Promoting Active Pharmaceutical Ingredients (APIs) Manufacturing in India: Policy Challenges for Make in India and Way Forward

Summary

Policy Context and Concerns

The Indian pharmaceutical industry is challenged by the gradual erosion of domestic manufacturing capacity for certain key APIs and their advanced intermediates. Over a period of time, Indian pharma players have steadily migrated up the value chain to focus on value-added formulations with higher margins. As a result, there are not many domestic producers manufacturing APIs and key intermediates thus relying heavily on China for imports. Not only this makes Indian industry more vulnerable to supply side shocks from China, which would affect access to generic medicines to domestic market as well as in LICs at the same time there could be concerns related to quality of imported raw material. This is all the more relevant considering Government's emphasis on "Make in India."

Project Details

An analytic study was commissioned under the Government of UK's Department for International Development (DFID) supported Knowledge Partnership Programme (KPP) to understand API manufacturing eco-system in India and what specific policy measures would boost investments in country. Study methods involved review of secondary data for assessing extent of imports in value and volume terms. Additionally a stakeholders meeting was held to gather information about key policy barriers and challenges in investing for API manufacturing.

Findings

A SWOT analysis of API Industry indicates growing potential for pharmaceutical manufacturing in China and India, huge domestic and export market with increasing focus on biosimilars. Indian Industry needs right policy incentives to offset advantages enjoyed by China industry in terms of access to capital and ease of doing business. Arbitrary interpretation of relevant environment pollution regulations by local officials is also perceived as a major negative for growth of Industry.

Key Recommendations

The key recommendations for incorporating in policy are as follows:

- *Securing short-term supply of essential drugs and advanced intermediates*
  - *Identify key drug categories that address disease areas*
  - *Build end–to–end manufacturing facilities at scale*
  - Encourage process and chemistry innovation

- *Formation of API clusters/ mega parks for shared infrastructure and scale*
  - *Design based approach in formation of Large Manufacturing Zones (LMZs)/ mega parks for APIs*
  - *Streamlining approval process – focus on environmental clearance and licenses*
  - *Requirement of aligning the provisions of the Acts and rules*
  - *Introduce an integrated regulatory system through the constitution of a National Drug Administration*
  - *Hastening of approvals and clearances process*

- *Invest in R&D to foster innovation and promote collaboration through PPP models*
  - Establishment of a strong IPR enforcement regime
  - Encourage synergy between industry and major government institutions and universities
  - Incentivize continuous process innovation especially rewarding R&D
  - Collaborative approach with the industry including funding of private sector initiatives in PPP mode

- *Strong enforcement of Anti-dumping barriers*
  - Concession on raw material: 2 to 3% (from current 7.5%)
  - Intermediates: 7 to 9%
  - Increase tariff on API: 10-15%

- *Provision of financial incentives for promoting domestic manufacturing of APIs*
  - Promote schemes pertaining to cost of capital especially for the SMEs
  - Provision of capital expenditure loan to manufacturers of APIs for high priority identified drugs
  - Provisions for providing soft loans through interest subvention
  - Capacity building workshops should be initiated within the govt. department

Background

India, known as the 'Pharmacy of the World,' is exporting pharmaceuticals to more than 200 countries and ranks 13th in value terms and 3rd in volume terms in the global pharmaceutical market. India is expected to join the league of the top 10 global pharmaceuticals markets in terms of sales by 2020, with the total value reaching USD 50 billion.

Expanding medical care infrastructure, increasing health insurance penetration, rising healthcare spending, a huge untapped healthcare market and changing disease patterns will provide a surge in growth of the Indian generic pharma industry.

Additionally, the impending patent expiries will make an over US$100 billion market available (at innovator price) to explore by generic pharma industry.

Generic APIs are already outpacing growth of innovator and branded APIs and growth is expected to continue in future.

Overall generic API market is expected to increase at an annual rate 7.7% to USD 30.6 billion in 2016. In case of bulk drugs (APIs), there are almost 2500 manufacturing units with estimated turnover of about USD 12 Billion that accounts for approximately 10% of the global bulk drug market.

Clearly India is poised to achieve pole position as the provider of high-quality and affordable generic medicines for the whole world, given that all countries are taking cost containment measures in quest of providing Universal Health Coverage.

WHO defines APIs as substance used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.*(WHO 2011)*

Firms either sell APIs on the open market ("merchant market") or use them to do their own final formulations manufacturing.

Firms that manufacture both APIs and final formulations will usually still buy and sell APIs on the merchant market.

Make in India initiative of Government of India acknowledged the need for giving a thrust to bulk manufacturing in India. Appropriate policy framework would provide necessary stimulus to domestic API Industry to compete with China to be a preferred partner for global players by 2020.

TYPOLOGY OF API MANUFACTURERS

The APIs industry has three kinds of manufacturers: captive, merchant, and contract manufacturers. Captive manufacturers are backwardly integrated pharmaceutical companies. The APIs produced by these manufacturers are used for in-house production of drug formulations.
Merchant Manufacturers -They produce APIs only for the purpose of selling them in the open market. Mostly these manufacturers sell APIs to the traders or distributors in the open market, who in turn supply them to the drug formulating companies.
Contract Manufacturers- These manufacturers produce APIs for specific drug producers and supply them directly. These are manufacturing companies to whom the drug formulators have outsourced the manufacturing of APIs through a contract. Sometimes these Contract Manufacturing Organisations (CMOs) are also vertically integrated with the drug formulating companies.

Study Purpose

APIs are integral components of both the quality and the cost of pharmaceutical products. Easy access to quality APIs at low costs for finished product manufacturers should be pursued as a public health goal in light of Universal Health Coverage. This requires looking at the API market from a sustainability and quality as well as from a price perspective. As every specific API market is diverse, each market should be examined individually to determine if it is competitive with affordable prices.

The Indian pharma industry is a leader in finished pharma products segment. Increasing burden of Non communicable diseases including mental health and emerging prophylactic options such as polypills offers an opportunity to Indian industry for developing a strong product pipeline. Concerns are raised about growing dependence of Indian manufacturers on Chinese API suppliers.

Make in India initiative of Government of India acknowledged the need for giving a thrust to bulk manufacturing in India. Appropriate policy framework would provide necessary stimulus to domestic API Industry to compete with China to be a preferred partner for global players by 2020.*(Centre's 'Make in India' thrust to fuel API sector growth & cut imports from China: Anjan K Roy).*Arguably Indian API industry will be on a high growth trajectory since the new government is looking to encourage domestic manufacturing with a slew of benefits.

Study Findings

This paper provides a landscape of API manufacturing in India, challenges from China and possible policy measures to promote API manufacturing in country. Some of the key areas of consideration addressed in this paper are:

- *Securing short-term supply of essential drugs and advanced intermediates*
- *Formation of API clusters/ mega parks for shared infrastructure and scale*
- *Streamlining approval process – focus on environmental clearance and licenses*
- *Invest in R&D to foster innovation and promote collaboration through PPP models*
- *Strong enforcement of Anti-dumping barriers*
- *Provision of financial incentives for promoting domestic manufacturing of APIs*

Global API Market

The global API market can broadly be divided into regulated and semi regulated markets. The semi regulated markets offer low entry barriers in terms of regulatory requirements and intellectual property rights. The highly regulated markets, like the United States and Europe, have high entry barriers in terms of intellectual property rights and regulatory requirements, including facility approvals. As a result, there is a premium for quality and regulatory compliance along with relatively greater stability for both volumes and prices. The API manufacturers specialize and target their manufacturing based on a combination of the market opportunities and firm's experience and skills.

Driven by lower costs, API manufacturing has slowly been shifting from the historical leaders in Western countries to newer firms in India and China. The distribution of API manufacturers in Asia clearly points China having presence of about 61 percent manufacturers and India having only 33 percent. Remaining 6 percent manufacturers are in other Asian countries.

The role of Indian bulk drug industry in the global pharmaceutical supply chain is gradually evolving with increasing presence in synthesis and manufacture of late stage intermediates and APIs

Traditionally, innovators have frequently opted to perform final stages of API synthesis in-house or partner with specialised European suppliers while outsourcing early stage intermediates to Indian manufacturers. However, in recent times, the reputed track record of Indian companies in supplying quality products coupled with complex synthesis capabilities has enabled increasing participation in supply of late stage intermediates to innovator companies.

The global API 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 CAGR of 10.92% for the next 4 years. Over the next five years, the market of the APIs is expected to reach US$ 206.9 billion by 2017. The market in the near future is expected to witness consolidation and an increased demand for generic APIs in developing countries, especially in China and India.

As per reports, India is running the risk of a severe shortage of medicines because of overdependence on China for supply of APIs. According to the National Security Adviser, India should take immediate concrete steps to create adequate infrastructure to become self-sufficient for manufacturing medicines which are essential in nature. This is crucial because any kind of tension or adverse circumstances between the two countries have potential to lead to a crisis in public health in India and elsewhere. *(Times of India, 2014)*

The Chinese Scenario and Its Influence on Indian API Industry

China has emerged as the dominant player in the global API industry due to its large-scale manufacturing capabilities of APIs and intermediates, with strengths in fermentation technology. In the last few years, large-scale imports from China have impacted API manufacturing in India. Chinese imports are cheaper and highly subsidised. Approximately US$2.1 billion of Chinese API, and intermediates (the raw material for manufacture of API), is being consumed by the Indian pharmaceutical industry in 2013. China presently supplies over 30% of India's requirements of APIs.

The focus of the Chinese government to drive innovation and scale leading growth and support to pharma as a key area, in turn was responsible for the Chinese API industry with large scale, low cost and better infrastructure such as power, transportation etc. China has also built large capabilities in intermediate space and has gained significantly in the global API market with lower cost and scale as the key drivers.

Globally, innovator companies do not outsource APIs for their products till they are protected by patents. However, after the patent expires, innovator companies gradually begin outsourcing APIs in order to achieve greater cost efficiencies to compete with generics. Companies like Pfizer, AstraZeneca, GSK and others are partnering with API suppliers in China to fulfill their bulk drug requirements

The table below presents the positives and negatives for Indian API Industry:

Table 1: Summary of Indian API scenario

Parameters	What's working	What's Not Working
Research and Development (R&D) and Innovation	Existing National Centre for Research & Development in Bulk Drug (NCRDBD) at National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad	• Large-scale Indian manufacturing firms have stopped spending money on R&D for APIs due to high cost and low margins; their primary focus is promoting formulations • The overall spend of pharmaceutical industry on R&D is estimated at a mere 2% of sales as against 10-20% global average • Currently there are no specific tax benefits available to units engaged in contract R&D or undertaking R&D for group companies. At present, the weighted tax deduction on R&D is 200% which is insufficient to cover the cost of R&D.
Policy and tax incentives	The government has announced 5% interest subsidy for SME to upgrade their facilities to WHO and GMP standard under Pharmaceutical Technology Up-gradation Assistance Scheme (PTUAS) and Credit Linked Capital Subsidy Scheme (CLCSS)	• Due to stringent regulations related with pollution control around 14 API manufacturing plants were closed in Andhra Pradesh • The process for new API approval takes approximate 2 – 3 years • 74 API's prices are controlled by National Pharmaceutical Pricing Authority (NPPA), these APIs account for a large share of formulations. The price mechanism discourages the manufacturers. • High central excise duty of 12% (plus 3% cess) on APIs, whereas formulations are subject to central excise duty of 6% (plus 3% cess) • Unfavourable anti-dumping duties on bulk drugs from China. For e.g. Indian government levies a low registration fee of INR 2,000 per product for the Chinese pharma companies, whereas China imposes INR 20,000 per product for Indian pharma companies.
Skill development	Qualified population base is providing technical manpower to the industry. Every year around 300,000 post graduates and 1500 PhDs are qualifying in biosciences in India.	Need to develop strong manufacturing capabilities in terms of scientific and technological skills to develop product segments such as antibiotics, vitamins etc. which are primarily imported from China.
Infrastructure	More than 500 manufacturing plants in the county are registered with the US Food and Drug Administration (USFDA), the largest outside the US, over 800 plants have approval from the European Directorate for the Quality of Medicines (EDQM) and 845 plants have Australian regulatory approvals.	• The non-availability of key raw materials such as Phosphorous, Potassium & Sulphur and slow logistic services is increasing the cost and dependency on China. • Lack of development of industrial infrastructure such as dedicated industry zones and plant modernization
Investment Environment	Big pharma companies are investing in India as the cost of R&D and production is comparatively low in India	• At present there is no provision of low interest loans to companies manufacturing APIs • Although Indian pharmaceutical products are globally recognized, it lacks in terms of investment in API production which require inter alia cheap power and other infrastructure facilities.

The global API market of both generic and innovator APIs is expected to reach US$ 206.9 billion by 2017 with a growth rate of CAGR 11%. The findings from study commissioned under the Knowledge Partnership Programme is in synchronisation with the recommendations from the high-level Katoch Committee constituted by the Government of India to study and identify the APIs of critical importance and work on interventions for the same.

Recommendations from the Review study commissioned under the Knowledge Partnership Programme (2015)

An in-depth study of API industry in India was commissioned under the Knowledge Partnership Programme supported by the DFID of the UK Government. 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 initial findings were shared with the advisory committee meetings and views were gathered for promoting favourable policy environment. The findings are given in the form of the rationale for each set of recommendations:

I. Securing short-term supply of essential drugs and advanced intermediates

Recommendations

a) The government should identify key drug categories that address disease areas with significant burden in India. We recommend the following drug classes:

- First–line antibiotics (for example, Semi-Synthetic Penicillins (SSPs), Semi-Synthetic Cephalosporins (SSCs), Fluoroquinolones)
- Analgesics (Like Paracetamol, Ibuprofen)
- First–line cardiovascular drugs (for example, ARBs, Ace Inhibitors)
- First–line Anti–diabetes drugs (Like Metformin)
- Anti–cholesterol drugs (for example, Statins)
- Anti-Hypertensive (for example, Sartans)
- Anti-Retroviral (for example, Acyclovir)

b) Build end–to–end manufacturing facilities at scale: The government should promote the setting up of vertically integrated manufacturing facilities for essential drugs, at a competitive scale.

These facilities must be built at optimal scale to achieve economic scale. The govt. can help set up capacities for these APIs / intermediates by providing fiscal incentives such as subsidized debt, tax and duty breaks on capital equipment.

c) Encourage 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.

Rationale

a) The import of advanced intermediates and fine chemicals is 80-82% dependent on China due to low price differential of 2-2.5% as compared to India making it viable for Indian manufacturers to import it from China.

b) Currently, India is facing a slack in availability of advanced intermediate and fine chemicals for API manufacturing like: Among top 30 products imported from China, for example, Antibiotics, Prazoles, Quinillons, Sartans (Anti-hypertensive, sulphnylureas, anti-diabetic), Prils, antiretroviral, Pen-G, OTBN etc. are completely dependent on China as domestic manufacturing has moved out of India.

c) Lack of clear definition by the government for intermediate, fine chemicals, finished products and APIs

d) Low economies of scale deter India from manufacturing basic chemicals and entirely dependent on China.

II. Adopt a cluster based approach for shared infrastructure

Recommendations

a) Adopt a design based approach in formation of Large Manufacturing Zones (LMZs)/ mega parks for APIs with common facilities maintained by separate Special Purpose Vehicle (SPV) needs to be explored to enable companies to build scale and vertical integration.

b) The mega parks should promote common facilities except for processes such as common Effluent Treatment Plants (ETPs), Testing facilities, Captive power plants/ assured power supply by state systems, common utilities/ services such as storage, testing laboratories, IPR management etc.

c) Cluster should be developed in such a way to support small and mid size industry by promoting pay and use model and key starting material (KSMs).

d) Provision of 'no taxation' should be levied for any internal transaction within the cluster. Subsidization and focused export scheme should be promoted such as meeting working capital for SMEs etc.

e) State Governments should be a partner in promoting cluster based approach in India. The zones/ clusters could be established in National Manufacturing Investment Zones/ Petroleum, Chemical and Petrochemical Investment Regions (PCPIRs) in states that have requisite facilities and services

Rationale

a) China has a cluster system where they have pre-approved design starting from raw materials, power, infrastructure, common boiler, lab space etc. The govt. prepares mini cluster alongside the main cluster in the region which results in overall cost reduction by 20-30%.

b) Currently, China has 15 to 16 pharma clusters (Beijing Zhongguancun Science Park, Wuhan Biolake etc.) spanning over ~15,000 acres in areas of Guangzhou, Sichuan, Beijing etc.

III. Streamlining approval process – focus on environmental clearance and licenses

Recommendations

a) Government should recruit experts for granting licenses and industry should be allowed to get licenses approved from government accredited experts.

b) Requirement of aligning the provisions of the Acts and rules regarding pollution, quality control, custom and excise duty, export bodies, coal allocating bodies, electricity authorities by allocating a cell in the proposed API clusters/zones/ mega parks

c) The government should introduce an integrated regulatory system through the constitution of a National Drug Administration so that technological, financial and regulatory challenges can be truly assessed

d) Hastening of approvals and clearances process through setting up of 'single window clearance mechanism' for the cluster as there are more than 25 departments for approvals.

Rationale

a) The Government levies an extremely low registration fee of INR 2,000 per product for Chinese pharmaceutical companies, whereas China imposes an exorbitant fee of INR 20,000 per product for Indian pharma companies.

b) In case of change of products to be manufactured, the company is required to get environment clearances even if the company has improved its yield and increase the production, the industry has to get environment clearances for reducing pollution and increasing production.

c) Currently, different regulatory bodies are performing a checks and balances on the API manufacturing, access and price of essential drugs etc. leading delay in approvals and licenses.

d) India industry bodies do not visit China to check the products imported by India whereas Chinese industry bodies always keep a check of products exported to India.

e) For a Chinese manufacturer to sell its products in India, the registration takes just 4 months whereas an Indian manufacturer to sell its products in China takes 2 to 3 years for registration.

f) From 1990 to 2000, API manufacturers faced bans and closures due to lack of awareness by the chemical industry to the manufacturers regarding environmental issues and regulations.

IV. Invest in R&D to foster innovation and promote collaboration through PPP models

Recommendations

a) Establishment of a strong IPR enforcement regime that would protect innovation and stimulate the growth of Indian pharmaceutical industry

b) 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.

c) Encourage 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.

d) Currently, the research in India has immense scope for development. There is need to develop R&D for processes such as fermentation, biosimilar, enzymatic chemistry, fluronation, peptile chemistry etc. The government needs to attract international scientists and collaborate with international labs.

e) Incentivize continuous process innovation especially rewarding R&D in key technologies such as fermentation, chiral chemistry, bio–catalysis etc. to encourage SMEs to carry out significant innovations at pilot production level.

f) The government should promote collaborative approach with the industry including funding of private sector initiatives in PPP mode

- Utilize capacities of public sector undertakings (PSUs) like Indian Drug & Pharmaceutical Ltd. etc. that invested in manufacturing infrastructure required for many of these APIs and intermediates
- Engage private players to manage operations so that optimal utilization of the existing capacity is ensured. These capacities need to be enhanced in order to achieve economic scale of production.

Rationale

e) Currently, lack of strong IPR enforcement regime in India is impacting the pharma company's ability to recoup their cost and invest in research projects. Enormous investments are necessary to support this time-intensive, extremely expensive, and risky effort.

f) In countries like US, professors are required to produce a set number of research papers to qualify as faculty. The government supports international scientists to work for the upliftment of the industry.

g) China follows a pattern in R&D which includes monitoring technology on fine chemicals and invests in building capacity and skills. Whereas India lacks set pattern and focus on price margins rather than research.

V. Strong enforcement of Anti-dumping barriers

Recommendations

a) A possible scenario of increasing rates of tariff ascending from Basic Chemicals/Fine Chemicals group to KSMs/Intermediates Group to APIs Group to Formulations Group. The Basic Customs Import Tariff today for the entire gamut APIs, Intermediates and Fine Chemicals/other early stage chemicals are all at 7.5%. Very few specified items attract duty of 10% and 12.5% etc. It should be proposed:

- Concession on raw material: 2 to 3% (from current 7.5%)
- Intermediates: 7 to 9%
- Increase tariff on API: 10-15%

b) Anti-dumping money should be used for creating infrastructure and creating a fund corpus.

Rationale

Currently, there is no anti-dumping duty on Chinese products, only few products are levied with anti-dumping duty whereas China levies anti-dumping duty from 11 to 17% on all the India products.

VI. Financial Incentives

Recommendation

b) The government should promote schemes pertaining to cost of capital especially for the SMEs. A scheme where 25% can be SME's own contribution, 50% can be borne by the government and remaining 25% can be given by the financial institution at low interest rates and soft terms.

c) Provision of capital expenditure loan to manufacturers of APIs for high priority identified drugs, with moratorium of 10 years for repayment. Alternatively, debt instruments should be long term i.e. 3 to 5 years for APIs/ intermediates and 3 to 7 years duration for fermentation

d) The state government should make provisions for providing soft loans through interest subvention upto 7.5%, at least at par with interbank lending rates to the SMEs for setting up of manufacturing units.

e) All central and state duties, taxes, etc. in creating the entire community cluster infrastructure and individual unit infrastructure should be zero. If a unit promises more than 50% capacity utilized for national list of essential medicine (NLEM) products then atleast these benefits should be provided.

f) Capacity building workshops should be initiated within the govt. department in order to build exposure to new technologies, increase knowledge on sector and attract quality professionals by providing high payscale

g) Favourable policies such as special export rebates for large companies for domestic sourcing or captive sourcing of advanced intermediates

- Benefits in form of incremental rebates of 8-9% for large companies sourcing KSM in house or from small-mid scale companies.
- Potentially mandate 20-30% domestic sourcing for KSMs and intermediate for large companies

a) The level of assistance provided under MAI scheme is 50% of the registration charges/ expenses subject to a ceiling of INR 50 lakhs per annum, it should be increased from INR 50 lakhs to INR 1 crore per annum

Rationale

a) Indian API Industry is facing deterioration of the working capital cycle especially on the domestic debtor days and inventory periods. For most API companies, working capital cycles tend to be between 120-180 days. The banking community however continues to ignore this business aspect of the industry and refuses to fund the longer cycle

b) The overall cost of manufacturing in India is high as compared to China in areas such as:

- Overhead cost
- Power cost – interrupted and inefficient supply leading to high replacement cost on generators/ power backups

c) Management cost – labour cost is low in India whereas supervisor/ management cost is relatively high in India

Recommendations resonate with High-level Katoch Committee released in September 2015 constituted by Government of India to study and identify the APIs of critical importance and to work out a package of interventions/concessions required to build domestic production capabilities and to examine the cost implications. These recommendations are being examined for formulation of a Policy for Promotion of Manufacturing of Bulk Drugs.

The Way Forward

The Katoch Committee has inter-alia recommended establishment of Mega Parks for APIs with common facilities such as common effluent treatment plants (ETPs), testing facilities and captive power plants/assured power supply by state systems. It has also suggested establishment of common utilities and services such as storage, testing laboratories, IPR management, designing, guest house/accommodation etc. maintained by a separate special purpose vehicle (SPV).

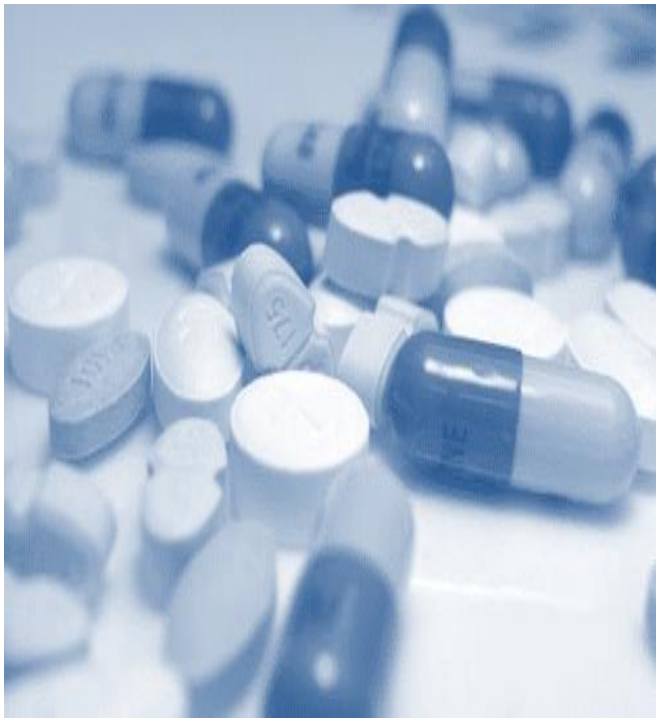
The Committee further recommended a scheme aimed at providing financial assistance to states in acquiring land, revival of public sector units for starting the manufacturing of selected and very essential critical drugs.

A separate financial investment support from the government has also been recommended towards the development of clusters. The Committee recommends that the investment from the government may be in the form of professionally managed dedicated equity fund for promotion of manufacture of APIs. (EThealthworld.com, 2015)

The Committee also suggests the government to extend fiscal benefits for creation of the entire community cluster infrastructure, individual unit infrastructure and for promotion of the bulk drugs sector. The Committee, on the whole, makes a primary pitch for the industry-academia interaction, enhanced research and development promotion activities by the government agencies, incentivizing scientists, duty exemptions for capital goods imports.

India is very much dependent on import from a single source for basic chemicals, intermediates and APIs for many commonly used medicines. To avoid the price and supply risks associated with such situation and ensure assured and sustained availability of these basic inputs to formulation sector, there is a felt need to focus the attention to promote the manufacturing of API in India. This is also consistent with the avowed objective of the government regarding 'Make in India'. In recognition of the situation, Department of Pharmaceuticals has declared the Year 2015 as the Year of API.

The Government will take measures to facilitate the growth of the sector and also interact with the industry on a more regular basis to improve Government to Business interactions and promote better and more coordinated efforts to achieve the objective of 'Make in India', especially for the API sector. Failing to do so would make India vulnerable to supply side shocks and compromise realisation of goal of universal health coverage.



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's 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'.

Contact Us: Dr Dinesh Agarwal
Policy Lead: Health & Disease Control
IPE Global Pvt. Ltd. B – 84, Defence Colony, 110 024, New Delhi, India
Phone Main: 0091 11 4075 5974; Direct: 0091 11 4075 5984
E-mail: dagarwal @ipeglobal.com
www.ipekpp.com

Knowledge Partnership Programme
IPE GLOBAL Expanding Horizons. Enriching Lives.
Supported by UKaid from the British people