Supporting Countries to Expand HIV Diagnostics

Diagnosis through Monitoring

HIV Diagnostics Manufacturers Engagement
18 September 2014
Objectives for the day

1. Provide an update on our Quality Assurance Policy for Diagnostics

2. Provide an update and initiate a consultation on the development of procurement strategies for HIV Diagnostics
## Agenda

### Morning session: Introduction and Quality Assurance

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### Afternoon session: Evolving the Global Fund’s HIV Diagnostics Strategy: acquiring and implementing diagnostics better

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Who’s in the room?
# Agenda

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Sourcing
Update on transformation and strategy

Christopher Game,
Chief Procurement Officer

September 2014
For the Purpose of today’s discussion I will concentrate on a quick overview and then a more detailed update on the sourcing.

There are 4 clear work streams in which we are engaged:

1. Introduction and Background
2. Organization
3. Direct Procurement
4. Supply Chain
   a. Upstream
   b. Downstream
   c. Compliance
5. Systems and Tools
   a. 100 Things
   b. Strategy Tool kit
   c. Amazon.com for Aid / Indirect Procurement
   d. Training
6. Performance
Stepping back: why does procurement matter?

36.8%

Rate of orders delivered On time and in Full (OTIF)

And while some of this performance will reflect in the quality of lives of patients, much of it will reflect in the mitigation created by countries to deal with it.
Stepping back: why is Global Fund involved in Sourcing?

Over the last 7 years, the Board determined that the organization should play a greater role in procurement and market shaping of health products that it finances with 4 objectives:

1. Accelerate the introduction and maturation of new, more cost-effective products;
2. Ensure recipients procure the most cost-effective, WHO-recommended health products or regimens that meet the Global Fund quality assurance policies;
3. Strengthen countries’ capacity to implement strategic procurement practices;
4. Ensure the continued availability, affordability, and innovation of products, including those for which there are not currently sustainable market conditions, through multiple approaches.

1 GF/B23
Global Fund has stepped up its sourcing and procurement strategy through a *Procurement 4 Impact (P4i)* transformation.

One Sourcing team dedicated to fundamentally change the way we work across the supply chain to *increase access to products*.

- Earlier involvement and closer collaboration with manufacturers
- Improving our purchasing capability and changing our contracting models
- Optimising the international supply chain to reduce cost and improve quality and efficiency
- Better planning and scheduling to support continuity of supply
- Delivering more products at the right time and place to more people
**Procurement 4 Impact (P4i) approach follows 6 objectives fully aligned with the Global Fund’ strategy**

1. The Global Fund will become the **benchmark organisation** in the sector for **Sourcing and Procurement**

2. Using **simple, clear leading edge processes and tools** designed by and for the organisation

3. With **measurable performance** in value and lives saved

4. Building **collaborative relationships** with partner agencies, suppliers and donors

5. Ensuring **effective governance** and **watertight compliance**

6. Minimising **waste** and eliminating non value adding activities

---

**The Global Fund** 

The Global Fund is an international financial institution established in 2001 to help combat the AIDS pandemic. It raises funds from public and private donors to support countries in their fight against HIV, tuberculosis, and malaria. The Global Fund works in more than 130 countries, providing nearly US$15 billion in 2021 to these efforts.
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Sourcing team is gradually building expertise and knowledge at all supply chain levels

Team re-organized and reinforced…
- (In)Voluntary Pooled Procurement, Corporate procurement and Amfm merged into one single Sourcing team
- New Indirect / Direct Sourcing, Supply Chain, and Business Intelligence teams created, with greater capability
- We have created product, market and supply experts (e.g., Business Planning and analysis, Active Pharmaceutical Ingredients and Formulation)

With greater responsibilities…
- Spend under control is increasing, PP up to $1.2Bn
- Relationships upstream and downstream are accountable
- Changing the locus of control from manufacturer to buyer
A Rigorous Foundation

Our Strategic Cycle

Market Analysis

Supplier Analysis

Opportunity Analysis

One page strategy

API & Formulation Review
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Direct sourcing aims at optimizing upstream sourcing and procurement of health products

- Reviewing suppliers, formulators and API manufactures’ COGS, process and capacity to understand a COGS based pricing structure of health products as opposed to market based, in order to ensure sustainability and the best possible value for money.
- This is has been achieved by in-sourcing sourcing
- Creating Scale and leverage
- Improving funds flow
- Engaging and contracting directly with manufacturers
- Improving forecasting and closing down fragmentation
- Making us a customer of choice
We have created an up-to-date, refreshable, easy to use but secure data source that serves to help us, as a community make better informed decisions.

- Position resourced with a recognized expert
- Initial shared data with USG, DFID and SA Govt. concluded
- Working group across these organizations formed to consolidate data and align sourcing strategies
- First manufacturer visits concluded, reviewing process, COG’s and capacity
- Links to other essential global databases established
- Source plan generator under construction
- Data used to leverage ACT pricing successfully

This resource is available to all partners who work with the global fund.
The three diseases

HIV

- Pediatric ARV’s project initiation concluded / being implemented, this was the UNITAID & partners consortium
- Male circumcision (Prepex) joint negotiation concluded with PEPFAR, deal agreed, potential 40% saving
- Viral Load / CD4
  - Working with PEPFAR / SA Gov. / CHAI / others on viral load strategy
  - Diagnostic joint strategy launched with PEPFAR / SA Gov. tender issued by SA Gov. for access pricing
- Working group on ARV’s established
- Database prepared to facilitate demand planning and forecasting
- ARV strategic collaboration launched with ARV manufacturers and Global Fund partners
- Collaborative approach with partners to leverage specification and demand
• LLIN Global tender concluded
  • UNICEF / PMI / DFID engaged
  • Specification Harmonised
  • Demand flattened
  • $140M Value contribution
  • Market re-structured from duopoly
  • Open to non-funded country procurement
• AMFm……Private Sector Co-Payment
  • Migrating to an automated system
  • Integrated into our conventional operations
• ACT Global Tender concluded
  • Value contribution of $102M
  • Different landscape, strong competition between Originators and Generics
  • Includes private sector co-payment
  • COGS transparency and API proved revealing
  • Originators moving close to generic pricing
• IRS
  • Global supplier meeting recently held with partners present
  • Primary issue is poor supply due to quality failures
  • Multiple causes
  • Harmonization to facilitate a global tender is in process

The three diseases

Malaria
## Malaria Strategy and Outcomes

<table>
<thead>
<tr>
<th>Strategy</th>
<th>LLIN</th>
<th>ACT</th>
</tr>
</thead>
</table>
| **Local Manufacture** | • Local Manufacture  
• Reduce Duopoly 
• Manage Specification 
• Harmonize Demand 
• Recognize Innovation 
• $400M Spend (approx) | • Cogs Based with very detailed upstream analysis  
• Weighted Tender  
• Improved delivery performance  
• Local Production  
• Rapid Supply Mechanism  
• $300m Spend (Approx) |

| Value added        | $140M                                                               | $102M                                                               |
| Vendors            | 8 Suppliers                                                         | 9 Suppliers                                                         |
| Term               | 2 Year Term                                                         | 2 Year Term                                                         |
| Scope              | Available to non Global Fund Procurers                             | Available to non Global Fund Procurers                             |
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Supply chain aims at several objectives to improve delivery performance and mitigate risks

Objectives

- Improve availability of products/reduce stock-outs, improve OTIF and reduce lead-time
- Increase visibility on supply chain
- Improve in-country supply chain capability
- Improve counterfeiting/theft/diversion avoidance
- Improve manufacturers quality
- Take an integrated approach with partners
- Build a lean, skilled and efficient supply chain team
Upstream: The Rapid Supply Mechanism will address stock-outs leading to treatment disruptions

**HIV: Responding to Stock-outs & Supplying Regular Orders**
- Selected commonly used ARVs
- Rapid Supply to any GF PR in shortage
- Regular Supply to Cameroon, Côte d’Ivoire, Nigeria (+ potentially other PPM PRs)

**TB: Market Shaping & Responding to Stock-outs**
- Majority of Second Line Drugs
- Rapid Supply to any GF PR in shortage
- Regular Supply to any GF PR & potentially other countries (TBD)

**Low-volume Paediatric HIV: Market Shaping Only**
- Selected Paediatric ARVs where demand aggregation is needed to secure supply
- Regular Supply to any GF PR + other agencies (CHAI, UNICEF, …)

**Malaria: Stock-out Response Only**
- Most commonly used ACTs
- Stock to be held by manufacturers, who will also supply regular orders as normal
- Rapid Supply to any GF PR in shortage

Manufacturers to be selected from ACT tender winners; locations indicative only
Downstream: In country supply chain: example of Nigeria Program scope – 2014 to 2017 for 14 Focus States

Program scope – 2014 to 2017 for 14 Focus States

- North West
- North East
- North Central
- South West
- South South
- South East

Results of workshop with National Supply Chain team and overlay with GF Focus States.

- Lagos
- Abuja
- Plateau
- Nasarrawa
- Kaduna
- Rivers
- Cross River
- Benue
- Akwa Ibom
- Abia
- Anambra
- Bayelsa
- Kano
- Katsina
Sourcing Unit Special Projects Group (SPG)
Assuring Legitimate Supply Chain, Product Quality, and Detecting, Preventing and Responding to Theft, Diversion, and Counterfeiting of Medicines

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<td>Capabilities</td>
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<tr>
<td>Product Quality Assurance Audits</td>
<td>Market surveys to identify TDC and facilitate targeted responses</td>
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<tr>
<td>Quality Assurance Systems Audits</td>
<td>Tracking where theft is identified</td>
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<tr>
<td>Manufacturer ethics and compliance Audits</td>
<td>Testing and reporting where counterfeit is identified</td>
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<tr>
<td>Information Management – GF Exec. Committee Priority 2</td>
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<tr>
<td>Developing data systems, collating all data relating to existing Product Quality Assurance Mechanisms</td>
<td>Developing data systems, collating all supply chain and distribution flows for ACTs</td>
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<td>Exporting product Quality Assurance mechanisms data into SPG mapping system</td>
<td>Developing market survey intelligence database</td>
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<td>Development of SPG mapping system</td>
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TGF-led Steering Committee (Norbert Hauser)
International Engagement Strategy (IES)
National Engagement Strategy (NES)
Arthur Mutambara
Strategic-level political engagement in sub-Saharan Africa
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Systems and tools

- Comprehensive market intelligence
  - Upstream Active Pharmaceutical Ingredient and Formulation capability
  - Cost of goods sold transparency
  - Downstream supply chain

- Track and trace is up and running on HIV available soon on ACT’s and LLIN’s

- 100 Things as a precursor to a wider platform (Amazon)

- Tender and E-Procurement capability

- Rapid response mechanism
A groundbreaking e-marketplace would enable buyers to source aid products and commodities from multiple suppliers.

- An online marketplace where buyers and suppliers meet to buy and sell products and services.
- Intended to Global Fund recipients at first, with the aim to spin it off as a self-sustained sourcing platform for aid.

**Online marketplace**

**Buyers**

- Recipients countries
- Aid agencies

**Suppliers**

- Manufacturers
- Wholesalers/Distributors
- Shippers

**Platforms**

- Global platform
- Regional platforms
- Local platforms
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## P4i Transformation – Strategy meets Delivery

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<th>API &amp; Form</th>
<th>Strategy</th>
<th>Partnering</th>
<th>Opportunity Analysis</th>
<th>Project</th>
<th>Implementation</th>
<th>Repeat Cycle</th>
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- **July 2013** to **Dec 2013**
- Approximate Time

- Diagnostics / Machine
- Diagnostics / RDT
- Indirect Spend

- TheGlobalFund
- LeFondsmondial
- ElFondoMundial
- Глобальный фонд
- 全球基金

**Diagnostics / RDT**

**Indirect Spend**
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**Jan 2013**
- Reactive procurement based on grant disbursement
- Spot tendering through PSA
- Minimal cross agency leverage
- Multiple negotiation processes
- Stock-outs and missed delivery windows
- Lack of standardised processes between Sourcing and PSM
- Wide discrepancy in prices between VPP and non VPP purchasing

**August 2014**
- Procurement based on improving forecast demand
- Long term, multi agency, collaborative contracts
- Single negotiation process
- ‘Remote’ inventory forecasting for Pooled Procurement
- A standardised project based approach.
- Contractually assured best price promulgated to all PR’s and / or countries and partners that might benefit from leveraged, value based procurement.
Back Up
Reference Terminology

- **ARV**  Anti-Retroviral
- **API**  Active Pharmaceutical Ingredients
- **VPP**  Voluntary Pooled Procurement
- **PPM**  Pooled Procurement Mechanism
- **COGS**  Cost of Goods Sold
- **Sourcing**  Locating Manufacturers / Suppliers / Developing Relationships
- **Purchasing**  Physically Procuring Goods Sourced
- **RSM**  Rapid Supply Mechanism
- **GDF**  Global Drug Facility
- **VMI**  Vendor Managed Inventory
- **LLIN**  Long Lasting Impregnated Net
- **KPI**  Key Performance Indicators
- **AMFm**  Affordable Medicines Facility for Malaria
- **ACT**  Artemisinin Combination Therapy
- **RDT**  Rapid Diagnostic Test
- **LFA**  Local Fund Agent
- **OTIF**  On Time In Full
- **POC**  Point of Care
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Global Fund grants and Procurement and Supply Management principles

Dr Angelica Perez, MD, MPH
Health Products Management Hub
September, 2014
The Global Fund

- The Global Fund is a partnership between governments, civil society, the private sector and people affected by the diseases.
- The Global Fund mobilizes and invests nearly US$4 billion a year to support programs run by local experts in more than 140 countries.
- Global Fund Secretariat manages the grants portfolio, including screening proposals submitted, issuing instructions to disburse money to grant recipients and implementing performance-based funding of grants. More generally, the Secretariat is tasked with executing Board policies; resource mobilization; providing strategic, policy, financial, legal and administrative support; and overseeing monitoring and evaluation.
- It is based in Geneva and has no staff located outside its headquarters.
The new funding model has been designed to bring the **Global Fund Strategy of ‘Investing for Impact’** to life. The new model will improve the way the Global Fund assesses, approves, disburses, and monitors grants.

**Principles of the new funding model**

- **Bigger impact**: focus on countries with the highest disease burden and lowest ability to pay, while keeping the portfolio global.

- **Predictable funding**: process and financing levels become more predictable, with higher success rate of applications.

- **Ambitious vision**: ability to elicit full expressions of demand and reward ambition.
  - **Flexible timing**: in line with country schedules, context, and priorities.

- **More streamlined**: for both implementers and the Global Fund.
How does the new model differ from the previous model?

From previous model

• Passive role by the Secretariat in influencing investments

• Timelines largely defined by the Global Fund

• Hands-off Secretariat role prior to Board approval

• Low predictability: timing of Rounds, success rates and available funds

• Cumbersome undifferentiated process to grant signing with different delays

To new funding model

• More **active portfolio management** to optimize impact

• Timelines largely defined by **each country**

• **Engagement** by Global Fund Country Teams in country dialogue and concept note development

• **High predictability**: timing, success rates, allocation amount

• **Disbursement-ready grants** with differentiated approach
Grant implementation period

The Global Fund will work flexibly with countries to determine the best strategy to invest for maximum impact, including adapting the implementation periods.

- The typical duration of a grant is three years, but the Global Fund can work with countries to be flexible on timing.

  - Timeline will be determined based on multiple factors including:
    - Ambition to achieve increased impact and sustain gains
    - Relative under-/over-allocation of countries
    - Alignment with national plans and schedules
Why is pharmaceutical and other health product management important?

- Approximately 40% of grant funds are budgeted for the procurement of medicines and other health commodities
- Health products, including pharmaceuticals, are key components of HIV, TB, and Malaria interventions
- In many countries, limited PSM capacity (people, processes, systems) is a major cause of delays in grant implementation

PSM systems must be effective if we are to improve access to health products and have an impact on the 3 diseases
The Global Fund’s approach to PSM

- Principles and minimum standards

- Build upon existing systems

- Expanded definition of **Procurement**: Pharmaceuticals & other Health Products Management (How health products arrive in a country and what happens to them subsequently)

- Principal Recipients (PR) are responsible for all PSM activities (whether directly implemented or sub-contracted)
Key documents

• Guide to the Global Fund’s policies on PSM
• The interagency guidelines
  ✓ Operational Principles for Good Pharmaceutical Procurement and
  ✓ A Model Quality Assurance System for Procurement Agencies
• Guidance documents on website (e.g. HIV diagnostic kits)
Guide to the Global Fund’s Policies on PSM (Jun 12)

- Outlines the Global Fund’s PSM Policies
- Based on the Global Fund Board’s decisions
- Governs what PR’s need to do
- May be amended from time-to-time
General Procurement Principles

• Conduct procurement processes in a transparent and competitive manner

• Procure quality assured products

• In the most adequate form to support adherence (Fixed dose combinations, children forms)

• At the lowest possible price

• Adhere to National Laws
PR responsibilities

- Implement according to approved list of health products and approved implementation arrangements.

- For major changes, request approval prior to implementation.

- Regularly check the website for changes (e.g. new guidance notes).

- PQR
Health Product Management in the New Funding Model

- **Modular Tool with list of health products**
- **Country Dialogue**
  - Concept Note
  - Grant making
- **Year 1**
- **Year 2**
- **Year 3**

**PSM coordination mechanism**
- Health product management
- Supply chain strategy/
- Health systems Strengthening

**Capacity Assessment Tool**
- ADCD
- ADCD
- ADCD
- Reporting
Tools in the NFM

Earlier...

- PSM plan:
  Arrangement description + attachment 1a & 1b: List of health products, quantities and costs

- OR

  - Country profile
  - Procurement plan
  - Action plan

Now...

- LFA assessment report

- List of health products, quantities and costs

- Capacity Assessment tool

List of health products, quantities and costs
Questions
## Agenda

### Morning session: Introduction and Quality Assurance

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>08.30 - 09.00</td>
<td>Registration of participants</td>
</tr>
<tr>
<td>09.00 - 09.15</td>
<td>Meeting objectives and format</td>
</tr>
<tr>
<td>09.15 - 09.45</td>
<td>Welcome Remarks and overview on P4i (Procurement for Impact)</td>
</tr>
<tr>
<td>09.45 - 10.15</td>
<td>Global Fund: overview on grant making process - New Funding Model</td>
</tr>
<tr>
<td>10.15 - 10.45</td>
<td>Break</td>
</tr>
<tr>
<td>10.45 - 13.00</td>
<td>Global Fund Quality Assurance Policy</td>
</tr>
<tr>
<td><strong>Objective:</strong> inform manufacturers on the principles and eligibility criteria for procurement: short presentations and panel for questions after each sub-section (Global Fund, WHO PQ, USAID)</td>
<td></td>
</tr>
<tr>
<td>13.00 - 14.00</td>
<td>Lunch</td>
</tr>
</tbody>
</table>

### Afternoon session: Evolving the Global Fund’s HIV Diagnostics Strategy: acquiring and implementing diagnostics better

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.00 - 14.45</td>
<td>HIV Diagnostics Market analysis and observations: Existing procurement strategy /components; high level strategy objectives</td>
</tr>
<tr>
<td>14.45 - 16.30</td>
<td>Initiating the consultative process: identifying issues of concern or opportunities for improvement; suggested priorities</td>
</tr>
<tr>
<td>16.30 - 17.00</td>
<td>Plenary - high level feedback on group work</td>
</tr>
<tr>
<td></td>
<td>Wrap-up and next steps; consultation process</td>
</tr>
</tbody>
</table>
GLOBAL FUND QUALITY ASSURANCE POLICY for DIAGNOSTICS

Global Fund Consultation with Manufacturers of HIV related Diagnostics

18 September 2014
Outline of the Presentation

• Background
• Global Fund QA policy for Diagnostics principles
• QA Policy for Diagnostic Products
  • Clinical criteria
  • Quality criteria
  • Ensuring quality of use
  • Procurement principles
• Tools:
  • Global Fund HIV Diagnostics List
  • Website Guidance documents
Background

- The Board approved the Global Fund QA Policy for Diagnostic Products in December 2010
- The QA Policy was implemented in March 2011

- The QA Policy is based on the recommendations of a group of experts on regulatory, technical, implementation issues related to diagnostics, including Manufacturers representatives.

- After 3 years of implementation, the Secretariat reviewed the policy in light of experiences with implementation, advances in technologies, market developments, new products assessed and partners’ harmonization efforts
- Updated version adopted in February 2014
Global Fund QA policy for Diagnostics

**Main principles**

1. Clinical criteria
2. Quality criteria
3. Quality monitoring at country level
4. Ensuring quality of use
5. Monitoring of compliance of POs with GF QA policy requirements

**Products subject to the policy:**

All durable and non-durable In Vitro Diagnostic Products and important for diagnosis

- Rapid diagnostic tests
- Equipment/consumables
- Reagents, Calibrators, Software

**Not subject to this policy:**

Products for general laboratory use: gloves, syringes, needles, general reagents, test tubes
QA Policy for Diagnostic Products

(a) Clinical Criteria

Product types must be selected in compliance with:

• National guidelines
• WHO guidance

(b) Quality Criteria

Manufacturing site for all products:
• compliant with ISO 13485
(except for microscopes for which ISO9000 applies)

+ Product standards for HIV diagnostics

(c) Monitoring Quality and Ensuring Adequate Use

• Adequately trained staff
• Adequate storage and distribution
• Lot testing
• Reporting of failures
Quality criteria

For Malaria RDTS:
Approved by WHO after technical assessment,
After positive advice received from WHO when assessed according to requirements of authorities member of GHTF

List of Malaria RDTs
(WHO evaluations and information note)

For HIV RDTs, ELISA, WB, CD4, VL, EID and TB tests:
Approved by WHO after technical assessment
or
Assessed according to requirements of authorities members founder of GHTF
( not applicable to CD4)
or
ERPD recommended

List of HIV RDT
(WHO eligible for procurement)
+ “GHTF”-approved

Phased implementation of Quality Standards
• HIV, Malaria RDTS, reagents: applicable since March 2011
• CD4, VL, EID technologies applicable since July 2014
Ensuring quality of use

Recipients must:

1. follow **WHO guidance** for good practice in storage and distribution of diagnostic products,

2. **develop and maintain a QA system** for the PSM and use of Diagnostics

3. ensure that diagnostic products are only used by appropriately **trained and qualified staff** in adequate settings,

4. use best efforts to **participate in External Quality Assessment** (EQA) programs,

5. organize **calibration and maintenance** of equipment,

6. arrange for **systematic reporting of defects**.
Procurement principles (1)

Procurement of RDTs

- In line with national guidelines
- Guided by programmatic needs: training requirements for health workers, completeness of the kits, and ease of use, previous experience in use of RDTs, and level of deployment in the country
- In a competitive and transparent manner, according to specific recommendations, depending on type of diagnostics.

For HIV RDTS: 2 situations depending of the country algorithm

- No testing algorithm defined and validated: selection through competitive process
- One or several testing algorithm(s) for the diagnosis of HIV infection defined and validated within the last 5 years: compliance of the selected Dx with GF policy to be checked
Procurement principles (2)

Products selected as part of the validated national testing algorithm(s), compliant with the QA criteria

- PR to follow the recommendations of the validated algorithm(s) to order the products **without competition**, for the validity period of the algorithm

Products selected as part of the validated national testing algorithm(s), **not compliant** with the QA criteria defined in the Global Fund QA policy

- PR inform the National HIV Programme and request a replacement HIV assay.
- Selection through competitive process
Procurement process (3)
Total Cost of ownership

Principal Recipients should budget and consider the total cost associated with a specific product, including for example:

- (Re-)design of guidelines, job aids etc. and (re-)training of staff if introduction of a new product,

- Maintenance of equipment and costs of consumables, and reagents for durable products.
**Global Fund HIV Diagnostics List**

**List of Diagnostic test kits for HIV and HIV equipments classified according to the Global Fund Quality Assurance Policy**

According to Global Fund Quality Assurance Policy for Diagnostic Products, rapid diagnostic tests (RDTs) and enzyme immunoassays (EIAs) are recommended for use in HIV/AIDS programs based on a technical review of quality and performance indicators. Criteria applicable currently to HIV Rapid Diagnostics, Immunodiagnostics and after 2nd July 2014 also applicable to CD4 and Virological Technologies (VL and EID) are as follows:

1. **Rapid Diagnostic Tests (RDTs)**
2. **Enzyme Immunoassays (EIAs)**
3. **HIV Supplemental assays**
4. **CD4 Enumeration technologies**
5. **HIV virological technologies**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product Name</th>
<th>Number of tests per kit</th>
<th>Initial Sensitivity</th>
<th>Final Specificity</th>
<th>Manufacturer</th>
<th>Analyte</th>
<th>Spectrum Type</th>
<th>Shelf Life</th>
<th>Comments</th>
<th>Eligibility</th>
<th>WHO/PQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARON Biopharm (Hangzhou) Co., Ltd.</td>
<td>HIV-1/2 Rapid Test Device</td>
<td>50</td>
<td>100.00%</td>
<td>99.70%</td>
<td>ARON Biopharm (Hangzhou) Co., Ltd.</td>
<td>HIV-1/2 antibodies combined</td>
<td>Whole blood, Serum/Femur</td>
<td>18 months</td>
<td>2 to 30°C</td>
<td>if whole blood, if not, strip in sterile water or 0.9% NaCl solution, may be stored up to 30°C</td>
<td>W001-PQ</td>
</tr>
<tr>
<td>InThi Products, Xiamen, PR China</td>
<td>Advanced QualiSoft HIV Rapid Test Device</td>
<td>40</td>
<td>99.00%</td>
<td>98.6%</td>
<td>InThi Products, Xiamen, PR China</td>
<td>HIV-1/2 antibodies combined</td>
<td>Serum, Plasma and whole blood</td>
<td>24 months</td>
<td>2 to 30°C</td>
<td>if whole blood, if not, strip in sterile water or 0.9% NaCl solution, may be stored up to 30°C</td>
<td>W000-PQ</td>
</tr>
<tr>
<td>Aloe Medical, Japan, Matobo, Japan</td>
<td>Aloe Determine™ HIV-1/2 Ag/Ab Combo</td>
<td>100</td>
<td>100%</td>
<td>99.4%</td>
<td>Aloe Medical, Japan, Matobo, Japan</td>
<td>HIV-1/2 antibodies combined</td>
<td>Serum, Plasma and whole blood</td>
<td>14 months</td>
<td>2 to 30°C</td>
<td>if whole blood, if not, strip in sterile water or 0.9% NaCl solution, may be stored up to 30°C</td>
<td>W001-PQ</td>
</tr>
<tr>
<td>Aloe Medical, Japan, Matobo, Japan</td>
<td>Aloe Determine™ HIV-1/2 Ag/Ab Combo</td>
<td>100</td>
<td>100%</td>
<td>98.6%</td>
<td>Aloe Medical, Japan, Matobo, Japan</td>
<td>HIV-1/2 antibodies combined and HIV-1/2 p24 antigen</td>
<td>Serum, Plasma and Whole blood</td>
<td>12 months</td>
<td>2 to 30°C</td>
<td>if whole blood, if not, strip in sterile water or 0.9% NaCl solution, may be stored up to 30°C</td>
<td>W001-PQ</td>
</tr>
<tr>
<td>Aloe Medical, Japan, Matobo, Japan</td>
<td>Aloe Determine™ HIV-1/2 Ag/Ab Combo</td>
<td>20</td>
<td>100%</td>
<td>99.75%</td>
<td>Aloe Medical, Japan, Matobo, Japan</td>
<td>HIV-1/2 antibodies combined</td>
<td>Serum, Plasma and Whole blood</td>
<td>14 months</td>
<td>2 to 30°C</td>
<td>if whole blood, if not, strip in sterile water or 0.9% NaCl solution, may be stored up to 30°C</td>
<td>CE-marked</td>
</tr>
</tbody>
</table>

*Note: The list is updated regularly based on evidence received by the Global Fund.*

**Additional Information**

- **WHO/PQ**: World Health Organization Prequalification Program (WHO/PQ) information is available for some of the listed products.

---

**References**

- Global Fund HIV Diagnostics List
- WHO Prequalification Program (WHO/PQ) Information
- Product manufacturer information

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**Related Resources**

- Global Fund HIV Diagnostics List
- WHO Prequalification Program (WHO/PQ) Information
- Product manufacturer information

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**Footnotes**

- The list is updated regularly based on evidence received by the Global Fund.
- WHO/PQ information is available for some of the listed products.
A compilation of relevant guidance is available on Global Fund website

- Global Fund’s QA policy for Diagnostic Products
- List of HIV Diagnostics tests
- Price and quality reporting
- Guidance for best practice
- Global Fund Guidance for Procurement and Use of HIV Diagnostic Test Kits with Global Fund Grants

Quality Assurance of Diagnostic Products

Effective from 5 February 2014.

NOTE: The QA Policy shall apply with immediate effect for all Diagnostic Products as defined in section 7 and 8, except the requirements defined in section 8 for HIV Virological and CD4 Technologies which shall commence and apply in full force and effect on 1st July 2014.

1. Quality Assurance Policy for Diagnostic Products
2. Applicable laws and regulations
3. Clinical Standards and Selection of product types
4. Quality standards for manufacturing sites
5. Quality standards for products
6. Ensuring quality of use
7. Additional provisions
8. Contact us
THANK YOU
HIV Global Diagnostic Working Group

Established 2013

• Collaboration on the quality and procurement of HIV related diagnostic products
• Reducing duplication and enhancing collaboration between members and other partners

Objectives

• To strengthen communication, collaboration & coordination towards the **optimal selection and use of quality-assured products**
• To effectively **respond in a timely and coordinated manner to urgent quality-related issues**
• To provide **aligned messages to global, regional, and country level users on quality assurance for product selection and testing implementation**
• To provide **aligned messages to manufacturers**
• To advocate for diagnostic tests that are **appropriate and affordable**
QUALITY ASSURANCE POLICY for DIAGNOSTICS

The Expert Review Panel mechanism

Global Fund Consultation with Manufacturers of HIV related Diagnostics

18 September 2014
Outline of presentation

• Purpose of ERPD
• Operationalization
• Membership
• Mechanism
• Responsibilities
• Risk categories for ERPD reviewed products
• Implementation of ERPD
• Recommendations to Manufacturers
• ERPD schedules
• Conclusions
ERPD: Purpose

• To assess the potential risks/benefits associated with the procurement of diagnostic products that may have a high public health impact, but have not yet undergone a stringent assessment, either by WHO Prequalification or by a SRA.

• To advise the Global Fund/UNITAID in their decision on whether to allow grant funds to be used for the time-limited procurement of the diagnostics reviewed by the ERPD.

• ERPD risk/benefit assessment does not replace WHO PQ/SRA assessment, but should be seen as a step towards a WHOPQ/full regulatory review.

• ERPD mechanism should help expediting access to innovative diagnostic products, if the associated risks are deemed less than the potential benefits.
ERPD: Operationalization

- ERPD funded by UNITAID & The Global Fund, hosted by WHO
- TORs, EoI calendar published on GF & UNITAID websites
- Managed according to Terms of Reference (TORs) developed under the oversight of The Global Fund and UNITAID with inputs from partners (MSF, OGAC, UNICEF, USAID, WHO).

- Organized for selected diagnostic technologies according to agreed upon timelines:
  - Product categories for review are defined according to market demand and product availability.
  - Expression of Interest (EoI) is developed and published
  - Review of product questionnaires and reporting performed in a 4 month timeline
ERPD: Membership

An independent technical body:

- Established and administered with guidance from WHO Essential Medicines and other Health Products Department leading the technical implementation.

- Composed of external technical experts: representatives from a wide range of expertise in the field of in-vitro diagnostics medical devices:
  - in-vitro diagnostic medical device regulatory affairs,
  - manufacturing of diagnostic products including quality management systems,
  - quality assurance/performance of diagnostic products,
  - public health, use of diagnostic products in health programs in low income countries.
ERPD: Mechanism

- Submission of product documentation
  - product questionnaire
  - The submission of documentation is subject to eligibility criteria
- Assessment of submitted product questionnaires
- Transmission of ERPD’s advice to The Global Fund/UNITAID and other partners as to whether the benefits of procurement outweigh the potential risks.
- Definition of the validity period of the advice: to be determined by ERPD.
ERPD submission: Eligibility criteria

Regulatory status
• The product either has a dossier already under review by WHO Prequalification or is undergoing an SRA approval process, OR
• There is a commitment from the manufacturer to submit a dossier to WHO Prequalification or to a SRA for stringent assessment,

AND

Quality Management System (QMS) status
• ISO 13485:2003 or an equivalent QMS documentation, AND
• Any component of the diagnostic technology for which section above does not apply, must be manufactured at a site compliant with all applicable requirements of the ISO 9000 series.
Documentation to be submitted by manufacturers as per EoI requirements

1. A cover letter expressing interest to submit to ERPD review,
2. A letter from the WHO Prequalification Programme or from an SRA confirming that the product is currently under review for the intended use,
OR
a letter of commitment to submit product dossier either to WHO prequalification or to an SRA,
3. QMS documents substantiated by one or two recent and valid inspection reports,
4. A completed product questionnaire as per generic instructions outlined in the EoI.
ERPD: GF Secretariat responsibilities

The Global Fund QA Senior Officer:

- prepares and circulates the invitations for EoI in close collaboration with UNITAID and partners,
- manages the receipt of product questionnaires sent by manufacturers,
- forwards complete questionnaires and associated documents to ERPD Coordinator,
- notifies manufacturers of the outcome of the ERPD’s review of their respective submissions,
- maintains a website up-to-date list of diagnostics eligible for procurement, based on ERPD advice.
ERPD: Coordinator's responsibilities

- manages the selection of ERPD members
- organizes timely review of the product questionnaires,
- reports the conclusions of the ERPD review regarding acceptability for procurement for each product,
- provides advice on measures to mitigate identified risks,
- drafts the respective communications to the Global Fund/UNITAID and ensures timely delivery of ERPD reports.
ERPD: Member's responsibilities

The selected ERPD members:

- **Assess submitted data**, draft the corresponding quality risk assessment reports, and allocate each product questionnaire to the appropriate risk category. The data for each product will be reviewed by two assessors at least,

- **Assessors present** their findings at the ERPD meeting and provide advice on measures to mitigate identified risks,

- Advise the ERPD coordinator on which products can be considered as acceptable for **time-limited procurement**.
Assessment criteria for ERPD review

The following major product attributes will be used as a basis for assessment:

a. QMS status of the manufacturing process,
b. IVD risk management and control of the manufacturing processes,
c. Performance specification, study design and evidence of performance: analytical and clinical study data,
d. Stability data,
e. Labelling, including Instructions For Use, suitability of the product for the settings of intended use, customer support
Risk categories of ERPD reviewed products

Classification of products in 4 risk categories:

- **risk categories 1 and 2**
  products may be considered for time-limited procurement.

- **risk category 3**
  products may be considered for time-limited procurement only if there is no other option

  And

  if the risk of not diagnosing and/or making treatment decisions is higher than the risk of using the product.

- **risk category 4**
  products may not be considered for procurement under any circumstances.
## ERPD Implementation

<table>
<thead>
<tr>
<th>ERPD steps</th>
<th>Pilot Round</th>
<th>ERPD round 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>GF/UNITAID EOI: selected products</td>
<td>POC HIV EID</td>
<td>POC CD4/ VL/ EID lab-based molecular VL techniques using DBS</td>
</tr>
<tr>
<td>EOI publication</td>
<td>13 Feb 2014</td>
<td>4 July 2014</td>
</tr>
<tr>
<td>Manufacturer's questionnaire submission to GF</td>
<td>8 April 2014</td>
<td>29 August 2014</td>
</tr>
<tr>
<td>Number of dossiers received</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of dossiers eligible for review</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>Number of dossiers eligible for review</td>
<td>2</td>
<td>?</td>
</tr>
<tr>
<td>ERPD review</td>
<td>Mid April- mid June 2014</td>
<td>Mid September- Mid November</td>
</tr>
<tr>
<td>Conclusion letters sent to Manufacturers</td>
<td>20 June 2014</td>
<td>Last week of November</td>
</tr>
</tbody>
</table>
Recommendations to Manufacturers

- CHECK publication of EoI and range of products to be reviewed

- SUBMIT Product questionnaire with the following critical documents:
  - A valid QMS certificate, either ISO 13485 or equivalent, substantiated inspection reports,
  - The outline of the manufacturing process and SOP to ensure adequate control and risk management,
  - Evidence of performance together with study protocols and analytical and clinical data
  - Data and study protocols to support claimed shelf-life (accelerated studies are acceptable if real-time studies are ongoing)
  - Instructions for use, information regarding customer support network
Next Steps –Q4 2014/ 2015

• Open dialogue with manufacturers & partners through briefing sessions
  – Individual requests for teleconferences via e-mail
    Joelle.Daviaud@theglobalfund.org and Martine.Guillerm@theglobalfund.org
  – UN manufacturers meeting (Copenhagen, 23-25 September 2014)
  – ASLM meeting (Cape Town, November 2014)

• Schedules for up-coming EoI for ERPD review :
  – Up-coming EoI issued on ad-hoc basis (in Q4 2014 if needed)
Conclusion: ERPD as a unique mechanism

The ERPD is designed to:

- Be a single expert review mechanism intended to be endorsed and used by multiple stakeholders and avoid unnecessary duplication,
- Promote harmonization of quality standards for the procurement of needed diagnostic products, prior to their full assessment by WHO or SRA,
- Promote the rational use of scarce expertise and resources

The ERPD sponsors (Global Fund/UNITAID) encourages stakeholders to share ideas on:

- Time-limited procurement of diagnostic products
- Prioritization of diagnostic products to be reviewed by ERPD.
Where to find the Information?

**Information for Suppliers**

Quality Assurance Policy for Diagnostics Products amended in February 2014

  - Download
- Quality Assurance Policy for Diagnostics - The Expert Review Panel mechanism Presentation
  - Download [PDF - 252 KB]
- Invitation to manufacturers of Diagnostic Point-of-Care Technologies for CD4, HIV viral load, HIV Early Infant Diagnosis and for HIV molecular technologies using dried blood spots to submit an Expression of Interest (EoI) for product evaluation by an Expert Review Panel for Diagnostics (ERPD)
  - Download [PDF - 397 KB]
  - Submission deadline: 29 August 2014
- Expert Review Panel for Diagnostics (ERPD) - Lessons learned from the Pilot round
  - Download [PDF - 207 KB]
- ERPD Product questionnaire
  - Download [DOCX - 111 KB]
- Expert Review Panel for Diagnostics - Terms of Reference
  - Download [PDF - 158 KB]

Click here for details.

**Quality Assurance Policy for Pharmaceutical**
THANK YOU
A streamlined approach to the WHO Prequalification of In Vitro Diagnostics Programme

Global Fund Meeting with HIV IVD Manufacturers
18 September, Geneva

Anita Sands
Prequalification Team – Diagnostics
Department of Essential Medicines & Health Products
Dept of Essential Medicines & Health Products: structure

Essential Medicines and Health Product [EMP]

Policy, Access and Use [PAU]

Regulation of Medicines and other Health Technologies [RHT]

Public Health, Innovation and Intellectual Property [PHI]

Technologies Standards and Norms [TSN]

Regulatory Systems Strengthening [RSS]

Prequalification Team [PQT]

Safety and Vigilance [SAV]
WHO Prequalification Team: structure
What is streamlining of WHO PQ of IVDs?

- **Objectives of streamlining**
  - Increase efficiency (timelines for WHO work) and improve transparency (PQ requirements, process)
  - Strengthen work with key partners (manufacturers, NRAs, procurement and other agencies)
  - Strengthen communication

- **How will we streamline?**
  - By focusing on active applications
  - Defining turn-around times for WHO and for Mx
  - Reducing number of rounds of submissions to fulfill requirements for dossier and inspection aspects
WHO prequalification assessment

- Pre-submission form
  - Priority product
    - Yes
      - Dossier screening
        - Dossier incomplete
          - Prequalification decision
    - No
      - Dossier incomplete
        - Prequalification decision
  - Dossier complete
    - Dossier review
    - Site inspection
    - Laboratory evaluation
      - Prequalification decision
PQDx pre-submission form (formerly known as application form): requirements

- Manufacturer may submit a form at any time to diagnostics@who.int
  - Must use the Prequalification of In Vitro Diagnostics pre-submission form
  - Instructions for the completion available
  - Instructions for use must be submitted

- Updated form asks for more detailed information on regulatory versions of the product submitted to determine if eligible for abbreviated PQ procedure
## Prioritization criteria

<table>
<thead>
<tr>
<th>Current prioritization criteria</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Already listed on WHO/UN procurement scheme and procured by UN organizations in significant levels</td>
<td>Ensure continuity of supply and quality of products procured</td>
</tr>
<tr>
<td>Assist diagnosis of infection with HIV-1/HIV-2, malaria and hepatitis C</td>
<td>Focus on priority disease areas – highest historical procurement</td>
</tr>
<tr>
<td>Rapid test format/for use at point-of-care</td>
<td>Bringing testing closer to the community</td>
</tr>
<tr>
<td>Original product manufacturers</td>
<td>Ensure known supply chain; no duplication of effort, best possible prices</td>
</tr>
<tr>
<td>Few other prequalified products exist in the product category such as CD4, viral load</td>
<td>Focus on unmet market / procurement needs</td>
</tr>
<tr>
<td>Adult male circumcision devices</td>
<td>Focus on the needs of WHO disease programmes</td>
</tr>
</tbody>
</table>
WHO prequalification assessment

Pre-submission form

Priority product

Yes

No

Dossier screening

Dossier incomplete

Dossier complete

Dossier review

Site inspection

Laboratory evaluation

Prequalification decision
Streamlining product dossier review

- Maximum 2 rounds of supplements to dossier, 2 rounds of amendments after full assessment
- Improved current instructions for compilation of product dossier
  - E.g. sample product dossier for POC CD4 IVD, next for VL and EID
- Defined minimum requirements
  - Defined critical dossier sections with high impact on product quality, safety and performance
  - Grading of non-conformities (level 1 through 5)
  - Additional sections needed/redundant sections
- Abbreviated assessment waives requirement for dossier submission and review by WHO
Dossier: requirements

- Based on best international practice (ISO, EN, GHTF, CLSI); follow the content of the GHTF STED

- PQ examines critical aspects for WHO Member States often not dealt with from a local prospective by SRAs
  - stability, suitability of instructions for use, risk assessment, etc.

- Dossier must demonstrate that the IVD conforms to the Essential Principles of Safety and Performance of Medical Devices (GHTF/SG1/N41R9:2005)
Streamlining inspections

- Rethinking how to plan and perform inspection processes
  - New staging of inspection processes
    - Stage 1 inspection (may be desktop)
    - Stage 2 inspection (initial on-site inspection)
    - Follow up (to review if action plan has been implemented)
    - Re-inspection (of PQed products)
  - Maximum 2 action plans (to address nonconformities) for review
  - Abbreviated assessment leads to abbreviated inspection

- International harmonization: IMDRF, and particularly the Medical Device Single Audit Program (MDSAP)
The manufacturer must demonstrate that the IVD is produced under a functional quality management system e.g. conforms to ISO 13485:2003

Key Components

- **Quality management system**
  including documentation requirements
- **Management responsibility**
  including customer focus, quality policy
- **Resource management**
  including human resources, work environment
- **Product realization**
  including production and service provision, control of monitoring and measuring devices
- **Measurement, analysis and improvement**
  including control of nonconforming product, improvement
Streamlining laboratory evaluations

- WHO will work with partners
  - Review undertaken of which partner organization is doing what
    - Different evaluations have different objectives, e.g. Phase I proof-of-concept and prototype optimization, Phase II laboratory based evaluation, Phase III field (intended setting) evaluation, Phase IV clinical utility
    - Working towards harmonization of evaluation protocols where evaluation objectives are aligned

- Addressing priority areas not covered by partners

- Avoid duplication of effort on the same products
Laboratory evaluation: requirements

- WHO evaluation protocols followed, based on existing international standards and best practice and adapted to assay type
  - To evaluate performance and operational characteristics

- WHO Collaborating Centres performs evaluation under supervision of WHO

- WHO Composite Reports of all products produced
  - Report 17 published, Report 18 to come
WHO prequalification assessment

Pre-submission form

Priority product

Yes ➔ Dossier screening ➔ Dossier incomplete

No ➔ Dossier incomplete

Dossier complete

Dossier review

Site inspection

Laboratory evaluation

Prequalification decision
Prequalification: decision

Final prequalification outcome depends on:
- Results of dossier assessment and acceptance of action plan
- Results of inspection(s) and acceptance of action plan
- No level 5 nonconformities outstanding for either dossier or for inspection
- Meeting the acceptance criteria for the laboratory evaluation

WHO PQDx Public Report is posted on WHO website and product is added to the list of WHO prequalified products

Product is then eligible for WHO and UN procurement
Abbreviated WHO prequalification assessment

1. Pre-submission form
2. Priority product
   - Yes
   - No
3. Decision on abbreviated PQ assessment
   - Yes
   - No
4. Full PQ assessment
   - No
5. Abbreviated site inspection
6. Laboratory evaluation
7. Prequalification decision
Abbreviated prequalification assessment procedure (previously known as fast-track)

- Categories of products submitted to PQDx:
  - Scenario 1
    - Version submitted for PQ has been stringently assessed
  - Scenario 2
    - Version submitted for PQ has not been stringently assessed but a regulatory version exists that has been
  - Scenario 3
    - Version submitted to PQ has not been stringently assessed

- Where stringent assessment has been conducted by founding member of GHTF
  - CE (List A, Annex II), FDA (PMA or BLA), Health Canada (Class IV), TGA (Class 4), Japan (Minister's approval)
Abbreviated PQDx assessment: Scenario 1

• Version submitted for PQ has been stringently assessed

• Abbreviated PQ assessment procedure will be followed:
  1. WHO pre-submission form, with annex 1 filled
  2. **No dossier** requested by WHO
  3. Abbreviated WHO site inspection
     • Information package requested to prepare for the inspection, including receipt of previous satisfactory audit report;
     • Shorter duration, fewer inspectors; to verify WHO customer requirements;
     • 1 inspector, 1 technical expert.
  4. WHO laboratory evaluation of performance and operational characteristics to inform product selection
**Abbreviated PQDx assessment: Scenario 2**

- Version submitted for PQ has not been stringently assessed but a regulatory version exists that has been

- Procedure to be followed:
  1. WHO pre-submission form, with annex 1 filled
     - Comparison of key differences between stringent regulatory version and ROW regulatory versions is made:
       - Product description, intended use, test procedure, design, manufacturing site, key suppliers, labelling, instructions of use, quality management system, verification/validation studies, lot release criteria
       - If substantial differences (scenario 2a), usual PQ assessment procedure is followed (no abbreviated assessment)
       - If no substantial differences (scenario 2b), abbreviated PQ assessment procedure is followed
Abbreviated PQDx assessment: Scenario 3

- Where no stringently assessed regulatory version exists
- Usual PQ assessment procedure will be followed:
  1. Dossier reviewed by WHO
  2. Site inspection
  3. WHO laboratory evaluation of performance and operational characteristics to inform product selection
Expected impact of new PQDx process

- Increased transparency and efficiency
  - Fewer steps, defined timelines, defined number of rounds

- Cleaner pipeline
  - To enable better focus on active applications

- Division between PQDx assessment and assistance to Mx
  - More transparent PQDx assessment process in place
  - Additional guidance to assist Mx, WebEx briefings, sample dossiers, training plan for priority topics
  - Robust capacity building programme in place through TA group:
    - advisory visits to tackle specific gaps
    - training programme to address most common PQ issues
PQDx assessment status for all products

- WHO website updates the status of each product undergoing PQDx assessment monthly

Post-market surveillance of WHO PQed IVDs

- Onus on manufacturer and NRA, but often poorly executed

- WHO coordinates complaints through the "WHO PQDx IVD complaint form" for end users to report issues
  - GHTF/SG2-N54R8:2006
    - Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices
  - GHTF/SG2-N57R8:2006
    - Medical Devices Post Market Surveillance: Content of Field Safety Notices

- WHO guidance on post-market surveillance is forthcoming
Contact us

- Contact us by email
  - diagnostics@who.int

- Sign up to our mailing list
  - By emailing diagnostics@who.int

- Check our website
PEPFAR Procurement and QA of HIV Diagnostic Tests

Global Fund Consultation with Manufacturers of HIV Diagnostics

September 18, 2014
SCMS Procurements: 2007 - 2013 (delivered)
SCMS Non-Parmaceutical Procurements: 2013

- Reagents/Analyzers, $53,058,879, 37%
- HIV RDTs, $34,612,365, 24%
- Lab/clinical, $23,732,629, 17%
- MC Kits, $19,871,607, 14%
- Other RDTs, $1,033, 0%
- Service, $2,077,518, 2%
- Other, $8,727,137, 6%

117
Geographic Sources of Lab Commodities: 2013

- Africa Eastern: 16%
- Africa Southern: 27%
- Africa Western: 6%
- EU: 33%
- Americas: 6%
- Asia: 6%
- India: 1%
- USA: 5%
Procurement Criteria for HIV Rapid Test Kits (2006-2014)

- Must be included on national HIV testing algorithm or on national list of approved tests for country of use
- Must be registered in country of use
- Must meet USAID approval criteria

1. FDA-Approved
2. USAID-Evaluated (CDC evaluation using serum panel >1500 specimens)

Revisions to Approval Criteria (June 17, 2013)

1. Approval by a SRA other than the U.S. FDA is no longer a basis for approval.
   - U.S. FDA-approval confers technical approval, but USAID may require additional region-specific evaluations.

2. WHO Prequalification of a test kit is now a basis for technical approval.

3. USAID will publish the results of CDC/ILB technical evaluations for both “approved” and “not approved” test kits.

4. USAID may perform or participate in site inspections of manufacturing facilities.

5. USAID may conduct post-approval lot verifications to determine if a test kit continues to meet approval standards.

6. Failure to maintain performance that meets the approval standards can result in removal from the List.
Alignment with WHO PQ (Beginning September 2014)

- Revised HIV rapid test kit (RTK) approval process:
  - to avoid duplication of efforts
  - to develop a harmonized list for country decision-making

- Aligned Process:
  - Submit a pre-submission form to WHO PQ. See following link: http://www.who.int/diagnostics_laboratory/evaluations/Application/en/
  - A product dossier will be requested by WHO for review and approval;
  - WHO will schedule a manufacturing site inspection;
  - CDC will perform the technical evaluation as per protocol. (Note: This step can proceed in tandem with the inspection.)

- An RTK meeting all three requirements (dossier review, site inspection, technical review) will be approved by USAID and appear on the WHO PQ list.

- An FAQ providing further information on these changes is in process
Further Requirements for Manufacturers

1. USAID will publish the evaluation results for all submitted RTKS.
2. USAID may re-evaluate any approved test kit (est. 3-5 years).
3. USAID requires written notice within 30 days and prior to supplying an approved test of:
   - Any manufacturing or design change in the test kit or components;
   - Any change in manufacturing or component manufacturing sites;
   - Any service bulletins, safety notices, recall notices, etc.
4. USAID will be provided with the results of site inspection(s) by a 3rd party performed at any time during or after the approval process.
5. For submitted or approved products, USAID may inspect or participate in site inspections of the Manufacturer’s facilities and/or any component facilities.
6. For approved products, USAID will be notified of any possible counterfeiting, piracy, or unauthorized sales by third parties of any test.
Post-Marketing Surveillance: Individual Lot Testing

- Initiated PMS for all SCMS procurements for PEPFAR programs in 2010.
  - Credible threat
  - Catastrophic failure
  - Not a lot release testing program – RTKs are often distributed prior to receipt of results
- Policy to test every lot procured upon entry into country of use
- Sample size: 60 tests per lot
  - Combination of physical inspection and technical evaluation via serum panel
- UMD performs testing; failed lots confirmed by CDC and 2nd round testing at UMD
- PfSCM maintains a passive, online reporting system
Thank You!

USAID:
Vincent J Wong, MSc
Email: vwong@usaid.gov

Dianna Edgil, Ph.D.
Email: dedgil@usaid.gov

CDC:
Bharat S. Parekh, Ph.D.
Email: bparekh@cdc.gov
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Dianna Edgil, Ph.D.
Email: dedgil@usaid.gov

CDC:
Bharat S. Parekh, Ph.D.
Email: bparekh@cdc.gov
Implementation challenges

- Quality assurance for products/ EQA
- Selection of products by country programmes: national algorithms/products non interchangeable/suitability of technology
- Too few products/equipement qualified according to International standards
- Post marketing surveillance
- Placement of equipment/commodities/
- Lack or poor quality system / systematic approach to ensuring quality testing
- Lack of defect reporting
- Country readiness for adoption of new products/lab systems
- Registration in countries/barriers to market entry
# Agenda

## Morning session: Introduction and Quality Assurance

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## Afternoon session: Evolving the Global Fund’s HIV Diagnostics Strategy: acquiring and implementing diagnostics better

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Supporting Countries to Expand HIV Diagnostics

Diagnosis through Monitoring

HIV Diagnostics Manufacturers Engagement
18 September 2014
HIV: Low and Middle Income Country Burden and Progress

11.7 million
At the end of 2013 11.7 million had access to antiretroviral therapy in low and middle income countries

35 million
At the end of 2013, 35 million people were living with HIV

28 million
Over 28 million people are eligible for antiretroviral therapy under WHO 2013 consolidated ARV guidelines

Number of people receiving ART and percentage of all people living with HIV receiving ART in low- and middle-income countries overall and by WHO region, 2013a

TOTAL: 11.7 MILLION
36% [34–38%]

TheGlobalFund LeFonds mondial El Fondo Mundial Глобальный фонд

The Global Fund to Fight AIDS, Tuberculosis and Malaria
Maximising the value from procurement will contribute to the number of lives saved.
# The Global Fund Strategy Framework

## Vision
A world free of the burden of HIV/AIDS, tuberculosis and malaria with better health for all.

## Mission
To attract, manage and disburse additional resources to make a sustainable and significant contribution in the fight against AIDS, tuberculosis and malaria in countries in need, and contributing to poverty reduction as part of the MDGs.

## Guiding principles
- Being a financing instrument
- Additionality
- Sustainability
- Country ownership
- Multi-sectoral engagement
- Partnership
- Integrated, balanced approach
- Promoting human right to health
- Performance-based funding
- Good value for money
- Effectiveness and efficiency
- Transparency and accountability

## Goals
1. **10 million lives saved**¹ over 2012-2016
2. **140-180 million new infections prevented** over 2012-2016

### Targets (2016)

<table>
<thead>
<tr>
<th>HIV/AIDS</th>
<th>Global plan</th>
<th>Global Fund leading targets for 2016</th>
<th>Indicators for other selected services</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNAIDS 2011-2015 Strategy, 2011 Investment Framework, and UNGASS June 2011 Declaration</td>
<td>7.3 million people alive on ARTs</td>
<td>PMTCT: ARV prophylaxis and/or treatment, HIV testing and counseling, Prevention services for MARPs, Male circumcision</td>
<td></td>
</tr>
<tr>
<td>TB</td>
<td>Global Plan to Stop TB 2011-2015</td>
<td>4.6 million DOTS treatments (annual), 21 million DOTS treatments over 2012-2016</td>
<td>HIV co-infected TB patients enrolled on ARTs, MDR-TB treatments</td>
</tr>
<tr>
<td>Malaria</td>
<td>RBM Global Malaria Action Plan 2008 and May 2011 updated goals and targets</td>
<td>90 million LLINs distributed (annual), 390 million LLINs distributed over 2012-2016</td>
<td>Houses sprayed with IRS, Diagnoses with RDTs, Courses of ACT administered to confirmed malaria cases</td>
</tr>
</tbody>
</table>

¹ Based on impact of provision of ART, DOTS and LLINs using methodology agreed with partners. ² Targets refer to service levels to be achieved in low- and middle-income countries. Note: Goals and targets are based on results from Global Fund-supported programs which may also be funded by other sources; targets are dependent on resource levels.
Progress and Current Spend – Global Fund

- Between 2014 and 2016 the grants for HIV total USD 7.8 billion across 105 countries

http://www.theglobalfund.org/documents/fundingmodel/FundingModel_CountryAllocation_Table_en/

- Based on historical evidence this will translate into a spend of at least USD 3.4 billion on medicines and health products
The HIV Diagnostic Forecast Spend for 2014 is $90 million

<table>
<thead>
<tr>
<th>Approved funds for procurement in 2014</th>
<th>USD</th>
<th>Estimated tests planned for procurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid tests</td>
<td>34 million</td>
<td>40 million</td>
</tr>
<tr>
<td>CD4 tests</td>
<td>39 million</td>
<td>5 million</td>
</tr>
<tr>
<td>Viral load tests</td>
<td>14 million</td>
<td>500,000</td>
</tr>
<tr>
<td>EID tests</td>
<td>3 million</td>
<td>200,000</td>
</tr>
</tbody>
</table>
Procurement Principles

Are defined in the Global Fund Policies on Procurement and Supply Management of Health Products.

- Transparent competitive procedures for the purchase of health products in order to obtain the lowest possible price with the required quality

Sources of Funding and Routes to Market

A variety of models exist and PPM has now de-linked fund disbursement from supplier payment.

Diagram:
- **PPM**
  - Funding Agency
  - PSA
  - PR
  - Manufacturer
  - Long Term Agreements and Funds

- **National Procurement Mechanism**
  - Funding Agency
  - PSA
  - PR
  - Manufacturer

- **Procurement Agents**
  - Funding Agency
  - PSA
  - PR
  - Manufacturer

The diagram illustrates the flow of funds, procurement services, and recipient country through different routes to market.
In 2013 and 2014 to date the overall reported spend is $113m broken down as shown:

- **CD4** $34m (30%)
  - 5 manufacturers

- **Viral Load** $7.7m (7%)
  - 5 manufacturers

- **RDT** $77m (63%)
  - 82 million tests;
  - 15 manufacturers
# Top 10 Countries by Product Set
Reported spend 2013-2014 to date

<table>
<thead>
<tr>
<th>CD4</th>
<th>Viral Load</th>
<th>RDT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nigeria</td>
<td>$10.9m</td>
<td>Malawi</td>
</tr>
<tr>
<td>Mozambique</td>
<td>$9.3m</td>
<td>Ukraine</td>
</tr>
<tr>
<td>Uganda</td>
<td>$3.8m</td>
<td>Guatemala</td>
</tr>
<tr>
<td>Congo DRC</td>
<td>$2.8m</td>
<td>Uganda</td>
</tr>
<tr>
<td>Zambia</td>
<td>$1.6m</td>
<td>Congo DRC</td>
</tr>
<tr>
<td>Cameroon</td>
<td>$1.4m</td>
<td>Mali</td>
</tr>
<tr>
<td>Lesotho</td>
<td>$1.1m</td>
<td>Burkina Faso</td>
</tr>
<tr>
<td>Liberia</td>
<td>$1.1m</td>
<td>Niger</td>
</tr>
<tr>
<td>Malawi</td>
<td>$1.0m</td>
<td>Guinea</td>
</tr>
<tr>
<td>Guinea Bissau</td>
<td>$0.7m</td>
<td>Guinea Bissau</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$33.8m</strong></td>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>
Market Analysis Observations: Demand

- Demand is linked to an algorithm/programmatic recommendations that are complex to establish/change
- Normative guidelines not always clear especially on prioritization
- Demand is poorly understood - especially what portion is funded
- Demand is often disconnected from laboratory systems capacity and absorption ability
- Many technical options exist with lack of access to impartial technical information and practical advice to guide optimal selection decisions
- Poorly regulated environment with quality requirements often insufficiently understood; limited number of qualified products
- Timing of procurement linked to financing cycles; challenges in financing of recurrent costs such as maintenance contracts
- Significant social & financial implications of poor quality of testing
Market Analysis Observations: Supply

- Products not similar in terms of performance and specifications; not interchangeable or simple to switch
- Multiple product permutations and different regulatory versions; specific origin not always clear or transparent
- Significant underutilization for some deployed technologies
- Many proprietary closed systems
- Contracting modalities not always optimal and inconsistent
- Significantly variable pricing often depending on distribution model/arrangements
- Variable understanding of the country specific needs and contexts
- Short shelf life for some products
- Delays in the entry of Point of Care solutions for CD4 and viral load
Addressing the Challenges – example of viral load

To Scale-up effective Viral Load testing

1. Clinical algorithm and linkages to care
2. Funded Demand
3. Quality Assurance Policy
4. Effective Supplier Engagement
5. Optimal Selection and Placement
6. Laboratory & sample transport Systems
7. Planning and Forecasting

Some strategic elements are in place……………. 
Programmatic, Financing & Procurement actions underway

1. Quality Assurance Policy for Diagnostics

2. Expert Review Panel to expedite access to high public health impact products
   - POC for CD4, Viral Load, Early Infant Diagnosis, molecular technologies using dried blood spots for viral load – with UNITAID

3. Policies for the procurement of health products
   - Guidance for financing in Strategic Investment Notes for HIV and Health Systems Strengthening
   - Guidance for the Procurement & Use of HIV RDTs

4. Leveraging Global Diagnostics Working Group & African Society for Laboratory Medicine
   - Quality assurance for product selection & testing implementation adopting a harmonized approach
   - Optimal selection and use
   - Strengthening laboratory systems
   - Advocating for appropriate and affordable diagnostics
Guidance has been issued by both the WHO and the Global Fund.
Collaboration is Improving

- Global Diagnostics Working Group:
  - Provides aligned messages on quality assurance for product selection and testing implementation
  - CDC, CHAI, MSF, The Global Fund, UNICEF, UNITAID, USG (OGAC, USAID, CDC), WHO
The Technology Landscape is mapped

POC CD4 products: available and pipeline*

POC viral load & EID products: available and pipeline*

POC viral load products: available and pipeline*

*Estimated as of February 2016 - timeline and sequence may change.

**Available in limited volume.
The new procurement approach will be broad based and designed to address a range of objectives.

**Sustainable Supply**
- Continued supply of products
- Matching the specific needs of country programmes.

**On-Time Delivery**
- Reduced lead times
- Improved Delivery Performance
- Mitigate force majeure
- Simplify supply logistic chains and distribution models

**Competitive Pricing and Affordability**
- Leveraged volumes
- Improved planning and longer term contracts
- Use supplier expertise
- Product Standardisation

**Quality and Regulatory**
- Support up-take of new technologies improving programme performance
- Procurement of Quality Assured products

These objectives will result in a new form of supplier engagement.
Our Procurement Principles

When we come to market our tender may include the following key elements:

• The Global Fund will take over the contracting relationship and the PSA will be responsible for operational management.

• Longer term contracts with committed volumes for the appropriate period.

• Performance based management with ongoing measurement of delivery and quality.

• Closer collaboration to improve efficiency.

• A focus on value as well as affordability with tender evaluation considering both commercial and technical criteria.
**Indicative Timeline.**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Timeline</th>
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<tbody>
<tr>
<td>Market Assessment and Strategy Definition</td>
<td>Now until Q4 2014</td>
</tr>
<tr>
<td>Tender Issue Viral Load</td>
<td>Q4 2014</td>
</tr>
<tr>
<td>Tender Issue RDT and CD4</td>
<td>Q1 2015</td>
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Thankyou.
Working Session

HIV Diagnostics Manufacturers Engagement
18 September 2014
# Working Session Instructions

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
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<tr>
<td><strong>We would like the audience to divide into three interest groups:</strong></td>
<td><strong>We would like each group to consider 3 questions.</strong></td>
</tr>
<tr>
<td>a. RDTs</td>
<td>1. From the 10 pre-defined headings, identify and explain key issues within those aspects that prevent you adding value and those where there may be future opportunities</td>
</tr>
<tr>
<td>b. Laboratory based equipment for CD4 and VL</td>
<td>2. What key actions do the public health agencies and partners (including The Global Fund) need to carry out to make the changes happen?</td>
</tr>
<tr>
<td>c. Point of Care for CD4 and VL</td>
<td>3. What key elements would you like to see in any future contractual relationship with the Global Fund?</td>
</tr>
</tbody>
</table>

You may then sub-divide each group into 2 if you so wish.

Use flipcharts and please choose someone to present back at the end.

Partners should select a group to join

(Note: some headings may not apply; you can also add up to 2 other headings)
The 10 Headings

1. Product quality assurance requirements
2. WHO/normative guidance
3. Product selection and placement guidance
4. Forecasting and order visibility
5. Ambiguity around buyer community requirements
6. Laboratory system capacity and quality of testing
7. Sample logistics and results feedback
8. Procurement and contracting modalities
9. Logistics
10. Added value and innovation
A Rough Guide to Expected Outputs

Feel Free to use as many flip charts as you need
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### Objective
- Inform manufacturers on the principles and eligibility criteria for procurement: short presentations and panel for questions after each sub-section (Global Fund, WHO PQ, USAID)

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18 September engaged with 31 HIV Dx manufacturers and they told us of the following challenges and opportunities (1)
http://www.theglobalfund.org/en/p4i/events/

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<tr>
<td>Challenges</td>
<td>Complexity is increasing with more country registration.</td>
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<td>Limiting innovation and competition</td>
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<tr>
<td>Opportunities</td>
<td>Faster, Cheaper Simpler QA with common ‘CE’ like standards</td>
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<tr>
<td><strong>WHO Normative Guidance</strong></td>
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<tr>
<td>Challenges</td>
<td>Guidance issued but communication needs to improve</td>
<td>Gaps around DBS</td>
<td>Clarification on prequalification process</td>
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<tr>
<td>Opportunities</td>
<td></td>
<td>Improvement to guidance on sample transport</td>
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<tr>
<td><strong>Product Selection and Placement Guidance</strong></td>
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<tr>
<td>Challenges</td>
<td>Issues of non compliance with policies</td>
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<td>Different criteria for product selection within country</td>
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<tr>
<td>Opportunities</td>
<td>Standardized approach to funding</td>
<td></td>
<td>Cap volumes to support emerging technology</td>
<td>Improved information on future tenders</td>
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</table>
### Challenges and opportunities (2)

<table>
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<tr>
<th></th>
<th>RDT</th>
<th>Viral Load</th>
<th>Point of Care</th>
<th>CD4 Lab</th>
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<tbody>
<tr>
<td><strong>Forecasting and Order Visibility</strong></td>
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<tr>
<td><strong>Challenges</strong></td>
<td>Lack of realistic country based forecasts and significant movement in timing of tenders.</td>
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<tr>
<td><strong>Opportunities</strong></td>
<td>Rolling quarterly 12-18 month forecasts. A separation of need from demand</td>
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<tr>
<td><strong>Ambiguity Around Buyer Community Requirements</strong></td>
<td>Need matrix of agency responsibilities</td>
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<tr>
<td><strong>Challenges</strong></td>
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<tr>
<td><strong>Opportunities</strong></td>
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<tr>
<td><strong>Laboratory system capacity and quality of testing</strong></td>
<td>Donor expectation vs. Country reality. Infrastructure Gap, lack of clinicians</td>
<td>Training underfunded</td>
<td>Manufacturers need greater understanding of in country metrics</td>
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<tr>
<td><strong>Challenges</strong></td>
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<tr>
<td><strong>Opportunities</strong></td>
<td>Separate training budgets with basic ‘train the trainer’ supported by manufacturers. Greater focus on service levels in tender evaluation</td>
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</table>
## Challenges and opportunities (3)

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<tr>
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</thead>
<tbody>
<tr>
<td><strong>Procurement and Contracting</strong></td>
<td>Lack of a consistent, streamlined procurement process. Lack of awareness of in-country risk and impact on manufacturers of lack of compliance to Terms &amp; conditions and risk of non/late payment</td>
<td>Direct payments. Longer term commitments for term and volume, linkage of Capex and service contracts. Greater education in country on shelf life requirements which differ from pharmaceuticals. Manufacturers terms change to CIF. Adequate time to respond to tenders.</td>
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<tr>
<td><strong>Logistics</strong></td>
<td>Lack of on time collection caused by a variety of factors. Major impact on cash flow which is reflected in cost. Lack of clarity on tax exemptions and slowness of customs clearance in certain countries.</td>
<td>On time collection, greater visibility of product location to support urgent requirements. Tax exemption and standardized labelling.</td>
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</tbody>
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