



Improving Health Outcomes Through Strategic Sourcing of ARVs and Viral Load Technologies

Short version: Part I: ARVs

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The world requires a reliable supply of greater volumes of HIV products in order achieve the scale required to achieve global targets. In the pursuit of the 90–90–90 target by 2020, the targeted scale-up of ARV medicines and Viral Load technologies will be pivotal to reach these targets. The Global Fund is one of the largest financiers of HIV health products and has a key role to play to facilitate this scale-up and close the coverage gap.

The scale-up of ARV medicines and viral load technologies requires a healthy market. Product scale up can be accelerated when healthy market conditions exist across six key dimensions - innovation, availability, demand and adoption, quality, affordability and delivery.

The Global Fund has designed and implemented product strategies for ARV medicines and viral load technologies. The Global Fund aimed to leverage its procurement capabilities and market share to improve market conditions. Since the implementation of the Global Fund's ARV strategy in July 2014, it has focused on improving availability, affordability, innovation, adoption and reliable on-time delivery, while continuing to deliver quality-assured products. The ARV and viral load strategies involved in collaboration and consultations with partner organizations and manufacturers, both of which are supportive of the more comprehensive strategies.

The strategies aims to benefit other buyers beyond PPM. Grants participating in PPM will benefit from the strategy through the lower prices, shorter and more reliable lead-times and improved contractual terms negotiated by the Global Fund. Other ARV buyers will also indirectly benefit from this strategy through access to the PPM reference price information, new product innovations, and greater product availability.

The Global Fund will be closely monitoring the impact of all interventions in the future. In addition, it will continue to monitor key product markets for opportunities to support healthy market conditions, and to deliver improved health outcomes through strategic procurement initiatives.

Part I of this report highlights the strategic sourcing of ARVs.

The full report can be found at www.theglobalfund.org

Introduction

ARVs are segmented between first-line, second-line and third-line for adult and pediatric medicines. The market for ARVs consist of a high –value, low volume market in high-income countries and a high-volume, low value market in the rest of the world.

The market is expected to grow in the future, in part due to new treatment guidelines. A small number of manufacturers supply the majority of the products. The largest funders and buyers in the ARV market are the Global Fund, PEPFAR and government of South Africa. Global Fund finances approximately 40 percent of all ARVs for the LMICs; with about 50% going through the PPM thus representing about 20% of the LMIC market. Products face different challenges on their overall market potential and their stage in the product lifecycle. Affordability is the greatest concern for first line products. Low and fragmented demand limits the affordability and availability of second and limited use (WHO-recommended) products. Supply sustainability remains a challenge and on-time delivery and response to risks of stock-outs has been a challenge.

In response to these challenges, the Global Fund designed and implemented a procurement strategy for ARVs procured through the Pooled Procurement Mechanism (PPM).

The Global Fund issued the tender to operationalize its ARV procurement strategy in July 2014, with the objectives as described in the table below

Dimension¹	Desired outcomes	Interventions
Innovation	<ul style="list-style-type: none"> • Introduction of new products • Improved formulations • Longer shelf life 	<ul style="list-style-type: none"> • Implementation of collaborative projects • Evaluation recognized investment in product development • Inclusion of new products as they become available
Availability	<ul style="list-style-type: none"> • Improved availability of full range of needed products • Production capacity of low volume products maintained • Expanded country registration footprint • Faster responsiveness to risks of stock-outs 	<ul style="list-style-type: none"> • Bundling of high and low volume products to support the regular supply of all needed products • Multiagency coordination order placement and provide better visibility to facilitate supply of full batches of low volume products including paediatric ARVs • Optimization of API sourcing and production planning • Evaluation criteria that recognize registration of products in a broad scope of countries • Implementation of a Vendor Managed Inventory mechanism
Demand and adoption	<ul style="list-style-type: none"> • Adoption of WHO recommended regimens and products • Increased uptake of optimal products and formulations 	<ul style="list-style-type: none"> • Promotion of the uptake of optimal formulations • Pricing roadmaps to support uptake of optimal WHO-recommended products and formulations • Encouraging the update of treatment guidelines to use optimal products
Quality	<ul style="list-style-type: none"> • Adherence to Global Fund Quality Assurance policy 	<ul style="list-style-type: none"> • Tender restricted to products meeting the Global Fund's quality assurance policy
Affordability	<ul style="list-style-type: none"> • Sustainable price reductions (1st & 2nd line recommended products) • Stabilization of price (legacy, specialized low volume products) 	<ul style="list-style-type: none"> • Use of longer-term contracting • Implementation of pricing road maps, with price targets based on an analysis of the cost of goods (COGS) • Optimization of API sourcing
Delivery	<ul style="list-style-type: none"> • Increased OTIF • Reduction in lead-times • Faster responsiveness to risks of stock-outs 	<ul style="list-style-type: none"> • Evaluation criteria with emphasis on manufacturer OTIF • Use of longer-term framework agreements • Implementation of a Vendor Managed Inventory mechanism

¹ The Global Fund's Market Shaping Strategy, Committee Decision (SIIC) and Committee Information (FOPC), internal document, 2015.

Tender outcomes

The Global Fund established Framework Agreements with a panel of eight manufacturers. In year 1 of the strategy, 99.5% of all the ARVs by volume and value were procured from these manufacturers, and the remaining volumes which were low volume or originator products were purchased from six manufacturers outside the framework agreements.

Manufacturers under the framework agreements are supportive and complimentary of the strategy.

Market outcomes

The procurement strategies are already having positive impacts on the market. While implementation is still in the very early stages, initial successes have already be seen.

Improved affordability

The strategy uses longer-term contracting, coordination of demand and target pricing to achieve sustainable reductions and stabilization of prices. These commitments have enabled manufacturers to generate efficiencies and Manufacturers are encouraged to transfer efficiencies into lower product prices.

The Global Fund has also worked with manufacturers to implement target price trajectories. As a result of these price reductions, initial estimates suggest that the Global Fund will achieve cost savings of at least US\$35.1 million across the top 10 volume products in 2015. This saving will account for 10 percent of the value of the ARVs purchased. This equates to 96 percent of the Global Fund's target savings, and could provide treatment for an additional ~300,000 patients². Forecasts suggest that the procurement strategy could save the Global Fund an additional US\$63 million in 2016. If forecasted savings are achieved, the Global Fund will save a total of US\$98 million over the first two years of the strategy. The Global Fund is therefore on track to meet the two year savings target set at the outset of the strategy.

The Global Fund believes that target pricing can also play a useful role in mitigating excessive price volatility. It is a normal business practice that manufacturers sometimes use price reductions to attempt to gain market share or eliminate excess inventory. However, pricing or tendering that is too aggressive in the short-term might cause negative long-term effects in the market, such as undesired manufacturer exits or an inability for manufacturers to make investments in product development or other improvements while remaining competitive. The Global Fund believes that target pricing can function as a valuable tool to stimulate and preserve the positive effects of competitive pricing, while mitigating some of the potential long-term negative effects.

ARV price trajectory, 1 January – 22 October, 2015



² These forecasted cost savings calculated at the beginning of Q4 2015 have been calculated using the difference in price between the baseline price (weighted average price between July 2013 and June 2014) and the actual price, multiplied by the purchased or forecasted volume. The 2015 savings estimate includes actual savings on all orders placed in Q1 to Q3 2015 and orders placed in Q4 but not yet delivered, and forecasted savings from purchases expected to be made by 31 December 2015. 2016 forecasted savings are based on Q4 reference prices and 2015 volumes. The 2016 price for TLE and TEE is based on a conservative estimate of price point. The number of patients treated was calculated by dividing the savings by a conservative average cost of treatment (US\$120).

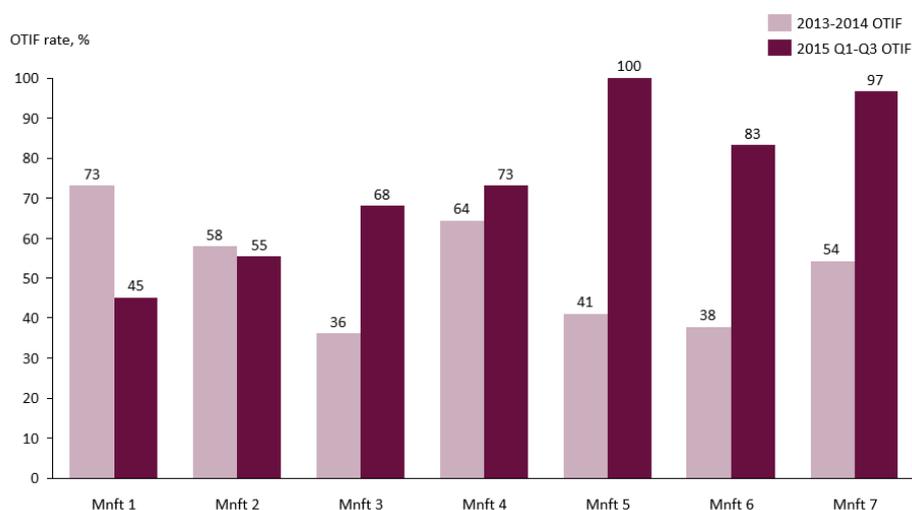
Improved delivery performance and fewer stock-outs

The strategy has placed emphasis on achievement of on-time, in-full delivery (OTIF) and a reliable and uninterrupted medicine supply. As a result of the procurement strategy, manufacturer OTIF has improved from 20 percent to 85 percent.³ The Global Fund has also developed a mechanism to respond rapidly to shortages of ARVs, which has reduced the delivery time for emergency orders to countries to three to seven weeks. Such improvements reduce risks of treatment interruptions that can have severe medical consequences and contribute to drug resistance.

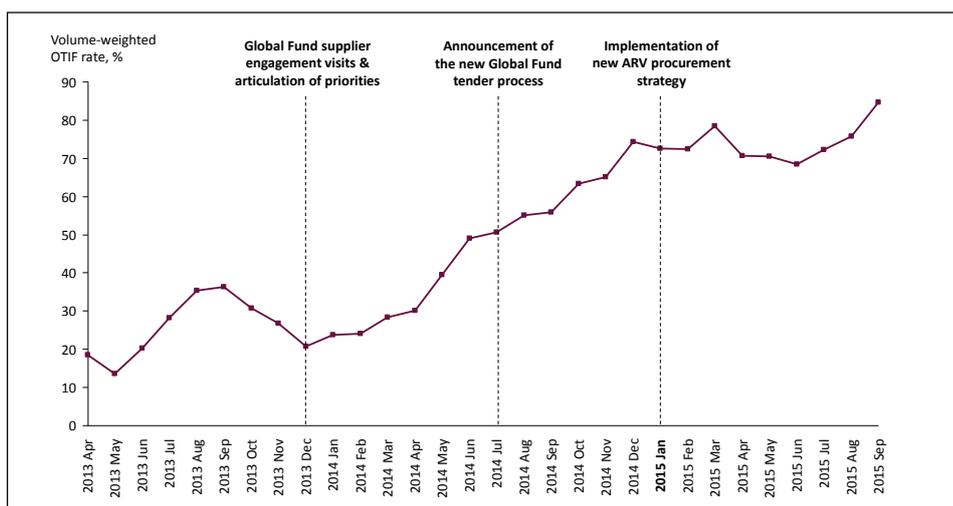
Recognition of timely delivery has led to an improvement in OTIF. By the third quarter of 2015 most manufacturers had improved their OTIF rate, and average monthly manufacturer OTIF across increased from 20 percent in April 2013, to 85 percent at the end of September, 2015.

Improvements in manufacturer OTIF has led to more timely delivery of orders to countries. During the first eight months of 2015, almost 80 percent of shipments were delivered on-time and in-full to countries, compared to an average of 45 percent between 2013 and 2014. This is very close to the average OTIF rate of the private sector, which was estimated at 89 percent in 2013.⁴

Manufacturer OTIF rate⁵



Improvement in manufacturer OTIF rate over time⁶



³ The improvement was from 20 percent in April 2013 to 85 percent at the end of September 2015.

⁴ Private all sectors, Europe, Asia, Americas PwC, Global Supply Chain Survey 2013

⁵ Seven of the ARV manufacturers who entered the Global Fund framework agreement in 2015 have been included in the analysis. The eighth manufacturer did not supply any ARVs in 2015. Manufacturer OTIF rates have been weighted by the volume of ARVs each manufacturer supplied to the Global Fund in the respective period.

⁶ All ARV manufacturers included in the Global Fund tender process between 2013 and 2014, and only those manufacturers under the Global Fund framework agreements in 2015, were included in the analysis. Manufacturer OTIF rates have been weighted by the volume of ARVs supplied to the Global Fund by each manufacturer in the respective period.

Improved treatment availability

The strategy has improved ARV availability in a number of ways. First, the Global Fund has worked with manufacturers to diversify their supply base for active pharmaceutical ingredients (API). This can help prevent API shortages that might trigger volatile pricing or unreliable supply. Second, the Global Fund has bundled demand so that manufacturers receiving orders for high volume ARV products must also supply the lower volume and less commercially attractive products. Finally, the Global Fund continues to lead the Paediatric ARV Procurement Working Group (PAPWG) to improve the availability of paediatric ARVs. All of these interventions have improved the availability of the right treatment at the right time for patients worldwide.

The Global Fund established a new tool – the Vendor Managed Inventory – to rapidly respond to risks of shortages and stock-outs across the whole grant portfolio especially for non-PPM grants. Before the strategy, the Global Fund did not have an effective tool to respond to these urgent requirements other than to work to try to accelerate regular production.

The Vendor Managed Inventory has reduced the delivery time of urgently required products from the manufacturer to the country. Manufacturers commit to holding a proportion of their annual commitment in readily accessible stocks under the Vendor Managed Inventory. Manufacturers are also reporting on their overall stock levels for all products so the Global Fund has visibility on available products. This allows the Global Fund to be far more responsive to supply shortfalls and stock-outs, and deliver emergency products in just three to seven weeks. The Global Fund ensures that the Vendor Managed Inventory does not encourage poor forecasting and planning by conducting an analysis on the cause of each emergency request.

Country-level improvements in response to stock-outs have been achieved. In 2015, the Vendor Managed Inventory was accessed by five countries facing ARV stock-outs or supply interruptions. In Uganda, deliveries were made to the central medical store within six to eight weeks after a stock-out occurred in June. Similarly, when a stock shortage was reported in Niger in August, an emergency shipment occurred within just four weeks, and subsequent deliveries were completed within 6.5 weeks.

Multiagency coordinated procurement of vulnerable and new products

The Global Fund, along with partner organizations, established the PAPWG in 2011 by bringing together the major financiers and procurers of paediatric ARVs and technical bodies and experts to continue a coordinated approach to paediatric ARV procurement. The goal of the PAPWG is to secure the market to ensure timely and consistent access to paediatric ARVs in order to sustain and scale-up paediatric HIV treatment.

The Procurement Consortium of the PAPWG improves paediatric markets by aligning and coordinating operational procurement. Since 2011, the PAPWG has achieved tremendous progress towards securing a steady supply of paediatric ARVs in more than 70 countries and has worked effectively to promote the procurement of optimal paediatric ARVs.

The Global Fund pursues its strategic objectives for paediatric ARVs through the PAPWG. For example, a key objective of the procurement strategy was to ensure rapid adoption of WHO recommended regimens. The advocacy and country support provided by the PAPWG has contributed to 87 percent of paediatric ARV spend going to IATT optimal or limited use products in 2014. Of paediatric ARVs purchased through the PPM, almost 95 percent of spend was on optimal products by August 2015, compared to only 50 percent in 2011.

Going forward, the Global Fund, in partnership with UNITAID will leverage the PAPWG platform to pursue similar interventions for other small, fragmented markets supporting the supply of existing introduction of new optimal WHO-recommended products – expanding to scope to adult and adolescent ARVs from Q1 2016.

Increased innovation.

A number of manufacturers have joined the Global Fund in collaborative projects aimed at driving product improvements to better meet patient.

Next Steps

The new ARV and viral load procurement strategies have already shown early signs of positive impacts on the market. These impacts will continue to emerge. Meanwhile, the Global Fund is continuously assessing the achievement of its market shaping objectives and pursuing additional opportunities.

The Global Fund recognizes that additional actions might be required to further enhance the impact of the ARV strategy. The main points of feedback from manufacturers and partners were for the Global Fund to closely monitor the risk of market exits or unsustainable pricing offered by manufacturers that received reduced volumes as result of the tender, and to monitor the long-term impact on the ARV market structure.