PFSCM
Partnership for Supply Chain Management

Quality assurance of essential medicines (when prequalified products are not available)

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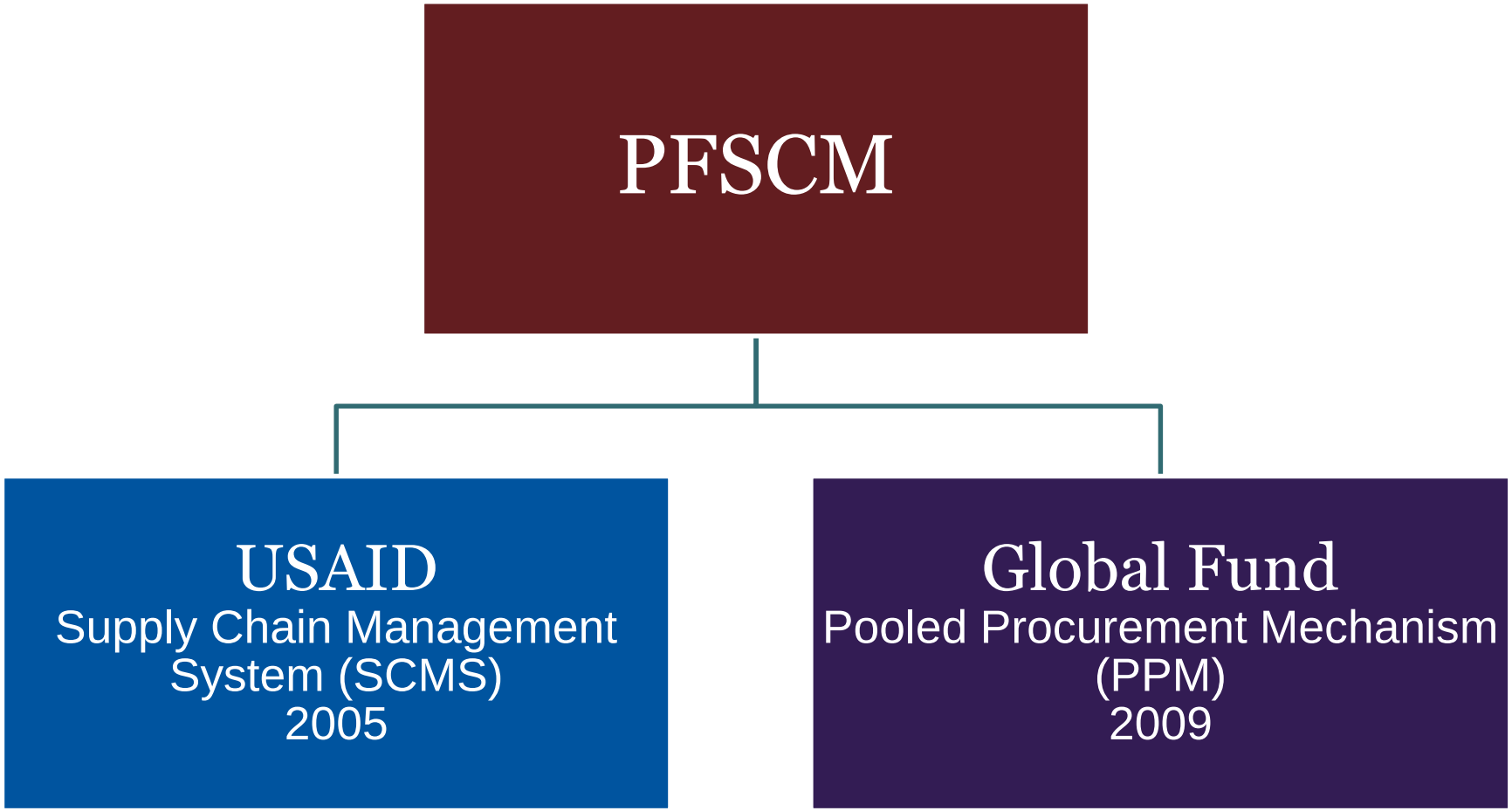
PFSCM was established in 2005 to bid on the SCMS contract, but our work is expanding



Our public-private partnership brings multi-sectoral non-profit and commercial expertise

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PFSCM's approach to procuring essential medicines

- PFSCM actively procures essential medicines and uses a quality assurance process which was developed in collaboration with USAID

Approach

- Strategic sourcing identifies relevant products and potential supply sources per country
- Potential vendors are pre-screened
- Once a request for products is received:
  - The Procurement Unit, through a competitive process, invites companies to provide an expression of interest and submit product information
  - Product approval is conducted independently from procurement
  - Technical product information is handed over to the Quality Assurance Unit

Product approval process

The Quality Assurance Unit conducts the following activities prior to product approval:

- **Document review to evaluate the suitability of the manufacturer**
  - Review of manufacturing site GMP certification and corresponding inspection reports (SRA or WHO cGMP),
  - Initial sample analysis
  - If SRA or WHO cGMP compliance cannot be confirmed, a PFSCM-led site inspection is performed
- **Document review to evaluate the suitability of the product pharmaceutical product dossiers**
  - Determines if there is sufficient documentation to support approving a pharmaceutical product from a specific manufacturing site or from a specific procurement agent
  - Includes: COA, copies of labeling, product stability data, registration certificates

Post product approval: Product and supplier monitoring

- Products are classified by potential risk to the patient
- Suppliers are classified by the regulatory agency that performed the on-site inspection and approved the GMP compliance (see risk tables)
- Routine sampling frequency = Product risk * Supplier risk
- Compliance investigations
- Regular supplier re-evaluations

Product risk table

Pharmaceutical quality patient risk table - Sampling and testing frequency				
Product Category	**Examples**	**Potential Patient Risks**	**Non-compliant product risk to patient**	**#**
Injectable products	Oxytocin, Lidocaine	Potential sterility, endotoxin issues	Very high likelihood of infection, severe illness/injury or death.	5
Sterile ointments, ophthalmic drops	Tetracycline Eye Ointment	Potential sterility issues; could lead to infection or blindness	High likelihood of severe reaction or injury.	4
Narrow therapeutic index products	Digoxin, Warfarin sodium	Difficult to manufacture; inconsistencies in dosage could result in toxic levels of API		
Oral anti-infective products	Amoxicillin, Fluconazole , Lamivudine-Zidovudine*	Products are relatively straightforward to manufacture; however low dosage could result in resistance.	Moderate risk.	3
Other oral products	Aspirin, Paracetamol	No response, symptoms not alleviated.	Minimal risk	2
Topical products	Gentian violet, Hydrocortisone ointment, Povidone-Iodine	Symptoms not alleviated, risk of infections if not compliant, possible hypersensitivities.	Low risk to patient or disease resistance.	1

Supplier risk table

Source Description	Relative Risk
US FDA/SRA Approved/WHO Prequalified Pharmaceutical Products	Low – 1
Grade A Pharmaceutical Wholesaler	Med Low – 2
Grade B Pharmaceutical Wholesaler: SRA Approved/WHO Prequalified Products	
SRA or WHO GMP Inspected and Approved Pharmaceutical Manufacturing Site (Not product specific)	
Food by Prescription Supplier	
VMMC Kit Supplier	
Laboratory Commodity Supplier (Diagnostic Test Kits, Blood bags, Needles/Syringes, Gloves)	
Grade C Pharmaceutical Wholesaler or Distributor	Med High – 3
PFSCM Inspected and Approved Pharmaceutical Manufacturing Site (Non-SRA/Non-WHO GMP)	
National Drug Regulatory Authority Approved Pharmaceutical Manufacturers (Non SRA/Non-WHO GMP/Non PFSCM Inspected or Approved)	High – 4
Notice of Concern issued for supplier – Temporary increase in sampling frequency	Increased Surveillance - 12

Consignment model

A procurement model aimed to support local manufacturers, determined to be GMP compliant through PFSCM inspections

- Products are held in quarantine while samples from each batch are assessed for compliance to pharmacopeia standards

- Products which meet the standards are purchased for distribution and those which do not are released back to the supplier

Litigation model

A procurement model used for routine surveillance of products purchased from SRA/WHO-approved sources

- Products are sampled at the point of delivery to the client
- Product sampling is risk-based
- Three portions of the product are sampled
  - One is sent to the laboratory for analysis, the other two are held at the retention store
  - If the first portion fails to meet standards, the second portion is sent to a second laboratory to confirm the non-compliance
  - If confirmed, the supplier is instructed to take remedial action
  - If the supplier refuses to take appropriate action, the third sample portion is available for legal action to remedy the infraction

Key elements of PFSCM's quality assurance of essential medicines

1. Routine product sampling and testing

2. Complaint Monitoring

3. Supplier Re-evaluation

- USAID regularly updates their ADS 312 document, which provides an overview of approved sources, including those for essential medicines

Thank you

Questions?

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