers, distributors, and other supply-side actors may also find value in the perspectives presented here. Supported by case studies and historical examples, this primer provides an overview of the basics of market shaping, an analytical approach for tracing market shortcomings to their underlying root causes, and guiding principles for designing, implementing, and evaluating an intervention.

Dr. Ariel Pablos-Méndez
USAID Assistant Administrator for Global Health

Executive Summary

PART I. INTRODUCTION

Global health is inextricably linked to the health of the marketplace that delivers life-saving products to low-income populations. A well-functioning healthcare market with public and private sector participation requires manufacturers to produce high-quality products, distributors to deliver the necessary quantities, providers to administer them correctly, and patients to be educated and active participants in their own health. However, markets sometimes fall short. Developers may not see enough demand to develop a new product, manufacturers may not know how much to produce, and distributors may not see enough profit to justify delivery. The unfortunate reality is that a single breakdown in this complex system can keep life-saving products from those most in need.

Market shaping can disrupt current practices or transform existing market structures, creating efficiencies that lead to better health outcomes for the poor. Actors at both ends of the market – producers and purchasers – may face high transaction costs, critical knowledge gaps, or imbalanced risks that hamper their participation in the market and lead to market shortcomings. Countries, donors, and procurers can use their purchasing power, financing, influence, and access to technical expertise to address the root causes of market shortcomings and influence markets for improved health outcomes. Designed to be transformative, market shaping interventions aim to reduce long-term demand and supply imbalances and reach a sustainable equilibrium.

Across health sectors – from vaccines to HIV to family planning – market shaping has demonstrated its potential to enhance donor or national governments' value for money, diversify the supply base, increase shipment reliability, and ultimately increase product access for end users. Inspired by the possibility of this approach, USAID, UNITAID, UNICEF, Gates Foundation, DFID, Norad, the Global Fund, the Government of South Africa, and other donors and procurers are engaging in market shaping in partnership with CHAI, Dalberg, WDI, RHSC, McKinsey, R4D, and other implementing and advisory groups.¹

The evidence base for market shaping continues to grow and provide a basis for assessing historical impacts as well as opportunities for future application. In an effort to draw on learnings from past experience, this primer aims to pull together lessons learned and guidance on how to approach future opportunities through a Market Shaping Pathway framework and five case study Spotlights across the HIV, malaria, diarrhea, and immunization health areas. Seeing the shared interest and organizational momentum within the global health community, we hope this primer can foster a common dialogue and strengthen efforts to continue shaping healthy markets for life-saving products.

¹ The full names of the noted organizations are U.S. Agency for International Development, United Nations Children's Fund, Bill & Melinda Gates Foundation, UK Department for International Development, Norwegian Agency for Development Cooperation, the Global Fund to Fight AIDS, Tuberculosis and Malaria, William Davidson Institute, Clinton Health Access Initiative, Reproductive Health Supplies Coalition, and Results for Development Institute.

Market shaping interventions typically use three types of levers:

- 1. Reduce transaction costs** – Lowering structural hurdles to market interactions, such as by simplifying, smoothing, or rationalizing orders without money necessarily changing hands.
- 2. Increase market information** – Generating new data, aligning existing analyses, or improving the visibility of existing data to reduce asymmetries of information.
- 3. Balance supplier and buyer risks** – Transferring financial risks to donors/purchasers to encourage existing and new suppliers to operate more actively in the market.

However, market shaping alone does not address the multitude of health product uptake challenges in developing markets. It is only a powerful nudge toward further market optimization. Thus, it relies heavily on ongoing programmatic interventions by the global health community to implement and effect change. Market shaping is closely interlinked with, and dependent upon, programmatic interventions like healthcare provider training, health product procurement, and supply chain strengthening. Moreover, the distinction between market shaping and programmatic interventions is more of a continuum than a clear divide. Similar interventions may fall closer to one end of the spectrum or the other based on the intervention's catalytic versus routine nature, time-bound versus ongoing duration, or intensity of focus on influencing buyer and supplier interactions.

PART II. A PATHWAY TO THE NEXT MARKET SHAPING SOLUTION

This primer offers the Market Shaping Pathway below as an approach for assessing whether and how interventions may be appropriate for a specific underperforming market. This Pathway organizes important market shaping questions and considerations into five critical steps (see Figure 1) to assess how a market shaping intervention could work.

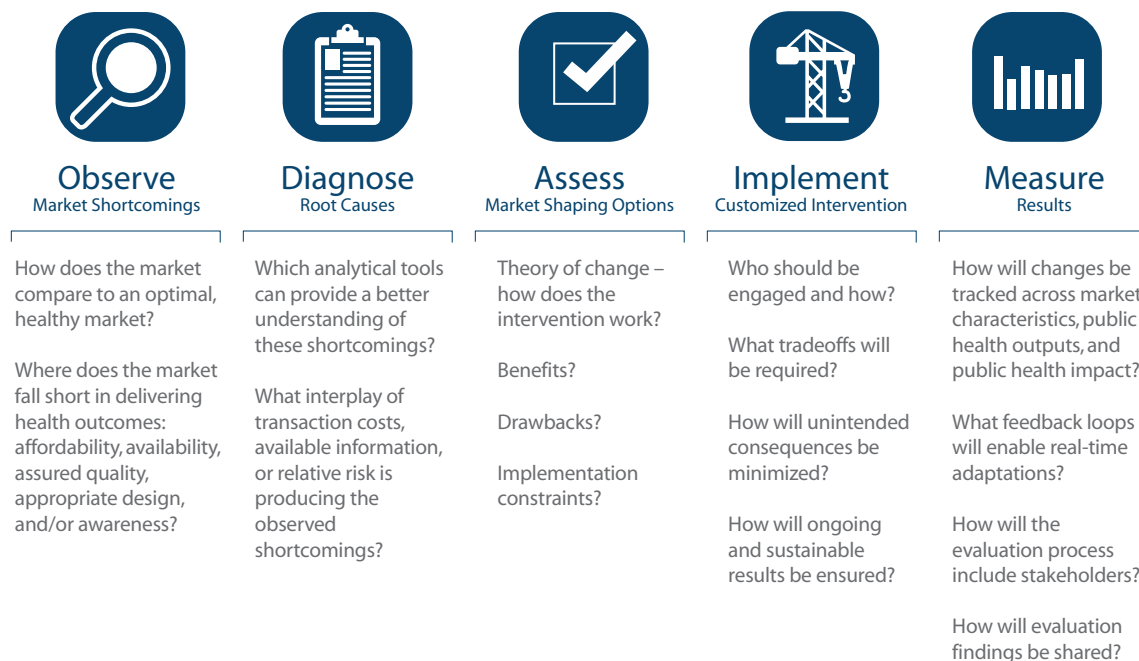
Step 1. Observe Market Shortcomings: The Market Shaping Pathway begins by assessing the current health of the market and identifying market shortcomings that limit health impact. To structure this process, organizations such as UNITAID, UNICEF, Dalberg, and R4D utilize different classification tools and assessment frameworks. For this primer, we've clustered these and other indicators into the following mnemonic set of five measurable market characteristics: Affordability, Availability, Assured Quality, Appropriate Design, and Awareness. Practitioners can use these "5As" to conceptualize an ideal market state with optimal health outcomes. By contrasting this ideal against the current market state, we can isolate the most critical market shortcomings and identify the diagnostics or analyses necessary to uncover the root causes.

Step 2. Diagnose Root Causes: The design of successful and sustainable market shaping interventions requires analytics to pinpoint the underlying root causes of the shortcomings. For example, the market shortcoming of unaffordable prices can lead to low product uptake. The reasons for high prices could stem from expensive inputs, high supplier margins, high transaction costs, uncertain demand, or a combination of factors. A cost of goods sold (COGS) or other analyses can help provide direction in this case. Only by identifying the relevant root causes can a market shaping intervention target market shortcomings effectively.

A range of analytical tools can help diagnose the root causes of a shortcoming by examining market actors, their interactions, or their regulatory systems. Multiple shortcomings may stem from the same root causes. Insufficient information and uneven risk allocation, for example, can jointly produce interconnected shortcomings of volatile affordability and availability. Depending on the shortcoming investigated, different analytical tools will be relevant. Common market shortcomings and an illustrative list of the analytical tools that can be used to study them are included in the full text of this primer.

Step 3. Assess Market Shaping Options: After observing market shortcomings and tracing them to their underlying root causes, the third step of the Market Shaping Pathway is to assess market shaping options. Most importantly, the selected intervention's theory of change should address the root causes identified in Step 2. In addition, the expected benefits for the specific market

Figure 1. Five Steps of the Market Shaping Pathway



should clearly outweigh the drawbacks and must be feasible with that market's data availability, political environment, and other implementation constraints. During this step, practitioners should assess the opportunity cost of a market shaping versus a programmatic intervention and strive to build consensus on objectives in order to more easily weigh benefits and drawbacks.

In this primer, we try to capture current knowledge around market shaping interventions and present descriptions of common interventions to illustrate the available range. These are categorized by the primary lever utilized: (1) reduce transaction costs; (2) increase market information; and/or (3) balance risk between supply and demand actors. Some interventions use only one lever while others use a combination. While each intervention is listed separately, some could be considered close cousins with smaller operational differences rather than clearly defined boundaries. The full Primer notes the theory of change, benefits, drawbacks, and implementation constraints with examples of each intervention.

Step 4. Implement Customized Intervention: With differing product markets, geographies, stakeholders, processes, and objectives, the defining characteristics of proper execution can only be addressed on an individual basis. Nevertheless, implementation can be guided by common general principles.

- **Collaborate from the start** – Market shaping often requires active partnership and coordination. Donors, implementing partners, strategic advisory groups, suppliers, country policymakers, and end user advocacy groups can all be valuable stakeholders for the design and execution of market shaping activities. Examples of successful coordination include the collaborations across the U.S. Government in antiretroviral procurement, the UNITAID stakeholder engagement process, and the GAVI Alliance Supply and Procurement Roadmap process.

- **Know the tradeoffs** – Practitioners may need to make tradeoffs between desired market characteristics. Tensions could arise between affordability and availability, for example, since lower prices and margins may drive suppliers out of the market. There may even be tensions in how to best implement, such as between the goal to collaborate and the need to move quickly. Early agreement on objectives can help guide decision-making around tradeoffs.
- **Watch for unintended consequences** – Market shaping can have ripple effects, so practitioners should model scenarios of long-term results across all of the “5As” of market characteristics and closely examine these for unintended consequences.
- **Plan an exit** – Many market shaping interventions are intended to operate in a time-limited fashion but generate ongoing results and impact. To accomplish this, practitioners must build an exit plan into the intervention’s design that ensures long-term sustainability of health benefits.
- **Act soon and adapt** – Markets are constantly changing, so the sooner an intervention can be implemented after analysis, the more likely it will still be appropriate. In addition, practitioners should view the intervention as an iterative effort rather than a static solution.

Step 5. Measure Results: Monitoring and evaluating an intervention’s impact on both market and global health outcomes are important to measure achievements and track unintended consequences. Since markets are fluid, practitioners should conduct a rapid evaluation in order to make adjustments quickly. As an emerging field, market shaping does not have a standardized assessment framework, so this primer presents a “dominant logic” from the William Davidson Institute that guides the impact evaluation of many organizations active in market shaping.

By shifting the market equilibrium through changes to transaction costs, information, or risk, practitioners expect to produce better public health outcomes that reflect the overarching mission of saving lives and reducing morbidity. Thus, there are three fundamental areas that market shaping intends to affect and that should be measured in relation to an intervention: market characteristics, public health outputs, and public health impact.

PART III. CONCLUSION

This primer is not intended to be an exhaustive compilation of strategies and interventions for market shaping but rather a starting point for ideas that can be further developed and applied. As the global health field’s collective thinking around market shaping continues to evolve, there may be interest in deepening our understanding of specific interventions and how they might be best suited for different market conditions. Another important aspect is to consider new market shaping approaches, such as options for middle-income countries, demand-side activities, and service delivery interventions. Finally, it will be important to continue exploring new data and methods for monitoring and evaluating market shaping interventions to more fully capture changes in market characteristics, health outputs, and health impact.

Ultimately, the ideas shared here are only useful if applied to actual product markets in order to achieve tangible global health outputs and impact. The Market Shaping Pathway offers a disciplined approach to support ongoing market shaping activities led by the FP2020 Market Dynamics Working Group, the UN Commission on Lifesaving Commodities for Women and Children, UNITAID, and others.

As this field continues to grow, we are hopeful this dialogue on market shaping will produce collaborations to critically evaluate current market shortcomings across health sectors and thoughtfully implement interventions where applicable. Market shaping can better direct the full set of capabilities and resources in the marketplace – across donors, implementers, suppliers and developing country leadership – to achieve health goals. Market shaping alone cannot achieve health impact, but healthier marketplaces can play a critical role in delivering life-saving products to those most in need.

Part I Introduction

Global health is inextricably linked to the health of the marketplace that delivers life-saving products to low-income populations.

A well-functioning healthcare market with public and private sector participation requires manufacturers to produce high-quality products, distributors to deliver the necessary quantities, providers to administer them correctly, and patients to be educated and active participants in their own health. However, sometimes markets fall short. Developers may not see enough patient demand to develop a new product, manufacturers may not know how much to produce, and distributors may not see enough profit to justify delivery. The unfortunate reality is that a single breakdown in this complex system can keep life-saving products from those most in need.

Market shaping is a practice grounded in health ecosystem-level thinking – reframing issues, boundaries, and constraints. Despite being a new and loosely defined subject – some going as far as characterizing market shaping as “everything and nothing at the same time” – the common denominator of market shaping interventions is a design to disrupt current practices or to transform existing market structures rather than adapting or adhering to them. If likened to what lies at the proverbial fork in the road, market shaping is the strategic decision to avoid the two winding and unappealing roads ahead and instead chart a new, straighter path.

In practice, the application of market shaping interventions is far less adventuresome. But the notion of stepping off the commonly traveled road to address market shortcomings head on by adopting new and more efficient approaches is a construct that captures the innovative nature of market shaping.

Consider the challenge that the GAVI Alliance faces when negotiating prices for vaccines. Compared to pharmaceuticals, the process of manufacturing vaccines is more complicated and requires significant investment and adherence to complex production requirements. As a result, fewer companies participate, making for a less competitive marketplace. In certain circumstances, GAVI is faced with the decision to either renegotiate for lower prices with manufacturers – often at the risk of driving more companies from the market and putting long-term price sustainability at risk – or accept higher prices that might limit the scope and reach of operations.

By taking an ecosystem-level view that identifies market shortcomings and seeks to optimize or, in some cases, redesign the existing marketplace, GAVI is able to create “win-win” scenarios that attract new manufacturers and lower vaccine prices. The fruits of their labor are quantifiable. Between 2003 and 2013, GAVI helped catalyze a competitive marketplace for pentavalent vaccine from one manufacturer to six and achieved an up to 65 percent reduction in price from \$3.56 per dose to as low as \$1.19.² This new low pentavalent vaccine price – achieved in a 2013 tender – is projected to save GAVI up to \$150 million over the next 4 years.³

The U.S. Government’s investment in coordinating the procurement and distribution of anti-retrovirals (ARVs) is another example of market shaping effectively mitigating supply, demand, and cost risks. Creating catalytic change by addressing multiple shortcomings in parallel, the U.S. Agency for International Development-(USAID)-administered Supply Chain Management System (SCMS) developed Regional Distribution Centers (RDCs) capable of minimizing shipping delays, improving demand forecasting, and

2. All currency figures are presented in U.S. dollars unless otherwise specified.

3. “GAVI 2013 Progress Report.” GAVI Progress Reports. GAVI, June 2014. [www.gaviprogessreport.org].

lowering unit costs related to the provision of products across sub-Saharan Africa. Designed to be a sustainable resource, the RDCs operated as independent commercial enterprises, attracting private sector clients such as GlaxoSmithKline (GSK), Merck Serono and Pfizer. Along with markedly decreasing unit costs, the RDC in South Africa increased on-time delivery from 60 percent to 90 percent compared to traditional methods from 2008 to 2012.⁴

In addition, the U.S. Food and Drug Administration (FDA) set up an expedited drug review process in 2004 to help suppliers enter the ARV market more quickly. This “tentative approval” designation encouraged applications from manufacturers of approved ARV therapies, even if the products were still under patent or exclusive market protection in the United States. In enabling procurement by the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), the “tentative approval” designation paved the way for a more diverse and competitive supply of ARVs for developing countries. Today, 170 new ARV products have been approved or tentatively approved, including many from generic manufacturers.⁵

In the same product class, South Africa’s ARV treatment program procures more ARVs than any country in the world and serves as an example of a country-led market shaping intervention. With the support of PEPFAR, the United Kingdom’s Department for International Development (DFID), the Clinton Health Access Initiative (CHAI), and others, South Africa conducted careful analysis of the market landscape and reached out to suppliers in India and China to increase supplier competition. In doing so, they were able to negotiate better prices, incentivize timely delivery, and improve transparency. In aggregate, the collective efforts of all parties helped cut the cost of ARVs by more than 50 percent in the initial post-intervention tender and by nearly 30 percent in the second, saving an estimated \$700 million and \$260 million, respectively.

In family planning, market shaping is playing a critical role in scaling up access to contraceptive implants. Limited competition between manufacturers had kept implants priced around

\$18.00 per device, a price point considered prohibitively expensive for many women in developing countries. As part of the global market shaping work undertaken by a consortium of partners in global health,⁶ minimum volume guarantees were established with Merck/MSD and Bayer HealthCare, effectively cutting the price of their products (Implanon and Jadelle, respectively) in half. In the first 11 months of fiscal year 2014 – after the volume guarantee was in place – USAID shipped 1.97 million implants, almost double the 1.04 million shipped in all of fiscal year 2013. This increase in volumes required only a 1 percent increase in commodity, shipping and handling, and surcharge costs.⁷

These success stories are the tip of the iceberg. While product price reductions were clearly an important outcome in each, affordability is far from the only way that market shaping achieves impact, and an overemphasis on price can, in some cases, actually do more harm than good. Issues of availability, assured quality, appropriate design and awareness also are all important and addressable factors. To capture the full scope of impact, we later present (Figure 5) a collection of frameworks designed by technical experts and practitioners on the frontlines of market shaping, including UNITAID, the United Nations Children’s Fund (UNICEF), Dalberg, and Results for Development Institute (R4D). These experts and practitioners have all designed systems and processes to measure market shortcomings as a product of multiple performance indicators that go far beyond lowering a product’s price.

The success of these and countless other initiatives are the product of a broader movement that traces back to UNITAID’s groundbreaking approach to correcting market shortcomings and extends to nearly every corner of the global health community today. Inspired by the possibility of how these innovative approaches could tackle global health challenges, USAID, UNICEF, the Bill & Melinda Gates Foundation (Gates Foundation), DFID, and The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), among others, have each developed, or are in the process of developing, market dynamics or market shaping strategies. The Norwegian

4 Larson, Burn, et al. “Mitigating Supply, Demand and Cost Risks in ARV Supply Chains.”

5 “Approved and Tentatively Approved Antiretrovirals in Association with the President’s Emergency Plan.” FDA International Programs. U.S. Food and Drug Administration. [www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/AsiaandAfrica/ucm119231.htm].

6 Merck and the Bill & Melinda Gates Foundation were direct parties to the agreement, and the Clinton Health Access Initiative (CHAI), the governments of Norway, the United Kingdom, the United States and Sweden, the Children’s Investment Fund Foundation, and the United Nations Population Fund (UNFPA) were facilitating parties, and this built on a previous partnership with the Reproductive Health Supplies Coalition (RHSC).

7 USAID/DELIVER Project Quantity and Value Summary Report, run Aug. 18, 2014. Volume figures include both Implanon and Jadelle shipments.

Agency for Development Cooperation (Norad) works with multilateral organizations and other partners to develop market shaping strategies for efficient procurement. In addition, UNICEF and implementing partners such as CHAI and the numerous organizations involved in the Partnership for Supply Chain Management and SCMS have all worked closely with manufacturers, governments, and global agencies to design and implement new market shaping interventions. Strategy and analytics groups like the William Davidson Institute, Dalberg, McKinsey, and R4D have provided pivotal technical and advisory support in these efforts. The ongoing strategic and analytical approaches shared by these groups – including those in the recently released Reproductive Health Supplies Coalition (RHSC)/Dalberg “Market Shaping for Family Planning” report⁸ – have advanced the field and set the stage for continued progress.

The state of the practice in market shaping is indeed encouraging. The evidence base for market shaping continues to grow, providing a rich and extensive landscape from which to assess historical impact and analyze opportunities for future application. In an effort to draw on learnings from past experience, this primer aims to pull together lessons learned and guidance on how to approach future opportunities in a disciplined manner. Seeing the shared interest and organizational momentum within the global health community as harbingers of future progress, we hope this primer can foster a common dialogue and strengthen collective efforts to continue shaping healthy markets for life-saving products.

Confronting the Definition Question: What Is Market Shaping?

The primary objective of market shaping is to maximize public health impact; optimizing markets is only an intermediate goal along that path. While similar activities could be undertaken for other goals, we consider market shaping in this primer to be focused on interventions that serve the public good, since that is the primary interest of the global health community. As a result, candidates for market shaping interventions include both failing markets that impede health goals and economically well-functioning markets struggling to achieve optimal public health impact. Designed and implemented correctly, market shaping interventions can achieve a range of benefits by addressing either chronic issues underpinning these market shortcomings (e.g., limited production volumes or substandard quality) or acute issues that lead to periodic market instability (e.g., cycles of low and high prices or volumes).

Additional names for this type of thinking around supply and demand interactions between public, private, and non-profit actors include “market dynamics” and the “total market approach.” Here, we consider “market dynamics” a description of how market actors – including manufacturers, distributors,

buyers, regulators, and donors – make strategic choices to produce, distribute and deliver global health products. The “total market approach,” which is slightly different than market dynamics but often considered with it, describes a system in which the public, private, and social marketing sectors all work together to deliver health choices for all population segments. Organizations use different terms for the activities that influence or change these interactions at the level of the whole market or health ecosystem; we refer to these activities as “market shaping.” In addition, while market shaping could be applied to enhancing delivery or support of health services or insurance, this primer focuses on product markets in which physical drugs, vaccines, diagnostics, or devices are bought and sold.

SUSTAINABILITY

While market shaping interventions can and should be designed to improve healthy market characteristics on both the supply side and demand side, historical trends demonstrate a tendency to focus on upstream supply-side actors, which

8. “Market Shaping for Family Planning.” Dalberg Global Development Advisors and Reproductive Health Supplies Coalition. June 2014. [www.dalberg.com/documents/Market_Shaping_for_Family_Planning.pdf].

Not every situation of low health product usage calls for market shaping; it is important to consider all options.

is reflected in the area of focus for this primer. Whether by facilitating participation, increasing access to information or reducing risks, these interventions encourage current suppliers to contribute more actively in the market or new suppliers to enter it. Nonetheless, public health impact is not achieved by engaging only the supply side, and supply without demand is not sustainable over the long term. Thus, active exploration of future market shaping options for demand-side shortcomings and actors is necessary.

Market shaping is about accelerating the market to a more optimal equilibrium point in terms of improved health outcomes and sustainability. It is intended to be a catalytic intervention that achieves lasting results. Envisioned here, the concept of “sustainability” can adapt to the context of the specific product market and could refer to a more vibrant and competitive commercial market or to a reconfigured procurement process that leads to greater value for money in the public sector.

From a product perspective, goods and services that an individual tends to under-consume when accounting for population-level benefits or externalities (i.e., public goods and merit goods, such as vaccines or ARVs that reduce disease transmission) are likely candidates for market shaping. Even without externalities, an economically efficient product market may still produce suboptimal health outcomes. In these situations, market shaping would face a higher bar of demonstrating the public health rationale for intervening in a stable, otherwise sustainable marketplace.

UNINTENDED CONSEQUENCES

Since market systems are complex with many moving and interconnected parts, practitioners should be wary of creating unintended consequences. For example, public subsidies for the social marketing of products that the private sector deems unprofitable to supply may crowd out the emergence of a long-term and commercially sustainable solution. Or, in striving to stimulate availability and demand, market shaping may inad-

vertently encourage overuse or inappropriate use of a product. Similarly, in driving down prices to enhance affordability, market shaping may compromise sustainability because related costs, like service delivery, may be left out of budgets and planning. In addition, market shaping that lowers risks for existing suppliers may inadvertently decrease incentives for new suppliers to invest in product innovations or enter the market.

Indeed, the success of any market shaping intervention requires a thorough inventory of the benefits, tradeoffs, and unintended consequences from multiple perspectives in the market – including leadership from recipient countries. These potential unintended consequences are an essential component of the evolving conversation around the role of market shaping in global health and are discussed at length throughout this primer with examples in the section on assessing options (Step 3), as well as guidance in the section on implementing interventions (Step 4).

THE MARKET SHAPING CONTINUUM

Market shaping alone does not address the multitude of health product uptake challenges in developing markets. It is merely a powerful nudge toward further market optimization. Thus, it relies heavily on ongoing programmatic interventions by the global health community to implement and effect change. Market shaping is closely interlinked with, and dependent upon, programmatic interventions like healthcare provider training, health product procurement, and supply chain strengthening.

Another critical programmatic element is strategic planning for product introduction and scale across marketing, manufacturing, distribution, and other areas. CII has examined these aspects with case studies in its complementary reference, *Guide to Introduction and Scale of Global Health Innovations*.

Moreover, the distinction between market shaping and programmatic interventions is more of a continuum than a clear divide. Similar interventions may fall closer to one end of the spectrum or the other based on the intervention’s catalytic versus routine nature, time-bound versus ongoing duration, or intensity of focus on influencing buyer and supplier interactions. For example, ongoing activities like information, education and communication (IEC) campaigns or brand-specific social marketing efforts may sit closer to programmatic interventions, whereas a time-limited channel subsidy for a new product category to increase manufacturer or retailer

participation falls closer to market shaping. Acting in different ways, both interventions lower supplier risks with demand-side investments that expand potential sales volumes.

In addition, not every situation of low health product usage calls for market shaping. For example, one of the challenges of providing access to oxytocin (an important drug for preventing and treating postpartum hemorrhage) is that it degrades quickly when exposed to high heat. To deliver the existing oxytocin formulation in developing countries, the focus may be best placed on structural improvements to the cold chain and safe integration of new products into the cold chain. Thus, it is important to consider all options – both those closer to programmatic interventions as well as those more commonly viewed as market shaping – in determining the most appropriate next steps.

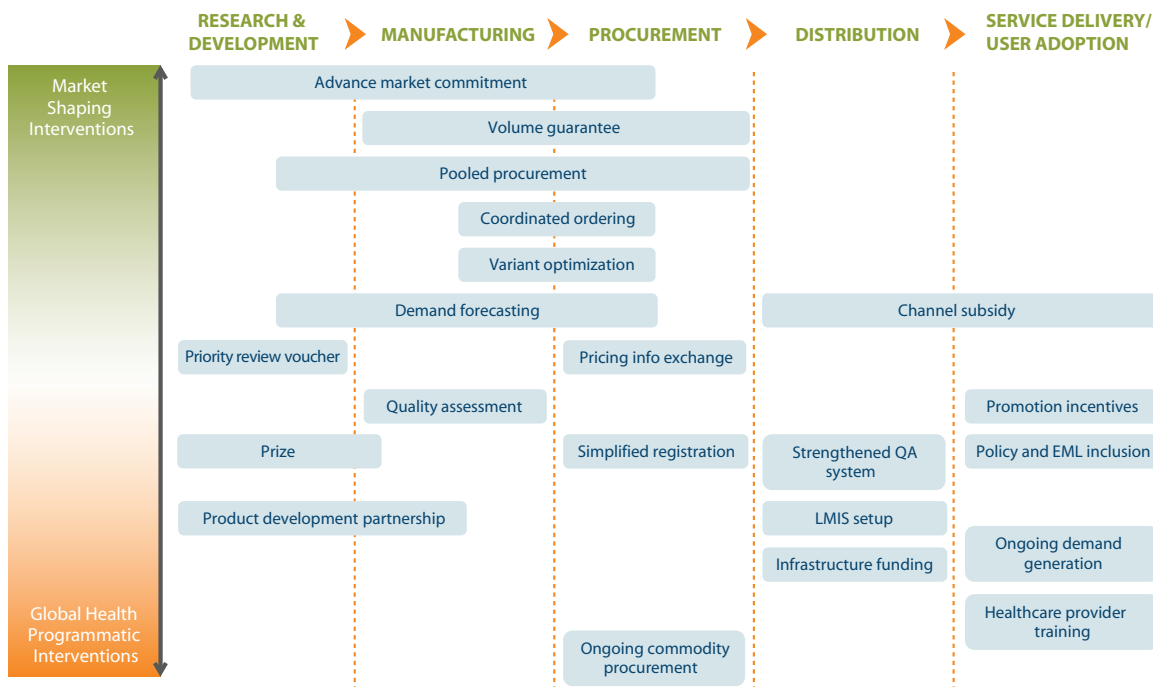
Market shaping interventions act upon different stages of a product's value chain, from defining the target product profile to increasing end user awareness and adoption. Selecting an appropriate intervention should be linked to which stage

Market Shaping vs. Programmatic Interventions

The distinction is more of a continuum than a clear divide. Similar interventions may fall closer to one end of the spectrum or the other based on the intervention's catalytic versus routine nature, time-bound versus ongoing duration, or intensity of focus on influencing buyer and supplier interactions.

along the value chain it intends to target. The schematic below (Figure 2) illustrates a rough mapping of interventions along the market shaping/programmatic continuum and the product value chain. The graphic is not intended to be comprehensive or definitive but rather to illustrate the range of market shaping interventions and how they can complement programmatic interventions at overlapping value chain stages. Many of the market shaping interventions below are described further in the section on assessing market shaping options (Step 3).

Figure 2: Illustrative Market Shaping/Global Health Programmatic Continuum



Beyond Market Shortcomings: Addressing Root Causes

Market shaping is designed to improve a market's health outcomes by targeting the root causes of market shortcomings. Actors at both ends of the market – producers and purchasers – may face high transaction costs, critical knowledge gaps, or imbalanced risks that hamper their participation in the market.

Countries, donors, and procurers can use their purchasing power, financing, influence, and access to technical expertise to address the root causes and influence market dynamics for improved health outcomes. Designed to be transformative, market shaping interventions aim to reduce long-term demand and supply imbalances to achieve sustainable health benefits. These market shaping interventions typically use three types of levers to reduce market shortcomings:



1. Reduce transaction costs – Lowering structural hurdles to interacting in the market, such as by simplifying, smoothing, or rationalizing orders. No money necessarily changes hands, although donors or health-focused stakeholders may invest in technical assistance to produce more efficient processes.



2. Increase market information – Generating new data, aligning existing analyses, or improving the visibility of existing data to reduce asymmetries of information. In doing so, transaction costs and operational risks can potentially be reduced, thus supporting the two other levers.



3. Balance supplier and buyer risks – Offsetting financial risks borne by suppliers and shifting them to donors/purchasers in order to make market engagement more attractive. This can entice new suppliers to enter or existing suppliers to operate more actively.

Cataloging every conceivable root cause of a market shortcoming would be unwieldy, of limited use for practitioners, and probably impossible. Instead, we strove for a useful organizing principle, grouping the most common root causes observed across market shaping interventions into three categories – high transaction costs, limited market information, and risk imbalances between supply and demand. We then focus on the potential levers to address these three root causes and how they are connected to different types of market shaping interventions (see Step 3 and Figure 10). For example, reducing transaction costs could mean pooling procurement to create a more robust and consistent demand, thereby improving profitability and predictability in the market.

As interventions are customized for specific markets, they may use one or more of these levers. In the pooling procurement example, placing public orders that aggregate demand across countries can both reduce transaction costs and increase market information. In contrast, aggregating and publicizing the results of a demand forecasting exercise would primarily operate by increasing market information. In addition, since markets evolve over time, market shaping interventions will need to adapt accordingly and may draw on different levers at different points in time.

Countries, donors, and procurers can use their purchasing power, financing, influence, and access to technical expertise to address the root causes of market shortcomings for improved health outcomes.

A graphic of a spotlight shining down from the top left corner of the page, illuminating the title area.

SPOTLIGHT on Addressing Root Causes

Coordinating Efforts in the Second-Line ARV Market

Few product classes provide a clearer example of market shaping's impact than second-line ARVs. Interventions targeting each of the three levers have been employed in second-line ARVs to cut costs, improve quality and access, and streamline procurement.

In early 2007, at the start of the DFID/UNITAID-financed and CHAI-supported second-line ARV scale-up, the price of a second-line ARV treatment regimen was roughly 10 times higher than a suitable first-line therapy. Under this pricing structure, the ARV treatment cost of a population doubles when only 10 percent of patients start to require second-line therapy. As first-line treatment populations grew and governments added second-line treatment into their guidelines, the demand for second-line ARVs rose as well.

Recognizing the situation as untenable, these organizations moved forward with a strategic approach to increase access to treatment in 25 countries. The initiative had two primary objectives: to reduce the price of second-line therapy and to increase the number of suppliers. As governments incorporated second-line ARVs into their guidelines, CHAI increased market information by conducting demand forecasts and communicating the expected higher demand to existing and potential suppliers and reduced transaction costs by negotiating volume-based discounts. By addressing inefficiencies in the relatively nascent second-line therapy market, UNITAID and CHAI effectively reduced the annual cost of treating a patient with a combination of tenofovir, lamivudine, and lopinavir/ritonavir – a popular second-line ART regimen – from \$965 in 2006 to \$492 in 2011.⁹

In addition to negotiating price reductions with public tenders for ARVs, CHAI balanced supplier and buyer risks by establishing new “non-price” selection criteria in the tender process, including the number of in-country registrations and historical supplier performance. The inclusion of these criteria led to a more reliable and competitive supply of pediatric and second-line ARVs, increasing on-time deliveries by 17 percent and reducing the duration of delays by 52 percent.¹⁰ Moreover, the initiative further reduced risk on both sides by providing technical assistance to procurers on forecasting and tendering, and to suppliers on achieving greater efficiencies in sourcing inputs and manufacturing. By strengthening actors on both the demand and supply side, and increasing information between them, the interventions facilitated price drops and streamlined processes, while enabling sufficient production to meet the growing demand.

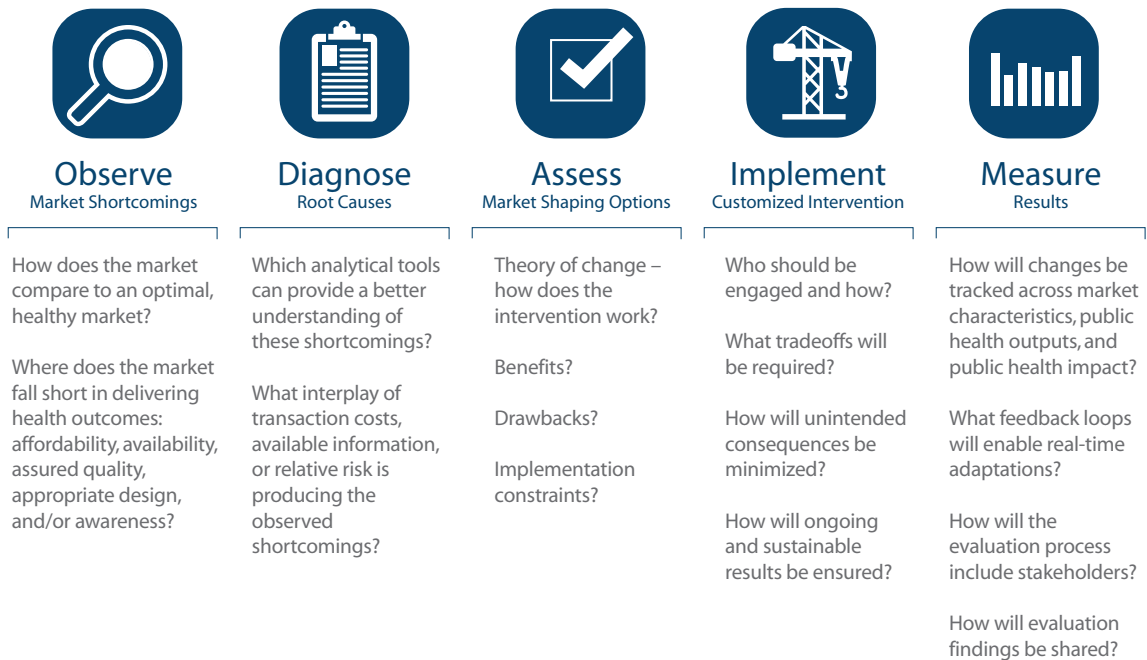
9 HIV/AIDS in Ethiopia: The Clinton Health Access Initiative and UNITAID. Addis Ababa: Clinton Health Access Initiative (CHAI), 2011. Web. < <http://www.clintonhealthaccess.org/files/CHAI-UNITAID-Ethiopia-Report-August-2011.pdf> >.

10 Clinton Health Access Initiative, UNITAID, and DFID Announce Lower Prices for HIV/AIDS Medicines in Developing Countries: Partnership to Reduce ARV Prices Will Yield Savings of at Least \$600 Million Over 3 Years. UNITAID; CHAI; DFID. Print.

This primer seeks to aggregate the field’s collective knowledge to address the overarching questions of what market shaping means and how to approach assessing whether interventions may be appropriate for a specific underperforming market. To that end, we offer the Market Shaping Pathway below, which organizes important market shaping questions and key considerations into five critical steps. Figure 3 presents these five steps of the market shaping development process and lists core questions to be answered at each step. Whether a product is established or new, and whether the focus market is global or local, this approach can help assess how a market shaping intervention could work.

The Market Shaping Pathway begins with the first step of assessing the current health of the market. Are prices too high for consumers? Are they too low to encourage private sector participation? Are the products acceptable, and if so, are they available throughout the market? By observing market shortcomings, practitioners can begin to isolate critical bottlenecks. As these surface-level market shortcomings are often the product of multiple, interwoven root causes, the second step emphasizes the rigorous analysis necessary to uncover the underlying root causes that a market shaping intervention would target. The third step evaluates the range of market shaping options to determine which solution, if any, is capable of addressing the

Figure 3. The Five Steps of the Market Shaping Pathway



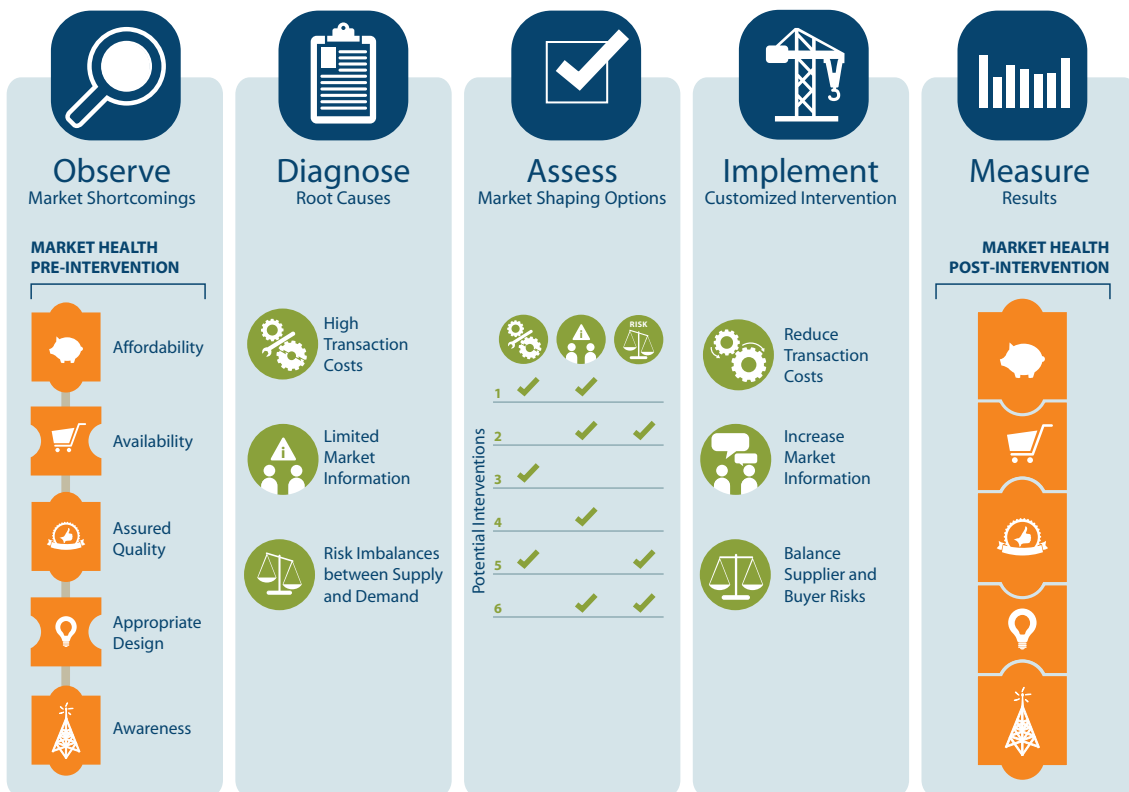
root cause(s). If a promising intervention is identified, the fourth step addresses the often challenging characteristics of design and implementation. Since these interventions directly or indirectly affect the transaction costs, information and risk exposure of demand and supply actors across the market, an intervention can generate far-reaching, follow-on effects. To minimize unintended consequences and respond to changes, the fifth step focuses on monitoring results and adapting the intervention as needed.

Each of the five steps is described in detail in the following sections. Figure 4 offers an accompanying visual to highlight the key activities involved throughout the Pathway. The introductory step, Observe Market Shortcomings, and the final step, Measure Results, reflect the “before” and “after” scenarios that connect a market shaping intervention to its intended health outcomes. Steps 2, 3, and 4 emphasize the process undertaken

to get there by employing analysis-driven, customized interventions that target market shortcomings by addressing any or all of the three categories of root causes: high transaction costs, limited information, and risk imbalances.

More important than any individual step in the approach is the need for a coordinated effort among the key stakeholders, especially representatives of the countries and end users of the health products. The unique perspective of each stakeholder group brings complementary information and data at each step in the process. In addition, their range of experience can shed light on what has been tried in the past to help identify new opportunities or barriers in the present. From initial analysis to results measurement, involvement by procurers, producers, policymakers, advocates, and implementers will help aggregate critical information and support the establishment of a more holistic and impactful solution.

Figure 4. Conceptual Framework of the Market Shaping Pathway*



* As noted earlier, the three root causes presented here reflect themes drawn from a range of market shaping interventions. Although other root causes may emerge in other market situations, the overall approach of the Market Shaping Pathway can still be applied.

To illustrate the importance of each step, we include case study Spotlights to ground these principles in tangible terms. Each of the four case studies introduced below describes specific examples of the process identified within the Market Shaping Pathway. Each case study is designed to focus on a particular component of the process identified in the Pathway

and is not intended to capture the full story of the product, the market shaping intervention, or the stakeholders involved. These Spotlights focus on global market shaping interventions, but as the earlier example of South Africa's ARV program demonstrates, there are opportunities for country-level market shaping activities as well.

Spotlights Mapped to the Market Shaping Pathway



Spotlight on Observing Market Shortcomings and Diagnosing Root Causes:

Identifying Global Forecasting Challenges for Artemisinin Combination Therapy (ACT)

The ACT market faced shortcomings of inconsistent affordability and unstable availability, as evidenced by high price volatility and cycles of product shortages and surpluses. Financiers, researchers, and stakeholders aggregated and analyzed market data to identify root causes around insufficient information on demand, which is especially acute for suppliers because of the long product lead time and uneven risk allocation. Global financiers shared procurement plans and collaborated to establish a demand forecasting consortium, financing support, and an ACT Task Force to address the root causes that were identified.



Spotlight on Assessing Market Shaping Options:

Mapping Market Shaping Possibilities for Oral Rehydration Salts (ORS) and Zinc

In late 2004, the WHO/UNICEF issued a joint statement recommending a combination of ORS and zinc as the preferred diarrhea treatment. However, despite decades of promoting the use of ORS, access and utilization in many parts of the world remained insufficient. With a number of market shaping and programmatic interventions to consider, USAID's Point-of-Use Water Disinfection and Zinc Treatment project (POUZN) sought market-specific solutions to promote increased private sector participation in the scale-up of ORS and zinc.



Spotlight on Implementing Customized Interventions:

Launching an Advance Market Commitment (AMC)

A pilot AMC for the pneumococcal vaccine was launched in 2007 with support from GAVI and others donors. Key AMC elements included a pre-determined product price, a discounted tail-price ceiling, and a subsidy via price "top-up" to manufacturers. These structures were designed to motivate suppliers to accelerate the late-stage development and manufacture of pneumococcal vaccines in order to meet developing country needs at low, sustainable, and predictable prices.



Spotlight on Measuring Results:

Improving the Pooled Procurement of Vaccines

UNICEF pools procurement of vaccines for over 80 low-income countries. This includes negotiating prices and terms with suppliers, creating aggregate forecasts, placing orders, making payments, and posting transaction prices. As UNICEF monitors the changing market dynamics in the vaccine markets, the organization continues to revise its approach to better strike the balance between low prices and supply sustainability.



Observe
Market Shortcomings



Diagnose
Root Causes



Assess
Market Shaping Options



Implement
Customized Intervention



Measure
Results

▶▶ Step 1. Observe Market Shortcomings

How can we recognize market shortcomings?

The first step in the Market Shaping Pathway is to identify market shortcomings that limit health impact. Key questions to consider at the outset include the following:

- How does the market compare to an optimal, healthy market?
- Where does the market fall short in delivering health outcomes: affordability, availability, assured quality, appropriate design, and/or awareness?

To address these questions, practitioners can begin by conducting a high-level market landscape analysis to better understand product features, competitive products, market size, etc. In doing so, it is important to consider the number and relative power of buyers and suppliers. Additionally, since markets are constantly changing with entering and exiting suppliers, emerging research and development (R&D), and changing budgets, it is important to describe both the current market and how the market is likely to evolve without an intervention. Taken together, the features outlined in these descriptions can paint a picture of the inefficiencies or shortcomings affecting a complex and fluid market for products and services.

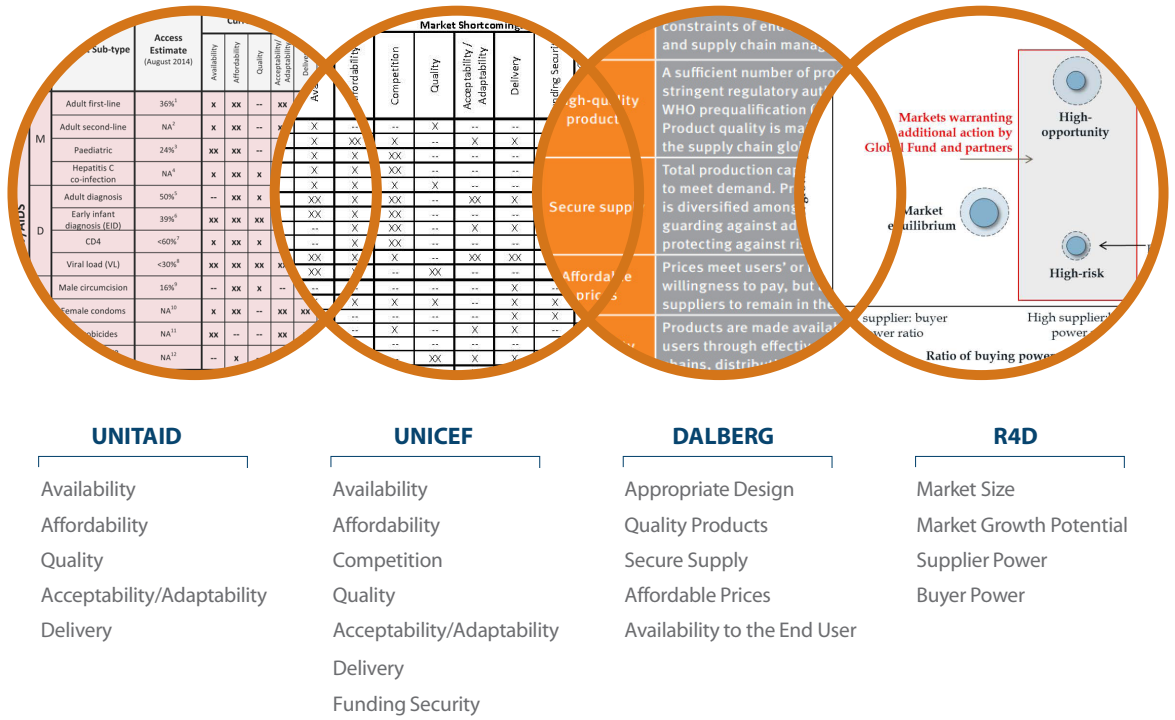
To provide structure to the process, organizations utilize different classification tools and assessment frameworks to observe and categorize market shortcomings. UNITAID, as a pioneering practitioner of market shaping, utilizes a Market Dynamics Dashboard (shown on page 20) to assess five critical market shortcomings – availability, affordability, quality,

acceptability/adaptability, and delivery – across multiple product and intervention classes. UNICEF’s Supply Division, inspired by UNITAID’s work, uses a similar market dashboard with seven key indicators to categorize market shortcomings into a composite severity score that supports a ranking system for intervention opportunities in the near and medium term. Other examples include Dalberg’s five indicator framework for family planning products and the assessment framework created by R4D and the Global Fund, which classifies markets into three buckets – equilibrium, high-opportunity, and high-risk – based on market size, market growth potential, supplier power, and buyer power.¹¹

For the purposes of this primer, we’ve clustered these and other organizational indicators into the following set of five measurable market shortcomings: Affordability, Availability, Assured Quality, Appropriate Design, and Awareness. Each of these five factors starts with the letter A, as we’ve found the “5As” mnemonic to be a simple and memorable way to codify market shortcomings. Similar in nature to the shortcomings analyzed by both UNITAID and the UNICEF Supply Division in their respective market dynamics dashboards, these “5As” should be assessed collectively, with each characteristic forming an integral and interrelated part of a sustainable and healthy market. In practice, some of the “As” may appear to be in tension with each other. For example, a push for increasing affordability via lower prices could be seen as undermining long-term supplier availability. Thus, it is important to gain

¹¹ “Market Dynamics Study: Phase II Report for the Global Fund Market Dynamics Committee (MDC).” R4D and Global Fund to Fight AIDS, Tuberculosis and Malaria, 28 Mar 2011. Pp. 2–3.

Figure 5. Illustrative Examples of Market Dynamics Dashboards (note: organizations may define shortcomings differently)








early agreement among stakeholders on the most important objectives in order to navigate these tensions and jointly make tradeoffs to build a stronger market with a sustainable set of market characteristics. Figure 6 further defines each of the “5As” and provides a small sample of metrics used by Dalberg and others to measure progress.

Practitioners can use the 5As to conceptualize an ideal market state with optimal health outcomes. By contrasting this ideal against the current market state, we can begin to isolate the most critical market shortcomings (see Figure 6 illustrating potential shortcomings across the 5As), and identify the

types of diagnostics or analyses necessary to uncover the root causes in Step 2.

In the simplest of terms, Step 1 is about establishing direction through structured thinking. Organizations leading on market shaping have all developed strong institutional processes that effectively capture the complexity of a market and break it into analyzable parts. Similar to a physician initially checking the vitals of a patient for symptoms, observing market shortcomings is a surface-level exercise that narrows possibilities and prompts further inquiry in Step 2.

Figure 6: The “5As” of Market Characteristics and Potential Shortcomings¹²

	DEFINITION	SAMPLE METRICS	POTENTIAL MARKET SHORTCOMINGS
 <p>Affordability</p>	Extent to which the price point maximizes market efficiency between payers and suppliers to support health outcomes	<p>Prices are low enough to make widespread use of the product cost-effective</p> <p>Prices are high enough to incentivize suppliers to remain in the business</p>	<p>High, unaffordable prices or high price variance across geographies</p> <p>Cyclical swings in prices</p>
 <p>Availability</p>	Capacity and stability of global supply to meet demand; and consistency of local access at service delivery points	<p>Sufficient volumes are produced by a competitive, stable supply base</p> <p>Products are equitably and appropriately dispensed to the end user</p>	<p>Volumes: shortages, stockouts, excess, or cycles of shortage/excess</p> <p>Supply base: few suppliers or supplier exit or failure</p>
 <p>Assured Quality</p>	Level of evidence that a product is consistently efficacious and safe	<p>Products meet SRA or WHO PQ quality assurance standards</p> <p>Quality control is maintained throughout the production process and in-country supply chain</p>	<p>Substandard or counterfeit products</p> <p>Insufficient information on quality or inadequate quality markers</p>
 <p>Appropriate Design</p>	Degree to which possibilities of technology maximize cultural acceptability, choice, and ease of use	<p>Products are culturally appropriate for low-income settings</p> <p>Designs meet the constraints of end users, providers, and supply chain managers</p>	<p>Ill-adapted designs for low-income settings</p> <p>Too many variants fragment demand or too few limit choice</p>
 <p>Awareness</p>	Extent to which end users, healthcare providers, and key influencers can make informed choices about product use	<p>Target markets are educated on product benefits and side effects</p> <p>Healthcare providers are adequately trained in diagnosis and product provision to ensure appropriate and consistent use by patient</p>	<p>Low awareness or misinformation of product or health condition</p> <p>High misdiagnosis rates or overuse (leading to resistance)</p>

¹² Definitions and sample metrics build off analysis presented in the Dalberg/RHSC report, “Market Shaping for Family Planning,” cited earlier.



▶▶ Step 2. Diagnose Root Causes

How can we diagnose the root causes of market shortcomings?

Observing market shortcomings is a starting point that allows us to develop a problem set with testable hypotheses. The design of successful and sustainable market shaping interventions requires additional analytics to pinpoint the underlying root causes behind the most critical shortcomings:

- Which analytical tools can provide a better understanding of these shortcomings?
- What interplay of transaction costs, available information, or relative risk is producing the observed shortcomings?

For example, the market shortcoming of high or unaffordable prices is a commonly cited problem because it leads to low product uptake. The reasons for high prices could stem from a range of factors: expensive inputs, complex or inefficient manufacturing, high supplier margins, low competition, high transaction costs, low or fluctuating demand, or some combination of these factors. Analyses of the supplier landscape, cost of goods sold (COGS), procurement and tendering, pricing and financing, and/or production capacity can help provide direction in this case.

Only by identifying the relevant root causes can a market shaping intervention target market shortcomings effectively. The relatively few patients requiring second-line ARVs constituted a small market for these medications, and this was often viewed as an important driver of high prices. However, limited diagnostic capabilities and complicated treatment guidelines with numerous regimens were further splitting the demand among different second-line ARVs. This fractured demand weakened incentives for new suppliers to enter the market and for existing suppliers to invest in process efficiencies or better-adapted products.

Shortcomings can also interact with each other. For example, in the markets for ORS and zinc (described further in the Spotlight on page 38), there is low uptake because prices for a full course of treatment can appear relatively high. Where awareness of the products' benefits is low, the perceived price appears higher. Since the sales volume is low, manufacturers do not focus on supplying the market, leading to poor product availability. With a small scale of production, manufacturers also cannot reach economies of scale, keeping unit costs (and therefore prices) high. The market cannot grow unless these shortcomings, and this feedback loop of their interactions, are addressed.

A similar dynamic can occur when the potential demand or market size is uncertain. Suppliers offer high prices to reflect this risk, which dampens demand. Facing low sales volumes, suppliers are reluctant to build capacity, keeping prices high. These interactions may occur in markets for new products like vaccines, where capacity investments are costly and only made in large increments. These types of fragile markets may be good opportunities for market shaping (see, for example, the pneumococcal vaccine Spotlight on page 43).






A range of analytical tools can help diagnose the root causes of a shortcoming by examining market actors (e.g., supplier landscape, COGS, production capacity, consumer behavior, cost-effectiveness, and stakeholder analysis), their interactions (e.g., demand forecasting, pricing and financing, and procurement and tendering) or regulatory systems (e.g., product quality and quality assurance). Depending on the shortcoming being investigated for a particular market, different analytical tools will be relevant. In the long-lasting insecticide-treated net (LLIN) market, for example, one market shortcoming was

excessive product variety. R4D combined a COGS analysis with a consumer behavior analysis to understand both production costs and drivers of use in order to identify which product variants delivered the highest value for money.¹³

Potential market shortcomings and an illustrative list of the analytical tools that can be used to study them are included in Figure 7. More information about these analytical tools, including the types of data each examines, is provided in Appendix 1.

Figure 8 provides a summary of the shortcomings and root causes found in the four case studies shared in this primer. While this is a small sample of potential shortcomings and root causes, it shows how the Market Shaping Pathway can help assess observed market shortcomings and trace them back to root causes. Additionally, these examples show the interconnectivity between multiple shortcomings and root causes. A well-designed market shaping intervention should account for these interactions.

Figure 7: Analytical Tools to Evaluate Market Shortcomings


MARKET CHARACTERISTIC	POTENTIAL MARKET SHORTCOMINGS	RELEVANT ANALYTICAL TOOLS
 Affordability	High, unaffordable prices or high price variance across geographies Cyclical swings in prices	Supplier Landscape Assessment, Cost of Goods Sold Analysis, Procurement/Tendering Analysis, Price/Financing Analysis, Production Capacity Analysis
 Availability	Volumes: shortages, stockouts, excess, or cycles of shortage/excess Supply base: few suppliers or supplier exit or failure	Demand Forecasting, Price/Financing Analysis, Production Capacity Analysis, Cost-Effectiveness Analysis Supplier Landscape Assessment
 Assured Quality	Substandard or counterfeit products Insufficient information on quality or inadequate quality markers	Product Quality Analysis, Quality Assurance Assessment
 Appropriate Design	Ill-adapted designs for low-income settings Too many variants fragment demand or too few limit choice	Consumer Behavior Analysis, Cost-Effectiveness Analysis
 Awareness	Low awareness or misinformation of product or health condition High misdiagnosis rates or overuse (leading to resistance)	Demand Segmentation, Demand Stakeholder Analysis, Cost-Effectiveness Analysis, Consumer Behavior Analysis

13 Bahl, Kanika, and Shaw, Pooja. "Expanding Access to LLINs: A Global Market Dynamics Approach." Washington, DC: Results for Development (R4D). [r4d.org/sites/resultsfordevelopment.org/files/resources/R4D_LLIN%20report_24Apr_Final.pdf]

Figure 8. Connecting Market Shortcomings to Root Causes: Examples from the Spotlights*



* As noted earlier, each Spotlight is designed to focus on a particular component of the Market Shaping Pathway. Thus, this figure highlights the relevant market shortcomings and root causes for that component and is not intended to capture other aspects of the market.



SPOTLIGHT on Observing Shortcomings and Diagnosing Root Causes Identifying Global Forecasting Challenges for ACT

BACKGROUND

Artemisinin-based combination therapy (ACT) is the most effective treatment for uncomplicated malaria. In 2002, WHO revised its malaria treatment guidelines to recommend ACTs over all other therapies. In less than a decade, the scale-up of ACTs has been one of the most important health technologies to see a widespread increase in demand. Overall, the demand for ACTs increased from 2 million treatment courses in 2003 to 200 million by 2010. While in the initial days of ACT scale-up Novartis was the only qualified manufacturer (i.e., with approval of its fixed-dose combination pill by a strict regulatory authority), there are now over 10 WHO prequalified manufacturers of different formulations with an overall capacity of well over 300 million treatment courses.

The active chemical ingredient for ACT is artemisinin, which is extracted from the *Artemisia annua* crop in a complex process that takes approximately 12–18 months from planting to pharmaceutical production of ACTs. In addition, a range of stakeholders are involved throughout the ACT market, including artemisinin growers and extractors, ACT manufacturers and ACT financiers encompassing the Global Fund, the President's Malaria Initiative (PMI), UNITAID, the World Bank, and malaria-endemic country governments.

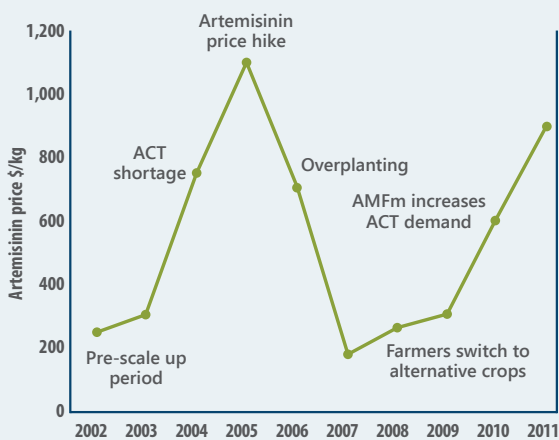
OBSERVING MARKET SHORTCOMINGS

In the ACT market, the most prominent market shortcomings were inconsistent affordability, as reflected in volatile artemisinin prices, and unstable availability, as evidenced by cycles of shortages and surpluses. For both suppliers and financiers, these two aspects of erratic pricing and supply generated serious concerns. Despite the relatively rapid incorporation of ACT into national treatment guidelines, the uneven pace of actual ACT scale-up across countries contributed to significant market volatility as supply and demand struggled to achieve equilibrium. In addition, growers and extractors faced the volatilities inherent in crop farming. ACT suppliers (growers, extractors, and ACT manufacturers) experienced cycles of boom and bust, which threatened the long-term sustainability of the ACT market and, therefore, of this highly effective malaria treatment.

In 2010, the Affordable Medicines Facility-malaria (AMFm) – a malaria medicines subsidy intended to rapidly increase access to low-cost, high-quality ACTs and decrease use of oral artemisinin monotherapies – was introduced in nine geographic pilots.¹⁴ This change produced a sudden spike in ACT procurement by AMFm first-line buyers. However, nearly half of AMFm purchases were for adult formulations, even though mortality rates are highest among children (although volumes later shifted toward more pediatric presentations in 2012 and 2013). Also, irrational use of ACTs was a potential hazard in the private sector where ACTs may have been sold to individuals who did not have malaria, due in part to missing components around diagnosis and appropriate case management. There were also consequences around unforeseen market domination by the private sector in some areas and poorly planned distributions that targeted urbanized areas where, historically, malaria endemicity is low. These factors increased demand, but they also may have aggravated demand spikes and diverted resources from the target segment of rural children most at risk of malaria mortality.

¹⁴ These pilots took place in eight countries, although implementation in Cambodia happened significantly later than in the others. Please refer to the Global Fund Website: www.theglobalfund.org/.

Figure 9: Timeline of Market Events and Volatility in the Price of Artemisinin



DIAGNOSING ROOT CAUSES

Erratic pricing hampered adequate planning in both the short- and long-term. In some instances, this has put the ability to ensure greater access to effective malaria treatment at risk. In response, the underlying causes for the demand and supply mismatches were explored more extensively in 2006. Modeling and analysis of the overall ACT market was carried out to understand the overall epidemiological need, the portion of need with committed funding, and the overall existing market demand. While data on epidemiological need, country treatment guidelines, and current/projected financing for ACTs were not readily or systematically available, the pooling of quantitative and qualitative data from multiple sources enabled the analysis to go forward. The exercise revealed that a key underlying root cause for the shortcomings around affordability and availability was insufficient information on ACT demand.

Important market stakeholders – financiers and suppliers alike – were keenly aware that critical information on ACT consumption by target populations was, and continues to be, weak. Country uptake was uncertain and the lack of high-quality national data on real-time ACT use throughout sub-Saharan Africa hampered the development of robust forecasts and quantifications. Global agencies such as the Global Fund, PMI, WHO-Global Malaria Program, UNITAID, UNICEF, and Roll Back Malaria Partnership (RBM) were relatively better informed than manufacturers on ACT demand, but the poor availability of ACT consumption data significantly hampered demand forecasting efforts.

Nevertheless, PMI always made planned procurements and sales volumes publicly available, such as by posting annual malaria operation plans on the PMI website and sharing volumes procured in the annual reports of PMI's procurement agent John Snow, Inc. (JSI). Starting in 2011, PMI provided 12-to-18-month ACT demand planning schedules to major ACT manufacturers in an attempt to improve visibility into global ACT needs. In addition, the Global Fund's AMFm database shared its planned procurements and purchase volumes. While manufacturers did have less visibility into vital information, such as future funding and ongoing policy changes, this information was often not available to global financiers either. In addition, global financiers often faced budgeting constraints that did not give them the flexibility to plan far in advance, which was particularly important for the ACT industry because of the long lead time required to produce ACTs. Moreover, global agencies might hold information about expected future demand or procurement plans in isolation, and the challenges of information sharing either between these groups or with growers, extractors, or manufacturers intensified the information asymmetry in this market.

Another identified root cause was uneven risk allocation. Artemisinin growers, extractors, and ACT manufacturers bore the brunt of the direct financial risks of inaccurate demand, which resulted in excess inventory or missed investments, especially since suppliers had to plan far in advance. The long duration of the artemisinin production cycle limited their ability to respond to unexpected changes in demand. While major financiers faced limited financial risk from overcapacity or shortages, and therefore may have seemed less incentivized to invest in accurate forecasts, global financiers like PMI were under significant scrutiny to scale up ACT coverage while managing limited financial resources with high accountability since they were responsible for serving as good stewards of taxpayer dollars. At the same time, some global financiers faced delays in making their disbursements, which exacerbated the market volatility by undermining procurement reliability and forced other financiers or donors to compensate.

Several attempts were made to improve the ability to forecast the ACT market needs. WHO-Global Malaria Program and RBM's malaria medicines supply services were involved in generating ACT forecasts from 2004 to 2006. From 2007 onward, CHAI, Boston Consulting Group (BCG), Dalberg Global Development Advisors, McKinsey, and Massachusetts Institute of Technology (MIT)-Zaragoza were involved in developing forecasts, with subsequent support from UNITAID, a long-time supporter of improving visibility in the ACT market to better inform forecasting capacity. While the stakeholders recognized the technical merit of multiple forecasting approaches, they realized that it was important to have a single consensus forecast to build wider acceptability and relevance for decision-making. ACT manufacturers, the Global Fund, RBM, PMI, and other stakeholders strongly articulated the need for a forecast that (a) incorporated multiple forecasting techniques but reconciled the differences and (b) was timely and able to absorb up-to-date information on the ACT market. In response, and especially with the increased demand stemming from the AMFm, the ACT Demand Forecasting Consortium (consisting of BCG, CHAI, and MIT-Zaragoza, inter alia) was formed with funding from UNITAID and others. The consortium produces a consensus forecast for global ACT demand that is widely disseminated by different stakeholders in global markets.¹⁵

From 2009 to 2011, to further facilitate a more stable market, UNITAID developed and funded the Assured Artemisinin Supply Service (A2S2) to provide financing to artemisinin extractors who had contracts with qualified ACT manufacturers as well as collect and disseminate market intelligence to promote greater transparency around the artemisinin market. Additionally, collaborative efforts led by WHO, PMI, UNITAID, Global Fund, and others produced an ACT Task Force in 2011, which monitored ACT levels to identify countries at risk of ACT shortages and increased transparency and opportunities for coordination of orders and deliveries among global donors.¹⁶

▶▶ LESSONS LEARNED

A systematic approach to global ACT forecasting and increased information-sharing contributed to improving global product availability, thereby building confidence and increasing participation of different stakeholders in the market. Major shortages were eliminated and price fluctuations were moderated, relative to the ups and downs observed in the ACT market between 2004 and 2009.

Nevertheless, global ACT forecasting was not able to address all of the factors leading to market instability. While forecasting and coordination addressed issues of some information asymmetries, intrinsic demand uncertainty and supplier risk exposure remained. Furthermore, the accuracy of global forecasts depends on robust national quantification. Obtaining and sharing reliable data across markets and global agencies continues to present a variety of challenges.

▶▶ KEY TAKEAWAYS

- Multiple market shortcomings may stem from the same set of root causes, so it is critical to conduct the analysis to identify the underlying root causes. In the ACT market, insufficient information and uneven risk allocation jointly produced the interconnected shortcomings of volatile affordability (erratic pricing) and availability (shortages and surpluses).
- Coordination among stakeholders is as important in the data gathering and analysis stages of observing shortcomings and diagnosing root causes as it is during implementation. Early collaboration can produce stronger analyses and better decision-making.

15 BCG: Global ACT Market, Demand Forecast, 15th January 2013. Nairobi: A2S2, Artemisinin Conference, 2013. [www.a2s2.org/upload/5.ArtemisininConferences/1.2013Kenya/Presentations/Day1/12.ACTForecastingConsortiumPresentation.pdf].

16 WHO: ACT Supply Taskforce: Report to RBM Board, May 2012. Geneva: World Health Organization; 2012. [www.who.int/hiv/events/malaria_task_force_silvia2.pdf].



▶▶ Step 3. Assess Market Shaping Options

What are the different types of market shaping interventions?

After observing market shortcomings and tracing them to their underlying root causes, the third step of the Market Shaping Pathway is to assess market shaping options. For each market shaping possibility, consider the following when evaluating which type of intervention may be appropriate for a specific market:

- Theory of change – how does the intervention work?
- Benefits?
- Drawbacks?
- Implementation constraints?

These assessment criteria provide a starting point to evaluate whether a market shaping intervention is well-suited for the market at hand. Most importantly, the selected intervention's theory of change should address the root causes identified in Step 2, and Figure 10 presents a non-exhaustive list of market shaping interventions categorized by the primary lever used (or root cause addressed). In addition, the expected benefits for the specific market should clearly outweigh the drawbacks.

As a feasibility check, the implementation constraints point to the required financial investment, time to implement, and political support, and these may limit the available options for a specific market. Different interventions require different levels of data, technical skills, and champions. Non-market prerequisites, like the political environment and the motivations of critical decision-makers, can also be important selection factors. During this step, practitioners should assess the opportunity cost of a market shaping versus a programmatic intervention, or of using market shaping for one product market versus another, especially if similar stakeholders are involved. Even with agreement to explore market shaping for

a specific product, practitioners should build consensus on their objectives in order to more easily weigh benefits and drawbacks and decide on an intervention to pursue.

Often times, a thorough market assessment will uncover multiple shortcomings, many stemming from more than one root cause. In these situations, strategic prioritization is critical when assessing options. One example of this in practice is the prioritization assessment tool utilized by GAVI to analyze objectives, define tradeoffs, and compare alternatives within its Supply and Procurement Roadmaps. The tool prioritizes objectives across the short, medium, and long-term, by assessing the following three elements in terms of the organization's influence and potential impact: (1) balance of supply and demand; (2) cost of vaccine to GAVI and countries; and (3) appropriate and innovative vaccines. In doing so, GAVI is able to calculate a priority index of objectives to guide its strategic planning efforts around market shaping.

As mentioned earlier, the market type or classification can affect which market shaping interventions may be most appropriate. For example, whether buyers are institutional (donors or governments) versus out-of-pocket consumers affects who makes purchase decisions, which stakeholders influence these choices, and how much pricing transparency may exist; whether a product is prescribed or over-the-counter affects the nature of regulatory oversight required; and whether a product is new or long-standing affects the supply base and demand today as well as their expected trajectories.

Some interventions use only one lever while others use a combination. Pooled procurement and strategic demand forecasting, for example, often go hand in hand to both reduce

Figure 10: Market Shaping Interventions Categorized by Root Causes Addressed



transaction costs and increase market information. Some interventions could be considered close cousins with small operational differences rather than clearly defined boundaries. For example, both pooled procurement and coordinated ordering consolidate demand, but the implementation details – which purchase terms are negotiated jointly, which transactions conducted jointly, which budgets combined or which products bundled together – can produce many variations.

To capture current knowledge around these considerations, we present descriptions of common types of interventions that fall under each of these categories and the lever they use to address root causes. These descriptions try to illustrate the range of interventions available rather than serve as a comprehensive list. Implementing any of these requires customization to the relevant market (described in Step 4). The accompanying tables call out the key aspects to consider in assessing an intervention – theory of change, benefits, drawbacks, and implementation constraints – as well as examples that span a range of health sectors and products, such as vaccines, ORS and zinc, ACTs, and family planning products. Understanding these past interventions can be useful in generating ideas for future solutions.



Reduce Transaction Costs

Interventions that aim to reduce transaction costs can address obstacles to operating in a health product market. One hurdle could be the complexity of placing or responding to orders, and interventions that streamline demand can address these, such as by consolidating orders among buyers or product options. Another hurdle can be the cumbersome, ambiguous, and delayed regulatory processes that may discourage manufacturers from attempting the registration process. Thus, regulatory interventions that accelerate or clarify the registration or quality assurance process can lower the hurdles that new supply side actors face when joining the market and existing actors face when investing in higher quality production. Demand can also be streamlined into fewer product variants, which increase manufacturing economies of scale and demand predictability. However, demand consolidation decreases product choice, so the benefits of grouping must be weighed against buyer independence. The following interventions illustrate different approaches to reducing transaction costs in more detail:

Pooled procurement: *Orders from multiple buyers, possibly across a range of products, consolidated by a third party who acts as a procurement agent.* Orders could be pooled among global donors or across countries within a region or of a similar income level. By expanding order sizes and smoothing demand, pooled procurement reduces transaction costs for supply-side actors. This is often accompanied by greater demand visibility, which increases market information. For example, UNICEF negotiates vaccine prices and terms, creates aggregate demand forecasts, and places purchase orders with suppliers on behalf of more than 80 low-income countries for a range of vaccines (thus using both pooled procurement and demand forecasting). This pooling of procurement has resulted in lower vaccine prices, better demand visibility, and more sustainable supply. Nevertheless, UNICEF's pooled procurement process has faced challenges as well. This evaluation and iteration process for pooled procurement is described in the Spotlight on Measuring Results (page 47).

Coordinated ordering: *Prices and sales terms negotiated by a third party on behalf of multiple buyers who purchase individually.* Similar to pooled procurement, coordinated ordering can increase incentives for supply-side actors by lowering transaction costs through streamlined negotiations. Even if procurement is done separately, coordinated ordering can enable staggered orders over time (avoiding a sudden flood of orders) to allow manufacturers to respond efficiently and shorten lead times. In the reproductive health sector, the United Nations Population Fund (UNFPA) AccessRH system is an example of coordinated ordering. Originally developed by the RHSC, AccessRH offers a product catalog for national governments, non-governmental organizations (NGOs), and others that purchase for the public sector. Prices are negotiated upfront by UNFPA, and suppliers must undergo UNFPA's quality assurance process, enabling AccessRH clients to access volume pricing for high quality products.¹⁷

Variant optimization: *Design of guidelines or other arrangements to steer demand toward a specified, optimized set of products.* This approach aggregates demand that is otherwise fragmented across multiple products into small orders, which can discourage new suppliers from entering and hamper existing suppliers from achieving economies of scale. On the procurement side, this could lead to substantial cost-savings, as suggested by analyses on rationalizing LLIN specifications and procuring products based on cost-effectiveness in the

17 AccessRH website: www.myaccessrh.org



Table 1: Intervention Options to Reduce Transaction Costs

Intervention	Theory of Change (How It Works)	Benefits	Drawbacks	Implementation Constraints	Examples
Pooled procurement	<p>Aggregates demand that is otherwise fragmented across multiple buyers</p> <p>Reduces transaction costs by bundling orders into larger sizes and smoothing demand</p> <p>Potentially increases market information with greater demand visibility</p>	<p>Lower and less variable prices</p> <p>Greater forecast accuracy from more predictable demand, enabling suppliers to better plan capacity</p> <p>Enhanced economies of scale through larger order sizes</p>	<p>Hampers differential or tiered pricing</p> <p>Creates monopsony power, possibly reducing individual country ownership</p> <p>Risk of delays from complex coordination</p> <p>Lower prices may cause suppliers to exit</p> <p>Reduces competition due to buyer preference for fewer contracts</p>	<p>Complex coordination of purchase funds, terms and legal processes across multiple buyers and/or products</p> <p>Longer term supplier contracts with flexibility</p>	<p>UNICEF Vaccine Pool</p> <p>Pan American Health Organization Revolving Fund</p>
Coordinated ordering	<p>Multiple buyers individually purchase based on group-negotiated prices and terms</p> <p>Reduces transaction costs by streamlining negotiations</p> <p>Potentially increases market information with greater demand visibility</p>	<p>Lower and less variable prices</p> <p>Greater forecast accuracy from more predictable demand, enabling suppliers to better plan capacity</p> <p>Enhanced economies of scale through larger order sizes</p>	<p>Hampers differential or tiered pricing</p> <p>Creates monopsony power, possibly reducing individual country ownership</p> <p>Risk of delays from complex coordination</p> <p>Lower prices may cause suppliers to exit</p>	<p>Complex coordination of terms, but not purchase funds, across multiple buyers and/or products</p> <p>Longer term supplier contracts with flexibility</p>	<p>UNFPA's AccessRH for reproductive health products</p> <p>Global Fund Voluntary Pooled Procurement in the ARV markets</p>
Variant optimization	<p>Steers demand toward a specified, optimized set of products</p> <p>Reduces transaction costs by streamlining demand into rationalized set of product variants</p>	<p>Lower and less variable prices</p> <p>Greater forecast accuracy from more predictable demand, enabling suppliers to better plan capacity</p> <p>Enhanced economies of scale through larger order sizes</p>	<p>Reduced product choice by countries and programs</p> <p>Risk of reduced product innovation</p>	<p>Detailed product variant analysis, including volume-based cost breakdowns</p> <p>Credible party to set clear guidelines and monitor adherence</p>	<p>Long-lasting insecticide-treated nets size standardization</p> <p>Pediatric ARV formulary</p>
Simplified or harmonized registration system	<p>Lowers administrative burden of registering new products</p> <p>Reduces transaction costs for new suppliers entering low-income markets</p>	<p>Faster in-country access to new products</p> <p>New products and/or suppliers increase competition, enhance stability of supply and possibly lowering prices</p> <p>Increased incentives to invest in product development for low-income markets</p>	<p>Reduced control and independence by individual countries over registration processes</p>	<p>Technical assistance and coordination support</p> <p>Government support and participation</p> <p>Understanding of regulatory processes</p>	<p>Global Medicines Regulatory Harmonization Multi-Donor Trust Fund</p>
Strengthened QA system	<p>Lowers administrative burden of demonstrating product quality</p> <p>Reduces transaction costs for suppliers providing high-quality products</p>	<p>Higher overall product quality in the market</p> <p>Greater incentives for high quality suppliers to operate in low-income markets or existing suppliers to invest in high quality production processes</p>	<p>Potentially higher short-term costs to respond to new system</p> <p>May rely on global mechanisms with uncertain timelines and efficiency</p>	<p>Technical assistance</p> <p>Government support and participation</p> <p>Understanding of regulatory processes</p>	<p>WHO prequalification system</p>

LLIN market.¹⁸ For manufacturers, variant optimization can enable greater economies of scale, increasing supplier incentives. Cost-benefit and consumer behavior analyses should be conducted to both identify products that offer the highest value for money and ensure a sufficiently diverse product range to meet demand.

Simplified or harmonized registration system: *Simplification of the product registration process in one country and/or alignment of registration processes across multiple countries.* Lowering the barriers to entry for new suppliers reduces transaction costs, making low-income markets more attractive to suppliers and enabling products that are more effective, affordable, or otherwise superior to reach more end users sooner. Moreover, it creates incentives for manufacturers to invest in product development for low-income markets. For example, as part of the market launch for ORS and zinc products, in-country registration processes in several countries were streamlined, leading to faster product registrations from new manufacturers.¹⁹

Strengthened quality assurance (QA) system: *Improvements to the global or national system for ensuring product quality.* By lowering the administrative burden, a more efficient QA system can reduce suppliers' costs of producing high quality products and complement the work of national regulatory authorities. Specific activities include streamlining quality documentation requirements, establishing a sampling system to regularly test product quality with clear feedback mechanisms, or standardizing procurement guidelines. Examples include UNITAID and Gates Foundation support to the WHO-PQ system.



Increase Market Information

Information-driven interventions collect, analyze, and share market data to reduce uncertainty, increase transparency (i.e., reduce information asymmetry), align views, and inform decision-making. Producing high quality, robust information can reduce transaction costs

and help coordinate multiple market actors. However, the process can be expensive so it is important to demonstrate clear value and sustainability from a potential information-driven intervention.

Market landscape analysis: *Review of market structure and dissemination of the findings to highlight strengths and challenges facing product uptake.* The analysis may include product features, competitive products, market size, and power distribution between demand and supply actors. The market assessment should also consider likely market and product evolution over time. To vet assumptions, this analysis should draw on information from a range of both market actors (buyers, suppliers, and regulators) and sector experts. It can be complex and expensive to implement this effort sustainably, but the UNITAID market landscape reports, the RHSC RHInterchange, UNICEF's Influencing Markets reports, and ACTwatch²⁰ all provide important market information on an ongoing basis.

Strategic demand forecasting: *Aggregation of data and inputs from the major market players to quantify and disseminate a forecast of funded demand.* This provides market information for all actors and may create incentives for suppliers who have less visibility into demand. By aligning suppliers' understanding of future demand with buyers' best estimates, suppliers can make more informed decisions around buying raw materials, planning for production, investing in future capacity and promoting their products. In the ACT market (Spotlight on page 27), credible global forecasting helped reduce the severity of swings between product excess and shortage. However, global health forecasts have suffered from variable accuracy, so vetting assumptions and calculations is important. The Center for Global Development (CGD) report *A Risky Business* outlines the need for improved demand forecasting in global health and provides a concrete set of recommendations for doing so, including the establishment of a global health infomediary for data collection and sharing.²¹

Pricing information exchange: *Forum for purchasers and suppliers to post sales prices for their transactions, which*

18 Bahl, Kanika, and Shaw, Pooja. "Expanding Access to LLINs: A Global Market Dynamics Approach." Washington, DC: Results for Development (R4D). [r4d.org/sites/resultsfordevelopment.org/files/resources/R4D_LLIN%20report_24Apr_Final.pdf].

19 UN Commission on Life-Saving Commodities for Women and Children: Implementation Plan." Every Woman Every Child, 2012. Web. [www.rhsupplies.org/fileadmin/user_upload/CoLSC/Documents/UN_Commission_Implementation_plan_Sept_2012.pdf].

20 UNITAID landscape reports: www.unitaid.eu/en/resources/publications/technical-reports; RHInterchange website: www.myaccessrh.org/rhi-home; ACTwatch website: www.actwatch.info; UNICEF Influencing Markets Reports website: www.unicef.org/supply/index_54214.html.

21 Sekhri, Levine, Pickett, et. al. *A Risky Business: Saving Money and Improving Global Health Through Better Demand Forecasts*. Center for Global Development Global Health Forecasting Working Group. 2007. [www.cgdev.org/publication/risky-business-saving-money-and-improving-global-health-through-better-demand-forecast-0]



Table 2: Interventions Options to Increase Market Information

Intervention	Theory of Change (How It Works)	Benefits	Drawbacks	Implementation Constraints	Examples
Market landscape analysis	<p>Conducting and disseminating review of market structure that may include product features, competitive products, market size, and power distribution between demand and supply actors</p> <p>Provides market information for all actors</p> <p>May offset supplier risk by providing more market visibility</p>	<p>Reduced uncertainty for all market actors, encouraging more active market participation</p> <p>May reduce transaction costs</p> <p>May facilitate coordination among actors with aligned incentives</p> <p>Potential to attract new suppliers</p>	<p>Can be complex and expensive to implement sustainably</p>	<p>Participation by most buyers and sellers</p> <p>Commitment by third party to maintain information systems and oversee data quality</p>	<p>UNITAID Market Landscape reports</p> <p>RHSC RHInterchange</p> <p>UNICEF Influencing Markets reports</p>
Strategic demand forecasting	<p>Aggregation of data and inputs from the major market players to create and disseminate a forecast of funded demand</p> <p>Provides market information for all actors</p> <p>May offset supplier risk by providing more market visibility</p>	<p>Greater demand transparency, enabling suppliers to shorten lead times and provide more stable availability</p> <p>Increased predictability of funded demand</p> <p>Aligned market size perceptions</p>	<p>Forecasting may not accurately predict actual demand</p>	<p>Information provided by many countries and biggest funders</p> <p>Analytical team with technical skills to create the forecast</p> <p>Commitment by third party to maintain information systems and oversee forecast quality</p>	<p>ACT Demand Forecasting Consortium</p> <p>CHAI ARV forecasting</p> <p>GAVI Secretariat biannual vaccine demand forecasts</p>
Pricing information exchange	<p>Forum for purchasers and suppliers to post sales prices for their transactions, ideally representing the majority of sales</p> <p>Provides market information for all actors</p>	<p>Less variation in prices, enabling small buyers to obtain better prices and reducing corruption</p> <p>Risks of non-transparent procurement become more visible</p> <p>Volume-based and other discounts are more visible to potential buyers</p>	<p>Possible disincentive for suppliers to offer tiered pricing with lower prices for lowest-income markets</p>	<p>Information gathering and participation of most purchasers and suppliers</p> <p>Commitment by third party to maintain information systems and oversee data quality</p> <p>Political support to post public prices</p>	<p>RHSC RH Interchange</p> <p>UNICEF Supply Division vaccine price data and reporting</p> <p>WHO Vaccine Product, Price, Procurement database</p>
Quality assessment	<p>Objective and publicly available assessment of product quality</p> <p>Provides procurers with market information to help them maximize value for money in their purchases</p>	<p>Procurers can better select the most appropriate product for their needs and budget</p> <p>Transparency can create positive competitive pressure to increase product quality</p>	<p>May be costly to conduct quality tests on a regular basis</p>	<p>Technical capacity to conduct quality tests</p> <p>Commitment by third party to maintain information systems and oversee data quality</p> <p>Political support to post prices publicly</p>	<p>Malaria RDT Product Testing Reports²²</p>

22 *Malaria RDT Product Testing Report: Round 1*. World Health Organization, Foundation for Innovative New Diagnostics. 2008. [www.finddiagnostics.org/export/sites/default/resource-centre/reports_brochures/docs/Full-report-malaria-RDTs.pdf]; *Malaria RDT Product Testing Report: Round 4*. World Health Organization, Foundation for Innovative New Diagnostics. 2012. [www.finddiagnostics.org/export/sites/default/resource-centre/reports_brochures/docs/RDTMalariaRd4_Web3.pdf].

helps reduce price variations and prevent corruption. Typically hosted online and ideally representing the majority of sales, the sharing of market information on purchase prices can highlight variations across different buyers (both donors and national governments), suppliers, and sales volumes (if volumes are captured). This record of sales over time can be analyzed for trends in demand, availability, and the supply base, among other factors. Since price transparency provides information to all actors, however, it may also provide a disincentive for suppliers to offer tiered pricing with lower prices for the lowest-income markets. Pricing information exchanges include the Global Fund Price and Quality Reporting (PQR) tool, the RHSC RHInterchange and UNICEF's practice of posting commodity and vaccine price data online.²³

Quality assessment: *Standardized and publicly available assessments of product quality can help procurers evaluate manufacturers and product variants.* A respected third party can provide standardized assessments on different dimensions across multiple products. This information can aid donors and national governments in making purchase decisions that maximize value for money by better matching needs and budgets. For example, the Malaria Rapid Diagnostic Test (RDT) Product Testing Reports (an evaluation program funded by WHO and the Foundation for Innovative New Diagnostics through a UNITAID grant) score malaria RDTs from a variety of manufacturers and publicize the results. Within 4 years of conducting and publicizing these quality assessments, lab tests performed by the U.S. Centers for Disease Control and Prevention showed the proportion of RDTs consistently detecting high densities of *p. falciparum* malaria rose from 73 percent in 2008 to 93 percent in 2012.



Balance Supplier and Buyer Risks

Risk sharing interventions redistribute risks between suppliers and buyers. For example, when buyers commit to minimum purchase quantities and prices in advance, existing suppliers can more confidently invest in production, and new suppliers are encouraged to enter the market. In return, buyers receive the assurance that there will be enough supply to meet demand.

Another aspect of balancing risks may involve donors or national governments investing in time-limited efforts to generate demand for a new class of products, such as by sponsoring supplier promotion efforts, offering a channel subsidy or facilitating the process for a product to be included in the national essential medicines list (EML). In this case, suppliers still bear the risk of promoting their specific brand or product variant, but the risk around the entire product category's success is shared more with donors or national governments.

To create agreements that maximize health benefits and avoid unintended consequences (such as discouraging other suppliers or setting a future price too high), it is critical to understand demand trajectories, scale-up challenges, and the cost structure of supply. Prominent examples of risk sharing interventions are described below, but additional variations include volume-based pricing, cost sharing, rebates, and performance-based incentives.

Advance Market Commitment (AMC): *Explicit agreement by buyers to guarantee a market for new products that meet a target product profile (TPP) at an agreed-upon price.* An AMC encourages either R&D of a product in clinical development or more predictable supply of a new product by aligning the actions of developers and potential suppliers with the interests of donors or other buyers. An AMC steers supply-side funds toward the development or production of commodities that meet requirements for low-income markets and demand-side funds toward creating awareness and interest in the upcoming product. A critical component of an AMC design is conducting the necessary analyses to identify an appropriate price that motivates suppliers without imposing undue risk on donors or other buyers. In 2007, multiple donors committed \$1.5 billion to launch an AMC for the pneumococcal vaccine (see Spotlight, page 43).²⁴

Volume guarantee: *Explicit agreement by buyers to purchase a minimum quantity of an existing product, typically matched with a long-term supply contract that sets the price for multiple years.* By offsetting some supplier risk with a purchase agreement, buyers can negotiate lower prices and better terms, and they more confidently invest in stimulating demand. Since this approach requires buyers to "pick winners" by signing contracts with specific suppliers, buyers should be

23 PQR: www.theglobalfund.org/en/procurement/pqr; RHInterchange website: www.myaccessrh.org/rhi-home; UNICEF vaccine price data: www.unicef.org/supply/index_57476.html.

24 GAVI Alliance timeline: <http://www.gavialliance.org/funding/pneumococcal-amc/timeline/>

way of dampening incentives for other suppliers to enter the market. The terms of a volume guarantee should be tailored to the needs of the specific market, from agreement duration to the number of suppliers engaged to the proportion of the market volume guaranteed. Recent volume guarantees for contraceptive implants cut prices for low-income countries in half and helped increase uptake.²⁵

Promotion incentives: *Below-market financing, subsidized marketing activities, or other motivations to increase product promotion efforts among distributors and retailers.* By absorbing some of the product promotion or inventory costs or by supplementing these activities with broad (and unbranded) demand generation campaigns, this intervention reduces the individual risk suppliers face in marketing their products and develops long-term demand for the product category. Often designed as a time-limited activity for a nascent or underutilized market, promotion incentives are designed to help the supply channel “push” the product into the market and increase consumer uptake. For example, subsidized credit to wholesalers for a limited period encourages product stocking and promotion – one aspect of the broader POUZN program that USAID conducted through Abt Associates to promote uptake of ORS and zinc (see Spotlight, page 38). The major challenge is that if the product is not well positioned and/or if the launch is not executed well, any increase in adoption will be short-lived, and usage will drop once the intervention ends.

Channel subsidy: *Reduction in the price of the product to consumers by injecting a price subsidy in the distribution channel.* This is designed to increase affordability and create awareness and long-term adoption of a product. A channel subsidy can be paired with a promotion campaign to help displace a more established but less effective product. The subsidy acts as a direct incentive to suppliers to stock and promote the product and is most relevant in markets with significant care-seeking through the private sector. However, there is the possibility that instead of lowering consumer prices, top-level subsidies to manufacturers could instead lead to higher mark-ups or overuse. The AMFm for antimalarials is an example of channel subsidy.

EML and guidelines inclusion: *Addition of a product to the EML and WHO or national treatment guidelines to increase public sector demand.* These important endorsements are critical to incorporating a product into routine service delivery in public facilities, which leads to increased product demand. In addition, trainings, organizational incentives, and other supporting steps for healthcare providers draw on the EML and treatment guidelines and thereby reinforce product use. Although planning for EML and guidelines inclusion should be a part of regular product introduction planning, the simultaneous effort in multiple countries to add an improved formulation or optimized product can quickly and steeply increase demand, lowering supplier risks and encouraging their participation.

Prize: *Competitive crowdsourcing of innovative solutions to global health problems that matches new ideas with technical support and capital.* By connecting promising ideas to tools that support their advancement, these “pull” interventions are utilized by donors and foundations, multinational corporations and start-ups to reduce the financial and execution risk of bringing a new product to the market. The streamlined process can also reduce transaction costs for innovators to enter a new sector. The Saving Lives at Birth Grand Challenge is an example of a prize mechanism in global health. Supported by the Governments of Canada, Norway, and the United Kingdom and by USAID and the Gates Foundation, the initiative has seeded over \$30 million in funding to nearly 60 innovators since launching in 2011.

Product Development Partnership (PDP): *Support for the development of a new product or solution by providing financial support and risk sharing for R&D to organizations with critical technical expertise.* The traditional PDP model is a partnership between one or more public sector funders and one or more private sector partners that provides the technical expertise for R&D. As a push incentive for R&D, PDPs offer two advantages: (i) reduced R&D risk by spreading it across a portfolio of products and between partners and (ii) subsidies or cost-sharing that reduce the R&D cost borne by any single organization. PDPs tend to focus on a particular therapeutic area, although there are exceptions. The PDP model has proven effective in developing a number of novel drugs and diagnostics for global health, such as a new vaccine for meningitis A and a combination therapy for late-stage sleeping sickness.²⁶

25 More information on the volume guarantees for implants is provided in the “Market Shaping for Family Planning” report cited earlier.

26 The Meningitis Vaccine Project is a PDP that facilitated the development of MenAfriVac, the meningitis A vaccine; Drugs for Neglected Diseases Initiative (www.dndi.org) is a PDP that facilitated the development of nifurtimox-eflornithine combination therapy for human African trypanosomiasis or sleeping sickness.



Table 3: Intervention Options to Balance Supplier and Buyer Risks

Intervention	Theory of Change (How It Works)	Benefits	Drawbacks	Implementation Constraints	Examples
Advance market commitment	<p>Agreement by buyers to guarantee a market for new products that match a TPP at an agreed-upon price</p> <p>Offsets some supply risk, especially for products with uncertain demand</p>	<p>Accelerates development of a better adapted or otherwise superior product</p> <p>Increases production for low-income markets, increasing availability</p> <p>Potential to attract new suppliers</p> <p>Creates incentives for buyers to stimulate and grow demand</p>	<p>Predicted demand may not materialize</p> <p>Locking in prices may result in too high or too low a price being paid</p> <p>Concern around setting precedent for new global health products</p>	<p>Willingness of global donors or other buyers to assume risks of uncertain demand</p> <p>Sophisticated design of TPP, appropriate price, duration and contract structure</p> <p>Likely more suited for products in early-stage development with intensive, upfront investment</p>	Pneumococcal vaccine
Volume guarantee	<p>Purchase commitment of minimum volumes for existing products matches a TPP</p> <p>Offsets some supply risk, especially for products with uncertain demand</p>	<p>Lower prices</p> <p>More stable and visible demand, enabling better production planning and more stable availability</p> <p>Signal of long-term viability may attract new suppliers</p> <p>Creates incentives for buyers to stimulate and grow demand</p>	<p>Predicted demand may not materialize</p> <p>Locking in prices may result in too high or too low a price being paid</p> <p>May discourage new suppliers from entering the market</p> <p>May lower incentives for innovation in product design</p>	<p>Willingness of donor, buyer or coalition to provide funding that guarantees purchase volumes</p> <p>Scale up activities (possibly separately funded) to meet demand targets</p>	<p>Jadelle and Implanon implants</p> <p>UNICEF's Long Term Arrangements for the rotavirus vaccine</p>
Promotion incentives	<p>Time-limited launch increases product awareness among distributors, retailers and consumers</p> <p>Offsets risks for suppliers to stock and promote the product</p>	<p>Greater user awareness of product benefits</p> <p>Increased availability at service delivery points</p>	<p>Distributors may only stock and promote the product until the intervention ends, so the health benefits would not be sustainable</p>	<p>Deep understanding of product positioning with consumers and channel actors</p> <p>Insight into motivations and activities of supply chain actors</p>	ORS/Zinc POUZN program
Channel subsidy	<p>Price reduction for consumers by injecting a price subsidy in the channel, potentially paired with a promotion campaign</p> <p>Offsets risks for suppliers to stock and promote the product</p>	<p>Increased availability at service delivery points</p> <p>Increased awareness of product benefits</p> <p>Direct incorporation of other benefits (e.g., population-level gains of reduced transmission) into end user prices</p>	<p>Top-level supply subsidy may not lead to lower end user prices</p> <p>Lower prices may lead to overuse</p>	<p>Insight into costs, motivations and activities of supply actors</p> <p>Understanding of the end user</p>	AMFm

continued from previous page

Intervention	Theory of Change (How it works)	Benefits	Drawbacks	Implementation Constraints	Examples
EML and guidelines inclusion	<p>Ensures a product is included on the WHO or national EMLs and/or guidelines to incorporate into routine service delivery</p> <p>Offsets risks for suppliers by increasing demand from public facilities</p>	<p>Greater product awareness among healthcare providers by influencing official trainings and job aids</p> <p>Potential increase in product awareness and demand by private providers</p>	<p>Process can be slow, resource-intensive and nontransparent</p>	<p>Champion to garner support among decision-makers</p> <p>Government support and participation</p> <p>Understanding of policy-making processes</p>	<p>PMTCT and pediatric ARV formulations changes</p>
Prize	<p>Allocates capital and technical assistance to support new product innovation</p> <p>Offsets risks associated with new product development</p>	<p>Connects donors to new innovations by crowdsourcing solutions</p> <p>Aggregates resources and coordinate efforts</p> <p>Accelerates development of a better adapted or otherwise superior product</p>	<p>Difficulty in determining an appropriate prize amount to properly incentivize innovation</p>	<p>Likely more suited for products in early-stage development with intensive, upfront investment</p>	<p>Saving Lives at Birth Grand Challenge</p> <p>Gates Foundation Grand Challenges Explorations</p>
PDP	<p>Shares the risks and costs associated with R&D, incentivizing private companies to engage in the global health space</p> <p>Offsets risks associated with new product development</p>	<p>Aggregates resources and coordinates efforts</p> <p>Sharing of costs and risks between partners provides an incentive for private sector investment in global health R&D</p>	<p>R&D funders bear a disproportionate amount of risk (i.e., funders pay for inputs without guarantee of a successful product)</p>	<p>Establishment of a new legal entity with funders and public and private partners willing to take on risk</p> <p>Likely more suited for products in early-stage development with intensive, upfront investment</p>	<p>Meningitis Vaccine Project</p> <p>Drugs for Neglected Diseases Initiative</p>



SPOTLIGHT on Assessing Market Shaping Options

Mapping Market Shaping Possibilities for ORS and Zinc

BACKGROUND

Despite reductions in overall mortality, diarrheal disease remains the second leading cause of global death among children under-5 in the post-neonatal period. The WHO-recommended treatment for diarrhea is a combination of oral rehydration salts (ORS) and zinc, two products that are both effective and affordable. Taken together, ORS and zinc is a cost-effective course of treatment capable of preventing more than 90 percent of under-5 fatalities.²⁷ Yet, only a fraction of the children who need this treatment are receiving it.

In the case of ORS, a product socially marketed for decades, availability has not necessarily translated into utilization. Perceptions of limited efficacy and misinformation have led to the use of suboptimal products like antibiotics and antimotilities, and partial or incorrect product administration has further narrowed the treatment's effectiveness. Some markets, such as Bangladesh, have succeeded in achieving high coverage and utilization rates, but other developing nations continue to struggle.

The private sector plays a uniquely important role in the delivery of ORS and zinc. Typically, for diarrhea treatment, between 50 percent and 80 percent of consumers will go through private channels to obtain treatment. In this case, interventions targeting local market shaping efforts by stimulating demand for ORS and zinc have shown promise. The Social Marketing Plus for Diarrheal Disease Control: Point-of-Use Water Disinfection and Zinc Treatment (POUZN) Project was a 5-year project funded by USAID that was designed to expand access to and use of point-of-use (POU) water disinfection and zinc products for the prevention and treatment of diarrhea. The goal of the POUZN program was to expand the use of water disinfection and zinc products for the prevention and treatment of diarrhea through private sector channels. Population Services International (PSI) and Abt Associates implemented the project with the provision of household water treatment and ORS combined with zinc in the following nine countries: Angola, Benin, Democratic Republic of the Congo (DRC), Haiti, Kenya, Madagascar, Malawi, Nepal, and Rwanda. Through POUZN, USAID also contracted with the Academy for Educational Development (AED, now part of FHI360) to introduce ORS combined with zinc in India, Tanzania, and Indonesia.

ASSESSING MARKET SHAPING OPTIONS

The inefficiencies of the ORS and zinc market have been described as an example of a life-saving treatment stuck in an “uptake trap,” wherein a combination of demand- and supply-side inefficiencies work in a mutually reinforcing manner to stifle market growth. Demand-side factors such as poor awareness, improper use, and lack of perceived effectiveness combine with supply-side factors such as poor availability, inadequate distribution incentives, and higher prices to create a self-perpetuating cycle of challenges.

Considering the multi-dimensional nature of the “uptake trap” facing the ORS and zinc market, POUZN considered a number of interventions to help kick-start the market. A sample list of ORS and zinc market shortcomings and underlying root causes include:

- Availability: low channel margins, which led to low manufacturer and channel push or promotion efforts (risk imbalances)

²⁷ Every Woman Every Child website: www.everywomaneverychild.org.

- Awareness: low perceived efficacy of ORS and zinc for end users; insufficient incentive for suppliers to individually invest in demand generation (limited information)

The POUZN project ultimately applied both social marketing and commercial approaches to increase access to diarrhea prevention (low-cost water disinfection solutions) and treatment products (ORS and zinc) for caregivers of children under 5. In countries without local pharmaceutical manufacturing capacity, POUZN employed a social marketing approach, importing both ORS and zinc products from suppliers in India and France; repackaging the products into a diarrhea treatment kit; and supporting demand generation through interpersonal and mass media channels.

However, in countries with a robust local manufacturing base such as India, Indonesia, Nepal, Pakistan, and Tanzania, POUZN employed market shaping interventions to encourage local pharmaceutical companies to manufacture and market the zinc supplement themselves. To catalyze private sector participation, POUZN staff made the business case to firms; provided wholesaler credit; partnered with the public sector on development of training materials; provided companies with cost-sharing marketing grants to educate retailers, pharmacists, and clinical providers; and financed media campaigns to generate consumer and provider demand. In doing so, the project was designed to leverage a time-limited injection of capital to build up sufficient customer awareness that would ultimately allow the private sector to generate profits on its own.

▶▶ LESSONS LEARNED

In assessing potential interventions, POUZN understood that utilization bottlenecks, consumer preferences and private sector activity were unique to each market. A country with a vibrant commercial market will likely require an entirely different approach than one dominated by public sector programs – even when dealing with the same product.

Recognizing that scale-up of ORS and zinc required a localized, multifaceted solution, the POUZN India project approached the problem holistically, finding ways to partner with the private sector to jointly sponsor initiatives to market zinc nationwide through the firms' own supply chains and sales forces. Companies, often in partnership with USAID, invested in detailing, promotional materials, training, market research and public relations. At the same time, local NGOs trained by POUZN in Uttar Pradesh supported these efforts in rural markets by accelerating uptake of ORS and zinc in geographies outside the coverage area served by the pharmaceutical firms' marketing activities.

▶▶ KEY TAKEAWAYS

- The POUZN project assessed the dynamics of each market and tailored its solution accordingly. A combination of traditional programmatic activities and private sector-focused market shaping interventions were designed to simultaneously disrupt the cycle of limited demand and supply.
- Multiple market shortcomings were addressed through a number of initiatives aimed at breaking the low uptake trap for ORS and zinc.



▶▶ Step 4. Implement Customized Intervention

How do we tailor an intervention to a specific market?

While the implementation step of the Market Shaping Pathway is arguably the most critical, providing specific guidance for this phase is also the most difficult. With differing product markets, geographies, stakeholders, processes, and end objectives, the defining characteristics of proper execution can only be addressed on an individual basis. Nevertheless, an examination of historical examples in market shaping can help to ensure crucial questions are asked and overarching principles are recognized. A few of the many pressing questions in this implementation step are included below:

- Who should be engaged and how?
- What tradeoffs will be required?
- How to minimize unintended consequences?
- How to ensure the results are ongoing and sustainable?

Implementation can be guided by common general principles, outlined below, on how to start addressing these questions for a specific market. The Spotlight on the AMC case study and the other examples mentioned throughout illustrate how market shaping interventions have been tailored to specific conditions in the past.

Collaborate from the start – By operating at the level of the entire market, successful interventions typically require active partnership and coordination from multiple stakeholders and experts. This underscores the importance of a consultative process and of building broad support early on. Donors, implementing partners, strategic advisory groups, suppliers (including manufacturers, distributors, and retailers), country policymakers and end user advocacy groups can all play an important role in informing the design and execution of market shaping activities. These diverse viewpoints can pro-

vide critical information to customize the intervention to the specific product market and build political support.

Multi-stakeholder coordination has been foundational to most, if not all, of the interventions examined here, but its relevance is particularly evident in addressing HIV and AIDS. As discussed in the Introduction, the U.S. Government, as the largest financier of HIV and AIDS interventions in the world, has taken a leadership role in shaping the global market for ARVs and diagnostics. By combining the technical and financial resources of the U.S. Department of State, USAID, the U.S. Department of Health and Human Services (HHS), external bodies such as the Global Fund, and others, the United States has helped facilitate significant reductions in the annual cost of diagnosing and treating patients while ensuring that the quality of purchased generic ARV drugs meet the standards of the FDA. By procuring generic ARV drugs that have been tentatively approved by the FDA, PEPFAR has saved hundreds of millions of dollars over the lifetime of the initiative.

The UNITAID stakeholder engagement process serves as another instructive example of how a collaborative process can work in practice. The process starts by analyzing the market in a landscape report that covers market shortcomings and their root causes. This report forms the basis of a forum for all major stakeholders to provide input on the report's findings and to offer ideas on potential interventions. Building on these insightful conversations, the strategy evolves as UNITAID continues to examine the utility and feasibility of the identified interventions.

The GAVI Alliance Supply and Procurement Roadmap process is a third example of collaboration in action. Led by the

GAVI Secretariat Market Shaping team, the process closely engages the Gates Foundation Market Innovations team and the UNICEF Supply Division as equal owners of the resulting roadmap’s target outcomes and action plans. The development process also includes consultation with WHO and other GAVI Alliance members with product, disease or market expertise connected to a specific roadmap issue. Through this consultative process, the GAVI Alliance seeks to both improve the accuracy of information and strengthen its long-term approach to shaping each vaccine market.

Know the tradeoffs – To create a healthier market that better addresses health needs, practitioners may need to make tradeoffs between multiple, desired market characteristics. A push for lower prices to increase affordability, for example, could lead to higher product uptake and better health outcomes. However, a narrow focus on reducing prices might shrink the supply base and reduce availability if suppliers exit as their margins drop – potentially leading to global shortages or reduced competition. Moreover, remaining suppliers may not see enough incentive to invest in more suitable formulations. Consequently, a healthy market may not offer the lowest prices at a given time but may instead offer the lowest sustainable prices when a stable supply base and continued innovation are taken into account. See the Spotlight on the pooled procurement of vaccines (page 49), which highlights this type of tradeoff.

Similarly, a push for higher quality standards can incur tradeoffs by delaying the time to market or by limiting the supplier base. To ensure only high quality products reach end users, purchasers such as donors or national governments may insist on stringent regulatory approvals (SRAs), proof of good manufacturing practices (GMP), or other strict requirements for product quality. However, this documentation requirement for product dossiers and other safety evidence can be resource-intensive. As a result, suppliers with high-quality products may be unwilling to undergo lengthy registration processes for low-income markets.

There may even be tensions between the various principles outlined here for Step 4, and practitioners need to balance competing goals according to the individual features of the focus market. For example, seeking agreement is an important aspect of collaborating, and this political support may be crucial to an intervention’s success. But the time required for all parties to align can delay the implementation process,

Principles for Market Shaping Implementation:

- Collaborate from the start
- Know the tradeoffs
- Watch for unintended consequences
- Plan an exit
- Act soon and adapt

making the intervention’s design outdated. As mentioned previously, early agreement among key stakeholders on the most important objectives can help guide decision-making throughout the Market Shaping Pathway in making these tradeoffs, whether they arise in evaluating market shortcomings, selecting an intervention or customizing an intervention for implementation.

Watch for unintended consequences – When influencing the complex systems of markets, market shaping practitioners need to model different scenarios of long-term results and closely examine these for unintended consequences. It is important to ensure transparency in how goals are defined, what data are used and, ultimately, how decisions are made. Analysts should consider likely changes in all of the “5As” of market characteristics as well as competitive product development and service delivery trends.

Since market shaping can have ripple effects on secondary and tertiary market actors – including new suppliers or buyers who are not currently in the market – strategic scenario planning can help practitioners plan for and mitigate the risk of unintended consequences. For example, market shaping interventions that engage current suppliers in long-term contracts such as volume guarantees or advance market commitments may inadvertently discourage new suppliers from entering the market who may view a lower profit opportunity with the new set of market dynamics. By mapping potential scenarios during the intervention design, practitioners can be on guard for such consequences and proactively mitigate these risks.




Plan an exit – Many market shaping interventions are intended to operate in a time-limited fashion but still generate ongoing results and impact. To do so, practitioners must

build an exit plan into the intervention’s design that ensures long-term sustainability of health benefits. This may require the upfront establishment of a system that preserves the more efficient processing of transactions, produces consistently updated market information, and/or safeguards risk rebalancing. For example, pooled procurement may require an initial agreement among participating countries, but it is continued afterwards by integrating the practice into regular procurement practices and systems. Similarly, an information pricing exchange requires a secretariat or focal point to continue

updating sales information and ensuring high data quality. If ongoing funding is required to sustain the new market dynamics after a market shaping intervention, practitioners should gain agreement on how these resources will be allocated in annual budgets of the appropriate procurers, donors, or other stakeholders.

Act soon and adapt – Markets are constantly changing with market actors reconfiguring and reshaping market dynamics in unpredictable ways. The sooner an intervention can

Figure 11. Implementing Customized Interventions: Examples from the Spotlights*

	Market Shortcomings	Root Causes	Interventions
ACTs	 	 	<p>Consolidation and publicizing of a consensus demand forecast for ACTs to stabilize demand projections, prices, and production</p>
ORS & Zinc	 	 	<p>Public- and NGO-driven market development through social marketing in areas with limited commercial solutions</p> <p>Promotion incentives: co-financing and/or co-promotion resources that helped fast track the entrance of new products</p>
Pneumococcal Vaccine	 	 	<p>Establishment of an AMC to increase predictability of pricing and demand for manufacturers</p>
Vaccines Pool	 	 	<p>Responsible pooled procurement practices (including using “healthy market” indicators)</p>

* As noted earlier, each Spotlight is designed to focus on a particular component of the Market Shaping Pathway. Thus, this figure highlights the relevant market shortcomings, root causes and interventions for that component and is not intended to capture other aspects of the market.

be implemented after analysis, the more likely it will still be appropriate for that market. At the same time, market shaping practitioners should recognize that the original design of an intervention should be continuously monitored and modified to respond to new market conditions. Stakeholders should view the intervention as an iterative effort to be refined throughout its implementation rather than as a static solution. The speed with which an intervention can be executed after design and its flexibility to adjust to market changes are important elements of implementation.

Figure 11 revisits the market shortcomings and root causes found in the case studies and provides a summary of the market shaping interventions used. Since these case studies were selected for their market shaping relevance, almost all of the root causes are addressed by the respective intervention, which will not always be the case. The Market Shaping Pathway is designed to help uncover root causes and provide guidance on whether these are better addressed through programmatic activities, market shaping interventions, or a combination of both.



SPOTLIGHT on Implementing a Customized Intervention

Launching an Advance Market Commitment (AMC)²⁸

BACKGROUND

Pneumococcal disease, a major cause of pneumonia and meningitis, kills an estimated 500,000 children under 5 every year.²⁹ While an adult vaccination has existed for decades, it was not until 2000/2001 that a pneumococcus vaccine for infants became available in the United States and Europe. The vaccine, manufactured by Wyeth (now Pfizer), was effective against seven strains of pneumococcus, but these did not include the most common strains in Africa and Southeast Asia. Both Wyeth and GSK were conducting R&D on a new pneumococcal conjugate vaccine (PCV) that would protect against more strains; however, it was unclear whether either company would expand their manufacturing capacity enough to supply developing countries. Even if GSK or Wyeth did expand their manufacturing capacity, there was a concern that introduction in developing countries would be significantly delayed.

Given the anticipated high cost and limited profit opportunity of the vaccine in developing countries, the market shortcomings of limited affordability and availability emerged. Upon further analysis, the following root causes were identified:

- **Insufficient Market Information:** There were high levels of uncertainty around the timing of country adoption for a pneumococcal vaccine and, therefore, around the pace and volumes of demand scale-up. While forecasts existed, given the slow introduction of health products in the past, vaccine manufacturers were reluctant to invest upfront in production capacity.

²⁸ This section draws from: Chau, Hausmann, et. al. The Advance Market Commitment For Pneumococcal Vaccines: Process And Design Evaluation. GAVI, 2013.; Sharma, Towse. New Drugs to Tackle Antimicrobial Resistance. Office of Health Economics, 2010; Towse, Keuffel, et al., Drugs and Vaccines for the Developing World. Office of Health Economics, 2011.

²⁹ GAVI website: www.gavialliance.org/support/nvs/pneumococcal/

- **Imbalanced Risk Allocation between Suppliers and Buyers:** The risk of excess supply if demand did not materialize was borne entirely by suppliers because major vaccine buyers like UNICEF's Supply Division did not offer guarantees of future orders. This was especially important because manufacturers would need to incur significant costs in advance in order to expand production capacity.

In the early 2000s, the idea of an Advance Market Commitment (AMC) was gaining traction among policymakers as a means of incentivizing private sector R&D of novel global health products. An AMC is an explicit agreement by buyers (public or private) to guarantee a market for products that meet a target product profile (TPP) at an agreed-upon price. It has two primary goals: (1) to incentivize R&D for drugs and vaccines that primarily serve developing countries where the profit motive is weak and (2) to incentivize production and provision of these drugs and vaccines to poor countries. AMCs operate by increasing the size and certainty of a market, thereby decreasing the risk manufacturers face when investing in less lucrative markets where it is more difficult to recoup their investment.

The AMC must be large enough to ensure that companies earn reasonable returns, but it is important to strike the right price: a price set too high overpays manufacturers, while a price set too low may not provide enough incentive for manufacturers to engage. Suppliers are only rewarded through an AMC if they succeed in developing a product and if there is country-level demand, so they still bear the technical and demand risks.

IMPLEMENTING A CUSTOMIZED INTERVENTION

Although first put forward in 2000, the AMC concept did not gain traction until 2005 when it was endorsed by then UK Chancellor of the Exchequer, Gordon Brown, and later the G8 under leadership from Italian Finance Minister Giulio Tremonti. This high-level political endorsement, with clear project champions, was instrumental in generating momentum for a pilot AMC. Around the same time, the Center for Global Development (CGD) convened a working group of public health experts, policy makers, and economists to further develop the concept. Their 2005 report *Making Markets for Vaccines* provided a blueprint for creating an AMC, and was instrumental in informing the design of the eventual Pneumococcal AMC.³⁰ This report not only helped make a compelling case for AMCs, but also outlined the steps and processes for developing a pilot.

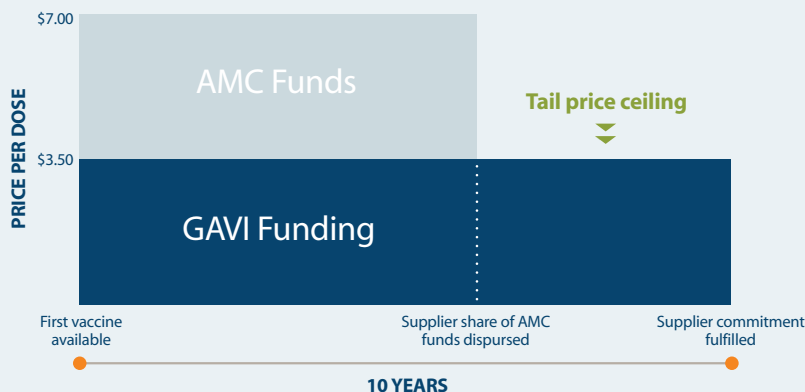
The design process was complex and lengthy, as it required new funding mechanisms, procurement processes, and legal structures. Since so many aspects of the AMC were created from scratch, an important design element for smoother rollout was engaging a diverse set of stakeholders and relying heavily on existing organizations and structures. For example, GAVI was chosen to house the AMC Secretariat and administrative functions, the UNICEF Supply Division to manage PCV procurement, and the World Bank to hold annual donor payments in a trust fund for GAVI.

The general AMC structure includes three components: (1) pre-determined product price topped up with a subsidy; (2) the subsidy that helps manufacturers recoup their capital investment; and (3) a tail price ceiling that covers the marginal cost of production after the subsidy is depleted (see Figure 12). For the Pneumococcal AMC, the pre-determined price with subsidy was set at \$7.00 per dose of PCV, and the AMC pledged to purchase and distribute 2 billion doses.

To fund the subsidy, the Governments of Canada, Italy, Norway, Russia, and the United Kingdom and the Gates Foundation pledged a total of \$1.5 billion. The subsidy is used to top up the tail price to reach the predetermined price of \$7.00 per dose. Each manufacturer receives a portion of the subsidy based on the fraction of the total 2 billion doses that manufacturer supplies. If the manufacturer agrees to the maximum \$3.50 tail price, the top-up is \$3.50 per dose. If the manufacturer agrees to a lower tail price of \$3.30, for example, the top-up is increased to \$3.70

³⁰ This report is available here: <http://international.cgdev.org/doc/books/vaccine/MakingMarkets-complete.pdf>

Figure 12. AMC Pricing Structure



per dose. The top-up is provided until the manufacturer's share of the AMC funds has been disbursed (based on volume supplied); afterwards, the remaining doses are purchased at the tail price for the remainder of the 10 years. The subsidy will end when each participating manufacturer has depleted its share of the subsidy funds.³¹

The third AMC component, or the tail price ceiling, is the highest price paid by GAVI and countries after the subsidy funds are

depleted. This was set at \$3.50 per dose. Thus, manufacturers enter into an agreement to supply a specified volume of PCV annually, over 10 years, at a pre-agreed tail price that cannot exceed \$3.50 per dose. Figure 12 shows the Pneumococcal AMC pricing structure.

To date, two manufacturers have qualified for AMC funding: GSK for its 10-valent vaccine and Wyeth/Pfizer for its 13-valent vaccine. Between 2010 and 2012, more than 100 million doses of these vaccines were procured and delivered under the AMC. Estimates project a total of 57 countries will have introduced PCV with GAVI support by 2015, compared to the initial GAVI target of 45 by that year. Importantly for assessing global health impact, PCV uptake is occurring at a faster rate than that of comparable vaccines, such as the pentavalent vaccine and the rotavirus vaccine.

Customizing the AMC to the PCV market required tradeoffs, and an important decision was choosing a “multiple-winner” structure over a “winner-takes-all” structure. This choice avoided deterring manufacturers from continuing to invest in R&D if they knew that another manufacturer was closer to product registration. In addition, a multiple winner AMC encourages more than one supplier to participate and thus provides countries with a choice of vaccines. Even within this structure, however, an unforeseen global preference for the Pfizer vaccine resulted in the undersupply of the Pfizer vaccine and delayed introduction in certain countries, despite the availability of the GSK vaccine in 2012.³² Supply challenges can also be a problem. For example, GSK manufacturing issues the following year led to supply shortages and delayed introduction in two GAVI countries.

With a multiple-winner AMC, the size of an individual incentive is lower because the reward is shared among multiple manufacturers. To date, a third PCV manufacturer has yet to enter the market although at least two additional manufacturers have registered to supply their vaccine under the AMC. Indeed, some PCV manufacturers stated that they did not factor the AMC into their business plan because they believed the funds would be exhausted before their vaccine was available. These manufacturers have yet to produce a PCV candidate, suggesting that they may also have encountered other obstacles, such as a lack of funding or R&D challenges, which could also have limited their participation in the AMC.

Another design decision was evaluating how much risk each market actor would bear. The Pneumococcal AMC sets procurement based on time-limited purchase contracts that are conditional on country demand and do not guarantee manufacturers a share of the global market (unlike more stable purchase agreements). As a result, the

31 Note that the rate at which the subsidy is disbursed varies because it is spread out over time and contracts. For example, the subsidy is only applicable to the first 21 percent at most of doses (based on strategic demand forecasts) for each AMC contract. If, however, the tail price is lower than \$3.50, the per dose subsidy will be higher and, therefore, may not apply to the full 21 percent of doses.

32 For GAVI countries the preference has been evenly split between the two vaccines.

manufacturers bear almost all of the demand risk. Since vaccine manufacturing requires high upfront costs, the AMC designers offset some of this risk through commitments that guarantee a percentage of each contract with the subsidy. Nevertheless, both GSK and Pfizer have stated that the current purchase guarantees are insufficient, and there is a concern that they and/or future manufacturers might stop investing in PCV.

Beyond design decisions, inaccurate demand forecasts were an implementation challenge. The Strategic Demand Forecast for the AMC underestimated the total demand and supply of PCV. In the first 8 months of 2012, the number of PCV doses shipped was nearly the total amount estimated for 2012. GAVI and UNICEF have improved the short-term demand forecasts, but projecting demand remains challenging.

Many criticized the lack of transparency surrounding the AMC design process in terms of vaccine selection and pricing discussions. By selecting a late-stage vaccine, the AMC designers focused on incentivizing investment in manufacturing capacity rather than R&D. Critics contend that this was a poor use of public funds since there was already a lucrative, high-income market for PCV. Prevnar, the original Wyeth vaccine, was the first billion-dollar vaccine in the United States.

Since the pricing models and assumptions were never made public, some critics also believe that the AMC is overpaying manufacturers. The tail price ceiling was based on multiple COGS analyses by external consultants who did not have access to actual data from the manufacturers. As a result, there was considerable variation in estimates of COGS, production opportunity costs, and breakeven volumes and prices, which informed the final tail price ceiling decision of \$3.50. However, it is important to note that the tail prices on some of the current contracts have been renegotiated downward.



▶▶ LESSONS LEARNED

Collaborate from the start – Find strong project advocates to drive the design process and launch. Early support for the AMC by the G8 Ministers of Finance led to wider support among donors and critical momentum for the pilot.

Know the tradeoffs – Recognize the implications of intervention decisions, such as the selection of a multiple-winner structure over a winner-take-all format with the AMC. Practitioners also recognized that pricing the AMC was one of the most challenging design aspects, and they tried to incorporate robust data gathering, but they could have sought greater transparency throughout the process. In addition, it is important to identify and understand the risks private sector participants face and then assess how these risks would be shared between the private suppliers and the buyers or donors.

Act soon and adapt – Throughout the AMC design process, practitioners should set clear targets and track progress. It is important to adapt to rollout challenges, as the AMC did by refining its strategic demand forecasting after initial underestimates.

▶▶ KEY TAKEAWAYS

- Broad support from, and coordination by, multiple stakeholders in the global health and international community was integral to the successful implementation of the AMC.
- Leverage existing organizations, systems and events to the extent possible, especially in implementing a new and complex market shaping intervention.



▶▶ Step 5. Measure Results

How do we best track results, adapt the intervention, and glean lessons for the future?

The fifth step of the Market Shaping Pathway is to monitor and measure results, examining the following questions:

- How will changes be tracked across market characteristics, public health outputs, and public health impact?
- What feedback loops will enable real-time adaptations of the intervention?
- How will the evaluation process include stakeholders?
- How will evaluation findings be shared?

Monitoring and evaluation (M&E) of a market shaping intervention's impact on both market and global health outcomes is important to measure both achievements and unintended consequences. Since markets are fluid, practitioners should plan to conduct a rapid evaluation after an intervention has been implemented in order to make adjustments where necessary. Sharing these M&E results will also help build the market shaping sector, as practitioners look for guidance and best practices in this relatively new field.

However, traditional M&E approaches may not always work for market shaping interventions. Since these interventions are macro in nature and impact all actors in the market, there is no control group for comparison. Furthermore, as most markets are dynamic in nature, some variables will change rapidly, making results difficult to regularly and accurately measure. Moreover, a market shaping intervention can often be one of multiple programmatic activities and initiatives underway, which can make it difficult to properly calculate attribution for progress to the overarching goal of improving health outcomes.

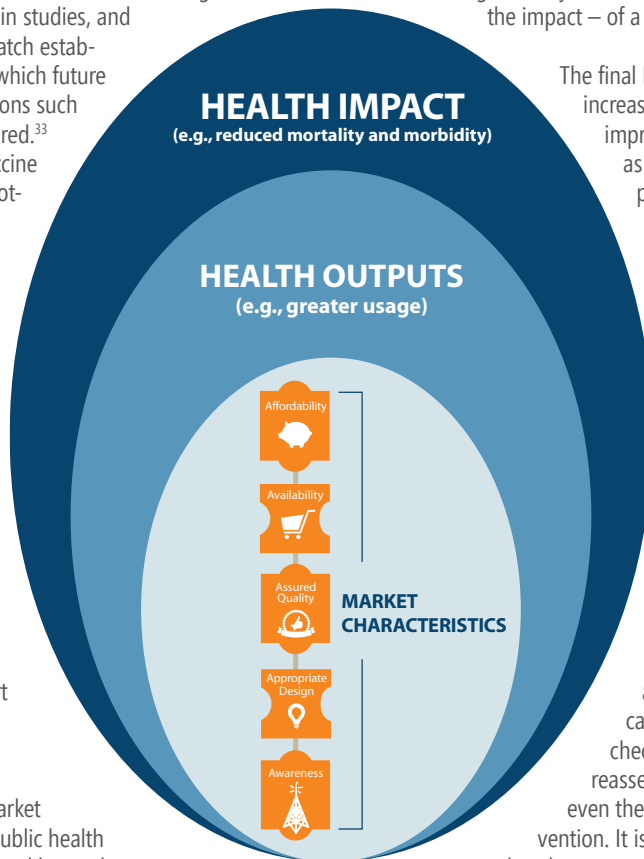
As an emerging field, market shaping does not have a standardized framework for assessing the impact of interventions. Here, we present a "dominant logic" from the William Davidson Institute that follows the goals of market shaping and guides the impact evaluation of many organizations active in market shaping. By shifting the market equilibrium through changes to transaction costs, information or risk, practitioners expect to produce better public health outcomes that reflect the overarching mission of saving lives and reducing morbidity. Thus, there are three fundamental areas that market shaping intends to affect: market characteristics, public health outputs, and public health impact.

To capture results in market characteristics, market shaping M&E can track changes along the first two steps of the Market Shaping Pathway. Corresponding to the first step, M&E can assess differences in market shortcomings along the "5As" of market characteristics: affordability, availability (global and local), assured quality, appropriate design, and awareness (among users and providers). Matching the second step, M&E can probe how the intervention addressed the identified root cause(s) for that product market: transaction costs, market information, and/or supplier and buyer risks. While the focus should be on the market characteristics and root cause(s) targeted by the intervention's "theory of change," any changes to the overall market health should be tracked, such as market size, new competitive products, or usage trends. For a fuller understanding of market changes, including the motivations and decisions of market actors, both quantitative and qualitative metrics should be used, and this may require developing new indicators or data collection systems.

For example, the multi-country project ACTwatch filled existing data gaps in the antimalarial market by measuring availability in the private and public sector, price points, and buyer characteristics over time and across countries. Through outlet surveys, supply chain studies, and household surveys, ACTwatch established a baseline against which future market shaping interventions such as AMFm could be measured.³³ For the pneumococcal vaccine AMC (described in the Spotlight on page 49), GAVI created a “late baseline study” in 2008 that captured the number of vaccine candidates in development and capacity investments by existing market actors. The study also modeled counterfactual scenarios to estimate the potential impact of the AMC vis-à-vis traditional financial and procurement strategies. Both the ACTwatch and the GAVI baseline study used expert interviews to inform the quantitative analysis.

As the ultimate goal of market shaping interventions is public health impact, M&E needs to extend beyond market assessments to coverage or use of a health product – essentially, the public health outputs. There should be evidence that changes in market variables have translated into higher uptake or into new possibilities for uptake (in the case of a new product launch). While standardized surveys like the Demographic and Health Surveys (DHS) capture informa-

tion on some health areas and indicators, others may require new field surveys. Coordination across multiple agencies in designing and systematically tracking these uptake metrics can significantly increase the learning – and ultimately the impact – of a market shaping intervention.



The final M&E area is examining how increases in uptake translate into improved health outcomes, such as mortality, morbidity, and patient-recorded outcomes. In some cases these outcomes are systematically captured by WHO, the global burden of disease project, the Joint United Nations Programme on HIV and AIDS (UNAIDS) or other such groups and initiatives. In other cases, practitioners may need to model likely changes in health outcomes from increased product utilization.

Although M&E for market shaping interventions follows a linear logic, in practice it can be an iterative process with checkpoints that may require a reassessment of the metrics and even the design or details of the intervention. It is also important to recognize that the extent of change in any of these areas (market variables, health outputs, and health impact) cannot always be precisely captured because of the complexities of market shaping described earlier. Focusing only on conventional, quantifiable metrics in assessing the impact of market shaping interventions can mask the broader and more significant high-level impacts.

33 ACTwatch website: www.actwatch.info



SPOTLIGHT on Measuring Results

Improving the Pooled Procurement of Vaccines

BACKGROUND

In developing countries, the vaccine market is often driven by the influence of public sector purchasers. Most vaccines for low-income countries are purchased by UNICEF, which procures for 80 to 100 countries annually, and PAHO, responsible for a regional grouping of 37 Latin American countries. Together, UNICEF and PAHO operate in approximately 7.5 percent of the global vaccine market by value, although this constitutes more than 70 percent of the global market by volume. The striking disparity between value and volume is the result of vaccine manufacturers providing their products to low-income countries at deeply discounted prices.

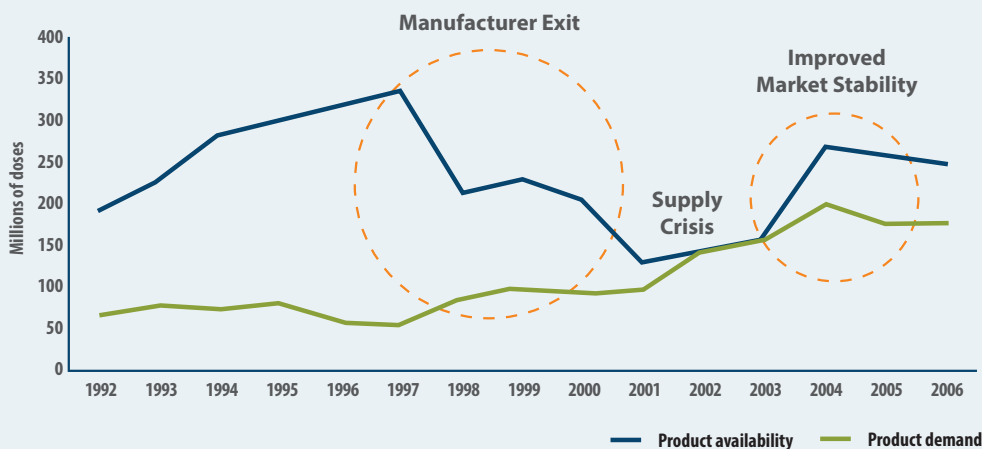
Due in part to the complex and capital-intensive nature of vaccine development and manufacturing, markets for vaccines are typically characterized by high supplier concentration with two to three firms dominating the market. To respond to this oligopolistic market, UNICEF implemented pooled procurement to reduce transaction costs in two ways:

- Aggregating order volumes across countries, which created an opportunity to negotiate preferential pricing and foster competition among qualifying suppliers; and
- Standardizing procurement processes across countries to ensure timeliness and reliability in tendering, ordering, receipt, and payment, which improved predictability and process management for suppliers.

MEASURING RESULTS

In the early 2000s, UNICEF started experiencing early symptoms of supply shortages for the measles vaccine as suppliers exited the market due to mergers, low price points, and a focus on more profitable vaccines. As shown in Figure 13, production capacity from all UNICEF suppliers dropped to a level below demand, creating a shortage. As a result of supplier exits, prices rose substantially.

Figure 13. Measles: Availability vs. Demand



Because UNICEF monitored the market closely, it was prepared to make significant changes in its approach to address the unintended consequences of supplier exits and product shortage. Adaptations to existing processes centered around solving the following issues: (1) excess capacity and/or excessive downward pricing pressure capable of pushing suppliers from the market; (2) limited demand forecasting that struggled to effectively match manufacturer capacity with demand; and (3) winner-take-all tendering practices that posed high profitability risks for suppliers.

By choosing to add “market health” as an important new indicator in their ongoing market assessment practices, UNICEF sought to achieve price points that were simultaneously affordable to governments and donors and financially acceptable to manufacturers to ensure continued supply in the market. In addition, UNICEF made changes to enable a more predictable and sustainable allocation of UNICEF procurement for principal suppliers. These changes included:

- Increasing market information by (a) providing more accurate and transparent long-term forecasting to support pooled procurement and (b) actively discussing how forecasts aligned with manufacturers’ long-term capacity and production plans
- Balancing supplier and buyer risks by (a) implementing 2-year supply arrangements and long-term contracts with flexibility for changing quantities and the inclusion of additional manufacturers and (b) shifting to multiple awards per vaccine – split tendering – instead of a single award to the lowest cost supplier

▶▶ LESSONS LEARNED

While pooled procurement can help procurers attain better prices and lower transaction costs, an exclusively low-price-centered procurement strategy can inadvertently put market sustainability at risk by triggering supplier exits and underinvestment in capacity.

In the case of UNICEF’s pooled procurement program, it was revised to include multiple and long-term awards, more accurate forecasting, and greater information transparency between suppliers and purchasers. Pooled procurement is a valuable method but should be carried out responsibly, tracked carefully, and adapted as needed to ensure market health. In this case, UNICEF changed its approach to achieve long-term global availability, assured quality, and affordability.

The pooled procurement method used by UNICEF has evolved over the years to include elements that ensure supply sustainability and better coordinate matching of supply and demand. Strategic guidance is determined on a market-by-market basis. The application of pooled procurement continues to evolve as new aspects are considered, such as the rollout and price structuring of new vaccines in countries transitioning from low- to middle-income status.

▶▶ KEY TAKEAWAYS

- Practitioners can position themselves to rapidly respond to unintended consequences by developing flexible and adaptive systems.
- Feedback loops that effectively capture and communicate a changing market landscape through key performance indicators can help to ensure benefits are sustained.

This primer is far from an exhaustive compilation of potential strategies and interventions for market shaping but rather a starting point for ideas that can be further developed and applied. As the global health field's collective thinking around market shaping continues to evolve, the three areas below may be of interest for further exploration and study.

- **Understand market shaping interventions in more depth**

Although this primer offers a high-level overview of a range of market shaping interventions, each intervention could be examined more fully along all aspects of how it would work: operational details, benefits, drawbacks, and implementation constraints. As described earlier, markets may be dominated by only a few buyers or suppliers, may focus on providers or end users, may operate in different stages of growth, and/or may focus on products with high startup costs or persistently low demand. Additional case studies representing these different types of markets would provide valuable insight into how an intervention could adjust to different market conditions. Some experts have pointed to the value of mapping interventions to the types of markets for which they are best suited. While it may be difficult to offer universal principles, analytical guidance could serve as a helpful tool for practitioners.

- **Consider new market shaping approaches, such as for middle-income countries (MICs), demand-side activities and service delivery interventions**

The global disease burden for tuberculosis, many vaccine-preventable diseases, and other health conditions is concentrated in MICs that mostly cover health costs through domestic financing or out-of-pocket payments rather than through global payers or donors. Expanding access to

health insurance or national health coverage will also change MIC market conditions and actors. National governments with large purchase volumes can use innovative arrangements or partnerships to shape the market and enable better health outcomes. In addition, most market shaping interventions have historically focused on supply-side activities or product-based markets. Other areas of further study would be considering interventions that leverage market actors and dynamics to stimulate demand or enhance delivery of important health services.

- **Explore new data and methods for monitoring and evaluating market shaping interventions**

As mentioned earlier, traditional M&E approaches often do not capture the full impact of market shaping interventions, and this is further complicated by the dynamic nature of markets and the lack of systems regularly tracking market indicators. Establishing market data systems and standardizing models could facilitate better evaluation of market interventions, especially in understanding their global health impact. Further research to improve evaluation methods for interventions will help advance the field.

Ultimately, the ideas shared here are only useful if applied to actual product markets in order to achieve tangible global health outputs and impact. The Market Shaping Pathway offers a disciplined approach, with an emphasis on analyzing market shortcomings and assessing whether market shaping is appropriate before moving ahead with implementation and rigorous evaluation. When embarking on each step, practitioners may find it useful to reference relevant sections in this primer and the lessons learned from the Spotlight case studies on the ARV, ACT, ORS/zinc, pneumococcal vaccine, and general vaccine markets. These experiences across the HIV, malaria, and child

health sectors offer insights into the real-world complexities of applying the Market Shaping Pathway.

Ongoing market shaping activities led by the FP2020 Market Dynamics Working Group, the UN Commission on Lifesaving Commodities for Women and Children, UNITAID and others speak to the continued interest and potential for exploring market shaping opportunities in new health product markets. As this field continues to grow, we are hopeful this dialogue on market shaping will produce collaborations to critically

evaluate current market shortcomings across health sectors and thoughtfully implement interventions where applicable. In these cases, market shaping can help direct the full set of capabilities and resources in the marketplace – across donors, implementers, suppliers, and developing country leadership – to achieving health goals. Market shaping alone cannot achieve health impact, but healthier marketplaces can play a critical role in delivering life-saving products to those most in need.

■ Key Takeaways

Below are some key takeaways for practitioners as they consider whether and how to use market shaping interventions:

1. Market shaping interventions are designed to address market shortcomings through three levers: reduce transaction costs, increase market information, and/or balance supplier and buyer risks. These interventions often draw on the purchasing power, financing, influence, or access to technical expertise of countries, donors, or procurers.
2. Past market shaping efforts have demonstrated impact in public and private sector markets, yet potential benefits must be weighed against questions of sustainability and unintended consequences.
3. Not every situation calls for market shaping, and this approach alone cannot address the multitude of health product uptake challenges. Instead, market shaping interventions should serve as complementary efforts to catalyze the impact of ongoing global health programmatic interventions.
4. The Market Shaping Pathway offers a structured approach for assessing market shaping opportunities through five steps: (1) observe market shortcomings; (2) diagnose root causes; (3) assess market shaping options; (4) implement a customized intervention; and (5) measure results.
5. Market shortcomings hamper use of global health products and could affect affordability, availability (sufficient volumes and stable supply base), assured quality, appropriate design, and awareness (among end users, providers and influencers). Through a range of analytical tools, practitioners can uncover the root causes underlying these shortcomings.
6. Common market shaping interventions can be categorized by the main market shaping lever they employ: reduce transaction costs (e.g., pooled procurement and variant optimization), increase market information (e.g., strategic demand forecasting and pricing information exchange), and balance supplier and buyer risks (e.g., advance market commitment and promotion incentives).
7. In selecting and implementing a market shaping intervention, practitioners should consider these guiding principles: collaborate from the start, know your tradeoffs, watch for unintended consequences, plan an exit, and act soon and adapt.
8. Market dynamics are complex, fluid and evolving, so interventions can create follow-on effects or unintended consequences. Coordinating efforts across multiple actors can enhance both market analysis and an intervention's effectiveness.
9. Capturing high-quality, timely indicators of an intervention's effects across market characteristics, public health outputs, and public health impact is important to both learn about the approach and improve the intervention itself, especially as the market changes. Coordination across the sector can facilitate nearly real-time monitoring, provide access to a wider data set, and share the assessment costs.

Appendix 1: Analytical Tools for Evaluating Market Shortcomings*

Analytical Tools	Shortcomings to Investigate	Examples of Critical Analytical Details
Supplier landscape assessment	<ul style="list-style-type: none"> Unaffordable prices Few suppliers Supplier exit or failure 	<p>Existing and potential suppliers/pipeline:</p> <ul style="list-style-type: none"> – Development phases; regulatory status – Projected costs for development – Differential production costs, prices, and supplier capacity – Technology comparison – Patent/IP assessment <p>Supply market concentration ratios</p>
Cost of goods sold analysis	<ul style="list-style-type: none"> Unaffordable prices 	<p>Production process, costs and lead times</p> <p>Input costs (e.g., active pharmaceutical ingredient cost, procurement, lead time, etc.)</p> <p>Economies of scale</p>
Demand forecasting, segmentation, stakeholder analysis and cost-effectiveness analysis	<ul style="list-style-type: none"> Cycles of global product excess and shortage Cyclic swings in prices 	<p>Preferences of stakeholders related to different presentations</p> <p>Demand forecast – comparing past and future, current delivery, different user segments</p> <p>Price point at which intervention is cost-effective</p>
Price/financing analysis	<ul style="list-style-type: none"> Unaffordable prices High dispersion in prices paid by countries with the same income level Cycles of global product excess and shortage Cyclic swings in prices 	<p>Price over time</p> <p>Price variations across countries, procurement mechanisms or purchase volumes</p> <p>Nature and size of financing sources over time</p> <p>Mark-ups from warehouse to final service delivery point</p>
Procurement/tendering analysis	<ul style="list-style-type: none"> High dispersion in prices paid by countries with the same income level 	<p>Identification of major buyers – volumes tendered, percent of market share</p> <p>Procurement history and projections</p> <p>Existence of coordination</p>
Production capacity analysis	<ul style="list-style-type: none"> Cycles of global product excess and shortage Cyclic swings in prices 	<p>Capacity of each supplier over time</p> <p>Capacity increments and cost</p> <p>Lead time to add capacity</p>
Consumer behavior analysis	<ul style="list-style-type: none"> Lack of product adoption Lack of uptake and scale-up Overuse (leading to resistance) Too many or too few product variants Products ill adapted to maximize use and uptake Product stockouts at retail outlets and clinics 	<p>Buying patterns and preferences</p> <p>Drivers of use</p> <p>Delivery channels – coverage, performance, availability</p>
Product quality analysis and quality assurance assessment	<ul style="list-style-type: none"> Proliferation of low-quality products in the market Counterfeit products 	<p>Current assessment of product quality in the market</p> <p>Assessment of procurement policies and behaviors of major buyers</p> <p>Assessment of related quality capacity</p>

* Descriptions of these tools are based on analyses prepared by Dalberg for Gates Foundation.

Appendix 2: Additional Sources

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Acronyms

A2S2	Assured Artemisinin Supply Service
ACT	Artemisinin Combination Therapy
AED	Academy for Educational Development (now part of FHI360)
AMC	Advance Market Commitment
AMFm	Affordable Medicines Facility – malaria
ART	Antiretroviral therapy
ARV	Antiretroviral
BCG	Boston Consulting Group
CGD	Center for Global Development
CHAI	Clinton Health Access Initiative
COGS	Cost of goods sold
DFID	United Kingdom Department for International Development
EML	Essential medicines list
FDA	U.S. Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunizations
GMP	Good manufacturing practice
GSK	GlaxoSmithKline
HHS	Department of Health and Human Services
HIV	Human immunodeficiency virus
IEC	Information, education and communication
JSI	John Snow, Inc.
LLIN	Long-lasting insecticide-treated net
M&E	Monitoring and evaluation
MIC	Middle-income country
MIT	Massachusetts Institute of Technology
NGO	Non-governmental organization

Norad	Norwegian Agency for Development Cooperation
ORS	Oral Rehydration Salts
PAHO	Pan American Health Organization
PCV	Pneumococcal conjugate vaccine
PDP	Product Development Partnership
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
POU	Point-of-use
POUZN	Point-of-Use Water Disinfection and Zinc Treatment project
PMI	President's Malaria Initiative
PQR	Price and Quality Reporting
PSI	Population Services International
QA	Quality assurance
R&D	Research and development
R4D	Results for Development Institute
RBM	Roll Back Malaria Partnership
RDC	Regional Distribution Center
RDT	Rapid Diagnostic Test
RHSC	Reproductive Health Supplies Coalition
SCMS	Supply Chain Management System
SRA	Stringent regulatory approval
TPP	Target Product Profile
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNDP	United Nations Development Programme
USAID	United States Agency for International Development
WDI	William Davidson Institute
WHO	World Health Organization

Notes:

U.S. Agency for International Development

1300 Pennsylvania Avenue, NW

Washington, DC 20523

Tel: (202) 712-0000

Fax: (202) 216-3524

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