



SUPPLIER SUMMIT

**USAID Global Health
Supply Chain Program
Supplier Summit
February 21-23, 2017**

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USAID Global Health Supply Chain Program

MALARIA PHARMACEUTICALS



USAID
FROM THE AMERICAN PEOPLE



PEPFAR
U.S. President's Emergency Plan for AIDS Relief



USAID
FROM THE AMERICAN PEOPLE



U.S. President's Malaria Initiative

PROGRAM OVERVIEW: PRESIDENT'S MALARIA INITIATIVE GHSC-PSM TASK ORDER 2



U.S. President's Malaria Initiative (PMI) Mission

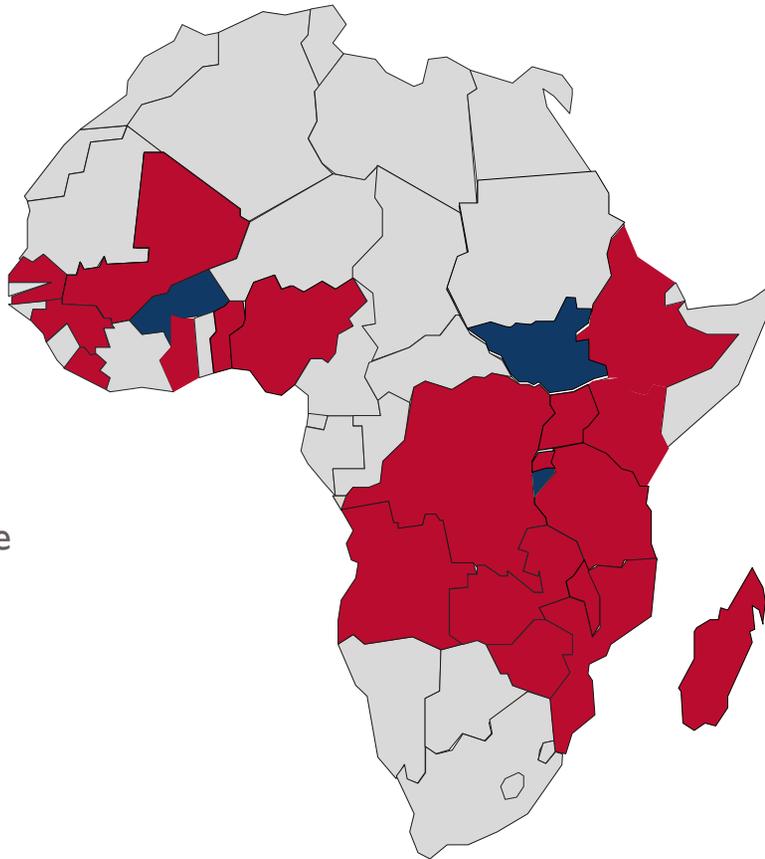
Work with PMI-supported countries and partners to further reduce malaria deaths and substantially decrease malaria morbidity towards the long-term goal of elimination

PMI'S OBJECTIVES

- Objective 1
 - Reduce malaria mortality by one-third from 2015 levels in PMI supported countries, achieving a greater than 80% reduction from PMI's original baseline levels
- Objective 2
 - Reduce malaria morbidity in PMI supported countries by 40% from 2015 levels
- Objective 3
 - Assist at least five PMI supported countries to meet the WHO criteria for national or sub-national pre-elimination

CURRENT PMI FOCUS COUNTRIES

- Angola
- Benin
- DRC
- Ethiopia
- Ghana
- Guinea
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nigeria
- Rwanda
- Senegal
- Tanzania
- Uganda
- Zambia
- Zimbabwe



- Burkina Faso*
- Burundi*
- South Sudan*

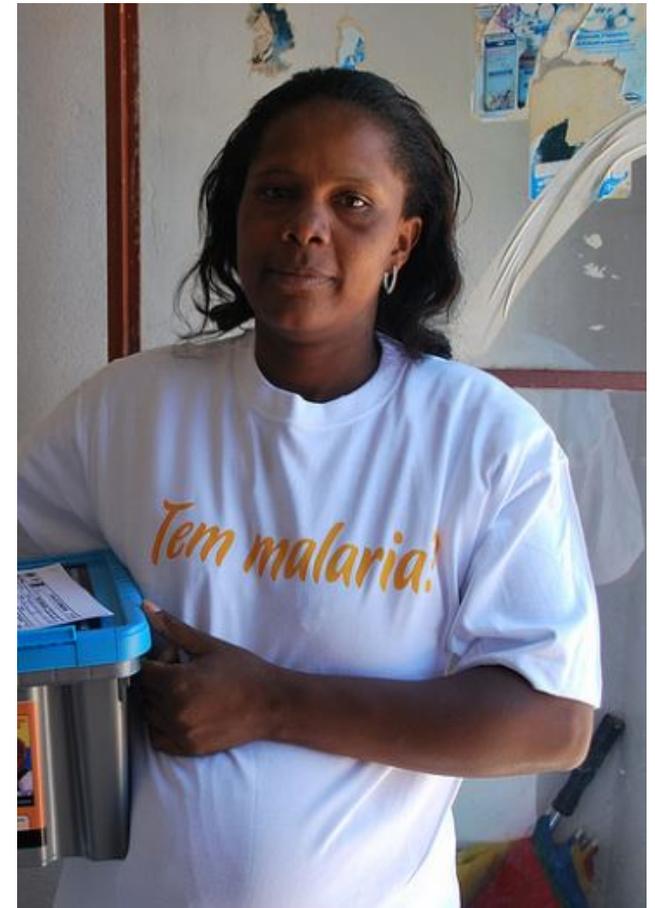
- Burma
- Cambodia
- Thailand/Regional



*non-presence countries

MALARIA OPERATIONAL PLANS (MOPS)

- One-year costed implementation plans for PMI Focus Countries
- Country led!
- MOPs review current status of malaria control and prevention policies and interventions; also identifies challenges and unmet needs to achieve NMCP national goals, and provides a description of planned PMI-funded activities
- Each MOP has been endorsed by the U.S. Global Malaria Coordinator and reflects collaborative discussions with the national malaria control programs and partners in country
- Standardized formats – primary focus for external partners are tables 1 & 2
- Available publically on the PMI website
 - <https://www.pmi.gov>
- **Jennifer / Alexis to add bullet on gap analysis?**



MOP TIMELINE

Month	Activity
Feb. – Jun. 2016	FY17 MOP development visits (writing the MOP)
Apr. – Aug. 2016	FY17 MOP HQ review & revision
Oct. 2016	MOP approval after IAG convene (posted online by November)
Mar. – Jun. 2017	FY18 MOP development visit (time to write the MOP again) FY17 MOP reprogramming (revised table 2 posted on-line) -Add/remove activities -Change activities: implementing partner, budget or scope -Program additional funding
May – Jul. 2017	Start placing commodity orders outlined in FY17 MOP
Sep. 2017 +	FY17 funding available
Oct. 2017 – Sep. 2018	Implement activities in FY17 MOP (for orders to arrive in CY 2018)

For more information on how the MOPs are incorporated into supply plans, please attend the breakout session on “Global Forecasting and Supply Planning”

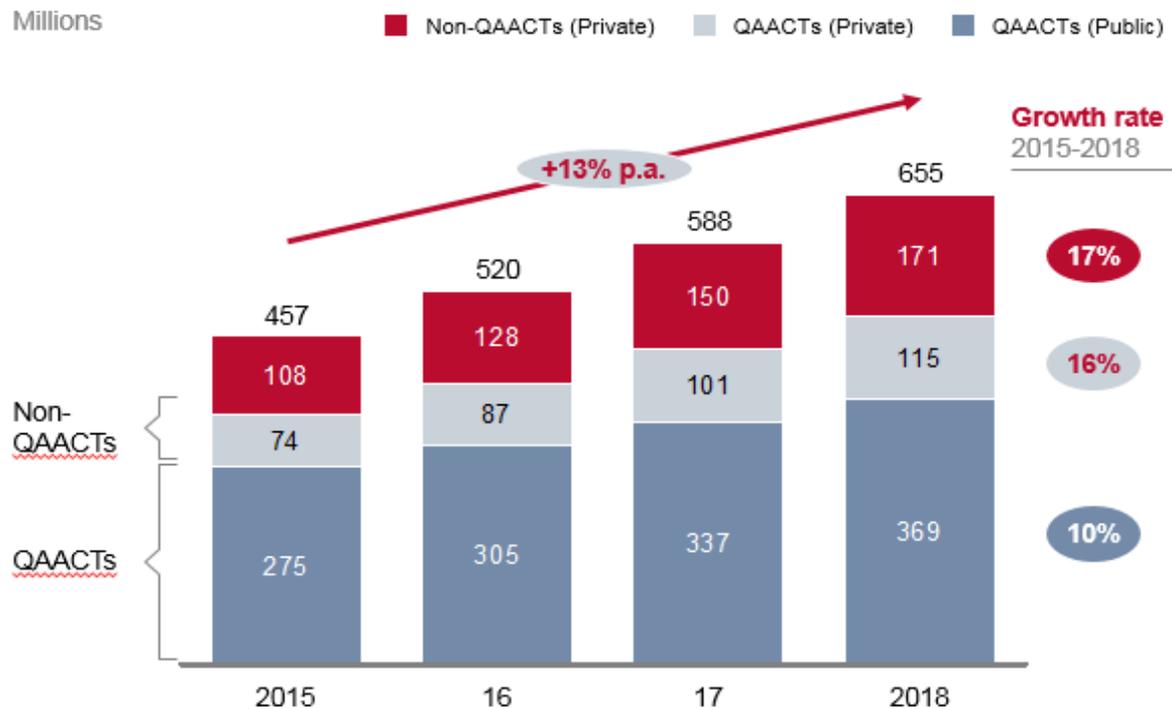
DEMAND FORECASTING

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GLOBAL ACT DEMAND¹ IS GROWING RAPIDLY AT 13% P.A.

Forecasted global ACT demand, 2015-18



- Demand for non-QAACTs is growing faster than QAACT demand, which may be partially due to the transition from other anti-malarials (or not seeking treatment) to ACTs
- Private sector demand for QAACTs and nQAACTs are growing at about the same rapid rate of 16-17% while public sector demand is growing slightly slower but still robust at 10%
- Public demand makes up 75-80% of QAACT demand

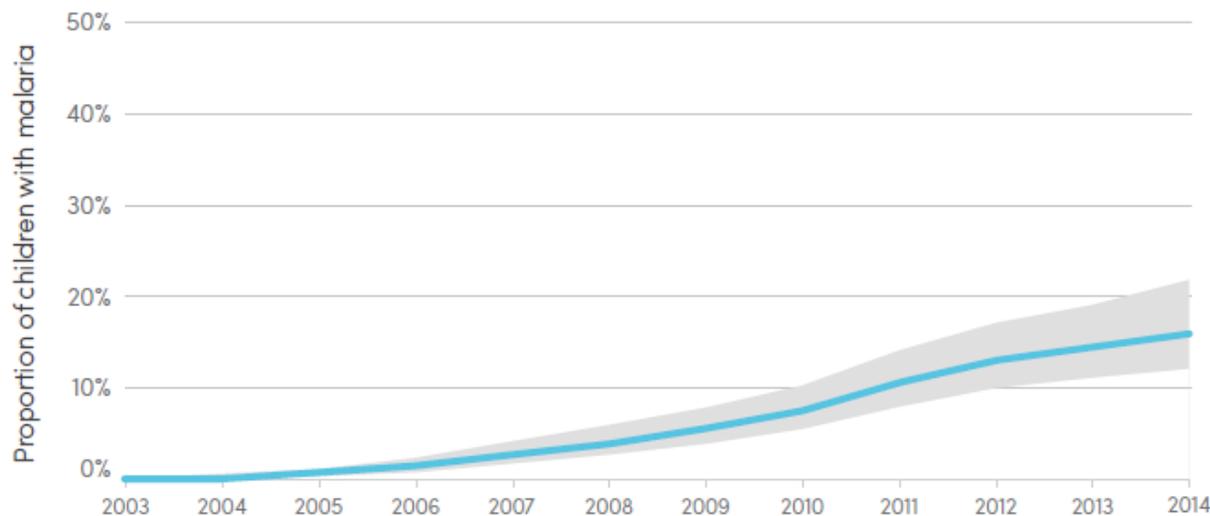
¹ Defined as the number of customers seeking ACT treatment

SOURCE: UNITAID Global Malaria Diagnostic and Artemisinin Treatment Commodities Demand Forecast, 2015-2018

NOTE: Non-QAACT (Public) <1; not shown. For private sector in both QAACTs and non-QAACTs, it's slightly more informal market than formal

INCREASE IN DEMAND IS PARTIALLY ATTRIBUTED TO INCREASED COVERAGE RATES

Proportion of children under 5 with confirmed *P. falciparum* malaria who received ACTs



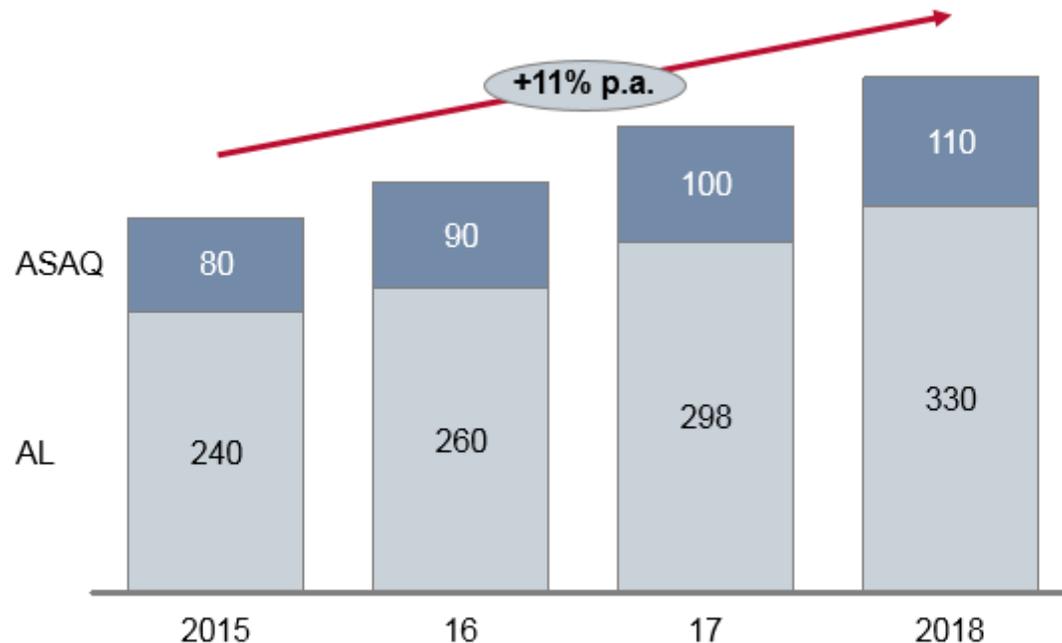
- Coverage rates of ACTs have **increased dramatically in the last 10 years to 15-20%**, but we still have **a lot of opportunity** to increase coverage
- **Adult coverage rates likely trend similar to children for confirmed cases**; however, a **lower fraction of adult cases receive a definitive diagnosis**

SOURCE: World Malaria Report 2015, referencing the malaria treatment model from the Center for Applied Malaria Research and Evaluation (Tulane), the Global Health Group (UCSF), and the Malaria Atlas Project (Oxford).

GLOBAL AL AND AS/AQ DEMAND ARE PROJECTED TO GROW AT 11% PER YEAR

QAACT global demand, AL and AS/AQ, 2015-2018

Millions



- Both the QAACT AL and AS/AQ demand market are growing at 11% per year
- AL demand makes up ~75% of the market (besides AS/AQ others are <5% together)
- As SMC ramped up (using SP/AQ), we would expect to reduce countries' demand for AS/AQ due to resistance issues

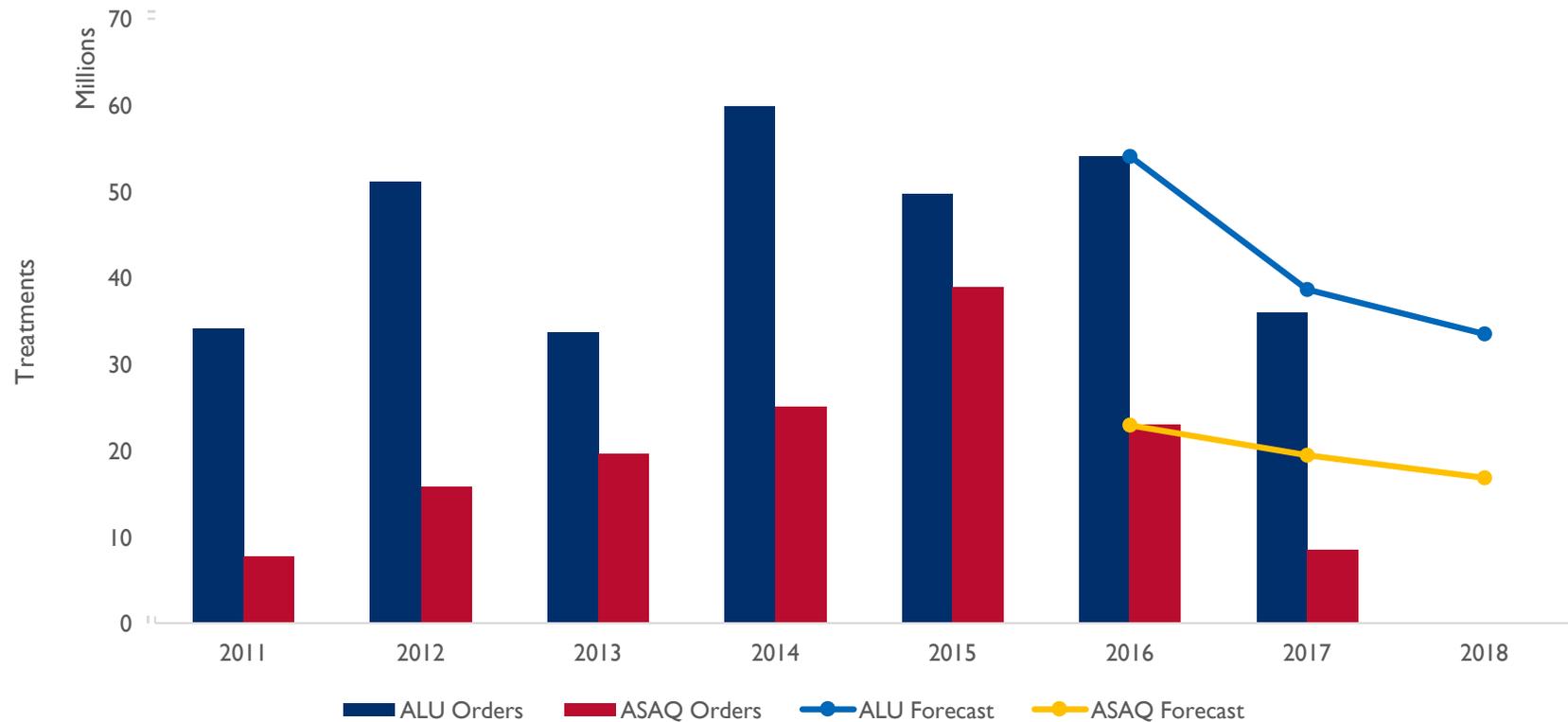
SOURCE: UNITAID Global Malaria Diagnostic and Artemisinin Treatment Commodities Demand Forecast, 2015-2018

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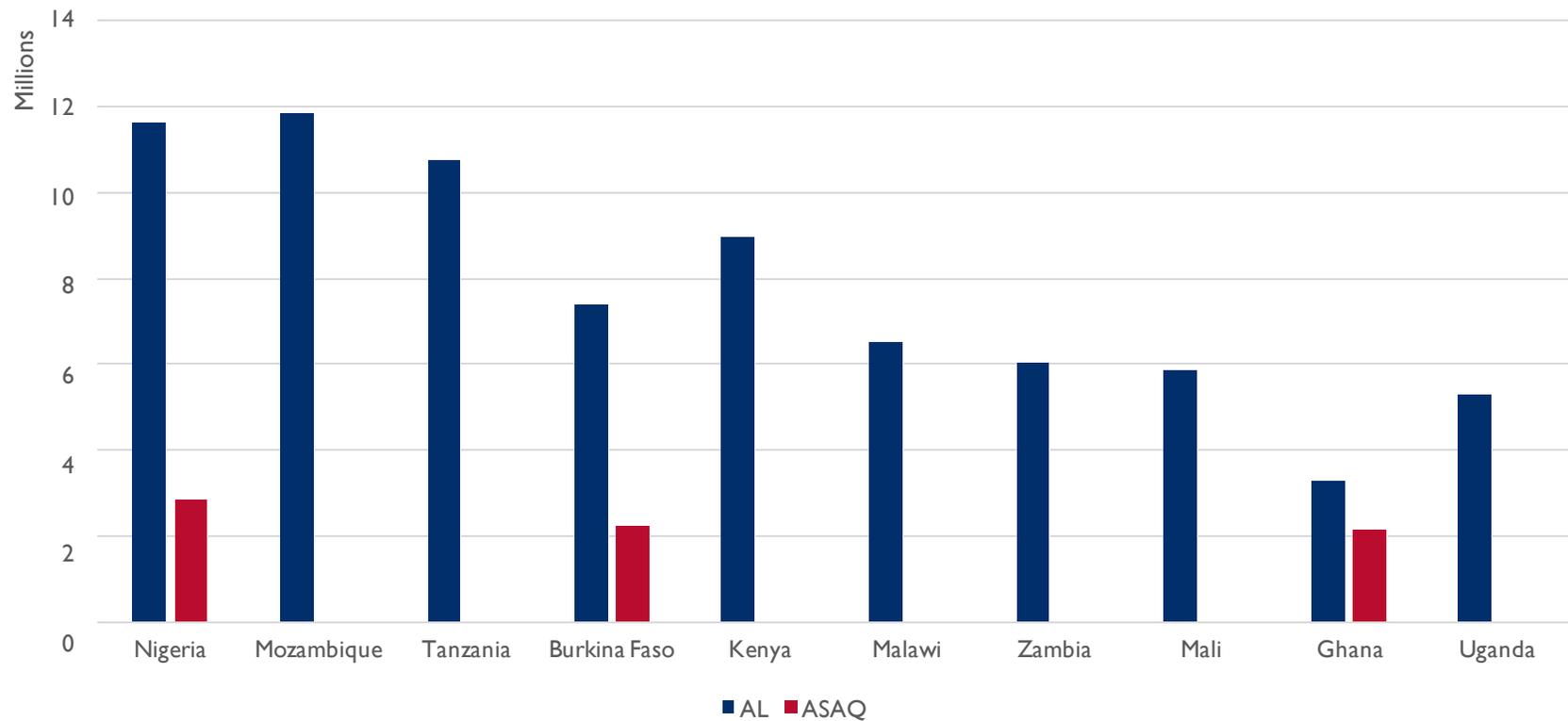
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GHSC-PSM ACT FORECAST REFLECTS QUANTITIES BASED ON PROJECTED FUNDING



10-15% of ALU demand is fulfilled from warehouse stock

10 COUNTRIES PROJECTED TO REPRESENT >75% OF GHSC-PSM DEMAND



DRC historically top destination, funding currently dictates lower quantities

GHSC-PSM MALARIA PHARMACEUTICAL SOURCING

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PROCUREMENT STRATEGY

Current state

- IDIQs (WHO prequalified products)
 - Artemether/Lumefantrine
 - Artesunate/Amodiaquine
- One-offs (Some WHO prequalified products and all non-WHO PQ'd products)
 - Sulfadoxine/pyrimethamine
 - Sulfadoxine/pyrimethamine + Amodiaquine
 - Injectables (Artesunate, Artemether, Quinine)
 - Rectal Artesunate
 - Dihydroartemisinin/Piperaquine (DHA-PPQ)
 - Essential medicine tablets (chloroquine, primaquine, quinine, malarone)
 - Others as required



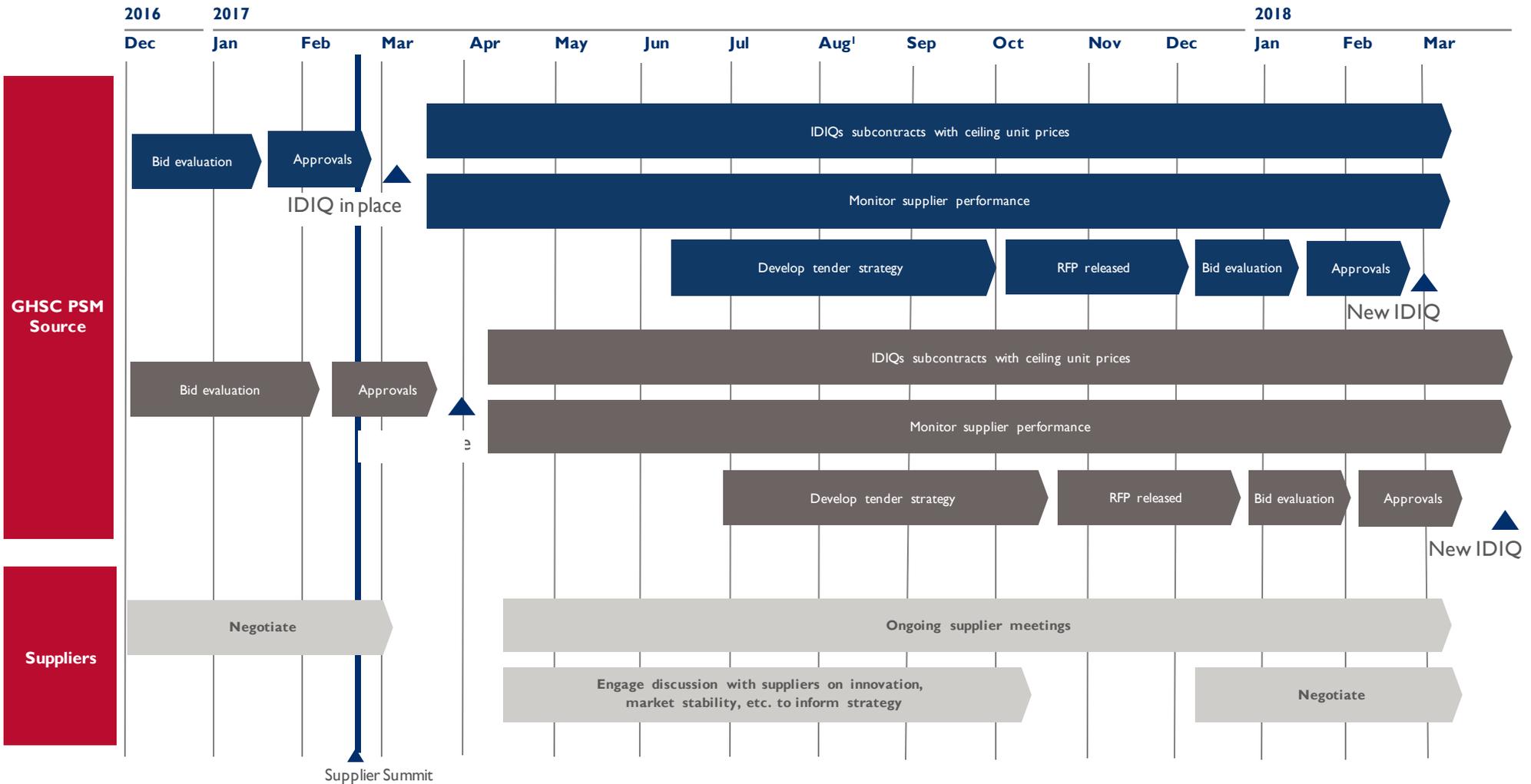
MID-TERM TENDERING APPROACH FOR ALU & ASAQ

	2016	2017	Considerations for 2018
Tendering Mechanism	100% spot	100% Long-term agreements (IDIQs)	100% Long-term agreements (IDIQs); exploring alternatives (e.g. – volume allocations)
Price Structure	Ceiling	Ceiling	<ul style="list-style-type: none"> • Exploring fixed price vs ceiling price • Exploring tie to artemisinin commodity price index
No. of Suppliers (ALU)	7 hard tablets 2 dispersible		2015-2016
No. of Suppliers (ASAQ)	2 hard tablets	3-5 hard tablets	3-5 hard tablets

MALARIA PHARMACEUTICALS SOURCING CALENDAR



For informational purposes only; subject to change



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GHSC-PSM EVALUATION CRITERIA

EVALUATION CRITERIA (AQSCIR-P)

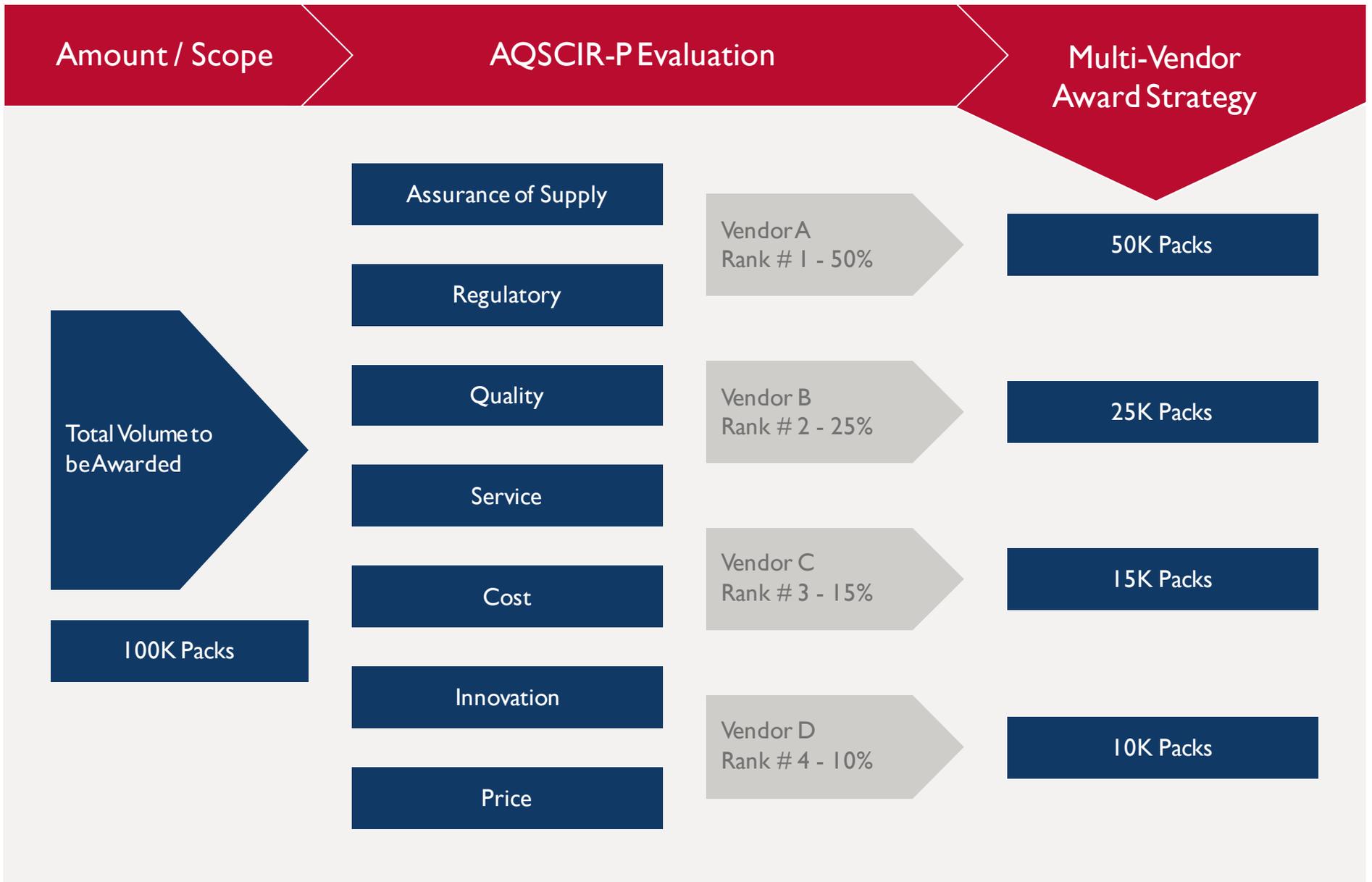
EXAMPLES

Assurance of Supply	<ul style="list-style-type: none">• Production capacity• Quantity in stock (when required)• Past performance
Regulatory	<ul style="list-style-type: none">• Administrative requirements• Registration in country
Quality	<ul style="list-style-type: none">• QA requirements (USFDA, WHO, GHSC-QA)• Shelf life• Stability studies / climatic zone standards
Service	<ul style="list-style-type: none">• Lead time (stock, fresh production)• Customer service• Product Identification
Cost	<ul style="list-style-type: none">• Specific / Unique label language• Unique Distribution requirements
Innovation	<ul style="list-style-type: none">• Serialization• Packaging optimization• New /improved products
Price	<ul style="list-style-type: none">• FCA Unit price

Criteria and %
Weights are
tailored to the
Commodity
and/or Product
and Specific
Sourcing
Strategy

BEST VALUE AWARD STRATEGY TO ACHIEVE DESIRED MARKET OUTCOME

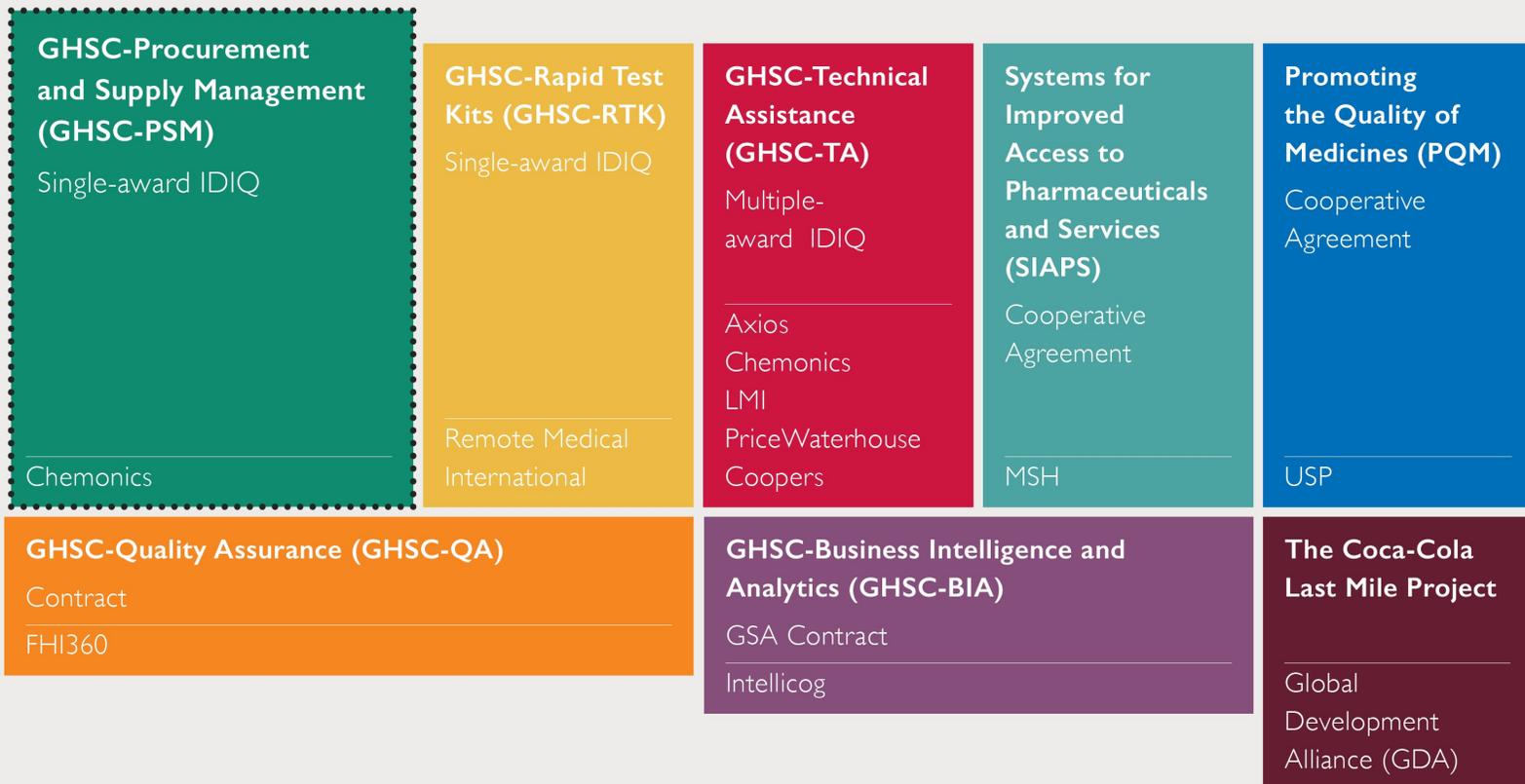
GHSC-PSM APPROACH FOR MULTI-VENDORS AWARD



MALARIA QA OVERVIEW

GENERATION NEXT

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM



FOUR KEY STEPS IN THE QA PROCESS

1. Supplier communicates goods are ready

- Provide packing list, invoice and CoAs to GHSC-PSM QA
- Sampling/inspection location and point of contact

2. GHSC-PSM executes sampling and inspection

- SGS representative will inspect and sample goods and ship to testing lab

3. Qualified labs test samples

- India (SGS-Chennai & Stabicon) or Europe (SGS-Belgium & Proxy)

4. GHSC-PSM QA makes final determination

GHSC-PSM QA INTERACTION IN PROCUREMENT PROCESS

Establish list of preferred suppliers

- Clear eligibility criteria
- Recommendation based on evaluation of quality proposal

Tender to list of preferred suppliers or one off procurements

- Use of standard QA requirements and terms and conditions

Execute QC requirements

- SRA/PQ/wholesaler category determination specific

FREQUENCY OF INSPECTION, SAMPLING AND TESTING

Commodity	Category	QC Requirement
Antimalarial medicines	SRA ¹	<ul style="list-style-type: none"> Each batch: <ul style="list-style-type: none"> - Document Review Subset of batches: <ul style="list-style-type: none"> - Annual testing ²
	WHO PQ	<ul style="list-style-type: none"> Each batch: <ul style="list-style-type: none"> - Pre-shipment or Concurrent ³
	USAID pre-approved wholesaler	<ul style="list-style-type: none"> Each batch: <ul style="list-style-type: none"> - Pre-shipment

1: As per ADS 312: <https://www.usaid.gov/sites/default/files/documents/1864/ADS312AdditionalHelpDocument.pdf>

2: Sampling and testing guided by ISO 2859-1;S2

3: After reaching compliant results for 10% of the annual production capacity all further batches → concurrent

STRATEGIC PRIORITIES

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AL SUPPLY OBJECTIVES & PRIORITIES

Dimensions

Ideal 12-18 month outlook

Global capacity	<ul style="list-style-type: none"> ▪ Maintain at least 5 WHO prequalified suppliers for adult formulation ▪ Increase WHO prequalified dispersible suppliers to 3+
Affordability & funding	<ul style="list-style-type: none"> ▪ Achieve more sustainable average unit price ▪ Maximize volume-based opportunities through improved forecasting, stockpile strategy, etc. ▪ Consider awards taking into account total cost of ownership vs. total benefit
Supply risk	<ul style="list-style-type: none"> ▪ All suppliers sourcing quality-assured vegetal Artemisinin ▪ Increase Semi-synthetic Artemisinin suppliers in market from 1 to 2+ ▪ Encourage suppliers to register in all PMI countries
Product quality & appropriateness	<ul style="list-style-type: none"> ▪ Maintain QA SOPs ▪ Increase QAed dispersible availability to at least 2-3 suppliers ▪ Observe increased 80/480 use

ASAQ / DHA-PPQ SUPPLY OBJECTIVES & PRIORITIES

Dimensions	Ideal 12-18 month outlook: AS/AQ	Ideal 12-18 month outlook: DHA-PPQ
Global capacity	<ul style="list-style-type: none"> Maintain at least 4 WHO prequalified suppliers for adult formulation on the market 	<ul style="list-style-type: none"> Increase WHO prequalified suppliers to 2+
Affordability & funding	<ul style="list-style-type: none"> Achieve more sustainable average unit price 	<ul style="list-style-type: none"> Develop long-term demand forecast and pricing projections
Supply risk	<ul style="list-style-type: none"> All suppliers sourcing quality-assured vegetal Artemisinin Encourage suppliers to register in all PMI countries 	<ul style="list-style-type: none"> All suppliers sourcing quality-assured vegetal Artemisinin Encourage suppliers to register in all PMI countries that may demand DHA-PPQ in next 2 years
Product quality & appropriateness	<ul style="list-style-type: none"> At least 2 suppliers submit WHO advance studies for 3-year shelf life Maintain QA SOPs 	<ul style="list-style-type: none"> Maintain QA SOPs

ARTEMISININ API SUPPLY SECURITY

Background

- **Vegetal Artemisinin API prices have fluctuated widely over the last 2 decades** from \$200-1100/kg, and have 1-2 year planting and production cycles
- Global partners began investing in 2004 in a **semi-synthetic form of artemisinin, which can save time over vegetal API and targets competitive or lower costs**

Current

- **Artemisinin demand appears to be stabilizing** (from very rapid growth in the last decade), and **current prices have remained consistently low for the past 3 years**
- One supplier has **developed an SSA process at scale and at a price premium over vegetal API (with future reductions possible), but FDF suppliers have not expressed interest** as vegetal API is accessible at a lower price
- During years of relative supply security, it **benefits the market to mitigate against future risk**



- **How do we maintain a quality assured sustainable stable API source that is appropriately priced?**
- **How does SSA fit into broader ACT market and innovation pipeline?**
- **How interested are FDF ACT suppliers in SSA? What are the barriers?**

SP & SP/AQ SUPPLY OBJECTIVES & PRIORITIES

Dimensions	Ideal 12-18 month outlook: SP	Ideal 12-18 month outlook: SP/AQ
Global capacity	<ul style="list-style-type: none"> 2+ WHO prequalified suppliers Maintain quality SP API sources Reduce order-to-delivery lead time to 6 months (or less) 	<ul style="list-style-type: none"> 2+ WHO prequalified suppliers Maintain quality SP API sources Reduce order-to-delivery lead time to 6 months (or less)
Affordability & funding	<ul style="list-style-type: none"> Maintain sustainable prices 	<ul style="list-style-type: none"> Ensure sufficient donor coverage to meet demand Achieve more sustainable average unit price
Supply risk	<ul style="list-style-type: none"> Maintain and grow quality supplier base Encourage suppliers to register in all PMI countries Secure timely access to stock (e.g., consider stockpiling or VMI) 	<ul style="list-style-type: none"> Maintain and grow quality supplier base Encourage suppliers to register in all PMI countries Secure timely access to stock (e.g., consider stockpiling or VMI)
Product quality & appropriateness	<ul style="list-style-type: none"> Accelerate scale up through addressing in-country service delivery challenges 	<ul style="list-style-type: none"> Increase dispersible uptake Accelerate scale up through addressing in-country service delivery challenges

SMC AND SP+AQ

What is SMC?

- Seasonal Malaria Chemoprevention
- Children 3 to 59 months in the Sahel sub-region with highly seasonal malaria transmission
- Implement treatment during malaria transmission season, up to 4 one-month cycles
- Has been shown to prevent up to 75% of malaria cases

Challenges

- Scale up/adequate availability
 - 1 WHO prequalified supplier with long lead times
 - PMI is currently procuring for Burkina Faso, Mali and Senegal, Guinea in FY2017 MOP. More countries TBD.
- Timing is critical
- Need to transition away from AS/AQ for resistance
- Donor coordination; global demand

ARTESUNATE SUPPLY OBJECTIVES & PRIORITIES

Dimensions	Ideal 12-18 month outlook: Injectable Artesunate	Ideal 12-18 month outlook: Rectal Artesunate
Global capacity	<ul style="list-style-type: none"> 2+ WHO prequalified suppliers Reduce order-to-delivery lead time to 6 months (or less) 	<ul style="list-style-type: none"> 2+ WHO prequalified suppliers Improve demand forecasting to ensure adequate supply
Affordability & funding	<ul style="list-style-type: none"> Maintain donor funding coverage of demand Maintain sustainable prices 	<ul style="list-style-type: none"> Ensure sufficient donor coverage to meet demand
Supply risk	<ul style="list-style-type: none"> Maintain and grow quality supplier base Encourage suppliers to register in all PMI countries Secure timely access to stock (e.g., consider stockpiling or VMI) 	<ul style="list-style-type: none"> Clarify treatment guidelines on 100mg vs. 50mg vs. 200mg to streamline procurement requests Encourage suppliers to register in all PMI countries
Product quality & appropriateness	<ul style="list-style-type: none"> Improve appropriate treatment through addressing in-country service delivery challenges 	<ul style="list-style-type: none"> Harmonize country and WHO treatment guidelines Accelerate scale up through addressing in-country service delivery challenges

IDENTIFYING SOLUTIONS TO KEY CHALLENGES – NON-ACT PHARMA

Long lead times	In-Country Registration	Regulatory Status
<ul style="list-style-type: none"> • SP • SP+AQ • Artesunate Injectable 	<ul style="list-style-type: none"> • SP <ul style="list-style-type: none"> • various suppliers and pack sizes • competition with local suppliers • Rectal Artesunate <ul style="list-style-type: none"> • 50mg/200mg • 100mg 	<ul style="list-style-type: none"> • SP+AQ <ul style="list-style-type: none"> • 1 PQ'd supplier • Artesunate Inj. <ul style="list-style-type: none"> • 1 PQ'd supplier • Rectal Artesunate <ul style="list-style-type: none"> • 0 PQ'd suppliers • SP <ul style="list-style-type: none"> • 0 PQ'd suppliers

ADOPTION OF GLOBAL STANDARDS FOR IDENTIFICATION AND DATA CAPTURE AND EXCHANGE

- Implement global standards for:
 - Product and location identification
 - Packaging, presentation, and data capture
 - Data exchange of orders, shipment status and delivery notification
- Goal is to achieve:
 - End to end data visibility
 - Supply chain efficiency
 - Supply chain security

For more information, we suggest you attend the following sessions:

- Implementation of GSI Global Standards for Product Identification
- Data Exchange with GHSC

VENDOR MANAGED INVENTORY

- Benefits of VMI
 - Reduction in one-off purchase orders
 - Can replenish based on inventory levels = fewer stockouts and less inventory
 - Reduced product production lead time
 - No transit to 3rd party warehouse
 - No repacking/relabeling
 - Increased product shelf life upon delivery
- Vendor's perspective?





GENERAL FEEDBACK FROM SUPPLIERS: Q+A

- For more information on business practices, please attend “How to Win Business for New Suppliers” or “How to Win Business for Existing Suppliers”

RESOURCES

- PMI general information <https://www.pmi.gov/>
- PMI technical guidance [https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/pmi-technical-guidance-\(march-2016\).pdf?sfvrsn=8](https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/pmi-technical-guidance-(march-2016).pdf?sfvrsn=8)
- Malaria Operational Plans <https://www.pmi.gov/resource-library/mops>
- USAID approved Wholesalers: https://scms.usaid.gov/sites/default/files/documents/1866/pharm_annex.pdf
- WHO prequalified pharmaceuticals <https://extranet.who.int/prequal/content/prequalified-lists/medicines>

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The USAID Global Health Supply Chain-Procurement and Supply Management project provides commodity procurement and logistics services, strengthens supply chain systems, and promotes commodity security. We support USAID programs and Presidential Initiatives in Africa, Asia, Latin America, and the Caribbean, focusing on HIV/AIDS, malaria, and population and reproductive health commodities.

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