Breaking Down Market Barriers by Capturing Market Intelligence and Building Procurement Capacity

14TH GENERAL MEMBERSHIP MEETING OF THE REPRODUCTIVE HEALTH SUPPLIES COALITION

Presented by
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DEAN AND DIRECTOR

Technical Support from
Pharmexcil, Pharmaceutical Export Council of India

NEW DELHI
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Empower team met / interviewed 86 people from the following organizations:

- Ministry of Health (n=35)
- UN agencies (n=5)
- International NGOs (n=8)
- Donors (n=6)
- National Drug Regulatory Authorities (n=12)
- Manufacturers (n=10)
- Private and public sector importers / exporters (n=10)
Market Situation: Barriers in Procurement of Public Health Commodities
Buyers’ Information Needs

- Products
- Quality
- Price
- Manufacturers
# Product Information

## Needs

- Product registration information
- Product specifications
- Product recalls
- Others

## Challenges

- Public health programs need drugs, diagnostics, supplies, devices, reagents and many other products
- Estimated total SKUs – 3,000 – 5,000
Buyers' Information Needs

- Products
- Quality
- Price
- Manufacturers
Quality

- National requirements [International Conference on Harmonization (ICH), Pharmaceutical Inspection Co-operation Scheme (PIC/S), European Free Trade Association (EFTA), Rest of the World (ROW)]
- Technical Organization (WHO, UNFPA, UNICEF, CDC etc.)
- Donor quality requirements
- Buyer quality requirements
  - Procurement agents
  - Public health organizations (PSI, MSI, etc.)
- Many of the non ICH and PICS NDRAs have limited capacity to control quality of [imported] drugs (WHO, PAHO, HERA)
Buyers’ Information Needs

- Manufacturers
- Products
- Price
- Quality
Price – Value for Money

- Large variation in purchase price for same product (e.g. MSH’s IDPIG quotes a price differential of 15x among RH products)
- 10-20 different sites / publications
- Complex (with various INCOTERMS like EXW, FOB, CIF etc.)
- Varies by volume (Lesotho vs. Nigeria), packaging, bidding terms etc.
- Needs to be “peeled”, extrapolated and analyzed to be understood and used properly
Buyers’ Information Needs

- Manufacturers
- Products
- Quality
- Price
Manufacturers

- More than 50,000 manufacturing sites in major pharmaceutical producing nations (India has around 10,000)
- Self manufacturing, contract manufacturing, loan licensed manufacturing (1/3rd of Indian manufacturing plants are loan licensed)
- Registered, unregistered or unknown
- Supplier base of global health products shifting from ICH countries to non-ICH markets
  - 70-90% of global health products are supplied by India and China
- There is a massive fragmentation in Indian pharmaceutical market where there are more than 4000 manufacturers but the market is dominated by not more than 350 manufacturers (~95% market). The export market is also skewed and top 50 companies control the 75% of the total export market. (Source: CMIE data, 2009-10).
Buyers’ information needs

...and it is constantly changing!
Current market situation

INFORMATION

Capacity

Weak

Medium

Strong

Information Opacity

Information Asymmetry

Information visibility
Intervention and Innovation

INFORMATION

- Information Opacity
- Information Asymmetry
- Information Visibility

CAPACITY

- Weak
- Medium
- Strong
Proposed ‘Market fixing’ Intervention
Proposed Intervention

International Buyer’s Guide
<table>
<thead>
<tr>
<th>S.no.</th>
<th>Product Name</th>
<th>Strength</th>
<th>Company</th>
<th>Manufacturing Country</th>
<th>Manufacturing City</th>
<th>Site Accreditations</th>
<th>Registered in</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Paracetamol</td>
<td>1000mg</td>
<td>Cipla</td>
<td>India</td>
<td>Goa</td>
<td>US-FDA MHRA TGA NAFDAC</td>
<td>Nigeria</td>
</tr>
<tr>
<td>2</td>
<td>Paracetamol</td>
<td>1000mg</td>
<td>Ranbaxy</td>
<td>India</td>
<td>Verna</td>
<td>US-FDA MHRA</td>
<td>Ethiopia</td>
</tr>
<tr>
<td>3</td>
<td>Paracetamol</td>
<td>1000mg</td>
<td>Hetero</td>
<td>India</td>
<td>Hyderabad</td>
<td>MHRA TGA NAFDAC</td>
<td>Kenya</td>
</tr>
<tr>
<td>4</td>
<td>Paracetamol</td>
<td>1000mg</td>
<td>Aurobindo</td>
<td>India</td>
<td>Hyderabad</td>
<td>US-FDA TGA NAFDAC</td>
<td>Benin</td>
</tr>
<tr>
<td>5</td>
<td>Paracetamol</td>
<td>1000mg</td>
<td>IPCA</td>
<td>India</td>
<td>Daman</td>
<td>MHRA TGA NAFDAC</td>
<td>Ghana</td>
</tr>
<tr>
<td>6</td>
<td>Paracetamol</td>
<td>1000mg</td>
<td>Ajanta</td>
<td>India</td>
<td>Aurangabad</td>
<td>CDSCO MHRA TGA NAFDAC</td>
<td>Afghanistan</td>
</tr>
<tr>
<td>7</td>
<td>Paracetamol</td>
<td>1000mg</td>
<td>Strides Acrolab</td>
<td>India</td>
<td>Bangalore</td>
<td>US-FDA MHRA TGA NAFDAC</td>
<td>Indonesia</td>
</tr>
<tr>
<td>8</td>
<td>Paracetamol</td>
<td>1000mg</td>
<td>Lupin</td>
<td>India</td>
<td>Pithampur</td>
<td>US-FDA MHRA Health</td>
<td>Russia</td>
</tr>
</tbody>
</table>
Manufacturers

- China
- India
<table>
<thead>
<tr>
<th>Years of Operation</th>
<th>Manufactures Location</th>
<th>Product Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Years</td>
<td>Goa, Cochin, Delhi, Patna, Indore</td>
<td>HIV, TB, Malaria, RCH, Typhoid</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Certification and Accreditations</th>
<th>Global Clientele</th>
</tr>
</thead>
<tbody>
<tr>
<td>US-FDA Approved, MHRA, WHO-GMP Approved</td>
<td>USA, UK, Nigeria</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Registered Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir registered in United States</td>
</tr>
<tr>
<td>Artemether registered in Nigeria</td>
</tr>
</tbody>
</table>
Select Therapeutic Categories

- Anti-malarial
- Anti-retroviral
- Anti-TB
- Anti-cancer
- Anti-diabetic
- Anti-emetics
- Analgesic
- RCH drugs
- Drugs for Opportunistic infections
- Drugs for Viral hepatitis
- Drugs for palliative care
Select Therapeutic Categories

- Anti-malarial
- Anti-retroviral
- Anti-TB
- Anti-cancer
- Anti-diabetic
- Anti-emetics
- Analgesic
- RCH drugs
- Drugs for Opportunistic infections
- Drugs for Viral hepatitis
- Drugs for palliative care

List of Products:

- Medicine1
- Medicine2
- Medicine3
- Medicine4
- Medicine5
- Medicine6
- Medicine7
- Paracetamol
- Medicine9
- Medicine10
**Quality Assured**

- Registered in
  - ICH (International Conference on Harmonization) countries
  - EFTA (European Free Trade Association) countries (Iceland, Liechtenstein, Norway, Switzerland)
  - Or
  - Prequalified by WHO

**Quality Verified**

- Reviewed, inspected and verified by various global health programs
  - International procurement agents (Crown agents, IDA, IMRES, MEG, ACTION MEDEOR)
  - Global health organizations (PSI, MSI, CHAI)

**Quality Inferred**

- The company has been registered or have supplied at least one product to the organizations / countries in the Quality Assured or Quality Verified category
  - The product of the company is registered in a PIC/S country e.g. Brazil, Argentina, Australia etc.
Country Registered in

- Liberia
- Madagascar
- Malawi
- Mali
- Mauritania
- Mauritius
- Burma
- Morocco
- Mozambique
- Namibia
- Niger
- Nigeria
- Rwanda
- Sao Tome and Principe
- Senegal

List of Products

- Medicine1
- Medicine2
- Medicine3
- Medicine4
- Medicine5
- Medicine6
- Medicine7
- Paracetamol
- Medicine9
- Medicine10
• Very dynamic, multivariate and complex
• Lots of valuable information in lots of sites
• Some very user friendly, others less
• Some updated live and some not
Proposed Intervention

Building Procurement Capacity
Building Procurement Capacity

Country Focus

Targeted Training

“Hand Holding” Technical Resource Center
Building Procurement Capacity

Country Focus

- High mortality and morbidity
- Largest procurement value
- Biggest bottlenecks
Building Procurement Capacity

Targeted Training

- Identify need / gaps
  - Organizational
  - Departmental
  - Individual

- Topic specific training
  - Procurement methods
  - Quality Assurance in PSM
  - Forecasting and LMIS

- Disease / condition / commodity
  - HIV, TB and Malaria
  - RCH
  - Vaccines
Building Procurement Capacity

“Hand Holding”
Technical Resource Center

- 12 months online support after training
  - Discussion group
  - Skype
  - e-mail
  - Phone

- Dedicated “call center”
Application of Buyer’s Guide and Capacity Building

- HIV
- TB
- Malaria
- Viral Hepatitis
- Reproductive Health
- Oncology
- Neglected tropical diseases
- Cardiovascular diseases
- Diabetes
More than 60% of the respondents ranked HIV and Reproductive Health as the top priorities

[feedback of 18 respondents from India, Kenya, Ghana and Ethiopia]
• One of the 13 affordable, effective, but underutilized commodities identified by the UN commission on life saving commodities for women and children [source: http://www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities/life-saving-commodities#sthash.QUjQaGKA.dpuf]

• Key information about Oxytocin is available on the web, including therapeutic information, price information, available brands in different countries
  ○ A market landscape analysis was also conducted by USAID in 2011: Oxytocin in Uniject
Available information: Summary

**Product**
- Oxytocin 10iu/ml, injectable (WHO EML)
- Oxytocin 5iu/ml, injectable

**Manufacturers**
- Produced by more than 100 manufacturers globally
- UNFPA sources from 2 procurement agents; 2012-13 procurement shows 3 companies
- MIMS database shows 230 results for Oxytocin from 10 countries

**Therapeutic category**
- Oxytocics and anti-oxytocics (as per WHO EML)

**Quality**
- Eligible for the WHO Prequalification of Medicines Program. To date, no manufacturers have qualified,
- Unregistered and unapproved medicines are often widely accessible, and weak national regulatory authorities are unable to restrict their availability

**Registration**
- Oxytocin is registered in most of the 30 USAID maternal health priority countries

**Price**
- US$0.4487 for 10iu (buyer median price) from SADC medicine price database 2012-13
- US$0.1755 for 10iu (buyer median price) from MSH 2012
- US$0.3663 for 5iu (buyer median price) from MSH 2012

**Source:** Every Woman, Every Child; RH interchange; MSH; Oxytocin in Uniject (USAID, 2011); MIMS
## Available information: RH Interchange

<table>
<thead>
<tr>
<th>ITEMID</th>
<th>PRODUCTNAME</th>
<th>LONG DESCRIPTION</th>
<th>CATEGORY ID</th>
<th>SUBCATEGORY ID</th>
<th>SUBCATEGORY</th>
<th>ACCESS</th>
<th>HPRICE</th>
<th>VENDOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>MISOPROS</td>
<td>Misoprostol 200mcg tablet. Package = 60 tabs. in a blister.</td>
<td>Misoprostol 200mcg tablet. Package = 60 tabs. in a blister. Delivery Lead Time = 3-4 weeks.</td>
<td>350000</td>
<td>Pharmaceutica Products</td>
<td>Oxytocics and Anti-oxytocics</td>
<td>The medical export group</td>
<td>29.00</td>
<td>BV</td>
</tr>
<tr>
<td>RINE0.2MG</td>
<td>Ergometrine maleate 0.2mg/ml, 1ml. Package = 100 amps. Delivery lead time = 14-16 weeks.</td>
<td></td>
<td>350000</td>
<td>Pharmaceutica Products</td>
<td>Oxytocics and Anti-oxytocics</td>
<td></td>
<td>11.00</td>
<td>Imres</td>
</tr>
<tr>
<td>RINE0.5MG</td>
<td>Ergometrine maleate 0.5mg. Package = 1000 tabs. Delivery lead time = 4-6 weeks.</td>
<td></td>
<td>350000</td>
<td>Pharmaceutica Products</td>
<td>Oxytocics and Anti-oxytocics</td>
<td></td>
<td>13.00</td>
<td>Imres</td>
</tr>
<tr>
<td>LHR0.05</td>
<td>Fenoterol hydrobromide 0.05mg/ml, 10ml (partusisten). Package = 25 amps. Delivery lead time = 4-6 weeks.</td>
<td></td>
<td>350000</td>
<td>Pharmaceutica Products</td>
<td>Oxytocics and Anti-oxytocics</td>
<td></td>
<td>70.00</td>
<td>Imres</td>
</tr>
<tr>
<td>METHYLER</td>
<td>Methylergometrine maleate 0.2mg/ml, 1ml. Package = 10 amps. Delivery lead time = 14-16 weeks.</td>
<td></td>
<td>350000</td>
<td>Pharmaceutica Products</td>
<td>Oxytocics and Anti-oxytocics</td>
<td></td>
<td>0.85</td>
<td>Imres</td>
</tr>
<tr>
<td>OXYTOCIN</td>
<td>Oxytocin 10 I.U./ml, 1ml. Package = 100 amps. Delivery lead time = 14-16 weeks.</td>
<td></td>
<td>350000</td>
<td>Pharmaceutica Products</td>
<td>Oxytocics and Anti-oxytocics</td>
<td></td>
<td>20.00</td>
<td>Imres</td>
</tr>
<tr>
<td>OXYTOCIN</td>
<td>Oxytocin 5 I.U./ml, 1ml. Package = 100 amps. Delivery lead time = 14-16 weeks.</td>
<td></td>
<td>350000</td>
<td>Pharmaceutica Products</td>
<td>Oxytocics and Anti-oxytocics</td>
<td></td>
<td>10.00</td>
<td>Imres</td>
</tr>
</tbody>
</table>

**Note:** The prices and vendors are subject to change and should be confirmed with the appropriate medical supplier.
## Available information: MIMS

<table>
<thead>
<tr>
<th>COUNTRY OF PRODUCTION</th>
<th>NUMBER OF DRUGS (OXYTOCIN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>5</td>
</tr>
<tr>
<td>India</td>
<td>32</td>
</tr>
<tr>
<td>Indonesia</td>
<td>26</td>
</tr>
<tr>
<td>Hong Kong</td>
<td>24</td>
</tr>
<tr>
<td>Malaysia</td>
<td>28</td>
</tr>
<tr>
<td>Philippines</td>
<td>34</td>
</tr>
<tr>
<td>Singapore</td>
<td>24</td>
</tr>
<tr>
<td>Thailand</td>
<td>22</td>
</tr>
<tr>
<td>Vietnam</td>
<td>16</td>
</tr>
<tr>
<td>USA</td>
<td>19</td>
</tr>
</tbody>
</table>
## Available information: South African Development Community

<table>
<thead>
<tr>
<th>Country</th>
<th>Price per Base Unit (USD)</th>
<th>Pack Price (USD)</th>
<th>Manufacturer</th>
<th>Country</th>
<th>MSH Ratio</th>
<th>Incoter m</th>
<th>Pack Size</th>
<th>Volume (Packs)</th>
<th>Procurement Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>0.6735</td>
<td>0.6735</td>
<td>Novartis South Africa (Pty) Ltd</td>
<td>South Africa</td>
<td>3.8376</td>
<td>DDP</td>
<td>1 ml (ampoule)</td>
<td>45000</td>
<td>2012-02-07 to 2012-02-07</td>
</tr>
<tr>
<td>Botswana</td>
<td>0.6414</td>
<td>0.6414</td>
<td>Novartis South Africa (Pty) Ltd</td>
<td>South Africa</td>
<td>3.6547</td>
<td>DDP</td>
<td>1 ml (ampoule)</td>
<td>22000</td>
<td>2012-04-16 to 2012-04-16</td>
</tr>
<tr>
<td>Lesotho</td>
<td>2.024</td>
<td>2.024</td>
<td>Unknown</td>
<td>Unknown</td>
<td>11.5328</td>
<td>DDP</td>
<td>1 ml (ampoule)</td>
<td>2300</td>
<td>2013-03-01 to 2013-03-31</td>
</tr>
<tr>
<td>Lesotho</td>
<td>0.198</td>
<td>19.803</td>
<td>Unknown</td>
<td>Unknown</td>
<td>1.1282</td>
<td>DDP</td>
<td>100 ampoule (pack)</td>
<td>556</td>
<td>2012-03-01 to 2012-03-31</td>
</tr>
<tr>
<td>Malawi</td>
<td>0.2</td>
<td>Ningbo Tisun Medic Biochemic Co. Ltd</td>
<td>China</td>
<td>1.1396</td>
<td>UNK</td>
<td>1 ml (vial)</td>
<td></td>
<td>12013-01-01 to 2013-12-31</td>
<td></td>
</tr>
<tr>
<td>Seychelles</td>
<td>1.3406</td>
<td>1.3406</td>
<td>Gland Pharma Limited</td>
<td>India</td>
<td>7.6387</td>
<td>FOB</td>
<td>1 ml (injection)</td>
<td>1000</td>
<td>2012-09-03 to 2012-09-03</td>
</tr>
<tr>
<td>Seychelles</td>
<td>0.1393</td>
<td>13.926</td>
<td>Gland Pharma 5 Limited</td>
<td>India</td>
<td>0.7937</td>
<td>FOB</td>
<td>100 ampoule (pack)</td>
<td></td>
<td>24 2013-02-26 to 2013-02-26</td>
</tr>
<tr>
<td>Zambia</td>
<td>0.0938</td>
<td>0.0938</td>
<td>Unknown</td>
<td>Unknown</td>
<td>0.5345</td>
<td>DDP</td>
<td>1 ml (ampoule)</td>
<td>400000</td>
<td>2013-01-08 to 2013-01-08</td>
</tr>
<tr>
<td>Zambia</td>
<td>0.0938</td>
<td>0.0938</td>
<td>Unknown</td>
<td>Unknown</td>
<td>0.5345</td>
<td>DDP</td>
<td>1 ml (ampoule)</td>
<td>400000</td>
<td>2013-01-10 to 2013-01-10</td>
</tr>
</tbody>
</table>
## Additional information from the Buyer’s guide

<table>
<thead>
<tr>
<th>Product</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturers</strong></td>
<td>List of quality assured / verified / inferred manufacturers in India and China, and their:</td>
</tr>
<tr>
<td></td>
<td>- Product registrations in different countries</td>
</tr>
<tr>
<td></td>
<td>- Quality certifications</td>
</tr>
<tr>
<td></td>
<td>- Historical performance</td>
</tr>
<tr>
<td></td>
<td>- Organization information</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td>List of accreditations from international and national authorities:</td>
</tr>
<tr>
<td></td>
<td>- Quality verified</td>
</tr>
<tr>
<td></td>
<td>- Quality assured</td>
</tr>
<tr>
<td></td>
<td>- Quality inferred</td>
</tr>
<tr>
<td><strong>Registration</strong></td>
<td>- List of countries where the product is registered by each manufacturer, and its validity</td>
</tr>
<tr>
<td><strong>Therapeutic category</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Price</strong></td>
<td>- Information aggregated from various sources</td>
</tr>
</tbody>
</table>
Potential Impact

Promote competition
Promoting supply security by expanding the number of quality suppliers
Promote quality

Increase procurement of better quality products
Promote lower prices and value-for-money
Reduce time for procurements

Public and private sector
THE GLOBAL PHARMACY PRIVATE LIMITED, INDIA
Acknowledgements

- DfID India, Ethiopia, Kenya and Ghana
- USAID Ethiopia and Kenya
- DKT International Ethiopia
- Marie Stopies International, India
- MSF India
- Red Cross Kenya
- CHAI Ethiopia, Kenya
- World Bank, Kenya
- PSI, India, Kenya
- Ministry of Health – India, Ethiopia, Kenya and Ghana
- National Drug Regulatory Authority – India, Ethiopia, Kenya and Ghana
- Public Procurement Unit – PFSA – Ethiopia; Ghana Procurement unit
- Private sector manufacturers and importers (India, Kenya, Ethiopia and Ghana)
- Academics and policy specialists in India
Empower is composed of Empower School of Health and Empower Pragati, a joint partnership with the government of India’s non-profit 25c corporation.

Empower School of Health was established by a group of professionals formerly from United Nations (WHO, Global Fund), and private corporate sector; all of whom have a rich and varied experience at senior management levels.

Empower is providing research, consulting and healthcare services across 30 countries in Africa, Asia and Eastern Europe.

We have 7 offices across India with more than 200 staff + 50 independent consultants globally.
Pharmaceutical Export Promotion Council (Pharmexcil) is an organization under the Ministry of Commerce and Industry and is responsible for the promotion and oversight of export of quality assured pharmaceuticals from India.

Pharmexcil is only agency which can issue RCMC (Registration cum Membership Certificate) to the exporters, without which no manufacturer/exporter can export pharmaceuticals.