



SUPPLIER SUMMIT

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

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USAID Global Health Supply Chain Program



HIV/AIDS PHARMACEUTICALS (ARVS)



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



SESSION OBJECTIVES

- Introduce GHSC-PSM and global supply chain activities relevant to ARVs
- Present sourcing processes and a tentative calendar of sourcing events
- Provide insight into strategic priorities and market levers
- Engage in dialogue and obtain feedback on how we can better collaborate

INTRODUCTION TO GHSC-PSM

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ARV PORTFOLIO

Product Categories Procured

- Adult first- and second-line
- Pediatric first- and second-line

Programmatic Initiatives Supported

- 90-90-90 goals
- Pre-exposure prophylaxis (PrEP)
- Post-exposure prophylaxis (PEP)



COUNTRIES FOR WHICH WE PROCURE HIV COMMODITIES



GLOBAL AND GHSC-PSM ARV FORECASTS

GLOBAL FORECASTS

WHO Antiretroviral Demand Forecasting Meeting, March 28–30, Geneva

- PEPFAR and GHSC-PSM, with other global stakeholders, contribute data to a global forecasting exercise
- Results will be shared at the WHO meeting in March

USAID/PEPFAR FORECASTS

Quantifications

- Demand for ARVs is quantified annually with country inputs
- GHSC-PSM then shares those expectations for ARV purchase volumes in the RFPs for IDIQ contracts

COUNTRY-LEVEL DEMAND FORECASTS ARE CRITICAL

General Country Forecasting Process

- Ministries of Health and other stakeholders at the country level conduct forecasting exercises to determine demand.
- Through a budgeting process the allocations to each funding source are determined.
- USAID operational planning budgeting guidance has been sent to country missions to begin planning for FY2018.

FORECASTING TECHNICAL ASSISTANCE

GHSC-PSM provides technical assistance to countries through our system strengthening work by:

- Establishing roadmaps for institutionalizing forecasting and supply planning (FASP)
- Updating FASP tools
- Creating guidelines and guidance for technical opportunities, such as:
 - Product transition/new product introductions
 - Multi-month dispensing

GHSC-PSM SUPPLY AND DISTRIBUTION MECHANISMS

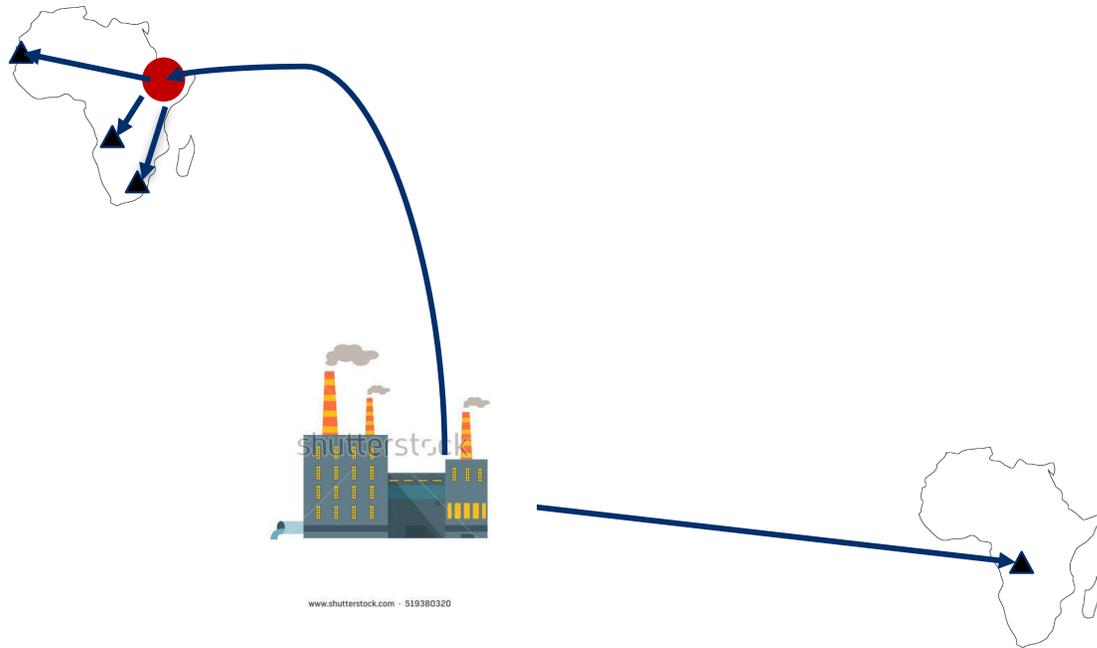
Source to Inventory

Adult Formulations

- ABC+3TC (600/300mg)
- ATV/r (300/100mg)
- AZT+3TC (150/300mg)
- AZT+3TC+NVP (300/150/200mg)
- EFV (600mg)
- LPV/r (200/50mg)
- TDF+3TC (300/300mg)
- TDF+3TC+EFV (300/300/600mg)

Pediatric Formulations

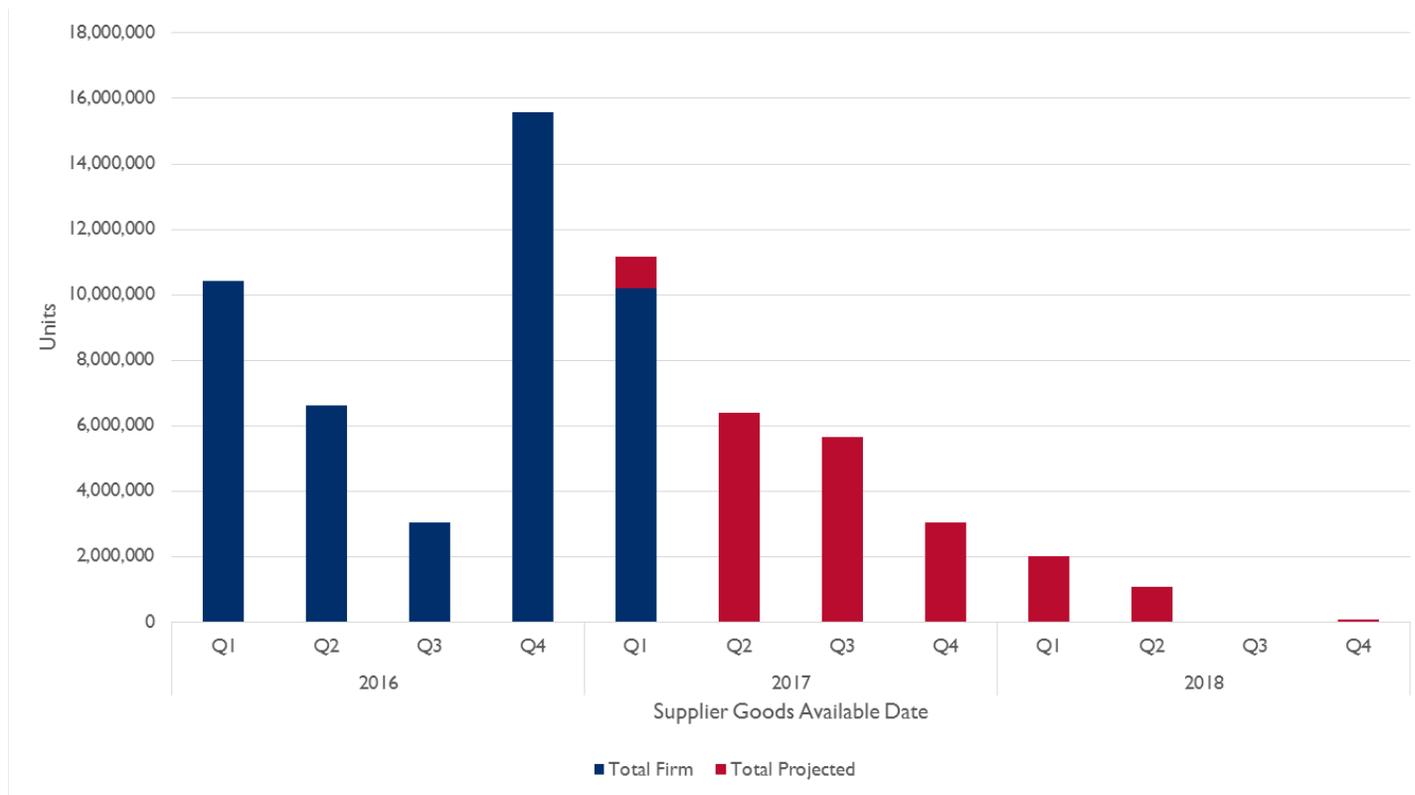
- AZT+3TC+NVP (30/50/60mg, disp)
- ABC+3TC (60/30mg, disp)
- NVP (10mg/ml, oral suspension)
- EFV (200mg, scored tablet)
- AZT+3TC (30/60mg, disp)
- NVP (50mg, disp)
- LPV/r (40/10mg, "Pellet")



Direct Drop

All other ARV formulations

GHSC-PSM PROCUREMENT FORECAST – ADULT FIRST-LINE TRIPLE FDCS



- Total projected quantities are those for which deliveries have been designated to PEPFAR
- Demand is subject to change significantly after completion of FY2018 COPs

GHSC-PSM ARV SOURCING

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SOURCING EVENT PROFILE

Issue an RfX (RFP/RFQ) and Collect Responses in Emptoris

Evaluate Bid Responses

Determine Allocations and Share Results with USAID

Proceed with Awards, Contracts, and Letters of Decline

I

Issue an RFx (RFP/RFQ) and Collect Responses in Emptoris

- The production environment is now available!
- Supplier training is planned for **January 27** and **January 30**
- For more information, please contact Jasmine Jarvis: jjarvis@ghsc-psm.org

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Evaluate Bid Responses

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

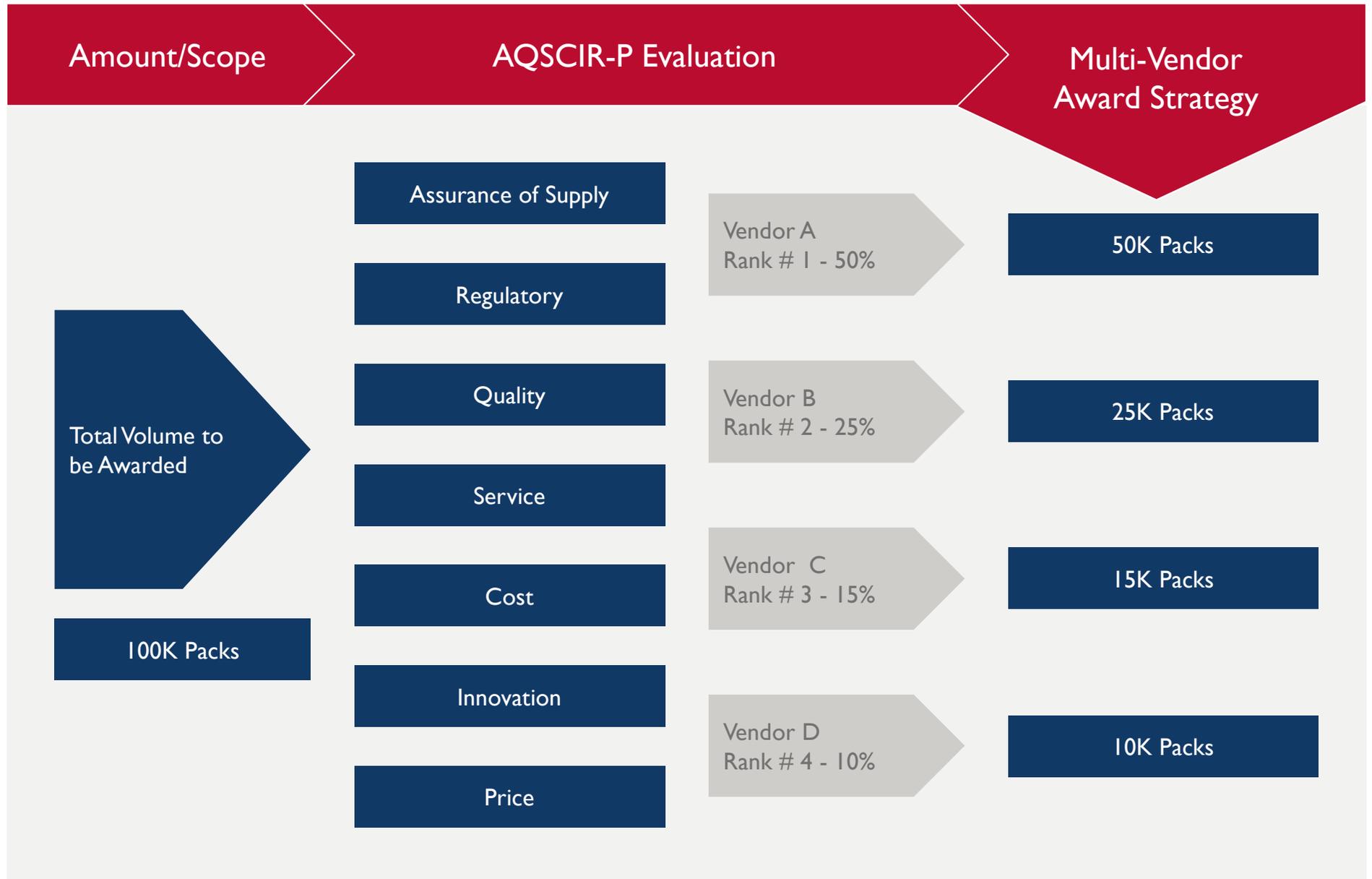
Criteria and percent weights are tailored to the commodity and/or product and specific sourcing strategy

BEST VALUE AWARD STRATEGY TO ACHIEVE DESIRED MARKET OUTCOME

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Determine Allocations and Share Results with USAID

GHSC-PSM APPROACH FOR MULTI-VENDORS AWARD



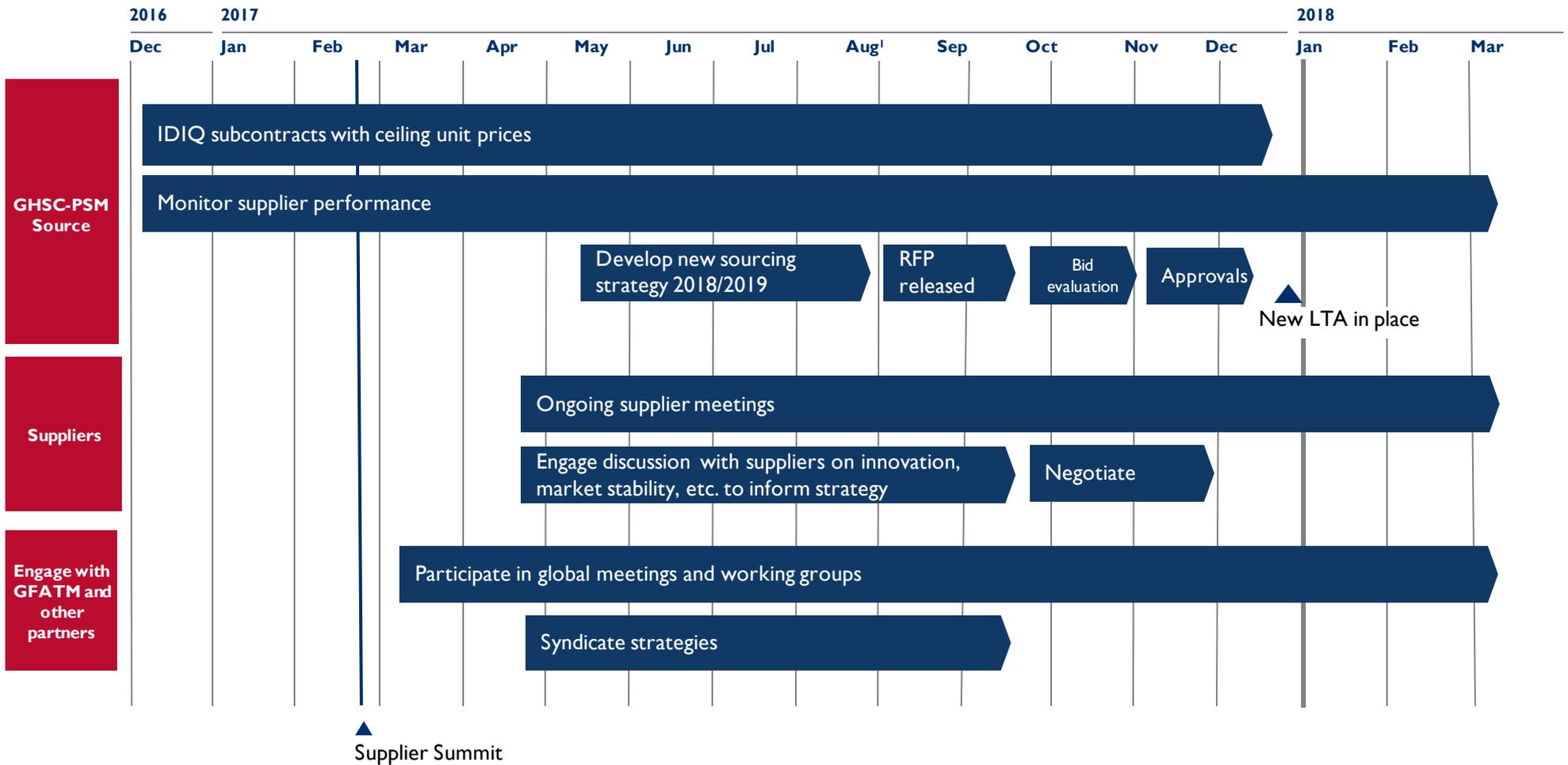
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Proceed with Awards, Contracts, and Letters of Decline

- Regardless of the result, all bidders will receive communication.
- Each letter of decline will contain specific information about why the proposal was not selected.

ARV SOURCING CALENDAR

For informational purposes only; subject to change



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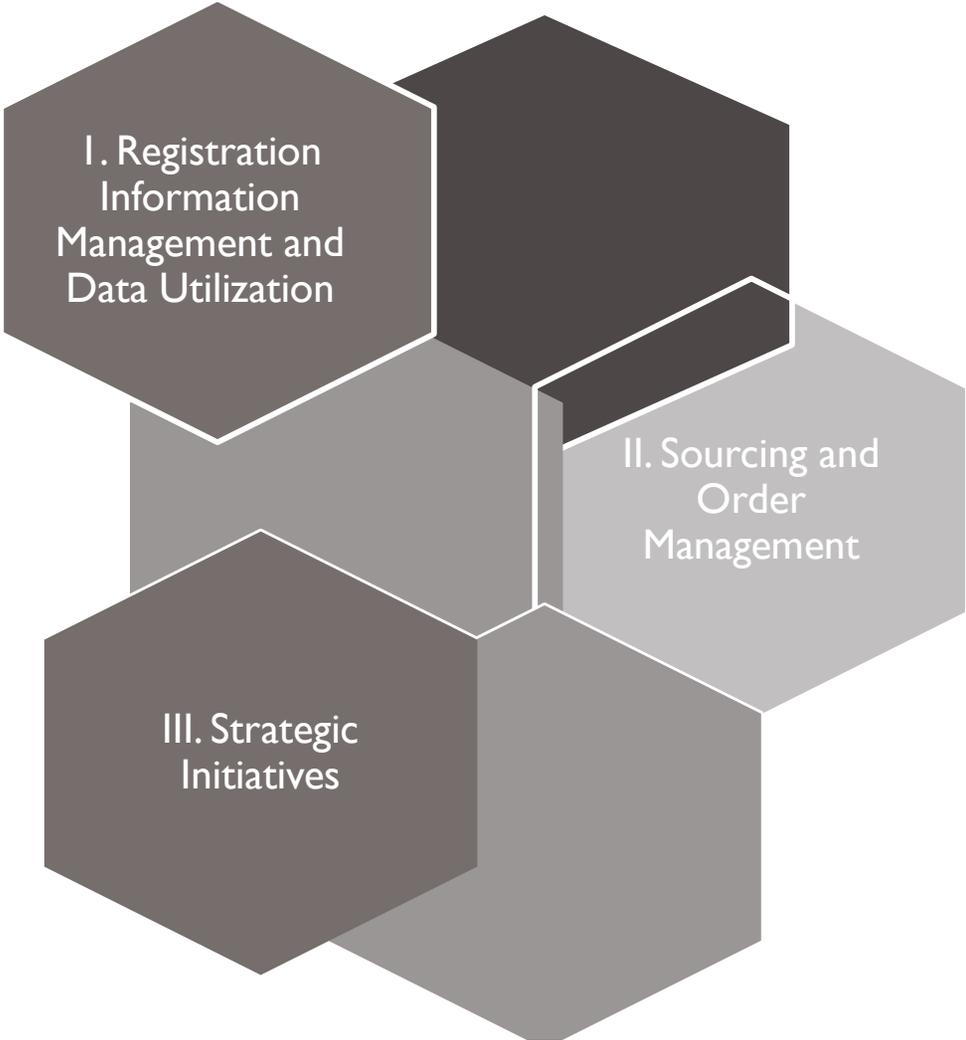
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STRATEGIC PRIORITIES AND MARKET LEVERS

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REGISTRATION



HEALTHY MARKETS

We Consider Four Critical Dimensions In Determining Market Health

Dimensions	Key questions and output metrics	Potential levers for market impact
Global capacity	Is supply sufficient to meet demand? <ul style="list-style-type: none">— Supply and demand gap— Existence of demand forecast— Forecast accuracy— Lead times, global-level stockout rate	<ul style="list-style-type: none">▪ Closure of supply-demand gap▪ Lead time reduction▪ Improved forecast accuracy
Affordability and funding	Is pricing affordable? <ul style="list-style-type: none">— Price relative to substitute and peer markets— Percent supply base used— Funding and demand gap— Projected funding	<ul style="list-style-type: none">▪ Sustained price decrease▪ One-off gain from accelerating market transition
Supply risk	Is supply of these products sustainable and secure? <ul style="list-style-type: none">— Number and diversity of suppliers— Margins/price relative to cost— Product registration coverage— Scalability of capacity	<ul style="list-style-type: none">▪ Reduction in supplier concentration risk<ul style="list-style-type: none">— New suppliers/sites— Improved registration coverage
Product quality and appropriateness	Are there quality products that meet user needs? <ul style="list-style-type: none">— Effective products with regulatory approvals— Quality of products— Appropriateness based on target customer needs— Incentives for innovating improved products	<ul style="list-style-type: none">▪ Increased product effectiveness, safety, and/or reduction in side effects▪ Increased R&D pipeline

MARKET LEVERS

Committed Volume Contracts

- TLE - Selection was done for an award under the TLE solicitation that includes a minimum-order commitment based on the offered price and selected country registrations
- 75 percent of expected demand is committed to suppliers during the RFP process

Other Market Levers

- Create a win-win situation by reducing information asymmetry in the market
- Opportunities such as global minimum-volume guarantees create an incentive for countries to demand new products while promoting market stability for manufacturers

NEW PRODUCT INTRODUCTIONS AND TRANSITIONS

The goal is smooth introductions of new products that allow countries to provide superior products to patients.

Products we are interested in are:

- TDF+3TC+DTG and/or TDF+FTC+DTG
- TAF and TAF/FDC/DTG
- Darunavir
- Improved pediatric formulations
- Injectable ARVs
- Microbicides and other MPTs

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

THANK YOU!

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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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