



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

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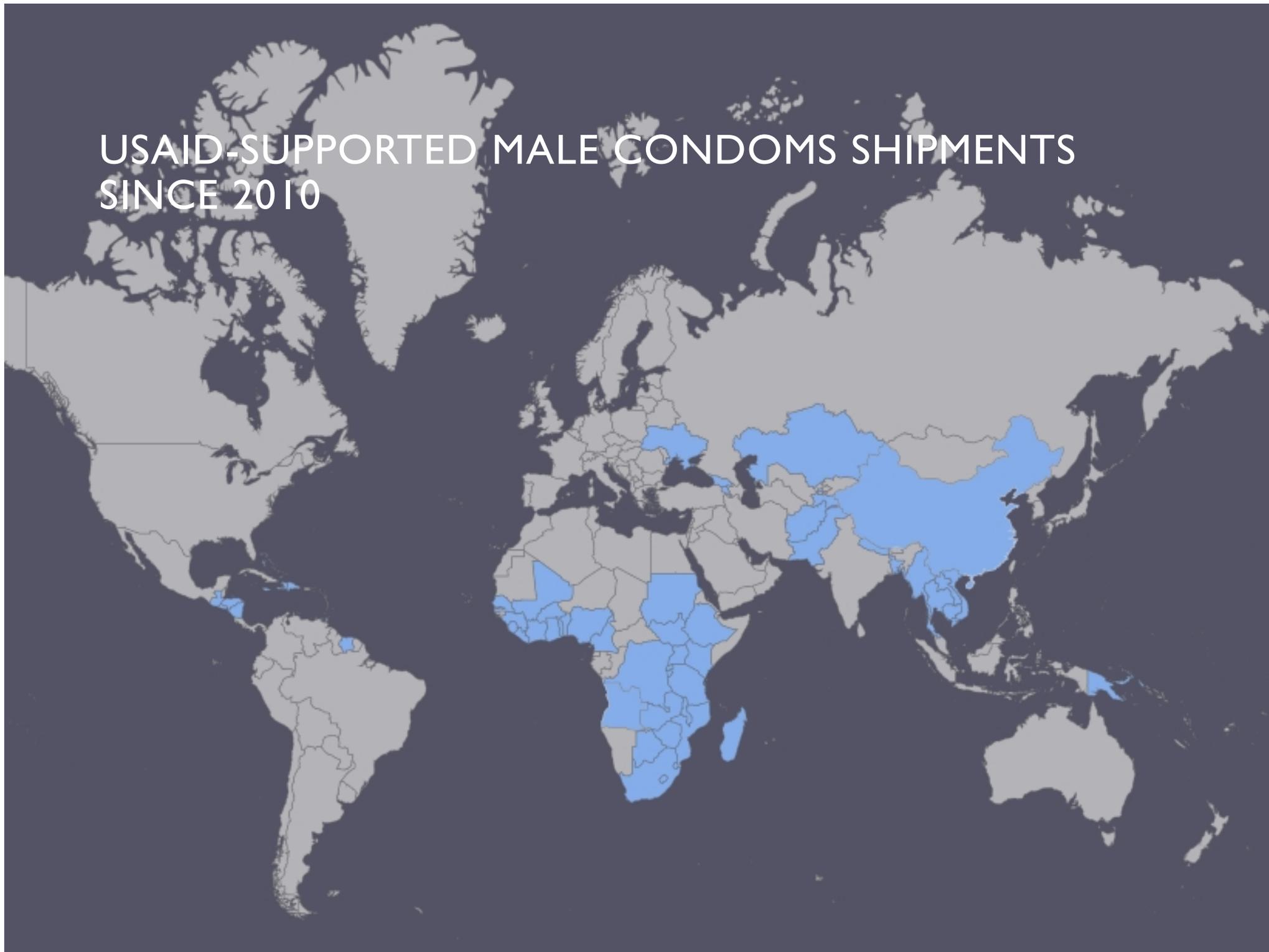
USAID's Condom Programs

- 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**

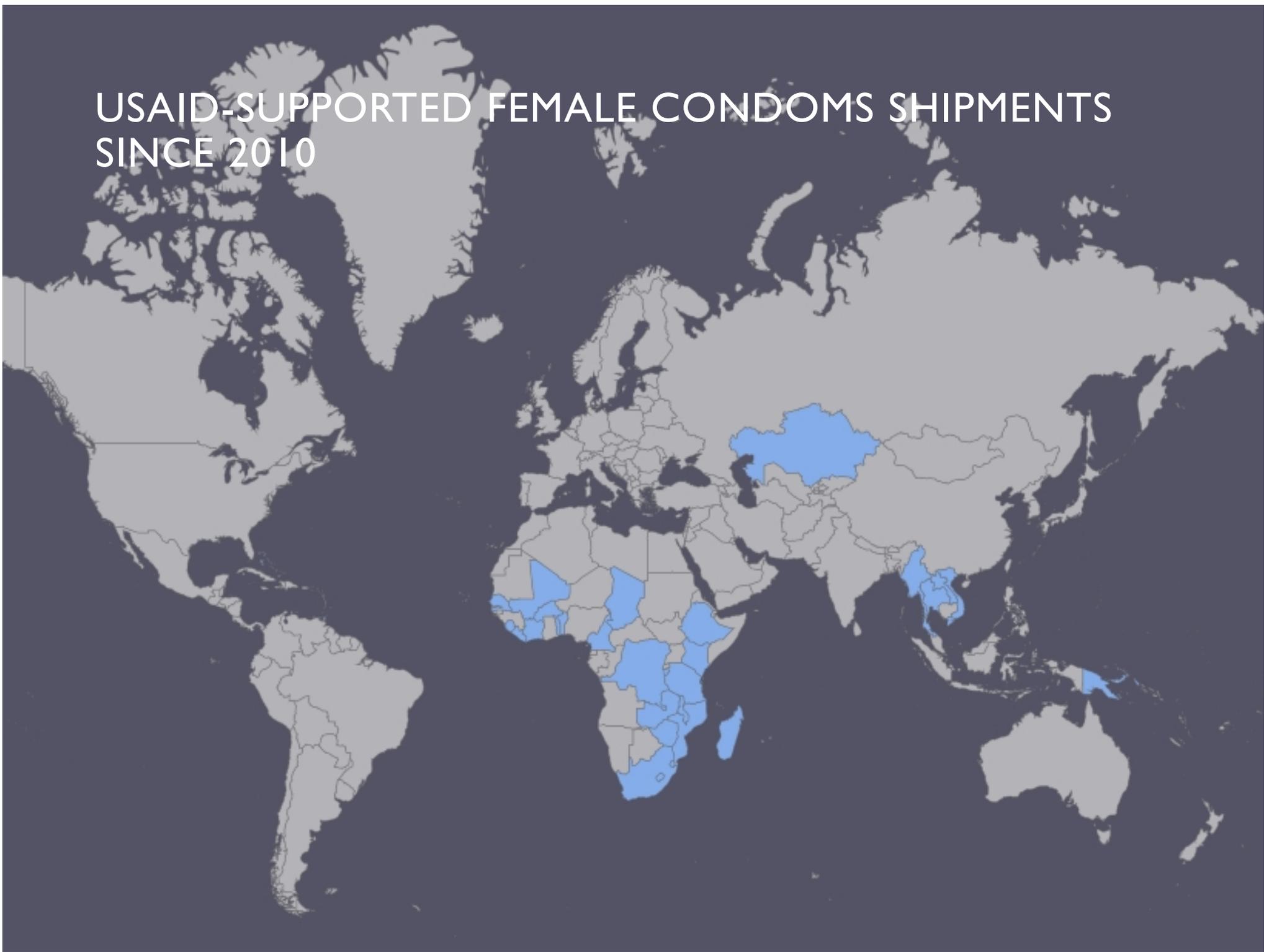
- USAID established family planning program in 1965
- World's largest family planning bilateral donor
- Supports programs in nearly 40 countries, including 31 priority countries including the 7 Ouagadougou countries
- Committed to advancing FP 2020 goal to enable 120 million more women and girls to use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

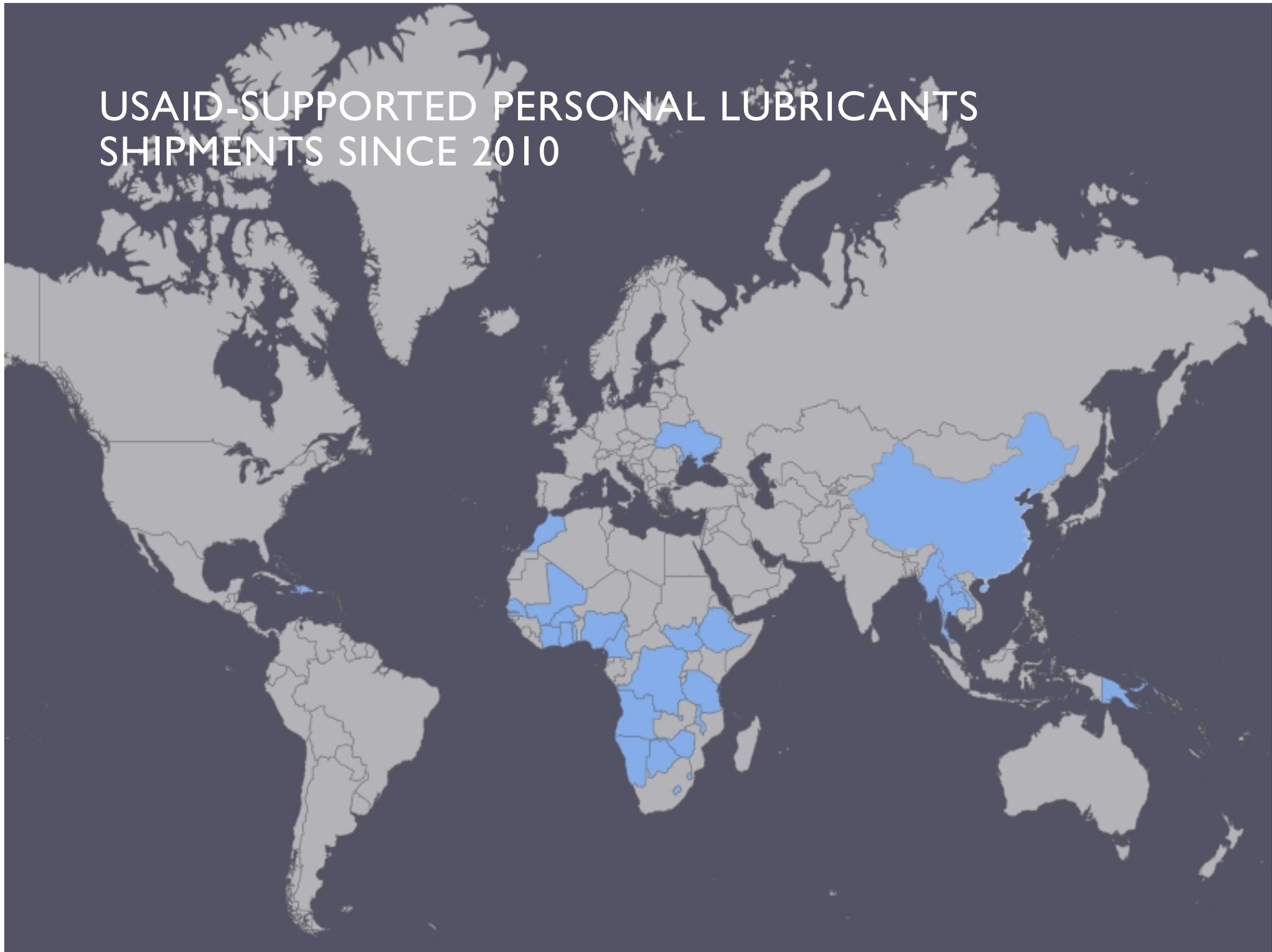
USAID-SUPPORTED MALE CONDOMS SHIPMENTS SINCE 2010



USAID-SUPPORTED FEMALE CONDOMS SHIPMENTS SINCE 2010



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

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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	<p>Is there sufficient supply to meet demand?</p> <ul style="list-style-type: none">— Supply and demand gap— Existence of demand forecast— Forecast accuracy— Lead times, global level stock out rate	<ul style="list-style-type: none">▪ Closure of supply-demand gap▪ Lead time reduction▪ Improved forecast accuracy
Affordability & funding	<p>Is pricing affordable?</p> <ul style="list-style-type: none">— Price relative to substitute and peer markets— % Supply base utilized— Funding and demand gap— Projected funding	<ul style="list-style-type: none">▪ Sustained price decrease▪ One-off gain from accelerating market transition
Supply risk	<p>Is there sustainable, secure supply of these products?</p> <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 & appropriateness	<p>Are there quality products that meet user needs?</p> <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

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

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GHSC-QA PROJECT MANAGEMENT TEAM



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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

- Product reviews (product questionnaire/technical information)
- Eligible/approved supplier and product list
- Technical requirements and specifications for EOIs, RFQs, and RFPs
- Manage product complaints and incidents (including monitoring regulatory warnings)
- Product recall management
- Quality technical assistance
- Audits/CAPAs
- Statistical trending (CpK)
- Annual review and risk management

Quality Control

- Sampling
- Product testing
- Test method/transfer
- New technologies

Technical Assistance and Leadership

- NDRA training
- Laboratory capacity building
- Tanzania
- Afghanistan
- Côte d'Ivoire
- Uganda
- Zimbabwe
- Ethiopia
- Nigeria
- Ghana

Global Collaboration

- Donors
- WHO
- UNFPA
- UNICEF
- Global Fund
- Independent advisory groups

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

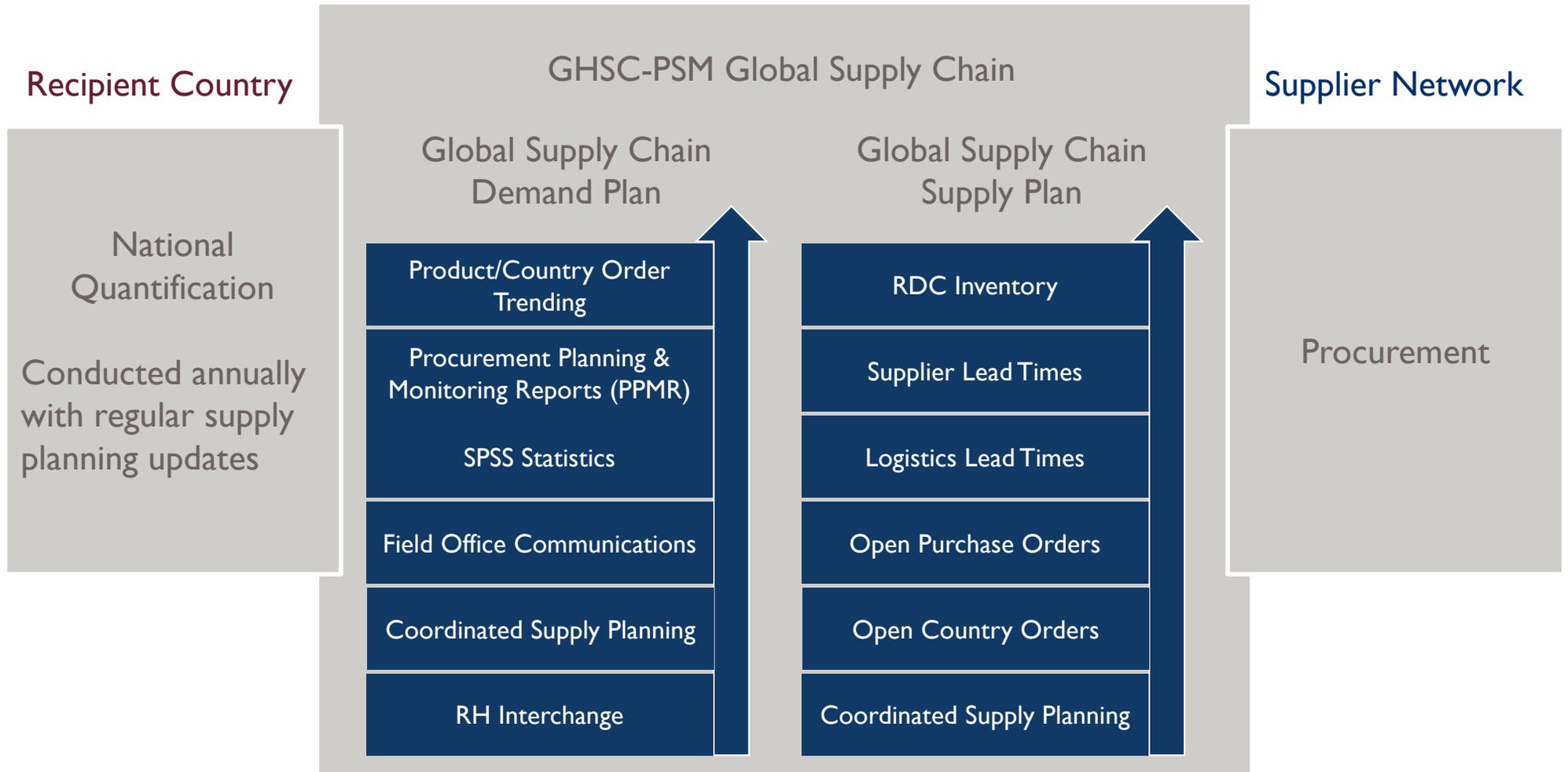
- US FDA 510K
- Compliance with WHO/UNFPA/FHI360 Advisory Note
 - Water-based
 - Osmolality < 1200 mOsm/kg
 - pH 5.5 - 7
 - Avoid polyquarternary compounds
- EU CE Mark
- GMP registered facility
- ISO Certified to 9001, 13485, 14000
- GHSC – QA Medical Device Product Assessment required
- Presentation: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

QA and QC activities

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

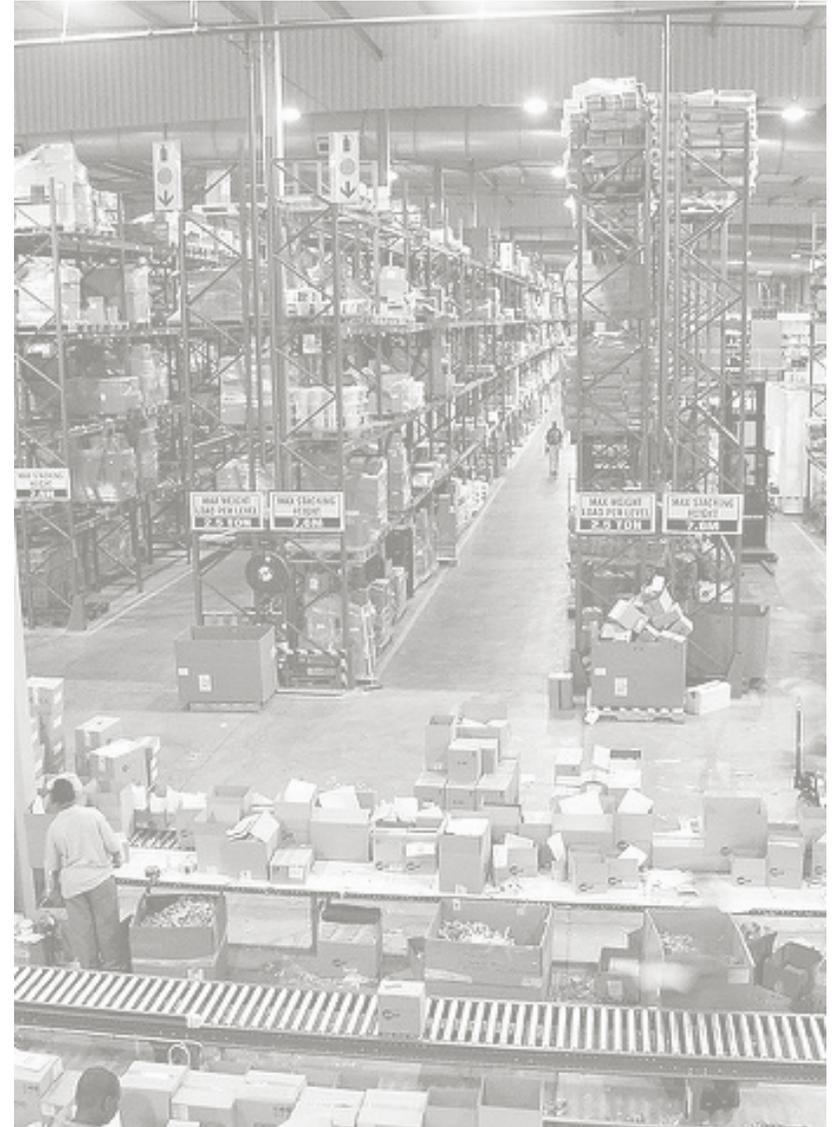
DEMAND FORECASTING, INVENTORY MANAGEMENT, AND SOURCING

GHSC-PSM PLANNING OVERVIEW



GHSC-PSM INVENTORY MANAGEMENT

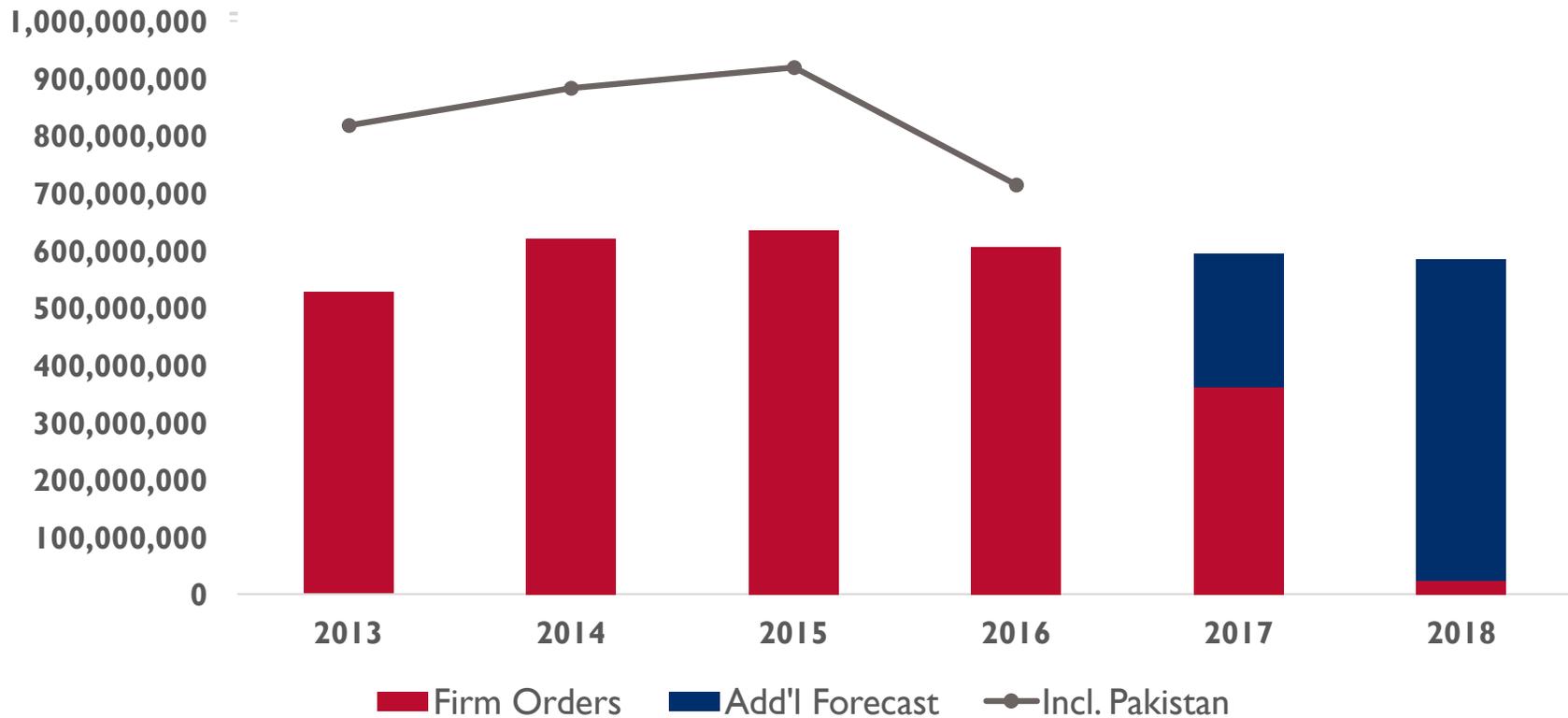
- Source-to-Forecast Products include (stocked)
 - No logo male condoms (53mm)
 - Blue/Gold male condoms (53mm)
 - Female condoms
- Optimize safety stock formulas
- Reduce order-to-receipt lead times
- Explore vendor-managed inventory



DEMAND FORECAST: ALL MALE CONDOMS

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

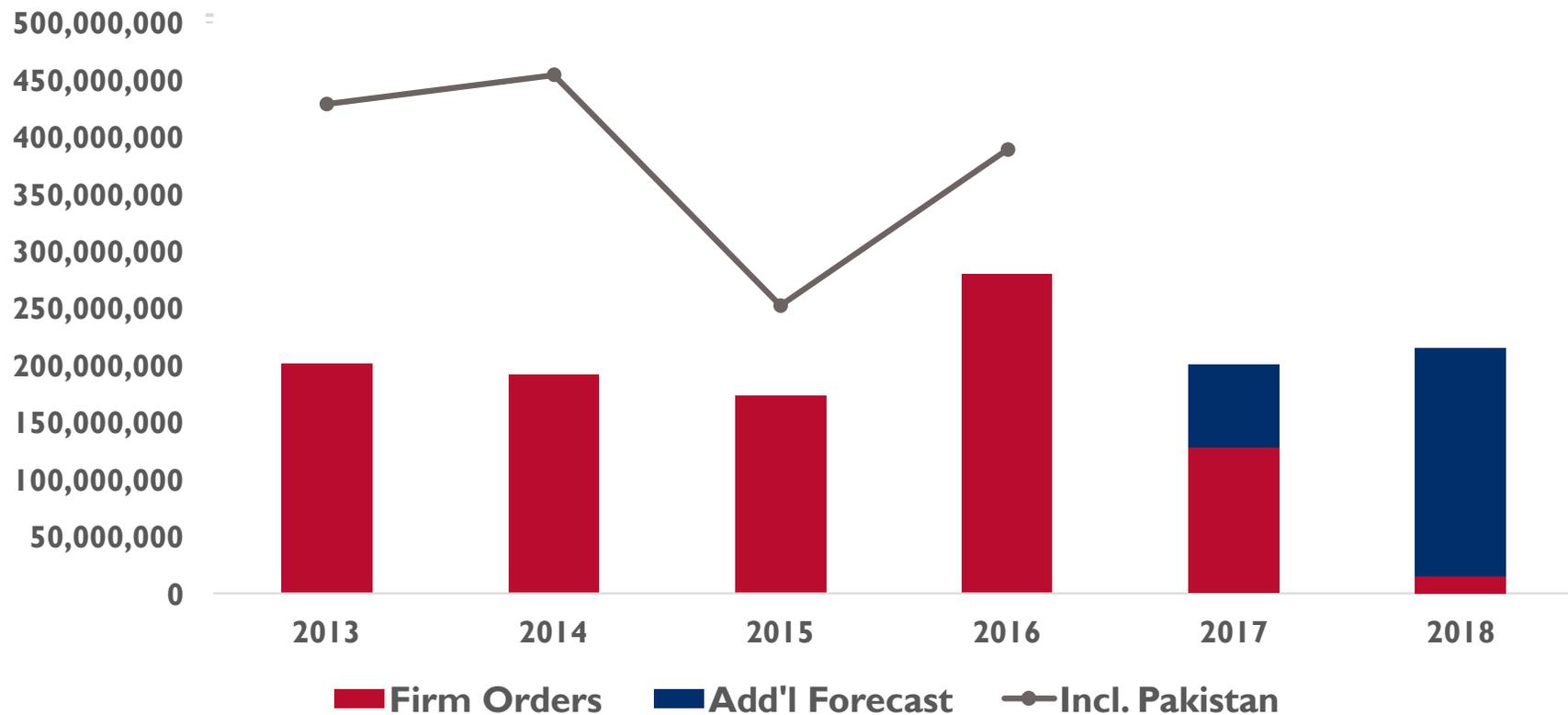
DELIVER/GHSC-PSM country orders by requested delivery date



DEMAND FORECAST: NO LOGO MALE CONDOMS

Orders from 15-20 countries per year

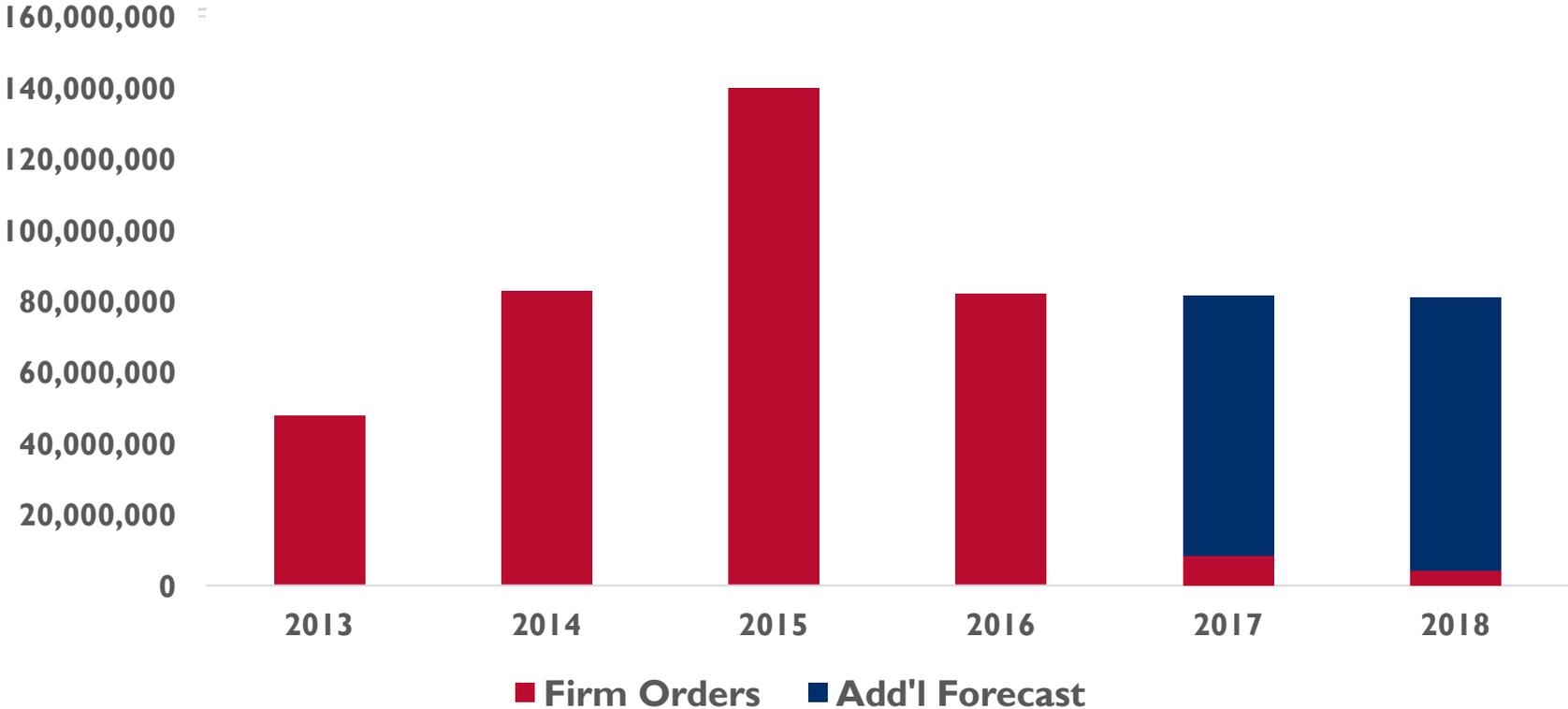
DELIVER/GHSC-PSM country orders by requested delivery date



DEMAND FORECAST: BLUE/GOLD MALE CONDOMS

Seven countries accounting for 94% demand since 2012

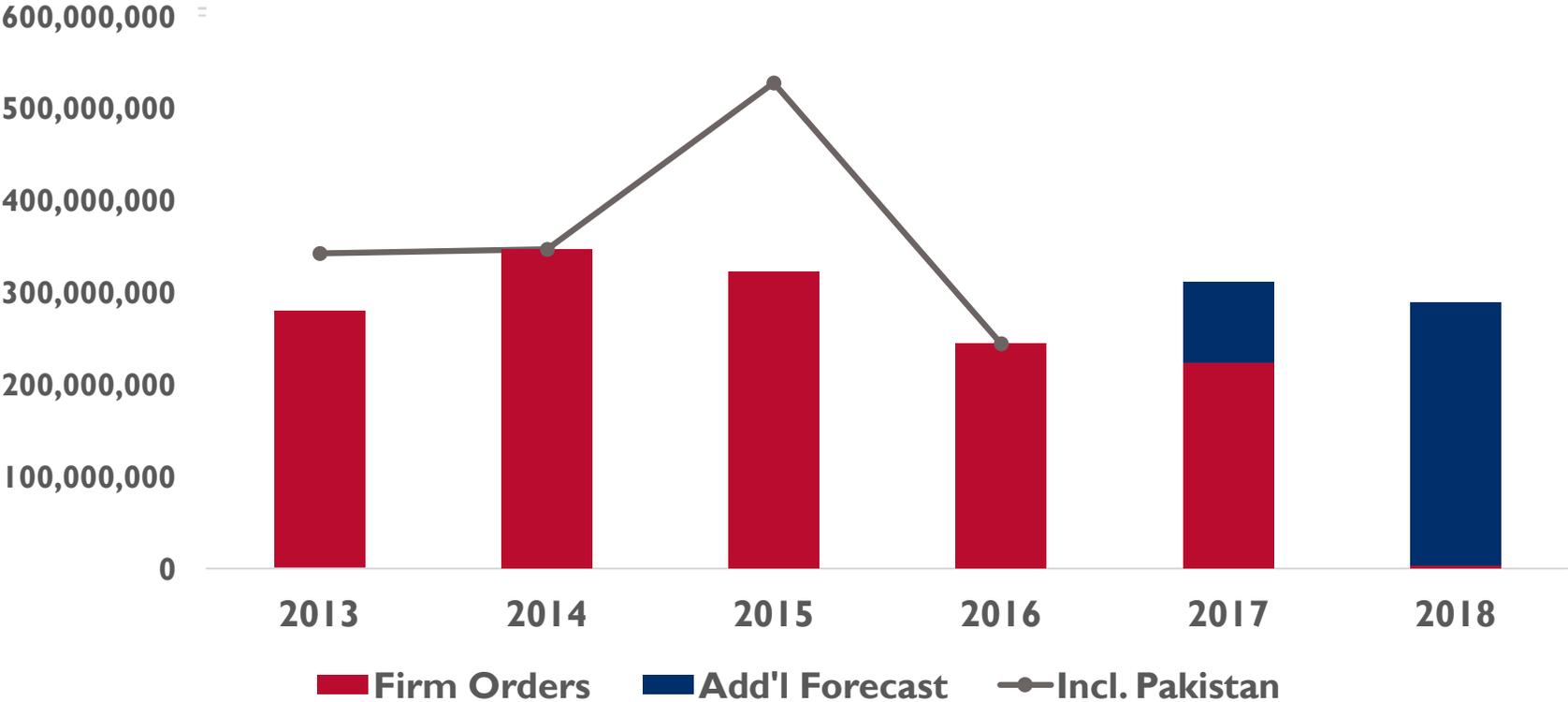
DELIVER/GHSC-PSM country orders by requested delivery date



DEMAND FORECAST: SPECIALTY MALE CONDOMS

25 procuring countries and 39 different products since 2014

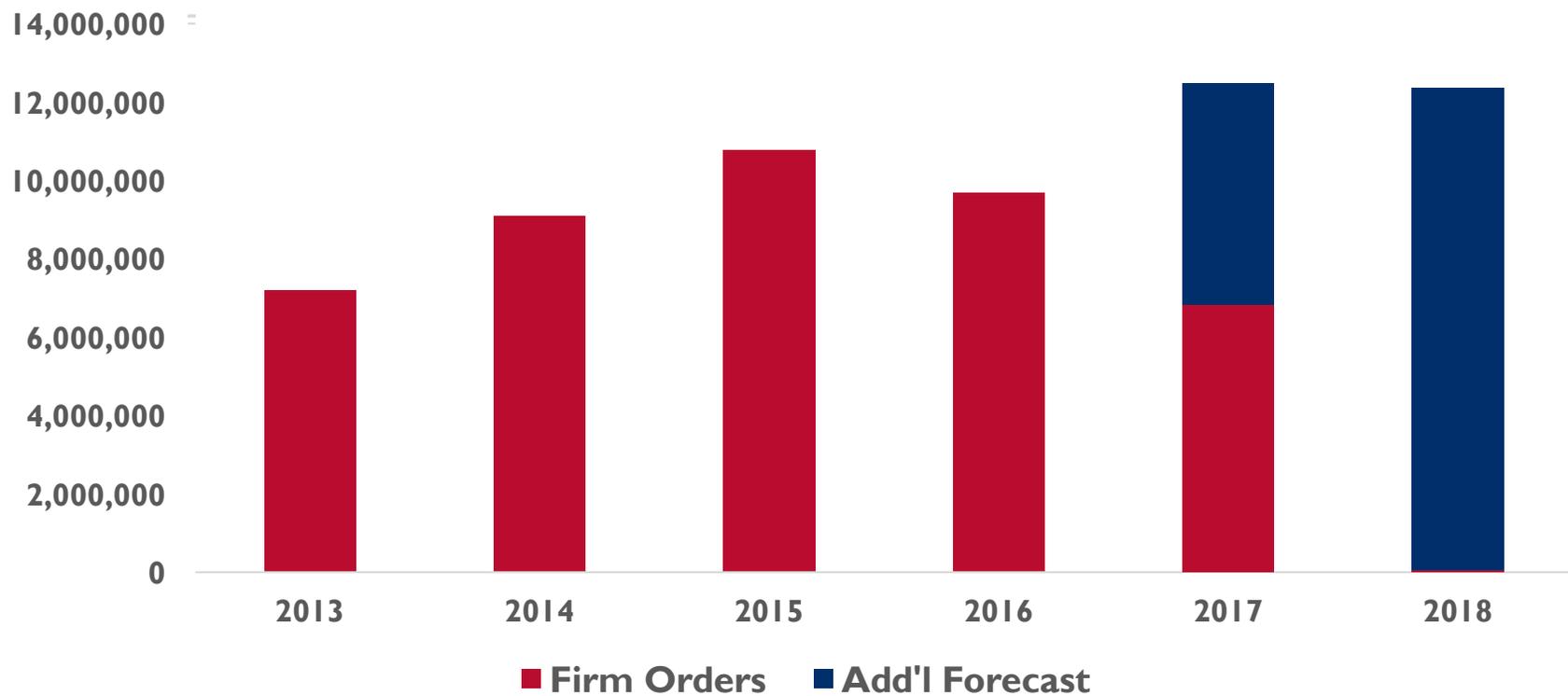
DELIVER/GHSC-PSM country orders by requested delivery date



DEMAND FORECAST: FEMALE CONDOMS

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

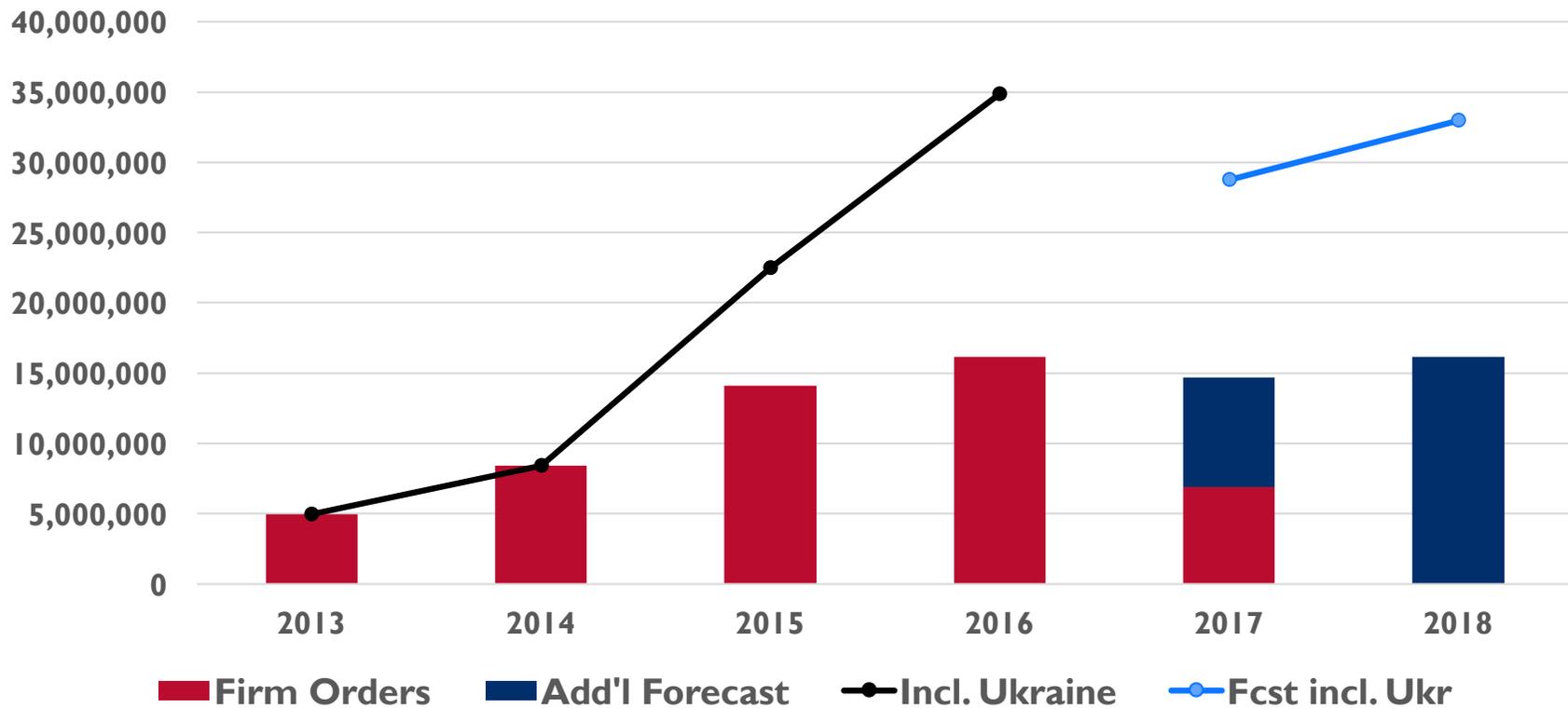
DELIVER/GHSC-PSM country
orders by requested delivery date



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

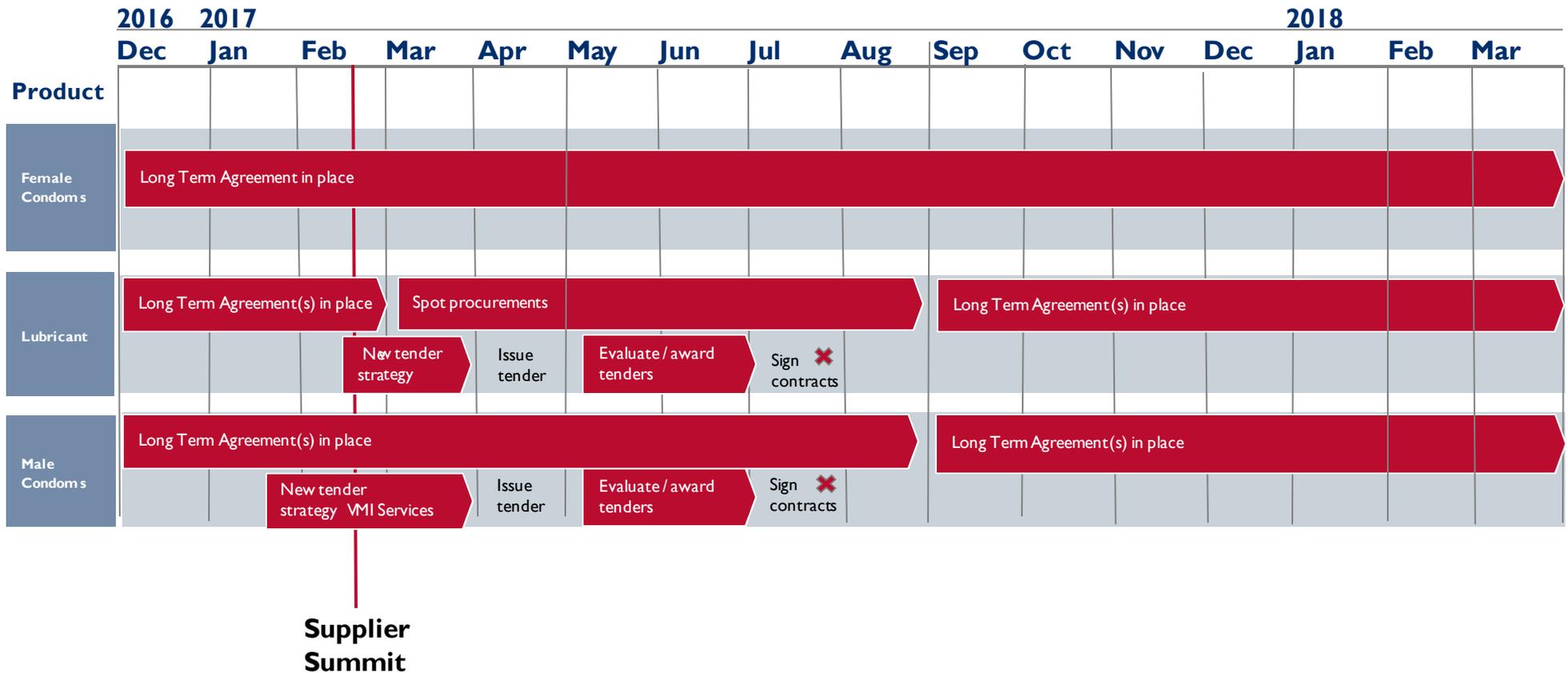
Next Steps for Male Condoms

- 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)

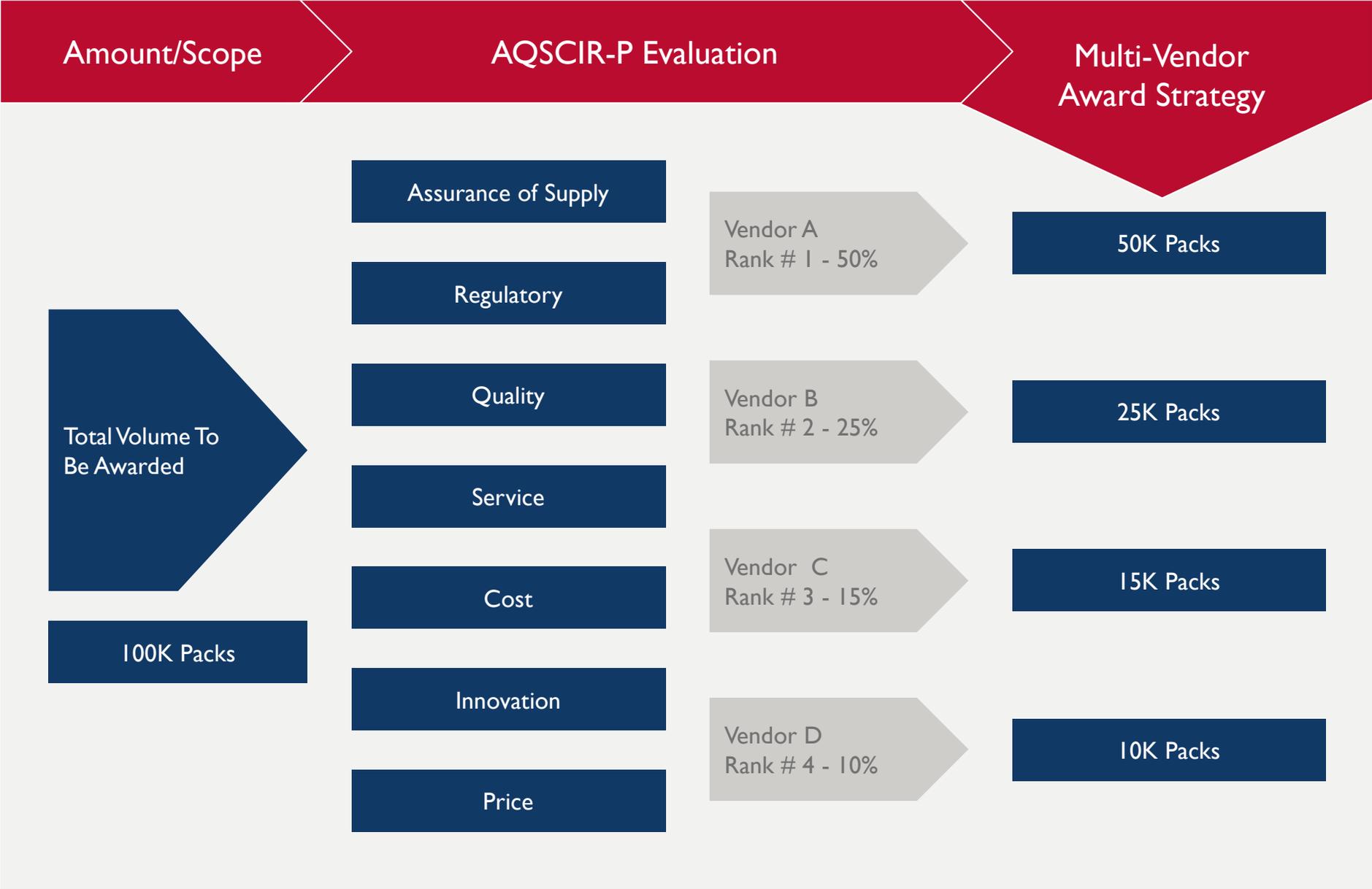
EXAMPLES

Assurance of Supply	<ul style="list-style-type: none">• 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



QUESTIONS?

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, maternal and child health, and reproductive health commodities.

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