



# SUPPLIER SUMMIT

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

# SUPPLIER SUMMIT

USAID Global Health Supply Chain Program

## ESSENTIAL MEDICINES



**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

## AGENDA

- Historical Overview of Essential Medicines
- GHSC-PSM Essential Medicines Sourcing Strategy
- GHSC-PSM Strategic Sourcing Priorities
- Quality Assurance for Essential Medicines

# HISTORICAL OVERVIEW

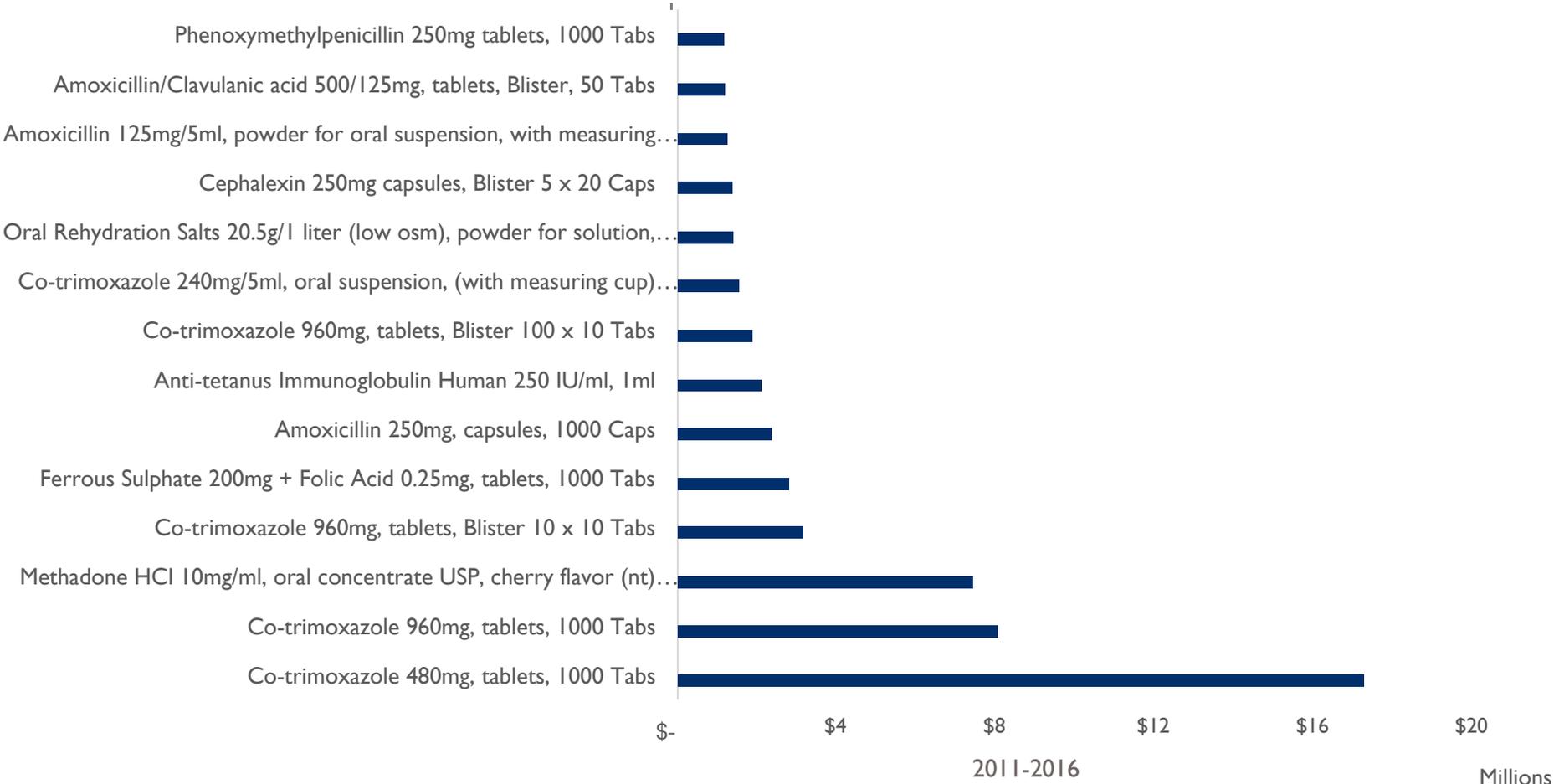
# ESSENTIAL MEDICINES PORTFOLIO

*Essential medicines are those that satisfy the priority health care needs of the population*

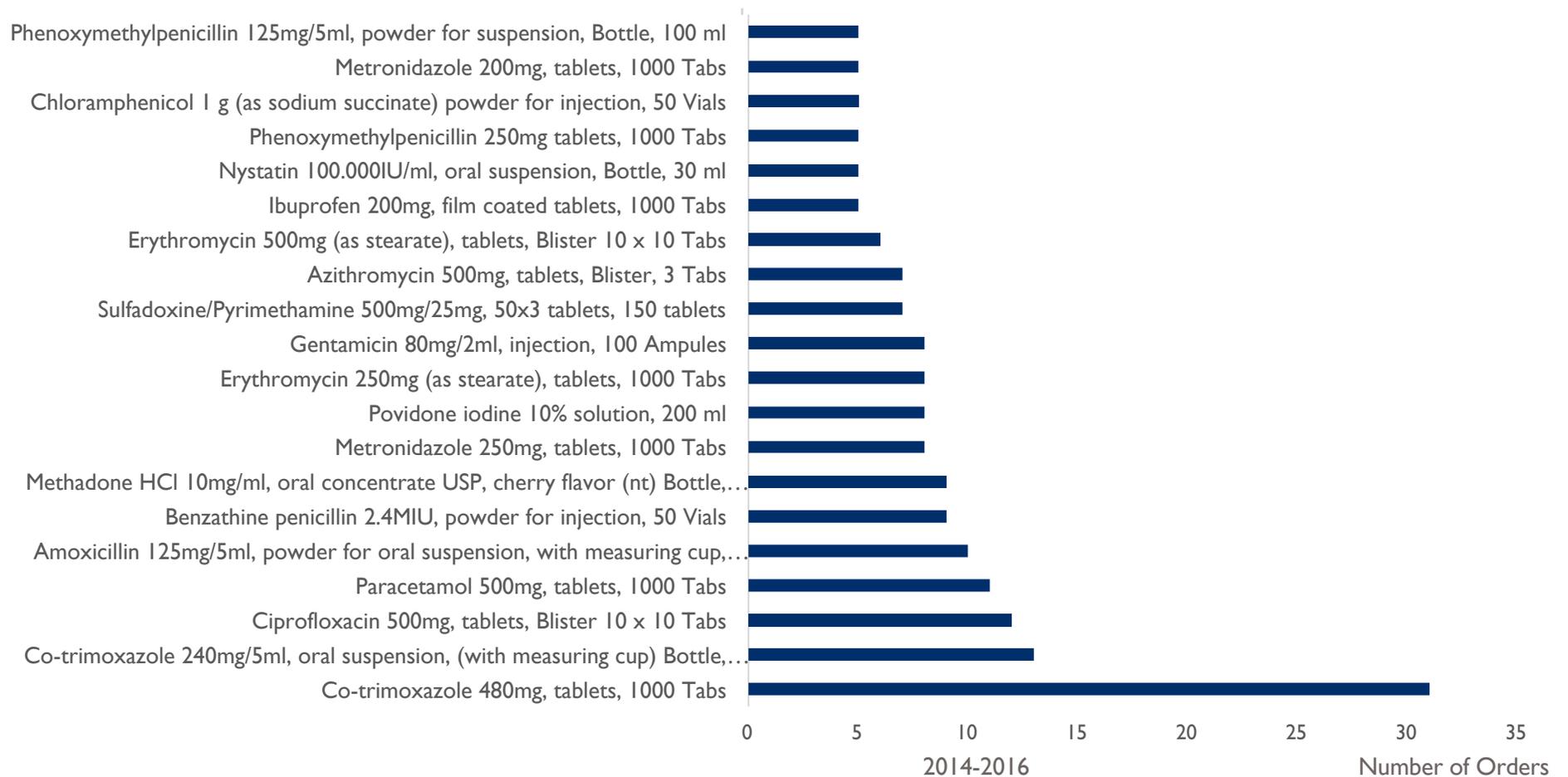
GHSC-PSM categorizes essential medicines across task orders as follows:

- Task Order 1 (HIV/AIDS)
  - 500+ essential medicines
- Task Order 2 (Malaria)
  - Malaria essential medicines: Quinine, SP, Rectal Artesunate, Artemether Injectable
- Task Order 3 (Population and Reproductive Health)
  - None
- Task Order 4 (Maternal, Newborn, and Child Health)
  - 500+ essential medicines.
  - Focus on 9 products: Oxytocin, Misoprostol, Magnesium sulfate, Injectable antibiotics, Antenatal corticosteroids (ANCS), Chlorhexidine, Amoxicillin, Oral rehydration salts (ORS), Zinc

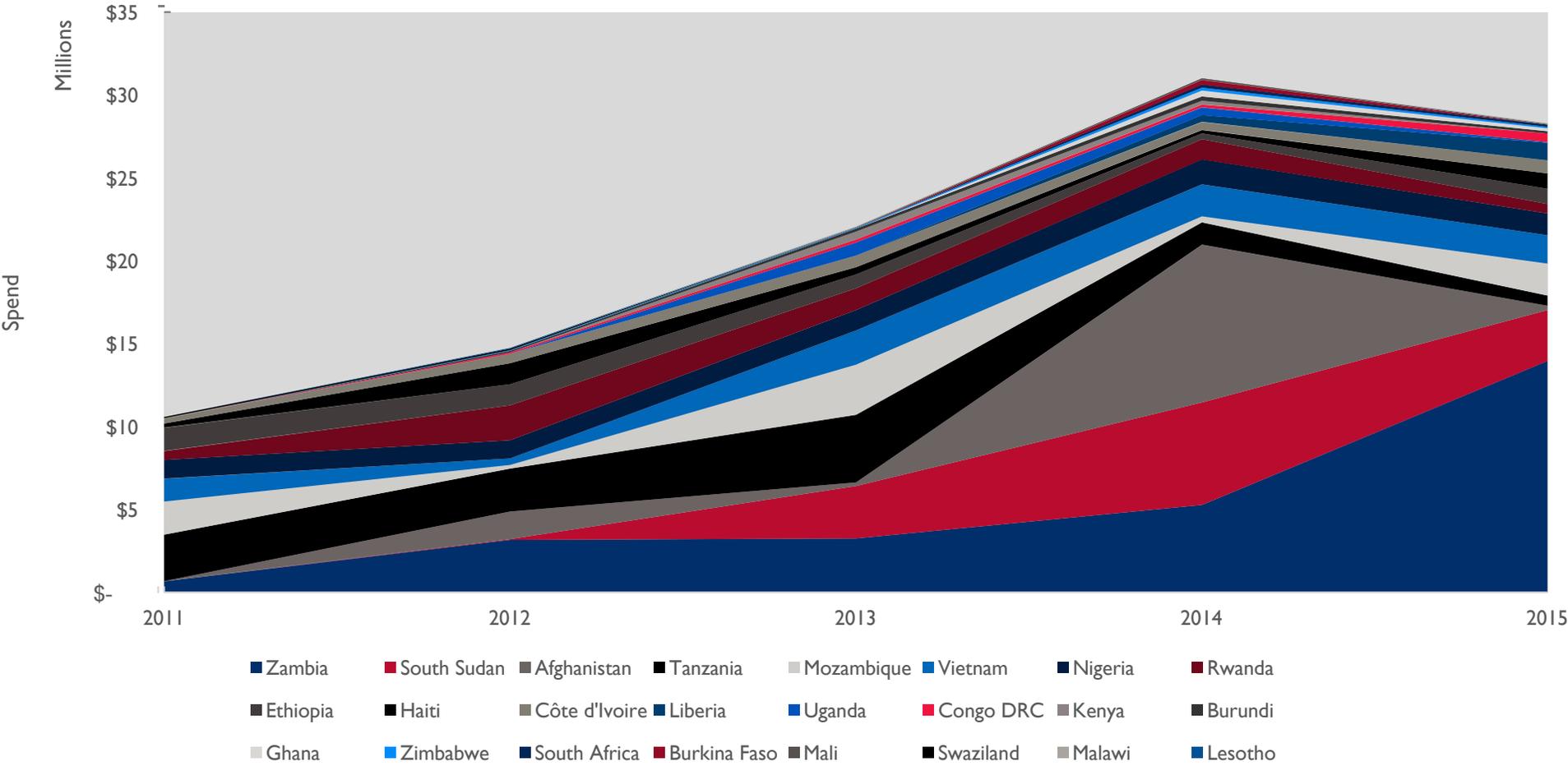
# HIGHEST HISTORICAL ESSENTIAL MEDICINES BY VALUE



# MOST FREQUENTLY ORDERED ESSENTIAL MEDICINES



# HISTORICAL SPENDING BY COUNTRY



# GHSC-PSM SOURCING STRATEGY: ESSENTIAL MEDICINES

**SUPPLIER  
SUMMIT**

USAID Global Health Supply Chain Program Supplier Summit



## GOAL

To reduce supply chain risk through a solid understanding of the supply base of quality-assured products and an optimal sourcing strategy.

# GHSC-PSM ESSENTIAL MEDICINES SOURCING STRATEGY

- Phase One: Spot procurements
- Phase Two: International wholesalers
- Phase Three: Framework agreements with suppliers for select products
- Phase Four: Local solutions



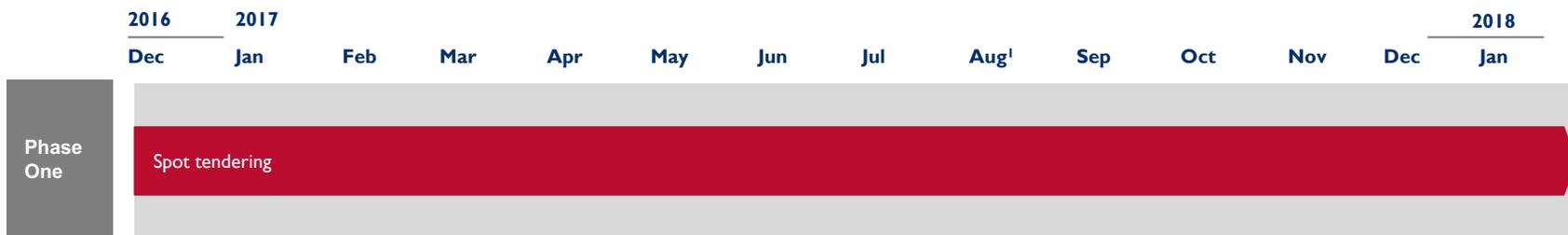
# PHASE ONE: SPOT PROCUREMENTS

## Overview:

- Respond to order requests as they are received from clients
- Issue Request for Quotes (RFQs) for single orders or combination of multiple country orders separated by lot

## To Date:

- ✓ 271 line items requested
- ✓ 76 purchase orders issued to date



# GHSC-PSM ESSENTIAL MEDICINES SOURCING STRATEGY

- Phase One: Spot procurements
- Phase Two: International wholesalers
- Phase Three: Framework agreements with suppliers for select products
- Phase Four: Local solutions



# PHASE TWO: INTERNATIONAL WHOLESALERS

## Overview:

- Establish agreements with USAID-approved international wholesalers for a range of essential medicines with fixed unit prices
- GHSC-PSM will utilize agreements with international wholesalers for small procurements estimated to be under \$150k
- For high volume, high value products, GHSC-PSM will conduct separate sourcing events



# GHSC-PSM ESSENTIAL MEDICINES SOURCING STRATEGY

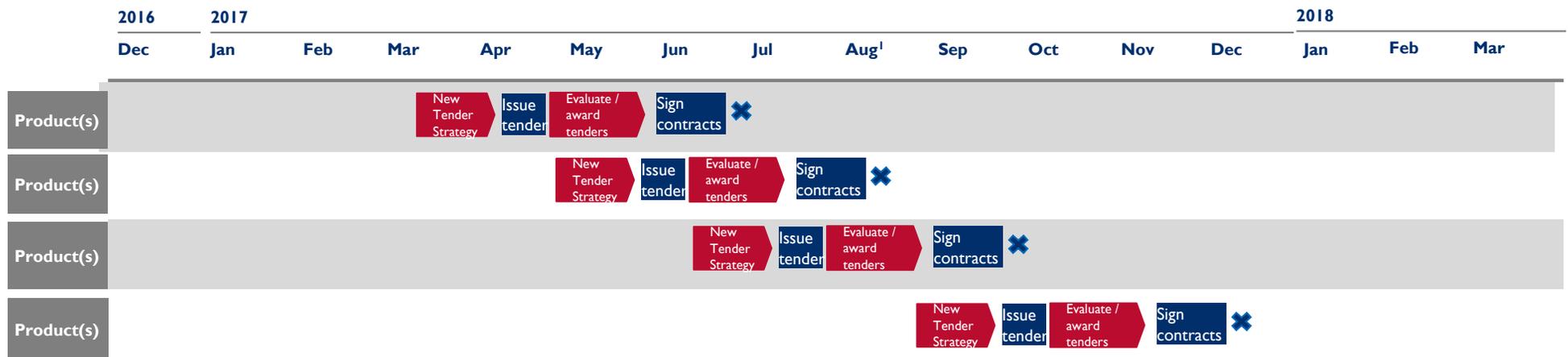
- Phase One: Spot procurements
- Phase Two: International wholesalers
- Phase Three: Framework agreements with suppliers for select products
- Phase Four: Local solutions



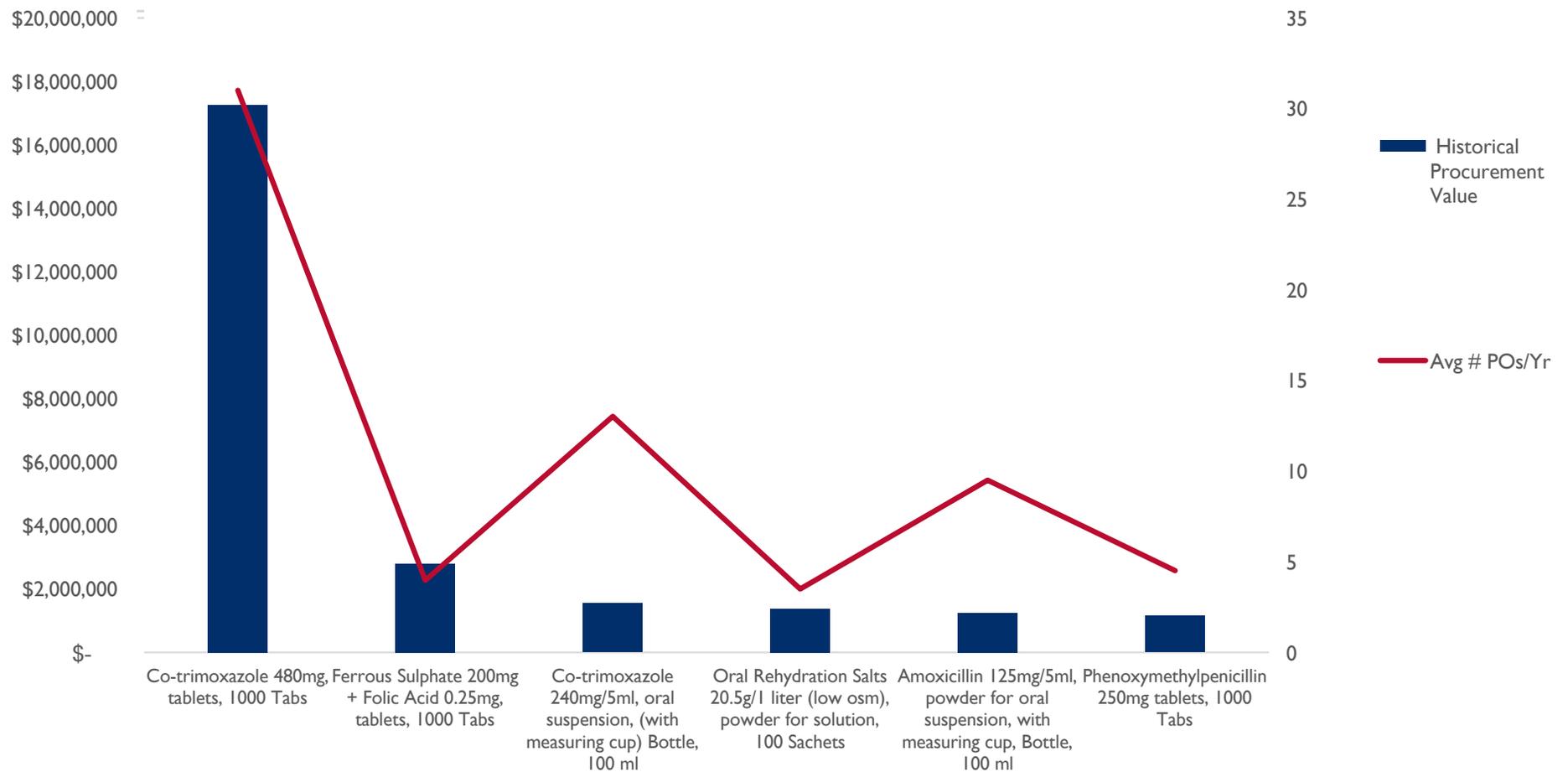
# PHASE THREE: FRAMEWORK AGREEMENTS

## Overview:

- Determine select products for framework agreements by conducting a commodity profile and spend analysis based on value, volume, order frequency, and other USAID product priorities
- Consider country-specific demands and requirements
- Conduct market research to strengthen understanding of market and suppliers for priority products
- Initiate sourcing events and evaluate based on best value
- Establish framework agreements with manufacturers and/or wholesalers for a minimum of one year with specified quantities

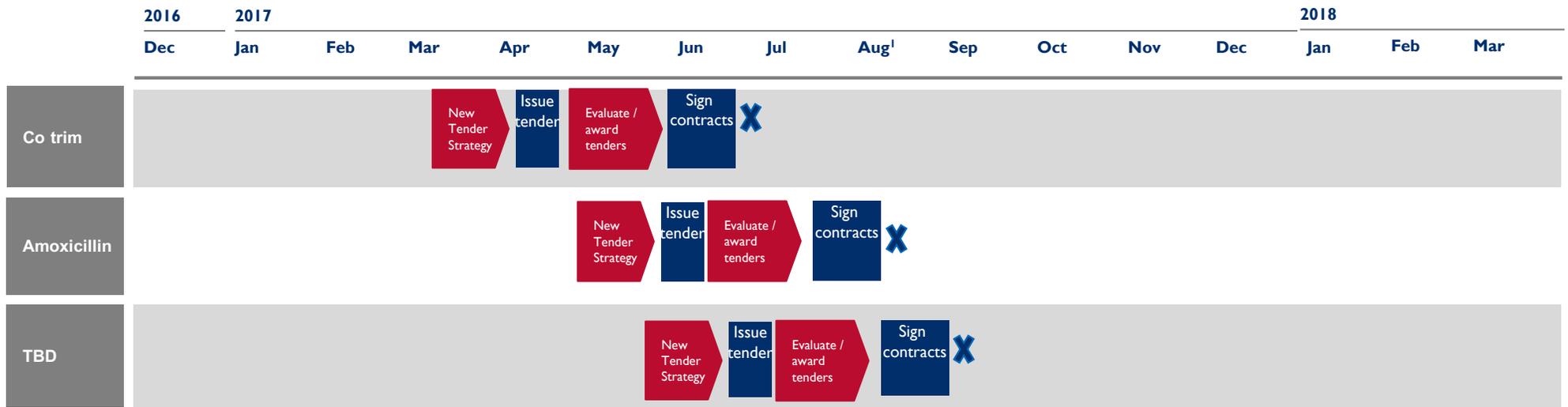


# HIGH VALUE & HIGH ORDER FREQUENCY PRODUCTS



# SELECTED PRODUCTS FOR FRAMEWORK AGREEMENTS

1. **Co-trimoxazole:**
  - Co-trimoxazole 480mg, 1000 Tablets
  - Co-trimoxazole 960mg, dispersible, 1000 Tablets
  - Co-trimoxazole 960mg, non-dispersible
  - Co-trimoxazole 120mg, dispersible
2. **Amoxicillin:**
  - Amoxicillin 250mg, capsules, 1000 capsules
3. **To be determined**



# GHSC-PSM ESSENTIAL MEDICINES SOURCING STRATEGY

- Phase One: Spot procurements
- Phase Two: International wholesalers
- Phase Three: Framework agreements with suppliers for select products
- Phase Four: Local solutions



# PHASE FOUR: LOCAL SOLUTIONS

## Overview:

- Identify demand for procurement from local sources
- With USAID and GHSC-QA, prioritize products based on classification, e.g., life-saving essential medicines, local availability of quality-assured products and other considerations
- Conduct supply base analysis to identify local/regional manufacturers and wholesalers
- Procure from quality-assured local suppliers to promote sustainability and growth in USAID-supported countries
- Challenge: lengthened sourcing process and high quality assurance costs



# EVALUATION CRITERIA (AQSCIR-P)

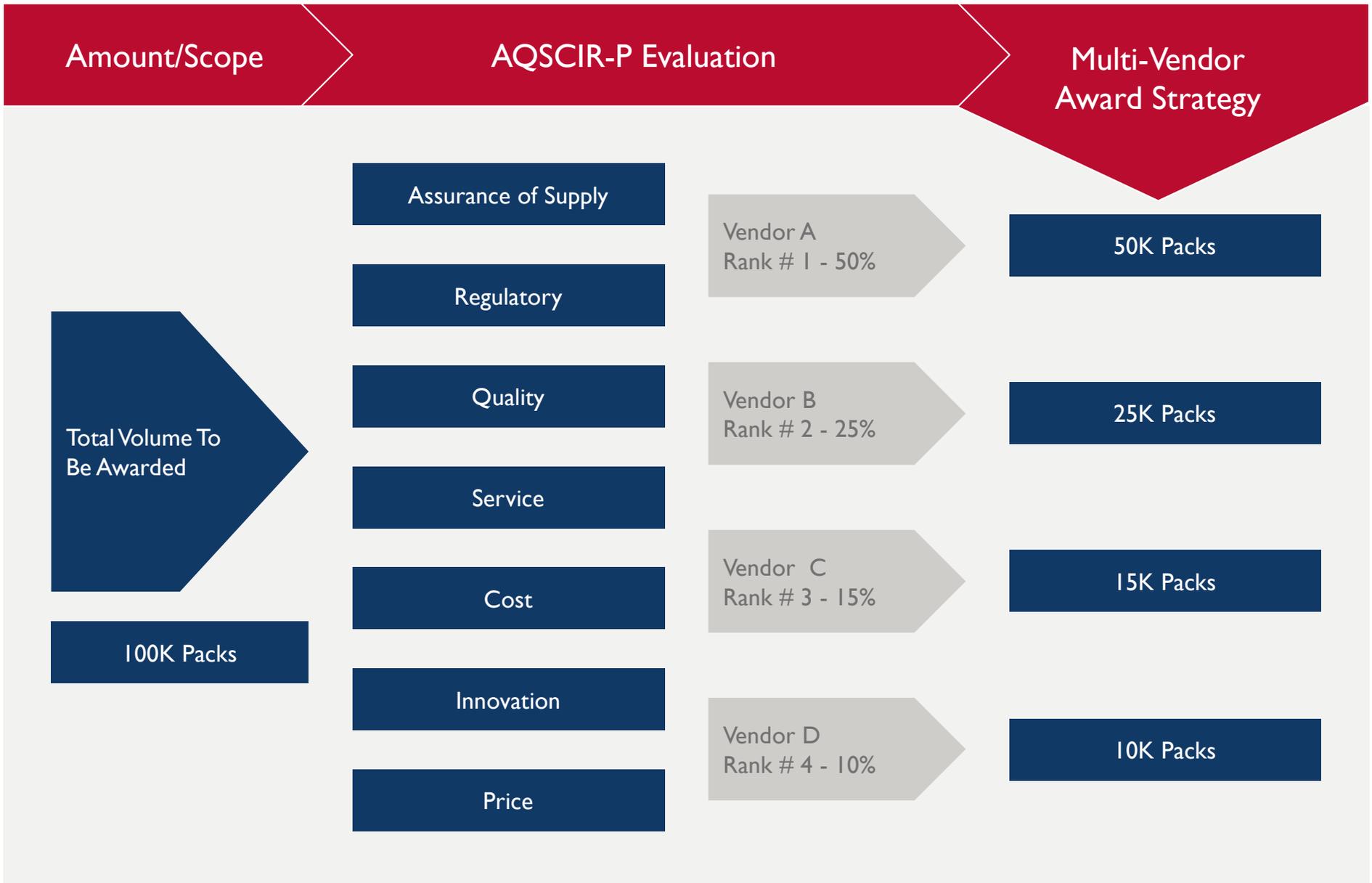
EXAMPLES

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



# ELIGIBILITY AND GENERAL QUALITY ASSURANCE REQUIREMENTS

# USAID (ADS 312) ELIGIBILITY OF COMMODITIES

## Stringent Regulatory Authority (SRA)

- USAID recognizes the following:
  - (a) the U.S. Food and Drug Administration, the Japanese Ministry of Health, Labor, and Welfare and the European Agency for the Evaluation of Medicinal Products (EMA) centralized procedure;
  - b) SwissMedic or Health Canada
  - (c) European Union member states admitted prior to 1996 (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom).

## WHO Pre qualification

- WHO ERP 1 or 2 considered only in special cases

## Approved USAID Wholesalers

- Approved by GHSC-QA to provide essential medicines, laboratory supplies and medical equipment

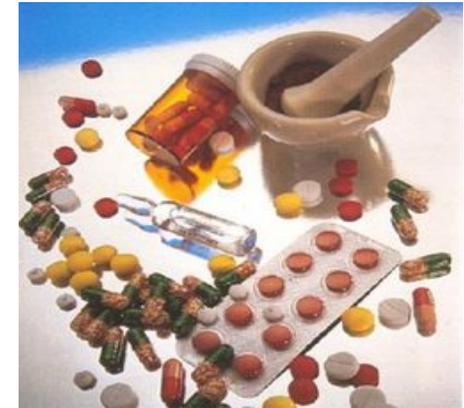
## Other

- Pharmaceuticals that do not qualify under any of the above categories
- Require additional quality information
- Assessment conducted by GHSC-QA based on risk analysis
- Additional quality testing by independent accredited laboratory

# ESSENTIAL MEDICINES (PHARMACEUTICALS)

## Eligibility Requirements

- SRA
- WHO-PQ
- Approved USAID wholesalers
- Other- GHSC-QA process
  - GHSC-QA technical evaluation required
  - Abbreviated for SRA and WHO PQ products
  - Full review for non-SRA, non-WHO-PQ



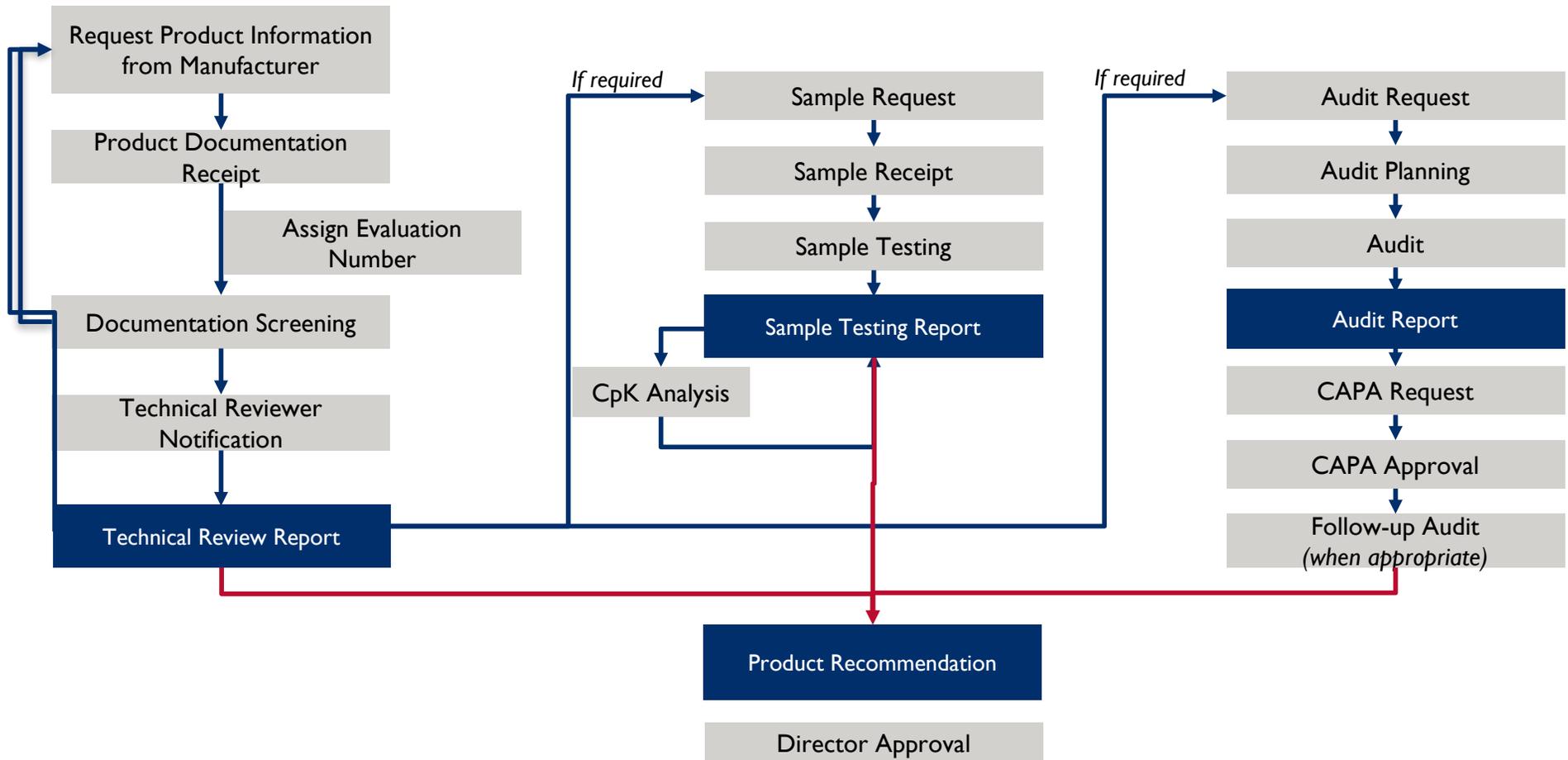
## QA and QC Activities

- Compliant cGMP, QMS and/or MQAS audits
  - Frequency dependent on regulatory status and/or risk assessment
- CoA review required for each lot
- Pre-shipment, concurrent, or post-shipment testing depending on risk assessment



# PRODUCT ASSESSMENT (APPROVAL PROCESS)

The Product Assessment is a comprehensive evaluation of the product and manufacturer.



# PHARMACEUTICAL TECHNICAL QUESTIONNAIRE

1.0	APPLICANT INFORMATION.....	3
2.0	PRODUCT IDENTIFICATION .....	4
3.0	FPP MANUFACTURER INFORMATION .....	5
3.1	FPP Manufacturer Identification .....	5
3.2	FPP Manufacturing Activities.....	5
3.3	FPP Good Manufacturing Practice (GMP) Inspections .....	5
4.0	FINISHED PHARMACEUTICAL PRODUCT .....	6
4.1	Product Formulation .....	6
4.2	FPP Specifications .....	6
4.3	Method of Manufacture and Process Validation .....	6
4.4	Sterile Aspects of the Product .....	6
4.5	FPP Packaging .....	7
4.6	FPP Shelf-life and Storage Conditions .....	7
5.0	ACTIVE PHARMACEUTICAL INGREDIENT(S).....	9
5.1	API Details and Manufacturer Identification .....	9
5.2	API Manufacturing Activities .....	9
5.3	API Good Manufacturing Practice (GMP) Inspections .....	9
5.4	API Specifications .....	9
5.5	API Regulatory and Licensing Status .....	10
6.0	SAFETY AND EFFICACY AND/OR THERAPEUTIC EQUIVALENCE .....	11
6.1	For FPPs approved by Stringent Regulatory Authorities.....	11
6.2	For Generic Product: Therapeutic Equivalence Information .....	11
7.0	FPP REGULATORY AND LICENSING STATUS .....	13
7.1	Licensing Status .....	13
7.2	Certificate of Pharmaceutical Product (CPP).....	13
7.3	Stringent Regulatory Authority (SRA) Approval Status.....	13
7.4	WHO Prequalification Status .....	14
7.5	Registration status .....	14
8.0	SAMPLES FOR TECHNICAL EVALUATION .....	15
9.0	CHECKLIST OF ATTACHMENTS .....	16
10.0	AUTHORIZATION AND COMMITMENT .....	17
10.1	Authorization for sharing information with other Agency(ies) .....	17
10.2	Commitment.....	18

\*There are other GHSC-QA Product Questionnaires for Medical Devices, RTKs, Food by Prescription

# PRODUCT/MANUFACTURER CHANGES: MAJOR VARIATIONS MUST BE COMMUNICATED TO GHSC-QA

## Applies To

- Products approved for direct procurement
- Documentation required: Refer to Annex 3:WHO guidelines on variations to a prequalified product for pharmaceutical variations  
[http://apps.who.int/prequal/info\\_general/documents/TRS981/TRS981\\_annex3.pdf](http://apps.who.int/prequal/info_general/documents/TRS981/TRS981_annex3.pdf)

## Example of Major Variations

- Replacement or addition of a new manufacturing site or manufacturer
- Changes in the composition, manufacturing process, or lot size
- Changes in the standard claimed, specifications, or analytical procedures
- Changes in the immediate packaging (primary and functional secondary components) for the storage and shipment
- Change to an administration or measuring device
- Changes in the labeled storage conditions, shelf-life, or the in-use period

# GHSC-PSM STRATEGIC SOURCING PRIORITIES: ESSENTIAL MEDICINES

**SUPPLIER  
SUMMIT**

USAID Global Health Supply Chain Program Supplier Summit

# BIGGEST CHALLENGES WITH ESSENTIAL MEDICINES

Challenges

- Manufacturing lead times
- Shelf life
- Label language
- Packaging
- Stability data
- Registration

# GHSC-PSM ENGAGEMENT ON COUNTRY REGISTRATION

## Supplier Engagement:

- Develop strong understanding of supplier capacity, priorities, and interest
- Communicate country and product priorities with current and potential future suppliers
- Maintain continuous communication with current suppliers on registration statuses

## Global Initiatives:

- Define GHSC-PSM level of engagement on initiatives such as the African Medicines Regulatory Harmonisation Programme (AMRH) and WHO collaborative procedures

For more information, please attend the “Product Registration” session

# REGISTRATION PRIORITIES FOR ESSENTIAL MEDICINES

- Haiti



- Nigeria
- South Sudan
- Tanzania
- Uganda
- Zambia
- DRC
- Ethiopia
- Malawi
- Mozambique



# 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



## INTERESTED IN BECOMING A SUPPLIER? LET US KNOW!

Please email expression of interest to [sperkins@ghsc-psm.org](mailto:sperkins@ghsc-psm.org) with expression of interest.

**SUPPLIER  
SUMMIT**

USAID Global Health Supply Chain Program Supplier Summit

# THANK YOU!

Siobhan Perkins, Sourcing, GHSC-PSM  
sperkins@ghsc-psm.org

Robert (Butch) Staley, Market Dynamics, GHSC-PSM  
rstaley@ghsc-psm.org

Chryste Best, GHSC-QA  
cbest@fhi360.org

**SUPPLIER  
SUMMIT**

USAID Global Health Supply Chain Program Supplier Summit