Antiretroviral & other selected medicines used in HIV programs

Establishment of multi-year Framework Agreements for procurement: 2018-2021

External briefing

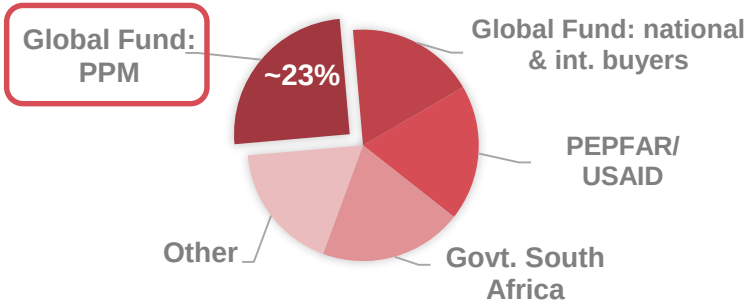
19 July 2018

The Global Fund

Establishing multiyear performance-based ARV Framework Agreements is a key lever in the implementation of our Market Shaping Strategy

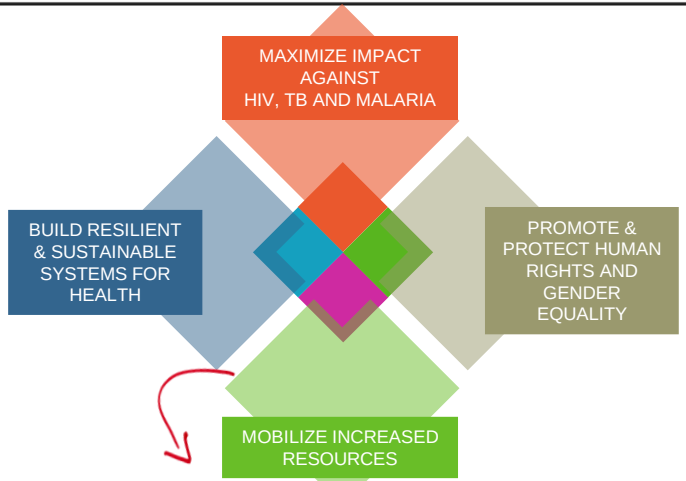
TENDER SCOPE REPRESENTS ~23% OF THE ESTIMATED ANNUAL LMIC SPEND ON ARVs…

Estimated Annual LMIC Spend on ARVs, by source of funding



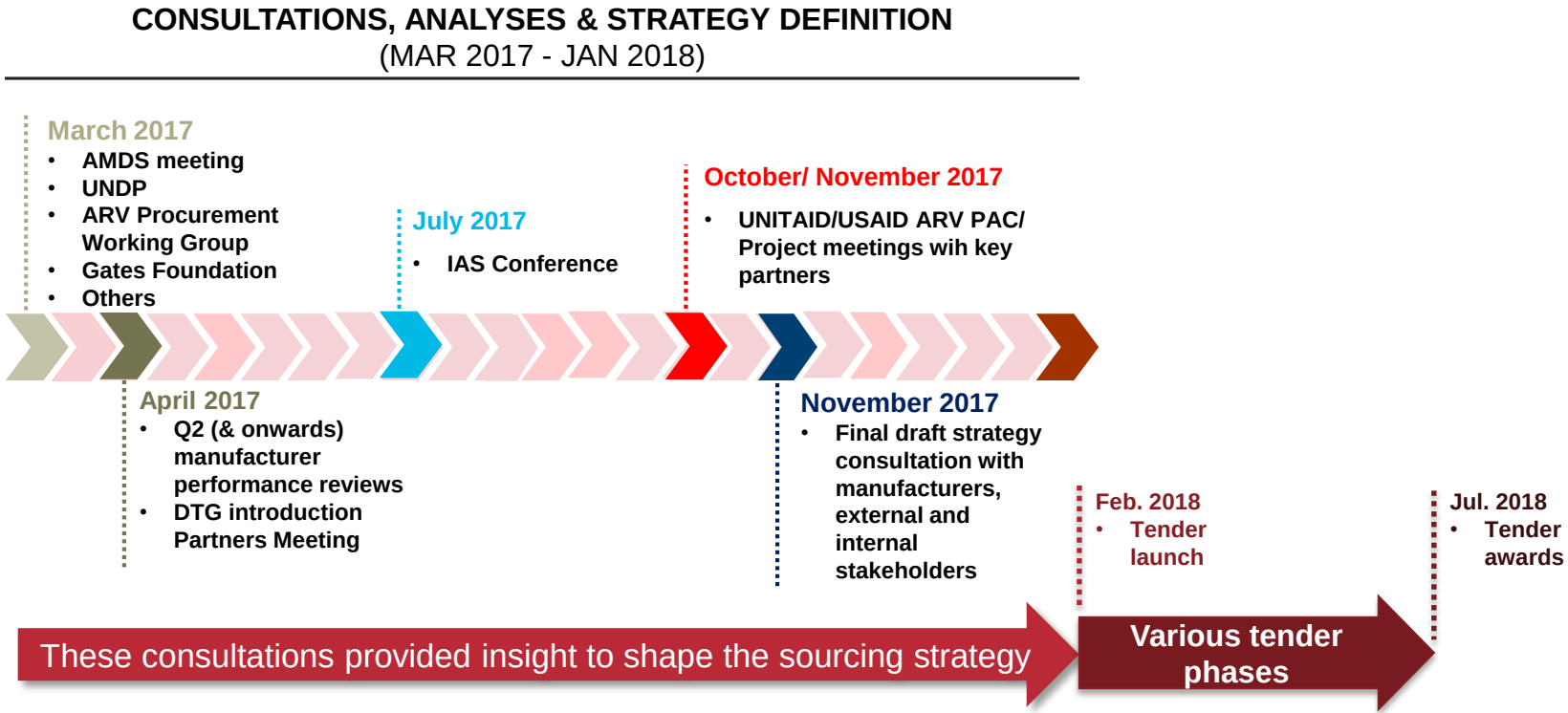
Total = US$ ~1.5 billion

… ENABLING A MARKET SHAPING ROLE WITHIN & BEYOND GF SPEND



- c Implement and partner on market shaping efforts that increase access to affordable, quality-assured key medicines & technologies
- d Support efforts to stimulate innovation & facilitate the rapid introduction and scale-up of cost-effective health technologies & implementation models

Since early 2017, we have consulted with manufacturers and various partners to inform our strategy development prior to the tender launch on 1 February 2018



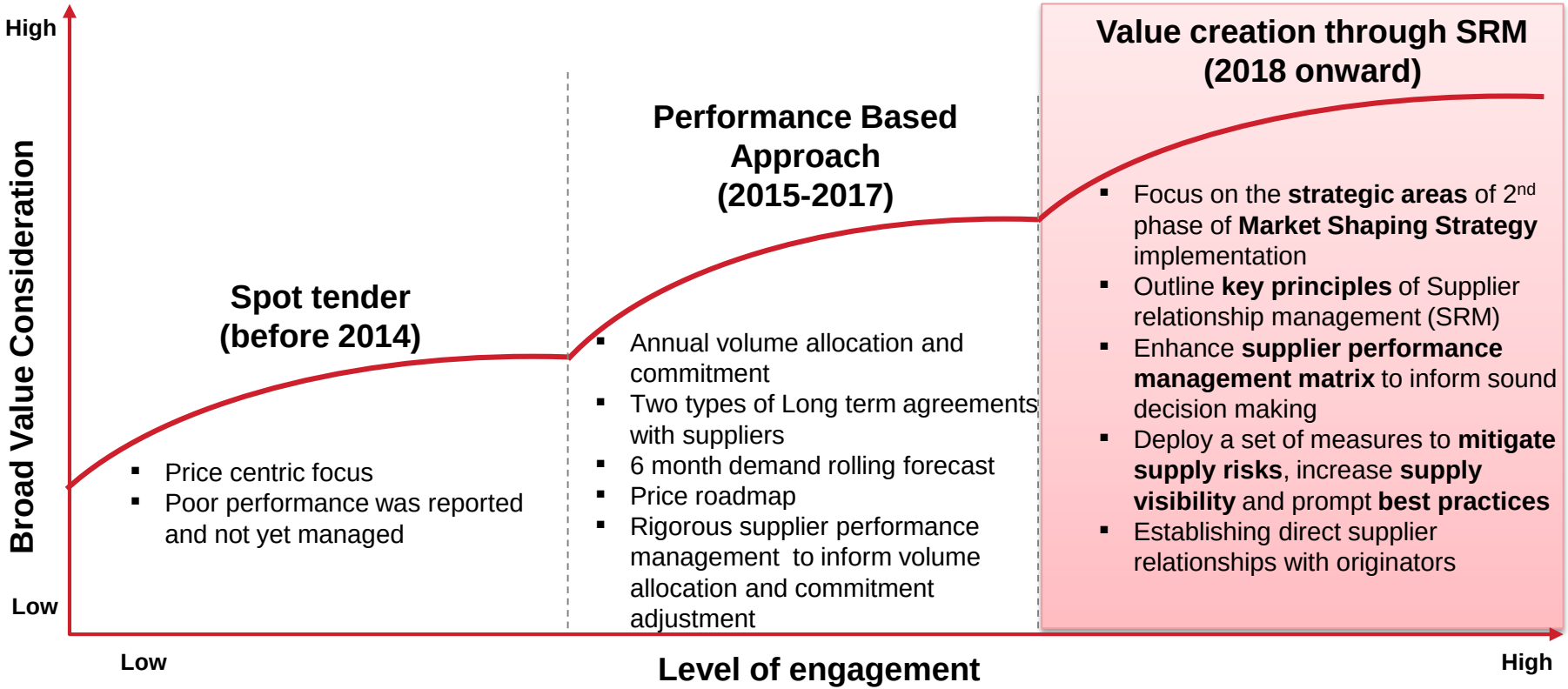
AMDS = AIDS Medicines and Diagnostic Service meeting convened by WHO; DTG = dolutegravir, a new ARV; IAS = International AIDS Society Meeting; PAC = Project Advisory Committee Co-chaired by WHO

ARV Procurement strategy and risk mitigation approach builds on key market insights identified from consultations and analyses in 2017

- **High volume and complex business**, with a number of specific challenges
- Active ingredient (API) **"make or buy" decisions** fundamental to determining cost competitiveness, supply security and long term strategy
- **Key Starting Material (KSM) supply challenges** are becoming an emerging issue in terms of cost and supply continuity
- Formulation capacity is not necessarily a capacity bottleneck, but **availability of API and intermediates** can be a limiting factor
- Mid- and long-term 1st line ARV **product landscape is not yet clear**
- Competition is rising, and the **product lifecycle is becoming shorter**
- Signals of **anti-competitive and cartel behaviors** including lobbying through third parties

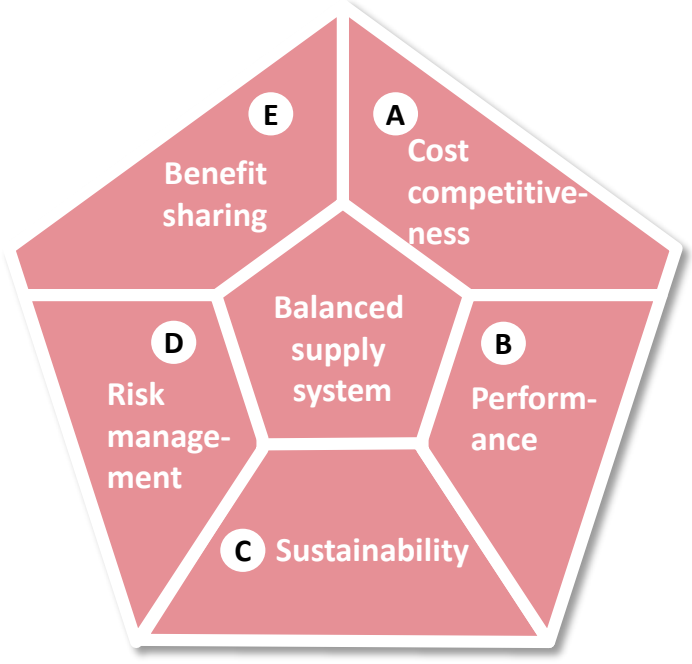
Market insights informed ARV strategy development and risk mitigation approach

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



The Antiretroviral Procurement Strategy 2018-2021 is anchored in the balanced supply system of the Global Fund's Market Shaping Strategy

Increase access to all the needed WHO-recommended antiretroviral medicines and formulations, at the optimum price, whilst simultaneously maintaining a sustainable competitive market



A

- Providing quality assured products **at the lowest possible affordable and sustainable price** to reach the maximum number of patients
- **Reducing price volatility** and eliminating predatory pricing
- Operationalizing **value creation levers**

B

- Supplying product **timely and in full** (increasing target from 80% to 90%)
- Incentivizing the **introduction of new regimens and better formulations**

C

- **Supporting existing and new suppliers** to ensure **sufficient supply of all the needed products and mitigate geographic supply risks**
- Investing in suppliers with **responsible and sustainable practices**

D

- Maintaining a **well-diversified supplier base**
- Meeting the **Global Fund and national quality** requirements
- Mitigating **implementation risks** including quality & supply security risks

E

- Publishing **reference prices**
- **Building capabilities** and implementing rapid supply mechanisms
- Providing **access of terms to other buyers**
- Further incentivizing **broad national registration footprints**
- Leveraging volumes to **improve access to other non-ARV medicines used in HIV programs**

Detailed 2018 Procurement Strategy objectives underpinned the tender process

	Sustainable supply	Competitive pricing & affordability (Total Cost approach)	Availability & reliable delivery	Quality, regulatory & risks
Detailed objectives	▪ Continued supply of all needed anti-retroviral medicines ▪ De-risking API/KSM supply ▪ Accelerating the introduction and uptake of new products and formulations ▪ Promote responsible procurement, including good business practices, through the supply chain ▪ Improved demand forecasting and management ▪ Encourage bids and make conditional allocations for strategic products for WHO PQ/SRA approvals expected in the current calandar year ▪ Encourage new entrants with volumes being available to include new entrants where needed, especially for products in the early lifecycle stages	▪ 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 a country ▪ Require GS1 barcoding standards (aligned with USAID & South Africa) ▪ More proactive engagement on most-favoured nation clause	▪ 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	▪ More proactive management of quality and other risks ▪ Broad national registration footprints ▪ Evolve ERP to be more strategically focussed ▪ Mitigate risks ○ Product quality & safety ○ Geographic diversity for API and FPP
Leveraging impact	▪ All ARVs under Global Fund direct management scope (including originators) ▪ Coordinate tender timelines with other big buyers ▪ 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 ○ 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

API = active pharmaceutical ingredient; ERP = Expert Review Panel; FPP = finished pharmaceutical product manufacturer; KSM = key starting material; OTIF = on time in full; PPM = Global Fund's Pooled Procurement Mechanism; PQ = pre-qualification; QA = quality assurance; RFP = request for proposal; RSM = rapid supply mechanism; SRA = stringent regulatory authority; VMI = vendor-managed inventory

Products were segmented into sets, with multi-set offerings valued in support of strategic objectives

Antiretroviral and other strategic medicines used in HIV programs

Product set		Spend	Focus	Notes
1	WHO preferred and alternative regimens	98% of ARV spend	Full scope and leverage of strategy objectives	▪ 30 mainstream adult and paediatric 1st and 2nd 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 a) Low/medium volume b) Very low volume c) Not procured 2016-17	2% of ARV spend	Availability across multiple procurement channels	▪ Panel of suppliers ▪ Utilize the multiagency ARV procurement working group to inform allocation ▪ Communicate longer lead-times ▪ Disaggregate in OTIF measurement and performance management

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

The full set of the performance criteria will be applied for the annual re-allocations

- Commercial offers for 2019 including Base Price and advanced Purchase Order discount; consideration of total landed cost
- Price roadmap if applicable
- Product and country registration approval coverage
- Supply Performance: OTIF, Responsiveness (Lead Time)
- Supply security and reporting
- Projects to deliver on the strategic objectives if applicable
- Production footprint in sub-Saharan Africa progress monitoring
- Compliance on the Most Favored Nation (MFN) clause
- Other past and foreseen implementation challenges

2018 annual performance reviews: 15-22 February 2019

OTIF = on time in full

Commercial and non-commercial benefits

→ ***Access to and reliable availability of both currently needed and new products, now and throughout implementation***

Improved access through sustainable supply

- US$ 90 million savings per year (US$ 324 million savings over contract period)
- 1st line regimens < US$ 72 /person/ year in 2nd half 2018 and lower through implementation

- Access to all needed products through bundling high and low volume products and multiagency coordinated procurement of low volume products with other buyers
- Clear entry route for new products and new suppliers
- Optimal number of manufacturers especially for 1st line regimens
- Assessing, mitigating and managing API/KSM supply risks
- 4 additional ARV suppliers compared to 2014 (broadened supply base, greater geographic diversification)
- Manufacturers for products with longer shelf life products allocated, especially for declining/legacy phase
- Significant potential to: (a) further drive shorter lead-times and efficiencies with manufacturers and (b) better manage demand and specifications

- Driving manufacturer OTIF from 80% to 90%
- Strengthened offering for the rapid supply mechanism for emergency needs

Sharing benefits and responsible procurement

- Supporting transition through leveraging PAHO volume
- Providing access to other buyers of the same terms
- Publishing reference prices (benchmarking)
- Including better business practices through the supply chain
- Packaging reduction (freight cost and environmental impact)

Strengthened reporting for performance management: 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

Most Favored Nation (MFN) Clause

- MFN clause in contract supports our efforts to ensure best value for Global Fund

Planned Capacity

Production lead time and responsiveness

Upstream supply visibility

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

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

We look forward to implementing this procurement strategy and delivering affordable and quality-assured medicines for people living with HIV/AIDS.