Antiretroviral & other selected medicines used in HIV programs

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

External briefing

19 July 2018
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:
- Global Fund: PPM ~23%
- Global Fund: national & int. buyers
- PEPFAR/USAID
- Govt. South Africa
- Other

Total = US$ ~1.5 billion

... ENABLING A MARKET SHAPING ROLE WITHIN & BEYOND GF SPEND

- MAXIMIZE IMPACT AGAINST HIV, TB AND MALARIA
- BUILD RESILIENT & SUSTAINABLE SYSTEMS FOR HEALTH
- PROMOTE & PROTECT HUMAN RIGHTS AND GENDER EQUALITY
- MOBILIZE INCREASED RESOURCES

- Implement and partner on market shaping efforts that increase access to affordable, quality-assured key medicines & technologies
- 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.

CONSULTATIONS, ANALYSES & STRATEGY DEFINITION
(MAR 2017 - JAN 2018)

March 2017
- AMDS meeting
- UNDP
- ARV Procurement Working Group
- Gates Foundation
- Others

April 2017
- Q2 (& onwards) manufacturer performance reviews
- DTG introduction Partners Meeting

July 2017
- IAS Conference

October/November 2017
- UNITAID/USAID ARV PAC/Project meetings with key partners

November 2017
- Final draft strategy consultation with manufacturers, external and internal stakeholders

February 2018
- Tender launch

Various tender phases

July 2018
- Tender awards

These consultations provided insight to shape the sourcing strategy.

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)

**Performance Based Approach (2015-2017)**
- Annual volume allocation and commitment
- Two types of Long term agreements with suppliers
- 6 month demand rolling forecast
- Price roadmap
- Rigorous supplier performance management to inform volume allocation and commitment adjustment
- Price centric focus
- Poor performance was reported and not yet managed

**Level of engagement**
- Low
- Spot tender (before 2014)
- High

**Value creation through SRM (2018 onward)**
- Focus on the strategic areas of 2nd phase of Market Shaping Strategy implementation
- Outline key principles of Supplier relationship management (SRM)
- Enhance supplier performance management matrix to inform sound decision making
- Deploy a set of measures to mitigate supply risks, increase supply visibility and prompt best practices
- Establishing direct supplier relationships with originators
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

- 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

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

- 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

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

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### Detailed 2018 Procurement Strategy objectives underpinned the tender process

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

| All ARVs under Global Fund direct management scope (including originators) | Extending impact by including PAHO volumes in RFP | Benchmarking, monitoring and intervening on GF non-PPM procurement performance: price and non-price factors | Encourage participation in WHO collaborative and regional pooled registration initiatives |
| Coordinate tender timelines with other big buyers | Extension of terms to other public sector funders and buyers | Extend principles of performance-based procurement to others, especially Global Fund volumes | Strategic initiative funding to strengthen national capabilities for QA |
| Zero tolerance for anticompetitive behaviour in the market | Leverage access to other strategic medicines used in HIV from same supplier base: | Sourcing decisions due to quality risk assessments extended beyond PPM | Systemize and structure information sharing mechanisms on QA with partners and countries |
| | ▪ Hepatitis B & C | |
| | ▪ Preventative therapies | |
| | ▪ Advanced HIV disease | |

*API = active pharmaceutical ingredient; ERP = Expert Review Panel; FFP = 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

<table>
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<th>Antiretroviral and other strategic medicines used in HIV programs</th>
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<td><strong>Product set</strong></td>
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| 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 | 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 |
| a) Low/medium volume | b) Very low volume | c) Not procured 2016-17 |
| 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
### 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

#### Sharing benefits and responsible procurement

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

- 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)

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