

Not Everything is healthy in the Health sector- Imperatives for CMAs

Nitin Parekh
CFO, Cadila Healthcare Ltd.

Presentation at
National Cost Conference -2013
Institute of Cost Accountants of India
19th Jan. 2013

Indian Pharma Industry – key facts

Domestic market

1. Indian pharma market : valued at over Rs. 69K Cr, growing at 15% (source : AWACS MAT Nov-12)
2. One of the fastest growing in the world – ranked 3rd in terms of volume, 12th in terms of value (source : IMS)
3. Self-reliant – almost entire requirement of pharma goods met by domestic production
4. Highly fragmented – top 10 pharma cos. hold only ~42% of the total market
5. Increasing interest of MNCs – evident from Ranbaxy – Daiichi and Piramal – Abbott deals (4 MNCs amongst top 10 players)

Pharma exports

1. Valued at \$ 12 bn+, growing at a CAGR of 18 % over last 3 years (source : Dept. of Commerce, GoI)
2. Skilled manpower and low cost of production – key success factors for exports to regulated generics markets of US and Europe
3. India having largest no. of USFDA approved mfg. sites outside US

Current Challenges for Indian Pharma Industry

Overall

1. **Changes in the pattern of the disease** and constant pressure of new drugs from multinationals
2. India needs to gain much **larger global market share** to play larger role (current share negligible at 1.5% of global market in value terms)
3. **Reputation management** - Improving compliance of regulatory and quality standards to improve image about quality of Indian Pharma goods in certain countries like Japan
4. India's contribution in **basic pharma research is insignificant**
5. **Strengthening of regulatory standards** and compliance levels across geographies
6. Wide **fluctuations in exchange rates** for Indian Rupee vis-à-vis global currencies
7. **Highly knowledge based industry** – requires the constant up-gradation of skills of the human resources
8. **Changes in the technology** – up-gradation of the mfg. and research infrastructure
9. Constant pressure to maintain **high standards of EHS**

Current Challenges for Indian Pharma Industry

Domestic Market

1. **Increasing competition** - Numerous players, incl. MNCs, vying for share in various therapy areas
2. **Shrinking pipeline of new products** available for launch with strengthening of IP related laws post 2005
3. **Regulatory changes** made by MCI guidelines from time to time
4. **Reducing margins** with mounting price pressures and increasing costs
5. **New pricing policy**
 - **Coverage increase** – from present 74 drugs to 348 drugs (614 specified SKUs in NLEM)
 - **Price reduction** across portfolios expected to be in the range of **18-20% for domestic** players, while MNCs will have to take higher price cuts
 - **value reduction expected to be ~3% (~ Rs. 2000 cr.)** for covered products, putting pressure on margins, RoI and RoE
 - **Indirect impact** – on non-NLEM covered strengths, export realizations and existence of small players

Current Challenges for Indian Pharma Industry

Global Markets

1. **Price erosions** have become normal way of life - 98%+ price erosion within a few weeks of launch for almost all products
2. **Generic penetration** levels have already increased significantly in key markets like US (>80%), limiting scope for further growth
3. **Heightened level of regulatory scrutiny** and stringent actions for non-compliance - evident from increasing cases of warning letter / import alerts on pharma cos. by USFDA
4. **New products availability**
 - No 'cream' left in vanilla generics, while 'Niche' generics are difficult and require significantly high amount of resources (time, skilled manpower and money)
 - US 'patent cliff' opportunity size reducing (2011 and 2012 saw patent expiries of big brands having market size of \$ 50bn+, while for 2013 and 2014, this number is expected to be \$ 30 bn)
 - Para IV / FTF might offer big rewards, but is a risky strategy (litigation costs might not be recovered if patent infringement case is lost)
 - Innovator companies resorting to alterations in formulations / technology of patented drugs frequently, making it difficult to develop generic version in approvable form

Imperatives for pharma industry to sustain challenges

1. Focus on **basic research** as well as **new products, new technologies, new delivery based solutions** etc.
 - Biosimilars, Vaccines, Injectables, Aerosols, Ointments, Transdermal patches.....
2. Focus more on **fatal diseases** like Cancer (largest segment, fastest growing globally as per IMS) and **life style diseases** (cardiovascular, diabetes, CNS etc.)
3. **Regulatory compliance** – devotion of **highest amount of time by senior management**
4. Continuously work on **reducing costs and improving operational efficiencies**
 - Use of various tools and techniques
 - invest in new automated technologies to improve operational costs
5. Take up **crucial matters with Govt.**
 - More flexible labour laws to help in automation of technologies
 - More incentive for Pharma exports to compensate for loss of profits due to new pricing policy
 - Higher incentives / subsidies for basic pharma research

Challenges for CMAs in pharma industry

1. **Long period of research** – proper allocation of infrastructure over running projects on a acceptable and ongoing base
2. **Cost of risk** – loading of the cost of 'on hold' projects not reaching the final stage on the products / services commercialized successfully
3. **Co developments** – determining the basis to allocate the joint cost and infrastructure cost
4. Revenue vs. capital treatment of the development and launch expenses, as well as funding there of
5. **Infrastructure / capacity imbalance and allocation of infrastructure cost** on product and services to take the business decisions
6. **Cost of reserved capacity** and resources used for constant up-gradation of the manufacturing process to reduce the cost
7. Use of historic cost for decisions of future business

Role of CMAs in mitigating these challenges

1. Go beyond the normal role of cost accountant

- consider overall business and organisation strategy - cost is an input for decision making but not decision in itself
- look beyond conventional methods to help management in decision making

2. Make cost reduction as a way of life - go beyond product cost

- look at production processes, cycle time, wastage, yield parameters...

3. Work out **innovative and dynamic costing methodologies** to take care of special situations

- tender costing, patented product costing, brand product costing and pure generics product costing etc.
- over and under recovery of overheads,
- choice of total costing vs marginal costing

4. Help management by providing some **ready reckoner to take specific decisions** on make vs. buy, to invest in project or go for job work etc.

Role of CMAs in mitigating these challenges

5. Explore avenues for revenue maximization

- Evaluate the current costs of manufacturing and provide the supportive data to government to arrive at the reasonable cost (norms) for fixation of the ceiling prices.
- Identify products / molecules not covered by price control
- For price controlled products – constantly watch cost of goods and initiate actions for price revision at appropriate time

6. Identify 'stop loss trigger point' – help management decide on when to 'pull the plug' of

- projects going overboard on cost / time / resources
- Products having negative / marginally positive contribution

7. Challenge the cost components in the out sourced items – using clean sheet costing concept to minimise the cost of outsourced items to improve the gross margins.

Role of CMAs in mitigating these challenges

8. Evaluate efficiency of operations – Provide constant update on current as well as future efficiency to management.

- Productivity in terms of Man and Machines.
- Capacity utilisation in terms of equitable production unit i.e. Reactor liter or equalized pills
- Yield monitoring - end to end yield of API as well Formulations.
- Solvents recovery at API manufacturing

Thank You