

Promoting Local Production of Generic Medicines in Small African Countries

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Context

- Low access to essential medicines in Africa
- High dependence on imports of medicines
- Hence, local production of medicines: a major political economic issue in Africa today

Local production: Industrial Policy Vs Health Policy?

- Economic benefits:
 - Employment
 - Balance of payments
 - Etc
- Access to medicines:
 - More reliable supplies
 - Better quality control
 - Better marketing reach specially in rural areas
 - **But cost competitiveness and pricing?**

Argument

- Many developing countries, for example in Africa trying to promote local production suffer from several cost disadvantages
- Small size of domestic markets is often cited as a reason why companies cannot exploit economies of scale and hence cannot be cost competitive
- More expensive local products negatively impact access

Our counter argument

- Higher costs may lead to neither higher prices nor unviable production
- The role of economies of scale is exaggerated
- Viable production is possible at much lower volume of production than is widely believed

Present status

- Local production already substantial in some African countries
- But some incentives such as import tariff, marketing preference, negative import list etc have helped
- Important question: Can local producers compete against imports after upgrading to GMP without further protection?

Scale of operations and viability

- The viability of a factory depends on the breakeven point
- Breakeven point is that sales volume (in units) where the total sales just cover the total costs and the company earns no profit. The company earns profits at any sales volume higher than the breakeven point and incurs loss below that
- Breakeven point depends on prices, average variable costs and fixed costs
- For given prices, if the average variable costs and fixed costs are higher for a firm, then the breakeven level of operations will also be higher
- If the markets that a company can access are not large enough, if the firm cannot sell more than the breakeven level of output, the firm will not be viable
- Therefore it is important to find out how large the breakeven point is.

Breakeven point

Q, where

$$\text{Profits} = (P \times Q) - (AVC \times Q) - \text{total fixed costs} = 0,$$

Or, $Q (P - AVC) = \text{total fixed costs}$

Or, $Q = \text{total fixed costs} / (P - AVC)$

Where,

- P = selling price
- AVC = variable cost per unit
- Q = quantity sold
- (P - AVC) = contribution per unit

Our Method

- Used India as the point of departure:
 - A team consisting of a cost accountant, two production executives of an Indian formulations manufacturing company and an economist estimated the actual cost, production and profitability data.
- Simulation exercises in Ghana:
 - Starting with the Indian situation and under alternative cost assumptions, estimate the breakeven and the level of viable operations in Ghana.

India

- It costs about Rs 92 million at Indian prices (2012) to set up in India a new Schedule M compliant formulations manufacturing plant with three compression machines
- 75% funded through loans at 12.5% interest rate
- 4 persons in quality control; 8 persons in production; 3 persons in administration and 3 persons in stores
- 12 workers
- 20 other casual workers
- Five types of tablets of different ingredient, strength and different sale prices manufactured – amlodipine, 2.5 mg, ofloxacin, 200mg, ciprofloxacin, 500 mg, amlodipine, 5 mg and metformin hcl, 500 mg

Costs higher in Ghana

- Dearth of technically qualified persons and skilled labour
- Higher raw materials costs
- Higher costs due to smaller batch sizes
- Higher costs of imported machinery
- Higher interest charges
- Higher electricity charges
- Etc

Ghana scenario 1

- Same five products manufactured as in the Indian case in same quantities and charging the same prices
- Same wage cost - assuming that the impact of lower wage rate is neutralized by lower productivity
- All casual workers are permanent
- Ghana fixed capital investment to set up a WHO-GMP compliant plant is double that of the Schedule M compliant plant in India
- Rate of interest in Ghana is considered to be 25% rather than 12.5% as in India
- All the other costs – material costs, power and fuel, repairs and maintenance, other running costs are considered to be 50% higher in Ghana.

	India	Ghana scenario 1
Total sales revenue (Rs million)	181	181
Total variable costs (Rs million)	65	63
Total fixed costs (Rs million)	79	125
Total quantity produced and sold (million tablets)	107	107
Contribution (Rs million)	116	118
Contribution per tablet (Rs)	1.08	1.10
Breakeven quantity (million tablets)	73	113
Total profits (Rs million)	37	-7
Profit margin (%)	20.3	

Ghana scenario 2

- Same cost structure as in scenario 1 but
- Volume of tablets manufactured is 50% more in Ghana for each of the five products

	India	Ghana scenario 1	Ghana scenario 2
Total sales revenue (Rs million)	181	181	271
Total variable costs (Rs million)	65	63	94
Total fixed costs (Rs million)	79	125	125
Total quantity produced and sold (million tablets)	107	107	161
Contribution (Rs million)	116	118	177
Contribution per tablet (Rs)	1.08	1.10	1.10
Breakeven quantity (million tablets)	73	113	113
Total profits (Rs million)	37	-7	52
Profit margin (%)	20.3		19.2

Ghana scenario 3

- Same as scenario 2 except
- the Ghana company is manufacturing only the lowest priced product amlodipine 2.5 mg and charging 20% less price compared to the Indian company

	India	Ghana scenario 1	Ghana scenario 2	Ghana scenario 3
Total sales revenue (Rs million)	181	181	271	245
Total variable costs (Rs million)	65	63	94	71
Total fixed costs (Rs million)	79	125	125	125
Total quantity produced and sold (million tablets)	107	107	161	472
Contribution (Rs million)	116	118	177	175
Contribution per tablet (Rs)	1.08	1.10	1.10	.37
Breakeven quantity (million tablets)	73	113	113	337
Total profits (Rs million)	37	-7	52	50
Profit margin (%)	20.3		19.2	20.3

Implications of the simulation exercise:

- The typical argument is that because of the small market size and other disadvantages, the costs are higher and hence prices are and hence access to medicines is negatively impacted
- But our study shows that even with higher costs, a firm can be viable without charging a higher price
- The lower profit margin can be compensated by a larger market to ensure viability

- Even in a scenario with fixed costs 100% higher, rate of interest 100% higher, other costs 50% higher, production of only low priced products with prices 20% lower, a production level of about 472 million tablets can generate a profit margin of more than 20%.

Realizing the potential

- Incentive package:
 - Ensure adequate market:
 - Public procurement through tendering restricting to local manufacturers.
 - technical evaluation restricted to local which are WHO-GMP compliant and which have the manufacturing capacities to satisfy the procurement requirements
 - financial bid
 - international tendering for drugs for which adequate capacities have not yet been developed in the country
 - Reduce fixed costs:
 - Interest rate subsidy

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