Procurement and Quality Assurance Updates

Joint meeting UNICEF, WHO, UNFPA with manufacturers and suppliers

19 September 2017
Sophie Logez, Health Product Management Hub

The Global Fund
Outline

• Overview of the Global Fund in key facts
• Update on the Market Shaping activities and Pooled Procurement Mechanism
• Revised QA policy for diagnostic products
The Global Fund

A 21st-century partnership organization to accelerate the end of HIV, tuberculosis and malaria as epidemics

Founded in 2002, the Global Fund is the leading contributor of resources in the fight against AIDS, tuberculosis and malaria. It mobilizes and invests nearly US$4 billion a year to support countries and communities most in need. It has an active portfolio of over 430 active grants in over 100 countries, implemented by local experts.
Number of Lives saved through Global Fund-supported Programs

Breakdown of investments by implementer type (active grants)

Breakdown of investments by region (active grants)
Successful replenishment for implementing the Global Fund Strategy in 2018-2020

- Fifth Replenishment Conference in Canada: September 2016
- Donors pledged over US$ 12.9 billion for the next three years
- Nearly US$ 1 billion more than the previous replenishment conference in 2013
- Countries were informed of their funding envelopes in December 2016 to take them through 2020

<table>
<thead>
<tr>
<th>Funding envelopes</th>
<th>Amount</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV/AIDS</td>
<td>5,098</td>
<td>105</td>
</tr>
<tr>
<td>Malaria</td>
<td>3,227</td>
<td>71</td>
</tr>
<tr>
<td>TB</td>
<td>1,842</td>
<td>98</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Funding envelopes</th>
<th>Amount</th>
<th>%</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health products</td>
<td>40-60%</td>
<td>40-60%</td>
<td></td>
</tr>
</tbody>
</table>
The Global Public Health Market

The **Global Public Health market amounts to ~ USD 30.7 billion** annually of which the Global Fund is one of the largest players.

**Global Public Health market by disease (2013)**

- **USD 30.7 billion**
- **Global Fund related diseases**

- Malaria: 6.1%
- TB: 1.8%
- Maternal/Newborn: 6.5%
- Other: 7.7%
- Unallocable: 1.3%
- Non-communicable: 6.1%
- HIV: 1.3%

**Global Public Health market by donor (2013)**

- **USD 30.7 billion**
- **Global Fund related diseases**

- USA: 7.4%
- NGOs: 4.9%
- WHO: 2.2%
- UN agencies: 9.6%
- Others: 13%

SOURCE: http://vizhub.healthdata.org/fgh/

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

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**STRATEGIC ENABLERS:** Innovate and differentiate along the development continuum + Support mutually accountable partnerships

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

<table>
<thead>
<tr>
<th>Funding</th>
<th>Procurement Services Agent</th>
<th>Recipient Country</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA</td>
<td>PSA</td>
<td>PR</td>
<td>Products</td>
</tr>
<tr>
<td>PR</td>
<td>PR</td>
<td>PR</td>
<td>Products</td>
</tr>
</tbody>
</table>

Pooled Procurement Mechanism (PPM)

National Procurement Mechanisms

Other Procurement Agents; Global Drug Facility (TB)
The Global Fund has a set of tools it can use to shape markets

<table>
<thead>
<tr>
<th>Price &amp; Quality Reporting</th>
<th>Quality Assurance policies</th>
<th>Pooled Procurement Mechanism / wambo.org</th>
<th>Revolving fund</th>
<th>PSM policies</th>
<th>Guidance from Health Product Managers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Public database with transaction-level data on Global Fund-financed procurements of core health products, after delivery</td>
<td>• Policies to assure quality of pharmaceutical and diagnostic products financed by the Global Fund</td>
<td>• Mechanism to pool procurement of health products. Can be leveraged toward market shaping objectives, reduces grant implementation risks</td>
<td>• Small revolving fund that provides working capital to scale up new products</td>
<td>• Legal obligations and best practices that recipients should apply in procuring Global Fund-financed products</td>
<td>• Country Team members responsible for PSM topics throughout grant-making and implementation</td>
</tr>
</tbody>
</table>
Pooled Procurement Mechanism health product spend 2016

PPM spend is approximately 55% of the total Global Fund health product spend

“Core products”
- represent +/- 85% of procurement value
- between 25% & 70% of procurements financed by the Global Fund are channeled through PPM (depending on the category)

Source: Financial data from PPM 2016 approved orders

Acronyms:
- ARVs: Antiretroviral drugs
- ACTs: Artemisinin Combination Therapy
- LLINs: Long-Lasting Insecticide treated nets
- RDTs: Rapid Diagnostic Tests
- Lab: Laboratory equipment and supplies, medical consumables, etc.
Evolution of the Pooled Procurement Mechanism to implement the Market Shaping Strategy

Phase I
- Price and Lead time based
- Spot tendering
- Minimal performance monitoring

Phase II
- Building Market Knowledge, including through supplier visits
- Understanding cost
- First Framework Agreements
- Simple KPIs
- Performance-based contracting
- Supplier Relationship Management
- Improved data management
- Value creation by optimizing demand

Phase III
- Outcome-based contracting
- Cross-supplier collaboration
- A focus on responsible procurement
- Wambo.org implementation

Legacy
- Value creation

Tender and Framework Agreement Profiles
- LLIN
- ACT/antimalarials
- ARV

Timeline:
- 2012
- 2014
- 2016
Maximizing Value through Supplier Relationship Management

Previous approaches only focused on the price value lever. Value creation has been extended across a range of levers which will increase in importance as cost is optimized.

- Managed periodically by Tender
- Largely Ignored

Previously

<table>
<thead>
<tr>
<th>Price</th>
<th>Other Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower</td>
<td></td>
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</tbody>
</table>

Now

<table>
<thead>
<tr>
<th>Price</th>
<th>Other Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher</td>
<td></td>
</tr>
</tbody>
</table>

- Performance
- Projects to support objectives
- Process improvement

Ongoing management

Security of Value Created

Lower

Higher
The Global Fund has introduced a more balanced supply system based on 5 elements to improve performance:

- **A. Cost Competitiveness**
  - Providing products at the lowest possible affordable and sustainable price to reach the maximum number of patients
  - Reducing price volatility and eliminating predatory pricing

- **B. Performance**
  - Supplying product timely and in full (OTIF)
  - Incentivizing suppliers to introduce better formulations

- **C. Sustainability**
  - Supporting new suppliers to ensure sufficient supply and mitigate geographic supply risks
  - Investing in suppliers with sustainable manufacturing practices

- **D. Risk Management**
  - Maintaining well-diversified supplier base
  - Meeting The Global Fund and national quality requirements
  - Mitigating implementation risks

- **E. Benefit Sharing**
  - Publishing reference prices
  - Building capacity and implementing rapid supply mechanisms
PPM underwriting wambo.org – wambo.org as the “face of PPM”

All health products in wambo.org are managed through either PPM framework agreements; Procurement Service Agent (PSA) catalogues; or Partner MoUs. Performance is managed by PPM.

Added value of wambo.org – some key aspects

Country ownership
> Flexible approval chains mirror all different in-country processes
> One more tool available to in-country procurement professionals, empowering them; In synergy with, not in lieu of, capacity building

Transparency and auditability
> Complete audit trail automatically generated and stored
> Immediate visibility to country teams, LFAs, empowering preventative controls

Potential to accelerate scale-up of innovative products
> Partnership with UNITAID
> “Levers” in the platform inform the PR about certain characteristics of products at key moments in the P2P process

Key enablers:
1. Eligibility of Supplier – QA policy
2. Selection of Supplier – Global Tender
3. Negotiated Prices and conditions – Framework Agreement
4. Order processing - Allocation to supplier and volume
Sourcing & procurement of health products

- Category information
- Supply & demand information
- Previous RFP documentation
- Reference pricing

Transaction level data: procured & delivered
Price and Quality Reporting - PQR

Price & Quality Reporting

Price & Quality Reporting is an online database that collects data on purchases made by Global Fund supported programs, including:

- Medicines (ARVs, ACTs, etc.)
- Health products (nets, laboratory reagents, etc.)
- Equipment (microscopes, diagnostic machines, etc.)
- Other supplies

As part of its effort to be as transparent as possible, the Global Fund publishes this data, including:

- Supplier or manufacturer data
- Dosage
- Unit cost
- Packaging information
- Shipping or other related costs
- Total cost of the transaction

 Anyone can access the Price & Quality Reporting database. Registration is necessary only if you will be entering data (such as Principal Recipients or Local Fund Agents).

Reports can easily be downloaded from the database, and are based on data updated daily.

- PQR Login
- Price Reference Report: A summary of main international reference prices and recent market data
- Transaction Summary: A listing of transactions, either the complete set or a requested subset
- DRS Cutaways

http://www.theglobalfund.org/en/pqr/
37th Board Meeting
Revisions to the Quality Assurance Policy for Diagnostics Products
For Board Decision

GF/B37/06, Kigali, Rwanda, 03-04 May 2017

This document is part of an internal deliberative process of the Global Fund and as such cannot be made public until after the Board Meeting.
Revised Global Fund Quality Assurance Policy for Diagnostic Products
37th Board meeting, May 2017

The development of the QA Policy
– developed in 2009 with experts support (regulators, association of manufacturers, WHO)
– approved by the Board in 2010 based on the Market Dynamics Committee recommendation
– updated in 2014, noting needs for future revisions for the phase-in of specific products

The QA Policy is based on 3 sets of requirements
– Clinical standards: ensure consistency with WHO guidance and national guidelines
– Quality standards: establish minimum standards and additional standards for specific products
– Quality of use: refer to guidance for ensuring quality use and adequate outcome

Rationale for proposed policy revisions
– Alignment with new or updated WHO guidelines for key products
– Alignment with the Global Fund Policy on co-infection and co-morbidities (COIMs)
### Revisions related to changes/updates to normative guidance and policies

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
</table>
| **HIV self testing**            | WHO guidelines encourage countries to pilot/explore self-testing to scale up testing  
Global Fund supports operational research on HIV Self testing  
Proposed revisions to the policy include specific quality requirements for HIV self testing RDTs (section 8)                                                                                                            |
| **Procurement eligibility mRDTs** | As of 31 Dec 2017, WHO Prequalification Programme will determine procurement eligibility  
Proposed revisions to the policy reflect alignment with these changes (section 8)                                                                                                                                                                                                 |
| **PMS on IVDs**                 | In 2015, WHO guidance on Post-Market Surveillance of IVDs that describe measures to ensure on-going compliance of Diagnostics  
Proposed revisions to the policy include this WHO guidance (section 13)                                                                                                                                                                                                               |
| **G6PD testing**                | WHO recommends G6PD testing in regions with high prevalence of G6PD deficiency prior to primaquine treatment. Proposed revisions include quality requirements for G6PD tests                                                                                                                                                  |
| **Co-infections**               | Proposed revisions include quality requirements for In-vitro diagnostics (IVDs) for Hepatitis B and C, Syphilis co-infections (section 8)                                                                                                                                                                                                  |
HIV Self Testing compliant with the revised Policy

https://www.theglobalfund.org/media/5878/psm_productshiv-who_list_en.pdf

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product Name</th>
<th>Number of tests per kit</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Manufacturer</th>
<th>Analyte</th>
<th>Spécimen Type</th>
<th>Shelf Life</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OnaQuick HIV Self Test</td>
<td>50</td>
<td>99.02%</td>
<td>100.00%</td>
<td>OnaQuick Technologies Inc., Bangkok, Thailand</td>
<td>HIV 1/2 antibodies</td>
<td>Oral Fluid</td>
<td>24 Months 2 to 30°C</td>
<td>ERFD until 17th February 2016</td>
</tr>
<tr>
<td></td>
<td>On Request</td>
<td>On Request</td>
<td>On Request</td>
<td>On Request</td>
<td>On Request</td>
<td>Whole Blood</td>
<td>On Request</td>
<td>VRFD until 30th June 2018</td>
<td></td>
</tr>
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</table>

N/A: NOT APPLICABLE
HIV Co-infections compliant with the revised policy
https://www.theglobalfund.org/media/5878/psm_productshiv-who_list_en.pdf
Hepatitis C, Syphilis, Hepatitis B

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Test Name</th>
<th>Initial Sensitivity</th>
<th>Final Specificity</th>
<th>Manufacturer</th>
<th>Type</th>
<th>Specimen Type</th>
<th>Storage Temperature</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>04HIVos</td>
<td>SD BIOLINE HIV/Syphilis Duo</td>
<td>25</td>
<td>99.9%</td>
<td>99.9%</td>
<td>Standard Diagnostics, Inc. (Diliman, Philippines, Korea)</td>
<td>HIV/Syphilis Serum/Plasma</td>
<td>4-30°C</td>
<td>WHO PG</td>
</tr>
<tr>
<td>07HIVos</td>
<td>SD BIOLINE HIV/Syphilis 3.0</td>
<td>90</td>
<td>99.9%</td>
<td>99.9%</td>
<td>Standard Diagnostics, Inc. (Diliman, Philippines, Korea)</td>
<td>Syphilis Serum/Plasma</td>
<td>4-30°C</td>
<td>EP</td>
</tr>
<tr>
<td>09HIVos</td>
<td>SD BIOLINE HIV/Syphilis 5.0</td>
<td>90</td>
<td>99.9%</td>
<td>99.9%</td>
<td>Standard Diagnostics, Inc. (Diliman, Philippines, Korea)</td>
<td>Syphilis Serum/Plasma</td>
<td>4-30°C</td>
<td>EP</td>
</tr>
<tr>
<td>10HIVos</td>
<td>SD BIOLINE HIV/Syphilis 2.0</td>
<td>90</td>
<td>99.9%</td>
<td>99.9%</td>
<td>Standard Diagnostics, Inc. (Diliman, Philippines, Korea)</td>
<td>Syphilis Serum/Plasma</td>
<td>4-30°C</td>
<td>WHO PG</td>
</tr>
<tr>
<td>10010294</td>
<td>Genzyme HCV Rapid Test Kit</td>
<td>90</td>
<td>99.9%</td>
<td>99.9%</td>
<td>Genzyme Technologies (Singapore, USA)</td>
<td>HCV antibody detection</td>
<td>Serum/Plasma</td>
<td>WHO PG</td>
</tr>
</tbody>
</table>

N/A = NOT APPLICABLE
Quality Assurance Information

Sourcing & Management of Health Products

Overview
Updates
Information for Suppliers
Policies & Principles
Quality Assurance
- Medicines
- Diagnostic Products
Other Products
Expert Review Panel
Information Notice
Price & Quality Reporting
Sourcing & Procurement of Health Products
Implementer Support

Diagnostic Products

The Global Fund's quality assurance policy for diagnostic products applies to all durable and non-durable in-vitro diagnostics, imaging equipment and microscopes used in Global Fund-supported programs for diagnosis, screening, surveillance or monitoring purposes.

- Quality Assurance Policy for Diagnostic Products
download in English

Best practices in the procurement of diagnostic products include:

1. Complying with World Health Organization guidance on storage and distribution
2. Ensuring that products are used by appropriately trained and suitably qualified persons only
3. Using best efforts to participate in suitable external quality assessment programs
4. Using best efforts to organize calibration and maintenance of relevant equipment
5. Using best efforts to develop systematic reporting of product defects
6. Program laboratory investments with a focus on viral load testing

The cost of quality assurance and quality monitoring measures must be included in grant budgets. Those responsible for the procurement of diagnostic processes (in most cases, this will be the Principal Recipient of the grant) should ensure that they observe all applicable laws and regulations. In addition, World Health Organization guidelines or national guidelines should...