



# SUPPLIER SUMMIT

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



# SUPPLIER SUMMIT

USAID Global Health Supply Chain Program

## AN INTRODUCTION TO GHSC- PSM'S SUPPLY MANAGEMENT OF MALE AND FEMALE CONDOMS AND LUBRICANTS



**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 program and strategic priorities
- Discuss quality assurance program for these commodities
- Present global forecasting and inventory management overview
- Share sourcing priorities and tentative calendar of sourcing events
- Engage in dialogue

# PROGRAM OVERVIEW

# USAID's Condom Programs

- Condom programming supports HIV prevention and family planning programs
- Support public sector and social marketing programs
- More than **17 billion** male condoms supplied **since 1985**

- USAID established family planning program in 1965
- World's largest family planning bilateral donor
- Supports programs in nearly 40 countries, including 31 priority countries including the 7 Ouagadougou countries
- Committed to advancing FP 2020 goal to enable 120 million more women and girls to use contraceptives

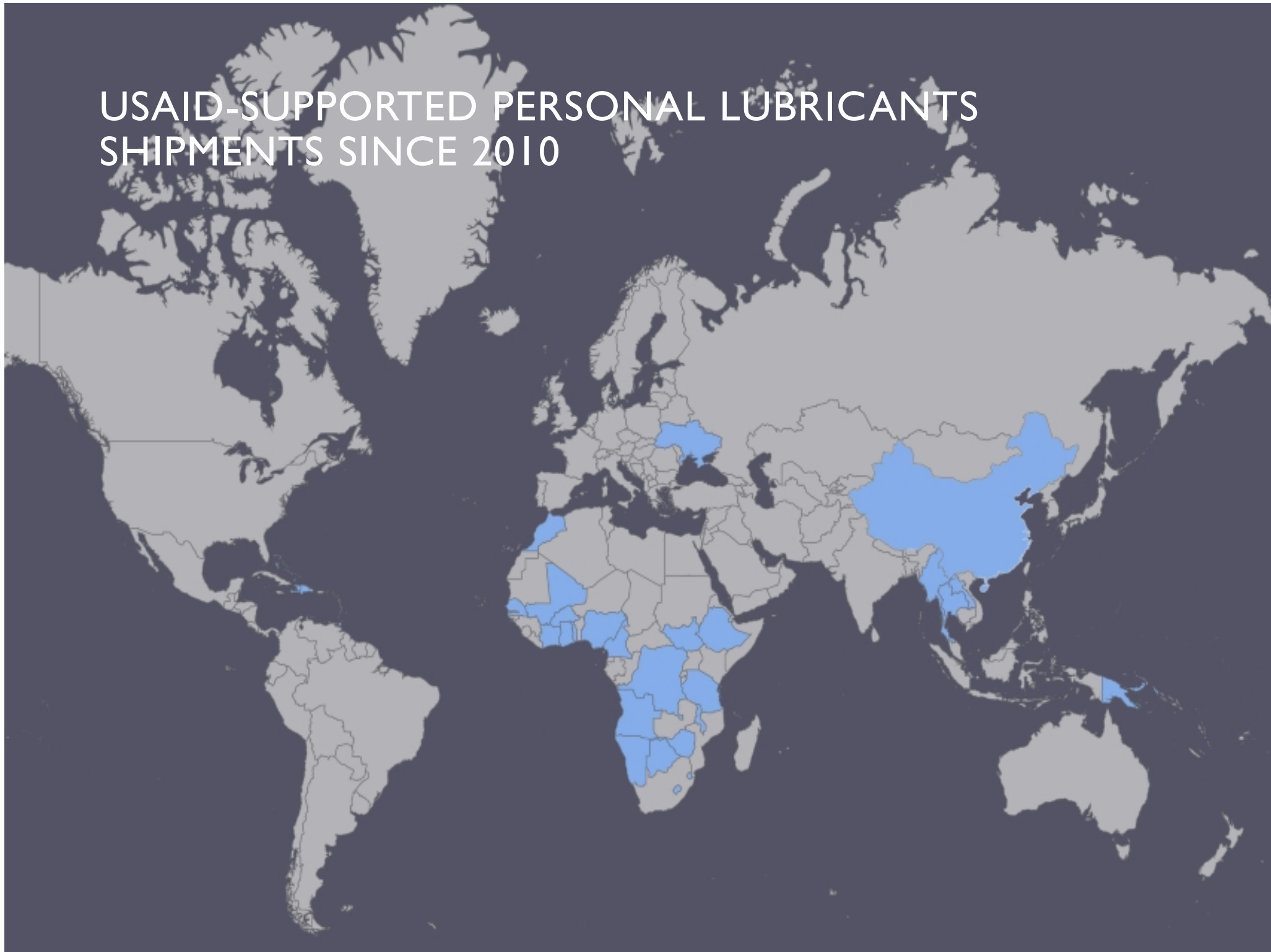
- USAID established HIV/AIDS portfolio in 1986
- Implementer of US President's Emergency Plan for AIDS Relief (PEPFAR)
- Support in over 35 countries and regional programs
- PEPFAR is the primary funding mechanism for condoms at USAID
- PEPFAR estimates that global condom programs averted 45 million new HIV infections from 1990–2015







# USAID-SUPPORTED PERSONAL LUBRICANTS SHIPMENTS SINCE 2010





## NOW MANAGED BY USAID OFFICE OF HIV/AIDS (OHA)

### Male Condom

- Plain (uncolored, unscented)
- Specialty (specialty foils, colored, and/or scented)
- 53mm and 49mm sizes

### Female Condom

- One female condom product now offered
- Female condom with specialty packaging

### Personal Lubricants

- Personal, water-based
- Aluminum foil sachets

# STRATEGIC PRIORITIES IN SUPPLY MANAGEMENT OF PROGRAM COMMODITIES

## Strategic Priorities



Support Healthier Markets

Country Registration

Adoption of  
Global Standards for  
Product Identification &  
Data Capture/Exchange

GHSC-PSM's strategic  
priorities for the supply  
management of male and  
female condoms and lubricant



# HEALTHIER MARKETS

We consider four critical dimensions in determining market health

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

# COUNTRY REGISTRATION OF PRODUCTS

## Information Management

- Formalize roles, responsibilities, and mechanisms
- Infrastructure to prioritize activities and monitor status

## Supplier Engagement

- Understand supplier capacity
- Communicate priorities with suppliers
- Collaborate to monitor registration status

## Country Registration Strategies

- Inter-agency harmonization initiatives
- GHSC-PSM-specific strategies
- Reduce barriers and facilitate country registration

# 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 Global Standards for Product Identification
- Data Exchange with GHSC



# GLOBAL HEALTH SUPPLY CHAIN – QUALITY ASSURANCE

# GHSC-QA PROJECT MANAGEMENT TEAM



Steve Hamel  
Director



**Chryste Best**  
Deputy Project Director



**Aida Cancel, PhD**  
Associate Director, Regulatory



**Katie Cretin, MPH**  
Associate Director, Business Operations



**David Jenkins, PhD**  
Associate Director, Research



**Thomas Layloff, PhD**  
Senior Technical Advisor



**Jeff Tremelling**  
Associate Director, Laboratory Testing



# GHSC-QA

Establish and implement a comprehensive **Quality Assurance Program** for USAID that:

- Provides global technical leadership regarding quality issues to the international quality assurance community
- Provides technical assistance to host country governments and other stakeholders
- Assures that health commodities purchased on behalf of USAID meet applicable quality standards
- Implements Model Quality Assurance System (MQAS) guidance (WHO Technical Report Series)
- Employs risk management practices to maintain diligence and recognizes that by limiting the risk of accepting products of inadequate quality, increased protection of the client/patient and USAID is ensured.

GHSC- QA provides independent Quality Assurance for:

- Task Order 1-HIV
- HIV RTKs (RMI)
- Task Order 3-Reproductive Health
- Task Order 4-Maternal and Child Health

## Objectives

Quality Assurance

Quality Control

Technical Assistance  
and Leadership

Global  
Collaboration



# GHSC-QA ACTIVITIES AND OBJECTIVES

Quality Assurance	Quality Control	Technical Assistance and Leadership	Global Collaboration
<ul style="list-style-type: none"><li>• Product reviews (product questionnaire/technical information)</li><li>• Eligible/approved supplier and product list</li><li>• Technical requirements and specifications for EOLs, RFQs, and RFPs</li><li>• Manage product complaints and incidents (including monitoring regulatory warnings)</li><li>• Product recall management</li><li>• Quality technical assistance</li><li>• Audits/CAPAs</li><li>• Statistical trending (CpK)</li><li>• Annual review and risk management</li></ul>	<ul style="list-style-type: none"><li>• Sampling</li><li>• Product testing</li><li>• Test method/transfer</li><li>• New technologies</li></ul>	<ul style="list-style-type: none"><li>• NDRA training</li><li>• Laboratory capacity building</li><li>• Tanzania</li><li>• Afghanistan</li><li>• Côte d'Ivoire</li><li>• Uganda</li><li>• Zimbabwe</li><li>• Ethiopia</li><li>• Nigeria</li><li>• Ghana</li></ul>	<ul style="list-style-type: none"><li>• Donors</li><li>• WHO</li><li>• UNFPA</li><li>• UNICEF</li><li>• Global Fund</li><li>• Independent advisory groups</li></ul>

# MALE CONDOMS

## Eligibility requirements

- Condoms must have a U.S. FDA 510(k) for plain, parallel- straight walled, 49 and 53mm.
- Color and scented condoms must have specific 510(k)
- ISO Certified to 9001, 13485, 14000
- WHO/UNFPA pre-qualified list (New)
- EU CE Mark
- GMP registered facility
- Monitor proteins, nitrosamines, and residual accelerators

## QA and QC activities

- Pre-shipment testing to ISO 4074
- GHSC-QA audits frequency dependent on risk assessment
- 180 day accelerated stability studies
- Odor evaluation
- Annual testing of proteins, nitrosamines, residual accelerators
- Trending of manufacturer's data

# FEMALE CONDOMS

## Eligibility requirements

- US FDA 510 (k)
- EU CE Mark
- UNFPA pre-qualified list – referenced
- GMP registered facility
- ISO Certified to 9001, 13485, 14000
- GHSC – QA Medical Device Product Assessment required

## QA and QC activities

- Pre-shipment testing
- GHSC-QA audits frequency dependent on risk assessment

# PERSONAL WATER-BASED LUBRICANTS

## Eligibility requirements

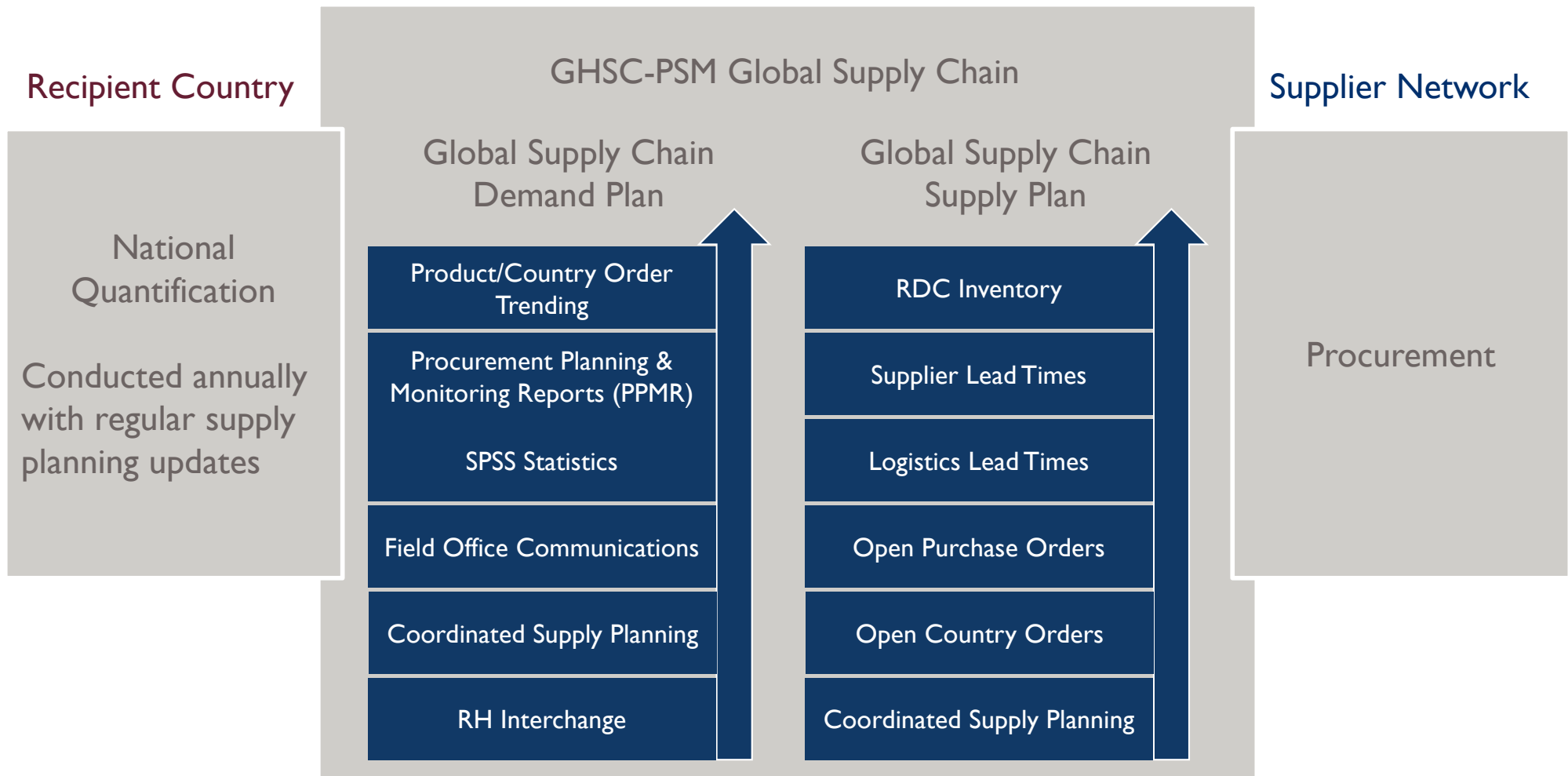
- US FDA 510K
- Compliance with WHO/UNFPA/FHI360 Advisory Note
  - Water-based
  - Osmolality < 1200 mOsm/kg
  - pH 5.5 - 7
  - Avoid polyquarternary compounds
- EU CE Mark
- GMP registered facility
- ISO Certified to 9001, 13485, 14000
- GHSC – QA Medical Device Product Assessment required
- Presentation: Sachet

## QA and QC activities

- GHSC-QA audits frequency dependent on risk assessment
- Pre-shipment or concurrent testing dependent on risk assessment

# DEMAND FORECASTING, INVENTORY MANAGEMENT, AND SOURCING

# GHSC-PSM PLANNING OVERVIEW





# GHSC-PSM INVENTORY MANAGEMENT

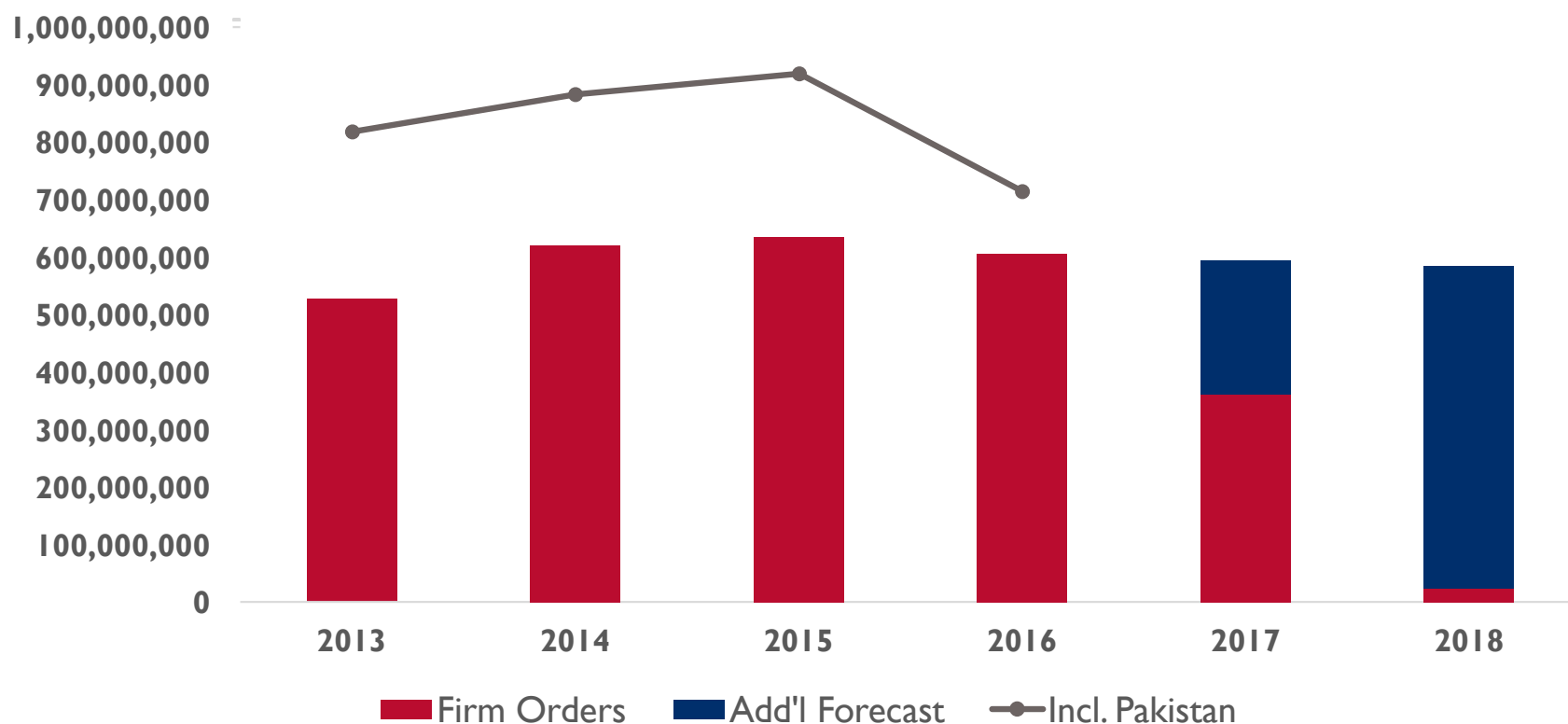
- Source-to-Forecast Products include (stocked)
  - No logo male condoms (53mm)
  - Blue/Gold male condoms (53mm)
  - Female condoms
- Optimize safety stock formulas
- Reduce order-to-receipt lead times
- Explore vendor-managed inventory



# DEMAND FORECAST: ALL MALE CONDOMS

*Long-term USAID commitment to commodity across broad range of countries*

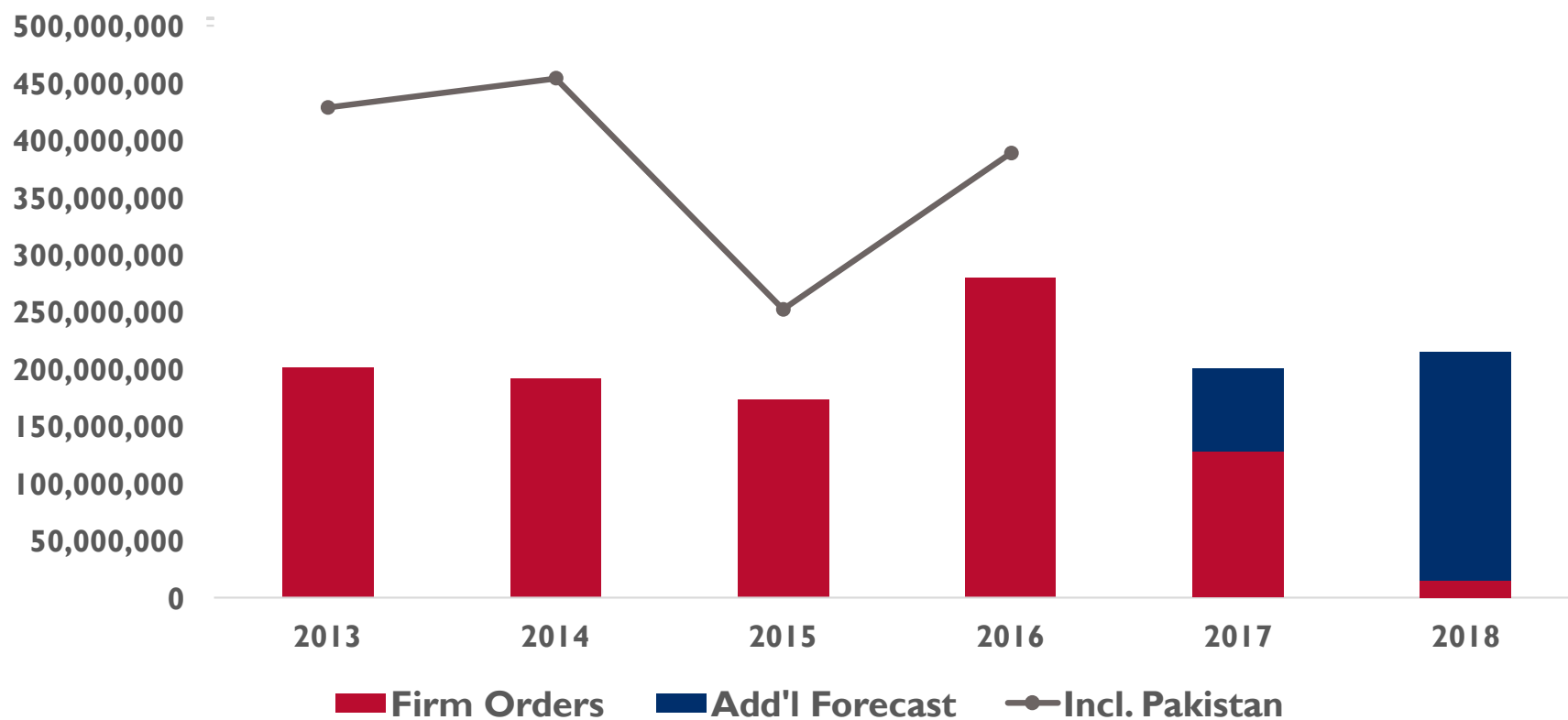
DELIVER/GHSC-PSM country  
orders by requested delivery date



# DEMAND FORECAST: NO LOGO MALE CONDOMS

*Orders from 15-20 countries per year*

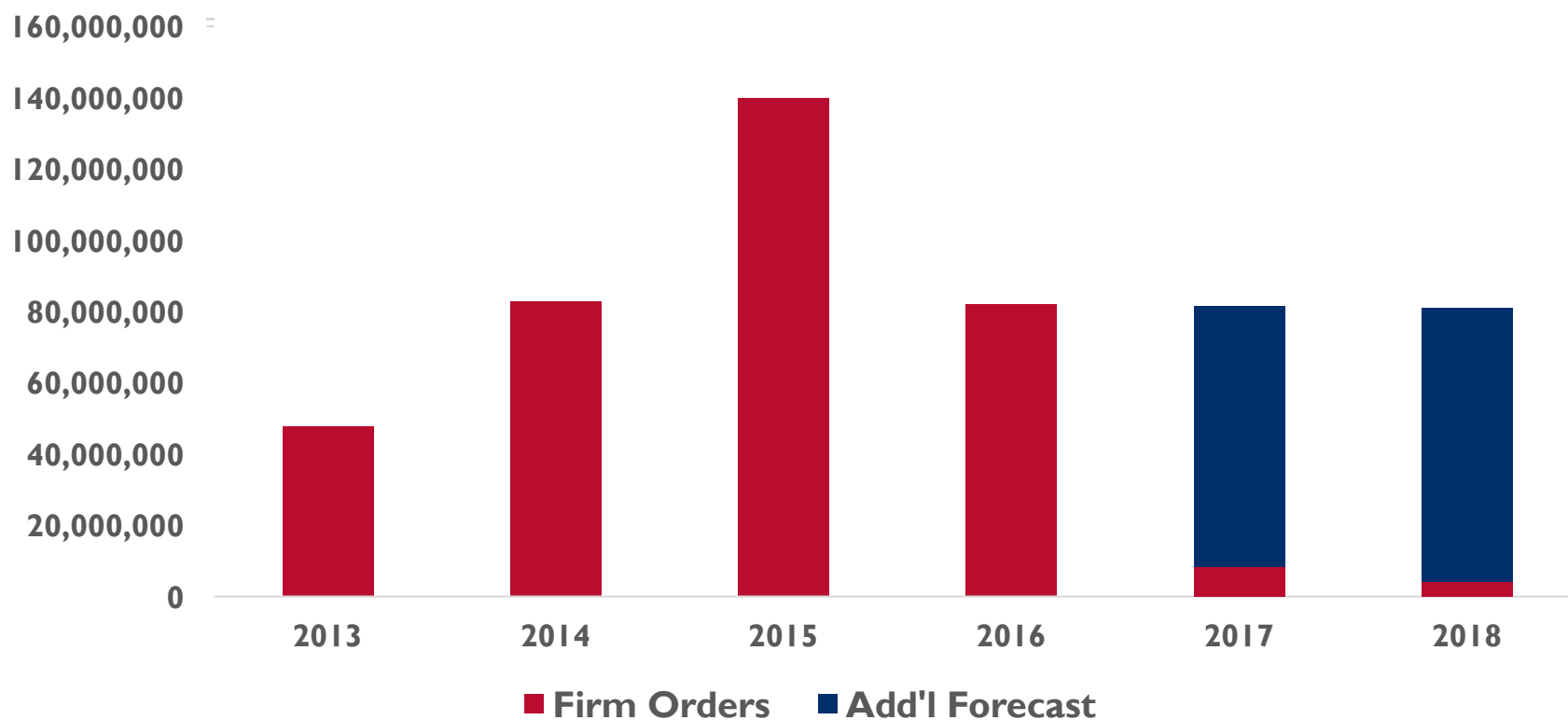
DELIVER/GHSC-PSM country orders by requested delivery date



# DEMAND FORECAST: BLUE/GOLD MALE CONDOMS

*Seven countries accounting for 94% demand since 2012*

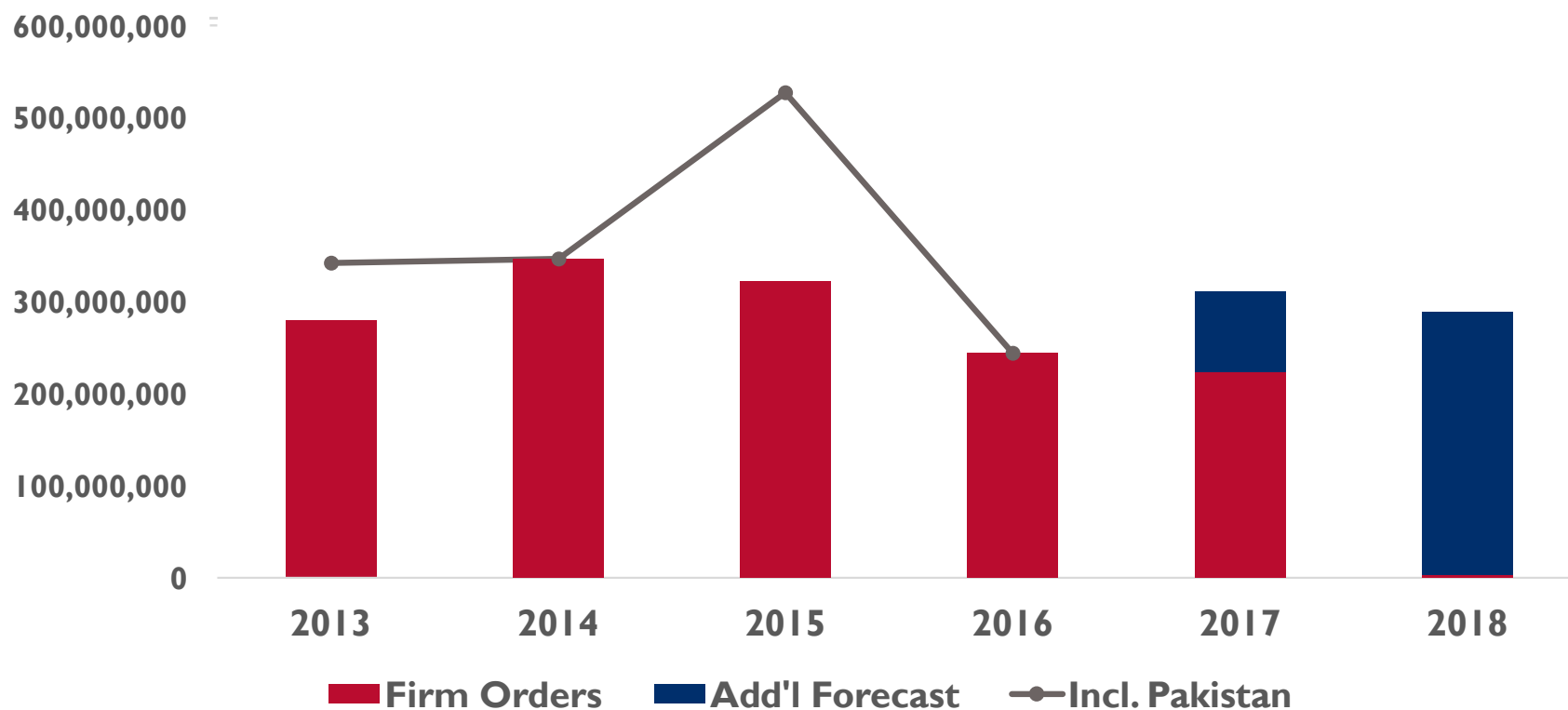
DELIVER/GHSC-PSM country  
orders by requested delivery date



# DEMAND FORECAST: SPECIALTY MALE CONDOMS

*25 procuring countries and 39 different products since 2014*

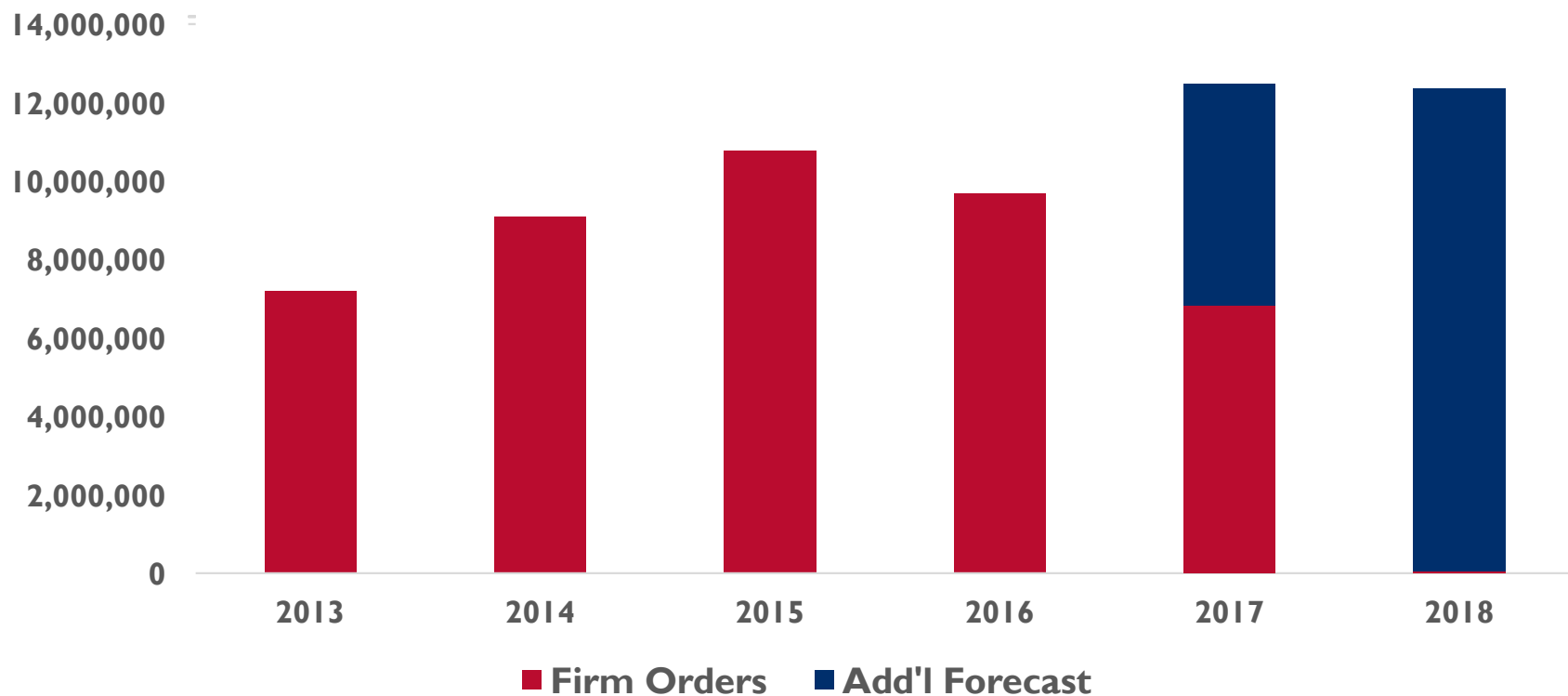
DELIVER/GHSC-PSM country  
orders by requested delivery date



# DEMAND FORECAST: FEMALE CONDOMS

*25 procuring countries since 2014, with Zimbabwe driving 60% of demand*

DELIVER/GHSC-PSM country  
orders by requested delivery date

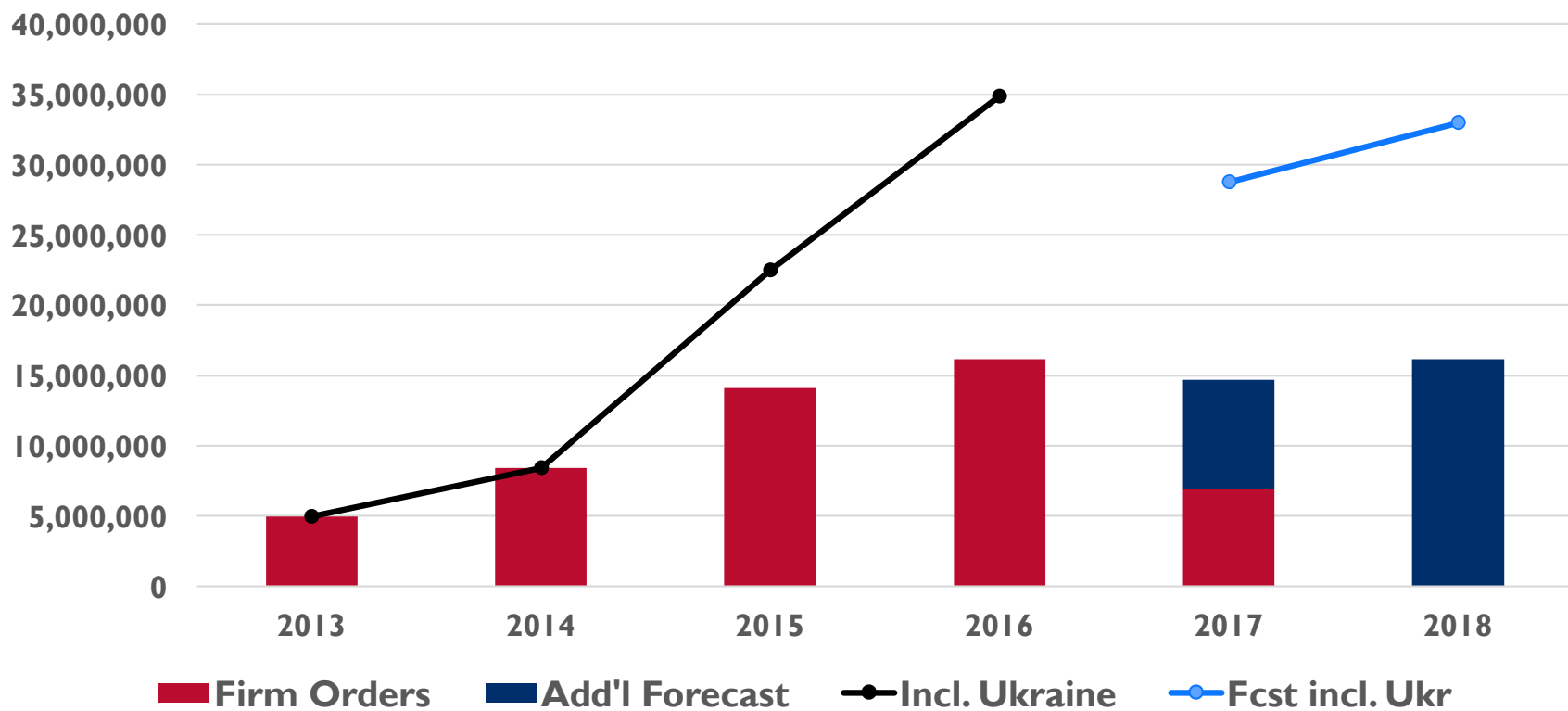




# DEMAND FORECAST: PERSONAL LUBRICANTS

*Introduction of single country can significantly increase demand uncertainty*

DELIVER/GHSC-PSM country  
orders by requested delivery date



# FUTURE SOURCING PRIORITIES

## Male Condom

- Lead time reduction initiatives (e.g., stocking foil, vendor-managed inventory)
- Ensure sourcing flexibility for specialty male condoms
- Consider options (i.e., pre-packaging)

## Female Condom

- Explore opportunities related to expanding product portfolio
- Consider vendor-managed inventory and alternate pack sizes

## Personal Lubricants

- Reduce supply risk
- Align sourcing timeline and supply base for lubricant with male condoms
- Consider artwork options

# COUNTRY REGISTRATION OUTLOOK

## Male Condom

- Requirements differ by country
- Countries may only allow registration of one manufacturer per brand
- Local partner typically required

## Female Condom

- Registration increasingly required
- Monitor and respond to new requirements

## Personal Lubricants

- Registration not now typically required for USAID-supported countries
- Monitor and respond to new requirements

# VENDOR-MANAGED INVENTORY (VMI)

## Objectives

- Savings in cost and time
- Greater demand visibility and improved planning for supplier

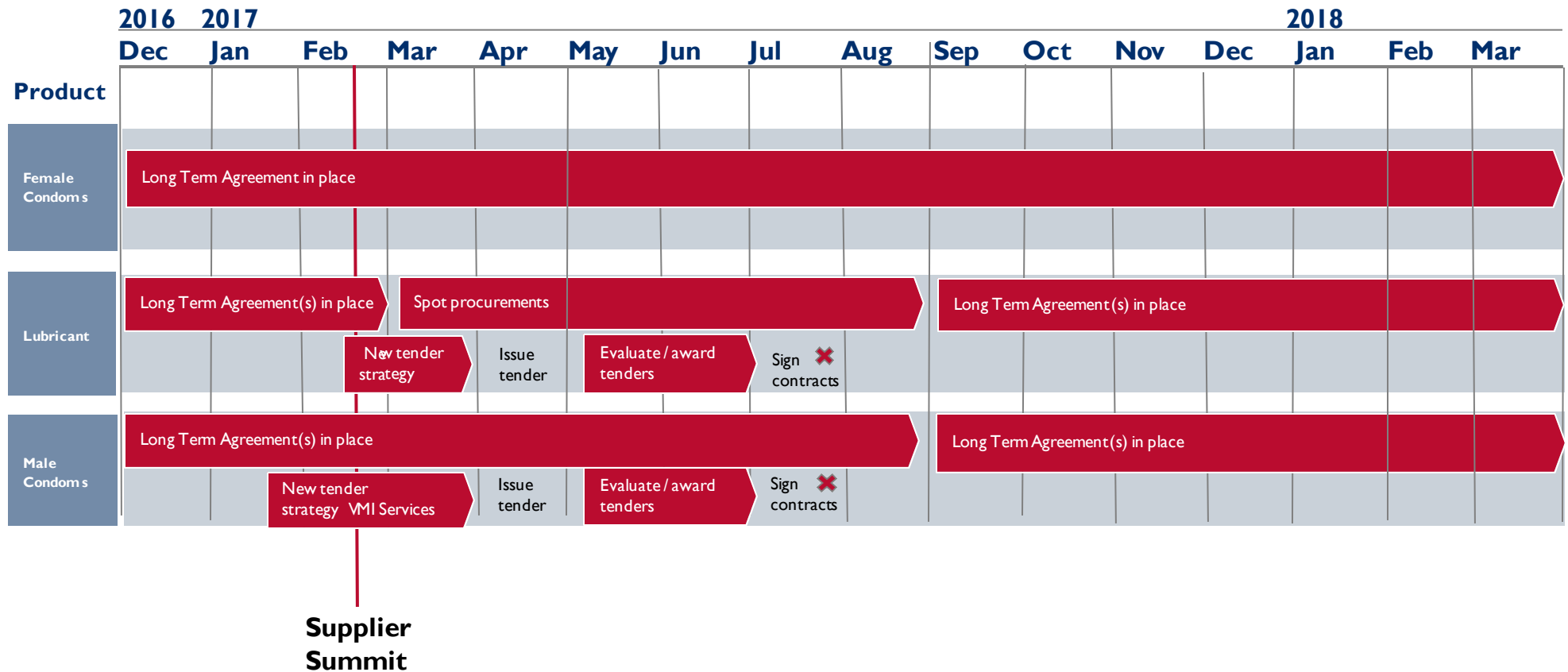
## Next Steps for Male Condoms

- Issue RFP for all male condoms
- Include VMI services for No Logo and Blue/Gold condoms in RFP
- Seek innovative responses to inform strategy

## GHSC-PSM's Use of VMI

- Continue developing and applying VMI strategies for other commodities, when feasible

# CONDOMS & LUBRICANT: SOURCING CALENDAR



# EVALUATION CRITERIA (AQSCIR-P)

EXAMPLES

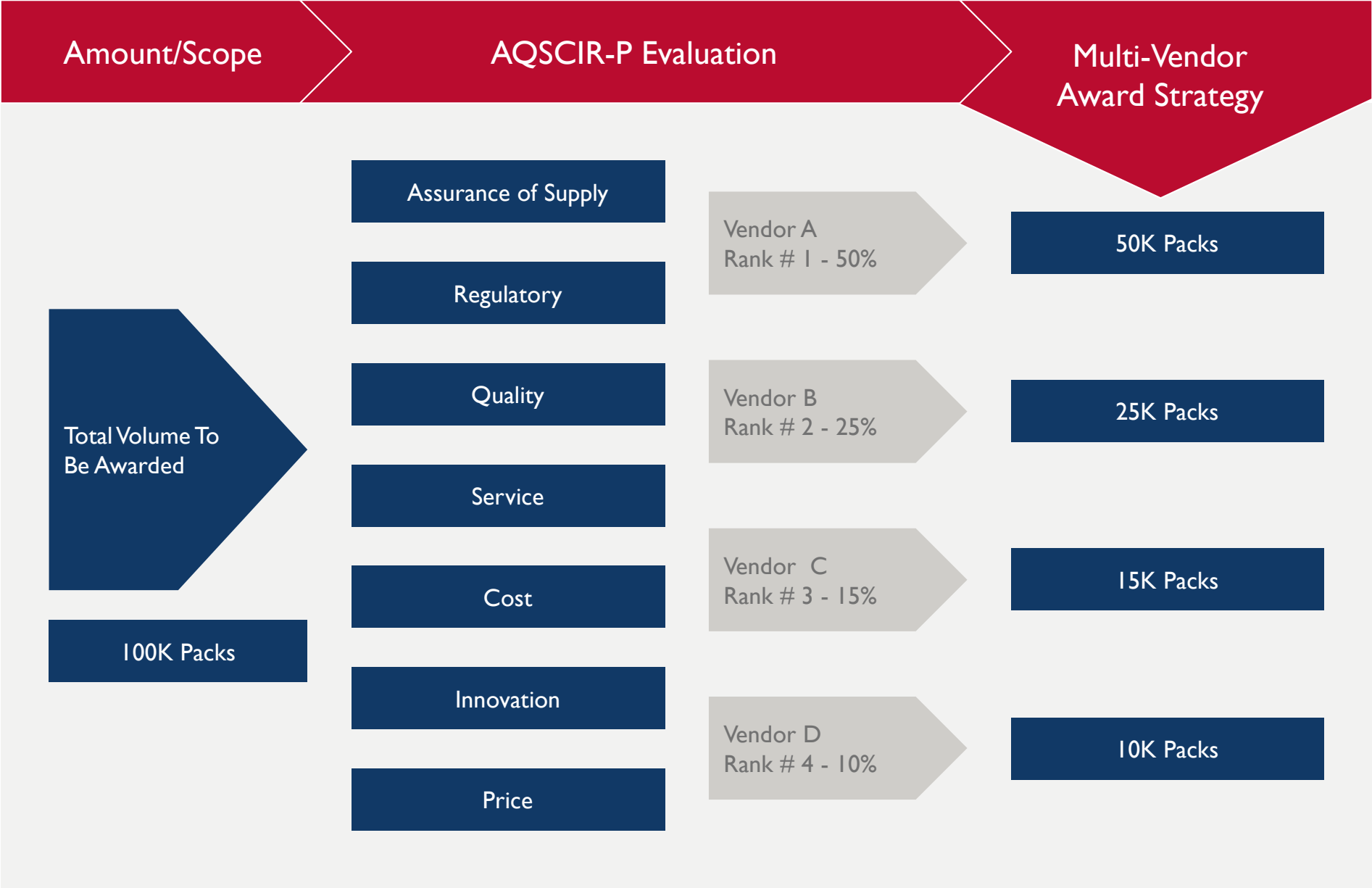
Assurance of Supply	<ul style="list-style-type: none"><li>• Production capacity</li><li>• Quantity in stock (when required)</li><li>• Past performance</li></ul>
Regulatory	<ul style="list-style-type: none"><li>• Administrative requirements</li><li>• Registration in country</li></ul>
Quality	<ul style="list-style-type: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

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



# QUESTIONS?

# THANK YOU!

Steve Hamel, GHSC-QA  
[shamel@fhi360.org](mailto:shamel@fhi360.org)

Safia Ahsan, Supplier Relationship Management  
[sahsan@ghsc-psm.org](mailto:sahsan@ghsc-psm.org)

Erin Seaver, Strategic Sourcing  
[eseaver@ghsc-psm.org](mailto:eseaver@ghsc-psm.org)

Dan Kiesa, Demand Planning  
[dkiesa@ghsc-psm.org](mailto:dkiesa@ghsc-psm.org)

Anita Deshpande, Market Dynamics  
[adeshpande@ghsc-psm.org](mailto:adeshpande@ghsc-psm.org)

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, maternal and child health, and reproductive health commodities.