



SUPPLIER SUMMIT

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

SUPPLIER SUMMIT

USAID Global Health Supply Chain Program

TO REGISTER, OR NOT TO REGISTER!

Registration Information Management at GHSC-PSM and How To
Address Barriers to Registration at the Country Level



USAID
FROM THE AMERICAN PEOPLE



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



USAID
FROM THE AMERICAN PEOPLE

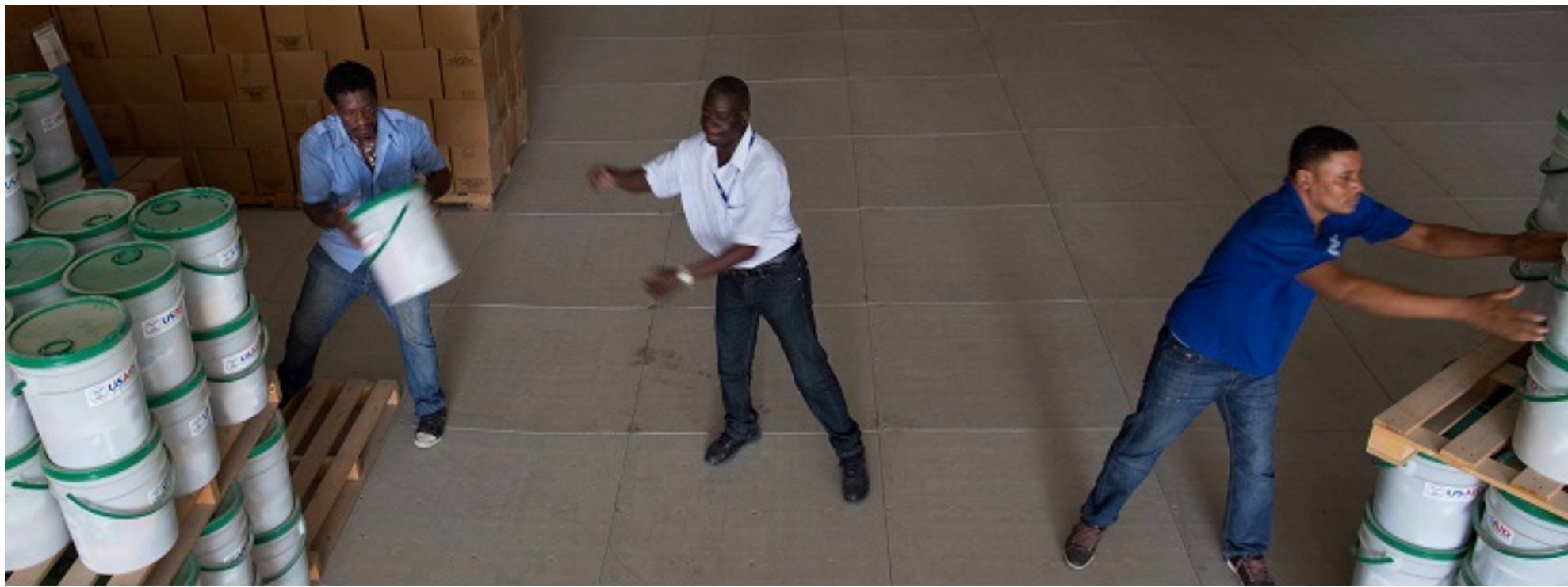


U.S. President's Malaria Initiative

BEFORE WE BEGIN...

DOWNLOAD THE SUMMIT APP:



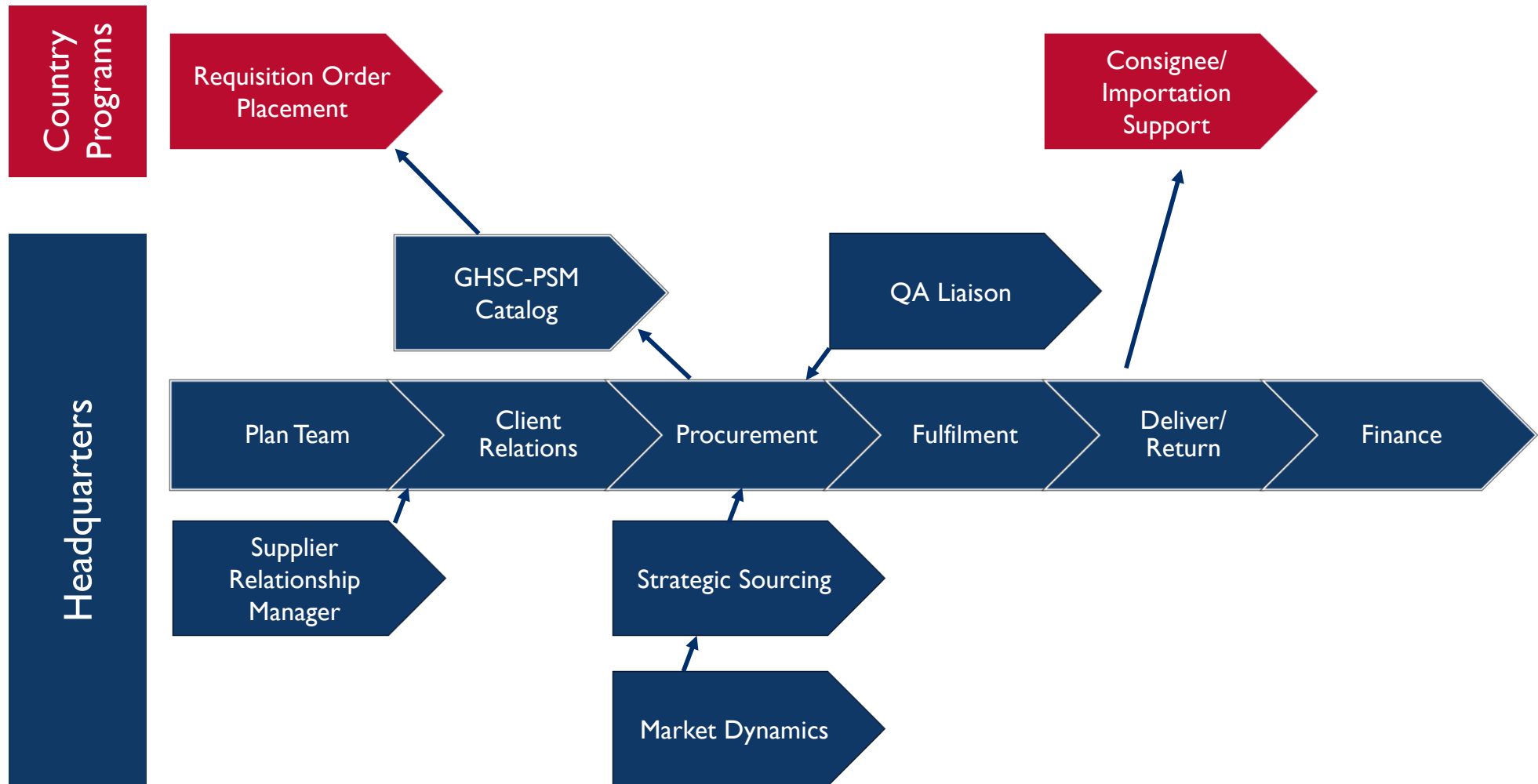


OBJECTIVES

- PART I: Develop a working partnership between GHSC-PSM and suppliers vis-à-vis registration
- PART II: Validate hypotheses regarding barriers and solutions to registration at the country level

PART I: DEVELOP A WORKING PARTNERSHIP BETWEEN GHSC-PSM AND SUPPLIERS

REGISTRATION INFORMATION IS USED THROUGHOUT THE GHSC-PSM SUPPLY CHAIN:



GETTING TO KNOW GHSC-PSM TEAMS

Demand & Distribution Planning

Plan Team

- Forecasting and supply management

Supplier Relationship Managers

- Primary point of contact for suppliers
- Organizes regular meetings

Client Relations Team

- Primary point of contact for clients
- Receive, review and validate orders

Country Programs

- GHSC-PSM Field Offices work with clients- USAID, MOH, etc. on procurement

Deliver/Return Team

Logistics

- Freight
- Reverse logistics as necessary

Procurement

Market Dynamics Team

- Conducts market research and analytics

Strategic Sourcing

- Works across functional areas to develop improved sourcing strategies

Procurement Team

- Conducts sourcing events
- Evaluates bids
- Awards sub-contracts

QA Liaisons

- Liaison between GHSC-PSM and GHSC-QA

Fulfilment Team

- Issues purchase orders to vendors
- Liaison with freight and delivery return team

EXERCISE 1: DIRECTIONS

- 1) Break into groups of 5-6 people (2 mins)
- 2) As a group, complete Exercise 1 on the worksheet by indicating which of these three divisions is responsible for each activity at GHSC-PSM: Demand and Distribution Planning, Procurement, or Logistics (4 mins)

EXAMPLE:

Select one: Demand and Distribution Planning, Procurement, or Logistics

Activity X: Evaluate the current registrations information by countries and products and works with USAID to determine the priorities.

Answer: PROCUREMENT

EXERCISE I: RESULTS

Demand Planning and Distribution

- **A:** Development of order requests, using the GHSC-PSM catalog
- **E:** Uses registration information to determine which suppliers' stock to pull from the RDC to fulfill purchase orders

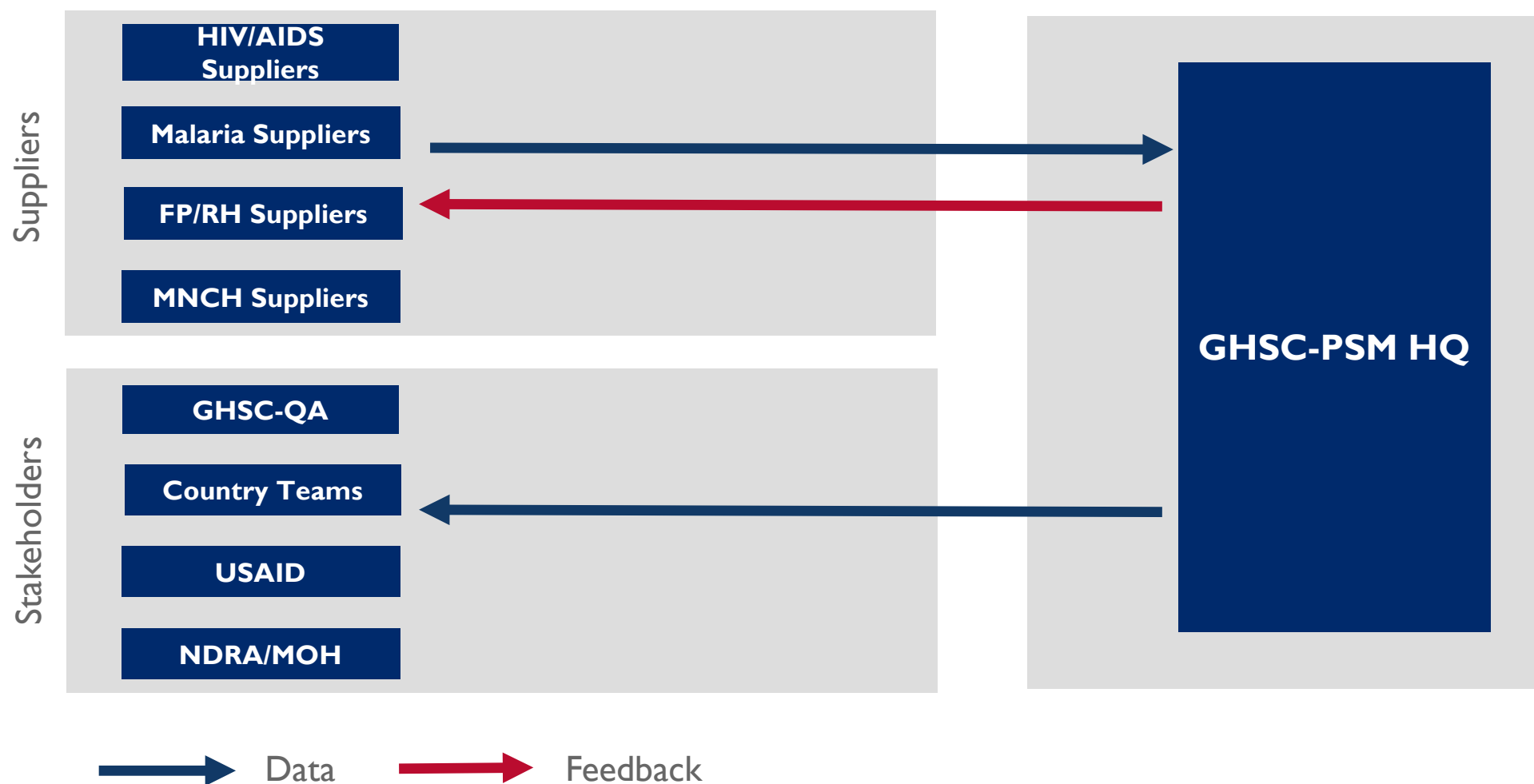
Procurement

- **B:** Registration information from each manufacturer is taken into account during the evaluation of a sourcing event.
- **C:** Works closely with manufacturers on a regular basis to understand changes to registration status
- **D:** Develops analysis to help determine the appropriate allocation % for IDIQ contracts, largely influenced by country registrations
- **G:** Uses registration data from prospective manufacturers to evaluate opportunities for improving supply security

Logistics

- **F:** Uses registration information to support the customs and importation processes and waiver based importation

REGISTRATION DATA FLOW



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REGISTRATION IS A PRIORITY FOR GHSC-PSM

- Management of registration information from suppliers *throughout the supply chain* is essential to ensure GHSC-PSM can provide product to recipients
- It is important to respect country NDA requirements
- GHSC-PSM/USAID is increasingly unable to secure waivers
- Disruptions in products creates risks throughout the supply chain



WHAT ARE SOME OF THE RISKS VIS-À-VIS REGISTRATION?

- Countries will stock out by the time we source an appropriate product, which puts lives at risk
- Products have to wait at the port while authorization is received from the country, incurring demurrage fees
- Obtaining waivers for multiple product-country combinations requires significant additional management costs and complexity to the GHSC-PSM program and USAID missions, which is unsustainable

What are some additional risks to GHSC-PSM, the supplier, and/or to the recipient?

GHSC-PSM REGISTRATION STRATEGY



Overall Goals:

- ✓ Reduction of supply-related issues due to registration
- ✓ Productive and positive working relationship with suppliers that achieves best value for USAID and clients at the country level in both the short- and long-term
- ✓ Efficient use of USAID, supplier, and GHSC-PSM time and resources vis-à-vis registration

REGISTRATION PRIORITIZATION CATEGORIES AND DEFINITIONS

USAID Supported Countries

Tier 1 (Highest Priority)

- Registration is required
- Product/brand not registered by any suppliers
- Knowledge of future demand
- Recent historical demand (within the past 4 years)

Tier 2

- Registration is required
- Product/brand is registered by one supplier
- Knowledge of future demand
- Recent historical demand (within the past 4 years)

Tier 3

- Registration is required
- Product/brand is registered by multiple suppliers
- No knowledge of future demand
- Recent historical demand (within the past 4 years)

Registration Priorities: Example Oral Contraceptives

High		Medium	
Bangladesh	Mozambique	Cambodia	Mali
Benin	Nepal	DRC	Rwanda
Ethiopia	Niger	Guinea	Senegal
Ghana	Nigeria	Madagascar	Tanzania
Haiti	Togo	Malawi	
Kenya	Uganda		
Zambia			

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

WHAT REGISTRATION INFORMATION DOES GHSC-PSM NEED?

GHSC-PSM needs accurate and updated information regarding:

Priority information:

- The specific countries and products that are registered
- The expiration dates for each registration
- Corresponding registration NDA numbers

Other information:

- Countries where registration has been submitted
- Countries where registration submissions are imminent
- Interest in leveraging the WHO collaborative procedure or regional harmonization initiatives

EXERCISE 2: APPROACHES TO DATA MANAGEMENT

At your table, in groups of 8 to 10 people, provide a consensus response to the following questions, referring to the data on the previous slide (10 min):

- 1) How often should we collect this data from manufacturers?
- 2) How should we validate this data from manufacturers?
- 3) What would be an ideal interface for data capture?
- 4) What are your recommendations for data storage?
- 5) Are there any processes or touchpoints with manufacturers that GHSC-PSM can streamline?

You will have **2 minutes per question**. Please write the consensus response to each question **separately** on the Post-its provided. Please place the Post-its on the appropriate place on the wall.

PLENARY DISCUSSION

What ideas do you have for GHSC-PSM that would encourage you to register?

How can we better approach data management?

PART II: REDUCING BARRIERS TO COUNTRY REGISTRATION

BARRIERS TO REGISTRATION AT THE COUNTRY LEVEL

1. Lack of information to build a business case for investment in particular countries
2. Lack of clarity on and understanding of country specific dossier requirements
3. Lack of clarity on the regulatory landscape in critical regions such as sub-Saharan Africa
4. Lack of well qualified local agents/representatives
5. Total cost of achieving and maintaining country registration
6. Lack of knowledge and information regarding collaborative procedures and harmonization initiatives
7. Overall registration processes take too long (NDRAs lack resources)

What are some additional barriers to registration at the country level?

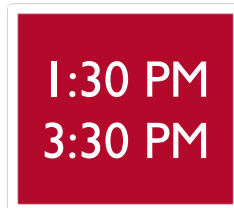
EXERCISE 3: PRIORITIZING WHICH BARRIERS TO MINIMIZE



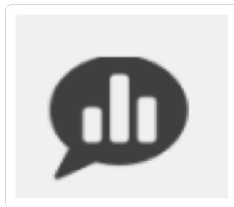
Log into the app



Click the schedule icon



Select Wednesday, February 22, then select Product Registration



Scroll down to Live Polls

QUESTION 1: CHECK ALL THAT ARE A PRIORITY



1. Lack of information to build a business case for investment in particular countries
2. Lack of clarity on and understanding of country-specific dossier requirements
3. Lack of clarity on the regulatory landscape in critical regions such as sub-Saharan Africa
4. Lack of well qualified local agents/representatives
5. Total cost of achieving and maintaining country registration
6. Lack of knowledge and information regarding collaborative procedures and harmonization initiatives

QUESTION 2: CHECK ALL THAT ARE ***NOT*** A PRIORITY



1. Lack of information to build a business case for investment in particular countries
2. Lack of clarity on and understanding of country-specific dossier requirements
3. Lack of clarity on the regulatory landscape in critical regions such as sub-Saharan Africa
4. Lack of well qualified local agents/representatives
5. Total cost of achieving and maintaining country registration
6. Lack of knowledge and information regarding collaborative procedures and harmonization initiatives

EXERCISE 3: SOLUTIONS TO BARRIERS



- 1) Consider which items you listed as the top 3 priorities.
- 2) Take **1 minute** and write down as many solutions as possible that any stakeholder in the global community could implement to reduce these 3 barriers. Write each one on a separate sticky note.
- 3) With the person next to you take **2 minutes** to share your solutions and select the **top 2** solutions in terms of feasibility, impact, and cost.
- 4) Share these solutions with the rest of the people at your table and determine the **top 3** solutions in terms of feasibility, impact, and cost in **5 minutes**.
- 5) Bring these to the front of the room, ensuring that you have indicated (by number) which barrier it addresses.

PLENARY DISCUSSION

What are some SOLUTIONS to reducing barriers in USAID-supported countries?

NEXT STEPS:

- Survey will be sent out in Q2 2017 to all suppliers with an aim to solicit additional solutions
- Communications on priorities?
- Want to become more involved with GHSC-PSM?

Please email an expression of interest to Anita Deshpande -
adeshpande@ghsc-psm.org

THANK YOU!

Siobhan Perkins, Procurement, GHSC-PSM

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Anita Deshpande, Market Dynamics, GHSC-PSM

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APPENDIX

POLL RESULT: TOP PRIORITIES

<https://api.cvent.com/polling/v1/api/polls/sp9nx5g4>

POTENTIAL SOLUTIONS

Barriers	Solutions
1. Priorities	
2. Business case	<ul style="list-style-type: none"> - Leverage a global initiative to achieve scale with transparency - Approach suppliers to build the business case for them (or explain how they can build it using available data)
3. Confusing dossiers	<ul style="list-style-type: none"> - Support global movement toward single-submissions (multi-country). Improve challenges around e-submissions (e.g., common technical dossier) - Build a website detailing requirements for each country and sustain it through advertisements and subscriptions - Partner with other orgs that have ongoing activities of publishing regulatory requirements (build business case)
4. Complex regulatory landscape	<ul style="list-style-type: none"> - MSI training for manufacturers - Training for agents in Africa - Partner manufacturers with orgs that are aware of regs in the priority countries to learn from them (business model?)
5. Local agents/ reps	<ul style="list-style-type: none"> - Create a list of qualified CSOs that are QA certified (ask Aida for list?) - Country office to scope consultant who can be used as local agent and navigate the environment - Partner Manufacturers with orgs that are aware of regs in the priority countries (create a business model for these orgs to provide the service?)

POTENTIAL SOLUTIONS (CON'T)

Barriers	Solutions
6.Total cost	
7. Collaborative procedures	
8. Harmonization initiatives	
9. Other resources?	
10.Takes too long	

INPUT TBD FROM NOTES

ADDITIONAL REGISTRATION ACTIVITIES



EXERCISE 2: DIRECTIONS

- 1) With the person sitting next to you, list ways in which suppliers and GHSC-PSM both benefit from products being registered (on the worksheet). Each item should be less than 5 words. (60 seconds)
- 2) With a group of 10, share your ideas and identify 2-3 key areas where GHSC-PSM and suppliers have a common interest. Add these responses to your worksheet. Also write each one on a separate large sticky note.
- 3) As you finish, have one member of the group come to the front table and place the sticky note next to other common themes.