

KNOWLEDGE PARTNERSHIP PROGRAMME Health & Disease Control

Promoting Indian API Industry: Increasing access to affordable and quality medicines in India and Developing Countries

Introduction

Currently the Indian pharmaceutical industry is valued around US\$ 14 billion. The global market of both generic and innovator APIs is estimated at US\$ 136.0 billion in 2013 and is expected to continue to grow moderately at a compound annual growth rate (CAGR) of 10.92% for the next four years. The focus of promoting API is also needed by the fact that India is one of the major suppliers of drug to the African market which is expected to grow exponentially. It is predicted that the African pharma market will be worth \$40 billion to \$65 billion by 2020. This necessitates India to focus all the more on strengthening the home grown API industry in order to cater to African markets.

In the last few years, large-scale imports from China have impacted API manufacturing in India. Chinese imports are cheaper and highly subsidised. There are concerns around erosion of domestic manufacturing capacity for certain key APIs and their advanced intermediates. Indian industry is more vulnerable to supply side shocks from China, which would affect access to generic medicines to domestic market as well as in LICs. There are also concerns related to quality of imported raw material. A comparative, Strength, Weakness Opportunities and Threat (SWOT) analysis table of India and China has been given below, with regard to future potential of the industry.

An in-depth study of API industry in India was commissioned under the Knowledge Partnership Programme supported by the DFID of the UK Government. This is from a perspective that India is termed as a global pharmacy for the developing countries, especially Africa. Strengthening Indian API is directly linked to effective quality and pricing in LICs.

The study objectives were (i) To understand and analyse pricing differentials in select categories of bulk pharmaceuticals in China and India. (ii) To review barriers in API manufacturing across processes employed, including strengths, weakness and challenges of Indian Industry. (iii) To understand how regulatory environment including environmental laws applicable to the sector are impacting growth of Industry.

Methodology

A situational assessment of the current global and Indian API industry was done through multiple sources of input, including publicly available databases like EXIM and Trademap, daily port-wise import figures, extensive interviews of 15 industry professionals, who also constituted the advisory committee for the study. The observation and discussion method along with secondary analysis and primary interviews with senior professionals of the Indian pharmaceuticals industry were followed to study the process of working.

| Future potential of the API Industry (SWOT Analysis) | | | |
|---|---|---|--|
| India | China | India | China |
| Strengths | | Opportunities | |
| -Stronger IP protection -Cost advantage -Capital efficiency due to local labour -Improved process engineering -Rich talent pool -Larger number of regulatory approved facilities | -Talented pool of scientists and engineers -Lower cost base -Improving IP and anti-counterfeiting environment due to increased FDA oversight -Leadership in fermentation based APIs and intermediates -Large scale of infrastructure -Government support | -Increased emphasis on FD for regulated markets -IT hub support to API manufacturers -Increased Contract Research and Manufacturing Services (CRAMS) business | -Strongest companies will expand into fixed dose formulations and regulated markets Focus more on final API mfg. -Booming local demand |
| Weakness | | Threats | |
| Increased costs as landed Chinese imports become more expensive -Greater reliance on China | Increasing cost of labour, power and land resulting in closure | -Cumbersome regulatory environment -Intense competition and squeezing margins | -Strengthened SFDA oversight -Further reductions in export incentives -Many manufacturers will not survive |

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Key Areas of Intervention for Stakeholders

Government

- The government should facilitate reduction in capital costs especially for the small and medium-sized enterprises (SMEs).
- The existing credit schemes should be made more SME industry friendly to encourage setting up of more units.
- A possible scenario of increasing rates of import tariff ascending from Basic Chemicals/Fine Chemicals group to Key Starting Materials (KSMs) /Intermediates Group to APIs Group to Formulations Group.
- Anti-dumping duty should be used for creating infrastructure and corpus to incentivize the API industry.
- Approvals and clearances process need to be hastened through setting up of 'single window clearance mechanism' for the cluster as currently there are more than 25 departments for approvals.
- India needs to develop R&D for processes such as fermentation, biosimilar, enzymatic chemistry, fluorination, peptide chemistry etc. The government needs to attract international scientists and collaborate with international labs.
- The government needs to encourage a design based approach in formation of large scale API cluster in form of Special Economic Zones (SEZs) to enable companies to build scale and vertical integration. The cluster should promote shared service platform/models for: Warehousing; Utilities - ETP, water supply; R&D etc.
- Cluster should be developed in such a way to support small and mid-size industry by promoting pay and use model and KSMs.
- There is scope for increasing synergy between industry and major government institutions and universities for technology transfer and IPR for research and innovation. The government should encourage universities to develop corpus for developing patents.

Industry

- The industry needs to build capacity and make the central quality lab responsible and accountable for the utilization of funds in R&D. In terms of incentives, a provision of 1-2% royalty by industry can be paid to the central lab for R&D projects.
- There is a need to foster process and chemistry innovation: Increased investments in the latest technology and R&D can facilitate novel, alternate routes to manufacturing, and help to bring down the cost of production through more efficient processes and improved yields. Additionally, alternative routes of synthesis can be explored to reduce effluents, thereby reducing the environmental impact as well as the costs of effluent treatment.

Conclusion

Given the focus in current policies to make in India and ease doing business, API industries in India is well poised to optimally undertake rapid expansion. This will serve the healthcare needs by increasing access to low cost quality drugs in India and LICs.

For the detailed report visit www.ipekpp.com

KPP is a South-South cooperation programme promoting knowledge sharing in the areas of Food Security, Resource Scarcity and Climate Change; Health and Disease Control; Trade and Investment; and Women and Girls. KPP is funded by the Government of UK, Department for International Development (DFID) and managed by a consortium led by IPE Global Private Limited under its Knowledge Initiative. The main objective of KPP is 'Gathering and uptake of evidence on issues central to India's national development that have potential for replication in LICs and impact on global poverty'.



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