

Competitive Position of East African Local Manufacturers:

Introduction to Market Shaping Activities

September 8, 2015



Executive summary

CHAI has undertaken a market shaping project to strengthen the position of **local pharmaceutical manufacturers (LM)** in the EAC. CHAI seeks to expand the market opportunity for LM by linking them with international and regional buyers.

CHAI is currently working with 3 LM in a three prong approach to 1) ensure **current good manufacturing practice (cGMP)**, the international quality standard, 2) demonstrate **international price competitiveness** and 3) link LM to **international buyers**.

The project aims to see 2 high quality products procured by 2 international procurement agencies at an internationally competitive price.

This presentation demonstrates the current market landscape of LM and the challenges they face to expand their market share. CHAI hopes to find ways the regional and international health community can support local procurement.

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Introduction: can LM comply with best procurement practices?

Procurement Best Practices¹

Local Manufacturers in the EAC

Achieve the lowest possible cost

- cGMP LM price competitive with international cGMP manufacturers in select products. LM competitive on ~80 essential medicine formulations²

Select high quality and reliable suppliers

- 5+ existing cGMP manufacturers operating in the EAC

Ensure timely delivery

- LM are active in Kenya, Tanzania, and Uganda with consistently shorter lead times when compared to international competitors

Procure cost-effective life saving commodities

- LM manufacture 60-80% of products on the essential medicines list³

1. WHO Operational Principles for Good Pharmaceutical Procurement
2. Based on CHAI analysis using international buyer catalogue of predominantly essential medicines
3. Preliminary analysis, excludes vaccines, contraceptives, ARVs and ACTs

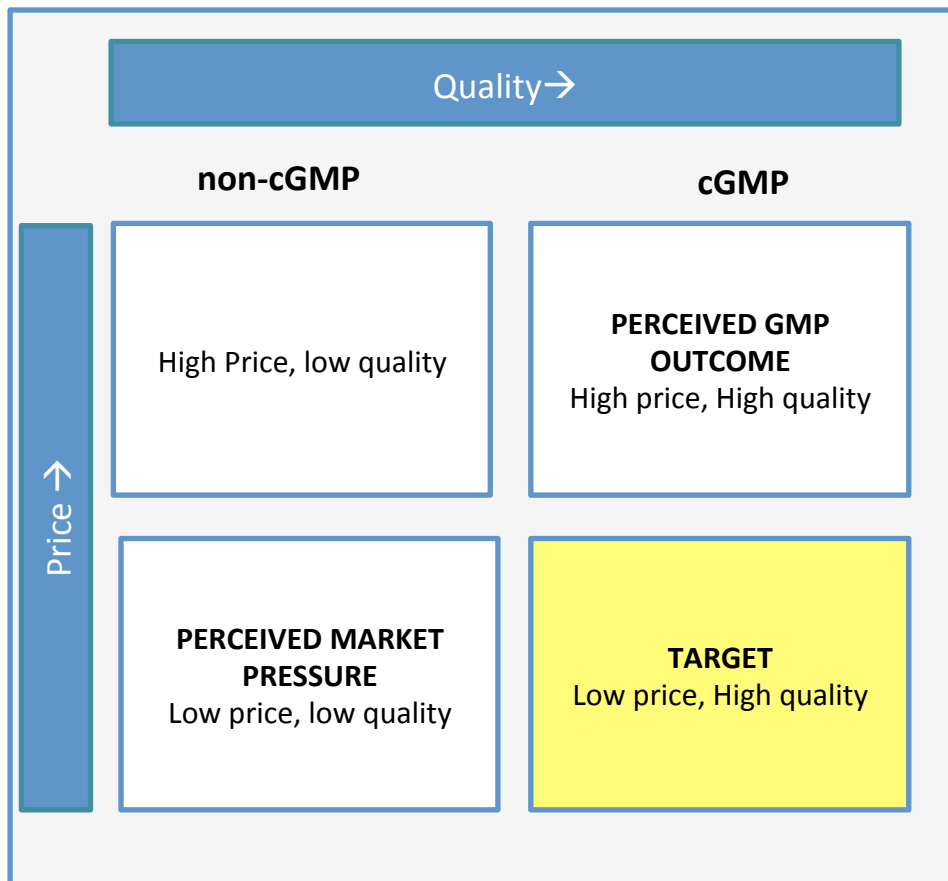
A2 Barriers to enter the regional market

Despite satisfying best practice procurement principles, LM comprise just about 15% of the EAC market by sales value.¹ The vast majority of the market- both public and private- is served by foreign imports, with over 60% coming from India.²

Barriers to entry

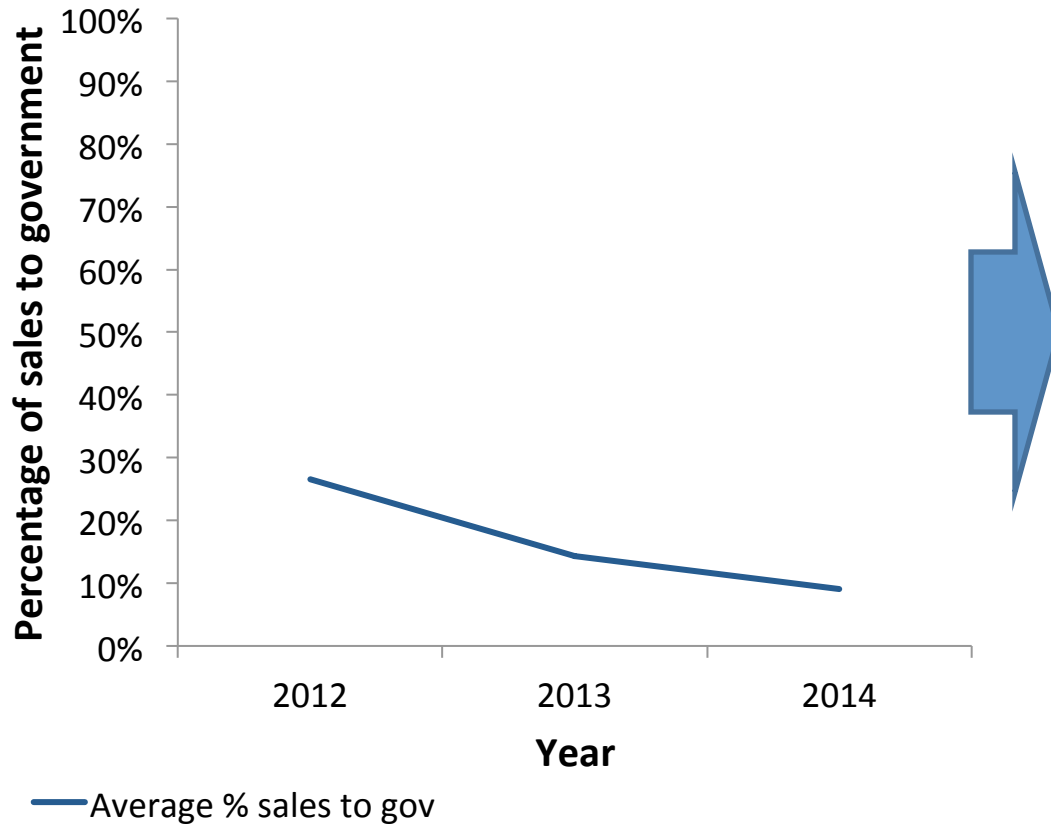
- Current market dynamics provide inadequate incentive for LM to reach cGMP because it places them in a higher cost position
- Significant pressure from low-cost competitors erodes viable market opportunity for cGMP LM
- 15% preference offered to LM, but not dependent on quality. Gains offset by similar preference offered to local wholesalers
- cGMP manufacturers at disadvantage in buyer segments that do not demand international quality

Perceived price and quality dynamics



1. Based on CHAI analysis.
2. Based on CHAI market sizing analysis

Average percentage of sale to regional government has declined almost 20% over the past 3 years for high quality LM



Why is government procurement from LM declining?

- A. LM can't compete on price with foreign imports
- B. LM don't manufacture the products governments procure
- C. Decreasing attractiveness of the public sector
- D. LM don't meet government quality standards
- E. All of the above

LM sale to government (2/2): why is government procurement from LM declining?

A. High quality LM can compete with high quality foreign imports on select products. There are roughly 50-90 products identified where LM match or beat the international procurement price point. However, high quality LM cannot compete against lower quality, low cost manufacturers.

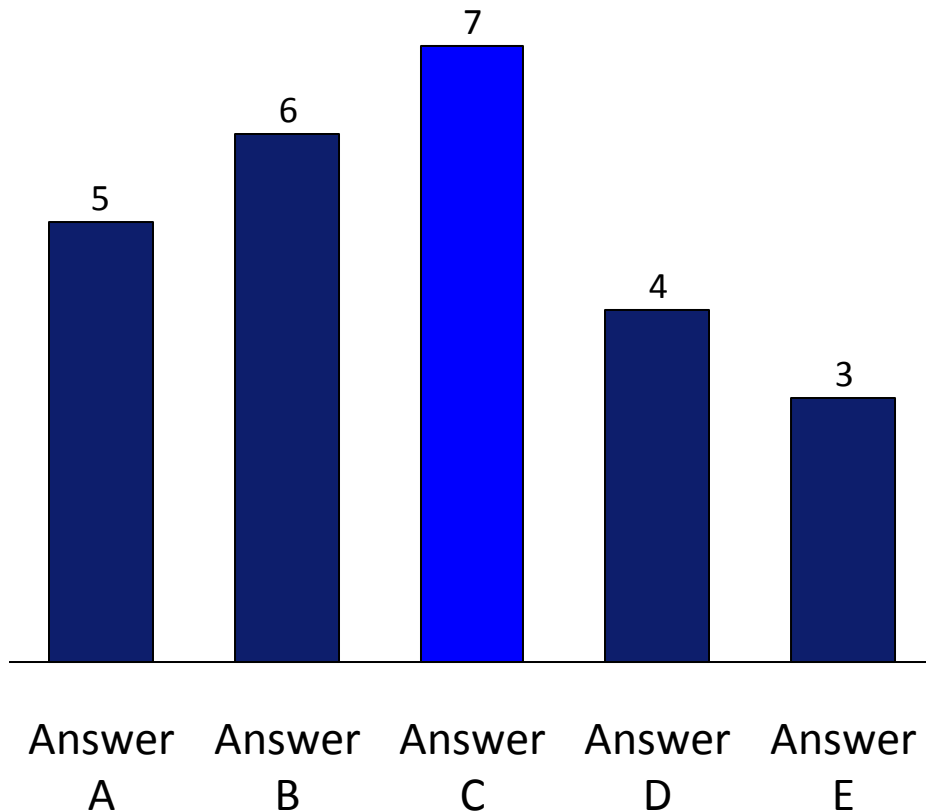
B. LM typically manufacture 300-600 SKUs. There is alignment between LM product catalogues and public tenders. However, there are registration barriers due to required bioequivalence studies for a number of products, processing time, unique dossiers for each Partner State and inconsistent standards for new and versus renewal applications.

C. The public sector has become less attractive to LM due to extreme pricing pressure and payment terms [length and currency]. The cost of capital is higher for LM than international competitors, thus delayed payment terms and foreign exchange losses significantly erode the marginal profits from tender items.

D. LM manufacture at a range of qualities, yet +5 are cGMP certified and meet government and international standards. However, manufacturers are not required to be internationally cGMP certified for most public tenders, contributing to intense competition from low cost companies.

A4 LM quality and price dynamics

Responses



Introduction to quality/cost challenges

Quality range

- LM produce at range of quality from non-GMP to cGMP
- High quality and low quality suppliers compete on same tenders
- Ongoing regional discussions to raise quality requirement for public tenders

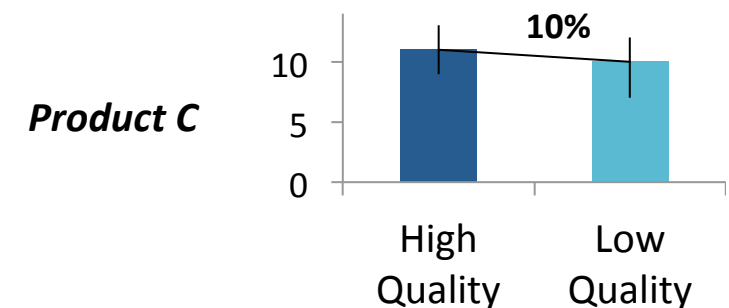
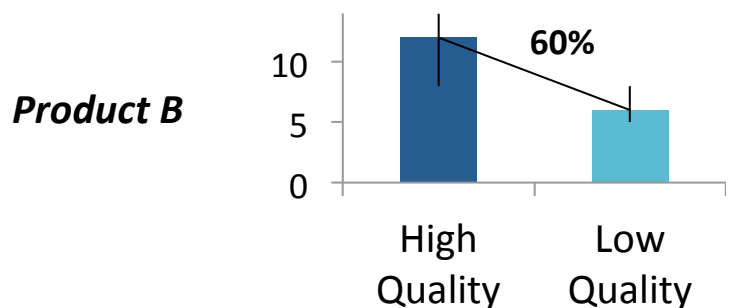
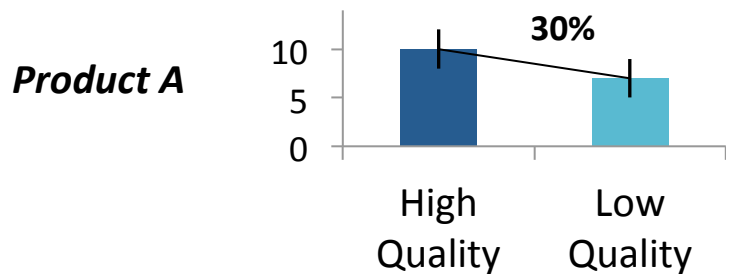
Price competition

- LM produce at a range of prices, dependent on quality
- Lower quality/low cost products can compete in the domestic market
- High quality/higher cost products can compete in international but not domestic market

B1 Low vs. high quality pricing (1/3)

Illustrative example

Price differences between high and low quality medicines are product-specific



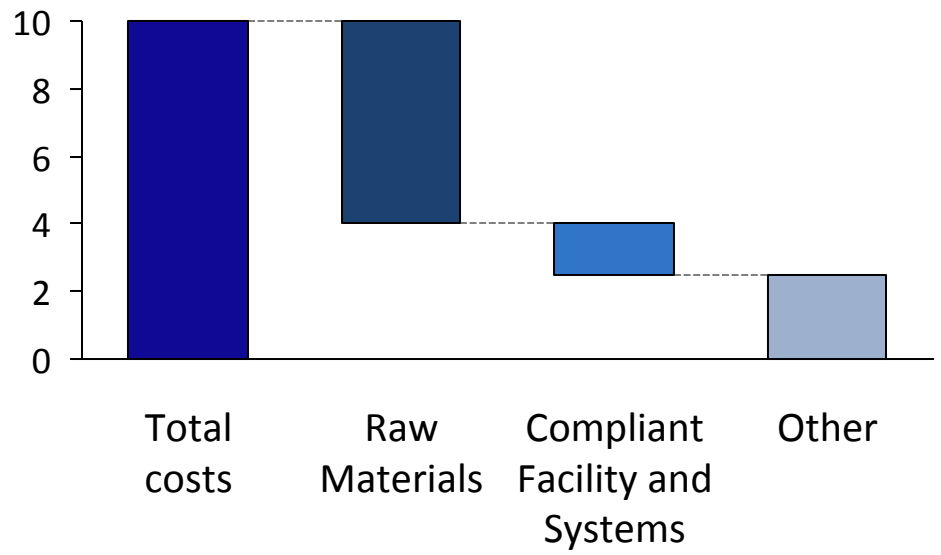
- cGMP products are more expensive than low quality products
- The price difference is highly product-specific, principally due to varying input costs of low/high quality raw materials
- There is a price range in each category (high and low quality) including domestic and international products
- In major product segments there is frequently a less than a 5-10% difference between domestic and international price points for cGMP manufacturers

B1

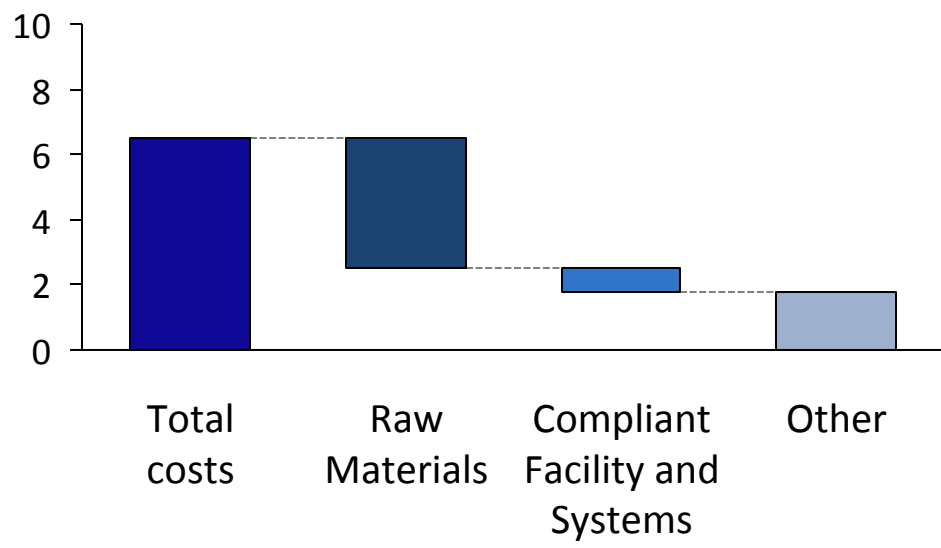
Low vs. high quality pricing: why is quality more expensive? (2/3)

Illustrative example

High Quality



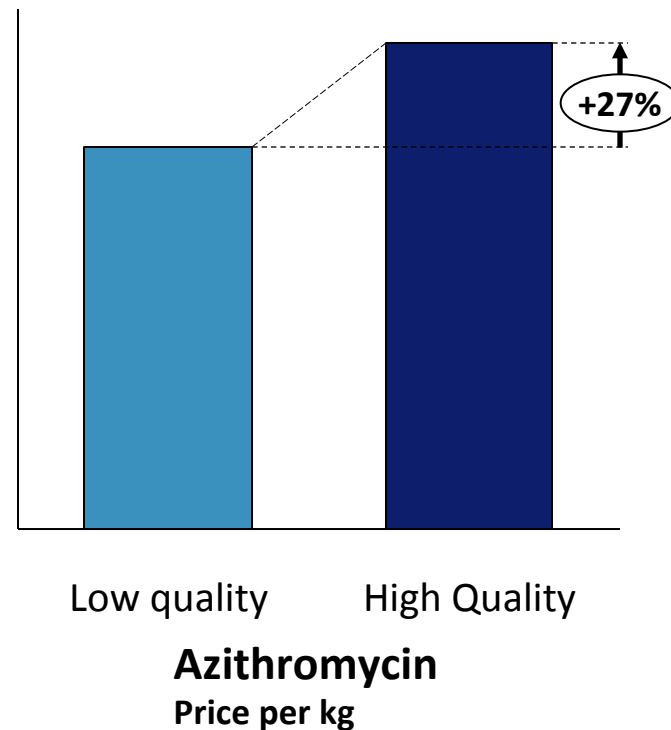
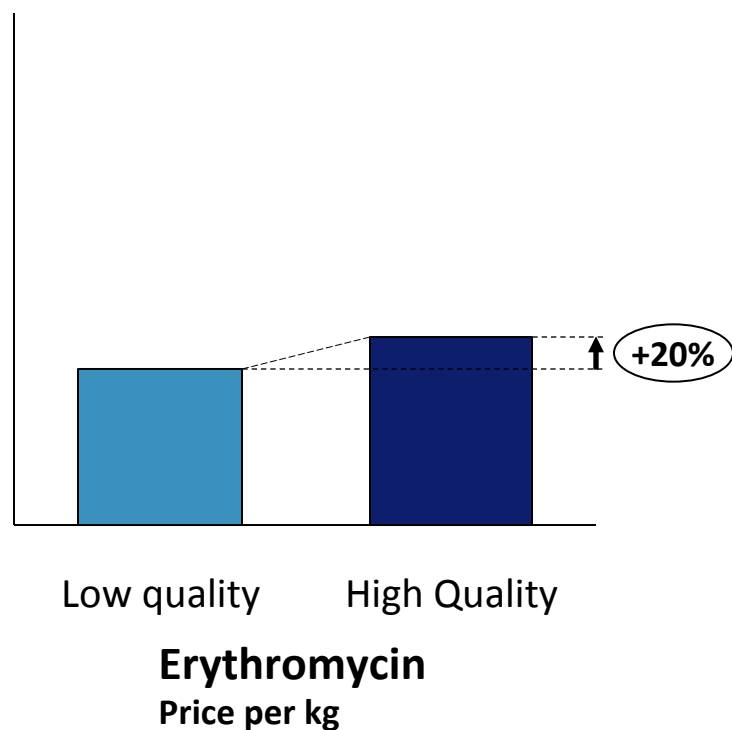
Low Quality



- cGMP requires high quality inputs that are more costly
- Specific facility and systems required to attain and maintain cGMP status, and requires larger investment in infrastructure, systems, and personnel
- QA/QC compliance costs for cGMP substantially greater. Driven by type/frequency/SOP compliance costs/ expensive BP/USP/EP samples

B1 Low vs. high quality pricing: API costs (3/3)

- API generally comprises 60-80% of total product cost for LM¹ majorly impacting final price
- Significant cost difference between high and low quality API when comparing current pharmacopeia to outdated versions (example: BP 2014 vs. BP 1999)
- API manufacturers produce various qualities for different markets, stringent regulatory authorities (SRA) require use of highest quality API

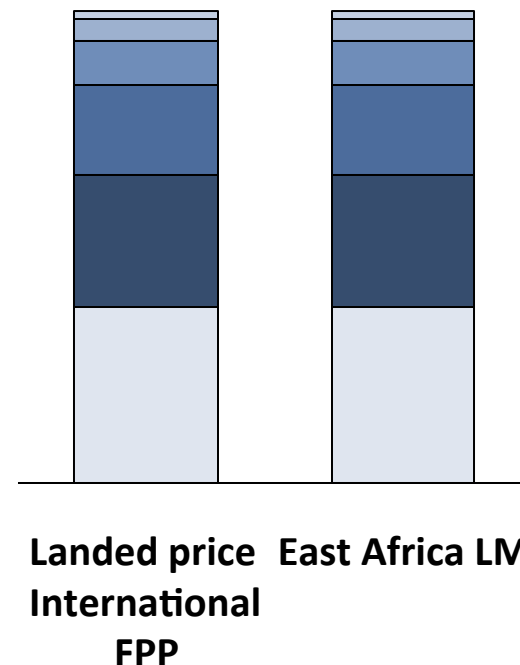


B2 Group Activity: cost comparison (1/4)

Each table has been given a piece of paper with two blank bar graph. Fill in each graph using the different colored pens to estimate the cost differences between India manufactured final product imported to the EAC and a locally manufactured product. Mark the largest cost bucket at the bottom of the paper and work up to the smallest. The sum of all input costs should total the estimated price for India vs. EAC product.

- Overhead
- Raw materials (API and excipient)
- Transport
- Other (financing costs, taxes, indirect overhead)
- Packaging
- Manufacturing

Example



B2 Group Activity: cost comparison (2/4)

What options are available to cGMP LM to compete in the market?

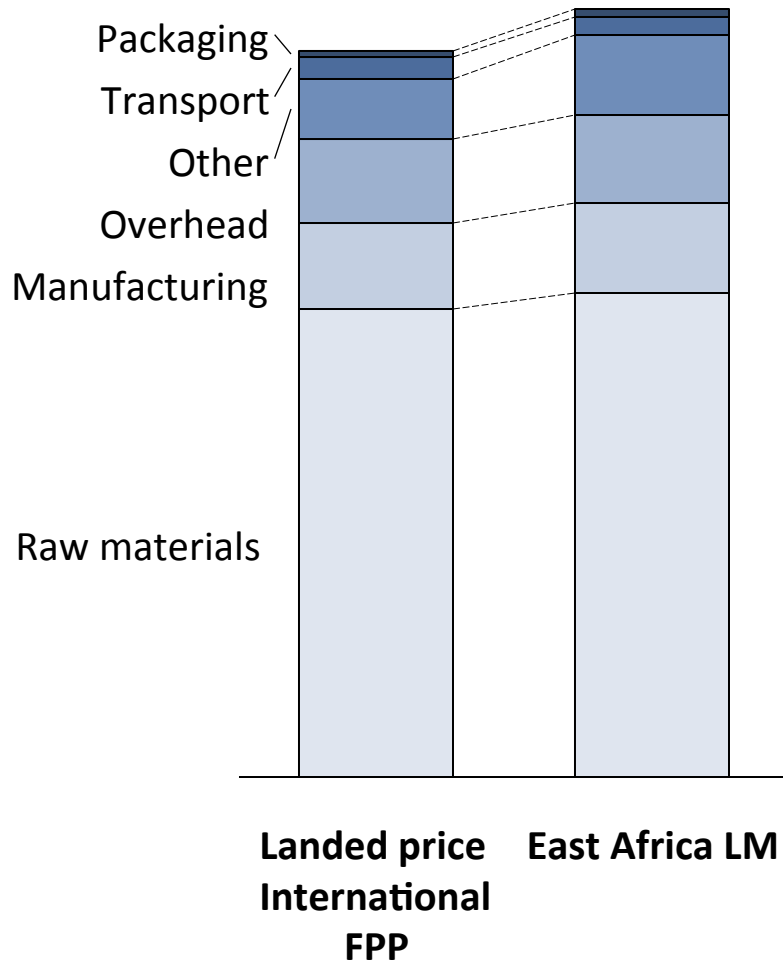
- A. LM should implement lean operations to reduce manufacturing costs to achieve price competitiveness with foreign imports.
- B. The difference in transport costs (i.e. sea freight) make LM competitive against foreign competitors.
- C. LM should focus on sales to the private sector with higher average prices to generate more revenue.
- D. LM should source lower quality inputs to reduce raw material prices.
- E. LM should take a bottom-line approach to reduce input and operational costs to close the cost gap.

B2 Group Activity: Price comparison (2/3)

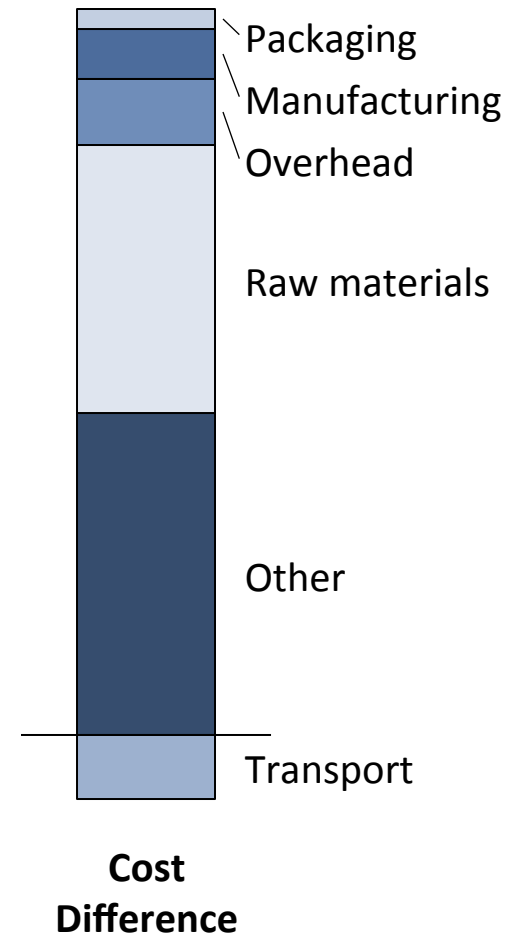
Illustrative example

Cost breakdown comparison

Product A, USD



Breakdown of cost difference



B2 Group Activity: Price comparison (3/3)

Raw Materials

India and China produce API, generally accessing 4-20% lower prices than African LM.

Other

Other expenses are driven predominantly by financing costs. EAC LM face higher cost for USD and local currency overdraft banking facility than international competitors

Overhead

Overhead costs decline with high volume products. LM are competitive in administrative and quality assurance costs, but pay over 10% more for electricity and wages.¹

Manufacturing

LM often have lean production operations. LM and cGMP counterparts incur similar costs due to the universal quality and testing standards.

Packaging

Bulk packaging materials (i.e. tins, tubs) are inexpensive. Blister and foil are higher cost and generally imported incurring additional taxes and fees.

Transport

EAC LM have a cost advantage in transport and delivery time due to strategic regional location. For example, in emergency orders, LM have significant advantage over air freight charges.

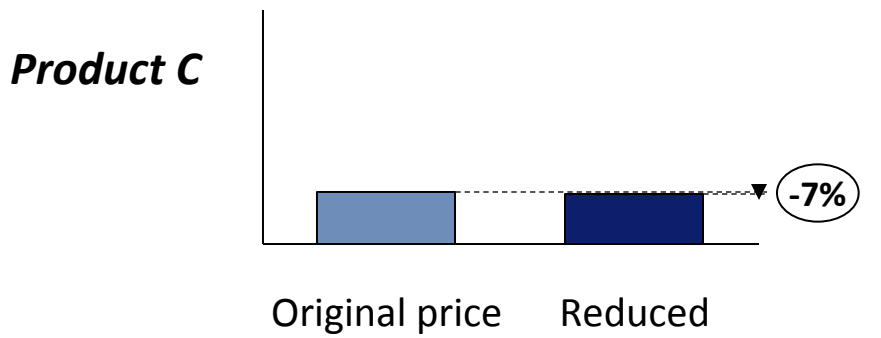
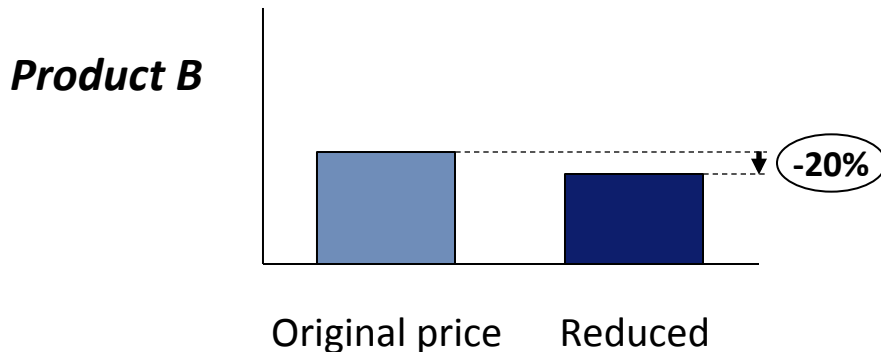
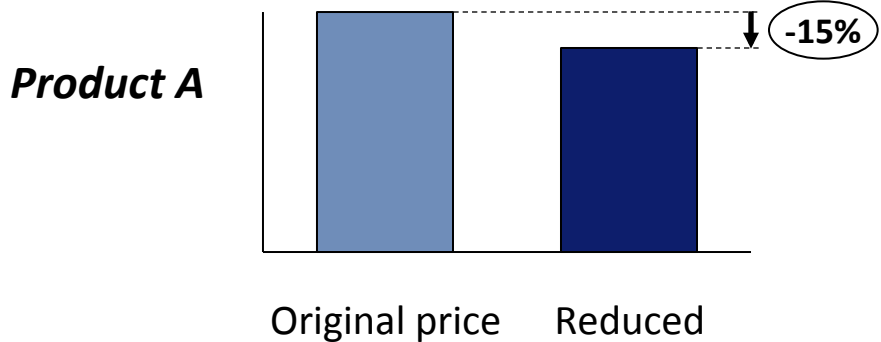
Targeted

- API
- Financing
- Overhead

C1 API price negotiations

Illustrative example

CHAI worked with API manufacturers and LM to negotiate bulk pricing deals.

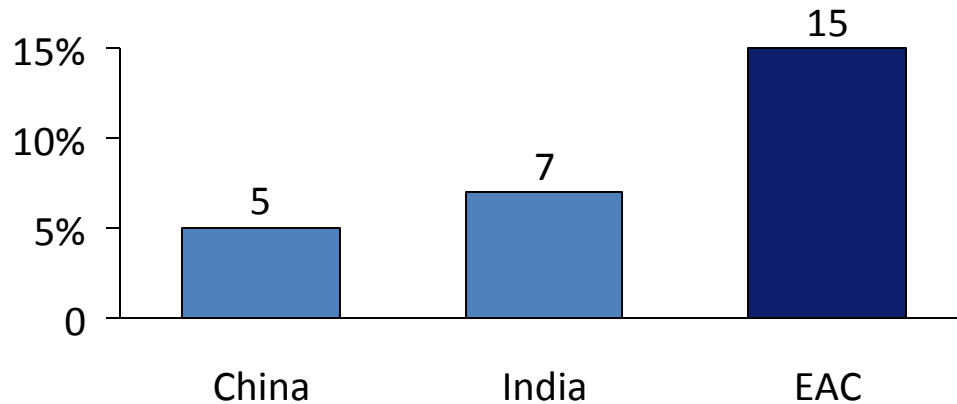


- Key insights :
- Chinese and Indian API manufacturers have credit concerns in African markets
 - LM are often requested to go through traders who mark up the price
 - LM generally order insufficient volumes to access bulk prices
 - Marginal reductions substantively impact absolute savings in high volume orders

C2 Financial cost reduction

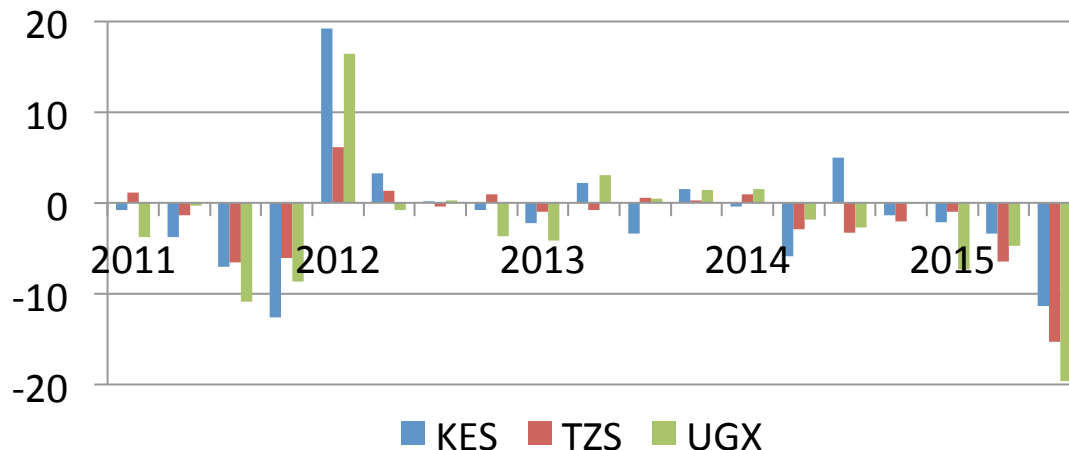
Overdraft interest rate

Local currency accounts



Forex Fluctuations

% change against USD



- **Financing costs sometimes > net profit**
- LM use **overdraft** tools to bridge funding gap between payment of raw materials and receipt of revenue
- Higher overdraft rates increase overall costs and weaken competitive position

- Continuous decline of local currencies against USD
- LM incur majority of costs in USD, but significant revenue in local currency
- **Currency loss** between payment for inputs and receipt of revenue
- **Delayed payment erodes LM margin**

C3 Overhead cost reduction

CHAI engaged LM in a collaborative overhead cost compression exercise:

Cost identification

- Analyze direct and indirect expenses
- Identify top 12 cost categories such as electricity, maintenance, lab equipment
- Breakdown categories into sub-components
- Triage cost areas to identify 5 most impactful interventions

Target Setting

- Problem solve with relevant LM departments to assess feasibility in each cost category
- Develop specific activities with investment requirement and potential savings
- Identify realistic and ambitious cost reduction targets

Implementation

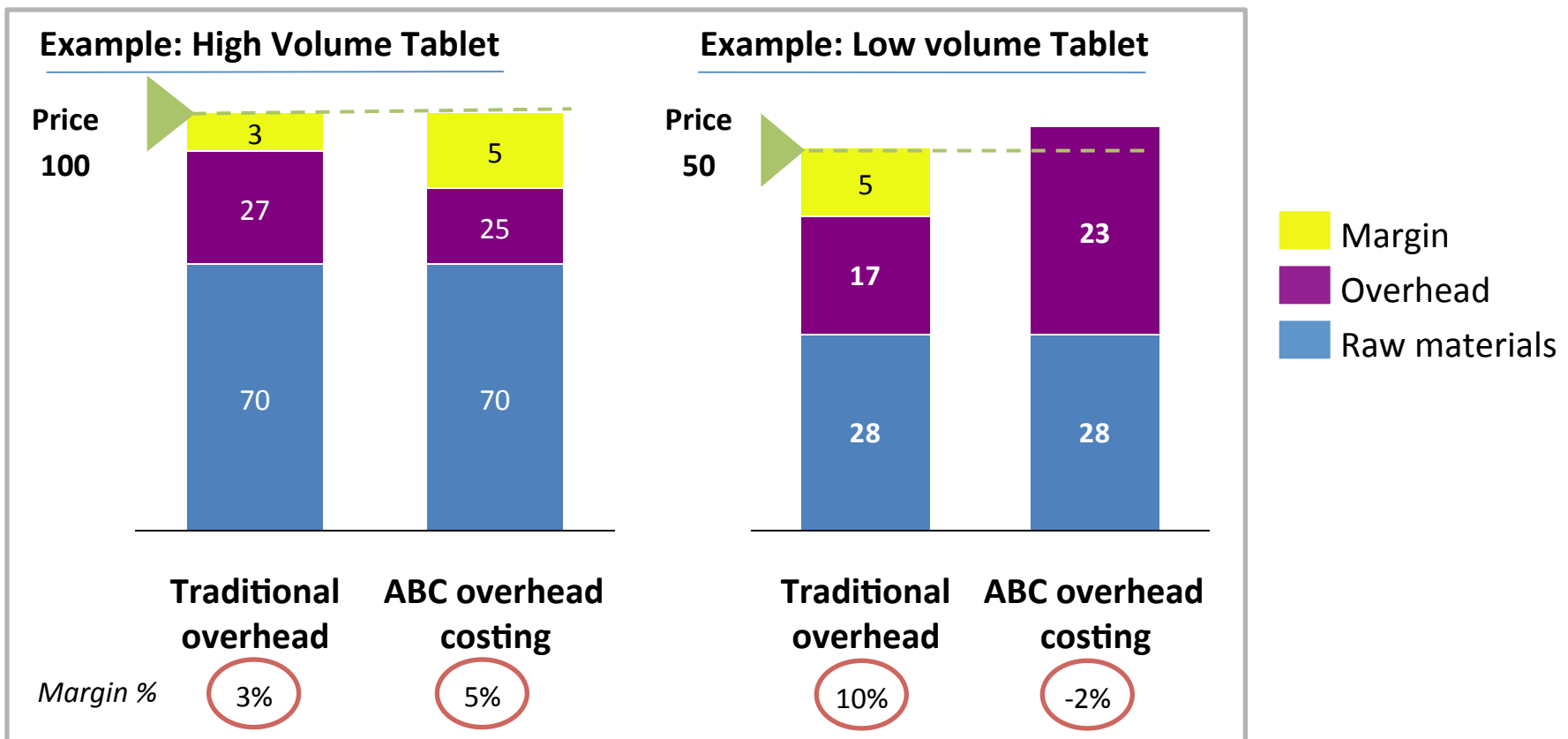
- Develop work plans with LM cost owners
- Host 'challenge sessions' with the CEO to refine targets and strategies
- Schedule touch points at 2, 4, 8, and 12 weeks to review progress & troubleshoot
- Support wave 2 overhead cost reduction

- Overhead cost reduction helps close the cost difference and improve the ability of LM to price competitively against international competitors
- Cost compression activities are applicable across all regional LM
- LM can save 2-5% of their budget by targeting key overhead cost areas

C3 Overhead cost allocation: ABC costing

Illustrative example

- Products accrue very **different input costs** (setup time, quality tests, marketing etc.)
- **Activity Based Costing (ABC)** is used to allocate overhead costs appropriately to each product
- ABC leads to **accurate pricing** and identification of **profitable vs. unprofitable products**



Group discussion: general solutions

Please respond to the questions below found on your individual notecards with two suggestions for each area. CHAI is interested in receiving feedback from procurement experts to incorporate into the LM engagement strategy.

- 1. How can the public sector develop procurement protocols that better incentivize high quality LM to bid, and at competitive prices?**
- 2. What can international stakeholders do to increase procurement from LM?**
- 3. How can high quality LM best improve/adapt to improve their market position?**

CHAI project overview

CHAI is currently working with 3 LM to provide technical support in two key areas necessary for participation in the international market: **GMP quality manufacturing and competitive prices**. Cost compression activities are underway and international cGMP audits will occur in October 2015. Given demonstrated success with the 3 initial companies, CHAI seeks to expand to + 6 high interest LM in the EAC region whose quality improvements required greater time and investment. This could be supplemented by LM in other regions that have expressed interest in CHAI support, and negotiating improved API prices for +30 essential medicine API that have been identified as high priority

cGMP Product

- Quality gap analysis
- cGMP audit
- Support to LM in developing and implementing work plan
- Quality testing
- Commercially produce high-quality product at scale

Cost competitiveness

- API deals reduce input costs
- Cost optimization and production efficiency
- ABC costing to improve pricing
- Technical expert develop work plan for cost-reduction strategies
- Financing solutions: replace overdraft with letter of credit and review payment terms to minimize forex losses

Project Goal Q4 2015

- Demonstrate LM can supply international buyers
- 2 products produced by at least 2 LM procured by 2 international buyers

Conclusion

Thank you for your time and participation

Please contact us with any questions or recommendations on the presentation topics. We look forward to incorporating the feedback into our LM strategy.

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