Global Fund / FAPMA Consultative Meeting
2017 African Pharmaceutical Manufacturers Conference
Addis Ababa, Ethiopia 14-15 June 2017

Mariatou Tala Jallow, Acting Chief Procurement Officer
Martin Auton, Manager, Global Sourcing: Pharmaceuticals
Alain Prat, Specialist, Quality Assurance, Grant Management Division

Lin (Roger) Li, Manager, Strategy, Analytics and Data Management, Sourcing
Jon Bastow, Private Sector Engagement Department
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

<table>
<thead>
<tr>
<th>Year</th>
<th>Amount disbursed (cumulative)</th>
<th>Number of lives saved (cumulative)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>0</td>
<td>20m</td>
</tr>
<tr>
<td>2006</td>
<td>0</td>
<td>20m</td>
</tr>
<tr>
<td>2007</td>
<td>0</td>
<td>20m</td>
</tr>
<tr>
<td>2008</td>
<td>0</td>
<td>20m</td>
</tr>
<tr>
<td>2009</td>
<td>0</td>
<td>20m</td>
</tr>
<tr>
<td>2010</td>
<td>0</td>
<td>20m</td>
</tr>
<tr>
<td>2011</td>
<td>0</td>
<td>20m</td>
</tr>
<tr>
<td>2012</td>
<td>0</td>
<td>20m</td>
</tr>
<tr>
<td>2013</td>
<td>0</td>
<td>20m</td>
</tr>
<tr>
<td>2014</td>
<td>0</td>
<td>20m</td>
</tr>
<tr>
<td>2015</td>
<td>0</td>
<td>20m</td>
</tr>
<tr>
<td>2016</td>
<td>0</td>
<td>20m</td>
</tr>
</tbody>
</table>

Breakdown of investments by implementer type (active grants)

- **Ministry of Health**: 45%
- **Multilateral organization**: 12%
- **Faith based organization**: 2%
- **Private sector**: 2%
- **NGO/CBO/ Academic**: 29%
- **Other government ministries**: 10%
- **Private sector**: 2%

Breakdown of investments by region (active grants)

- **Sub-Saharan Africa**: 64%
- **North Africa and the Middle East**: 8%
- **Latin America and the Caribbean**: 4%
- **Eastern Europe and Central Asia**: 5%
- **Asia and the Pacific**: 19%
Successful replenishment for the 2017-2019 allocation period for implementing the Global Fund Strategy

- 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>

*Health products = 40-60% spend depending on category*
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)

- **Non communicable**: 6.1%
- **Malaria**: 1.8%
- **Health support**: 1.3%
- **Maternal/ Newborn**: 6.5%
- **HIV**: 7.7%
- **Unallocable**: 6.5%
- **Others**: 0.4%

**Total**: USD 30.7 billion

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

- **WHO**: 2.2%
- **UN agencies**: 2.6%
- **NGOs**: 4.9%
- **Global Fund**: 2.6%
- **USA**: 7.4%
- **Others**: 9.6%
- **Others**: 9.6%

**Total**: USD 30.7 billion

**13% of global Public Health Market**

**SOURCE:** [http://vizhub.healthdata.org/fgh/](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

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
Global Fund has proactively shaped markets to improve health outcomes since 2004

- **2004**: With WHO, recipients transitioned to ACTs from suboptimal therapies
- **2007**: Market Shaping Strategy is approved by Board, with focus on pooling procurement, value for money, capacity building and ARVs
- **2011**: Board approves first Market Shaping Strategy, including Price & Quality Reporting and Voluntary Pooled Procurement
- **2013**: Operational initiatives through Procurement for Impact strengthen market shaping tools
- **2015**: Changing market dynamics, context, and new Global Fund strategy prompted revision of Market Shaping Strategy
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>
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>PS</td>
<td>PR</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>PR</td>
<td>Products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Funds</td>
<td>Orders</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pooled Procurement Mechanism (PPM)

National Procurement Mechanisms

Other Procurement Agents; Global Drug Facility (TB)
Implementing the Board-approved (2015) Market Shaping Strategy through the Pooled Procurement Mechanism (PPM)

Vision

*Market shaping supports health outcomes and access to critical health products by…*

...leveraging the Global Fund’s position to facilitate healthy global markets; generate cost savings and improve procurement and delivery conditions (lead time; on time and in full (OTIF))

Scope

- All pharmaceuticals and health technology products financed by Global Fund
- Sourcing strategies for core products (ARVs, Antimalarials, LLINs, diagnostics including RDT*, essential medicines used in HIV*) through Long Term Framework Agreements (LTAs) with suppliers
- Procurement methods for non-core products through PSAs and catalogues

Process

- Designing, issuing and managing competitive tenders to support category-specific market shaping objectives
- Managing Supplier allocations and PR requests & demand of core health products through framework agreements
- Execution of PPM orders from requests to deliveries via wambo.org, a PR-facing portal that increases country ownership of ordering operations with full visibility and a transparent and auditable process

* In progress, as indicated in workplan
Key expectations for Market Development

- **Value for Money**
  - Maximizing Investments
  - Competitive pricing
  - Board value base

- **Sustainability**
  - Reliable, Responsible and Responsive Supply
  - **On Time In Full deliveries**

- **Quality & Regulatory**
  - International Standards
  - Registration footprints

- **Market Intelligence**
  - Technology
  - Balanced Demand and Supply
  - Market trend
Quality Assurance Policy for Health Products

- **Pharmaceutical Products**
  - (December 2010)

- **Condoms**
  - WHO Procurement Guidelines

- **Diagnostic Products**
  - (revised in May 2017)

- **Long Lasting Insecticidal Nets, Pesticides for Indoor Residual Spraying**
  - WHOPES recommendations
  - WHO Public Health Pesticides Procurement Guidelines
# QA Policy for Pharmaceutical Products

## Selection

1. **Clinical Criteria**
   - Medicines listed in WHO EML or national or institutional Standard Treatment Guidelines
   - Require applicants/ recipients to provide justification for selection of unlisted products in one of the STGs

## Procurement

2. **Quality Criteria**
   - For all products:
     - Authorization for use in the recipient countries
   - For ARVs, anti-TB and antimalarial products
     - Specific requirements

## In-country management

3. **Monitoring Quality**
   - Monitoring quality of products all along the supply chain

4. **Implementing Pharmacovigilance**
   - Monitoring ADRs of pharmaceutical products
Quality Requirements for Pharmaceutical Products

• For all products
  • Registration / Marketing Authorization for use in the recipient countries
    • National requirements for registration applied

• For ARVs, Anti-TB medicines and Anti-Malaria pharmaceuticals
  • WHO Prequalified by WHO PQ Team
    • Internationally recognized standards (GMP, BE, Stability)
  • Authorized by Stringent Regulatory Authority
    • Internationally recognized standards (GMP, BE, Stability)
  • Found Eligible for procurement following the advise of the Expert Review Panel (ERP)
Expert Review Panel (ERP)

- Expression of Interest following extensive consultation
- A panel of experts hosted by WHO
- Eligibility criteria for dossier submission:
  - product manufactured in GMP site; and
  - dossier already submitted to and accepted for review by WHO PQ program or by a SRA
- Assesses the potential risks/benefits associated with the use of FPPs that are not yet WHO-prequalified or SRA-authorized
- Assessment of product dossiers submitted by manufacturers
- Makes time limited recommendations to Global Fund: maximum 12 months
Procurement Criteria for Pharmaceutical Products

For all products:
Procurement complies with the principles set forth in the WHO Model Quality Assurance System for Procurement Agencies (MQAS)

Describes a quality management system for procurement entity + package of useful guidelines

- to harmonize the format of data and information requested to the manufacturers
  - Inter-Agency Pharmaceutical Product Questionnaire
- to harmonize the evaluation of data and information on products
  - SOP for screening and assessing questionnaire
- Unified standards for inspection of manufacturers and suppliers to assess compliance with GMP
  - SOP for planning, preparation, performing and reporting of inspections
- for Good Storage and Good Distribution Practices
Main sections of the Inter Agency Finished Pharmaceutical Product Questionnaire

- Product identification
- Manufacturer of the product
- Supplier identification
- Regulatory status
- Samples
- Active pharmaceutical ingredients: Sources, specifications
- Finished product specifications: manufacturing & validation, specifications, stability
- Therapeutic equivalence (BE, Comparative in-vitro dissolution)

No prescribed requirements / standards / technical & regulatory guidelines
Operational arrangement for listing in Global Fund QA Lists

Initial listing

• Filing a product information sheet (PIS) with all requested information

Maintenance in the list

• Information on important variations related to the Product or manufacturing sites
• Information on serious ADRs and NCs
• Information on GMPs issues and potential regulatory actions
• Randomized quality control testing Covered by confidentiality agreement
MARKET SHAPING STRATEGY & SOURCING APPROACH
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
- Performance-based contracting
- Supplier Relationship Management
- Improved data management
- Value creation by optimizing demand

Phase III
- Building Market Knowledge, including through supplier visits
- Understanding cost
- First Framework Agreements
- Simple KPIs

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

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.

<table>
<thead>
<tr>
<th>Previously</th>
<th>Now</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Price</strong></td>
<td><strong>Price</strong></td>
</tr>
<tr>
<td>Managed periodically by Tender</td>
<td>Ongoing management</td>
</tr>
<tr>
<td>Largely Ignored</td>
<td></td>
</tr>
<tr>
<td>Other Elements</td>
<td>Other Elements</td>
</tr>
<tr>
<td>• Performance</td>
<td>• Performance</td>
</tr>
<tr>
<td>• Projects to support objectives</td>
<td>• Projects to support objectives</td>
</tr>
<tr>
<td>• Process improvement</td>
<td>• Process improvement</td>
</tr>
</tbody>
</table>
The Global Fund has introduced a more balanced supply system based on 5 elements to improve performance:

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
</tr>
</thead>
</table>
| **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 |
Sustainability: working across product categories, further diversifying our supplier base.

- Procure core health products from a range of suppliers, including originators, licensed generics, generics and Africa-based manufacturers. Newly approved suppliers may also have opportunities to supply, if needed.

<table>
<thead>
<tr>
<th>Core health product category</th>
<th># of suppliers supplied to GF PPM</th>
<th>Total eligible suppliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARVs</td>
<td>17</td>
<td>20</td>
</tr>
<tr>
<td>ACTs</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>LLINs</td>
<td>10</td>
<td>13</td>
</tr>
</tbody>
</table>

- We are proactively working on diversifying our supplier base by engaging with China- and Africa-based pharmaceutical, LLIN and diagnostics suppliers to understand challenges and explore opportunities, which will be considered in on-going procurement strategy development.
Supply Risk Management

1. **Robust regular performance review and allocation**: ~70% of PPM spend is covered by continuous supplier performance review and annual volume allocation is subject to adjustment based on previous year performance review.

2. Working closely with GF quality specialists team, and regulatory agencies to proactively address any emerging **quality issues** associated with suppliers. Product volume allocation can be timely adjusted to mitigate identified risks.

3. On-going supplier engagement keep our market intelligence up-to-date to inform our procurement strategy development and procurement planning. More importantly it enable us to accommodate any **newly approved products** and **suppliers** into the procurement process if needed.
Our strategy to encourage local production through the Pooled Procurement Mechanism

Defining new sourcing strategies and changing the procurement landscape:

- Engaging directly with African Manufacturers
- Encouraging 'local' manufacture for the first time as an explicit objective in procurement strategies (anti-malarial medicines, May 2017)
- Multi-year Framework agreements to provide a level of certainty that that enables a longer term vision on financing, volume and pricing (underwritten by allocations and commitments in the resulting framework agreements)
- Adjusting the commercial landscape to 'Level' the competition playing field through:
  - Broad definition of value beyond price
  - Responsiveness and customer proximity;
  - Re-balancing of tenders by increasing the emphasis on total landed cost
- Diversify our current supply base through intensive supplier engagement, including engaging with Africa-based manufacturers.
Volumes produced in Africa supplied through the Pooled Procurement Mechanism (2016)

Pharmaceuticals:

• Through our global tenders, we have increasingly procured ACTs (and ARVs) from Quality Chemicals, Uganda – reaching 15% total volume in 2016 for artemether-lumefantrine (amongst 7 suppliers)
• For essential medicines are sourced from a limited number of Africa-based manufacturers including Universal (currently through our procurement agents). We see other emerging opportunities with the increasing number of manufacturers and will be launching a new procurement strategy for essential medicines in H1-2018

Health technology: LLIN

• The result 2015 GF LLIN tender, A-Z Tanzania was allocated significant volumes: 13% volume in 2016
Benefit Sharing and Capacity Development

1. **PPM Reference prices** are published on website and Wambo.org and used for budgeting purpose by The Global Fund and others

2. **Framework Agreements extended** (depending on category) to partner agencies (PAHO; UNDP; UNITAID) and to Governments with national funding (e.g. Cameroun, Georgia, Guyana)

3. Enabling **manufacturing close to the demand and encouraging new entrants**.

4. **Sharing procurement expertise and experiences**: establishing a procurement community – including The Procurement Portal (Openshare); mentorship programmes etc. (pending launch)
POOLED PROCUREMENT MECHANISM

PROCUREMENT PORTFOLIO
Pooled Procurement Mechanism (PPM) Process Flow

Grant Program & Implementation Plans

Country teams

PR¹

Wambo PPM Platform

Processing transactions

PPM Sourcing

➢ Long-term agreements
➢ Supplier relationship management

➢ PSA management
➢ Supplier allocation

Supply Chain

➢ Upstream logistics
➢ In-country supply chain management

PO placement

Suppliers

PO placement

F/L³

Upstream logistics

Medical Store

Delivery

Downstream logistics

Health center

Raising Request

1. Principal Recipients
2. Procurement Services Agent
3. Freight Logistics
PPM spend is approximately 55% of the total Global Fund health product spend

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

**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.

Source: Financial data from PPM 2016 approved orders
<table>
<thead>
<tr>
<th>Africa</th>
<th>Asia Europe, Latin. America &amp; Caribbean (AELAC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angola</td>
<td>Eastern Europe and Central Asia</td>
</tr>
<tr>
<td>Benin</td>
<td>Armenia</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>Georgia</td>
</tr>
<tr>
<td>Burundi</td>
<td>Kazakhstan</td>
</tr>
<tr>
<td>Cameroon</td>
<td>Macedonia</td>
</tr>
<tr>
<td>Cape Verde</td>
<td>Latin America &amp; Caribbean</td>
</tr>
<tr>
<td>Central African Republic</td>
<td>Colombia</td>
</tr>
<tr>
<td>Comoros</td>
<td>Dominican Republic</td>
</tr>
<tr>
<td>Congo</td>
<td>Guatemala</td>
</tr>
<tr>
<td>Guinea</td>
<td>Guyana</td>
</tr>
<tr>
<td>Guinea-Bissau</td>
<td>Honduras</td>
</tr>
<tr>
<td>Lesotho</td>
<td>Nicaragua</td>
</tr>
<tr>
<td>Liberia</td>
<td>South East Asia</td>
</tr>
<tr>
<td>Madagascar</td>
<td>Bhutan</td>
</tr>
<tr>
<td>Malawi</td>
<td>Cambodia</td>
</tr>
<tr>
<td>Mali</td>
<td>Lao PDR</td>
</tr>
<tr>
<td>Mauritania</td>
<td>Mongolia</td>
</tr>
<tr>
<td>Mauritius</td>
<td>Multi-country Western Pacific</td>
</tr>
<tr>
<td>Niger</td>
<td>Nepal</td>
</tr>
<tr>
<td>Senegal</td>
<td>Papua New Guinea</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>Sri Lanka</td>
</tr>
<tr>
<td>Swaziland</td>
<td>Timor Leste</td>
</tr>
<tr>
<td>The Gambia</td>
<td></td>
</tr>
<tr>
<td>Togo</td>
<td></td>
</tr>
<tr>
<td>Yemen</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>High Impact Africa 1</th>
<th>High Impact Africa 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cote d'Ivoire</td>
<td>Mozambique</td>
</tr>
<tr>
<td>DR Congo</td>
<td>Tanzania</td>
</tr>
<tr>
<td>Ghana</td>
<td>Uganda</td>
</tr>
<tr>
<td>Nigeria</td>
<td>Zambia</td>
</tr>
<tr>
<td></td>
<td>Zanzibar</td>
</tr>
<tr>
<td></td>
<td>Zimbabwe</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>High Impact Asia</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td></td>
</tr>
<tr>
<td>Indonesia</td>
<td></td>
</tr>
<tr>
<td>Pakistan</td>
<td></td>
</tr>
<tr>
<td>Philippines</td>
<td></td>
</tr>
<tr>
<td>Thailand</td>
<td></td>
</tr>
<tr>
<td>Vietnam</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**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

---

**In the pipeline (2017)**
- LLINs
- ACTs
- ARVs
- Condoms & lubricants
- HRDTs
- MRDTs
- Viral Load
- Health Portfolio Tail
  - Non core pharma
  - Other diagnostics
  - General lab supplies

---

**Timeline:**
- January
- May
- July
- October
- November
- March
- End Q2
Sourcing & procurement of health products

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

Antiretroviral medicines

+/- 30 medicines including the following 10 responsible for around 95% spend

- efavirenz+lamivudine+tenofovir – FDC 600mg+300mg+300mg | tab bottle-30
- efavirenz+emtricitabine+tenofovir - FDC600mg+200mg+300mg | tab bottle-30
- lamivudine+nevirapine+zidovudine - FDC150mg+200mg+300mg | tab bottle - 60
- lamivudine+tenofovir – FDC 300mg+300mg | tabbottle-30
- lamivudine+zidovudine – FDC 150mg+300mg | tab bottle - 60
- lamivudine+nevirapine+zidovudine – FDC 30mg+50mg+60mg | dispersible tab bottle - 60
- lopinavir+ritonavir – FDC 200mg+50mg | tab bottle-120
- efavirenz 600mg | tab bottle-30
- nevirapine 200mg | tab bottle - 60
- atazanavir + ritonavir - FDC300mg+100mg | tab bottle-30

<table>
<thead>
<tr>
<th>Product Set</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Artemether-lumefantrine</td>
<td>High volume artemisinin-combination therapies (ACTs)</td>
<td>• artemether + lumefantrine (FDC)</td>
</tr>
<tr>
<td>Artesunate-amodiaquine</td>
<td></td>
<td>• artesunate + amodiaquine (FDC)</td>
</tr>
<tr>
<td>2 Severe malaria</td>
<td>Injectable and rectal artesunate</td>
<td>• artesunate (powder)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• artesunate (suppositories)</td>
</tr>
<tr>
<td>3 Specialized use and low volume ACTs</td>
<td>Chemoprophylaxis for special risk groups and low volume ACTs</td>
<td>• sulfadoxine-pyrimethamine (FDC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• amodiaquine + sulfadoxine-pyrimethamine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ artesunate + mefloquine (FDC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ artesunate + sulfadoxine-pyrimethamine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ dihydroartemisinin + piperaquine (FDC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ artesunate + pyronaridine</td>
</tr>
<tr>
<td>4 Other: low transmission, relapse, CQ-sensitive</td>
<td>Medicines for low-transmission, P. vivax relapse prevention and uncomplicated chloroquine-sensitive infections</td>
<td>• primaquine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• chloroquine</td>
</tr>
</tbody>
</table>
**Co-trimoxazole prophylaxis**
- Tablets: 960mg; 480mg; 120mg dispersible
- Suspension 200/40mg/5 ml

**Isoniazid preventive therapy**
- Tablets: 100mg, 300mg

**Cryptococcal disease**
- amphotericin B, injection vial 50 mg (deoxycholate); 50 mg (liposomal)
- flucytosine capsule 250mg; 500 mg scored/preferably slow release tablet; inj 10mg/ml
- fluconazole capsule 50 mg; 200 mg; injection 2mg/ml

**Hepatitis C (preferred regimens)**
- sofosbuvir 400mg
- ledipasvir 90mg/sofosbuvir 400 mg
- daclatasvir 30, 60mg
- ribavarin 200mg

**Isoniazid + co-trimoxazole + pyridoxine tablets** 300 mg/ 960 mg/25 mg
### Essential medicines: other WHO recommendations for use in HIV*

<table>
<thead>
<tr>
<th>Antiviral agents</th>
<th>Antibacterial agents</th>
<th>Antiprotozoal, antifungal &amp; anti- mycobacterial agents</th>
<th>Palliative care</th>
<th>Opioid substitution therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• acyclovir tablets</td>
<td>• amoxicillin/clavulanic acid, scored/tablet</td>
<td>• clarithromycin tablet</td>
<td>• amitriptyline tablets</td>
<td>• buprenorphine sublingual tablets</td>
</tr>
<tr>
<td>• gancyclovir injection</td>
<td>• azithromycin tablets</td>
<td>• Clindamycin injection, capsules</td>
<td>• chlorphenamine tablets; oral solution</td>
<td>• methadone, concentrate for oral solution; oral solution</td>
</tr>
<tr>
<td>• valganclovir tablets</td>
<td>• ceftriaxone injection</td>
<td>• dapsone tablets</td>
<td>• codeine tablets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ciprofloxacin tablets</td>
<td>• folinic acid tablets</td>
<td>• cyclizine tablets; injection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• sulfadiazine tablets</td>
<td>• rifabutin capsules</td>
<td>• dexametasone tablets; injection</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• itraconazole capsules</td>
<td>• diazepam tablets; injection</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• pentamidine injection</td>
<td>• docuscate capsules; oral solution</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• pyrimethamine tablets</td>
<td>• fluoxetine tablets</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• hyoscine hydrobromide tablets; transdermal patch</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• ibuprofen tablets</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• loperamide injection; oral solution</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• morphine tablets (immediate release &amp; controlled release); oral solution; sprinkles</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• ondansetron tablets; injection</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Prednisolone tablets</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• senna tablets; oral solution</td>
<td></td>
</tr>
</tbody>
</table>

* Source: WHO expression of interest (also details formulation strengths)
## Largest volume products – Pooled Procurement Mechanism

<table>
<thead>
<tr>
<th>Product</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>Q1 2016</th>
<th>Grand Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-trimoxazole</td>
<td>$4,510,167</td>
<td>$9,971,096</td>
<td>$12,135,479</td>
<td>$6,911,217</td>
<td>$33,527,958</td>
<td>58%</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>$405,700</td>
<td>$1,649,832</td>
<td>$2,263,132</td>
<td>$2,304,716</td>
<td>$6,623,381</td>
<td>11%</td>
</tr>
<tr>
<td>Methadone</td>
<td>$1,388,662</td>
<td>$1,260,603</td>
<td>$2,895,963</td>
<td>-</td>
<td>$5,545,228</td>
<td>10%</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>$63,049</td>
<td>$1,039,994</td>
<td>$2,000,402</td>
<td>$912,311</td>
<td>$4,015,755</td>
<td>7%</td>
</tr>
<tr>
<td>Phenoxymethylpenicillin</td>
<td>-</td>
<td>$500,000</td>
<td>$400,000</td>
<td>$652,500</td>
<td>$1,552,500</td>
<td>3%</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>$43,118</td>
<td>$233,293</td>
<td>$591,968</td>
<td>$597,971</td>
<td>$1,466,350</td>
<td>3%</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>$59,524</td>
<td>$461,839</td>
<td>$563,725</td>
<td>$286,401</td>
<td>$1,371,490</td>
<td>2%</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>$16,804</td>
<td>$365,783</td>
<td>$505,592</td>
<td>$288,506</td>
<td>$1,176,684</td>
<td>2%</td>
</tr>
<tr>
<td>Vincristine</td>
<td>$3,362</td>
<td>$860,384</td>
<td>$131,100</td>
<td>$110,933</td>
<td>$1,105,779</td>
<td>2%</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>$68,464</td>
<td>$278,910</td>
<td>$267,040</td>
<td>$230,707</td>
<td>$845,122</td>
<td>1%</td>
</tr>
<tr>
<td>Bleomycin</td>
<td>$57,745</td>
<td>$217,594</td>
<td>$328,063</td>
<td>$149,991</td>
<td>$753,393</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td><strong>$6,616,594</strong></td>
<td><strong>$16,839,328</strong></td>
<td><strong>$22,082,465</strong></td>
<td><strong>$12,445,252</strong></td>
<td><strong>$57,983,640</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Source: IDA Product report 04 April 2016

5 products/10 formulations = 89%
### Spend concentrated in a few countries

<table>
<thead>
<tr>
<th>Destination Country</th>
<th>Destination Region</th>
<th>Value USD</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mozambique</td>
<td>High Impact - Africa II</td>
<td>$ 25,867,246</td>
<td>38%</td>
</tr>
<tr>
<td>Malawi</td>
<td>AME-CA</td>
<td>$ 12,247,061</td>
<td>18%</td>
</tr>
<tr>
<td>Uganda</td>
<td>High Impact - Africa II</td>
<td>$ 10,481,374</td>
<td>15%</td>
</tr>
<tr>
<td>Congo (Democratic Republic)</td>
<td>High Impact - Africa I</td>
<td>$ 7,924,192</td>
<td>12%</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>High Impact - Asia</td>
<td>$ 5,501,228</td>
<td>8%</td>
</tr>
<tr>
<td>Cameroon</td>
<td>AME-WA</td>
<td>$ 2,823,937</td>
<td>4%</td>
</tr>
<tr>
<td>Burundi</td>
<td>AME-CA</td>
<td>$ 1,460,048</td>
<td>2%</td>
</tr>
<tr>
<td>Liberia</td>
<td>AME-CA</td>
<td>$ 1,202,126</td>
<td>2%</td>
</tr>
<tr>
<td>Guinea</td>
<td>AME-WA</td>
<td>$ 674,615</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td></td>
<td><strong>$ 68,181,827</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Source: IDA Product report 04 April 2016
2013 - Q1/2016

6 countries = 96%
Long lead-times of 200 or more days

<table>
<thead>
<tr>
<th>Product</th>
<th>Days</th>
<th>Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-trimoxazole</td>
<td>213</td>
<td>7.1</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>203</td>
<td>6.8</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>206</td>
<td>6.9</td>
</tr>
<tr>
<td>Phenoxyimethylpenicillin</td>
<td>271</td>
<td>9.0</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>175</td>
<td>5.8</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>166</td>
<td>5.5</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>210</td>
<td>7.0</td>
</tr>
<tr>
<td>Vincristine</td>
<td>216</td>
<td>7.2</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>159</td>
<td>5.3</td>
</tr>
<tr>
<td>Bleomycin</td>
<td>241</td>
<td>8.0</td>
</tr>
<tr>
<td>Nystatin</td>
<td>190</td>
<td>6.3</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td><strong>200</strong></td>
<td><strong>6.7</strong></td>
</tr>
</tbody>
</table>

Source: IDA Product report 04 April 2016
2013-2015
### WHO recommended long-lasting insecticidal nets

<table>
<thead>
<tr>
<th>Product name</th>
<th>Product type</th>
<th>Status of WHO recommendation</th>
<th>Status of publication of WHO specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>DawaPlus 2.0</td>
<td>Deltamethrin coated on polyester</td>
<td>Interim</td>
<td>Published</td>
</tr>
<tr>
<td>Duranet</td>
<td>Alpha-cypermethrin incorporated into polyethylene</td>
<td>Full</td>
<td>Published</td>
</tr>
<tr>
<td>Interceptor</td>
<td>Alpha-cypermethrin coated on polyester</td>
<td>Full</td>
<td>Published</td>
</tr>
<tr>
<td>LifeNet</td>
<td>Deltamethrin incorporated into polypropylene</td>
<td>Interim</td>
<td>Published</td>
</tr>
<tr>
<td>MAGNet</td>
<td>Alpha-cypermethrin incorporated into polyethylene</td>
<td>Full</td>
<td>Published</td>
</tr>
<tr>
<td>MiraNet</td>
<td>Alpha-cypermethrin incorporated into polyethylene</td>
<td>Interim</td>
<td>Published</td>
</tr>
<tr>
<td>Olyset Net</td>
<td>Permethrin incorporated into polyethylene</td>
<td>Full</td>
<td>Published</td>
</tr>
<tr>
<td>Olyset Plus</td>
<td>Permethrin and PBO incorporated into polyethylene</td>
<td>Interim</td>
<td>Published</td>
</tr>
<tr>
<td>Panda Net 2.0</td>
<td>Deltamethrin incorporated into polyethylene</td>
<td>Interim</td>
<td>Published</td>
</tr>
<tr>
<td>PermaNet 2.0</td>
<td>Deltamethrin coated on polyester</td>
<td>Full</td>
<td>Published</td>
</tr>
<tr>
<td>PermaNet 3.0</td>
<td>Combination of deltamethrin coated on polyester with strengthened border (side panels), and deltamethrin and PBO incorporated into polyethylene (roof)</td>
<td>Interim</td>
<td>Published</td>
</tr>
<tr>
<td>Royal Sentry</td>
<td>Alpha-cypermethrin incorporated into polyethylene</td>
<td>Full</td>
<td>Published</td>
</tr>
<tr>
<td>SafeNet</td>
<td>Alpha-cypermethrin coated on polyester</td>
<td>Full</td>
<td>Published</td>
</tr>
<tr>
<td>Veeralin</td>
<td>Alpha-cypermethrin and PBO incorporated into polyethylene</td>
<td>Interim</td>
<td>Published</td>
</tr>
<tr>
<td>Yahe</td>
<td>Deltamethrin coated on polyester</td>
<td>Interim</td>
<td>Published</td>
</tr>
<tr>
<td>Yorkool</td>
<td>Deltamethrin coated on polyester</td>
<td>Full</td>
<td>Published</td>
</tr>
</tbody>
</table>
## HIV Rapid Diagnostic Tests - 21 products

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Description</th>
<th>Accessories</th>
<th>Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV 1+2</td>
<td>Determine Complete HIV Kit</td>
<td>included</td>
<td>100</td>
</tr>
<tr>
<td>HIV 1+2</td>
<td>Determine HIV Kit</td>
<td>no accessories</td>
<td>100</td>
</tr>
<tr>
<td>HIV 1/2</td>
<td>Determine HIV Combo Kit</td>
<td>no accessories</td>
<td>100</td>
</tr>
<tr>
<td>HIV 1+2</td>
<td>Chase Buffer for Determine</td>
<td>2.5ml vial</td>
<td>100</td>
</tr>
<tr>
<td>HIV 1/2</td>
<td>Bioline 3.0 Kit</td>
<td>included</td>
<td>25</td>
</tr>
<tr>
<td>HIV 1/2</td>
<td>Bioline 3.0 Kit</td>
<td>no accessories</td>
<td>30</td>
</tr>
<tr>
<td>HIV 1/2</td>
<td>SD Bioline HIV/Syphilis Duo complete kit</td>
<td>included</td>
<td>25</td>
</tr>
<tr>
<td>HIV 1+2</td>
<td>Uni-gold HIV Kit</td>
<td>included</td>
<td>20</td>
</tr>
<tr>
<td>HIV 1/2-O</td>
<td>First Response HIV 1-2.0 v.3.0 Cards Kit</td>
<td>included</td>
<td>30</td>
</tr>
<tr>
<td>HIV 1/2-O</td>
<td>First Response HIV 1-2.0 v.3.0 Cards Kit</td>
<td>included</td>
<td>25</td>
</tr>
<tr>
<td>HIV 1+2</td>
<td>SD Bioline Ag/Ab Combo Kit</td>
<td>no accessories</td>
<td>30</td>
</tr>
<tr>
<td>HIV 1+2</td>
<td>OraQuick HIV Rapid Antibody Kit</td>
<td>included</td>
<td>100</td>
</tr>
<tr>
<td>HIV 1+2</td>
<td>Stat-Pak Dipstick Assay Kit</td>
<td>included</td>
<td>30</td>
</tr>
<tr>
<td>HIV 1+2</td>
<td>Stat-Pak HIV Kit</td>
<td>included</td>
<td>20</td>
</tr>
<tr>
<td>HIV 1+2</td>
<td>Vikia HIV Device Kit</td>
<td>included</td>
<td>25</td>
</tr>
<tr>
<td>HIV 1+2</td>
<td>INSTI HIV Antibody Test Kit</td>
<td>48</td>
<td></td>
</tr>
<tr>
<td>HIV 1</td>
<td>Generic Rapid Diagnostic Test Kit</td>
<td>1 test</td>
<td></td>
</tr>
<tr>
<td>HIV 1/2</td>
<td>Generic Rapid Diagnostic Test Kit</td>
<td>1 test</td>
<td></td>
</tr>
<tr>
<td>HIV 1+2</td>
<td>Determine HIV Kit</td>
<td>no accessories</td>
<td>20</td>
</tr>
<tr>
<td>Capillary Tubes</td>
<td>Determine - EDTA 50 uL</td>
<td>100 tubes</td>
<td></td>
</tr>
</tbody>
</table>

4 products with accessories included represent 91% of total category spend in 2016

## Malaria Rapid Diagnostic Tests

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Description</th>
<th>Accessories</th>
<th>Tests</th>
<th>Category Spend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria Rapid Diagnostic Test Kit</td>
<td>Antigen Pf</td>
<td>included</td>
<td>25</td>
<td>71%</td>
</tr>
<tr>
<td>Malaria Rapid Diagnostic Test Kit</td>
<td>Antigen Pf/Pan</td>
<td>included</td>
<td>25</td>
<td>14%</td>
</tr>
<tr>
<td>Malaria Rapid Diagnostic Test Kit</td>
<td>Antigen Pf / Pv</td>
<td>included</td>
<td>25</td>
<td>10%</td>
</tr>
<tr>
<td>Malaria Rapid Diagnostic Test Kit</td>
<td>Antigen Pf</td>
<td>POCT</td>
<td>25 x 1</td>
<td>4%</td>
</tr>
<tr>
<td>Malaria Rapid Diagnostic Test Kit</td>
<td>Antigen Pf/Pan</td>
<td>POCT</td>
<td>25 x 1</td>
<td>0.4%</td>
</tr>
<tr>
<td>Malaria Rapid Diagnostic Test Kit</td>
<td>Antigen Pf / Pv</td>
<td>POCT</td>
<td>25 x 1</td>
<td>0.1%</td>
</tr>
</tbody>
</table>
Transaction level data: procured & delivered

Price and Quality Reporting - PQR

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

- Medicinas (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.

http://www.theglobalfund.org/en/pqr/
# The business opportunities and requirements for manufacturers

<table>
<thead>
<tr>
<th>Feature</th>
<th>Impact for Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Long term contracts with volume allocation and</td>
<td>• Ability to make finance plans;</td>
</tr>
<tr>
<td>potentially commitment (2 - 5 years)</td>
<td>• Optimize plant loading</td>
</tr>
<tr>
<td>• Annual Volume Commitments</td>
<td>• Risk mitigation</td>
</tr>
<tr>
<td>• A focus on total cost of ownership</td>
<td>• Viability of inward investment</td>
</tr>
<tr>
<td>• Seek Value-added services</td>
<td>• Opportunity for innovation and investment</td>
</tr>
</tbody>
</table>

## Key requirements

| • Product need to be compliant with relevant Global Fund Quality Policy.  | • GMP and product approval are required + supporting admin processes. |
| • National registration also required                                                             |                                                                       |
Non-ARV Essential Medicine – Strategic direction

1. **Differentiated sub-strategies and approach** (and phased implementation)
   - Intervention: e.g. core WHO-recommended interventions; other essential medicines; Hepatitis C; narcotics
   - Volume and value potential
   - Regulatory framework
   - Supplier base: current & potential

2. **Qualification of international and sub-regional/national manufacturers and wholesalers**
   - Including (accelerated) review for new sources/products to enter
   - for those without WHO-PQ/SRA using WHO Model Quality Assurance System “principles”

3. **Contracting with manufacturers both directly and indirectly**
4. **Determine award and allocation criteria:** tender and individual order implementation
5. **Determine implementation dynamics including partnership/collaboration and supplier performance management**

We are listening as we evolve this procurement strategy
### Sourcing strategies and procurement timelines

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Lasting Nets (LLINs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACT/Anti-malarial medicines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-retroviral medicines (ARV)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-ARV Essential Medicines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Current/previous contracting periods**
- **Next contracting period**
- **Tender**

*Subject to change*
WHO Prequalification of in-vitro diagnostics, medicines, vaccines and vector control products

Overview of prequalification processes & product-specific updates

Deus Mubangizi
Coordinator,
WHO Prequalification Team

2017 African Pharma Manufacturers Conference
Addis Ababa, Capital Hotel

14th -15th June 2017
WHO prequalification of in-vitro diagnostics, medicines, vaccines and vector control products

Outline

Introduction

Prequalification role

Prequalification process

Product-specific updates

Conclusion
WHO prequalification of in-vitro diagnostics, medicines, vaccines and vector control products

Outline

Introduction

Prequalification role

Prequalification process

Product-specific updates

Conclusion
WHO-PQ contributed to the Millennium Development Goals (MDGs):

- Eight international development goals that 192 United Nations member states and at least 23 international organizations have agreed to achieve by the year 2015

4. Reduce child mortality
5. Improve maternal Health
6. Combat HIV/AIDs, Malaria and other diseases
WHO-PQ contributes to the achievement of Sustainable Development Goals (SDGs)

WHO-PQ by making safe quality priority health products available through efficient and scientifically solid assessment contributes to achieving SDGs and UHC. SDG 3 targets by 2030 include:

- reduce the global maternal mortality
- end preventable deaths of newborns and children under 5 years of age,
- end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases
- ensure universal access to sexual and reproductive health-care services, including for family planning
- Achieve universal health coverage, including access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all
- Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries and provide access to medicines for all
Organization structure: PQT within RHT within EMP

- 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]
Structure of the Prequalification Team

- Prequalification Team
  - Coordinator’s office
  - Vaccines Assessment
  - Medicines Assessment
  - Diagnostics Assessment
  - Inspections
  - Vector control
  - Administrative team
The prequalification team is responsible for the quality-assurance of IVDs, MCDs, FPPs, APIs, QCLs, vaccines, immunization devices, VCPs and VCIs

- **Diagnostics (Dx)** assessment of in-vitro diagnostics (IVD) & male circumcision devices (MCD)
- **Vaccines (Vx)** assessment of vaccines & immunization devices (ImD)
- **Medicines (Mx)** assessment of finished pharmaceutical products (FPP) & active pharmaceutical ingredients (API)
- **Vector control (VCx)** assessment of vector control products (VCP) & vector control active ingredients (VCAI)

- Inspections of manufacturing sites
- Laboratory evaluation & testing of Dx, Mx & Vx & Laboratory prequalification of Mx quality control laboratories (QCL)
- Technical assistance to manufacturers, NRAs and other stakeholders
- Facilitation of National regulatory approval for Dx, Mx & Vx
The prequalification team is responsible for the quality-assurance of IVDs, MCDs, FPPs, APIs, QCLs, vaccines, immunization devices, VCPs and VCI.

<table>
<thead>
<tr>
<th>Diagnostics (Dx)</th>
<th>Assessment of in-vitro diagnostics (IVD) &amp; male circumcision devices (MCD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines (Vx)</td>
<td>Assessment of vaccines &amp; immunization devices (ImD)</td>
</tr>
<tr>
<td>Medicines (Mx)</td>
<td>Assessment of finished pharmaceutical products (FPP) &amp; active pharmaceutical ingredients (API)</td>
</tr>
<tr>
<td>Vector control (VCx)</td>
<td>Assessment of vector control products (VCP) &amp; vector control ingredients (VCI)</td>
</tr>
<tr>
<td>Laboratory evaluation &amp; testing of Dx, Mx &amp; Vx</td>
<td></td>
</tr>
<tr>
<td>Technical assistance to manufacturers, NRAs and other stakeholders</td>
<td></td>
</tr>
<tr>
<td>Facilitation of National regulatory approval for Dx, Mx &amp; Vx</td>
<td></td>
</tr>
</tbody>
</table>

A pilot WHO prequalification process for similar biotherapeutic products to be launched on 1 September 2017.

WHO will invite manufacturers to submit applications for prequalification of biosimilar versions of two products in the WHO Essential Medicines List: rituximab and trastuzumab.
Through the prequalification process, WHO has made available numerous quality-assured products to WHO Member State markets.

At the close of 2016, PQT’s list of prequalified products included:

- **Medicines**
  - 416 FPPs
  - 100 APIs
  - 41 QCLs

- **Diagnostics**
  - 64 IVDs
  - 2 MCDs

- **Vaccines**
  - 147 Vx
  - 310 ImDs

**Vector control**
WHO prequalification serves as a guarantee of good quality for health products, is a reference in terms of internal technical expertise and has the power to convene external expertise.

### Benefits for stakeholders

<table>
<thead>
<tr>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Access to quality-assured products, adapted to their specific needs</td>
</tr>
<tr>
<td>✓ Accurate prevention, diagnosis, and treatment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WHO Member States &amp; NRAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Reduced burden for regulatory approval</td>
</tr>
<tr>
<td>✓ Increased regulatory capacity &amp; harmonization of regulatory practices in WHO MS</td>
</tr>
<tr>
<td>✓ Implementation of specifically developed and road-tested international guidelines</td>
</tr>
<tr>
<td>✓ Access to quality-assured products</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Donors, procurers and UN agencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ List of prequalified products</td>
</tr>
<tr>
<td>✓ Increased availability of quality-assured products</td>
</tr>
<tr>
<td>✓ Monitoring quality of prequalified products</td>
</tr>
<tr>
<td>✓ Healthy market: diversity and affordability of products</td>
</tr>
</tbody>
</table>
WHO prequalification serves as a guarantee of good quality for health products, is a reference in terms of internal technical expertise and has the power to convene external expertise.

**Manufacturers**
- Access to donor-sponsored tenders
- Faster regulatory approval
- Timely assessment of variations and changes
- International quality-assured product status (improved image)
- Recognition of GMP status, beyond prequalified products
- Increased capacity in quality management systems
- Target Product Profiles
- Harmonization of regulatory practices within WHO Member States
- Reduced operating and manufacturing costs

**QC labs**
- International recognition of prequalified QCLs
- Technical assistance and scientific advice
WHO prequalification has also raised awareness of the importance of quality-assurance of medical products in resource-limited settings, made available and facilitated the uptake of new products.

**Common achievements**

- Creation of awareness of **quality issues** to regulators, manufacturers and procurers
- Building of **NRA capacity** and regulatory **harmonization**
- Improvement of manufacturers **GMP status and QMS**
- Development and implementation of **quality policies** with procurement agencies
- Development of a **robust mechanism** applicable to different types of products and diseases
- Adaptation to the **needs of stakeholders**
- Creation of a **sustainable and affordable market** of quality-assured products
WHO prequalification has also raised awareness of the importance of quality-assurance of medical products in resource-limited settings, made available and facilitated the uptake of new products.
WHO prequalification of in-vitro diagnostics, medicines, vaccines and vector control products

Outline

Introduction

Prequalification role

Prequalification process

Product-specific updates

Conclusion
The mission of WHO prequalification is to ensure timely availability of quality-assured medical products for the prevention, diagnosis and treatment of priority diseases in LMICs.

**Goal**
- Make quality priority products available in a consistent and timely manner
- Ensure sustainable supply of quality-assured products
- Create national capacity to evaluate and monitor the ongoing quality of products

**Strategy**
- Apply and promote unified quality, safety and efficacy/performance standards, for a comprehensive evaluation of medical products
- Build the capacity of staff from NRAs, QC labs, manufacturers or CROs

**Key outputs**
- List of prequalified products and QCLs
- WHO public reports
- Accelerated national registration of prequalified products
- Increased regulatory capacity at national level
- Improved GMP and QMS
WHO prequalification assesses the quality, safety and efficacy/performance of medical products, while focusing on the specific needs in resource-limited settings.

### Unique PQ characteristics

- **Programmatic suitability**: specific emphasis on issues of particular relevance to resource-limited settings, such as:
  - Stability of products (heat conditions)
  - Adapted specimen type (Dx)/ formulation (Rx)/ presentation (Vx)
  - Labelling of products
  - Ease of use (in terms of training and material)

- Efficacy/performance evaluated in the **global population**
- **Life cycle management** of products
- **Strengthening** manufacturers and NRAs **capacity**
WHO prequalification assesses the quality, safety and efficacy/performance of medical products, while focusing on the specific needs of resource-limited settings.

**Unicef**

- Programmatic suitability: specific emphasis on issues of particular relevance to resource-limited settings, such as:
  - Stability of products (heat conditions)
  - Adapted specimen type (Dx)/ formulation (Rx)/ presentation (Vx)
  - Labelling of products
  - Ease of use (in terms of training and material)

- Efficacy/performance evaluated in the global population

- Life cycle management

- Strengthening manufacturers and NRAs capacity

**Added-value**

- Focus on the versions of products that have not been stringently assessed (RoW versions)
- Risk classification rules applied with a focus on RLS, therefore the stringency of the review is determined differently

- Prequalification of APIs and QCLs
- Participative process: significant involvement of regulators for low- and middle-income countries

- NRA functionality as an eligibility criteria
- Prequalification of immunization devices

- Prequalification of vector control active ingredients (VCAIs)
- Harmonized prequalification process including dossier review and manufacturing site inspection
The prequalification team interacts with a number of public and private stakeholders within the global public health environment.
WHO prequalification of in-vitro diagnostics, medicines, vaccines and vector control products

Outline

Introduction

Prequalification role

Prequalification process

Product-specific updates

Conclusion
WHO-PQm process

Expression of Interest

Product dossier
SMF

Assessment
Additional information and data

Acceptable

Inspections
Corrective actions

Compliance

Prequalification

Maintenance and monitoring
Collaborative registration

Variations
Requalification

Routine inspections
Special inspections
Handling complaints

François: GMP
API: GMP
CRO/BE: GCP/GLP

Follow-up
NOC

Closing letter
WHOPIR
WHO-PQT-Rx Inspections

- The evaluation of a medicine for prequalification includes inspection of FPP and API manufacturing sites, and CROs, i.e. no dossier, no inspection.
- The sites must be GMP, GCP or GLP compliant (as appropriate) for a product to be prequalified.
- The need for inspections of API sites and CROs are decided on a case by case risk basis.
- Inspections are conducted during the assessment process, on an on-going basis and in special circumstances.
WHO-PQT-Rx: Inspection Timelines

- **First inspection**: 6 months from dossier acceptance for assessment or from site confirming it is ready for inspection.
- **Notification**: 1 – 2 months before inspection.
- **Onsite days**: 3 – 5 days based on scope and complexity.
- **Report**: 30 days from last date of inspection.
- **CAPAs**: 30 days from receipt of report (max 2 rounds, comprehensive, soft and not hard copies)
- **Closing of inspection**: 6 months from inspection.
- **Follow-up inspection**: 6 months from inspection
- **Routine inspection**:
  - Due date 1 – 3 years from the previous inspection (*risk based*)
  - Actual ± 3 months from due date.
2. Prequalification process

→ **Inspections – Team and scope**

- Broad-based inspection team: qualified and experienced
  - WHO representative (qualified inspector)
  - Inspector from well-established inspectorate (Pharmaceutical Inspection Cooperation Scheme countries – PIC/S)
  - National inspector/s invited to be part and observe the inspection
  - Observer from recipient/developing countries (*nominated by NMRA of the country*)

- Scope
  - Compliance with guidelines: GMP for API and FPP sites, GCP for CROs, GLP for FPP/API factory QCL, CRO-BAL, NQCL, IQCL
  - Data integrity verification – data manipulation, falsification, (validation, stability, clinical, bioanalytical)
Prequalification Programme: Use of Inspection reports from other NMRAs

**Inspectorates whose reports are recognized:**
- √ PICS member inspectorates
- √ EU (EDQM + EMA)
- √ Level 4 and 5 under Global Benchmarking Tool (GBT)

**What GMP evidence to submit:**
- SMF – Up-to-date
- Inspection report - conducted NMT 2 years
  - + CAPAs to deficiencies + final conclusion
- Product Quality Review – not more than 1 year old

**Review of the report:**
- √ **scope covered the specific FPP or API**
- √ Is comprehensive and supports the final outcome.

**PQP reserves the right to inspect the FPP/API manufacturer** – as long as product is active in WHO-PQP.

**on-going GMP compliance will be confirmed by WHO**
For each type of product, prequalification includes a comprehensive dossier assessment and a manufacturing site inspection, as well as other product-specific elements of evaluation...
→ … such as the pre-submission form and laboratory evaluation for in vitro diagnostics
… or NRA functionality and programmatic suitability for vaccines
In addition, SRA-approved products are evaluated according to the abridged prequalification procedure.
<table>
<thead>
<tr>
<th>WHO GBT Performance Maturity Levels</th>
<th>ISO 9004</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHO GBT</strong></td>
<td><strong>1</strong></td>
<td><strong>2</strong></td>
<td><strong>3</strong></td>
<td><strong>4</strong></td>
<td><strong>5</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No formal approach</strong></td>
<td>REACTIVE AND/OR RESPONSIVE REGULATORY SYSTEM EXIST</td>
<td>REACTIVE approach</td>
<td>Stable formal system approach</td>
<td>Continual improvement emphasized</td>
<td>Best in class performance</td>
<td></td>
</tr>
<tr>
<td><strong>SOME ELEMENTS OF REGULATORY SYSTEM EXIST</strong></td>
<td><strong>SYSTEMATIC REGULATORY APPROACH AND FUNCTIONS WITH THE ESSENTIAL CAPACITY ARE IMPLEMENTED</strong></td>
<td><strong>FULLY INTEGRATED, INITIATIVE TAKING AND AUTONOMOUS REGULATORY SYSTEM IS IMPLEMENTED.</strong></td>
<td><em><em>ADVANCED</em>/REFERENCE NRAS, RECOMMENDED BY WHO TO BE RELIED ON BY OTHER NRAS, ELIGIBLE FOR PQ STREAMLINING</em>*</td>
<td><em><em>ADVANCED</em>/REFERENCE NRAS, RECOMMENDED BY WHO TO BE RELIED ON BY OTHER NRAS, ELIGIBLE FOR PQ STREAMLINING</em>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Can be consider as functional/minimal capacity if rely on other NRAs for some specific functions</strong></td>
<td><strong>Minimal capacity/functional NRA, eligible for vaccine PQ</strong></td>
<td><em><em>Advanced</em>/reference NRAs, recommended by WHO to be relied on by other NRAs, eligible for PQ streamlining</em>*</td>
<td><em><em>Advanced</em>/reference NRAs, recommended by WHO to be relied on by other NRAs, eligible for PQ streamlining</em>*</td>
<td><em><em>Advanced</em>/reference NRAs, recommended by WHO to be relied on by other NRAs, eligible for PQ streamlining</em>*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** currently known as stringent NRA, however the terminology is supposed to be changed.
## Regulatory Systems Functions and Maturity Level

<table>
<thead>
<tr>
<th>National Regulatory System (NRS)</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration &amp; marketing authorization (RMA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vigilance (VIG)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Trials Oversight (CTO)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory access and Testing (LAT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Licensing premises (LIC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inspection &amp; Enforcement (INE)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Market surveillance and Control (MSC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registration of health personnel (RHP)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRA Lot release (LTR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control of Narcotics, Psychotropic &amp; Substances and precursors (NPSP)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Elements to be considered under relevant functions**

- **PHASE 1**
  - NRA Lot release (LTR)
  - Registration of health personnel (RHP)
  - Control of Narcotics, Psychotropic & Substances and precursors (NPSP)
  - NO FORMAL APPROACH

- **PHASE 2**
  - BEST IN CLASS PERFORMANCE
  - Maturity level 1
  - Maturity level 5
Updated Figures of the WHO GBT

<table>
<thead>
<tr>
<th>Item Function</th>
<th>NRS</th>
<th>RMA</th>
<th>PVL</th>
<th>MSC</th>
<th>LIC</th>
<th>INE</th>
<th>LAT</th>
<th>CTO</th>
<th>LTR</th>
<th>Grand Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Sub-Indicators</td>
<td>62</td>
<td>33</td>
<td>25</td>
<td>26</td>
<td>20</td>
<td>29</td>
<td>37</td>
<td>32</td>
<td>24</td>
<td>288</td>
</tr>
<tr>
<td>Sub-Indicators measuring maturity level 1</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>25</td>
</tr>
<tr>
<td>Sub-Indicators measuring maturity level 2</td>
<td>6</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>7</td>
<td>4</td>
<td>32</td>
</tr>
<tr>
<td>Sub-Indicators measuring maturity level 3</td>
<td>24</td>
<td>19</td>
<td>14</td>
<td>14</td>
<td>13</td>
<td>15</td>
<td>26</td>
<td>17</td>
<td>15</td>
<td>157</td>
</tr>
<tr>
<td>Sub-Indicators measuring maturity level 4</td>
<td>28</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>2</td>
<td>69</td>
</tr>
<tr>
<td>Sub-Indicators measuring maturity level 5</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

Phase I

Phase II

Minimal capacity

Advanced/ reference NRAs
In addition, SRA-approved products are evaluated according to the abridged prequalification procedure.

Eligibility criteria for abridged assessment:

**Diagnostics**
- IVDs only
- Stringently assessed SRA-approved products & their RoW version if no substantial difference

**Medicines**
- FPPs only
- SRA-approved

**Vaccines**
- Vaccines only
- SRA-approved
WHO prequalification seeks to add value and never duplicate the work already performed by stringent regulatory authorities, while encouraging NRAs to rely on the work of WHO prequalification.

Example of WHO PQ reliance on other SRAs

- Development of **guidelines** only where gaps exist
- **Abridged assessment** for prequalification of SRA approved products
- Recognition of manufacturing site **inspections** performed by SRAs (Mx only)
- On request from the manufacturer, **listing** of products evaluated under EU art. 58, USFDA tentative approval, PEPFAR and Health Canada approval
- Use of **EDQM CEPs** in FPP and API application

Example of NRAs reliance on WHO PQ

- **Collaborative procedure** for national registration
- **API prequalification** recognized by NRAs
Ensuring the ongoing quality of prequalified products is an equally important responsibility of the prequalification team.
WHO prequalification of in-vitro diagnostics, medicines, vaccines and vector control products

Outline

Introduction

Prequalification role

Prequalification process

Product-specific updates

Conclusion
Medicines/finished pharmaceutical products

Reference Number: RH040 (a)
Date of prequalification: 08 April 2014
Basis of listing: Prequalified by WHO
Status: Active
INN: Desogestrel/Ethinylestradiol + Placebo
Therapeutic area: Reproductive Health
Dosage form & strength: Desogestrel/Ethinylestradiol Tablet + Placebo Tablet 150mcg/30mcg + 0mcg
Storage condition: Do not store above 30°C
Shelf life (months): 24
Packaging: Blister Alu/PVC/PVdC: (21+7)x1

Applicant:
Mylan Laboratories Ltd, Plot No.564/A/22, Road No. 92, Jubilee Hills, Hyderabad, Telangana, 500034, India

FPP Manufacturing Site:
Mylan Laboratories Limited, Sarkhej- Bavla NH No- 8A, Plot No 20/21 Pharmaceutical Special Economic Zone, Nr Village Matoda, Ahmedabad, Gujarat, 382213, India

API Manufacturing Site:
(Desogestrel) Aspen Oss B.V., Site De Geer, Veersemeer 4, JN OSS, 5347 JN, Netherlands (Ethinylestradiol) Aspen Oss B.V., Site De Geer, Veersemeer 4, JN OSS, 5347 JN, Netherlands (Desogestrel) Aspen Oss B.V., Kloosterstraat 6, Moleneind, AB Oss, 5349 AB, Netherlands (Ethinylestradiol) Aspen Oss B.V., Kloosterstraat 6, Moleneind, AB Oss, 5349 AB, Netherlands

FPP WHO Public Inspection Reports:

WHO Public Assessment Reports

New Funding Structure for PQ

• **Background and process:**
  – Fees to WHO in place – vaccine since 1999, In-Vitro Diagnostics since 2010 and medicines since 2013
  – following a year of discussions between WHO, Industrial groups and key partners
  – The new fee structure for vaccines and medicines was effective 01 January 2017, and in early 2018 for diagnostics.

• **Objectives:**
  – ensure the financial sustainability of WHO’s PQ
  – to make PQ better equipped to address current global quality challenges,
  – to lay the ground for strengthening and expanding services provided, and
  – to improve financial predictability and transparency

• **Fees structure:**
  – Designed to ensure equity among manufacturers
  – modelled on the practice of NRAs around the world,
New Funding Structure for PQ

- **Fees principles and structure:**
  - product nature: active pharmaceutical ingredient (API) or finished pharmaceutical product (FPP);
  - type of assessment: full or abridged assessment of new application, or assessment of major variation;
  - an annual maintenance fee tailored to whether the initial assessment was full or abridged.

<table>
<thead>
<tr>
<th>Assessment fee</th>
<th>Annual Fee per product</th>
<th>Variations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full</td>
<td>Full</td>
<td>Major</td>
</tr>
<tr>
<td>$25,000</td>
<td>$20,000</td>
<td>$3,000</td>
</tr>
<tr>
<td>Abridged</td>
<td>Abridged</td>
<td>Minor</td>
</tr>
<tr>
<td>$6,000</td>
<td>$5,000</td>
<td></td>
</tr>
<tr>
<td>FPP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$20,000</td>
<td>$8,000</td>
<td>$3,000</td>
</tr>
<tr>
<td>API</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$20,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$8,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$3,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 1: Fees for FPP and API prequalification applications (effective 1 January 2017)

<table>
<thead>
<tr>
<th></th>
<th>Single Registration Fee Per Product</th>
<th>Annual Fee Per Product</th>
<th>Post-PQ Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Application Fee</td>
<td>Annual Fee</td>
<td>Major variation</td>
</tr>
<tr>
<td>FPP – Full assessment</td>
<td>$25,000</td>
<td>$20,000</td>
<td>$3,000</td>
</tr>
<tr>
<td>FPP – Abridged assessment</td>
<td>$6,000</td>
<td>$5,000</td>
<td>NA</td>
</tr>
<tr>
<td>API</td>
<td>$20,000</td>
<td>$8,000</td>
<td>$3,000</td>
</tr>
</tbody>
</table>

1 Refer to SRA-Approved Multisource (Generic) or Innovator FPPs procedure - https://extranet.who.int/prequal/content/abbreviated-assessment-multisource-generic-or-innovator-product-0

Table 2: Fees for Vaccine prequalification applications (effective 1 January 2017)

<table>
<thead>
<tr>
<th></th>
<th>Application Screening Fee</th>
<th>Abridged assessment procedure</th>
<th>Full assessment procedure</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
<th>Tier 4</th>
<th>Site Audit Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple/Traditional Vaccines</td>
<td>$2,500</td>
<td>$25,000</td>
<td>$100,000</td>
<td>$4,800</td>
<td>$19,200</td>
<td>$41,500</td>
<td>$140,000</td>
<td>$30,000</td>
</tr>
<tr>
<td>Combinations or Novel Vaccines</td>
<td>$5,000</td>
<td>$66,500</td>
<td>$232,750</td>
<td>$8,400</td>
<td>$33,600</td>
<td>$72,500</td>
<td>$250,000</td>
<td>$30,000</td>
</tr>
</tbody>
</table>

PQT – revised fee model

• The fees are structured to consider the type of product, complexity, assessment procedure, and manufacturer sales (vaccines only)

• The model includes both an application fee and annual fee.

• The annual fee:
  
  – for medicines and APIs is fixed, whereas for vaccines the annual levy is linked to sales from PQ’d vaccines (PQ enabled sales).
  
  – The annual fee will be invoiced on the 1 October each year for all products that have been present on the list of prequalified APIs, or FPPs for 12 months or greater as of the 1 September of that year.

• The Medicine and API fee covers both assessment and inspection activities, whereas for vaccines assessment and inspection activities are charged separately.

The collaborative procedure enables NRAs to accelerate the registration of prequalified products so that they can enter local markets more quickly.

**Principles**
- WHO PQ shares the reports that served as the basis for the prequalification decision, so that NRAs do not conduct assessment and inspections.
- National registration based on PQT evaluation.

**Diagnostics**
- Procedure in development.
- Ongoing discussions with NRAs.

**Medicines**
- Started in 2012.
- As of December 2016:
  - 30 countries participating.
  - 183 registrations in 20 countries for 73 different products.

**Vaccines**
- In 2015:
  - Adopted by expert committee (ECBS).
<table>
<thead>
<tr>
<th>Participating NMRAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Armenia</td>
</tr>
<tr>
<td>2. Botswana</td>
</tr>
<tr>
<td>3. Burkina Faso</td>
</tr>
<tr>
<td>4. Burundi</td>
</tr>
<tr>
<td>5. Cameroon</td>
</tr>
<tr>
<td>6. *Caribbean Community (CARICOM)</td>
</tr>
<tr>
<td>7. Cote d'Ivoire</td>
</tr>
<tr>
<td>9. Eritrea</td>
</tr>
<tr>
<td>10. Georgia</td>
</tr>
<tr>
<td>11. Ghana</td>
</tr>
<tr>
<td>12. Kenya</td>
</tr>
<tr>
<td>13. Kyrgyzstan</td>
</tr>
<tr>
<td>14. Lao PDR</td>
</tr>
<tr>
<td>* CARICOM</td>
</tr>
<tr>
<td>15. Madagascar</td>
</tr>
<tr>
<td>16. Malawi</td>
</tr>
<tr>
<td>17. Mali</td>
</tr>
<tr>
<td>18. Mozambique</td>
</tr>
<tr>
<td>19. Namibia</td>
</tr>
<tr>
<td>20. Nigeria</td>
</tr>
<tr>
<td>21. Philippines</td>
</tr>
<tr>
<td>22. Senegal</td>
</tr>
<tr>
<td>23. Sierra Leone</td>
</tr>
<tr>
<td>24. South Africa</td>
</tr>
<tr>
<td>25. Tanzania</td>
</tr>
<tr>
<td>26. Uganda</td>
</tr>
<tr>
<td>27. Ukraine</td>
</tr>
<tr>
<td>28. Zambia</td>
</tr>
<tr>
<td>29. Zanzibar</td>
</tr>
<tr>
<td>30. Zimbabwe</td>
</tr>
</tbody>
</table>

*Member States: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago*

*Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands*

As at 12 May 2017
Country registrations & therapeutic area

Total registrations: 215
(As at 12 May 2017)
Pipeline of applications in countries

As at 12 May 2017

No products registered or under review yet: Georgia, Lao PDR, Sierra Leone, Zanzibar
Pipeline of applications, by company

- Registered
- Under review
- Dossier awaited

Company (when started) | No of applications
---------------------|-------------------
Macleods Pharmaceuticals... | 100
Strides Shasun Limited... | 60
Cipla Ltd (Jan-14) | 40
Hetero Labs Limited (May-... | 20
Jai Pharma (formerly:... | 0
Mylan Laboratories Ltd... | 0
Lupin Ltd (Jun-16) | 0
China Resources Zizhu... | 0
Strides Pharma Global Pte... | 0
Acme Formulation Pvt.... | 0
Cipla Ltd, Cipla (n/a) | 0
Ajanta Pharma Ltd (May-15) | 0
DNDi, Switzerland (Cipla... | 0
Cadila Pharmaceuticals Ltd... | 0

As at 12 May 2017
Time to registration

(2013 – 2017 to date, n=215)
Including regulatory time and applicant time

As at 12 May 2017

Time to registration (days)
Median time to registration

*Including regulatory time and applicant time

As at 12 May 2017
The same pharmaceutical product…

① Product (technical content) dossier,
② Manufacturing chain, processes and control of materials,
③ API and FPP specifications
④ Bioequivalence information and
⑤ Essential elements of product information.
Overview of Essential Medicines and Health Products

By
Deus Mubangizi
Coordinator, WHO Prequalification Team

on behalf

Dr Suzanne Hill, Director
• Transition from MDGs to SDGs
• Challenges, opportunities and trend
• Vision and strategic agenda
• How we work
• Measuring results
1

CHANGING LANDSCAPE:
FROM THE MDGS TO THE SDGS
Progress under MDGs – HIV, malaria, TB examples

Global HIV, malaria and tuberculosis incidence rates, world, 2000–2015

- HIV (per 100,000 uninfected people)
- Malaria (per 1,000 people at risk)
- Tuberculosis (per 100,000 population)
2

CHALLENGES, OPPORTUNITIES AND DOMINANT TRENDS
Achieving access to medicines and health products
Achieving access to medicines and health products

R&D and innovation

Manufacturing

Marketing registration

Selection, pricing and reimbursement

Procurement and supply

Prescribing

Dispensing

Use

Legislation, regulation, governance, monitoring
Targeting specific products

- Innovation and R&D focused on public health priorities
- New products needing regulatory and policy support, i.e. biosimilars, in vitro diagnostics, medical devices
Targeting priority diseases and conditions

• Antimicrobial resistance
• NCDs and ageing
• Health products for new and re-emerging threats (R&D preparedness for public health emergencies)
3
VISION AND
STRATEGIC
AGENDA
Vision

A world where every child, man and woman has access to the quality essential medicines, vaccines and other health products they need to have a healthy and productive life.
Two areas of work to get there

Facilitator
Innovation
Access
Use

Guardian
Quality
Safety
Efficacy
Towards Access 2030

- Measuring, monitoring and policy adjustment
- Quality products — strategic local manufacture
- R&D appropriate innovation
- Quality use — medicines & technologies
- Effective regulation — harmonisation & reliance
- Evidence based selection — HTA
- Financing and pricing policies
- Procurement and supply

Access 2030
WHO’s role in promoting access to quality medical products

- WHO has long supported regulators in fulfilling their mandates through:
  - Developing norms and standards
  - Promoting regulatory convergence and harmonization
  - Training and capacity building
  - Supporting information and work sharing initiatives

- Experience to date has helped characterize the benefits, challenges and potential evolution of such initiatives in accelerating in-country regulatory decisions
4

HOW WE WORK
One-WHO approach

Regional and country offices

Health system strengthening network

Disease departments
EMP Structure

- Knowledge management
- New policy development
- Resource mobilisation, project management
- Monitoring and evaluation

Office Of the Director

Innovation, Access and Use
- Innovation/R&D, intellectual property, local production
- Evidence based selection
- Pricing, reimbursement, HTA
- Procurement and supply chain management
- Improving use of medicines and health products

Regulation of Health Technologies
- Technical standards and norms
- Regulatory systems strengthening
- WHO PQ Programme
- Safety and vigilance

See next slide.....
RHT Structure in details

Regulation of Medicines and other Health Technologies (RHT)

Technologies Standards and Norms (TSN)
- Set global standards & nomenclature
- Global measurement standards*
- Quality assurance for Medicines Quality Control (QC) labs

*Including: biotherapeutics; blood products; in vitro diagnostic; medical devices; vaccines

Regulatory Systems Strengthening (RSS)
- Strengthen regulatory system
- Capacity building:
  - Good manufacturing practices
  - Laboratory quality systems
- Harmonization initiatives
- Collaborative registrations
- ICDRA support
- Technical assistance

Prequalification Team (PQT)
Prequalification (PQ) of medicines, vaccines, diagnostics, medical devices & vectors
- Dossier assessments
- Inspection
- Laboratory testing
- PQ of medicines QC laboratories
- Scientific advice

Safety and Vigilance (SAV)
- Global surveillance & monitoring, including substandard & falsified medical products
- Coordination of global response to health / safety events
- Policies, norms, standards & guidelines
- Classify medicines & assign defined daily doses (ATC/DDD)
The challenges we address

R&D and Innovation
- Limited budgets
- Changing markets
- Low capacity for evidence based selection methods
- Lack of legal frameworks
- Undue influence

Manufacturing
- Lack of market incentives for low priced products, small markets, low demand, excessive competition
- Shortages of APIs
- Products not adapted for LMICs
- Evergreening
- Poor manufacturing practice
- Lack of regulatory capacity to ensure GMP
- Trade barriers

Marketing authorization/quality assurance
- Low capacity to assess and approve
- Inadequate resources
- Differing regulation from country to country
- Emergence of biological products, cell and gene therapies require new capacities for regulation
- Lack of regulatory process for medical devices in many countries
- Lack of regulatory pathways or slow processes for emergency preparedness or childrens medicines
- Incoherent policy frameworks
WHO response

R&D and Innovation
- Creation of global platforms for public health driven R&D
- Global Strategy and plan of Action on Public Health, Innovation and Intellectual Property
- Consultative Expert Working Group on Research and Development
- R&D Blueprint for epidemics

Manufacturing
- Defining international reference preparations for priority diseases with epidemic potential
- Strategic local/regional production according to regulatory capacity and need
- Defining international standards
- Global nomenclature
- Prequalification

Marketing authorization/quality assurance
- Support for harmonization initiatives
- Promotes work sharing and convergence between regulatory authorities
- Good regulatory practices
- Good Reliance Practices
- Quality management systems for NRAs
- Prequalification
- Strengthening of regulatory capacity and frameworks for biosimilars
WHO Perspective on Local production

Recent Activities

- Series of case studies studying approaches to promoting local production
  - China, Cuba and India
  - Supported by European Commission

- Co-organized two meetings in Ethiopia:
  - 2016 NSPA-Pharma Implementation Review Meeting and Workshop to Establish a Consortium of RBEC Supporters
  - Supported by BMGF-WHO DG Strategic Grant

- Inter-agency consultation with UN and international agencies
  - WHO’s key leadership in strengthening local production is in regulatory system strengthening
WHO Perspective on Local production

Way Forward

• WHO’s key leadership in strengthening local production is in strengthening regulatory systems and quality
• Continued technical support for Member States
  – Strategic local production of select products
  – PMPA-BP and AMRH under AUC and NEPAD leadership
  – Etc.
• Collaboration with other stakeholders (e.g. Member States, development partners, private sector, academia, civil society, donors, etc.)
WHO Perspective on Local production
Technical support

- Dependent on available resources, WHO engagement in providing technical support to manufacturers will be based on the following criteria:
  - Response to an official request from the government identifying particular manufacturers
  - For medicines, manufacturers must be considered within 2 years of reaching prequalification status and preferably target products subject to EOI with low numbers of available manufacturers
  - For vaccines, on a case by case assessment for products for which there is a recognized public health need, the WHO has the expertise, capacity and is seen as the most viable option, and there is a good expectation of success.
- WHO will increasingly explore opportunities to support technical assistance to manufacturers through trusted 3rd parties.
The challenges we address

**Selection/ pricing/ reimbursement**
- High prices of new products
- Limited budgets
- Changing markets
- Low capacity for evidence based selection methods
- Lack of legal frameworks
- Conflict of interest influence

**Procurement and supply**
- Move away from reliance on donor funding for procurement of health products
- Lack of price control leading to mark-ups
- Weak management
- Lack of coordination between donors, programmes and partners
- Corruption
- Entry of substandard and falsified medicines
- Poor purchasing decisions

**Prescribing**
- Irrational prescribing
- Slow uptake of biosimilars and generics
- Over prescribing
- Lack of STGs or adherence to STGs
- Undue influence
WHO response

Selection/ pricing/ reimbursement
- Building evidence for a fair pricing model
- Evidence based selection
- Support for TRIPs flexibilities
- Ensuring that equipment purchases are costed throughout their life cycle
- Interagency list of medical devices for essential interventions for reproductive, maternal and child health
- Priority assistive devices list

Procurement and supply
- Coordination and collaboration: Interagency Supply Chain Group
- Model quality assurance systems
- Support for development of Logistics Management Information Systems
- Prequalification programme
- Convened and hosted international mechanism to stop circulation of substandard and falsified medicines
- Contributed to creation of global health financing and procurement programmes

Prescribing
- Standards for training of health care workers
- Measurement of prescribing
- Quality improvement processes
The challenges we address

Dispensing
- Inappropriate fees structures and incentives
- Stock outs

Use
- Irrational use
- Need for appropriate diagnosis
- Need for assistive care products

Cross cutting
- AMR
- Controlled substances
- Rise in epidemic prone pathogens
- Rise in NCDs
- Poor capacity for routine monitoring
- Low levels of transparency
- Lack of accountability

WHO/HIS/EMP | August 31, 2017
WHO response

Dispensing
- Monitoring of price
- Monitoring of availability
- Capacity building on AMR

Use
- Pharmacovigilance
- Training of patients
- Routine monitoring
- Monitoring and surveillance of antibiotic use
- Monitoring of SF products

Cross cutting
- Strengthen links with other health system initiatives
- Leverage knowledge of Ros and Cos
- Reinforce partnerships
- Data systems for monitoring
- Support for good governance
Threat of Substandard and Falsified products

Understand the global picture through validated evidence

Identify vulnerabilities in health systems and influence change

Provide technical support and capacity building

PROTECT  PUBLIC  HEALTH
WHO Response: Protect Public Health

**POLITICAL RESPONSE**

*Member State Mechanism*
- Political support
- Promote access to affordable, safe, efficacious, and quality medical products
- Effective Member States’ collaboration and coordination

**OPERATIONAL RESPONSE**

*Global Surveillance and Monitoring System*
- Immediate technical and operational support
- NRA capacity building and policy guidance
- Improve current knowledge for in depth analyses. landscape, SWOT, etc.
Global Surveillance and Monitoring System
since July 2013...

TRAINING of 126 member states and 18 procurement agencies...
...who have REPORTED JUST UNDER 1400 PRODUCTS in 90 COUNTRIES

WHO provided TECHNICAL ASSISTANCE for 100+ incidents...
and issued 17 GLOBAL ALERTS

PORTAL and SEARCH TOOL available in 3 languages

Healthcare professionals will also have a SMART PHONE APPLICATION
Update on AMR
WHO Global Action Plan on Antimicrobial Resistance

Five strategic objectives

1. Improve awareness and understanding of antimicrobial resistance through effective communication, education and training

2. Strengthen the knowledge and evidence base through surveillance and research

3. Reduce the incidence of infection through effective sanitation, hygiene and infection prevention measures

4. Optimize the use of antimicrobial medicines in human and animal health

5. Develop the economic case for sustainable investment that takes account of the needs of all countries, and increase investment in new medicines, diagnostic tools, vaccines and other interventions
5
MEASURING RESULTS
Measuring impact

• Broader SDG 3 targets on access to medicines

• Number of countries with national policies on medicines and other health technologies updated within past five years

• Number of countries that report data on product research and development investments for health

• Number of national regulatory authorities ensuring essential regulatory functions for vaccines.
What does impact look like?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>EFFECTIVE REGULATION</td>
</tr>
<tr>
<td>2</td>
<td>QUALITY PRODUCTS</td>
</tr>
<tr>
<td>3</td>
<td>NEEDS DRIVEN INNOVATION</td>
</tr>
<tr>
<td>4</td>
<td>PATENT TRANSPARENCY</td>
</tr>
<tr>
<td>5</td>
<td>EVIDENCE BASED SELECTION</td>
</tr>
<tr>
<td>6</td>
<td>EFFICIENT PROCUREMENT AND SUPPLY</td>
</tr>
<tr>
<td>7</td>
<td>FAIRER FINANCING AND PRICING</td>
</tr>
<tr>
<td>8</td>
<td>QUALITY AND APPROPRIATE USE</td>
</tr>
<tr>
<td>9</td>
<td>DATA, MONITORING AND EVALUATION</td>
</tr>
</tbody>
</table>

- Regulatory networks established / NRAs’ capacity improved
- PQ expanded to include broader range of essential medicines
- GARD funded and running / New quality assistive products
- Patent transparency for all patented essential medicines
- More countries effectively using EML, HTA, APL, EDL
- Policy on governance mechanisms in place for procurement and support systems
- Model legislation for reimbursement developed and greater transparency in global price setting
- Improved skills of prescribers and greater patient awareness of responsible use of medicines
- Countries’ access indicators established and measured
Thank you
UNICEF: PROCUREMENT OF MEDICINES & NUTRITION PRODUCTS

UNICEF SUPPLY DIVISION

David Muhia; Contracts Manager, Medicines & Nutrition Centre
### UNICEF expenditure by material groups, 2015

#### $3.428 billion of supplies and services

- **Vaccines**: $1.725 billion
- **Pharmaceuticals**: $151.4 million
- **Nutrition**: $150.6 million
- **Medical supplies & equipment**: $110.4 million
- **Bed nets & insecticides**: $58.7 million
- **Construction**: $102.3 million
- **Cold chain equipment**: $75.6 million
- **Water & sanitation**: $96.4 million
- **Education**: $66.1 million
- **International freight**: $104.3 million

- **Approximately $1.754 billion is procurement on behalf of governments and partners.**
Focus areas for medicines and Nutrition

Procurement focus that addresses UNICEF programmes, Emergencies and Procurement Services for governments

Follow and promote WHO recommendations on selection and use of medicines

Ensure availability of affordable essential medicines for primary health care and emergency relief

To ensure availability of therapeutic food (RUTF, F75/100), supplementary food (RUSF, CSB+), micronutrients (MNP, iron, zinc), and other nutrition supplies

Develop local sources in UNICEF program countries
Medicines and Nutrition Centre
Essential Supplies for Health Programmes

**Product Focus**

**Nutrition**
- Products for severe acute malnutrition, stunting and supplements for pregnant and lactating mothers

**Essential Medicines**
- Medicines for Primary Health Care, including NCDs, and emergency relief
- All medicines in WHO treatment guidelines

**ARVs and antimalarials**
- Development and supply of kits for delivery of basic services, including in emergencies

**Health Kits**
MNC Procurement by product categories

>120 suppliers in 35 countries
Delivery to >110 countries
UNICEF Catalogue: Product range and USD value
Medicines Product Selection: Sources

**EVIDENCE AND ADVOCACY**

1. 1st WHO Model List of Essential Medicines for Children, 2007
2. 2nd WHO Model List of Essential Medicines for Children, 2010
3. 3rd WHO Model List of Essential Medicines for Children, 2011

**Priority medicines**
- **Priority life-saving medicines**
  - for mothers and children
  - 2011

**Recommendations for management of common childhood conditions, 2012**

**ACTION**

- United Nations Commission on Life-Saving Commodities for Women and Children
- Global Plan towards the elimination of new HIV infections among children by 2015, and keeping their mothers alive

http://www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities
http://www.unaids.org/believeitdoit/the-global-plan.html
# Nutrition products range

## Women
- **Pregnancy and Lactation**
  - Iron + Folic Acid tablets
  - Multiple Micronutrient tablets

## Children
- **Micronutrient Supplementation**
  - Multiple Micronutrient Powder (MNP)
  - Vitamin A capsules
- **Moderate Acute Malnutrition (MAM)**
  - Ready to Use Supplementary Food (RUSF)
  - Lipid Nutrition Supplements (LN-SQ/MQ)
  - Therapeutic Milk (F-75, F-100)
  - Resomal
  - Ready to Use Therapeutic Food (RUTF)
  - Antibiotics, deworming…
UNICEF Procurement Process

- NEED Assessment (product range, warehouse replenishment, direct orders)
- VENDOR SELECTION
- SOLICITATION
- AWARD
- CONTRACT MANAGEMENT
- GMP Assessment
- Dossier Assessment
UNICEF supplies products to many countries world-wide, including those that have little or no regulatory control of the products supplied. UNICEF is therefore committed to ensure the quality of the products it supplies.

UNICEF Quality Assurance system is based on:

- Standard Operating Procedures
- International Standards for Quality Assurance (including WHO-GMP)
- Continuous review of product specifications
Evaluation of offers

• **Technical Evaluation**
  – Quality: product characteristics and manufacturing GMP

• **Commercial Evaluation**
  – Based on technical and QA reports received
    – ITB  “lowest evaluated bid”
    – RFP “most responsive evaluated proposal”
  – Based on lowest acceptable offer, including landed cost and possible discounts for early payment (payment terms), lead times, minimum order quantities, etc.
  – Considers commercial risks

Source: UNICEF Supply Division
Type of Contracts and Agreements

• UNICEF awards contracts (Purchase Orders) or establishes framework agreements (Long Term Agreements or LTAs) under which Purchase Orders are placed.

• LTAs can be time-bound (open quantity) or value targeted (specific quantity). Value targeted LTAs are established when there is confidence in forecast and consideration of multiple awards.

• Duration of LTAs vary from 1 to 3 year, with options for revision and renewal.

1. Establishment of Long Term Arrangements to supply for 1 to 3 years

2. Purchase Order

3. Purchase Order

4. Purchase Order

5. Purchase Order

Source: UNICEF Supply Division
Sourcing

- Suppliers can contact us directly through emails etc.
- Our online tender calendar ([http://www.unicef.org/supply](http://www.unicef.org/supply))
- U.N. roster (UNGM - [www.ungm.org](http://www.ungm.org))
- Requests for Expressions of Interest (REOIs)
- Market surveys
- Internet
- Sources and Prices
- Contacts made at trade fairs
- Recommendations from other partners

Source: UNICEF Supply Division
Thank you!
Federation of African Pharmaceutical Manufacturers’ Associations

Improving Access to Medicines the Benefits of Local Production of Pharmaceuticals

Global Fund/FAPMA Conference 14-15 June 2017 Addis Ababa Ethiopia – Capital Hotel

Emmanuel Mujuru Chairman
Objectives of The Conference

• Come up with modalities and programs to have affiliate companies of FAPMA who produce pharmaceuticals to a recognized international standard participate in the procurement schemes of the global fund
• Work out a roadmap for capacity building initiatives to assist the affiliate member companies of FAPMA who are not yet ready to participate in the procurement scheme to do so
Is to be a vibrant and self-sustaining pharmaceutical manufacturing industry in Africa by providing quality and affordable medicines so as to contribute to the reduction of disease burden and promote economic development of the continent.

To facilitate collaboration between regional pharmaceutical manufacturing associations to address the common challenges faced by the industry and enhance opportunities towards self-sufficiency.

This will be achieved through advocacy and partnership with other stakeholders in promoting the production of quality, affordable medicines” (1)
• Federation of East African Pharmaceutical Manufacturers’ Association
• Southern African Generic Medicines Association
• West African Pharmaceutical Manufacturers Association
- Critical mass of 231 manufacturers
- Multiple technologies
- Potential to meet most of Africa’s needs for generic medicines
Disproportionate High Disease Burden

25% of the global disease burden

- 75% of the global HIV/AIDS pandemic
- 90% of the malaria cases and deaths
- 9 countries (excluding North Africa) among the 15 countries with the highest TB burden in the world.
- MDR-TB and XDR-TB rated among the highest in the world.
- Significant child mortality – diarrhoeal, measles, URTI
**Background**

**Market**
Although it is relatively small in global terms (worth US $23.1 billion in 2011, or less than 2% of the global market), Africa’s pharmaceutical industry is the fastest growing in the world (Afdb)

**Pharmaceutical manufacturing**
There is clear momentum in Africa for developing the pharmaceutical industry. African Heads of State stressed the potential for local production and technology transfer in the Pharmaceutical Manufacturing Plan for Africa. (afdb) the creation of PMPA

African manufacturing is still in its infancy and is curtailed by a number of structural shortcomings..... Manufacturing sectors around the continent are however showing signs of expanding, driven by factors like strong growth in demand, improving infrastructure, and increased openness to foreign investment (KPMG report 2014 Manufacturing in Africa)
i. Local Pharmaceutical Production (LPP) makes it easier for national medicines regulatory authorities to ensure proper quality and safety of medicines sold in the country

ii. LPP reduces dependence on foreign sources supplies and improves sustainability of reliable medicines supplies

iii. LPP promotes local value addition, generates income, economic growth and scientific development

iv. LPP creates jobs and reduces balance of payment positions through import substitution

v. LPP can serve the expanding markets that are brought about by a growing population and the advance of non-communicable diseases in Africa

vi. LPP can be a step towards sustainable treatment programs and prepare grounds towards access beyond the current era of drug donations
Support local pharmaceutical manufacturing to:

- increase access to affordable quality medicines
- ensure sustainable supply of essential medicines
- improve public health outcomes
- promote industrial and economic development
PMPA Package of Solutions

Quality, Access, Availability, Affordability

Competitiveness, Sustainability & Self Reliance

HR Development
Access to Product & Technology
Access to Affordable Finance & Timely Limited Incentives
Regulatory Systems Strengthening & Enforcement
Partnerships, Collaborations & Fostering Business Linkages
Enhancing Market Data Collection & Facilitating Market Access

Sound Sector Strategy
Policy Coherence
Political Commitment
Quality and GMP Improvements by African Pharmaceuticals Companies

A number of companies in Africa have achieved High GMP standards e.g.

WHO PQ:
• Universal in Kenya – WHO PQ Products
• Quality Pharmaceuticals in Uganda – WHO PQ
• Varichem in Zimbabwe – WHO PQ
• Aspen in South Africa – WHO PQ

GMP Certified by WHO:
• Chi Pharmaceuticals; Evan Medical Plc; May and Baker Nigeria Plc and Swiss Pharma Nigeria Limited.

However, the anticipated business from the donor markets has not been forthcoming.
Major Challenges

- Cost competitiveness
- Failure to access donor markets (e.g. Global Fund) by WHO PQ or certified companies leading to lack of confidence and poor return on investment
- Prices of medicines and the perception that this will negatively affect access
- Low capacity utilization and its impact on prices and profitability
- Quality issues – regulators seen as non stringent and industry as non GMP compliant
- Proliferation of fake counterfeit and substandard medicines – challenge to both local companies and NMRA’s
- Lack of Capital
Global Fund plays an important and sometimes active role in shaping African market dynamics for medicines used in HIV/AIDS, Malaria and Tuberculosis and other complimentary medicines. The decision it makes with regards to:

- Quality
- Price
- Sustainable supply

Will have an impact on the long term development of African pharma industry and sustainable access to quality, affordable and efficacious medicines long after the donations will have dried up.
Inclusive and Sustainable Industrial Development

Achieving Industry-related goals and targets in the 2030 Agenda for sustainable Development

- **Goal 3.** Ensure health lives and promote well being for all at all ages
- **Goal 8.** Promote sustained, inclusive and sustainable economic growth, full and productive employment
- **Goal 9.** Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation
Global Fund Policy Support for LPP

• Policy clarity and commitments to procure from African based pharmaceutical manufacturing companies that meet quality standards
• Volume or price based procurement system leveraged on the value offered by LPP that includes proximity, short delivery times, distribution efficiencies/effectiveness and sustainability.
• Long term supply contracts for LPP
• Time limited incentives for LPP and levelling of playing field
“The time for Africa to break its dependence on foreign imports is now. The local manufacture of pharmaceuticals in Africa is an opportunity to develop a broader manufacturing and knowledge based economy”

Michel Sidibe UNAIDS Executive Director 7th AUC Conference of Ministers Abuja Nigeria 25-30 November 2014

26th – 27th of September 2016.
Pharmaceuticals made in Africa for Africa the economic opportunity
Africa is rapidly changing...

Demographic, epidemiological and economic shifts are transforming the pharmaceuticals market.

The population is growing and aging; new areas of medical need are emerging; and the diseases from which people in developing countries suffer are increasingly like those that trouble people living in the developed world.

Africa will have the world’s largest workforce.

Africa’s urbanization is at 40% and expected to reach 50% in the near future.

Household spending in Africa is rising and expected to reach USD 2.4 trillion by 2020.

The African market for pharmaceuticals will be worth between USD 40 billion and USD 60 billion by 2020.

Africa’s attractiveness lies not in its market size but in its rapid growth.

All pharma segments are expected to grow in Africa:
1. Prescription drugs
2. Generic drugs
3. Over-the-counter drugs
4. Medical devices
...and to realize its potential we need to meet the challenges of our lifetime

**Challenges**

- Chronic Diseases is soaring
- Health policy makers and players are increasingly mandating what doctors can prescribe
- The boundaries between different forms of healthcare are blurring
- Emerging economies are driving demand for medicines
- Governments are beginning to focus on prevention rather than treatment
- Regulators are more cautious

**Required Shift**

- Collaboration with key actors inside and outside the sector
- Switch from selling medicines to managing outcomes
- Increase Research and Development Productivity

Source: PwCPharma 2020 report
Research shows that Africa Pharma Market is Growing (1/2)

Africa’s pharma markets can expect strong growth

A clear correlation between a company’s DQ and its financial performance

Source: McKinsey&Company

1 Algeria, Angola, Cameroon, Egypt, Ethiopia, Ghana, Kenya, Libya, Morocco, Nigeria, South Africa, Sudan, Tanzania, Tunisia, and Uganda
Source: WHO; World Bank; IMF; African Development Bank; BMI Research; McKinsey analysis
Research shows that Pharma Market is growing (2/2)

Ten countries represent 70 percent of Africa’s pharma market

Market size, US$ billions

<table>
<thead>
<tr>
<th>Year</th>
<th>Rest of Africa</th>
<th>Top 10 countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>4.2</td>
<td>1.2</td>
</tr>
<tr>
<td>2002</td>
<td>5.5</td>
<td>4.1</td>
</tr>
<tr>
<td>2004</td>
<td>7.8</td>
<td>5.9</td>
</tr>
<tr>
<td>2006</td>
<td>10.4</td>
<td>2.5</td>
</tr>
<tr>
<td>2008</td>
<td>14.2</td>
<td>4.1</td>
</tr>
<tr>
<td>2010</td>
<td>16.7</td>
<td>4.5</td>
</tr>
<tr>
<td>2012</td>
<td>19.9</td>
<td>5.8</td>
</tr>
</tbody>
</table>

CAGR, %
- Rest of Africa: 9
- Top 10 countries: 9, 10

Africa’s spend per capita, US$
- 41

Top 10 countries’ spend per capita, US$
- 3
- 4
- 41
- 43
- 46
- 47
- 49
- 55

1 Algeria, Egypt, Kenya, Ivory Coast, Libya, Morocco, Nigeria, South Africa, Sudan, and Tunisia
Source: BMI Research; World Bank; McKinsey analysis

Source: McKinsey&Company
Africa carries 25% of world disease burden but consumes less than 1% of global health expenditures. Africa’s capacity for pharmaceutical R&D and local drug production is amongst the lowest in the world. There is a reliance on imported active ingredients. Pharmaceutical market in Africa is at 70%. To pave a sustainable path for Africa’s health systems, scaling up pharmaceutical production is essential. It involves legal, scientific, technical, fiscal and financial aspects. Local will create modern jobs and stimulate economic activity. There is a need for fewer structures and harmonization of policies through regional integration.
To accelerate this growth Africans needs to own their destiny and play an active role like Africans for Africa (A4A)

Commenced the journey to raise over $1 billion USD for catalytic interventions to turn hope into tangible socio-economic transformations, whilst making a sustainable impact in the lives of over 1 billion Africans.

Working together with like-minded leaders, individuals, and institutions, A4A is mobilising African resources, will and skills to enable prosperity, and a thriving African continent in our lifetime.

*A4A is an Initiative by the MyAfricaThriving Foundation and the Ecobank Foundation, in Collaboration with The Global Fund*
What differentiates A4A?

**Leveraging Private Sector Mechanisms to accelerate and achieve sustainable development**

An investment vehicle focused on increasing return on investments for institutional and private investors to enable prosperity in Africa

<table>
<thead>
<tr>
<th>Philanthropic Giving on the following focus areas:</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Health</td>
</tr>
<tr>
<td>– Education</td>
</tr>
<tr>
<td>– Economic Inclusion</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Driven by Africans</th>
</tr>
</thead>
<tbody>
<tr>
<td>– African Private Sector</td>
</tr>
<tr>
<td>– HNWI &amp; Philanthropists across the continent</td>
</tr>
<tr>
<td>– African private sector employees</td>
</tr>
<tr>
<td>– African diaspora</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sustainable Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>– We leverage Private Sector mechanisms to increase return on equity for greater impact</td>
</tr>
<tr>
<td>– We maximize investments to raise new sources of funding</td>
</tr>
<tr>
<td>– We invest in communities through high impact organizations to scale programs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Innovative Investment Vehicle</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Raise new funds through targeted share classes philanthropic investments for catalytic interventions on the African continent.</td>
</tr>
<tr>
<td>– Generate supplemental outcomes based on existing partner portfolio in Africa</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>A World Class Innovation Hub</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Build a center of innovation where ideas can be tested and deployed across the continent</td>
</tr>
<tr>
<td>– Provide subject matter expertise on solving Africa’s most pressing community challenges</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Global Visibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Execute a forward looking branding and marketing campaign</td>
</tr>
<tr>
<td>– Publish and share best practices in global arenas through innovation and stories of sustained impact.</td>
</tr>
</tbody>
</table>
A4A Strategy in Action

Collaborators
- Africa Private Sector Institutions
- African HNWIs & philanthropists
- Private Sector Employees
- Development Partners

Vehicle
- Social Investment Fund (80%)
- Philanthropic Trust (20%)

Focus Areas
- Health
- Education
- Economic Inclusion

Outcome
- Enabling Prosperity in Africa for ALL Africans
Thank You
African Pharmaceutical Manufacturer’s Conference
Addis Ababa | 14 June 2017
INTRODUCING CIPLA QCIL

STRATEGIC PARTNERSHIPS

EVOLVING RELATIONSHIP WITH THE GLOBAL FUND
OUR MISSION

To provide long-term, sustainable access to high quality and affordable medicines in order to improve the quantity and quality of life.
2005
- Company established
- 7-year off-take agreement signed with the Government of Uganda (“GoU”)

2006-2009
- Construction of the manufacturing facility located in the industrial development zone in Kampala

2009
- Commissioning of the manufacturing facility
- Launch of operations and production of first own medicines
  - AZT/3TC/NVP (ARV)
  - AL 20/120 (ACT)

2010
- Plant receives WHO pre-qualification and GMP compliance
- First SSA company to become a supplier to the Global Fund
- Extension of the off-take contract with the GoU to 2019

2011
- Launch of new ARVs: EFV and AZT/3TC

2012-2013
- Cipla becomes controlling shareholder, increasing its stake to 51.05% and name changed to CiplaQCIL
- Introduction of TDF/3TC and NVP (ARVs)
- WHO/GMP renewed
- Sales expansion into Kenya

2014
- CiplaQCIL enters private market
- Sales expansion into Angola, South Sudan and Tanzania
- The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) extends up to 2033 for least developed countries (e.g. Uganda)

2015
- Launch of Company’s first “one-pill-a-day” drug for HIV treatment TDF/3TC/EFV
- Entry to new product category - hepatitis B drugs (launch of TDF and Entecavir)
- Sales expansion into Cameroon

2016
- WHO/GMP renewed
- Sales expansion into Namibia and Zambia

2017
- MOU WITH Government of Zambia for supply of ACTs, ARVs, Hepatitis

(1) Quality Chemicals Limited (“QCL”) – a leading pharmaceutical distributor in Uganda and Company’s second largest shareholder owning a 22.05% stake
ASPIRATION TO BECOME ONE OF THE LEADING PHARMACEUTICAL MANUFACTURERS IN SSA

A Pharma Plant for Africa

- Leading positions in current markets & penetrate new markets
- Develop and expand the product portfolio
- Maintain the highest quality and further improve efficiency
- Further enhance capacity: 30% capacity increase
- Continue to build on strong foundation supporting future growth
The Company’s product portfolio is currently tailored to target the three major communicable diseases that are widespread in Uganda and SSA and comprises anti-malarials, anti-retrovirals and hepatitis B medications.

All products are approved and recommended by WHO as preferred treatment methods for the respective diseases.

- Company’s ARV portfolio comprises 6 products, all of which are in line with WHO’s latest treatment guidelines.

### Anti-malarials (ACT)

- **Artemether 20mg/Lumefantrine 120mg** is the only anti-malarial medication produced by the Company.
  - The medicine has been manufactured since CiplaQCIL’s launch in 2009.
  - Product is still considered to be the most effective anti-malarial treatment globally with very few cases of resistance.
  - A combination therapy medicine comprising two active ingredients.
  - Artemether 20mg/Lumefantrine 120mg was included in the WHO list of pre-qualified medicinal products for malaria treatment in 2009.

### Anti-retrovirals (ARV)

- **Company started ARV production in 2009.**
- **Released in 2015, TDF/3TC/EFV became Company’s first “preferred option” drug as per latest WHO guidelines for HIV treatment (thanks to its formulation).** It is a convenient “one-pill-a-day” drug and represents a fixed-dose combination therapy (several active ingredients in one pill):
  - Maximizes the level of HIV suppression.
  - Simplifies treatment (one daily pill, instead of three or four) and decreases dosing errors.
  - Decreases likelihood that the virus will become resistant to the treatment.
  - All of Company’s drugs can form a part of combination therapy.

### Hepatitis B

- **Driven by the rising health issues dictated by hepatitis across the African continent, in 2015 the Company launched its first hepatitis B medications.**
  - **TDF and Entecavir.**
  - TDF is recommended by WHO as the first-line treatment.
  - Entecavir, also recommended by WHO, is the first-line treatment for children and second-line treatment for adults.
CiplaQCIL’s medications are currently approved in 10 countries across Eastern, Western and Southern Africa.

- Company will complete registration of its key products in at least 7 other countries by end of 2017.
- Despite each country having its own regulatory requirements, the approval process is facilitated by the fact that most products have already been WHO Prequalified.
- Company’s production facility also has GMP approvals for Ethiopia, Ghana and Ivory Coast.

Registration status and 2016-2017 pipeline:

<table>
<thead>
<tr>
<th></th>
<th>AL 20/120</th>
<th>AZT/3TC/NVP</th>
<th>AZT/3TC</th>
<th>TDF/3TC</th>
<th>EFV</th>
<th>NVP</th>
<th>TDF/3TC/EFV</th>
<th>TDF</th>
<th>Entecavir</th>
<th>Plant approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uganda</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Kenya</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Tanzania</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Namibia</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Zambia</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Rwanda</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>South Sudan</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Angola(1)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Mozambique</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Ivory Coast</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td>-</td>
<td>-</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Ghana</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Nigeria</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td>-</td>
<td>-</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Botswana</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

- Approved
- Submitted
- To be submitted

Approved markets
Markets to be approved
EXPANDING THE FOOTPRINT ACROSS AFRICA

- Commissioned in 2009, WHO all ARV’s and ACT WHO prequalified
- Currently a supplier of ACTs to the Global Fund in the SSA region
- Fully-invested state-of-the-art production facility with all necessary infrastructure and land required for further expansion. Initial investment $45 million, further capex $22 million. 2017 $7 million capex on expanding capacity by 30% and $3 million on state of the art pharma warehouse.

The list of international and regional institutions that have pre-qualified CiplaQCIL:

- WHO
- National Drug Authority of Uganda (NDA)
- Red Cross
- Drugs for Neglected diseases Initiative (DNDI)
- Kenya Pharmacy and Poisons Board
- Tanzania Food and Drugs Administration
- Rwanda Biomedical Centre
- Malawi PMPB
- Ethiopia FMHACA
- Namibia Ministry of Health
- Ivory Coast Ministry of Health
- Ghana Ministry of Health

Products manufactured at CiplaQCIL have been distributed to:

- Uganda
- Kenya
- Zambia
- Tanzania
- Namibia
- Cameroon
- Angola
- South Sudan

- Cameroon
- South Sudan
- Angola
- Ethiopia
- Namibia
- Ghana

EXPANDING THE FOOTPRINT ACROSS AFRICA
I. INTRODUCING CIPLAQCI

II. STRATEGIC PARTNERSHIPS

III. EVOLVING RELATIONSHIP WITH THE GLOBAL FUND
### Selected key areas in the business supported by Cipla

<table>
<thead>
<tr>
<th>Technical knowledge</th>
<th>✓ Expertise related to new product launch, production operations, adoption of new technologies, efficiency improvements, expansion programs, etc.</th>
</tr>
</thead>
</table>
| **New product development** | ✓ Cipla’s product portfolio exceeds 1,000 medicines, that can potentially be transferred to the Company should commercial opportunity arise  
✓ Since Cipla's products are already registered globally, local market authorization time (e.g. if the Company is registered as an additional manufacturing site) can be significantly reduced |
| **Procurement** | ✓ Through Cipla, CiplaQCIL has access to API’s at competitive rates and on favorable payment terms  
✓ Cipla’s technical services include pre-qualifying suppliers consistent with WHO standards |
| **Quality control** | ✓ Regular and rigorous audits from Cipla ensure compliance with strict international standards  
✓ Established procedures across all areas of operations facilitate meeting global regulatory and customer standards (WHO pre-qualification and GMP have to be renewed every 3 years) |
| **Important relationships** | ✓ Access to global pharma producers, including for securing license agreements in cases when such agreements were provided to Cipla |
PARTNERSHIPS WITH GOVERNMENTS OF UGANDA AND ZAMBIA. OTHERS IN NEGOTIATION.

- Long term guaranteed offtake for supply of ACTs, ARVs and Hepatitis medicine
- Provision of locally-manufactured lifesaving medicines for Uganda and other African markets in need
- Local production guarantees consistent supply of high quality products (minimum level of adherence for ARV to work properly is 95%, which means one cannot miss more than 1 ARV pill per month on a “one-pill-a-day” treatment)
- Shorter lead time compared to imports

Gradual improvement of HIV- and malaria-related healthcare treatment in Uganda

<table>
<thead>
<tr>
<th>ARV coverage</th>
<th>AIDS-related deaths, '000</th>
<th>Use of ACTs in malaria treatment among children under-5</th>
<th>Malaria-related estimated deaths, '000</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011 24%</td>
<td>2015 56%</td>
<td>2009 53 (47%)</td>
<td>2009 39% 2015 87%</td>
</tr>
<tr>
<td>2009 28</td>
<td>2015</td>
<td>2005 35 (66%)</td>
<td>2013 12</td>
</tr>
</tbody>
</table>

CiplaQCIL's positive impact on the domestic economy

- Sizeable investments in construction of the industrial park and production facilities in Kampala
- Mentioned as a top-100 tax payers in Uganda by President Yoweri Kaguta Museveni in 2016
- Improving national trade balance (growing exports)
- Over 270 employees (over 98% are Ugandans) provided with consistent training, competitive wages and a range of other benefits
- Regular teaching sessions organized for Ugandan and other pharma students and participation in numerous charity events
INTRODUCING CIPLAQCI

STRATEGIC PARTNERSHIPS

EVOLVING RELATIONSHIP WITH THE GLOBAL FUND
EVOLVING RELATIONSHIP WITH THE GLOBAL FUND

- Currently supplying Anti-malarials financed by the Global Fund: both Co Payment and PPM.

- From tender award for 3 countries in 2014, CiplaQCIL supplied to 6 countries in Africa in 2016/17; #treatments ~5X of the 2014 allocation

- Entrusted with holding the GF’s rapid supply mechanism stock
  - CQCIL holds and regularly rotates 30 million Artemether 20mg/Lumefantrine 120mg tablets and undertakes to pack and deliver medicines to anywhere in Africa within seven days if the GF places an emergency order
  - the last emergency order for Comoros Islands was delivered in five days from receipt of order)
EVOLVING RELATIONSHIP WITH THE GLOBAL FUND

- Increasing regulatory footprint
- OTIF performance
- Priority to Global Fund supplies
- Short lead and delivery times
- African/SSA manufacturer

- 0 days Uganda
- 24 hours Kenya
- 48 hours Tanzania
- 8 days Zambia (over land)
Contact Details

Cipla Quality Chemical Industries Ltd.
Plot 1-7, 1<sup>st</sup> Ring Road
Luzira Industrial Park | P. O. Box 34871,
Kampala, Uganda
website: [www.ciplaqcil.co.ug](http://www.ciplaqcil.co.ug)

Nevin J Bradford, CEO
Tel: +256 312341100
Mob: +256 771 005 333
Email: nbradford@ciplaqcil.co.ug

“THANK YOU”
PHARMACEUTICAL MANUFACTURING PLAN FOR AFRICA
Presentation outline

- Mandate, Vision & Mission,
- Areas of Focus
- Initiatives
- Indicators of Success
- Governing Structure
  - PMPA Technical Committee composition
  - PMPA Consortium of Partners
  - AUC and NEPAD Agency
  - UNIDO
- Challenges
- Upcoming Events
Mandate
January 2005 AU Assembly decision 55 taken during the Abuja Summit which mandated the African Union Commission to develop a Pharmaceutical Manufacturing Plan for Africa within the framework of NEPAD

Vision
African people have access to essential, quality, safe and effective medical products and technologies

Mission
Facilitate the development of a competitive pharmaceutical industry in Africa to ensure self-reliance
Areas of Focus (1/2)

- Developing a Business Plan
- Building a Consortium of Partners for PMPA
- Developing a joint work plan
- Resource mobilization
- Development of solutions where further work is needed
  - GMP
  - Essential Medicines List risk assessment
  - Detailed design of syllabus for HR development along different dimensions of human capital requirements
Areas of Focus (2/2)

- Identification of member states and, if appropriate, RECs who wish to actively engage with the PMPA
- Identification of experts and service providers
- Interaction with other stakeholders involved in activities related to pharmaceutical manufacturing in order to derive inputs and identify opportunities for collaboration/alignment with the PMPA
- Setting up field representation for the PMPA
Initiatives (1/2)

- Legislation, policy and incentives
- Regulatory strengthening
- Good Manufacturing Practice
- Access to Capital
- Human resource development
Initiatives 2/2

- Market/management information system
- Business linkages
- Bioequivalence centre
- Innovation, research and development
- Traditional medicine
- Advocacy and communications
Indicators of Success (1/3)

- Proportion (value and volume) of pharmaceutical market supplied by Africa-based manufacturers
- Proportion of products in the market place that are found to be sub-standard and the severity of the non-conformity with requisite parameters
- Number of companies achieving Good manufacturing Practice (GMP) standards
- Proportion of products procured by international donors sourced from Africa-based manufacturers
Indicators of Success (2/3)

- Improved Capacity of National Medicines Regulatory Authorities
- Number of National Quality Control Laboratories prequalified by WHO
- Number of countries that have developed and are implementing strategies for local production
- Amount of capital investment in pharmaceutical manufacturing activities
- Number of countries amending legislation to incorporate TRIPS flexibilities and the number of products on the market as a result of exploiting the flexibilities and price of products versus originators
Indicators of Success (3/3)

- Number of industry professionals trained across different disciplines required by the pharmaceutical manufacturing system
- Number of Partnerships and Business Linkages facilitated
- Number of Partnerships and Business Linkages facilitated
- Emergence of supportive industries e.g. for manufacture of excipients and packaging material and are able to service and retool equipment
PMPA Technical Committee composed of

- 12 member states from across the five regions of the AU namely: East (Kenya, Ethiopia), West (Ghana, Nigeria, Senegal), North (Libya, Egypt), Central (Cameroon, Burundi), South (South Africa, Angola, Mozambique);
- Representatives from 8 regional economic communities recognized by AU and representing steering committees on AMRH
- UNIDO
- WHO
- Academia
- Federation of African Pharmaceutical Manufacturers Associations (FAPMA) and
- AUC&NEPAD Agency (serve as Joint secretariat)
Governing Structure (2/2)

- PMPA Consortium of Partners:
  - UNIDO (secretariat)
  - UNAIDS
  - WHO
  - UNFPA
  - UNECA
  - USP
  - ANDI
  - FAPMA
  - AfDB
  - NEPAD AGENCY
CHALLENGES

- Inadequate Funding
- Insufficient Human resources
- Limited Institutional capacity
Upcoming events

- Organize Continental conference on local production of pharmaceuticals in Africa;(24-26 October 2017)
- Preceded by the PMPA Partners Platform
THANK YOU
MERCI
AMASEGNALEN