

RIS Colloquium on India's Growing Dependence on Imports in the
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Indian API Industry and Imports: An Industry Perspective

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INDIAN PHARMACEUTICAL INDUSTRY

An Overview 1

- Almost non-existent before the 1970s.
- Policy interventions in the 1970s -- Patent Policy, Public sector pharma companies, etc
- Today ranks high among developing countries in terms of technology, quality and range of medicines being manufactured
- Estimated to be worth \$ 4-5 billion
- Annual growth rate 8-9 %
- FDI in pharma touched US\$ 172 million in 2005-06 growing at 62.6 % during 2002-06.

An Overview 2

- Became a provider of 95 % of country's pharmaceutical needs
- Largest generic drug supplier of the world
- Indian production constitutes about 13 % of world market in value terms and about 8% in volume terms

An Overview 3

- Highly fragmented
- More than 20,000 registered units
- Core of the Sector
 - About 250 large units control 70% of the market; market leader has about 7 % market share
 - About 8000 plus SMEs

[Source: A Brief Report Pharmaceutical Industry in India, Corporate Catalyst India, 2014.]

BULK DRUG INDUSTRY

Current Status

- More than 1150 bulk drug units produce about 350 bulk drugs
- 169 FDA (US) approved plants and 153 EDQM (EU) approved facilities
- 269 Drug Master File (DMF) in FDA out of total 524 with China having 89 in 2011.
- Most countries in the world were catered to by India.

Challenges of Pharma Industry 1

- Formulation sector self sufficient
- For API, 70% own and dependent mainly on China for 30 %
- As per Pharmaexcil statistics:
 - For Intermediaries More than 65 – 70 % dependence on China
 - Major products for which dependent on China: Antibiotics, Cephalosporins, Vitamins, Paracetamol, Mefenamic acid, Renitidine, etc. (Fermentation based products a challenge to India)

Challenges of Pharma Industry 2

- Fragmented with small balance sheet size
- Declining productivity of in-house R&D
- Mergers and acquisitions.

Advantages of the Industry

- Indian pharma industry is entrepreneur driven while China is mostly government supported
- Low capital requirement, low running cost running facilities, well established manufacturing process are our advantages
- Pharmaceutical production costs about 50 % lower than in developed countries
- Overall R & D costs about one-eighth of that in the West.

China's Advantages

- Low cost and high volume products.
 - Revenue of top ten companies of China like Sinopharm Shanghai Pharmaceutical etc. is more than 18000 to 20000 Million USD which is almost at par with total Indian Pharma industry.
 - They are traditionally State owned enterprise focusing on volume sales rather than profit.
- 15% to 17% draw back duty on exports cover up many losses of Chinese manufacturers.
- 12 hours working shift.
- Low power tariff
- Lending rate in China is 6.31% - India is double.
- Tax incentives in more than 54 Economic and Technology Zones. 15 free trade zones, 53 high tech parks, 56 Export processing Zones.
- China Govt. is drawing up a plan to invest USD 761 Million for API with a goal to raising export value of product by US 4 BN annually.

China's Focus

- China Govt. thrust is to have economy of scale of production in China
- Acquiring Innovation and Technological superiority
- Export driven growth

A Threat and Concerns

- More than 50% units registered in India are from China, 10% from Italy and rest is from other country.
- We are in risk Zone
 - Health security
 - Employment security
 - Manufacturing Growth

QUALITY AND GOOD MANUFACTURING PRACTICES: AN ISSUE

MAJOR AREAS OF GMP CONCERNS

<ul style="list-style-type: none">• Quality system elements / procedures documentation	<ul style="list-style-type: none">• Facilities and equipment status labeling
<ul style="list-style-type: none">• Design and maintenance of premises	<ul style="list-style-type: none">• Environmental monitoring
<ul style="list-style-type: none">• Design and maintenance of equipment	<ul style="list-style-type: none">• Supplier and contractor audit and technical agreements
<ul style="list-style-type: none">• Process validation	<ul style="list-style-type: none">• Equipment validation
<ul style="list-style-type: none">• Procedures and facilities sampling	<ul style="list-style-type: none">• Hygiene/clothing

MAJOR AREAS OF GMP CONCERNS

<ul style="list-style-type: none">• Manufacturing documentation issue (falsification)	<ul style="list-style-type: none">• Duties of key personnel
<ul style="list-style-type: none">• Potential for microbiological contamination	<ul style="list-style-type: none">• Potential for chemical/physical contamination.
<ul style="list-style-type: none">• Quality system elements / procedures documentation	<ul style="list-style-type: none">• Facilities and equipment status labeling
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WHAT IS TO BE DONE? INDUSTRY'S SUGGESTIONS

By Industry

- **Good Manufacturing Practices**
- Need to develop robust GMP systems that ensure that the plants are 'anytime ready' for Regulatory audits

Action *vis-a-vis* China 1

- **Registration of Units:** More than 50% units registered in India are from China, 10% from Italy and rest is from other countries. **We are in risk Zone.**
- **Registration time:** China takes more than 4 to 5 years to register our product whereas we are able to do it in 3 to 6 months or 9 months time: Need to get expedition in China
- Manpower with regulator of China is four times than what we have including State Province whereas population wise we are going to match China very soon. CDSCO has to be strengthened

Action *vis-a-vis* China 2

- **Registration Charges:** China registration charges are more than Rs. 8 Lakh per product whereas we are doing it @ 2500 USD. Why not Increase?
- **Inspection:** China registers our product after inspection whereas India has seen only 10 units so far three - four years ago.
- Simpler procedure

Action *vis-a-vis* China 3

- **Anti dumping process** takes almost two years; By that time domestic industry is at the verge of closure. It has to be **fast tracked** to protect the Indian industry.

Industry Expectations from Government 1

- **Cheap and stable power** particularly for fermentation based products otherwise companies like Torrent, HAL, Alembic, IDPL, SPIC and JK etc. suffered heavily.
- **Cheaper land.**
- **Cluster scheme:** China has many such mega parks to have common effluent treatment plant, common lab, etc.
- **Special fiscal benefits** for large economic scale of production.
- **Reviving of PSUs.**

Industry Expectations from Government 2

- There is a **paucity of Biological strains** and whatever is available, it has poor yield.
- **Special Purpose Vehicle** funding through banks. as well as larger time of moratorium.
- **Energy:** Priority allocation of coal and Bio fuel natural gas.

Industry Expectations from Government 3

- **Rational use of Anti dumping law.**
- **Single Window System:** Constitutions of coordination committees of various departments to help the industry through single window. Example of China
- **Simpler Procedures.**

Conclusion

- Because of India's Growing Dependence on Imports:
- **API industry will suffer**
- **Formulations may become costlier**
 - Reduction in drug availability at affordable prices
- **Adverse effect on economy**
 - 'Make in India' campaign may suffer
 - Employment generation may decline
- **Need urgent Action**

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