Long-lasting Insecticidal Nets 
Supplier & Partner Consultative Meeting 

26 September 2019 
Singapore
LLIN Supplier & Partner Consultative Meeting Agenda

1. ITN Policy Update
2. WHO Prequalification Vector Control Update & Progress
3. Global Fund Responsible Procurement Update
5. IVCC Vector Control Product Development Pipeline
6. UNICEF Procurement Update
7. PMI LLIN Sourcing & Procurement Update
8. Global Fund LLIN Procurement Strategy
ITN policy update

Dr. Kate Kolaczinski
Malaria Team, The Global Fund
LLIN suppliers meeting, Singapore, September 2019
Outline

1. Malaria and funding landscape
2. ITN policy landscape
3. Global Fund approach to funding ITN interventions
4. Question and answer
1. Malaria and funding landscape
Worldwide malaria progress: 2000–17

Number of malaria cases

Number of malaria deaths

Figures: Alastair Robb, Global Malaria Programme, WHO
ITN ownership and coverage (Sub-Saharan Africa), 2010–17

Figure: World Malaria Report, 2018

Percentage of population at risk with access to an ITN and sleeping under an ITN, and percentage of households with at least one ITN and enough ITNs for all occupants, sub-Saharan Africa, 2010–2017. Source: ITN coverage model from MAP.¹

¹ ITN: insecticide-treated mosquito net; MAP: Malaria Atlas Project.
http://www.map.ox.ac.uk/

The Global Fund
Le Fonds mondial
El Fondo Mundial
Глобальный фонд
全球基金
الصندوق العالمي
Barriers to progress

• Biological challenges
  o Insecticide resistance
  o Drug resistance

• Tools challenges
  o Durability
  o Efficacy
  o Residual transmission

• Systemic and contextual challenges
  o Health systems
  o Economic environments
  o Climate and climate change?
  o Insufficient funding for full needs
Stagnation in funding levels since 2010

**FIG. 2.3.**

Funding for malaria control and elimination 2010–2017, by channel (constant 2017 US$)  
Sources: ForeignAssistance.gov, United Kingdom Department for International Development, Global Fund, NMP reports, OECD creditor reporting system database, the World Bank Data Bank and WHO estimates.


Figure: World Malaria Report, 2018
2. ITN policy landscape
WHO Policy Guidance

- WHO Guidelines for malaria vector control
- New document published in mid 2019
- Combines all guidelines on different vector control interventions in one place
- Operational manuals remain separate
WHO vector control guidelines: Insecticide-treated nets

Universal coverage with effective vector control using a core intervention (ITN or IRS) is recommended for all populations at risk of malaria in most epidemiological and ecological settings.

**Good practice statement**

Priority should be given to delivering either ITNs or IRS at high coverage and to a high standard, rather than introducing the second intervention as a means to compensate for deficiencies in the implementation of the first intervention.

**Conditional recommendation**

- Universal coverage of populations at risk with at least one core intervention
- Core vector control interventions:
  - IRS
  - ITNs
- Supplementary interventions recommended only in specific defined contexts
- Combining ITNs and IRS recommended under specific conditions only
### INSECTICIDE-TREATED NETS

**Pyrethroid-only LLINs prequalified by WHO are recommended for deployment as a core intervention in all malaria-endemic settings.**

*Strong recommendation as an intervention with public health value, high-certainty evidence*

**Pyrethroid-PBO nets prequalified by WHO are conditionally recommended for deployment instead of pyrethroid-only LLINs where the principal malaria vector(s) exhibit pyrethroid resistance that is: a) confirmed, b) of intermediate level, and c) conferred (at least in part) by a monooxygenase-based resistance mechanism, as determined by standard procedures.**

*Conditional recommendation as an intervention with public health value, moderate-certainty evidence*

- Pyrethroid-only LLINs recommended as a malaria control tool in all areas
- Pyrethroid-PBO nets recommended in areas:
  - with specific IR context
  - where increased cost won’t lead to coverage gaps
- No policy recommendation yet for dual ai nets
3. Global Fund approach
General guidance given to countries:

All country requests for funding should be grounded in a national vector control strategy which is:

- Evidence based: entomologic and epidemiologic data
- In line with WHO global guidance
  - or with clear explanations if local decisions differ
- Aims to ensuring universal coverage of at risk populations with at least one core vector control intervention (IRS or ITNs)
  - While embracing the flexibilities needed to appropriately allocate limited resources to maximize impact
Intervention specific guidance given to countries:

**Insecticide treated nets:**
- Strong focus on maximizing coverage and use in at risk populations
- Pyrethroid-only LLINs:
  - procurement will continue to follow WHO guidance
- PBO nets:
  - procurement will continue to follow WHO guidance, specific IR and operational conditions to be met if price is higher
- Other prequalified nets that do not have a WHO policy (e.g. dual a.i nets):
  - continue to be available through the New Nets Project pilots only
- Countries deploying PBO nets (or dual a.i nets as pilots) are recommended to not revert back to pyrethroid-only nets in future
- No change to net characteristics policy (size, shape, colour etc) from current cycle
- More funding for net durability and efficacy monitoring likely
Indoor residual spraying and Insecticide treated nets:

- IRS continues to be supported as an effective malaria control intervention
- Countries recommended to maintain coverage in previously GF-supported IRS areas
- Must demonstrate sound insecticide-resistance management strategy and routine monitoring of the quality and coverage of IRS.
- TGF will consider funding ITNs and IRS in the same geographic areas if:
  1. Universal coverage of at risk populations with one method of vector control is ensured
  2. High coverage and utilization/acceptance of the first method
  3. Combination is proposed for the management of insecticide resistance and is proposed as a part of a national insecticide resistance monitoring and management plan.
Questions?
WHO Prequalification
Vector Control

Update and Progress

Marion Law, Group Lead
WHO Prequalification – Vector Control
Prequalification process: Application Statistics

Total prequalified products – 77
  ✓ Converted - 71
  ✓ Prequalified - 6

Requests for Determination of Pathway
  ✓ 116 actions to date

Pre submission meetings - many

New applications -23
Change applications - 39
Protocol reviews - 27
Prequalification – VC applications

Prequalified
✓ SumiShield 50WG
✓ Cielo ULV
✓ Fludora Fusion
✓ Aquatain AMF
✓ Royal Sentry 2.0
✓ Royal Guard

Under Assessment
✓ Aquastrike
✓ Sylando 240 SC
✓ Tsara
✓ MkitoNet
✓ Axient 440EW
✓ In2Care Mosquito Trap
✓ Imergard
Outputs and ongoing work from Assessment Sessions

Policies
✓ Product Labelling
✓ Accepting publicly available information to support applications
✓ Re-evaluation of active ingredients

Activities
✓ Risk assessment models review
✓ Label improvement plan
✓ Comprehensive Review of Chlorpyrifos
✓ Product review of combination of active ingredients in bednets
✓ Planning a re-evaluation program for PQ listed products.
✓ Regulatory framework - for a gene drive mosquito interventions /products
PQT-VC Assessment Sessions
Arusha, Tanzania 2018
PQT-VC Assessment Sessions
Rome, Italy, December 2018
PQT-VC Assessment Sessions
Rome, Italy, December 2018
PQT-VC Assessment Sessions
Dakar, Senegal May 2019
PQT- VC Priorities for 2019

Application assessment (new applications, protocols, changes)
✓ Assessor’s sessions

Post market activities
✓ Implementation of label improvement plan
✓ Complaint Process
✓ Targeted oversight-surveillance & monitoring
✓ Post-market product review

JMPs
✓ Continue the integration of processes

Capacity building in countries- fact finding

Guideline review
Opportunity

Build a system, i.e., WHO Vector Control evaluation process, that is robust and ensures access to safe, effective and high quality products throughout their life-cycle and at the same time flexible enough to encourage new product development, incorporate new science and meet diverse geographic and population needs.
Thank You

Questions / Comments?
Appendix 1
Guiding Principles

Engagement with colleagues, partners, all stakeholders
✓ Practice openness and transparency
✓ Collaborate, engage and listen through proactive/constructive 2-way communication
✓ Demonstrate integrity (judgement/confidentiality/tact/consistency)
✓ Be respectful and demonstrate respect

Process and Decision Making
✓ Action oriented, i.e., value-added processes which focus on end user access to products
✓ Evidence-based
✓ Adhere to established roles and responsibilities
✓ Transparent
✓ Timely
✓ Well documented policies and decisions
✓ Continuous evaluation and process improvement

Broader Impact
✓ Embrace innovation and creativity (Nick Hammon, Innovative Vector Control Consortium)
✓ Apply a global perspective to meet varying geographic and disease needs
✓ Monitor and evaluate current approaches to meet changing global needs, i.e., remain relevant
Responsible procurement

26 SEPTEMBER 2019, SINGAPORE
Global Fund Mission:
Investing the world’s money to defeat AIDS, TB & Malaria

32 million lives saved
Ending the epidemics & promoting human rights: Considering the total cost to human well-being

- **Environmental damage**
  - Source: www.cfp.cn

- **Unsafe facilities**
  - Source: davidmixner.typepad.com

- **Child or forced labour**
  - Source: Human Rights Watch (www.hrw.org)

- **Unfair working conditions**
  - Source: Human Rights Watch (www.hrw.org)
## Our values and what they mean for LLIN suppliers

<table>
<thead>
<tr>
<th>Dignity and respect</th>
<th>Integrity</th>
<th>Accountability</th>
<th>Duty of care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Working conditions:</strong></td>
<td><strong>Taking the total cost</strong></td>
<td><strong>Fair, honest and correct information</strong></td>
<td><strong>Full and accurate records</strong></td>
</tr>
<tr>
<td>• Labour rights</td>
<td>• No corruption</td>
<td>• Rules-based procurement</td>
<td>• Performance &amp; compliance systems</td>
</tr>
<tr>
<td>• Fair bargaining</td>
<td>• Managing conflicts of interest</td>
<td>• Continuous improvement</td>
<td>• Access and audits</td>
</tr>
<tr>
<td>• Health and safety</td>
<td>• No anti-competitive practices</td>
<td>• Third-party management</td>
<td></td>
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<tr>
<td>• No slavery</td>
<td>• Sustainability</td>
<td>• Prompt disclosure</td>
<td></td>
</tr>
<tr>
<td>• No child labour</td>
<td></td>
<td>• Supply chain visibility</td>
<td></td>
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<tr>
<td>• No discrimination</td>
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<tr>
<td>• Gender-consciousness:</td>
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<td></td>
<td></td>
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<tr>
<td>• No harassment</td>
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<td></td>
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<tr>
<td>• No exploitation</td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Environmental respect:</strong></td>
<td><strong>No anti-competitive practices</strong></td>
<td><strong>Rules-based procurement</strong></td>
<td><strong>Environmental respect:</strong></td>
</tr>
<tr>
<td>•Protection from hazards</td>
<td></td>
<td>• Continuous improvement</td>
<td>• Protection from hazards</td>
</tr>
<tr>
<td>• Waste management</td>
<td>• Managing conflicts of interest</td>
<td>• Third-party management</td>
<td>• Waste management</td>
</tr>
<tr>
<td>• Emissions scrubbing</td>
<td>• No anti-competitive practices</td>
<td>• Prompt disclosure</td>
<td>• Emissions scrubbing</td>
</tr>
<tr>
<td>• Waste minimization</td>
<td>• Sustainability</td>
<td>• Supply chain visibility</td>
<td>• Waste minimization</td>
</tr>
<tr>
<td>• Re-use and recycling</td>
<td></td>
<td></td>
<td>• Re-use and recycling</td>
</tr>
</tbody>
</table>

*We will invest in suppliers who share our values and who in turn invest in meeting these standards*
Making Ethics work at the Global Fund

- Accepted in 2014 by the Board
- Defines values and assigns roles
- Unifies codes and policies

Ethics Team

- Ethics Officer
- Specialists:
  - Conflict of interest
  - Counter-fraud & anti-corruption
  - Integrity due diligence

Ethics & Integrity Framework

Advice

Support services
Taking responsibility for LLIN manufacturing

Market-shaping strategy

Integrity pact

Responsible Procurement

Global Fund:
• Revised codes of conduct
• Clear direction
• Strengthened monitoring
• Enhanced disclosures
• Material encouragement
• Continuous engagement

Suppliers:
• Environmental and occupational health certification
• Accountability for full supply chain
• ‘Race-to-the-top’ innovation
• Responsiveness to raised issues
Specific steps for procuring LLINs responsibly

**STANDARDS & CERTIFICATION**
Suppliers encouraged to take proactive steps to obtain the EMS and OHS certifications, or work towards fulfilling specific criteria.

**SUPPLY CHAIN DISCLOSURE**
Each supplier must demonstrate the extent of ownership and flexibility over the entire supply chain, which allows to effect change.

**ENHANCED DUE DILIGENCE**
The Global Fund will be aligning with partners to conduct site reviews, undertake testing and strengthen integrity risk management.
LLIN QMS: collaborative expectations

Stuart Turner & Jennifer Wray
on behalf of
The Global Fund, UNICEF & PMI

26 September 2019 – Singapore
PMI-specific QMS enhancements

- Revised contractual requirements from procurement agent
  - Record & product retention
  - Definition of batch
  - Long-term agreements
  - WHO PQ
  - Desk audit - QMS review, in-place SOPs, ISO-9001 & cert documentation, etc
  - Environmental safety clauses

- Physical inspection & quality control testing continued
  - Alignment with GF/UNICEF on physical inspection
  - HPLC, GC on API; bursting strength; seam strength; etc

- LLIN durability monitoring continued

- Post-marketing surveillance – TBD
  - Influence on existing/future contracts and eligibility
  - Donor-level & WHO PQ data exchange

- Evolving as procurement evolves (e.g., PBO & dual AI)
**GF estimated Risk Profile along the Product life cycle (qual.)**

<table>
<thead>
<tr>
<th>Upstream life cycle</th>
<th>Downstream</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design &amp; Development</td>
<td>Maintenance &amp; End of life</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>Market surveillance</td>
</tr>
<tr>
<td>Registration / Market Authorization</td>
<td>Vigilance &amp; Complaint</td>
</tr>
<tr>
<td>Selection</td>
<td>Dispensation &amp; Use</td>
</tr>
<tr>
<td>Procurement</td>
<td>Import, Storage &amp; Distribution</td>
</tr>
</tbody>
</table>

| Manufacturers | NRA | National program | GF/PSA or NPA PSI+QC | In-country Supply Chain actors | National Program / Users | Manufacturer / NRA | NRA | Manufacturer / NRA |

- High
- Medium
- Low
- Managed
Overview of QA related requirements in manufacturer agreement

<table>
<thead>
<tr>
<th>SCOPE</th>
<th>GF/UNICEF</th>
<th>USAID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Requirements</td>
<td>• Reference to PSM Guide / QA Policy</td>
<td>• QA Policy: WHO Vector Control prequalified as minimum. Added testing and monitoring. QMS requirements.</td>
</tr>
<tr>
<td></td>
<td>• Packaging Requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Packing for shipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Packaging &amp; Labelling Requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• To ensure supplier product registration</td>
<td></td>
</tr>
<tr>
<td>Supplier related obligations</td>
<td>• To designate a Responsible person for QA</td>
<td>• Supplier to provide documentation &amp; evidence of compliance with GMP.</td>
</tr>
<tr>
<td></td>
<td>• To convey same obligation to supplier</td>
<td>• Assess impact of all changes (materials and process) on quality.</td>
</tr>
<tr>
<td></td>
<td>• To ensure compliance with Authorization</td>
<td>• PMI notified of any change requests to WHO PQ.</td>
</tr>
<tr>
<td></td>
<td>• To ensure compliance with QMS /GMP standards</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• To ensure compliance with GDP Standards</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• To notify any change that may impact the quality</td>
<td></td>
</tr>
<tr>
<td>Regulatory Authority &amp; Audit</td>
<td>• To provide report of Regulatory Authority inspection</td>
<td>• Notification of regulatory action within 2 business days.</td>
</tr>
<tr>
<td></td>
<td>• To notify in case of Warning letter</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• To accept GF audit</td>
<td></td>
</tr>
<tr>
<td>Verification and control activities</td>
<td>• To retain samples</td>
<td>• Retain samples from every order, one-year past expiration.</td>
</tr>
<tr>
<td></td>
<td>• To allow GF to test retained samples</td>
<td></td>
</tr>
<tr>
<td>Documentation</td>
<td>• To retain records technical files, manufacturing files and distribution files for traceability</td>
<td>• To maintain records one-year past expiration.</td>
</tr>
</tbody>
</table>
# Overview of QA related requirements in manufacturer agreement

<table>
<thead>
<tr>
<th>SCOPE</th>
<th>GF/UNICEF</th>
<th>USAID</th>
</tr>
</thead>
</table>
| Deviations & Out of specifications | • To inform in case of quality incidents, Out of specifications (internal)  
• To engage in investigations /root cause analysis | • Maintain records of all in-process check test results including OOS. Analyze/trend OOS result for root cause analysis.  
• Continuous improvement. Implement resolutions |
| Quality Defect & Recall          | • To inform GF of serious quality defect (external) and recall  
• To allow GF to recall a batch in case of serious risk for patient | • Define serious risk; active/insecticide content (efficacy), physical characteristics (efficacy) contaminant (health and safety) |
| Specifications and analytical methods | • To share specifications and analytical methods  
• To provide if not commercially available, the reference standards |                                                                         |
| Shelf –Life & Sales             | • To ensure remaining shelf-life  
• To provide data on sales | • Ensure shelf-life along production/freight continuum (e.g., integrity of product during shipping) |
| Vigilance                       | • To designate a qualified person and a system in place  
• To submit to the relevant authority  
• To inform of any safety communication |                                                                         |
Considerations

- Responsibility for timely transparency
  - Donors and vendors to provide data/info to WHO PQ
  - Mechanism? Type of data? Frequency?
  - Upstream subcontractor management?
- Dual API + pyrethroid
  - Procurement currently through NPP due in part to global volume supply
- PBO
  - PMI: 2/5 eligible; future volumes contingent on internal VC considerations on acceptable standardization
  - On-going ento/epi data collection to inform future procurements
- High-level donor transparency
  - Sharing of data, pre- & post-shipment
**GF NC & OOS Data Base**

- From February 2015 to Date
- 35 Events
- 17 Manufacturing sites
- More than 50 consignments / ??? batches

**Main deficiencies identified**

- Data Integrity / Data Manipulation
- Poor documentation practices
- Poor manufacturing practices
- Not authorized Variation in Design / manufacturing process / Testing Specifications
- Lack of efficacy (under investigations)
- Inadequate labelling and packaging
- Poor management of critical sub-contractors
- Poor practices in managing complaint

**Areas of improvement**

- Quality Management System (QMS)
- Registration / variations
- Complaint & Vigilance
- Design Verification / Validation
- Storage, distribution & transportation Practices
Proposed Future UNICEF QC Activity

• Ongoing QA collaboration with all procurement agencies – i.e. Durability studies
• Continue PDI to verify AI and Mechanical properties
• Surveillance on batches within lots
• Retain batch samples of all PO’s
• Critical Review and Revision of the standard PDI Guidelines to support proposed QMS enhancements.
• Provide data on complaints or any post market activity findings to PQ
• Initiate closer relationship with Vector Control PQ team by quarterly calls and an annual face to face (possibly in parallel with regular VCWG Meeting in Geneva)
Thank you!
Vector Control Pipeline Agenda

• What do we need from the vector control product development pipeline

• How does IVCC develop products

• What is the pipeline for IRS and LLINs

• New Nets Project Market intervention to enable the Dual AI net market.

• What else is in the pipeline

• What are the key barriers to bringing these products into beneficial use.
Resistance increasing in distribution and intensity

Source: IR Mapper (www.irmapper.com) June 2016
Rise in pyrethroid resistance
Restoring mosquito mortality improves vector control

First Programme use of Actellic Ghana 2012

Cluster randomised trial of Actellic Mozambique 2017

Cluster randomised trial of PBO nets Tanzania 2015

Bunkpurugu - Yunyoo district, Northern Ghana

- Mosquitoes Susceptible in 2010
- Resistant by 2012
- Surveys of 824 children under-five.
- Data collected on IRS, ITN ownership and usage, fever in children under-five and anti-malarial treatment.

- An. funestus densities were reduced by 50%
- Passive case incidence of under 5-year old RDT+ malaria reduced by 20% (RR 0.81; 0.79 – 0.83)

Protopopoff and Rowland LSHTM

30-50% reduction in prevalence

Data from Abt and PMI, In preparation for publication
Product Development Partnership for New Active Ingredients

Formulation of AI into product will engage many others
### IVCC portfolio

<table>
<thead>
<tr>
<th>Research</th>
<th>Proof of concept/ Optimisation</th>
<th>Pre-development/ Development</th>
<th>WHO PQ/ Registration</th>
<th>Access and Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novel chemistry screening (Various partners/IVCC)</td>
<td>Alternative AIs</td>
<td>AI 1</td>
<td>Royal Guard (DCT)</td>
<td>Actellic CS (Syngenta)</td>
</tr>
<tr>
<td>Repurposing/reformulation of crop protection AIs</td>
<td>Proof of Concept Studies from a wide range of early stage novel interventions</td>
<td>AI 2</td>
<td>Sylando (BASF)</td>
<td>Fludora Fusion (Bayer)</td>
</tr>
<tr>
<td>XLLIRS (IVCC / ZERO by 40 Consortium)</td>
<td>AI 3</td>
<td></td>
<td>Sumishield (Sumitomo)</td>
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<tr>
<td></td>
<td>AI 4</td>
<td></td>
<td>Interceptor G2 (BASF)</td>
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<tr>
<td></td>
<td>Novel AI IRS</td>
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<td></td>
<td>ATSB (Westham)</td>
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<tr>
<td></td>
<td>Application technology (Various)</td>
<td></td>
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</tbody>
</table>

- **Novel AI for ITN and IRS**
- **Insecticide Treated Net (ITN)**
- **Indoor Residual Spray (IRS)**
- **Outdoor transmission**

In partnership with IVCC Industry/Academia
New Nets Project Overview

Interceptor G2 and Royal Guard LLIN Cluster Randomised Efficacy Trials

Operational Cost Effectiveness Data from Pilots

Co-payments for Dual AI LLINs in Pilots

New Nets Project Duration 4 Years

2018
- Project Startup
- Country engagement
- Pre-pilot assessment
- COGs and Market research

2019

2020
• 4 Effectiveness Pilots:
  - Burkina Faso
  - Mali
  - Rwanda
  - Mozambique
• RCTs in Tanzania and Benin begin

2021
• 1 Effectiveness Pilot
• 1 Operational Pilot

2022
• 2 Operational Pilots

2023
• Repeat 2019 Pilots

Policy and Process evolution

Cost Effectiveness

Efficacy

Country Pilots

Market intervention

Operational learning for Dual AI LLIN implementation

Pilot Impact data

Public Health value of Dual AI LLINs

Validity of Ento correlates

Cost effectiveness of Dual AI LLINs

Transition to GF PMI

Co-payments for Dual AI LLINs in Pilots

Public Health value of Dual AI LLINs

Validity of Ento correlates

Cost effectiveness of Dual AI LLINs

Transition to GF PMI
The aim and current scope of NNP

The NNP is an initiative established by Unitaid and the Global Fund in partnership with PMI and BMGF, working with other key stakeholders to catalyse the market introduction of next generation ITNs, those with two active ingredients aka dual AI ITNs

**NNP countries**

- **Effectiveness pilots**
  - Burkina Faso
  - Mali
  - Mozambique
  - Rwanda

- **Pilots pending MOUs**
  - Nigeria
  - Cote d’Ivoire

- **RCTs**
  - Benin
  - Tanzania*

* Funded by UK MRC
New Nets Project Team Roles

**IVCC Lead and Coordinator**
- Negotiations with industry partners,
- Co-payment system and contracts to reduce price.
- COGs understanding and ability to get industry to cooperate on COGs.
- Links to the vector control product development pipeline.
- Links to Ag Chem CEO forum and the ask from industry.

**PATH**
- Cost effectiveness determination from pilot implementations

**AMP**
- Technical assistance to pilot implementations

**PSI**
- Compilation of cross-country lessons learned from pilot studies, funding for process evaluations

**LSHTM**
- Cluster Randomised trials of Dual AI LLINs and Entomological Correlates in trials

**Tulane**
- Cost effectiveness trials and data collection design

**Imperial College**
- Modelling of trials design and implementation impact

**LSTM**
- Entomological correlates of epidemiological Impact
Effectiveness Study objectives

In each pilot district (new net and standard LLIN comparator), enhanced surveillance activities will monitor the impact of mass distribution on 3 components, feeding into a broader analysis on cost-effectiveness.

**Epidemiological component** – measure impact of new nets and standard ITNs, and if feasible PBO ITNs, through observational studies comparing trends in:
- Malaria incidence rates passively reported to the national health system (passive case detection (PCD)).
- Malaria infection prevalence, measured through Rapid Diagnostic Tests (RDTs), from annual cross-sectional surveys during peak transmission periods.

**Entomological component** – evaluate the impact of new nets and standard ITNs, and if feasible PBO ITNs, on vector population density, behavior, infection and resistance status.

**Anthropological component** – map social determinants of impact for new nets and determine transmission risk through gathering evidence on ITN uptake and usage; collecting data on patterns, both indoors and outdoors, becomes an essential component of the evaluation of the ITN pilots for both modeling and contextual analysis of impact.

**Costing and cost-effectiveness component** – estimate the cost and cost-effectiveness of new nets through data on product price, delivery and deployment costs, and effectiveness based on incidence rates.
Current pilot plan: Mozambique

Note that project team is working to standardize map formats/colors.
Attractive Targeted Sugar Baits (ATSB)

Reduce mosquito population in the peri-domestic area (ongoing ento trials)

Will prevent malaria transmission (to be demonstrated through epi trials)

Expected launch date: 2024-2025

Information from M Mondy IVCC and Westham Corp.
How they work
1. Human odour
2. Attracts mosquitoes to Eaves
3. Blocked by EaveTubes
4. Pick up lethal dose insecticide
5. Leave the House
6. Die due to insecticide

Next steps
- 2019: PQ process started
- 2019: Operational manual large scale campaigns finalized
- 2020: Setup large scale production
- 2020: National registration in Tanzania and Ivory Coast
- 2021: National registration in 4 additional African countries

In2Care EaveTubes™ are easy-to-install ventilation tubes and removable mesh inserts that are installed in the wall under the roof of houses.

https://youtu.be/DGyI9i4fpyQ
Ivermectin is a complementary strategy against:

- Outdoor biting
- Outdoor resting
- Day / Night Biting
- Early exit
- Feeding upon livestock

<table>
<thead>
<tr>
<th>Trial Name</th>
<th>Lead Researcher</th>
<th>Country</th>
<th>Dose</th>
<th>Drug Combination</th>
<th>First results</th>
</tr>
</thead>
<tbody>
<tr>
<td>MASSIVE</td>
<td>Umberto D’Alessandro</td>
<td>The Gambia</td>
<td>3 x 300</td>
<td>DHA-P MDA</td>
<td>2019</td>
</tr>
<tr>
<td>RIMDAMAL II</td>
<td>Brian Foy</td>
<td>Burkina Faso</td>
<td>3 x 300</td>
<td>SMC</td>
<td>2020</td>
</tr>
<tr>
<td>TBC</td>
<td>Kobylnski &amp; Sattabongkot</td>
<td>Thailand</td>
<td>1 x 400</td>
<td>Ivermectin alone</td>
<td>2020</td>
</tr>
<tr>
<td>TBC</td>
<td>Anna Last</td>
<td>Guinea-Bissau</td>
<td>3 x 300</td>
<td>DHA-P MDA</td>
<td>2021</td>
</tr>
<tr>
<td>BOHEMIA</td>
<td>Rabinovich &amp; Chaccour</td>
<td>Tanzania, Mozambique</td>
<td>1 x 400</td>
<td>Ivermectin alone + ivermectin to livestock</td>
<td>2021</td>
</tr>
</tbody>
</table>

- **BOHEMIA** aims at creating an *enabling environment* for a WHO Policy recommendation by 2023
- Evidence generation in two independent trials
- Parallel work with manufacturers to help ensure supply of quality-assured product by 2023
- Parallel work with stakeholders to facilitate policy adoption

From Carlos Chacour  IS Global
Spatial Repellent – Mode of Action

Continuous release

Added Value:
Addresses daytime, early-evening and indoor/outdoor vector biting

Varied modes of action

Innovation:
New actives, alternate target sites, exploitation of post-exposure effects
• Global dossier complete by Dec 2019 to support registration across a broad range of malaria-endemic countries
• In process with VCAG evaluation + PQT-VC

2014-2019
• Sealed film containing a volatile insecticide that emanates once opened, for a 2-week duration of protection indoors
• Product evaluated in clinical trials in Indonesia and Peru

2019-future
• Improved version of our 2-week product that provides 1-month of protection indoors
• Will be evaluated in upcoming clinical trials in Kenya, Mali, and Sri Lanka
• Country registrations for this product starting in 2020

Next generation
• New spatial repellent product in SC Johnson development pipeline to extend duration of protection to an entire transmission season
## Barriers to adoption

<table>
<thead>
<tr>
<th>Workstream</th>
<th>Non Pyrethroid IRS</th>
<th>Dual AI LLINs</th>
<th>New AI IRS / LLINs</th>
<th>ATSB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use Case / Entomology</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Product Profile</td>
<td></td>
<td></td>
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<tr>
<td>Technology / IP Development</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>User compliance/ acceptability</td>
<td></td>
<td></td>
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<tr>
<td>Implementability</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Regulatory / Safety / Environmental impact Qualification</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturability Delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epidemiology</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Economics / Funding stream / Demand Forecasting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Policy / Strategy / Resistance management</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

- **Proximate barrier to adoption of new products in the pipeline is the time needed for epidemiological evidence.**

- **Most severe barrier is the availability of funding for new products and new intervention classes.**

- **Secondary barrier is policy Strategy and insecticide resistance management implementation.**
Conclusion

• There is a rich potential pipeline of new products

• The pipeline may dry up if product development barriers are too high.

• Some of the much discussed development plans are higher risk than is acknowledged

• Market interventions will be required to bring the products through development
Presentation Outline

About UNICEF Supply Division

Overview of UNICEF LLINs Procurement

2019-2021 LLINs Procurement Strategy, Objectives and Tender Outcomes

2019 LLINs Procurement

UNICEF Suppliers Performance Evaluation
UNICEF Supply Division

UNICEF’s Supply & Logistics headquarters located in Copenhagen, Denmark

It is also home to the largest humanitarian warehouse

Other UNICEF warehouse hubs are located in Dubai, Panama and Shanghai

UNICEF’s Supply Community of 1036 supply and logistics staff serve children in 97 countries

- Supports results for children with an effective, efficient supply operation
- Helps meet UNICEF’s Core Commitments for Children in emergencies by providing rapid response to emergency supply and logistics needs
- Contributes to influencing markets to ensure sustainable access to essentials supplies for children
- Serves as a centre of expertise and knowledge on essential supplies for children and supply chains and build capacities of national governments
- Provides procurement services to governments and development partners on strategic-essential supplies
- Establishes policies for supply chain activities
- Uses product innovation to increase results and decrease costs
UNICEF Supply Function – high level vision

- 2005: Direct Delivery
- 2008: Direct Delivery
- 2010: Direct Delivery
- 2013: Direct Delivery
- 2017 - 2030: Direct Delivery, Procurement Services, Capacity Development, Innovation
UNICEF procurement value by major commodity groups (2018)

- **Vaccines**: $1.453 billion
- **Pharmaceuticals**: $124.9 million
- **Water & Sanitation**: $117.2 million
- **Nutrition**: $184.0 million
- **Education**: $57.4 million
- **Medical supplies**: $106.0 million
- **Cold Chain Equipment**: $77.8 million

$3.480 billion of supplies + services for 150 countries and areas

$1.556 billion in procurement on behalf of 107 self-financing governments and partners

$2.379 billion supplies

$1.101 billion services

78% of UNICEF procurement is in collaboration with other UN agencies and partners
Key modality for market communication with public

**Market notes & Manufacturer specific pricing**

71 market notes published during 2014-16 covering 31 essential commodities/groups

Aims
- Inform demand (e.g. from COs, partners)
- Provide market signals (to suppliers, developers)

Content
- Product standards and specifications
- Market trends (procurement, pricing, products)
- Market deficiencies to be addressed

Manufacturers specific prices by product posted for vaccines, RUTF, LLIN, devices
UNICEF guiding procurement principles (1 of 2)

- Fairness, integrity and transparency through competition
  (clear & appropriate regulations/rules applied to all suppliers, fair process, equal treatment of suppliers, transparent system)

- Economy and effectiveness
  (meet requirement in terms of quantity, quality, timeliness at the right place. Economy=minimize cost, Effectiveness=meet end-user interest)

- Best value for money
  (Consider the optimum combination of factors in meeting the end user needs; BVM does not mean lowest cost but best ROI)

- Promotion of objectives of UNICEF
  (fulfilling the mandate, goals and objectives)

Each UN organization has a different mandate, but all UN organizations share the same procurement principles.
UN Supplier Code of Conduct

All UN and UNICEF registered suppliers sign on to the UN Code of Conduct.

- Based on the UN charter, the principles of the Global Compact and ILO standards;
  - The UN expects that these principles apply to suppliers and their employees, parent, subsidiary or affiliate entities, and subcontractors; that they are seen as minimum standards that suppliers strive to meet and exceed them.

- The code addresses:
  - **Labour conditions**: Freedom of Association, no force or compulsory, no child labour, discrimination, standards for working conditions.
  - **Human Rights**: No Harassment, Harsh or Inhumane Treatment, no manufacture or sale of mines.
  - **Environment**: Compliance with regulations, manage chemical and hazardous materials; waste and air emissions, Minimize Waste, Maximize Recycling.
  - **Ethical conduct**: No corruption, conflict of interest declaration, no gift and hospitality, post employment restrictions.
Presentation Outline

About UNICEF Supply Division

Overview of UNICEF LLINs Procurement

2019-2021 LLINs Procurement Strategy, Objectives and Tender Outcomes

2019 LLINs Procurement

UNICEF Suppliers Performance Evaluation
UNICEF’s procurement up to Q3 2019 reached 32 million LLINs for 26 countries and is expected to reach 45 million by the end of 2019 according to the available forecast.
UNICEF’s procurement up to Q3 2019 reached 32 million LLINs for 26 countries and is expected to reach 45 million by end of 2019 according to the available forecast.
Clear decrease in the weighted average prices for all LLINs procured irrespective of the size, colour or denier.

In the last five years we have witnessed a higher demand for commonly manufactured products, which also results in lower weighted average price. Joint industry meeting and joint forecast presentation to industry have also contributed to this achievement.
UNICEF LLINs Forecast Accuracy 2010-2020

Overview of UNICEF procurement of LLINs, – UNICEF | for every child
Presentation Outline

About UNICEF Supply Division

Health Technology Centre

Overview of UNICEF LLINs Procurement

LLINs 2019-20 Procurement Strategy, Objectives and Tender Outcomes

2019 LLINs Procurement

UNICEF Suppliers Performance Evaluation
UNICEF LLINs Procurement Strategy objectives for 2019-2021

- **AFFORDABILITY**: Secure access to affordably priced LLINs in situations of increasing and uncertain demand.
- **AVAILABILITY**: Ensure reliable, uninterruptable supply of LLINs to countries.
- **QUALITY**: Secure access to quality LLINs.
- **SUSTAINABILITY**: Improve LLINs deliveries by engaging Industry to address programmatic and supply challenges and reduce environmental sustainability risk associated with LLINs shipments and packaging.
- **DELIVERY**: Continue to reduce the overall cost of LLINs supplied to programs through the continued application of supply chain cost considerations to UNICEF’s LLIN procurement.
- **INNOVATION**: Secure access to newly innovative LLINs products.
- **secure access and availability of affordable LLINs of assured quality by maintaining a healthy and stable global market.**
2014-2020 Procurement Approach for the LLINs Procurement

- **2014-2015:** LTAs
  - 9 LTAs (40 million LLINs)

- **2015 UNICEF RFP:**
  - 6 LTAs (25 million LLINs)

- **2015-2018 Procurement Approach**
  - 6 LTAs (25 million LLINs)

- **2018 Extended LTAs (End 2018):**
  - 6 LTAs (25 million LLINs)

- **2019 New RFP:**
  - 10 LTAs (70 million LLINs)

- **2019-2021 Procurement approach, Tender and Timeline – UNICEF | for every child**
Updates

• 2018 LLINs Suppliers Meeting was held in Supply Division on 27th August, 2018
• UNICEF Request for Proposal was issued on 27th Sept, 2018
• Industry Webinar was held on 5th October 2018
• Tender closed on 18 October 2018
• Contract awards 18 December 2018
• LTAs commenced on 1st January 2019
Key Changes / highlights in UNICEF 2019-2021 Tender

• The adaption of the WHO PQ as a mandatory criterion instead of WHOPES phase 2 evaluation status > to ensure individual products are supported by existing specification and evaluation reports

• 2 years Validity of proposals (allocations of quantities were done for 2 years) - possible extension for additional 12 months

• The tender included price adjustment mechanism (optional) >> as a result of the consultation with industry)

• Change in standard sizes : Rectangular (L)190x(W)180x(H)150cm, Rectangular (L)180x(W)160x(H)150cm ,Rectangular (L)190x(W)180x(H)180cm, Colors: White, Blue, Green

• The tender included an option to Include an offer for any LLIN product currently in the WHO PQ pipeline >>Conditional awards for products currently in the WHO PQ pipeline
Sustainability Focus in UNICEF 2019-2021 Tender

• Maintain using the expanded tender evaluation criteria to consider supply chain elements, i.e. optimized container loading, which would impact on not only on freight and container costs but also on carbon footprints associated with freight (economic and environmental pillar) >>container loading capacity and landed cost as evaluation criteria in the tender document

• Eco-friendly packaging: e.g. bio/Oxo degradable bag are considered as UNICEF standard primary packaging with an option of Bulk packaging (without individual bags)

• Explore opportunities for local procurement in the countries where WHO PQed LLINs are being produced or finalized (economic and social pillar)

• As the WHO PQ process does not consider issues around sustainability and sustainable procurement, UNICEF SD are likely to still conduct site visit to determine suppliers Social Responsibility and Environmental impact
Progress towards the Procurement strategy objectives

1: Ensure reliable, uninterruptable supply of LLINs to countries;
- The new tender allowed access to all PQ LLINs with updated commercial information prices, production capacities, container stuffing.
- 10 LTAs with more than 12 different production facilities (FCA points) were established for more than 70 million LLINs
- The awarded suppliers have a total annual production capacity of more than 300 million LLINs with 170 millions offered to UNICEF
- Stock levels will be monitored during the implementation of the LTAs >>few suppliers offering a free-of-charge stockpiling solution to UNICEF

2: Secure access to affordably priced LLINs in situations of increasing and uncertain demand;
- Overall WAP was reduced by 5%
- LTAs are valid for 2 years including Price adjustment mechanism
- All forecasted countries will have access to supply as per the requirement

3: Secure access to quality LLINs;
- The new tender allowed the adaption of the WHO PQ as a mandatory criterion instead of WHOPES phase 2 evaluation status, to ensure individual products are supported by existing specification and evaluation reports
- The tender linked the validity of any subsequent LTAs/award to the validity of the product PQ status
- The PQ will include inspection of manufacturing sites and assessment of relevant information
- PDI -Inspection guidelines under review
- PDIs Will be monitored during the implementation of the LTAs
4: Secure access to newly innovative LLINs products;

- PBO LLIN item was added to UNICEF supply catalogue- (4 new PBO nets options)

5: Continue to reduce the overall cost of LLINs supplied to programs through the continued application of supply chain cost considerations to UNICEF’s LLIN procurement;

- Landed cost analysis was part of the evaluation of offers and factored in the allocation of quantities to the recommended suppliers
- Bidders were requested to provide their stuffing capacity for 40ft and 20ft container and that was the basis of calculation of the landed cost
- Landed cost analysis will continue to be implemented during the LTAs period 2019-2020

6: Improve LLINs deliveries by engaging Industry to address programmatic and supply challenges and reduce environmental sustainability risk associated with LLINs shipments and packaging;

- Stuffing capacity provided by suppliers was improved compared to the previous tender cycle, however, actual savings will be monitored throughout the LTA
- Landed cost calculation was included as explicit tender / quantity allocation criteria
- Biodegradable bags offered as standard and included in tender adjudication and landed cost calculation
- Awards included manufactures with local facilities in Africa
Supplier percentage of LLIN awards 2010 – 2020

2019-2021 Procurement approach, Tender and Timeline – UNICEF | for every child
The price range between the lowest and the highest unit price is less compared to the last 5 cycles of LTAs.

The estimated WAP for the 2019/2020 LTA Period for the standard size (190X180x150) white will be USD 1.85.

The estimated WAP is also 5% less than that estimated after UNICEF's last tender awards for 2016/2017 which was USD 1.94.
Increase in polyester nets stuffing capacity and slight improvement in polyethylene stuffing capacity
# UNICEF LLINs LTAs utilizations 2014-2020

![Bar chart showing LLINs LTAs utilizations 2014-2020](chart.png)

<table>
<thead>
<tr>
<th>Year</th>
<th>Target</th>
<th>Utilized</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014-2015</td>
<td>37,340,000.00</td>
<td>27,925,784.00</td>
</tr>
<tr>
<td>2016</td>
<td>41,800,000.00</td>
<td>41,414,218.00</td>
</tr>
<tr>
<td>2017</td>
<td>26,946,000.00</td>
<td>20,325,746.00</td>
</tr>
<tr>
<td>2018</td>
<td>28,000,000.00</td>
<td>13,000,000.00</td>
</tr>
<tr>
<td>2019</td>
<td>45,000,000.00</td>
<td>32,000,000.00</td>
</tr>
<tr>
<td>2020 (Forecast)</td>
<td>25,000,000.00</td>
<td></td>
</tr>
</tbody>
</table>
The procurement of conical nets has been reduced due to its higher price than the other standard sizes and the longer lead times for manufacturing.

Continued trend of preference for polyester vs polyethylene nets, especially during mass campaigns.
The procurement of conical nets has been reduced due to its higher price than the other standard sizes and the longer lead times for manufacturing.

Continued trend of preference for polyester vs polyethylene nets, especially during mass campaigns.

Overview of UNICEF procurement of LLINs, – UNICEF | for every child
UNICEF Procurement of PBO nets

- 8000 PBO nets were procured in 2016 and in 2018
- We have procured more than 700K PBO nets in 2019 to 3 countries from 2 suppliers
- Additional 1.8 M LLINs are on our pipeline (for 2 countries)
Presentation Outline

About UNICEF Supply Division

Overview of UNICEF LLINs Procurement

LLINs 2019-20 Procurement Strategy, Objectives and Tender Outcomes

2019 LLINs Procurement

UNICEF Suppliers Performance Evaluation
PO Quantity by Receiving Country and FCA Port

COTE D'IVOIRE
Sudan Campaign
- 9.6M LLINs
- 239 containers
- 18 shipments from 2 FCA ports
- 1 delivery point (12 Districts)
- All 239 containers shipped and received at port of arrival. Loaded and shipped from 2 locations within less than 4 months.

Burundi Campaign
- 6.3M LLINs
- 162 containers
- 13 shipments from 4 FCA ports
- 3 delivery points (20 districts)
- 10 container received at port of arrival, 152 still en route to port of arrival. All 152 containers loaded and shipped from 4 locations within 3.5 months.

Chad Campaign
- 8.2M LLINs
- 205 containers
- 18 shipments from 4 FCA ports
- 3 delivery points (13 districts)
- 129 containers en route to port of arrival, 76 containers still to be loaded. All 205 containers scheduled to be loaded and shipped from four locations within less than 2 months.
Challenges

Emergency Orders
- Fast response on emergency requirements
- Availability for smaller quantities
- In-country registration requirements

Campaigns
- Availability of large quantities at time of PO placement
- Proper markings on shipment and documents for easy identification
- In-country registration requirements

Transportation
- Availability of larger amounts of containers
- Close co-ordination of loading to avoid delays
- Congestion at port of arrival
Presentation Outline

About UNICEF Supply Division

Overview of UNICEF LLINs Procurement

LLINs 2019-20 Procurement Strategy, Objectives and Tender Outcomes

2019 LLINs Procurement

UNICEF Suppliers Performance Evaluation
UNICEF Suppliers performance evaluation

PO Delivery date
The date when the Freight forwarder receives the goods at port with the full set of documents as per the PO INCOTERMS.

Goods readiness date
The date when the supplier will make the goods and related documents available including PDI and ready for pick up as per the PO INCOTERMS.

Notification of Goods readiness date
Complete the NGR form of the PO 3 days before the goods are ready, send to FF copy SD.

Notification for PDI/QAC
Send notification to SD - 7 days before the goods readiness date.

Freight forwarders receives the goods & full doc
PO delivery date accepted by the supplier
Evaluating and monitoring supplier performance against their contractual obligations

KPI12 – % Timeliness of Supplier Deliveries (PO item schedule lines) Jan-June 2019

- Evaluating and monitoring supplier performance against their contractual obligations
- KPIs per supplier are closely monitored by SD
- UNICEF will check with the LTA holder(s) the availability for a given LLINs quantity prior to issuing any Purchase Orders – which should be aligned with the production capacity / Lead times mentioned in the LTA
Thank you
PMI LLIN Sourcing and Procurement Update

September 26, 2019
PMI’s current goal is to help countries reach and maintain universal coverage of long-lasting ITNs for all individuals living in malaria endemic areas, with a specific target that at least 90% of households with a pregnant woman and/or children under five years of age own at least one ITN.
Changes to Market Landscape and Procurement Processes Result in Shifting Market Share and Increased Market Health

Total Volume of LLIN Orders by Fiscal Year

<table>
<thead>
<tr>
<th>Supplier 1</th>
<th>Supplier 2</th>
<th>Supplier 3</th>
<th>Supplier 4</th>
<th>Supplier 5</th>
<th>Supplier 6</th>
<th>Supplier 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>4%</td>
<td>10%</td>
<td>16%</td>
<td>34%</td>
<td>3%</td>
<td>12%</td>
<td>21%</td>
</tr>
<tr>
<td>0%</td>
<td>30%</td>
<td>47%</td>
<td>1%</td>
<td>21%</td>
<td>21%</td>
<td></td>
</tr>
</tbody>
</table>

2018

2019

President’s Malaria Initiative
Fighting Malaria and Saving Lives
LLIN Standardization

• Rationalization of LLINs sized offered (8 specifications):
  — Rectangular, Polyester, 190x180x150, white
  — Rectangular, Polyester, 190x180x170, white
  — Rectangular, Polyester, 180x160x170, white
  — Rectangular, Polyester, 180x160x150, white
  — Rectangular, Polyethylene, 190x180x170, white
  — Rectangular, Polyethylene, 190x180x150, white
  — Rectangular, Polyethylene, 180x160x170, white
  — Rectangular, Polyethylene, 180x160x150, white

• Eliminated redundant sizes that add complexity
  — E.g. 190x180x170 vs. 180x190x170 (L x W x H)

• Ceased the procurement of hooks and strings packaged with LLINs

• Limited artwork to a single, standard PMI packaging logo

• Maintain 100 denier minimum standard for polyester nets
Four essential dimensions evaluated to assess “healthy market,” specific output metrics tailored to individual markets

<table>
<thead>
<tr>
<th>Key questions and output metrics</th>
<th>Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Global capacity</strong></td>
<td><strong>Standard nets:</strong> More than sufficient global capacity, however not all eligible per PMI standards. <strong>New nets:</strong> Information about country demand and potential for new manufactures to enter depends on efficacy studies required to qualify suppliers.</td>
</tr>
</tbody>
</table>
| Is there sufficient supply to meet demand? | - Supply and demand gap  
- Existence of demand forecast  
- Forecast accuracy  
- Lead times, stock out rate |
| **Affordability & funding**      | **Standard nets:** Opportunity to reduce COGS and bring down overall costs  
**New nets:** Lack of demand visibility and unknown adoption timelines inhibit forecast accuracy. Minimum volume guarantee and/or other subsidies could bring ITNs into a more affordable range. |
| Is pricing affordable?           | - Price relative to substitute and peer markets  
- % Supply base utilized  
- Funding and demand gap  
- Projected funding |
| **Supply risk**                  | **Standard nets:** Evaluation criteria is weighted using a best value approach with emphasis is placed on minimizing supplier concentration. **New nets:** Shifting demand should produce incentive for suppliers to innovate new effective nets to combat resistance. It is important that global market deals with first mover suppliers do not eliminate incentive for new entrants. |
| Is there sustainable, secure supply of these products? | - Number and diversity of suppliers  
- Margins / price relative to cost  
- Product registration coverage  
- Scalability of capacity |
| **Product quality & appropriateness** | **Standard nets:** Potential to become ineffective due to increasing pyrethroid resistance. **New nets:** Additional data required to ensure appropriateness based on efficacy compared to alternatives. Emphasis will be placed on providing the opportunity and incentive for suppliers to pursue production of new nets. |
| Are there quality products that meet user needs? | - Effective products with regulatory approvals  
- Quality of products  
- Appropriateness based on target customer needs  
- Incentives for innovating improved products |
Strategic Procurement Objectives

- Promote **competition** to the maximum extent practical
  - Competition among IDIQ holders for share of total PSM procurement

- Deliver critical health commodities **on time**
  - Supplier performance monitoring, staggered GADs, potential for make to stock

- Operate an **efficient** and effective supply chain
  - Reduced procurement lead time through reduced tendering burden, potential for improved planning resulting in cost savings across supply chain

- Retain **flexibility** in order to be agile and responsive to changing needs and priorities
  - Option to compete orders and re-solicit pricing or proposals

- Pursue near and long-term **best value** in accordance with program objectives
  - Best value determination per evaluation criteria
“Best Value” Determined across multiple Criteria in Support of Near and Long-Term Programmatic, Market, and Supply chain objectives

<table>
<thead>
<tr>
<th>Total Landed Cost</th>
<th>Supplier Performance</th>
<th>Registration Coverage</th>
<th>Product Portfolio</th>
<th>Quality</th>
<th>Market Health Considerations</th>
</tr>
</thead>
</table>
| Suppliers that offer competitive pricing minimize cost burden on recipient countries, enabling increased coverage and available funding for other life saving medical supplies. Additional benefit is derived when supplier(s) are able to make goods available closer to the destination, thereby minimizing the burden of the freight cost. | Inclusive of:  
- On-time delivery (GAD adherence)  
- Avoidance of incidents impacting on-time in full delivery  
- Quality control (nets that are in-line with product specifications) | Many countries impose varying levels of registration requirements. Suppliers that invest in broad registration coverage provide greater value by increasing the ability to import the required product(s) | Certain products may have infrequent or uncertain demand. But Suppliers’ investment in developing and maintaining such products within their portfolios increase the project’s ability to respond when the needs arise. | Strict minimum eligibility standards maintained for all nets procured for recipient countries to ensure that a manufacturer can produce product(s) capable of achieving the desired result for the end user. | PMI aims to limit supply risk while ensuring sufficient capacity exists to meet current and future global demand, as well as drive value through competitive market dynamics by procuring from multiple suppliers |

PMI
President’s Malaria Initiative
Fighting Malaria and Saving Lives
Allocation and Order Assignment Processes are Designed to Reward Suppliers Offering Best Value Without Compromising Project Goals

### Process

**Awarded suppliers are evaluated against each other to determine allocation (market share) targets**
- Evaluation objective is to score suppliers in terms of best value to PMI and thereby determine appropriate market share.
- Depending on demand/breadth of supply base, not all suppliers that were awarded LTAs will receive an allocation.

**Following receipt of firm orders from recipient countries, each order is assigned either individually or in bulk, depending on factors such as urgency, funding, etc.**
- Individual order assignments take into consideration a variety of constraining factors, such as country registration and shelf life requirements, production capacity, market share targets, etc.

### Communication

- **Supplier-specific volume forecasts are provided at the product level for the coming fiscal year.**
- **Suppliers are informed of strengths/weaknesses of offering that primarily influenced its allocation.**

- **Suppliers are informed of assigned orders, subject to confirmation of ability to meet GAD(s), registration status, etc.**
  - Period between order assignment and GAD can range from 1-18 months.
  - If confirmed, PO will be issued upon availability of funding.

---

*PMI President’s Malaria Initiative
Fighting Malaria and Saving Lives*
More than 100 million nets PMI procured in FY2018 through Q2 of FY2019: 93% were single pyrethroid.

Given expected demand increase for the PBO nets, additional PBO net suppliers being evaluated by PMI for QA approval and addition to the PSM list of eligible suppliers.
PMI Decision Tree for Selection of ITNs Based on Insecticide Resistance Monitoring Data

1. Use pyrethroid ITN with highest mortality/lowest resistance intensity; and
2. Potentially add IRS\(^+\); or
3. Use PBO ITN
Demand for PBO and Dual AI Net is Projected to Increase Substantially\(^1\) in FY20

\(^1\) For presentation purposes only. Not a confirmed commitment of PMI
Thank You
Long-lasting Insecticidal Nets Supplier & Partner Consultative Meeting

Global Fund LLIN Strategy

26 September 2019
Singapore
Global Fund Team
Disclaimer

The Global Fund Procurement Strategy on LLINs is currently under development and will be finalized in the forthcoming weeks.

This document presents the Global Fund’s current intention which is subject to change.

The data and information herein are provided for illustrative purposes and derived from a limited and preliminary analysis of the Global Fund.

The present document shall not be considered as the Global Fund’s representation or commitment of any kind.
Agenda

- The Global Fund: Introduction, Market Shaping Strategy & Strategic Sourcing
- LLIN Market Observations
- LLIN Procurement Strategy: 2020 - 2021
- Global Fund 2019 LLIN Tender Approach and Timelines
Key contacts on the LLIN Procurement Strategy

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Integrity Due Diligence Specialist
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.

The Global Fund is calling on the world to step up the fight against HIV, TB and malaria. In October 2019, President Macron will host the Global Fund’s Sixth Replenishment Conference in Lyon. This Replenishment seeks to raise at least US$14 billion to help save 16 million lives, avert 234 million infections and help the world get back on track to end these diseases. Of the at least US$14 billion, the Global Fund is calling on the private sector to mobilize at least US$1 billion to step up the fight.

The USD 4 billion per year spent by the Global Fund is critical in the fight against:

**HIV/AIDS**
- Global Fund accounts for 8% of global HIV funding and 20% of international financing

**Tuberculosis**
- Global Fund accounts for 10% of global TB funding and 69% of international financing

**Malaria**
- Global Fund accounts for 40% of global Malaria funding and 57% of international financing

**WHERE THE PROGRAMS ARE**
- **Eastern Europe and Central Asia:** 4%
- **Asia and the Pacific:** 19%
- **North Africa and the Middle East:** 8%
- **Latin America and the Caribbean:** 4%
- **Sub-Saharan Africa:** 65%

**Breakdown of Global Fund Portfolio by Type of Implementer (Active Grants)**

<table>
<thead>
<tr>
<th>Type of Implementer</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government</td>
<td>53%</td>
</tr>
<tr>
<td>Nongovernmental organizations, community-based organizations &amp; academic</td>
<td>24%</td>
</tr>
<tr>
<td>Multilateral organizations</td>
<td>16%</td>
</tr>
<tr>
<td>Faith-based organizations</td>
<td>4%</td>
</tr>
<tr>
<td>Private sector</td>
<td>2%</td>
</tr>
</tbody>
</table>

**Funding sources** (2016 data for HIV/Malaria, 2018 for TB): OECD DAC-CRS; UNAIDS FactSheet World AIDS Day 2017, UNAIDS; Global Tuberculosis Report 2018, WHO; World Malaria Report 2017, WHO. **GF share of international funding:** Global Fund 2017 Results Report. Figures are global and are not solely for countries where Global Fund resources are disbursed.
The Global Fund’s Market Shaping Strategy extends beyond its direct spend to help ensure healthy markets and value for money.
44% of the Pooled Procurement Mechanism (PPM) health product spend is for malaria-related products and 27% is spent on LLINs.

**Acronyms:**
- ARVs: Antiretroviral medicines
- ANTMs: Antimalarial medicines
- IRS: Indoor Residual Spraying
- LLINs: Long-Lasting Insecticidal Nets
- RDTs: Rapid Diagnostic Tests
- VL/EID: Viral Load/Early infant diagnosis
- Other: General lab equipment & supplies, essential medicines, condoms, and other diagnostics

**Total PPM spend on all health products: USD 913m**

- **ARVs, $383m, 42%**
- **LLINs, $247m, 27%**
- **ANTMs, $92m, 10%**
- **malaria RDTs, $37m, 4%**
- **HIV RDTs, $39m, 4%**
- **IRS, 23, 3%**
- **Other, $72m, 8%**

**Malaria product volumes**

**Prevention**
- LLINs
- 108m nets

**Diagnostics**
- Malaria RDTs
- 120m tests

**Treatment**
- IRS
- 1m liters
- ANTM medicines
- 110m treatments

**Data source:** 2018 Procurement Services Agent data, includes product cost, freight, logistics and other costs.
The Pooled Procurement Mechanism is the largest of the Global Fund’s procurement channels, representing just over half of the Global Fund health product spend, depending on the category.

<table>
<thead>
<tr>
<th>Funding</th>
<th>Procurement Services Agent</th>
<th>Recipient Country</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Fund</td>
<td>PSA</td>
<td>PR</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>National Procurement Mechanisms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Procurement Agents; GDF, UNICEF, UNDP</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

~55% of Global Fund health product spend
Partners, donors and other stakeholders expect the Global Fund to deliver a responsible procurement approach that supports the Sustainable Development Goals.

In 2015, countries gathered and committed to end poverty, protect the planet and ensure prosperity for all. Increasingly, partners and donors are keen to see how they can leverage their investments to deliver on shared objectives of the SDGs.
Responsible procurement features in the Global Fund’s market shaping work

### DIMENSIONS

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Economy</td>
</tr>
<tr>
<td>▪ Provide additional economic benefits to in-country community</td>
</tr>
<tr>
<td>▪ Empower community by sharing knowledge</td>
</tr>
<tr>
<td>Ecology</td>
</tr>
<tr>
<td>▪ Mitigate effect on environment along the end-to-end supply chain</td>
</tr>
<tr>
<td>▪ Use knowledge and skills to contribute to a constant rise in eco-efficiency</td>
</tr>
<tr>
<td>Society</td>
</tr>
<tr>
<td>▪ Promote fundamental human rights, e.g.,</td>
</tr>
<tr>
<td>— Advocate for decent labor conditions</td>
</tr>
<tr>
<td>— Promote children rights</td>
</tr>
<tr>
<td>▪ Promote workers’ health and safety</td>
</tr>
<tr>
<td>Business practices</td>
</tr>
<tr>
<td>▪ Promote best business practices among suppliers and other buyers</td>
</tr>
</tbody>
</table>

**Principles for building holistic standards**

- Build on existing guidelines
- Provide practical guidance
- Include phased approach
- Focus on procurement
- Align with GF objectives

The Global Fund addresses each dimension of the responsible procurement framework through a case-by-case approach

<table>
<thead>
<tr>
<th>Dimensions addressed</th>
<th>Case examples</th>
<th>Issues</th>
<th>Solutions</th>
</tr>
</thead>
</table>
| LLIN                 |▪ LLIN manufacturing countries have weak regulators’ focus on textile  
▪ Plastics and insecticides used for LLINs present high chemical risks for environment  
▪ Historical reputational issues related to corruption, environment and disposal |▪ GF mandated social and environmental assessment by a 3rd party for 7 LLIN production sites in 3 countries. GF provided action plans for each assessed site to implement environmental and labor regulations  
▪ GF encouraged Principal Recipients to order bulk packaging of LLINs for campaigns, reducing plastic waste by an estimated 940 tons in 2018 | |
| Artemisinin          |▪ Agricultural artemisinin prices are volatile due to:  
▪ Overproduction capacity because of low technical barrier to entry  
▪ Lack of harmonized quality standards  
▪ Agricultural artemisinin price volatility causes supply interruptions to ACT suppliers |▪ GF mitigated price volatility and environmental risks by visiting agricultural artemisinin producers and reviewing Environmental, Health and Safety (EHS) practices:  
▪ GF conducted agricultural artemisinin manufacturer qualification through 3rd party  
▪ GF incentivized best practices by manufacturers through 3 year volume allocations | |
| ARV                  |▪ Prior reliance on spot tenders contributed to an important reliance on delivery by air  
▪ Poor performing suppliers lobby when losing volumes  
▪ Outer/secondary paper cartons traditionally included for multi-month ARV packs increase transportation weight and waste |▪ GF implements performance-based allocations to suppliers, with more than 80% of ARV volume shipped by sea  
▪ GF encouraged Principal Recipients to switch to carton-less packaging of multi-month ARVs, reducing freight volume, costs, paper and waste |
We have been working with other buyers and partners to deliver market shaping value. We have been working with other buyers and partners to deliver market shaping value. We have been working with other buyers and partners to deliver market shaping value. We have been working with other buyers and partners to deliver market shaping value.

**Leveraging impact**

1. **Gain visibility** on procurement practice and planning
2. **Coordinate** tender cycle and timeline
3. **Align principles** of performance-based procurement approach
4. **Join/pool** Procurement practice

**Indicative % of the global LLIN market**

- **GF (PPM)**: 50%
- **GF (non-PPM)**: 9%
- **PMI**: 25%
- **UNICEF**: 13%
- **Others**: 3%
- **Total**: 100%

Moving forward, we are seeking for strengthening collaboration to further leverage volume and deliver Market Shaping Value collectively.

Data source: UNICEF, PMI websites; GF data, Net mapping project
Agenda

- The Global Fund: Introduction, Market Shaping Strategy & Strategic Sourcing

**LLIN Market Observations**

- LLIN Procurement Strategy: 2020 - 2021

- Global Fund 2019 LLIN Tender Approach and Timelines
Global Fund’s balanced supply system, embedded in its strategic sourcing work, has brought impressive results and helped shape the LLIN market

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| **A** | Provided **100m nets** per year **at the lowest possible affordable and sustainable price**  
Achieved an average **price reduction of 5%** over the past 3 years |
| **B** | Supplied **90% of LLINs timely and in full** in 2016-2019 |
| **C** | Created **a resilient supplier base** with production **in 6 different countries**  
Promoted **responsible and sustainable business practices:**  
**50% of nets** were supplied without bags resulting in **940 tons** of plastic waste avoided |
| **D** | Met the **Global Fund’s and national quality** requirements  
**Mitigated implementation risks** including supply continuity risks |
| **E** | Published **reference prices**  
**Provided access** to PPM long term agreements to **other partners**  
Incentivized a **broad national registration footprint** |
In simplified terms the LLIN production process involves 3 steps

1. **Active ingredients (AI) - Insecticide**
   - Most manufacturers **source AIs** rather than produce them in-house

2. **Formulation - key supplier know-how**
   - Coat the **polyester** (PES) fibers with insecticide;
     or
   - Incorporate insecticide into the **High Density polyethylene** (HDPE) fibers

3. **Manufacturing nets – Textile**
   - In-house process, outsourced or a mix of both
There is a wide variety of **production arrangements** across the end-to-end production process creating concerns about **supply continuity, transparency, consistent quality management, anti-competitive practices** and **business commitment**

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>• Manufactured in-house vs. sourced from a 3rd party</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Masterbatch/formulation</td>
<td></td>
</tr>
<tr>
<td>3 Incorporating masterbatch into fiber/coating fabrics</td>
<td>a) <strong>Manufactured in-house</strong> (ownership of fixed assets, technology-know-how, and production)</td>
</tr>
<tr>
<td>4 Knitting (making fabrics)</td>
<td>b) <strong>Co-owned and/or outsourced manufacturing</strong>: sub-contracted with some investment (e.g. in machinery)</td>
</tr>
<tr>
<td>5 Cutting, stitching, sewing and packing</td>
<td>c) <strong>Entirely outsourced manufacturing</strong> process – sub-contracted</td>
</tr>
</tbody>
</table>

*We observe overlapping arrangements – same contractor engages with a number of suppliers with different type of arrangements*
Additional market observations

- **LLIN volumes have increased significantly** over the past 15 years.
- **Barriers to market entry are low** leading to an increasing number of suppliers of pyrethroid nets. **Excess capacity** has resulted in **fierce competition**.
- **LLIN regulatory process is still relatively new**, **LLIN quality concerns** are not fully addressed.
- **WHO PBO guidelines** are **challenging to implement** and product specifications vary significantly. In addition **demand for PBO nets is increasing**, while only **few PBO nets are prequalified**.
- **Prequalified dual AI nets** are not eligible for mainstream Global Fund procurement.
- **Peaks in LLIN demand** are a continuing challenge.
- In response to the Global Fund’s previous procurement strategy, **production capacity in Africa** has increased over the past 3-6 years.
- **Inappropriate business practices** (disingenuous lobbying, predatory pricing, unreported non-compliance with MFN clause, anti-competitive behavior)

---

Data Source: Net Mapping Project as of Q2 2019 (trend line)

2019 volumes are a projection, H1 2019 volumes are multiplied by 2
Agenda

▪ The Global Fund: Introduction, Market Shaping Strategy & Strategic Sourcing

▪ LLIN Market Observations

▪ LLIN Procurement Strategy: 2020 - 2021

▪ Global Fund 2019 LLIN Approach and Timelines
Product scope and indicative product volumes* LLIN Bridging Procurement Strategy (2020 – 2021)

**Tender Product Scope**

<table>
<thead>
<tr>
<th>Product set</th>
<th>Indicative volume split across product sets</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pyrethroid nets</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /> 75 - 85%</td>
</tr>
<tr>
<td>2. PBO nets</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /> 15 - 25%</td>
</tr>
<tr>
<td></td>
<td><img src="https://via.placeholder.com/150" alt="Image" /> There is interest in increasing the demand for PBO nets</td>
</tr>
<tr>
<td>3. Dual AI nets</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /> Demand is currently managed through catalytic funding</td>
</tr>
<tr>
<td></td>
<td><img src="https://via.placeholder.com/150" alt="Image" /> Explore synergies for mainstream procurement</td>
</tr>
</tbody>
</table>

**LLIN Demand projection (millions)**

- 2020: 75 - 90 (PBO nets 15 - 20%)
- 2021: 85 - 100 (PBO nets 15 - 25%)

*Projected volumes for PPM countries
Strategic objectives

Leverage volume and joint effort to maximize market shaping value delivery with an emphasis on 5 dimensions, and provide data to support future regulatory and policy implementation.

1. **Quality** assured products
2. Greater **affordability** and improved **delivery** performance
3. **Supply continuity** and long-term **supply base sustainability**
4. Foster **innovation**, facilitate adoption and accelerate scale-up of new products
5. Promote **responsible procurement**
A Bridging Strategy
Evolving the LLIN Procurement Strategy in a shifting product and policy landscape

**4 Key Features of the Strategy**

1. Recognize supplier investment to ensure supply continuity, and prompt sustainable business practices

2. Joint effort to support WHO PQ process implementation with a focus on QMS strengthening

3. Gradually address Environment, Health and Safety (EHS) concerns through the Responsible Procurement Framework

4. Strategic projects: future ambitions on plastic recycling, reuse, and environmentally friendly materials
Provide a volume commitment to recognize supplier investment to ensure supply continuity and to prompt sustainable business practices

<table>
<thead>
<tr>
<th>Degree of ownership/investment in these 5 steps</th>
<th>Commitment as % of supplier allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. AI production</td>
<td>15%</td>
</tr>
<tr>
<td>2. Masterbatch/formulation technology</td>
<td>15%</td>
</tr>
<tr>
<td>3. Incorporating/coating</td>
<td>15%</td>
</tr>
<tr>
<td>4. Knitting (making fabrics)</td>
<td>15%</td>
</tr>
<tr>
<td>5. Cutting, stitching, sewing and packing</td>
<td>15%</td>
</tr>
<tr>
<td><strong>Total:</strong></td>
<td><strong>75%</strong></td>
</tr>
</tbody>
</table>

During contract implementation:

- Suppliers are required to provide evidence against Global Fund requirements as illustrated above. Subject to evaluation and review, the Global Fund may commit **up to 75% of annual supplier allocation** according to the level of the ownership.

Suppliers will need to provide evidence for each claimed level of ownership/investment.
Joint effort to support WHO PQ process implementation with a focus on QMS strengthening

<table>
<thead>
<tr>
<th>Strengthen Quality Management System (QMS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pyrethroid Net</td>
</tr>
<tr>
<td>🟢 Strengthen QMS building on PQ process, including but not limited to:</td>
</tr>
<tr>
<td>➢ Sample retention for Global Fund orders</td>
</tr>
<tr>
<td>➢ Comprehensive documentation and traceability</td>
</tr>
</tbody>
</table>

Provide data on procured PBO nets

During contract implementation:
- Failure to demonstrate QMS strengthening may lead to significant reduction of annual allocation and commitment
- A non-conforming product may lead to termination of the allocation and commitment or other commercial implications, as appropriate
Gradually address Environment, Health and Safety (EHS) concerns through the Responsible Procurement Framework

Enhancing Environment, Health and Safety (EHS)

<table>
<thead>
<tr>
<th>Pyrethroid Net</th>
<th>PBO Net</th>
<th>Dual AI Net</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

We will require a gradual improvement of the Environmental Management Systems (EMS) and Occupational Health & Safety Management Systems (OH&S) from corporate standards to national standards and towards international standards.

During contract implementation:

- Failure to demonstrate progress of EMS and OH&S strengthening may lead to significant reduction of annual allocation and commitment.
Strategic projects to address concerns around LLIN plastic in terms of recycling, reuse and introducing environmentally friendly materials

The projects will be assessed along the following dimensions:

<table>
<thead>
<tr>
<th>Effort/Investment</th>
<th>Is there additional significant effort or investment required to execute the project?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility</td>
<td>Are these strategic projects feasible to be implemented within the course of the implementation period? Are there any dependencies on other stakeholders (Global Fund, WHO, countries, etc.)?</td>
</tr>
<tr>
<td>Ability</td>
<td>Is the supplier able to implement these strategic projects within the course of the implementation period?</td>
</tr>
<tr>
<td>Potential value/impact</td>
<td>What is the total potential value/impact that can be yielded by these projects within the course of the implementation period?</td>
</tr>
</tbody>
</table>

During contract implementation, remaining cautious about the cost implications and country ability to implement

- Up to 10% of annual Global Fund volume may be reserved for strategic project implementation
Agenda

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## Principles of our approach

### Tender Eligibility

- **Global Fund Quality Assurance requirements for LLINs**
  
The tender also incorporates legal requirements and an Integrity and Due Diligence Process to **assess threats and risks to values, objectives and reputation of the Global Fund.**

### Performance Principles

1. **Volume allocations and commitments** will be managed throughout contract implementation via a **performance-based approach**
2. **On Time In Full (OTIF)** delivery against promised lead times is also part of the performance-based approach
3. **Sustainable supply and good business practices** will be key focus areas during contract implementation
4. The Global Fund values **responsible procurement** and will factor this during implementation
Tender Evaluation Structure

**Commercial (55%)**
- Base Price and Total Landed Cost

**Technical (45%)**
1. Product Coverage
2. Innovation
3. Country Registration Coverage
4. OTIF delivery performance
5. Production footprint in sub-Saharan Africa

- The full scope of evaluation criteria will be reapplied at annual performance reviews for subsequent allocation periods.
- There will be a process to consider new entrants and/or new products that become eligible for procurement after tender closure (subject to review).
- Volume discount will not be part of tender evaluation, but will be considered in implementation.

Evaluation ratios commercial (55%) vs. technical (45%) have remained the same as in the previous tender in 2015.
During contract implementation our focus will be on generating value through supplier relationship management.

Tender Evaluation
- Collect information
- Validate information
- Evaluation
- Award

Contract Implementation
- Performance-based allocation
- Risk assessment
- Regular reporting
- Supplier site visits
- Ongoing dialogue

Performance will affect future tender evaluations.
Key measures – Most Favored Nation (MFN) Clause

- MFN clause in contract supports our efforts to ensure best value for Global Fund
- We will proactively manage the principles and implementation of the MFN clause
- Suppliers are required to notify the Global Fund of all their tender price submissions within 7 days
- These notifications will not automatically trigger the MFN clause. Rather the Global Fund will review the submissions and accompanying justifications and decide accordingly.
2019 LLIN tender approach and timelines (indicative)

**Phase I:**
Supplier and Partner Consultation (Sep – Oct 2019)
1. LLIN Partner & Supplier Consultative Meeting in Singapore
2. Invite feedback from suppliers and partners to finalize the LLIN strategy

**Phase II:**
RFP issued and submissions received (Mid-Oct – Mid-Nov 2019)
- Global Fund issues RFP
  - RFP on Sourcing Platform, including both technical and commercial sections
  - Two rounds of questions/answers prior to the tender submission deadline
- Technical and commercial submissions due

**Phase III:**
Evaluation (Mid-Nov – Early Dec 2019)
1. Initial evaluation of bid submissions
2. Finalization of technical and commercial evaluation
3. Internal approvals
4. Award

**Phase IV:**
Contracting and implementation Plan (Dec 2019 – Jan 2020)
- Contract finalization and signing
- 2020-2021 Contract implementation
  - Supplier performance measurement
  - Risk assessment
  - Regular reporting
  - Supplier onsite visits
  - Ongoing dialogue
Request for Proposal Preparation

1. RFP Documentation will be available through the Sourcing Platform and posted on the Global Fund website for downloading

2. There may be a number of documents:
   - Main RFP document
   - Schedules
   - Certificate of Conformance
   - Confidentiality agreement
   - Integrity Due Diligence questionnaire
   - Draft Framework Agreement

3. To submit a complete response to RFP, bidders will need to comply with all requirements as specified

4. We will request a significant amount of information. We will clearly advise which information will be evaluated and which info is for implementation purposes only
Objectives for individual supplier meetings on 27 September

✓ Ensure the procurement strategy and approach are understood

✓ Listen to your views, and advise on any gaps and/or concerns

✓ We are listening through 4 October 2019 on any further clarifications on the overall strategy
Thank you!