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

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October, 2015
PFSCM was established in 2005 to bid on the SCMS contract, but our work is expanding.

PFSCM

- USAID
  Supply Chain Management System (SCMS)
  2005

- Global Fund
  Pooled Procurement Mechanism (PPM)
  2009
Our public-private partnership brings multi-sectoral non-profit and commercial expertise
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
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

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

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