SUPPLIER SUMMIT

USAID Global Health Supply Chain Program Supplier Summit
February 21-23, 2017
AN INTRODUCTION TO GHSC-PSM’S SUPPLY MANAGEMENT OF MALE AND FEMALE CONDOMS AND LUBRICANTS
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 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
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:

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Key questions and output metrics</th>
<th>Potential levers for market impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global capacity</td>
<td>Is there sufficient supply to meet demand?</td>
<td>• Closure of supply-demand gap</td>
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<tr>
<td></td>
<td>– Supply and demand gap</td>
<td>• Lead time reduction</td>
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<tr>
<td></td>
<td>– Existence of demand forecast</td>
<td>• Improved forecast accuracy</td>
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<td>– Forecast accuracy</td>
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<td></td>
<td>– Lead times, global level stock out rate</td>
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<tr>
<td>Affordability &amp; funding</td>
<td>Is pricing affordable?</td>
<td>• Sustained price decrease</td>
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<td></td>
<td>– Price relative to substitute and peer markets</td>
<td>• One-off gain from accelerating market transition</td>
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<td></td>
<td>– % Supply base utilized</td>
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<td></td>
<td>– Funding and demand gap</td>
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<tr>
<td></td>
<td>– Projected funding</td>
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<tr>
<td>Supply risk</td>
<td>Is there sustainable, secure supply of these products?</td>
<td>• Reduction in supplier concentration risk</td>
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<tr>
<td></td>
<td>– Number and diversity of suppliers</td>
<td>• New suppliers/sites</td>
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<td></td>
<td>– Margins/price relative to cost</td>
<td>• Improved registration coverage</td>
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<tr>
<td></td>
<td>– Product registration coverage</td>
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<tr>
<td></td>
<td>– Scalability of capacity</td>
<td></td>
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<tr>
<td>Product quality &amp; appropriateness</td>
<td>Are there quality products that meet user needs?</td>
<td>• Increased product effectiveness, safety and/or reduction in side effects</td>
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<td></td>
<td>– Effective products with regulatory approvals</td>
<td>• Increased R&amp;D pipeline</td>
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<td></td>
<td>– Quality of products</td>
<td></td>
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<td></td>
<td>– Appropriateness based on target customer needs</td>
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<td>– Incentives for innovating improved products</td>
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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

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Deputy Project Director

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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

Steve Hamel
Director
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
# GHSC-QA Activities and Objectives

## Quality Assurance
- Product reviews (product questionnaire/technical information)
- Eligible/approved supplier and product list
- Technical requirements and specifications for EOI, RFQ, and RFP
- 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

**Recipient Country**
- National Quantification
- Conducted annually with regular supply planning updates

**GHSC-PSM Global Supply Chain**
- Global Supply Chain Demand Plan
  - Product/Country Order Trending
  - Procurement Planning & Monitoring Reports (PPMR)
  - SPSS Statistics
  - Field Office Communications
  - Coordinated Supply Planning
  - RH Interchange

- Global Supply Chain Supply Plan
  - RDC Inventory
  - Supplier Lead Times
  - Logistics Lead Times
  - Open Purchase Orders
  - Open Country Orders
  - Coordinated Supply Planning

**Supplier Network**

**Procurement**

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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

- Firm Orders
- Add'l Forecast
- Incl. Pakistan

DELIVER/GHSC-PSM country orders by requested delivery date

Graph showing demand forecast from 2013 to 2018.
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

Firm Orders  Add'l Forecast

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

Firm Orders  Add'l Forecast  Incl. Pakistan

2013  2014  2015  2016  2017  2018
DEMAND FORECAST: FEMALE CONDOMS

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

DELIVER/IGHSC-PSM country orders by requested delivery date
DEMAND FORECAST: PERSONAL LUBRICANTS

Introduction of single country can significantly increase demand uncertainty

Firm Orders  Add'l Forecast  Incl. Ukraine  Fcst incl. Ukr

DELIVER/GHSC-PSM country orders by requested delivery date

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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

<table>
<thead>
<tr>
<th>Product</th>
<th>Registration Requirements</th>
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<tbody>
<tr>
<td><strong>Male Condom</strong></td>
<td>• Requirements differ by country</td>
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<tr>
<td></td>
<td>• Countries may only allow registration of one manufacturer per brand</td>
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<tr>
<td></td>
<td>• Local partner typically required</td>
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<tr>
<td><strong>Female Condom</strong></td>
<td>• Registration increasingly required</td>
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<tr>
<td></td>
<td>• Monitor and respond to new requirements</td>
</tr>
<tr>
<td><strong>Personal Lubricants</strong></td>
<td>• Registration not now typically required for USAID-supported countries</td>
</tr>
<tr>
<td></td>
<td>• Monitor and respond to new requirements</td>
</tr>
</tbody>
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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

<table>
<thead>
<tr>
<th>Product</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female Condoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long Term Agreement in place</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lubricant</td>
<td>Long Term Agreement(s) in place</td>
<td>Spot procurements</td>
<td>Long Term Agreement(s) in place</td>
</tr>
<tr>
<td>New tender strategy</td>
<td>Issue tender</td>
<td>Evaluate / award tenders</td>
<td>Sign contracts</td>
</tr>
<tr>
<td>Male Condoms</td>
<td>Long Term Agreement(s) in place</td>
<td></td>
<td>Long Term Agreement(s) in place</td>
</tr>
<tr>
<td>New tender strategy- VMI Services</td>
<td>Issue tender</td>
<td>Evaluate / award tenders</td>
<td>Sign contracts</td>
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**For informational purposes only; subject to change**
## EVALUATION CRITERIA (AQSCIR-P)

| Assurance of Supply          | • Production capacity  
|                             | • Quantity in stock (when required)  
|                             | • Past performance  
| Regulatory                  | • Administrative requirements  
|                             | • Registration in country  
| Quality                     | • QA requirements (USFDA, WHO, GHSC-QA)  
|                             | • Shelf life  
|                             | • Stability studies/climatic zone standards  
| Service                     | • Lead time (stock, fresh production)  
|                             | • Customer service  
|                             | • Product Identification  
| Cost                        | • Specific/Unique label language  
|                             | • Unique distribution requirements  
| Innovation                  | • Serialization  
|                             | • Packaging optimization  
|                             | • New/improved products  
| Price                       | • FCA Unit price  

**BEST VALUE AWARD STRATEGY TO ACHIEVE DESIRED MARKET OUTCOME**

Criteria and % Weights are Tailored to the Commodity and/or Product and Specific Sourcing Strategy
GHSC-PSM APPROACH FOR MULTI-VENDORS AWARD

<table>
<thead>
<tr>
<th>Amount/Scope</th>
<th>AQSCIR-P Evaluation</th>
<th>Multi-Vendor Award Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Volume To Be Awarded</td>
<td>100K Packs</td>
<td></td>
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<tr>
<td></td>
<td>Assurance of Supply</td>
<td>Vendor A Rank # 1 - 50%</td>
</tr>
<tr>
<td></td>
<td>Regulatory</td>
<td>50K Packs</td>
</tr>
<tr>
<td></td>
<td>Quality</td>
<td>Vendor B Rank # 2 - 25%</td>
</tr>
<tr>
<td></td>
<td>Service</td>
<td>25K Packs</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
<td>Vendor C Rank # 3 - 15%</td>
</tr>
<tr>
<td></td>
<td>Innovation</td>
<td>15K Packs</td>
</tr>
<tr>
<td></td>
<td>Price</td>
<td>Vendor D Rank # 4 - 10%</td>
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<tr>
<td></td>
<td></td>
<td>10K Packs</td>
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</tbody>
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Vendor Rankings:
- Vendor A: Rank # 1 - 50%
- Vendor B: Rank # 2 - 25%
- Vendor C: Rank # 3 - 15%
- Vendor D: Rank # 4 - 10%

Total Volume To Be Awarded: 100K Packs
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.