Antiretroviral & other strategic medicines used in HIV programs

Procurement Strategy: 2018-2020

Manufacturer Consultation

Martin Auton and Lin (Roger) Li 16 November 2017 Cape Town, South Africa



The Global Fund Procurement Strategy on Anti-retroviral medicines is currently under development and will be finalized in the forthcoming months.

This document presents the Global Fund's current intention which is subject to change.

The data and information herein are provided for illustrative purposes and derive from a limited and preliminary analysis of the Global Fund.

The present document shall not be considered as the Global Fund's representation or commitment of any kind.

Key contacts: Procurement Strategy here today



Patrick Latin
Chief Procurement Officer



Mariatou Tala Jallow Senior Manager, Sourcing of Health Products



Martin AutonManager, Global Sourcing, Pharmaceuticals



Lin (Roger) Li Manager, Strategy, Analytics & Data Management



Nathan Vasher Specialist, Strategy, Analytics & Data Management

Objectives of the Supplier Consultations

- 1. Present the Global Fund's Procurement Strategy for Anti-retroviral Medicines
- 2. Share the Global Fund tender processes and timelines
- 3. Obtain feedback in plenary meeting (...and also afterwards...)

Agenda

1. The Global Fund, Sourcing and the Pooled Procurement Mechanism

- 2. Implementing the 2nd phase of the Global Fund's Market Shaping Strategy
- 3. 2015-2017 ARV Procurement Strategy and implementation
- 4. 2018-2020 Procurement Strategy and tender timelines

The Global Fund A 21st-century partnership organization

to accelerate the end of HIV, tuberculosis and malaria as epidemics



Successful Replenishment for the 2018-2020 implementation period to finance the Global Fund Strategy

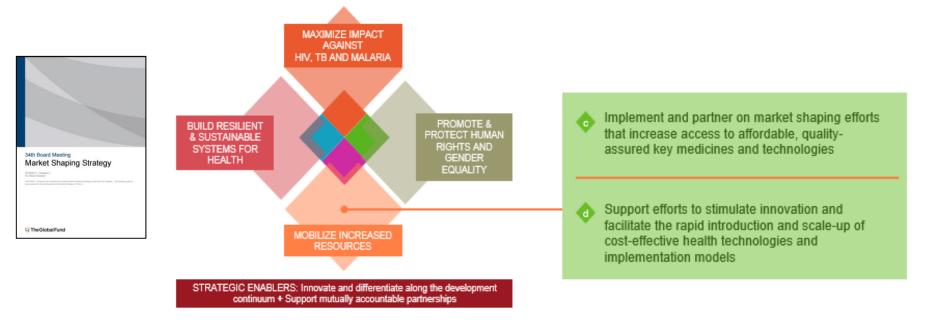
- Over US\$ 12.9 billion at the 5th Replenishment Conference in Canada; September 2016
- Most grants are now being made or signed to take them through 2020



Funding	Amount		Countries
envelopes	USD million	%	#
HIV/AIDS	5,098	50%	105
Malaria	3,227	32%	71
ТВ	1,842	18%	98

Health products = 40-60% spend depending on category

A market shaping role beyond the Global Fund spend



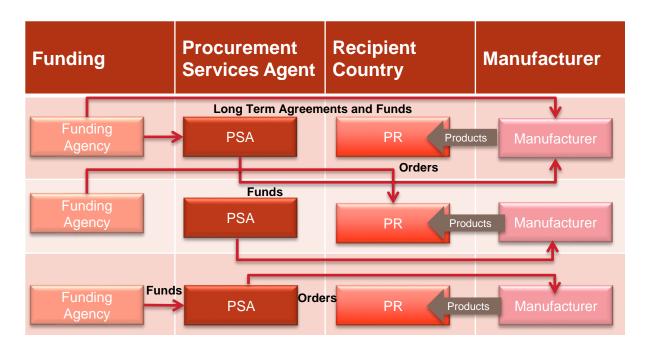
Procurement Channels and Routes to Market

There are a number of procurement channels - with the Pooled Procurement Mechanism representing around 55% total Global Fund health product spend (depending on category)

Pooled Procurement Mechanism (PPM)

National Procurement Mechanisms

Other Procurement Agents; Global Drug Facility (TB)



PPM: The Global Fund's Pooled Procurement Mechanism

Established in 2009 to aggregate order volumes from participating PRs in 60 countries with over 160 grants

Currently, leveraging market spend of US\$ 1.1 billion spend annually

Objectives of PPM

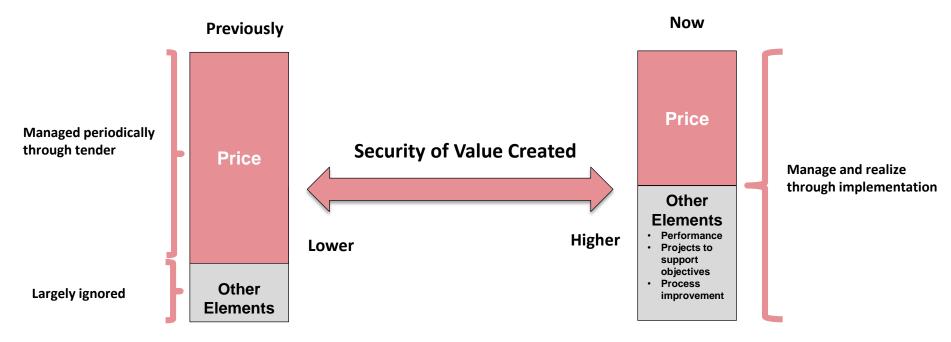
- secure quality-assured products
- obtain better value-for-money through best pricing and delivery conditions
- reduce lead times for critical health products by engaging with manufacturers using framework contracts
- contribute to sustainable markets for core life-saving health products

Sourcing team implements the Market Shaping Strategy by managing health products through PPM along 5 key dimensions

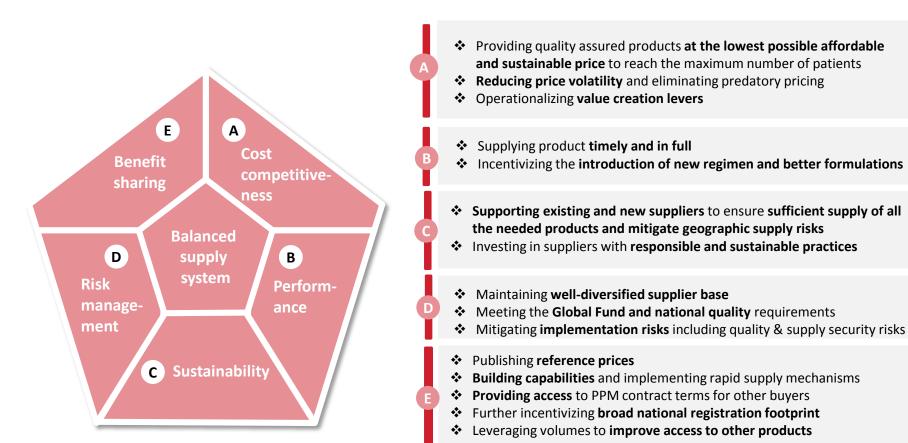
Pooled Demand	Registering Principal Recipients into the mechanism creates the opportunity to pool volumes of large and small volume countries	
Product Category Strategies	Design, issue and manage sourcing strategy including competitive tenders to support category- specific market shaping objectives	
Supplier Relationship Management	Manage the implementation of long term agreements including the allocation and performance management of suppliers	
Demand Management	Optimize resources to manage Principal Recipient demand along three dimensions: volume, time and specification	
Transaction Management	Execute PPM orders from requests to deliveries via wambo.org , a PR-facing portal that increases visibility of ordering operations with full visibility and a transparent and auditable process	

Maximizing Value through Supplier Relationship Management

- Previous approaches focused on the price value lever
- Value creation has been extended and can be further extended across a range of lever
- The importance of this will increase in importance as cost is optimized



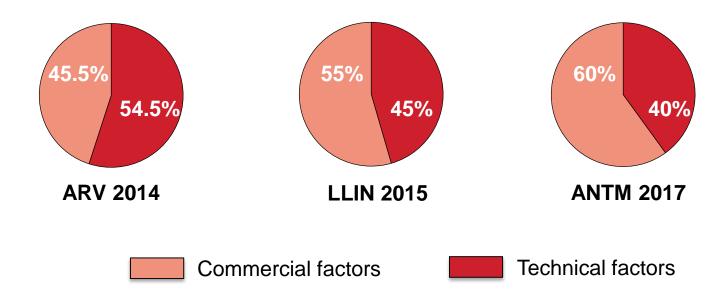
Global Fund's Balanced Supply System Based on Five Elements



⑤ The Global Fund ⑤ Le Fonds mondial ⑤ El Fondo Mundial ⑤ Глобальный фонд ⑤ 全球基金 الصندوق العالمي ⑤

The Approach in Current Practice

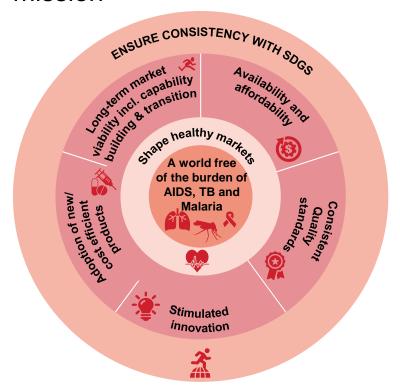
The commercial weighting during tender evaluation reflecting the specific category objectives and market situation



Agenda

- 1. The Global Fund, Sourcing and the Pooled Procurement Mechanism
- 2. Implementing the 2nd phase of the Global Fund's Market Shaping Strategy
- 3. 2015-2017 ARV Procurement Strategy and implementation
- 4. 2018-2020 Procurement Strategy and tender timelines

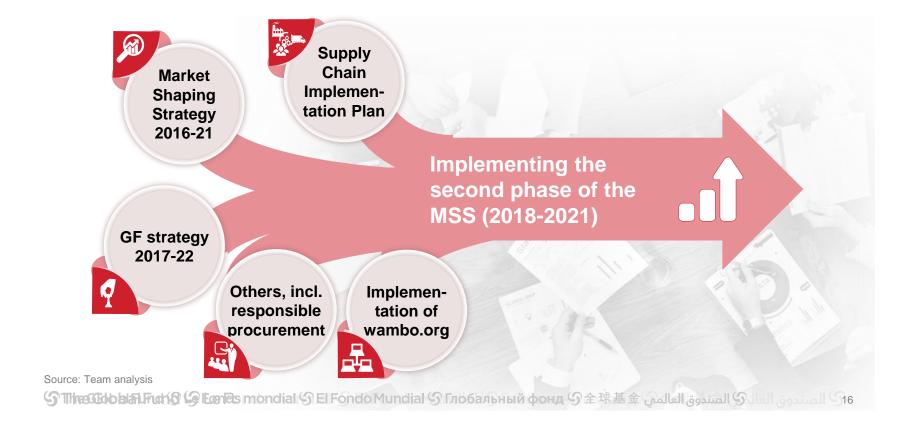
The Market Shaping Strategy is a key component of The Global Fund's mission



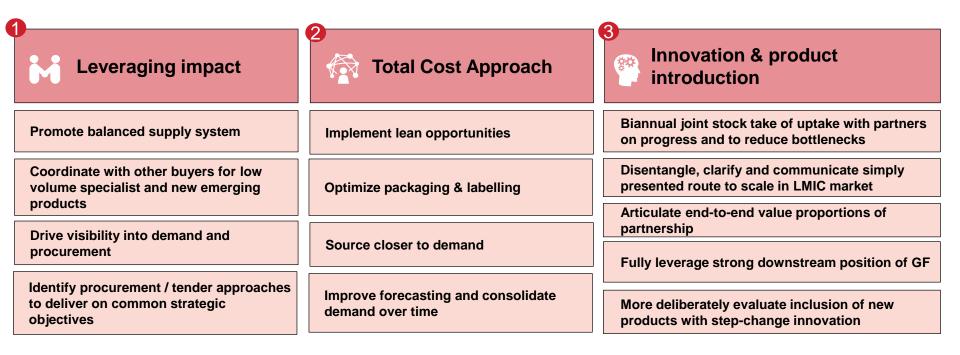
Mission of MSS: Leverage our position to facilitate healthier global markets for health products – today and in the future



The journey to evolve sourcing needs to take place against the backdrop of existing strategies and initiatives



Key elements: 1) leveraging impact; 2) total cost approach; 3) innovation and product introduction



Key element 4: responsible procurement

Description Provide additional economic benefits to incountry community **Economy** Empower community by sharing knowledge Mitigate effect on environment along the end-to-end supply chain **Ecology** Use knowledge and skills to contribute **Dimensions** to a constant rise in eco-efficiency Promote fundamental human rights, e.g., Advocate for decent labor conditions **Society** Promote children rights Promote workers' health and safety Promote best business practices among **Business** suppliers and other buyers practices



Principles to build holistic standards

- Build on existing guidelines
- Provide practical guidance
- Include phased approach
- Focus on procurement
- Align with GF objectives

SOURCE: Adapted from corporate responsibility's framework by Crane et al, 2014

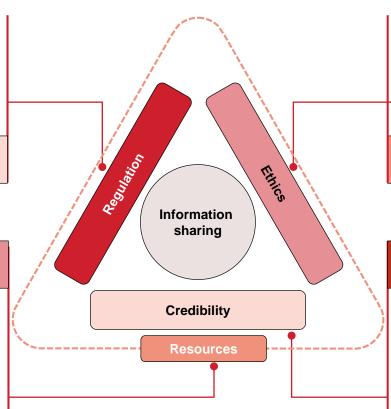
Key element 5: principles of information sharing

- Information that could distort markets might violate antitrust law
- IP law or contractual obligations set further constraints
- GF will always "better be safe than sorry" and prudent in information sharing

Ensure rigorous compliance with applicable regulations/obligations

Use resources efficiently and effectively

- GF gets approached by multiple stakeholders with information requests
- Answering requests binds significant resources
- As resources are limited, GF has to prioritize and optimize efficiency/ effectiveness of information sharing



Hard¹ constraints [Soft¹ constraints

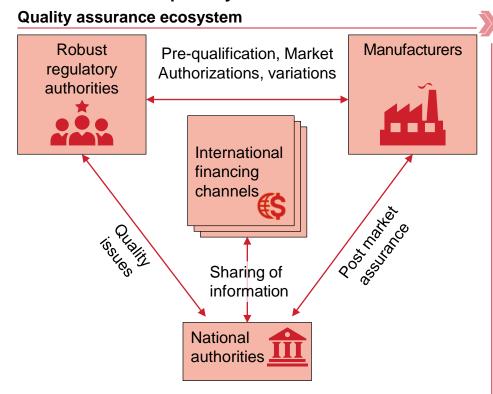
- Stakeholders place high trust in GF
- Trust- and loyalty-based relationships are the foundation of GF's ability to shape markets in the long-term
- GF will protect confidences and share information only to the extent that does not infringe upon legitimate stakeholder interests

Uphold high ethical standards

Safeguard GF's reputation a trusted source of reliable information

- Both market and stakeholders place high expectations in the quality and relevance of intelligence provided by GF
- Credibility is crucial for GF to be taken seriously in the market and remain a trusted partner

Key element 6: GF strives to evolve to further promote consistent quality standards



Initiatives

Foster in-country capacity to ensure generation of quality-relevant data/information

- Leverage external resource partners
- Structure GF financing for increased coherence

Systemize and structure information sharing mechanisms to accelerate and increase actionability

Extend rigorous information loop to all national authorities and facilitate information flow

Refine policies to enable application of own risk assessments and appetite

- Clarify GF's position to employ own risk appetite
- Formalize process for decision making

Pool and leverage resources, knowledge, and data of GF and other organizations by sharing of regulatory data with key stakeholders (e.g., PRs)

Agenda

- 1. The Global Fund, Sourcing and the Pooled Procurement Mechanism
- 2. Implementing the 2nd phase of the Global Fund's Market Shaping Strategy
- 3. 2015-2017 ARV Procurement Strategy and implementation
- 4. 2018-2020 Procurement Strategy and tender timelines

2015 - 2017 ARV Procurement Strategy

Challenges @ 2014

- Poor OTIF
- Relilable supply limited by API & Key Starting Material supply security and sourcing strategies
- Spend skewed to 1st line WHO-optimal regimens that is increasing with regimen rationalization
- Long tail of specialist adult and pediatric treatments with fragmented demand for small quantities
- Optimal products produced under license
- Small number manufacturing the broad range of needed products
- Short product life-cycle with high regulatory burden
- Some manufacturers not participating in the tenders for some products
- Competition for production between products of different margins

Procurement Strategy

- Maintain a sustainable and predictable supply of the full range of needed products
- De-risk supply of API & key starting materials (KSM).
- Improve OTIF and reduced lead times
- Competitive pricing through supplier engagement strategies
- Maintain sufficient supplier presence by understanding and supporting adequate returns to enable forward investment
- Encourage new entrants who can demonstrate sufficient value add to the program
- Quicker introduction of new products
- Encourage the development of products with longer shelf life and widespread country registration
- Use of longer-term contracting
- Implementation of a Vendor Managed Inventory mechanism to respond to stock-outs across the Global Fund grant portfolio
- The provision of increased visibility through better forecasting and a reduction in costs by streamlining administrative processes.

Active supplier performance management

- Performance is reviewed on a quarterly basis and adjusted annually
- Opportunity for incremental gain (or loss) of volume

Phase I Revised allocation base

Phase II Reallocate pooled volume

Phase III Implemention risk assessment

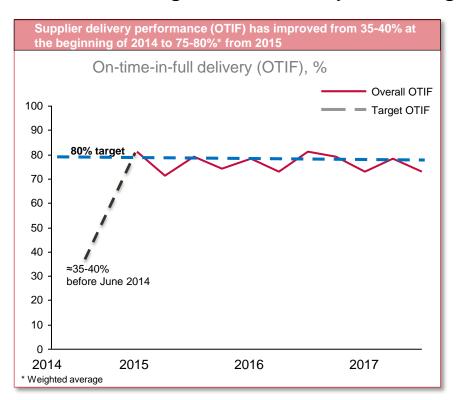
Phase IV Performance mgmt. & allocation adjustment

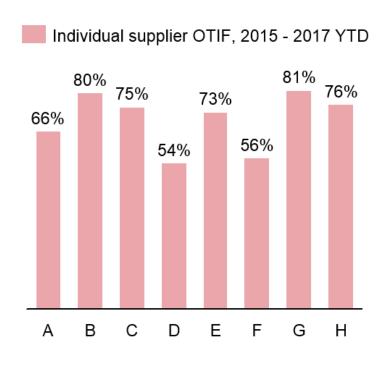
- Tender outcome informs the initial allocation base
- Supplier allocation base revised based on performance compared to target
- Volume pool created from under performance

- Reallocate pool volume through defined mechanism based on over-performance
- Range of risk factors considered including quality & other implementation constraints (pricing, registration footprint, long lead-times)
- Allocation finalized with risk mitigation plan

 Actual allocation may be adjusted according to performance and any emerging implementation challenges

Major improvements in reliable supply (OTIF) and a 4-5 week reduction in manufacturing lead-times by enabling more ocean freight





And many other outcomes

- Managed collaboration with suppliers through price strategy roadmaps enabling more for less
 - Substantial savings
 - Price of 1st line regimen down by 35% since 2014; 2nd line by 25%
- Clinical choices more in the forefront with price equalization of
 - alternate WHO recommended regimens: 1st & 2nd line
 - better formulations for children
- Rapid Supply Mechanism able to respond to ARV stock-outs in 12 countries
 - within 1 month from request to in-country delivery through vendor managed inventory
- Annual committed volumes met for each of 3 years
 - frequent sharing of forecast of upcoming orders at the line level
- Increased SMART engagement with other large buyers, partners and other Global Fund procurement channels
 - Terms extended to other buyers: PAHO and national governments
 - Procurement approaches evolving to include more non-price factors and stronger performance based contract implementation
 - Expanded scope of ARV Procurement Working Group: more partners & also adult products

Agenda

- 1. The Global Fund, Sourcing and the Pooled Procurement Mechanism
- 2. Implementing the 2nd phase of the Global Fund's Market Shaping Strategy
- 3. 2015-2017 ARV Procurement Strategy and implementation
- 4. 2018-2020 Procurement Strategy and tender timelines

Since the beginning of 2017, we have consulted with manufacturers, API suppliers, finished dosage form manufacturers and international partners

March:

- · AMDS meeting
- UNDP
- ARV Procurement Working Group
- Gates Foundation

July IAS

October/ November

UNITAID/USAID PAC meetings wih key partners

We are still listening through 1 December

April

- Q2 (& onwards) performance reviews with FPP
- DTG introduction Partners Meeting

November:

 Antiretroviral Medicines Procurement Strategy Manufacturers consultation

... which has provided insight to shape the ARV medicines strategy

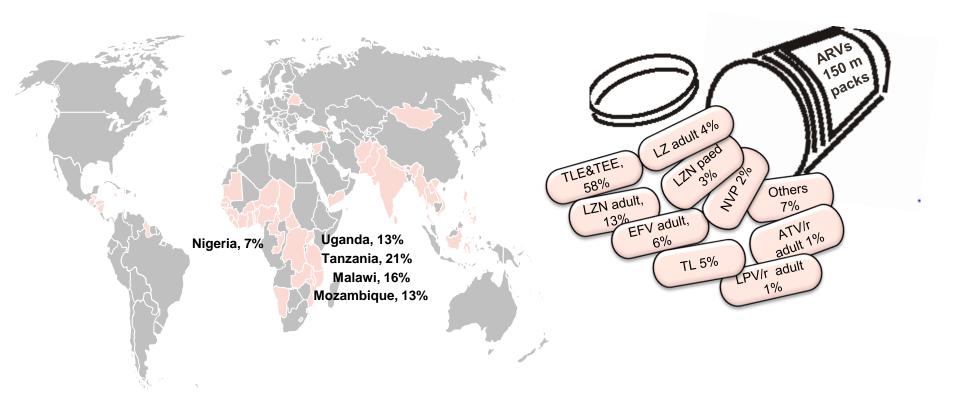
ARV Market Observations

- ARV FPP is a high volume and complex business with a number of challenges
- API make or buy decisions are fundamental to determining cost competitiveness, supply security and long term FPP strategy
- Mid and long term 1st line ARV products landscape is not yet clear
- Formulation capacity is not necessarily a bottleneck of the FPP capacity, but API/INT availability from the registered manufacturers can be the limiting factors of the continuous FPP supply
- KSM supply challenges become an emerging issue in terms of cost increase and supply continuity

ARV Market Observations

- Overall, competition is rising and product lifecycle is becoming shorter
- Varying level of understanding and maturity among suppliers
- External parties encouraging anti-competitive and cartel behavior
- Disingenuous lobbying concerning entitlement and equity distracts from overall market issues

150 million (monthly) packs delivered to 53 countries (2015-2017)



Afghanistan, Armenia, Belarus, Benin, Burkina Faso, Burundi, Cote d'Ivoire, Cameroon, Cape Verde, Central African Republic, Chad, Comoros. Congo, Congo DRC, Fiji, Gambia, Georgia, Ghana, Guatemala, Guinea, Guyana, Haiti, Honduras, India, Indonesia, Jamaica, Laos, Lesotho, Liberia, Malawi, Mauritania, Mongolia, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan. Philippines, Senegal, Sierra Leone, Sri Lanka, Syrian Arab Republic, Tanzania, Thailand, Timor-Leste, Togo, Uganda, Vietnam, Yemen, Zambia 31

Product segmentation & recognizing offering across different product sets

Antiretroviral and other strategic medicines used in HIV programs

Product set	Spend	Focus	Notes	
1. WHO preferred and alternative regimens	98%	Full scope and leverage of strategy objectives	30 mainstream adult and paediatric 1 st and 2 nd line products (including multi-month 90-packs) "Strategic" ARVs may include TLD; TLE-400; ATV/r; DRV/r; paed 4-in-1	
2. WHO limited use/ specialist products	2%	Availability across multiple procurement channels	across multiple allocation Communicate longer lead-times	
3. Related products used in HIV programs	low	Access and affordable pricing to Global Fund & other buyers	 Hepatitis B & C Preventative therapies Isoniazid cotrimoxazole/isoniazid/B6 Advanced HIV disease flucytosine amphotericin B: deoxcholate/liposomal pergolated liposomal doxorubicin 	

Objective: Increase access to all the needed WHO-recommended Anti-retroviral medicines and formulations at the optimum price whilst simultaneously maintaining a sustainable competitive market

- Sustainable supply
- Competitive pricing and affordability
- Availability and reliable delivery
- Quality and regulatory

Strategic objectives (supplier related aspects will be reflected in the tender scope, objectives & evaluation)

evaluation) Competitive pricing **Availability &** Sustainable supply & affordability Quality, regulatory & risks reliable delivery (Total Cost approach) Continued supply of all needed anti-Sustainable (lower) pricing Improved & sustained delivery More proactive management of quality and retroviral medicines other risks performance: moving OTIF target to Price roadmaps for strategic products De-risking API/KSM supply over 90% Broad national registration footprint Improve efficiencies by reducing SKUs, Accelerating the introduction and uptake cartonless packaging & customization More responsive supply Evolve ERP to be more strategically of new products and formulations **Detailed objectives** Shorter lead times including through Facilitating multi-month dispensing focussed Promote responsible procurement, innovative supply chain solutions Longer shelf life products allocated including good business practices, Mitigate risks VMI and stock visibility for low volume especially for later lifecycle products with through the supply chain Product quality & safety orders and stock outs falling sporadic demand Improved demand forecasting and Geographic diversity for API and FPP Further strengthen RSM (VMI) management Products with reduced volume Bundling of low and high volume products Encourage bids and make conditional packaging preferentially allocated once a allocations for strategic products for product is registered in country Coordinated procurement with other PQ/SRA approvals expected in the buvers for low volume/ niche products Require GS1 barcoding standards current calandar vear (aligned with USAID & South Africa) Alignment with UNITAID investments in Encourage new entrants with volumes new product introduction More proactive engagement on mostbeing available to include new entrants favoured nation clause where needed especially for products in the early lifecycle stages

- All ARVs under Global Fund direct management scope (including originators)
- Coordinate tender timelines with other big buvers
- Zero tolerance for anticompetitive behviour in the market

- Extending impact by including PAHO volumes in RFP
- Extension of terms to other public sector funders and buyers
- Leverage access to other strategic medicines used in HIV from same supplier base:
 - Hepatitis B & C
 - Preventative therapies
 - o Advanced HIV disease

- Benchmarking, monitoring and intervening on GF non-PPM procurement performance: price and non-price factors
- Extend principles of performance-based procurement to others especially Global Fund volumes
- Encourage participation in WHO collaborative and regional pooled

registration initiatives

- Strategic initiative funding to strengthen national capabilities for QA
- Sourcing decisions due to quality risk assessments extended beyond PPM
- Systemize and structure information sharing mechanisms on QA with partners and countries

Sustainable supply

 Continued supply of all needed anti-retroviral medicines De-risking API/KSM supply Detailed objectives • Accelerating the introduction and uptake of new products and formulations Promote responsible procurement, including good business practices, through the

supply chain Improved demand management

• Encourage bids and make conditional allocations for strategic products for PQ/SRA approvals expected in the current calandar year

needed especially for products in the early lifecycle stages

impact

Coordinate tender timelines with other big buyers

Zero tolerance for anticompetitive behviour in the market

• All ARVs under Global Fund direct management scope (including originators)

Encourage new entrants with volumes being available to include new entrants where

everaging impact

Competitive pricing & affordability (Total Cost approach)

- Sustainable (lower) pricing
- Price roadmaps for strategic products
- Improve efficiencies by reducing SKUs, cartonless packaging & customization
- Facilitating multi-month dispensing
- Longer shelf life products allocated especially for later lifecycle products with falling sporadic demand
- Products with reduced volume packaging preferentially allocated once a product is registered in country
- Require GS1 barcoding standards (aligned with USAID & South Africa)
- More proactive engagement on most-favoured nation clause
- Extending impact by including PAHO volumes in RFP
- Extension of terms to other public sector funders and buyers
- Leverage access to other strategic medicines used in HIV from same supplier base:
 - Hepatitis B & C; preventative therapies; advanced HIV disease

Availability & reliable delivery

- Improved & sustained delivery performance: moving OTIF target to over 90%
- More responsive supply
 - Shorter lead times including through innovative supply chain solutions
 - VMI and stock visibility for low volume orders and stock outs
 - Further strengthen RSM (VMI)
- Bundling of low and high volume products
- Coordinated procurement with other buyers for low volume/ niche products
- Alignment with UNITAID investments in new product introduction
- Benchmarking, monitoring and intervening on GF non-PPM procurement performance: price and non-price factors
- Extend principles of performance-based procurement to others especially Global Fund volumes

Detailed objectives

Quality, regulatory & risks

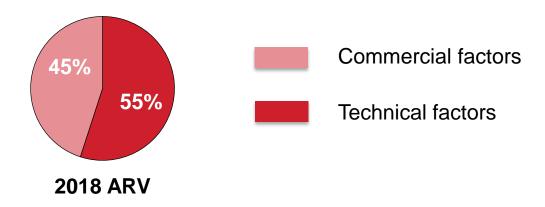
- More proactive management of quality and other risks
- Broad national registration footprint
- Evolve ERP to be more strategically focussed
- Mitigate risks
 - Product quality & safety
- Geographic diversity for API and FPP

everaging impact

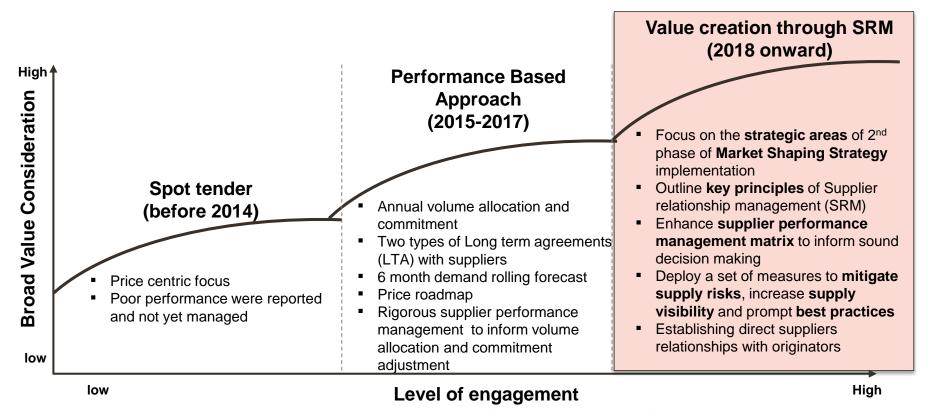
- Encourage participation in WHO collaborative and regional pooled registration initiatives
- Strategic initiative funding to strengthen national capabilities for QA
- Sourcing decisions due to quality risk assessments extended beyond PPM
- Systemize and structure information sharing mechanisms on QA with partners and countries

Global Fund will offer...

- 3 years framework agreement with option for extension with a process for new entrants/products
- Tender evaluation will comprise of 45% of commercial factors and 55% of technical factors



Evolution of the implementation of the ARV strategy with emphasis on value creation through Supplier Relationship Management (SRM)



The principles of our approach

Tender Eligibility

- Related firms may only submit one bid
- 2. Global Fund Quality Assurance Policy

Performance Principles

- 1. Volumes allocations will managed throughout implementation via a performance based approach (incentive volume pool)
- 2. Supply security will be a focus area
- 3. OTIF and Responsiveness vs promised lead times will be a factor in performance based approach
- Global Fund values responsible procurement and will factor this during implementation

Key measures to mitigate supply risks, increase supply visibility and prompt best practices

Scope:

Some of the measures may only apply for some products

Reporting:

Reports required on annual, quarterly or monthly basis depending on the specific measure

Confidentiality:

Commercially sensitive information will be kept confidential

Key measures – Most Favored Nation (MFN) Clause

- MFN clause in contract supports our efforts to ensure best value for Global Fund
- We will proactively manage the principles and implementation of the MFN clause
- We will require each supplier to inform the Global Fund their price bids for tender submissions
- These submissions would not automatically trigger the MFN clause, but supplier are required to notify the Global Fund within 7 days of tender award
- This notification will trigger a decision from the Global Fund

Key measures – Planned Capacity

- In order to smoothly implement the transition to new products we will require the reporting of future planned capacity for selected products
- This will include specifically reporting on capacity for a rolling 6-12 month period
- In addition to planned capacity we will require the reporting of any foreseen capacity constraints within that same time 6-12 month time frame

Active Pharmactutiacl **Key Starting Materials** Intermediate (INT) Ingredients (API) KSM may have impact Registered Intermediate (INT) and APIs in the FPP Scope on supplier security and dossier cost Name /CAS number Name /CAS number Information Supplier information Supplier information including current registered supplier and required suppliers are in the process with indicative approval timeline others others Copy of dossier with regards to the route of synthesis of the API (DMF open part); registered Supporting INT and API manufacturers in FPP the dossier: documents

Note: We may or may not share information with RSA and USG under mutually agreed confidentiality terms

Varation approval with regards to new API/INT suppliers or new INTs

Key measures – production lead time and responsiveness

Product sets

 WHO preferred and alternative regimens WHO limited use/ specialist products

Information required

- Promised lead times per product
- Actual lead times per product purchase order

Product set measurement objective

- Shorten lead times and increase overall responsives; key focus area of measure
- Maintain reliable lead times for planning purposes; shorten where possible

Following the tender evaluation process, we will focus our efforts on generating value through SRM during the implementation phase of the contracting cycle

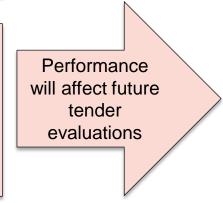
Tender Evaluation

- Collect information
- Valid information
- Evaluation
- Negotiation
- Award



Contract Implementation

- Performance based allocation
- Regular reporting measures
- Risk assessment
- Supplier onsite monitoring
- Ongoing dialogues



Phase I: Tender Launch (January-February 2018)

Phase II: Submissions and Evaluations (March-May 2018)

Phase III: Evaluations (June 2018) Phase IV: Contracting (June-July 2018)

- RFP on Platform
- Two rounds of questions/answers

Round 1: Bid submissions and initial evaluation

Round 2: Evaluation Workshop, including face to face negotiations (including price roadmaps/value levers)

- Final Evaluations
- Internal Approvals
- Award

 Contract finalizations and signing

Request for Proposal Preparation

- 1. RFP Documentation will be available through the Sourcing Platform and posted on the Global Fund website for downloading
- 2. There may be a number of documents
 - Main RFP document
 - Schedules
 - Certificate of Conformance
 - Confidentiality agreement
 - Draft Framework Agreement
- 3. To submit a complete response to RFP bidders will need to comply with all requirements as specified
- 4. We will request a significant amount of information. We will clearly advise which will be evaluated and which are for implementation purposes only

More information: https://www.theglobalfund.org/en/sourcing-management/health-products/

