Review of Operations Related to Medicines

Consultation with Pharmaceutical Manufacturers
25th September 2012
Organization Structure: Medicines & Nutrition Centre

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• UNICEF Procurement Process for Pharmaceuticals – David Muhia
• Overview of Procurement of Essential Medicines (non ARV, non Malaria) – David Muhia
• Overview of Procurement of ARVs and antimalarials – Gitanjali Sakuja
• Overview of Challenges in Procurement Process – Karin Thomsen
Overview of UNICEF’s Procurement Process for Pharmaceuticals

Tender & Evaluation of Offers

Establishment of LTA to supply medicines for 1-3 years

Placement of orders

Production & Shipment

Country / WH inspection

Arrival Report

Invoice payment
Procurement process is governed by UNICEF Financial Rules and Regulations and includes segregation of duties.
Guiding Principles of UNICEF’S Procurement Process

- Integrity
- Transparency
- Fair competition
- Equal Treatment
- Value for money
- Organizational Objectives
- Healthy market
UNICEF SD serves many programmes with different requirements, and needs to plan for these through:

Continuous review of products needed
- Essential Medicines List and Treatment Guidelines
- Programme priorities
- Specific programme needs (e.g. kits)

Appropriate procurement strategies
- Programme context
- Warehousing/Direct delivery

Quantification of needs
- Specific programme/country needs and procurement plans
- Historical data
Mainly through competitive bidding solicited through;

- Request for Quotation (RFQ)
- Invitation to Bid (ITB)
- Request for Proposal (RFP)
Common elements of solicitation documents

- Estimate of the quantities / volume required
- Specifications
- Mandatory requirements (Technical and Commercial)
- Evaluation criteria
- Additional terms and conditions
- Requirements for samples
- General Terms and Conditions

These can vary from tender to tender (even for same items) and must be read carefully.
Evaluation of offers

• **Technical Evaluation**
  - Quality: product characteristics and manufacturing GMP

• **Commercial Evaluation**
  - Based on technical and QA reports received
    - ITB  “lowest evaluated bid”
    - RFP  “most responsive evaluated proposal”
  - Based on lowest acceptable offer, including landed cost and possible discounts for early payment (payment terms), lead times, minimum order quantities, etc.
  - Considers commercial risks
Key Criteria for Contract Award

- Quality
- Price
- Delivery Time / Speed
- Market development
- Supplier past performance

- Best value for money

Healthy Market

The tender outcome is reviewed by an internal independent body (Contracts Review Committee) who recommends approval to SD Director.
Type of Contracts and Agreements

- UNICEF awards contracts (Purchase Orders) or establishes framework agreements (Long Term Agreements or LTAs) under which Purchase Orders are placed.

- LTAs can be time-bound (open quantity) or value targeted (specific quantity). Value targeted LTAs are established when there is confidence in forecast and consideration of multiple awards.

- Duration of LTAs vary from 1 to 3 years, with options for revision and renewal.

1. Establishment of Long Term Arrangements for supply for 1 to 3 years

2. Purchase Order  
   Purchase Order  
   Purchase Order  
   Purchase Order
‘Contract management is the process that enables both parties to a contract to meet their obligations in order to deliver the objectives required from the contract.’

Key enabling factors:

Communication
Monitoring (including performance)
Feedback

UNICEF values the relation it has with suppliers, and makes a priority the establishing effective processes to manage it.
Sourcing

• We are open for Business 24 hours – Suppliers can contact us directly through emails etc
• U.N. roster (UNGM - www.ungm.org)
• Requests for Expressions of Interest (REOIs)
• Market surveys
• Internet
• Sources and Prices
• Contacts made at trade fairs
• Recommendations from other partners
Ensuring Equal Treatment, no bias and ethics

- Contracting staff are governed by UNICEF Financial Rules and Regulation
- During tender process communication with suppliers is formal in accordance with tender instructions
- Bids/proposals are received and validated by an independent ‘Bid Section’ not Contracting staff
- UNICEF does not accept manufacturers to fund trips, hotels or offer gifts to UNICEF staff
- Business should be conducted during normal working hours
- Meetings should be with minimum two UNICEF staff members
Overview of Procurement of Essential Medicines (non ARV, non Malaria)
Essential Medicines are a critical part of UNICEF Programmes, Special Projects Kits & Emergencies

- Amoxicillin Dispersible tablets
- Albendazole chewable tablets
- Oral Rehydration Salt
- Sodium lactate injection
- Cotrimoxazole
- Mebendazole chewable tablets
- Zinc dispersible tablets
- Erythromycin

Where is my medicine?
Example of Kits: Malawi Public Health Kit 2012 (18 months project worth $25 millions)

- 35 different medicines
- 20 different medical consumables
- Components from 30 different suppliers
- Cost of 1 kit – about $2000
- Cost of shipment of 1 kit; Copenhagen to Malawi
  - By Sea - about $125
  - By Air - about $1000 using optimized charter
- The whole country depends on these kits
- Stock outs are highly visible with negative political consequences
- Delay of components means airlifting kits, disruption of other kit packing projects
2011 Essential Medicines Sales: 25% by air to meet emergencies and urgent requests
## Top 10 EM Products by PO Value in 2011

<table>
<thead>
<tr>
<th>Material</th>
<th>Value (Millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfameth.+trimeth.(120mg &amp; 480mg) tabs</td>
<td>$5.6</td>
</tr>
<tr>
<td>ORS</td>
<td>$4.7</td>
</tr>
<tr>
<td>Amoxicillin Dispersible (125mg &amp; 250mg) Tabs</td>
<td>$2.0</td>
</tr>
<tr>
<td>Zinc 20mg tablets/PAC-100</td>
<td>$2.0</td>
</tr>
<tr>
<td>Erythromycin 250mg tabs/PAC-100</td>
<td>$1.7</td>
</tr>
<tr>
<td>Fe(as fum.)+folic 60+0.4mg tab/PAC-1000</td>
<td>$1.7</td>
</tr>
<tr>
<td>Albendazole 400mg tabs/PAC-100</td>
<td>$1.7</td>
</tr>
<tr>
<td>Amoxici.pdr/oral sus 125mg/5ml/BOT-100ml</td>
<td>$1.5</td>
</tr>
<tr>
<td>Sulfameth.+trimeth.800+160mg tbs/PAC-100</td>
<td>$1.2</td>
</tr>
<tr>
<td>Sodium,lactate inj (500 + 1000ML)</td>
<td>$1.1</td>
</tr>
</tbody>
</table>
Essential Medicines Unit: We mainly procure medicines in WHO EML & WHO Priority Medicines List.
2011 throughput interrupted by internal activities
2012 (Projection) demand drivers include Malawi MOH, Zimbabwe MOH, Somalia emergency
Procurement pattern subject to variations due to peaks in demand (emergencies, urgent projects)
Forecasting Challenge: Annual Consumption historical data for ORS, Zinc & Amoxi DT

ORS – main driver emergencies and clear treatment guidelines
Zinc DT – erratic demand, absent in many countries treatment guidelines
Amoxi DT – New product, alternative for oral suspension, demand expected to grow
EM Procurement strategies

• Warehouse Replenishment / Kit packing / Direct shipments
  ▫ Prefers products with shelf lives of at least 3 years
  ▫ Reasonable lead time
  ▫ Competitive prices
  ▫ Previous supplier performance
  ▫ Minimum order quantity
  ▫ Establishment of 2-3 LTAs – more for strategic products such as ORS, Zinc, Amoxi DT

• Emergencies / Urgent projects
  ▫ Shortened procurement process
  ▫ Short lead time very important
  ▫ We accept alternative pack sizes
  ▫ Competitive prices (landed cost)
EM Medicines: Future trend; short, medium to long term

- Flavored ORS – follow the private market
- Smaller sachets of ORS – 0.5 & 0.2 litres
- 20mg Zinc DT (taste masked)
- Co-packaged ORS + Zinc
- 250mg Amoxicillin DT
- 480mg Cotrimoxazole
- Phase out bottles of 1000 tabs, bring in smaller pack sizes
- Country registrations; Ethiopia, Zambia, Uganda
- Mandatory patient leaflets
- Quality local manufacturers
THANK YOU