



RESULTS FOR
DEVELOPMENT

Progress Brief

Ethiopia Market Shaping Capacity Improvement Project (MSCIP)

December 2021

Acknowledgment

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About Results for Development

R4D is a leading non-profit global development partner. R4D collaborates with change agents – government officials, civil society leaders and social innovators – supporting them as they navigate complex change processes to achieve large-scale, equitable outcomes in health, education and nutrition. R4D works with country leaders to diagnose challenges, co-create, innovate and implement solutions built on evidence and diverse stakeholder input, and engage in learning to adapt, iterate and improve. R4D also strengthens global, regional and country ecosystems to support country leaders with expertise, evidence, and innovations.

R4D helps country leaders solve their immediate challenges today, while also strengthening systems and institutions to address tomorrow's challenges. R4D has supported improved health and nutrition in Ethiopia since 2014 using market shaping, health financing and capacity building approaches. Some R4D projects address the largest underlying cause of child mortality (malnutrition); R4D's longest standing work in Ethiopia focuses on child health commodities. This work has supported the government's leadership in increasing access to amoxicillin dispersible tablets from 56% to 93% at health centers and from 57% to 86% at health posts between 2016 and 2019, a major success that is helping to combat pneumonia, the leading infectious cause of deaths in under-5 children.

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PROJECT OVERVIEW

In response to a request from the Ethiopia Pharmaceuticals Supply Service (EPSS)* General Director, R4D proposed the *Ethiopia Market Shaping Capacity Improvement Project* (MSCIP) to provide support for the development of a system-level market shaping approach in Ethiopia. Under this project, R4D is working to co-design a comprehensive market shaping strategy and to build the capacity of the newly established Quantification Market Shaping Directorate (QMSD) to play a lead “market manager” role. In that role, QMSD will be able to proactively identify and address market inefficiencies, and therefore improve access to high quality and affordable essential health and nutrition products in the public health system.

Implemented since September 2019, MSCIP focuses on three broad activities: the assessment of key market shortcomings and design of market shaping interventions to address these challenges; the strategic structuring of QMSD; and catalytic capacity building through coaching, mentorship, and on- and off-job trainings.

THE CHALLENGE

As noted in EPSS’s Business Process Reengineering (BPR) assessment, the pharmaceutical supply system in Ethiopia suffers from frequent supply interruption, inefficient utilization, and high wastage of resources. Ultimately, this contributes to poor availability of critical health commodities at various levels of the health system.

Though the availability of tracer items was 85% for program products and 70% for Revolving Drug Fund (RDF) products in 2019, the broader essential medicines availability was low and not monitored on a regular basis. Significant wastage was reported in monetary value (with some variance across programs) due to inefficiencies in demand forecasting and distribution. At the time, EPSS did not conduct any market shortcoming assessments,

and no cross-cutting national-level market shaping strategies were in place.

While many actors contribute to these market outcomes, EPSS has a unique strategic imperative to improvement access to critical commodities. EPSS is involved in all aspects of the commodity supply system and has the potential to wield significant power to improve market outcomes. Utilizing market shaping approaches, EPSS can maximize their positive impact through the strategic use of their market power.

THE MARKET SHAPING APPROACH IN ETHIOPIA: RATIONALE, HISTORY AND FUTURE

Market Shaping is a Comprehensive Approach to Drive Improved Market Outcomes

In its BPR assessment, EPSS stated that “market shaping is designed to improve a market’s health outcomes by targeting the root causes of market shortcomings.” Market shaping, as a systematic approach, enables key market actors to holistically identify shortcomings across the key market aspects of supply, demand, financing and regulatory. Market shaping strives to improve health outcomes by addressing the root causes of pharmaceutical market shortcomings and influencing markets through the design and implementation of transformative interventions, with the ultimate aim of increasing efficiencies and effectiveness, and improving sustained access to lifesaving health and nutrition products. When designed and implemented correctly, market shaping interventions can achieve a range of benefits by addressing either chronic issues underpinning market shortcomings or acute issues that lead to periodic market instability, as outlined in ‘The Challenge’ section above. Market shaping can transform current practices and existing market structures, creating efficiencies that lead to better health outcomes in terms of availability, affordability, awareness, quality, and design of health commodities.

* The name of the agency has changed over time but is referred to as EPSS throughout this document for clarity.

Market Shaping in Ethiopia Has Historically Relied on Donors and NGOs

The revised Pharmaceutical Sector Transformation Plan (PSTP II) recommended strengthening the market shaping capability of EPSS through training and mentoring. However, EPSS has not made much progress in this regard. PSTP II also identified weak demand planning, little emphasis on market shaping, and long procurement lead times among the weaknesses of the Agency.

As in most sub-Saharan African countries, most of the core market shaping activities in Ethiopia are performed by NGO partners. These activities are largely project-based, short-term in nature, and are focused primarily on deliverables related to the introduction or scale-up of a specific product/product category. The government has been dependent on these partners to play a “market manager” role that supports the entry of new lifesaving products into the Ethiopian market and addresses demand, supply, regulatory and financial challenges. While this model has had some short-term impact, the dependence it has created significantly hinders the sector from owning the market manager role in the long term.

Nonetheless, EPSS Has the Ambition to Become a Trailblazing Leader in Market Shaping

In response to the BPR and PSTP II findings, EPSS has established a Quantification and Market Shaping Directorate (QMSD) to be the unit responsible for owning, leading and coordinating market shaping activities across the health sector and which, ultimately, will play the vital role of pharmaceutical market manager in Ethiopia.

As part of the overall value chain, EPSS’s market shaping approach can be understood as two interrelated processes: upstream and downstream market shaping workstreams. The upstream market shaping function takes a holistic approach that spans suppliers, financiers, regulators and centralized procurement agencies. The downstream market shaping function encompasses the in-country supply chain, including distribution, storage and transportation from central facilities to health facilities and end-users. The approach of

proactively identifying and resolving cross-cutting barriers to product introduction and scale-up in an iterative manner and through the establishment of a directorate responsible for market shaping represents not only a new approach for the Government of Ethiopia, but a unique model in sub-Saharan Africa. As such, EPSS has no blueprint to follow, and instead must blaze its own trail in developing an appropriate strategy.

THE MSCIP PROJECT: SUPPORTING QMSD TO BECOME THE MARKET MANAGER

The MSCIP Project supports EPSS by building the capacity of QMSD to own, standardize and effectively execute market shaping interventions aimed at reducing key market inefficiencies and improving continuous availability of high-quality and affordable health and nutrition products in the public health system. The core set of project activities being implemented include: co-conducting a holistic assessment and analysis of market shortcomings and co-developing a comprehensive market shaping strategy; co-designing an organizational blueprint to optimize the mandate, structure and role of QMSD; and catalyzing capacity building support for QMSD staff and leadership through coaching, mentorship, targeted technical assistance and training.

R4D is implementing these activities in close collaboration with EPSS and QMSD leadership, and is actively engaging QMSD staff throughout the entire process to ensure strong ownership and clear coaching on key market shaping techniques and skills. R4D is also collaborating with other key government actors, including the Ministry of Health (MOH) and the Ethiopia Food and Drug Authority (EFDA), to effectively address cross-cutting issues underpinning market failures. All the market shaping activities are coordinated through ongoing efforts with other development partners as well.

PROJECT PROGRESS TO DATE: COMPREHENSIVE DIAGNOSTIC AND INITIAL ACTIONS

Since late 2019, the following activities have been completed, which lay the foundation of a strong market shaping function within EPSS and have addressed immediate priority actions.

Findings of the Comprehensive Market Shortcomings Assessment Diagnostic (2020)

As an initial diagnostic activity, EPSS and R4D co-conducted a **Comprehensive Market Shortcomings Assessment** to diagnose barriers in the supply of medicines at the upstream level with the ultimate goal of informing market shaping strategies to improve the affordability, availability, appropriate selection, and appropriate use of high-quality medicines. The assessment specifically explored issues related to the Pharmaceuticals Procurement List (PPL), product registration, tender management, contract management, forecasting, support and incentives for local manufacturers, new product introduction, and financing. Some of the barriers identified during the assessment are summarized below:

Pharmaceuticals Procurement List (PPL) - The PPL is a defined list of selected medicines, medical supplies, laboratory reagents and medical devices to be procured and supplied to public health facilities. The PPL was not being used for supply base optimization and product registration, and was not always up to date with current needs, as there were no clear revision guidelines and no ongoing documentation of current data nor market/public demand assessments. Beyond the PPL, a clearer strategy is needed for private sector engagement to ensure optimal models for access to non-PPL products.

Product Registration - The lack of sufficient EFDA-registered suppliers for specific products contributes to procurement delays, unduly high prices, and supply constraints. Product registration processes do not appropriately prioritize dossier review of products where new supplier registration may be most beneficial (i.e., where there are

shortages of active registered suppliers for essential medicines to be procured in high volumes or at high prices). Evidence and data for better decision-making and prioritization is not routinely collected and analysed.

Tender Management - Proper tender management is important in ensuring timely procurements and thus access to health and nutrition products. Long procurement lead times are partially driven by tender management challenges. Ad-hoc or fragmented procurement requests for both RDF and program commodities are a major shortcoming. Absence of an electronic procurement system is another major challenge that increased transaction costs of routine procurement activities and emergency supply chain management at EPSS. In addition, the combination of having few registered suppliers for some products (see above) and a public procurement directive to select at least five suppliers/candidates for a tender creates challenges for EPSS to manage tenders. Selecting nonregistered suppliers to fulfill the five-candidate threshold has frequently led to procurement delays, given the long process and time required to get waiver approval for non-registered suppliers.

Contract Management - Several issues related to contract management contribute to delays across the supply chain and lead to supply insecurity. EPSS has had difficulties implementing long-term framework agreements (FWAs) with suppliers for some commodities due to the lack of interested suppliers, for whom the use of fixed prices in the FWA is cited as a major barrier. Within FWAs, EPSS has seen performance lapses: of the 249 RDF products under FWA, only about 100 products were supplied according to the contract agreement in terms of line of item, quantity, and delivery schedule. However, EPSS does not have any post-contract performance appraisal system to incentivize performance or affect future tendering decisions.

Support and Incentives for Local Manufacturers Support - Local manufacturers are crucial in improving the supply base and ensuring overall supply security for optimized products. Efforts to raise local manufacturing standards to meet Good Manufacturing Practice (GMP) standards have not

been fully successful. Original timelines, previously aiming for completion in 2018, have been extended by two to three years due to the failure of many firms to fulfill GMP requirements. Since competition for EPSS's tenders is based solely on price, a local GMP-certified firm cannot win a tender over a local non-GMP certified firm if the latter is offering a cheaper price; consequently, there is little immediate incentive for firms to take on the investment and overhead costs of achieving and maintaining GMP compliance.

Forecasting - Inaccurate forecasting and supply planning has contributed to resource allocation inefficiencies, including wastage and poor supply disruption. Despite a lengthy and labor-intensive quantification process, forecast accuracy is low for RDF and Health Program commodities. The lack of automated forecasting tools or software for the RDF quantification is one contributor to inefficiencies in the current process.

New Product / Product Category Introduction - Most RDF commodities are introduced to public procurement during PPL revision without a systematic market entry/new product introduction framework that holistically considers regulatory, financing, supply, and demand factors. Program commodity introduction, however, is initiated by partners working in the area and is done on an ad-hoc basis through national Technical Working Groups (TWGs) that coordinate the overall process.

Financing - Financing for health commodities varies between health program commodities and RDF commodities. **Program commodities** are primarily donor-funded; as a result, they are at risk when donor support falls. Shortcomings for financing of these commodities include the lack of predictability around donor resourcing that impedes advanced planning and appropriate market shaping for the commodities, as well as the overall high level of dependence and the lack of any transition planning/sustainability considerations for important health program commodities to prepare for instances where donor funding continues to fall. **RDF commodities** are financed on an ongoing basis, primarily through cost recovery for products sold, markups, as well as service fees paid by donors/partners for procurement, storage and distribution. RDF financing has substantial

challenges, including cost recovery rates that are set too low to achieve full supply chain cost recovery (including demurrage fees, etc.); a 70% collection rate for products sold on credit, compared with target rate of 90%; and concerns that service fees may decline if donor support for program commodities declines. In addition, lack of holistic financial planning discussions across program and RDF commodities leads to inefficiencies in resource allocation.

Actions in Response to Market Shortcomings and COVID-19 (2021-)

Pharmaceutical Procurement List (PPL) Revision and Process Update

The EPSS PPL was revised in an effort led by EPSS's QMSD team in collaboration with R4D, the Ministry of Health, the Ethiopia Public Health Institute, Regional Health Bureaus, and others. This revision serves as the foundation of future procurement design frameworks, supplier registration prioritization frameworks, and regulatory efficiency improvement solutions. In turn this will enable EPSS to use its procurement power to maximum effect, ensuring the expedited review of the most critically needed products so that regulatory delays are minimized.

Supply Base Analysis to Support Improved Medicine Registration

With the objective of optimizing the medicine registration process, R4D – in collaboration with EPSS and EFDA – conducted a supply base analysis to identify and analyze the number of registered suppliers for products that are included in the PPL. As part of the analysis, medicines, medical supplies, lab reagents and medical devices with limited number of suppliers were identified and a prioritization exercise was conducted to fast-track the registration of products based on their vitality and demand (consumption).

Key Downstream Market Shaping Activities Initiated

In order to identify and address market shortcomings at the health facility level and to improve access to and use of life-saving health commodities, EPSS and R4D jointly initiated downstream market shaping activities. As part of this initiative, EPSS's

market shaping training manual was co-reviewed and finalized, a downstream market shaping assessment tool was developed and training on basic market shaping concepts and principles was provided to 109 EPSS head office and hub staff.

The Supply Chain COVID-19 Response Strategic Task Force

EPSS, R4D, the United Nations Population Fund, USAID's Global Health Supply Chain Procurement and Supply Management project and McKinsey assessed gaps and risks to EPSS's COVID-19 response as well as risks posed by COVID-19 on the routine supply chain system, then developed guidelines to mitigate those risks. QMSD worked with R4D and other EPSS Directorates to assess and respond to potential stockout of essential medicines – for example, by fast-tracking the procurement process for essential medicines that are most at risk of stock out due to order cancellations, ingredient supply shortages, or delays when clearing customs.

expertise on an as-needed basis in the service of EPSS's strategic priorities.

Among other activities, R4D will support EPSS to systematically approach quality and delivery concerns with local manufacturers from the public health perspective, and to serve as a public entity on the frontline that prioritizes public health concerns on behalf of the end-users. R4D will support EPSS in creating a framework focused on developing incentives for quality-oriented and high-performing local manufacturers in order to create market-driven competition.

PLANNED ACTIVITIES (2022-)

During the remainder of the project, R4D will support EPSS in codifying a strategic market shaping vision and developing and ratifying an organizational blueprint for QMSD, using the comprehensive market shortcomings assessment and additional targeted research to inform its structure, mandate, scope, relationship and coordination mechanisms with other directorates within EPSS and with other government entities. A responsive and strong organizational design will be the cornerstone of QMSD's long-term ability to scope market shortcomings and design appropriate solutions.

R4D will continue providing catalytic support to build and strengthen the capacities of QMSD's leadership and staff. This capacity building support aims to create and codify in-house capability, with the ultimate goal of fostering QMSD's ability to own and continuously play the market manager role. Moreover, this work aims to make these capabilities robust and self-sustaining, so that EPSS can continue to grow its own internal capacity over time as well as leverage external