KPMG

CII
Confederation of Indian Industry

Indian bulk drugs industry – Regaining the lost glory

Published by Confederation of Indian Industry (CII), The Mantosh Sondhi Centre; 23, Institutional Area, Lodi Road, New Delhi 110003, India, Tel: +91-11-24629994-7, Fax: +91-11-24626149; Email: info@cii.in; Web: www.cii.in

Foreword

The Indian pharmaceutical industry has generated pride in both the global and domestic markets; it is eyeing a sea of opportunities as global demand for safe and quality drugs rises, especially in developed economies such as the US, EU and Japan.

However, the industry has faced several challenges in the last couple of years on the API front. China's increasing prowess in certain APIs and intermediates and the resulting import dependence have emerged as a significant threat.

Appreciating the significance of this concern, the Confederation of Indian Industry (CII) and KPMG in India have developed this API report to bring about the right discussion with policy makers on the need for action. This report attempts to re-analyse the extent of India's dependence, understand key drivers of dependence and make recommendations for the Indian government and industry stakeholders on key initiatives to reduce this dependence.

I thank KPMG in India for collaborating with CII and contributing in developing this contemporary report to regain Indian leadership in APIs. I also extend my sincere thanks to all the members of CII National Committee on Pharmaceuticals, for sharing their inputs to be included in this report, which I believe will be able to bring forth the best solutions that are directional in nature. The detailed initiatives will need to be developed involving all key stakeholders – API producers, upstream players (for example, chemical industry players) and various government stakeholders.

Dr. Rajiv I Modi

Chairman, CII National Committee on Pharmaceuticals
Chairman and Managing Director, Cadila Pharmaceuticals

Foreword

The Indian pharmaceutical industry enjoys an important position in the global industry. The industry ranks third in terms of volume and is the thirteenth largest in terms of value in the world today. The impact transcends the value chain, with Indian pharmaceutical companies leading in Active Pharmaceutical Ingredients (APIs) as well as formulations.

India, which was long a major player in APIs, is gradually losing ground to other countries and is becoming heavily dependent on imports of APIs and advanced intermediates used to manufacture key drugs. This development is of concern to all stakeholders, including Government, industry and academia.

The API paper aims at providing useful policy inputs and recommendations to the Government to develop a sustainable support system for the revival of the Indian API industry. It also highlights the gaps present in the Indian API Industry, and strategies to map these gaps to solutions to support the sector.

CII hopes that this document will enable both the Government and industry to drive a focussed growth agenda for the sector through further consultation on each of the ideas presented in the paper.

Chandrajit Banerjee

Director General
Confederation of Indian Industry

Foreword

With every passing decade since 1970, India's pharmaceutical industry has gone from strength to strength in terms of broadening of scope, to deepening its prowess across the industry value chain. In a short span of time, the industry has rightfully gained the epithet 'pharmacy to the world.' The growth of the industry has been fueled by adopting global standards and setting up plants of scale while leveraging the inherent competitive advantage that India offers in terms of its talent pool.

In the past, a well-developed bulk drugs manufacturing sector ensured that India remained self-dependent for its intermediates and APIs (active pharmaceutical ingredients) demand. India's bulk drug sector continuously innovated to supply high-quality, cost-competitive intermediates and APIs to both the domestic and international markets. Consequently, this led to India becoming the third-largest supplier of bulk drugs globally.[1]

In recent years, however, India saw increased competition from a number of emerging players, especially China. These countries have been able to leverage their inherent cost advantage, manufacturing intermediates and APIs at a cost much lower than those in India resulting in a gradual increase in imports and a slow but steady erosion of domestic manufacturing capacity for certain key APIs and their advanced intermediates.

While Indian players, over a period of time steadily migrated up the value chain to focus on value-added formulations with higher margins, India continued to become dependent on imports for many essential and large-volume drugs. This dependence increased the threat to the nation's health security as some of these APIs are crucial to mitigate India's growing disease burden.

Any disruption in supply chain of APIs can potentially result in significant shortages in the supply of essential drugs in India. Given the strategic nature of this dependence, urgent interventions from the Government as well as industry are desired.

To enable the Indian bulk drug sector retain its competitive advantage and achieve self-sufficiency, this position paper aims at reflecting the current state of the bulk drug sector in India, assessing the existing gaps and exploring suitable recommendations to mitigate the challenges.

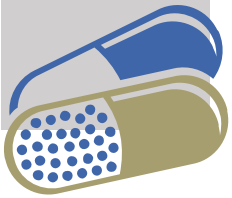
Ravind Mithe

Partner – Management Consulting
KPMG in India

Source: 1 - Manufacturing of Bulk Drugs, Government of Gujarat, Vibrant Gujarat, 2017

Table of Contents

Table of contents



Preamble

Over the past few decades, the Indian pharmaceutical industry has witnessed high growth and contributed significantly to the global generics market. India fulfils 20 per cent[1] of global demand for generic medicines in terms of volume, making the country the largest provider of generic medicines in the world. The Indian bulk drug industry is ranked the third-largest in the world and has grown at a compound annual growth rate (CAGR) of 5.6 per cent[2] over 2011–16; it is further expected to grow at a CAGR of 7.3 per cent during 2017–22, signifying its future potential and evolving global importance.[2]

Over the last decade, India has observed increased dependence on imports of many basic intermediates and APIs. From 2004 to 2016, the import of APIs have risen at a CAGR of 11 per cent.[3] In 2016, India's bulk drug import reached a value of USD2.8 billion,[3] contributing approximately 19 per cent to the total bulk drug market. The increasing import dependency can be attributed primarily to the availability of low-cost API imports from countries such as China.

The dependency of API imports specifically from China has been a cause of major concern for industry. India imports nearly 70 per cent[3] of API, by value, from China, and the latter is also a single supplier for many of the critical intermediaries and APIs. Some of the critical APIs for high-burden disease categories such as cardiovascular diseases (for example, Digoxin and Losartan), diabetes (Metformin and Glimepiride) and tuberculosis (Isoniazid and Streptomycin) are also listed in the National List of Essential Medicines (NLEM). In fact, the current market is largely dependent on China for many antibiotic APIs manufactured by the fermentation route such as penicillin, cephalosporins and macrolides. The increased dependency of low-cost API is mainly attributed to China's extensive efforts towards developing economies of scale, easing regulations for bulk drug manufacturers, availability of low-cost utilities, building process efficiencies and supporting manufacturers in the form of subsidy, low taxes and fiscal incentives.

The pharmaceutical industry is a sector of strategic importance that ensures the health security of the nation. Such a high dependency of intermediates and APIs on a single supplier poses a threat to the nation's health security. The current scenario thus demands urgent attention and immediate steps to ensure self-reliance.

The Government has taken constructive steps to improve the business ecosystem over the past few years and the country has climbed up 30 places to reach the 'Top 100' rankings on the World Bank's Ease of Doing Business (EoDB) index in Doing Business 2018 report.[4] It has also taken various positive steps for the pharmaceutical industry such as increasing the limit on foreign direct investment (FDI) in pharmaceutical projects, formulating a new intellectual property rights (IPR) policy to foster innovation and promoting industry academia collaboration. However, the Government needs to focus its attention towards the local API industry to help reduce import dependency.

The current scenario demands a need to build a conducive ecosystem and increase competitiveness for local manufacturers to match costs with other countries. This can be accomplished by adopting measures such as building API clusters, providing low cost utilities, financial incentives, facilitating single-window clearance and promoting innovation. These steps would not only enable the industry to build self-sufficiency in API manufacturing, but would also secure its pharma supply chain.

This thought leadership document presents the current state of the bulk drug industry in India; assesses gaps; and explores recommendations to mitigate the challenges associated with API import dependency thereby establishing self-sufficiency of APIs.

Sources: 1 - Domestic formulations, Crisil research database, accessed October 2017; 2 - Bulk drugs – Industry information, Crisil research database, accessed October 2017; 3 - Data by bulk drug and drug intermediates, Director General of Commercial Intelligence and Statistics, accessed October 2017; 4 - Doing Business 2018: Reforming to create jobs, World Bank Group, 2017

Key findings

Bulk drug industry in India

- The bulk drug industry in India is ranked third-largest globally, behind China and Italy
- About 36 per cent of bulk drugs produced in India are exported and the remaining bulk drugs are sold in the domestic market, including captive consumption by several large formulation players

Bulk drug import dependency

- In 2016, India imported nearly 272 million kgs of bulk drugs and intermediates valued at nearly USD2.8 billion. Imports of APIs have grown at a CAGR of 11 per cent from USD800 million in 2004 to USD2.8 billion in 2016
- China alone contributes about 60 per cent of all such imports by volume and 70 per cent by value in 2016
- For antibiotics, India is heavily reliant on Chinese imports for both the API as well as the key intermediates such as 6APA (100%); Penicillin (98.5%), Ciprofloxacin (99%), metronidazole in 2016
- India is also heavily dependent upon Chinese API imports for many drugs present in National List of Essential Medicines (NLEM) such as for anti-diabetic drug – Metformin (89%); cardiovascular drug – Digoxin (98%); anti-tuberculosis drug – Isoniazid (99%); anti-protozoal drugs – Metronidazole (99%) in 2016

Key challenges

- Inadequate Government support and API focused infrastructure; complexity in getting approvals for setting up a manufacturing plant; slow pollution clearances; high cost and low availability of utilities; complex regulatory and tax structure and price control regime are some of the key challenges faced by the bulk drug industry

Advantage of Chinese bulk drug manufacturers

- Government facilitation; low utility cost; presence of large chemical industry; large scale of operations; high availability of raw material and investment in technology are some of the key factors providing advantage to Chinese bulk drug manufacturers

Recommendations

- **Short-term**: Increase synchronization between center and state to facilitate approval process; increase competitiveness of Indian players by providing low cost utilities, incentives for manufacturing critical APIs and restrict price control regime; utilize existing capacities by providing fund for modernisation of technology and leverage PSUs; focus on quality by doing mandatory inspection of foreign manufacturing units and testing quality of imported APIs; map critical APIs with high diseases burden categories; secure supply chain by signing memorandum of understanding (MoU) with some friendly nations
- **Mid-term**: Increase investment in research and development (R&D); create financial incentives; provide conducive regulatory environment; increase collaboration between academia and industry; develop scientific talent pool; increase Government grants for R&D; declare API as a strategic sector; encourage reverse brain drain for Indian scientists; incentivize manufacturing of complex APIs; create production capacity abroad to secure supply chain
- **Long-term**: Adopt a cluster development approach to establish bulk drug parks. Clusters can provide various advantages such as economies of scale and common infrastructure such as effluent treatment plant, testing laboratories, R&D center etc.

Note – Sources are mentioned in next sections of the report

API manufacturing in India

The voice of the industry

Dependence on API imports

~70%

respondents stated that they are dependent upon imports

Bulk drugs and intermediate imports

203 mn kgs

India's overall API dependency on China (by value)

~70%

API Imports from China

~80%

respondents stated that they are dependent upon Chinese APIs

API import growth from China

10-25% import growth seen by respondents in last five years

Price difference between Chinese and Indian APIs

~25-30%

significantly lower price for Chinese APIs as compared to Indian APIs

Advantage for Chinese API manufacturers over Indian API manufacturers

100%

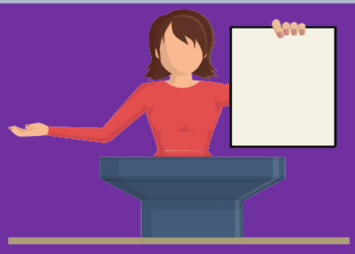
respondents feel that two key factors - Government facilitation and economies of scale are major advantages for Chinese manufacturers

The voice of the industry section is based on industry interviews (list of companies interviewed in Appendix) and KPMG in India research 2017

Note – Sources are mentioned in next sections of the report

API manufacturing in India

The voice of the industry



Major strengths of the Indian API industry

- Understanding of global regulatory norms
- High competency in chemistry related skills
- High-quality API manufacturing
- Indian entrepreneurship skills
- High manufacturing standards
- Competitive pricing

Key therapeutic areas where India is strong

- Cardiovascular
- Gastrointestinal
- Antibiotics
- Antidiabetic
- Antiretroviral
- Central Nervous System
- Oncology
- High-value complex APIs

Major challenges faced by the Indian API manufacturers

- Pollution clearance
- High utility and raw material cost
- High finance costs and taxes
- Drug price control regime
- Over dependency on China for raw materials
- Poor infrastructure
- Inadequate Government support

Measures to be undertaken by the public and private sector

Short-term measures to overcome challenges

- Offering low cost utilities
- Providing incentives, such as tax rebates and subsidies
- Relaxing drug price control
- Investing in clean technology
- Giving faster approvals
- Encouraging industry–academia collaboration
- Encourage fermentation technology based Industries

Long-term measures to overcome challenges

- Promoting small- and medium-sized industries
- Promoting skill development
- Encouraging infrastructure investments such as special industrial zones and pharma parks
- Offering grants for R&D
- Offering assured domestic consumption to manufacturers

How can private players participate in achieving self-sufficiency?

- Formulating transparent commercial policies
- Developing a long-term vision for producing high-value complex API
- Creating scope for process innovation

The voice of the industry section is based on industry interviews (list of companies interviewed in Appendix) and KPMG in India research 2017

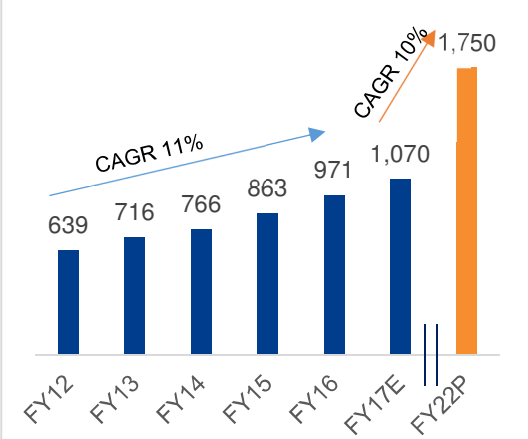
Overview of the Indian pharmaceutical and bulk drug industry

India's pharmaceutical industry has come a long way, establishing itself as a prominent 'drug producer' in the world

Pharmaceutical industry overview

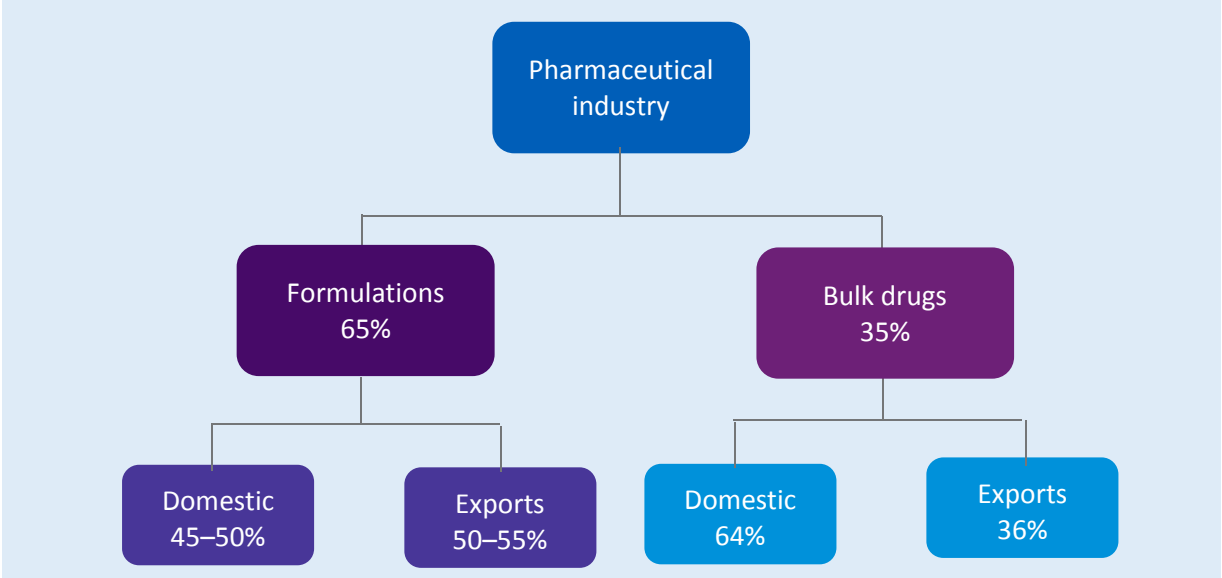
- Globally, India's pharmaceutical industry is ranked third by volume and thirteenth by value.[1] It also accounts for 20 per cent of the global generics export by volume.[1] The purported rise in lifestyle-related diseases, population growth, patent expiry and healthcare awareness are positively contributing to the growth in the industry
- India's domestic pharmaceutical market is estimated at INR1,070 billion in FY17 and is projected to grow to INR1,750 billion[1] by FY22. India's growing elderly segment and increasing burden of non-communicable diseases (NCDs), would primarily drive this growth
- Indian pharma companies are gaining scale, increasing their focus on diversified therapeutic classes, and stepping up pace in regulated and semi-regulated markets to take advantage of new opportunities.

Domestic pharmaceutical market (INR billion)



Source: Domestic formulations, Crisil research database, accessed October 2017

Structure of India's pharmaceutical market



Source: Bulk drugs – Industry information, Crisil research database, accessed October 2017

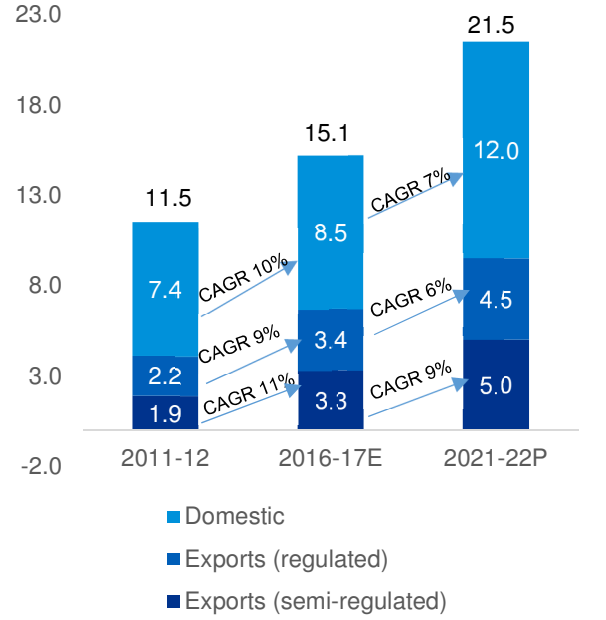
Sources: 1 - Domestic formulations, Crisil research database, accessed October 2017

Currently, India is one of the leading players in the global bulk drugs market, supplying high-quality products to both regulated as well as semi-regulated markets

Bulk drug industry overview

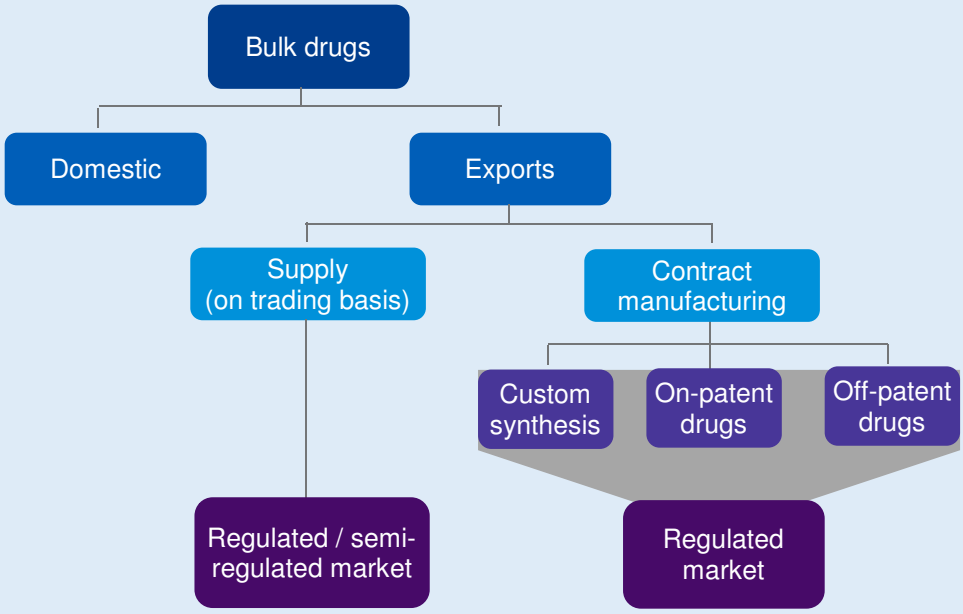
- The bulk drug industry in India is ranked third-largest globally,[1] behind China and Italy
- About 36 per cent of bulk drugs produced in India are exported and the remaining are sold in the domestic market, including captive consumption by several large formulation players[2]
- Between FY12 and FY17, bulk drugs export grew at a CAGR of 10 per cent, buoyed by strong growth in the generics market.[2] However, this growth is expected to slow down in the future as pricing pressure on domestic and exports market is likely to weigh more on players
- Exports to regulated markets, as a percentage of total exports, are increasing over the years. They were about 43 per cent in 2008–09 and 50 per cent[2] in 2016–17
- Semi-regulated markets such as Latin America, Commonwealth of Independent States (CIS), Africa and Asia are traditionally the target markets for micro, small & medium enterprises (MSME) bulk drug players. However, low-entry barriers have intensified the competition leading to margin pressure.

Bulk drug market (USD billion)



Source: Bulk drugs – Industry information, Crisil research database, accessed October 2017

Structure of India's bulk drug market



Source: Bulk drugs – Industry information, Crisil research database, accessed October 2017

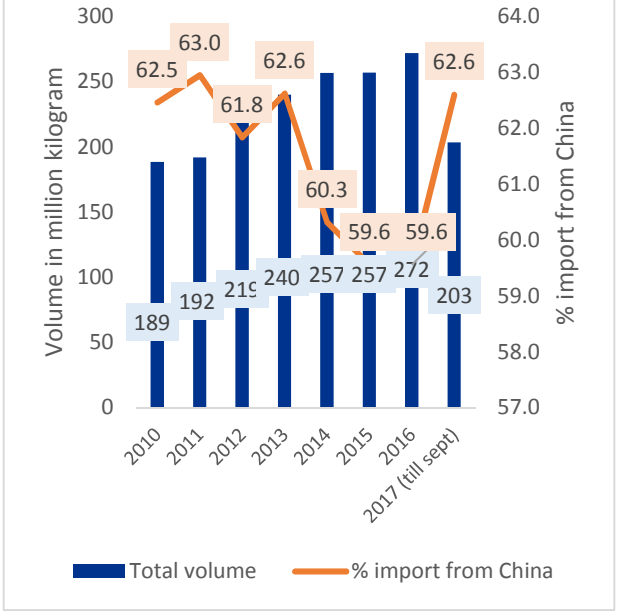
Sources: 1 - Financial Predictors Influencing the Ranking of Indian Pharmaceutical Companies 2016 International Journal of Accounting, Finance and Risk Management, December 2016; 2 - Bulk drugs – Industry information, Crisil research database, accessed October 2017

Over the last decade, India has become increasingly dependent on imports to meet its own requirements for many basic intermediates and bulk drugs

APIs and intermediates import dependency

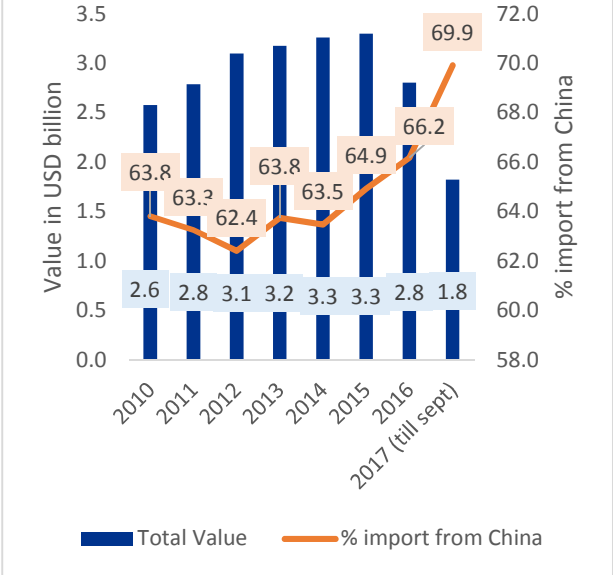
- In 2016, India imported nearly 271.8 million kgs of bulk drugs and intermediates valued at nearly USD2.8 billion.[1]
- Imports of APIs have grown at a CAGR of 11 per cent from USD800 million in 2004 to USD2.8 billion[1] in 2016
- China alone contributes about 60 per cent of all such imports by volume and 70 per cent by value[1] in 2016
- The share of other countries in India's API import basket in 2016 is small as compared to China i.e. Indonesia (6.8%), Singapore (6.2%), US (4.8%), Korea (4.6%), Thailand (4.2%) etc[1]
- Overdependence on any one country creates significant risk for India's domestic supply of essential drugs. For example, the shutdown of several Chinese API production units during the 2008 Summer Olympics[2] disrupted supply and also increased the prices of many bulk drugs.

Bulk drugs and intermediates imports (volume)



Source: Data by bulk drug and drug intermediates, Director General of Commercial Intelligence and Statistics, accessed October 2017

Bulk drugs and intermediates imports (value)



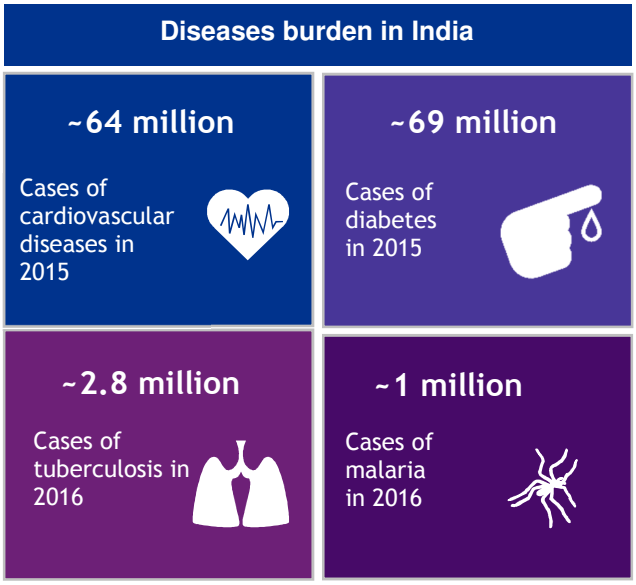
Source: Data by bulk drug and drug intermediates, Director General of Commercial Intelligence and Statistics, accessed October 2017

Sources: 1 - Data by bulk drug and drug intermediates, Director General of Commercial Intelligence and Statistics, accessed October 2017;
2 - Govt for reducing imports of pharma raw materials, Livemint, November 2014

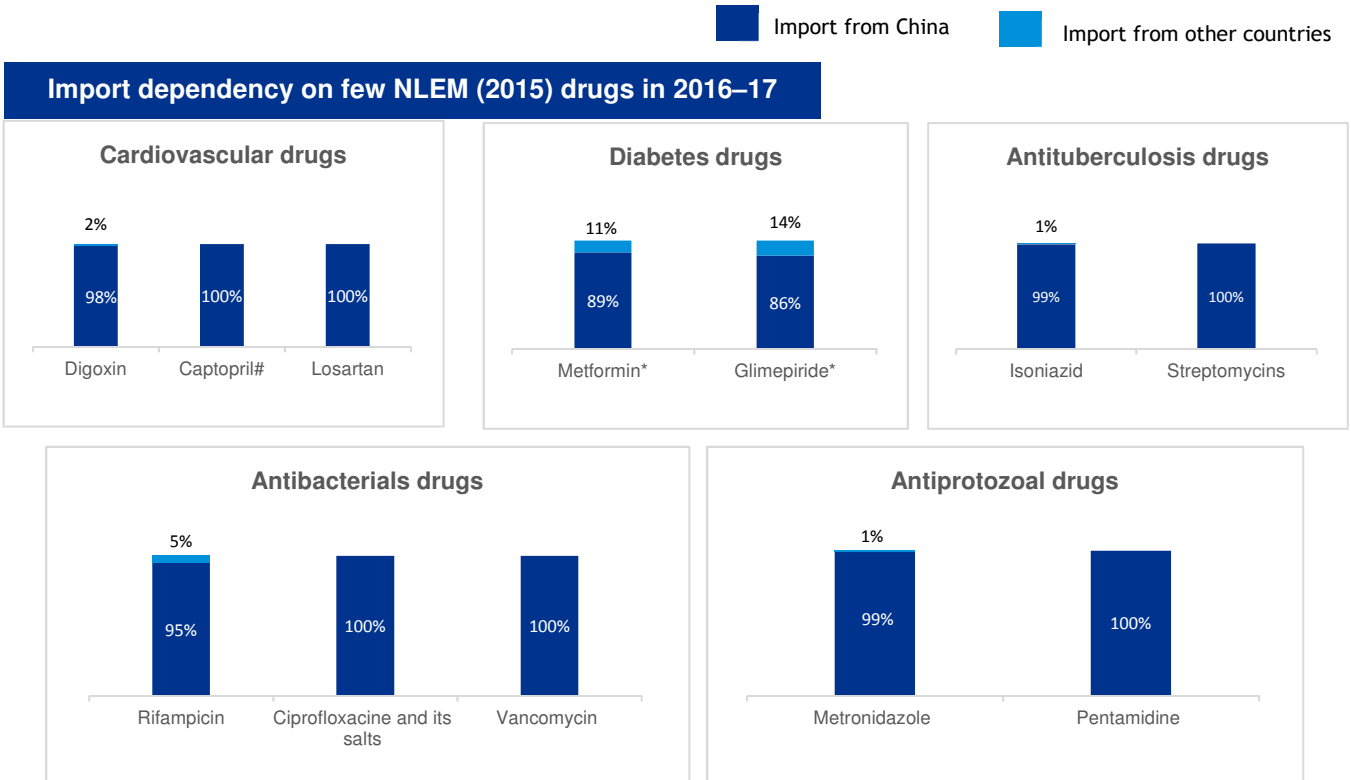
Some of these imported APIs are crucial to mitigate India's growing disease burden, therefore, the situation calls for urgent intervention from Government as well as industry

Growing disease burden and the need for self-sufficiency in important therapy areas in NLEM

- India accounts for 17.5 per cent of the world's population and bears 20 per cent of the global diseases burden.[1] While communicable diseases such as malaria and tuberculosis continue to remain challenging, the growing number of NCDs such as cardiovascular diseases and diabetes cannot be ignored any longer. In the current context, NCDs account for 60 per cent of all deaths in the country[2]
- The National List of Essential Medicine (NLEM) 2015, which has a total of 376 medicines[3], includes a number of drugs for which the import dependency is very high. Some of these fall under the category of cardiovascular drugs, diabetes drugs, anti-bacterial, anti-inflammatory, anti-tuberculosis and anti-protozoal drugs
- Needless to say that managing the supply of APIs for high disease burden categories would be key to the health security of the nation.



Source: Chronic Diseases, Lok Sabha, Question number 3291, Ministry of Health & Family Welfare, August 2016; TB India 2017, Revised National Tuberculosis Control Programme, Annual Status report 2017; Health Status Indicator, National Health Profile 2017, The Central Bureau of Health Intelligence, 2017



Note: *For Metformin and Glimepiride, the values of categories 'other sulphonamides', 'other imides and their derivatives', and 'other amides and their derivatives' are considered; # It also includes category such as Enalapril, Lisinopril, Perindopril and Ramipril
Source: Export-Import Data Bank, Ministry of Commerce & Industry, accessed October 2017

Source: 1- India bears 20% of global disease burden, senior economist of the World Bank, Times of India, January 2017; 2 - Economics of Non-Communicable Diseases in India, World economic forum, November 2014; 3 - Report of the Core-Committee for Revision of National List of Essential Medicines, CDSCO, November 2015

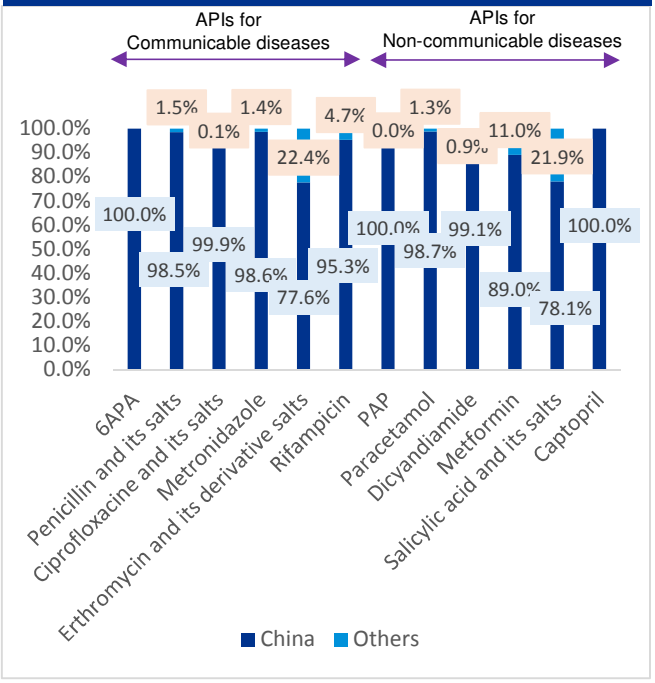
High import dependency on a single foreign supplier for many critical intermediaries and APIs is a health security risk

Health security risk due to increased dependence on import of key bulk drugs from China

- India has a large population and must be prepared to deal with public health emergencies that may, for example, require the availability of large quantities of antibiotics within a short timeframe. A foreign supplier or suppliers of APIs may not be as responsive to immediate public health demands as local producers. Moreover, India has a large volume demand for non-communicable diseases medicines. The inability to procure certain medicines could lead to a national health crisis
- India has national security concerns arising from reliance on a single foreign supplier of APIs, which may not always have India's best interests in mind.[1]
- India is largely dependent on China for almost all APIs manufactured by the fermentation route, such as penicillin, cephalosporins and macrolides
- In 2016, the Minister of State, Ministry of Commerce and Industry stated in the Lok Sabha that there is a significant dependence on imports in the case of 12 essential drugs[2], viz., paracetamol, metformin, ranitidine, amoxicillin, ciprofloxacin, cefixime, acetyl salicylic acid, ascorbic acid, ofloxacin, ibuprofen, metronidazole and ampicillin
- Imports from China have led to a gradual erosion of India's manufacturing capacity of many bulk drugs. For instance, Indian manufacturers such as Alembic, Sarabhai, Indian Drugs & Pharmaceuticals Ltd. (IDPL), Hindustan Antibiotics, JK Torrent, Ranbaxy and Standard[3] have had to close their units due to low-cost imports of the intermediary Penicillin-G/V.

The bulk drug and pharmaceutical industry is of strategic importance as it ensures health security of the nation. High imports from China has gradually eroded domestic manufacturing capacity and put us at a health security risk. Urgent steps are required to mitigate these.

Volume share of China in India's import basket for key intermediaries and bulk drugs (2016–17)



Source: Export Import Data Bank, Department of Commerce, accessed October 2017

Few non-functional API plants in India

Bulk drug	Manufacturers	Current status
Penicillin G/V	Alembic, Sarabhai, IDPL, Hindustan Antibiotics Ltd, JK Torrent, Ranbaxy, Standard	Plant not operational
Streptomycin	Alembic, Sarabhai, IDPL	Plant not operational
Erythromycin	Alembic, Themis, IDPL, Standard	Partially in operation for captive production
Rifamycin	Themis, Lupin, Sandoz	Protection, captive
Vitamin B12	Themis, Alembic, MSD	Closed
Ascorbic acid	Sarabhai, Jayant Vitamin	Closed

Source: Indian pharmaceutical industry challenges and prospects, Export–Import Bank of India, August 2016

Sources: 1 - Indian policies to promote local production of pharmaceutical products and protect public health, WHO, 2017; 2 - Import of Pharmaceutical Products, Parliament of India, Lok Sabha, May 2016; 3 - Indian pharmaceutical industry challenges and prospects, Export–Import Bank of India, August 2016

Lack of scale, change in the Patent act, rising cost of utilities, and policy inaction has led to the Indian bulk drug industry losing its cost advantage to China and become dependent on imports

India lost its cost advantage to China[1]

Scale of manufacturing

— Chinese firms have large bulk drug manufacturing capacities to reach economies of scale.

— Due to the fragmented nature of the Indian bulk drug industry, the country is unable to reach the desired scale to achieve cost competitiveness

Change in Patent Act

– the Indian Patents Act, 2005 resulted in many Indian bulk dug manufacturers moving up the value chain to become finished dosage suppliers, thus creating the need for import of bulk drugs

Cost of utilities

– China is able to manufacture APIs at a low cost due to low cost of utilities, access to cheaper labour and greater Government support

– Other utilities which constitute a significant share of production costs, such as steam, brine, chilled water, hot water and hot oil, are relatively costlier in India as compared to China.

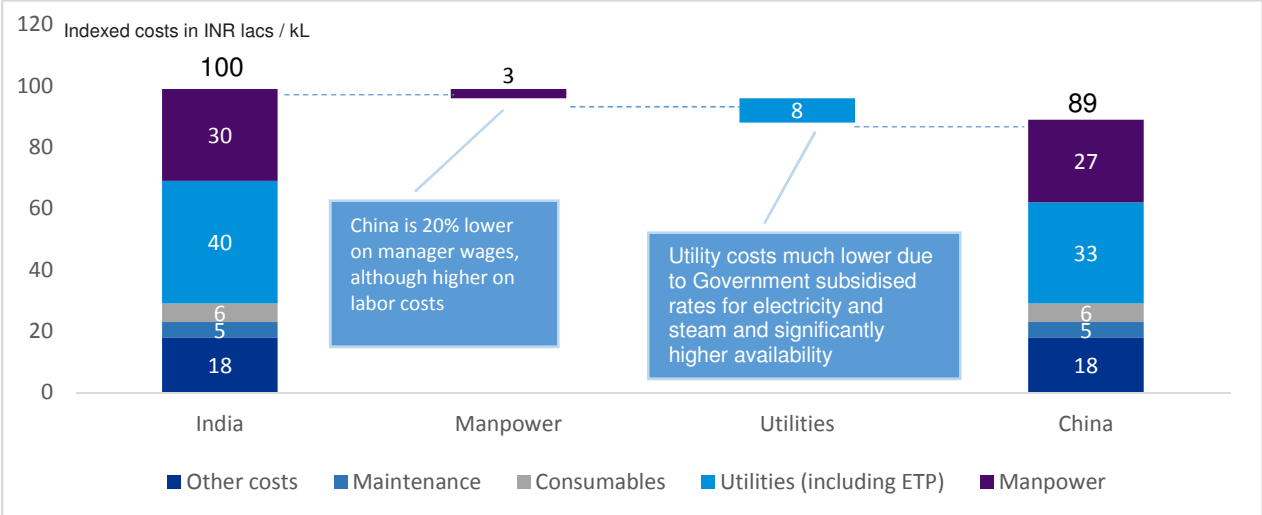
Policy inaction

– The Chinese Government has proactively supported the bulk drug industry in the form of subsidy, low taxes and fiscal incentives. Indian counterparts, on the other hand, have taken very few steps towards this

Process efficiencies

— China has invested significantly to improve technological capabilities, especially in fermentation processes

Cost comparison between China and India for chemical synthesis products

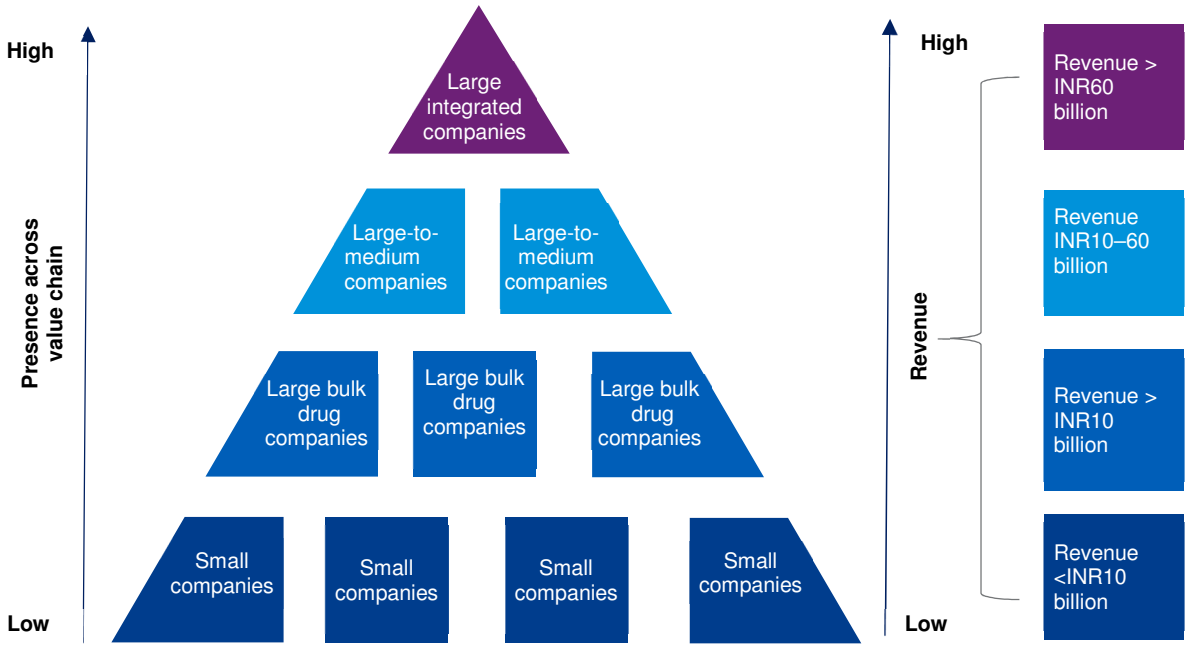


Source: Toward End–to–End Leadership in Select APIs, CII, 2013

Source: 1 – Interviews with API industry leaders

Due to the fragmented nature of the industry, India is unable to reach the desired scale to achieve cost competitiveness, leading to high import dependency for APIs

Bulk drug manufacturing segments



Bulk drugs manufacturing segments	Key players* (illustrative only)
Large integrated companies – Large integrated players focussing on formulations and APIs for domestic and export – Technically advanced, competitive and well-positioned to supply to regulated markets	Sun Pharma, Zydus Cadila, Aurobindo Pharma, Lupin, Cipla, Dr. Reddy's, Mylan, Glenmark
Large to medium companies – Companies involved primarily in domestic supply and export of APIs and formulations to regulated and semi-regulated markets – A few developed niche capabilities in either a technology or therapeutic area	Biocon, Alembic Pharma, IPCA Pharma, Granules India, Jubilant Life Sciences, Arch Pharmalabs
Large bulk drug companies – Bulk drug manufacturers focussing on intermediates and APIs for domestic and export – Technically advanced, quality focussed, supplying to regulated and semi-regulated markets	Divis Labs, Nectar Lifesciences, Shasun Pharma, Aarti Industries, Dishman Pharma
Small companies – Small manufacturers focussed on domestic markets for basic intermediates and APIs, and formulations – May or may not have a differentiating value proposition	Nakoda Chemicals, Hikal Pharma, Shilpa Medicare, , Kopran Ltd, Surya Pharma, Ind-Swift Laboratories, Morepen Labs

Note* - List not exhaustive

The Indian Patents Act 2005 saw many bulk drug manufacturers move up the value chain to become finished dosage suppliers, thereby creating a further bulk drug import burden

Patents Acts

The Patents Act, 1970

- The Patents Act, introduced in 1970, changed India's patent regime from 'product patent' to 'process patent'. This act was aimed at promoting the country's bulk drug and formulation industry
- Indian companies started developing low-cost generic versions of branded patented drugs
- India's manufacturing facilities[1] increased from 2,000 in 1970 to 24,000 in 1995
- Pharma companies started exporting APIs to the U.S., as it was more lucrative and required less time to market
- In 2002, bulk drug export volume and formulation export volume were 60 per cent and 15 per cent, respectively, of the total production.[1]

The Patents Act, 2005

- The Patents (Amendment) Act, 2005, re-instituted 'product' patents and the country started aggressively seeking other opportunities
- 35 years of focused process chemistry enabled Indian companies to deepen its prowess in manufacturing capabilities
- By 2005, Indian companies held approximately 70 per cent share in the domestic market[1]
- Indian pharma companies actively started transforming themselves from being API manufacturers to finished dosage suppliers
- Indian companies started facing competition from China as Chinese firms specialise in the production of low-value, large-volume intermediates and APIs
- A few Indian bulk drug players started creating large capacities for niche drugs to operate in high-margin, low-volume complex chemical products where competition was lower

Impact of the Patents Act

Patents Act, 1970

1970

Formulations

- Domestic industry flourished and gained market share - the share of multinational corporations (MNCs) reduced from 68 per cent in 1970 to 23 per cent in 2004
- Formulation sales in India rose from INR150 crore 1965 to INR7,935 crore in 1995.

Bulk drugs

- Several small and medium companies entered the pharma industry
- Production of bulk drugs in value term increased from INR18 crore in 1966 to INR1,518 crore in 1995.

Patents Act, 2005

2005

Formulations

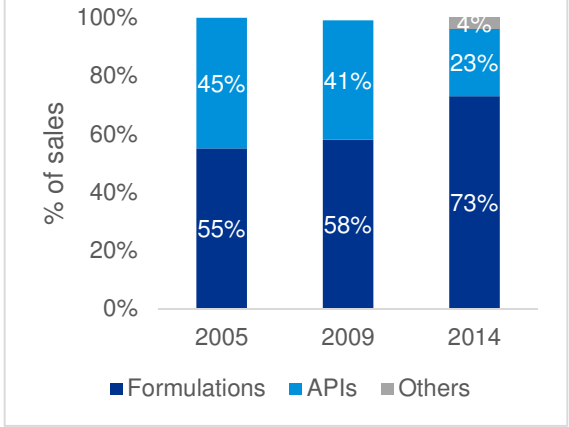
- MNCs re-entered the industry and some have re-established themselves strongly
- Penalty / high royalty was imposed on the sale of generic version of patented drugs
- The market turned unattractive for small and medium generic manufacturers of patented drugs.

Bulk drugs

- Many pharma companies moved up the value chain from bulk drugs to finished dosage suppliers.

Source: 'Where is Indian Pharma headed?, Lupin, Motilal Oswal conference, September 2017

Forward integration of pharma players



Source: 'Where is Indian Pharma headed?, Lupin, Motilal Oswal conference, September 2017

Source: 1 - Where is Indian Pharma headed?, Lupin, Motilal Oswal conference, September 2017

Leveraging capabilities in chemistry and low cost manufacturing, together with the right policy impetus can help India reduce import dependency of bulk drugs

Key differentiators for India

Low cost manufacturing capabilities

- Due to easily available skilled labour and cheap raw materials, cost of manufacturing APIs in India is comparatively lower than that of developed markets in the U.S. and Europe
- In addition, India provides a considerable cost advantage vis-à-vis other countries in terms of setting up of manufacturing plants and operational costs.

Chemistry skills and skilled personnel availability

- Excellent process chemistry skills make Indian API manufacturers a preferred choice for global innovators
- In addition, skilled personnel with high managerial and technical abilities at the senior level are available in India at a much lower cost compared with that of Europe and the U.S. However, at the entry level, there are employability challenges due to skill gap.

Large number of U.S. FDA-approved facilities

- India has the highest number of U.S. Food and Drug Administration (FDA) approved facilities outside the U.S. It has positively impacted the number of drug master files (DMFs) sent to the U.S. FDA
- Of the total DMFs sent to the U.S. FDA, India's share rose sharply to 50.4 per cent in 2016, from 19 per cent in 2001.[1]

Increased outsourcing in MNCs

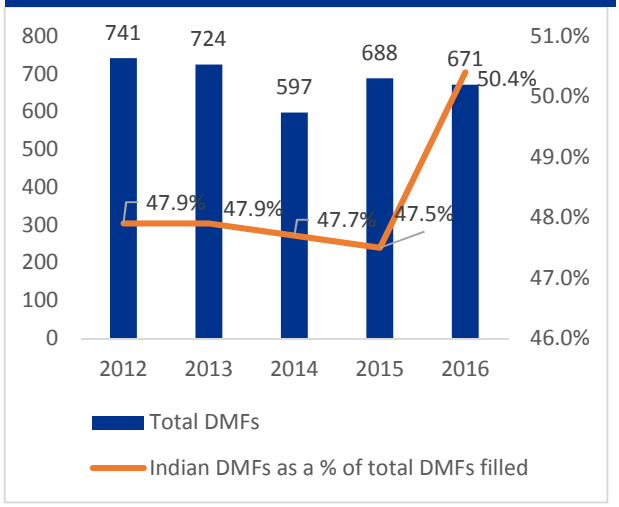
- Top innovators are restructuring their business operations to enhance profitability and growth
- This has increased the outsourcing of API development and manufacturing activities to India and China. For example, Divi's Lab has alliances with global MNCs such as Abbott, Merck & Co, Dishman with Solvay, AstraZeneca and GSK.[1]

Cost comparison for manufacturing drugs

Sr. No.	Geography	Value
1	U.S.	X
2	Europe	0.85X–0.90X
3	India	
a)	U.S. FDA-approved plant	0.45X–0.50X
b)	Others	0.35X–0.40X

Note - Cost indexed to the U.S.
Source: Bulk drugs, Crisil, accessed October 2017

DMFs filled (global vs India)



Note – Active, Type II DMFs considered till December 2016
Source: Bulk drugs, Crisil, accessed October 2017

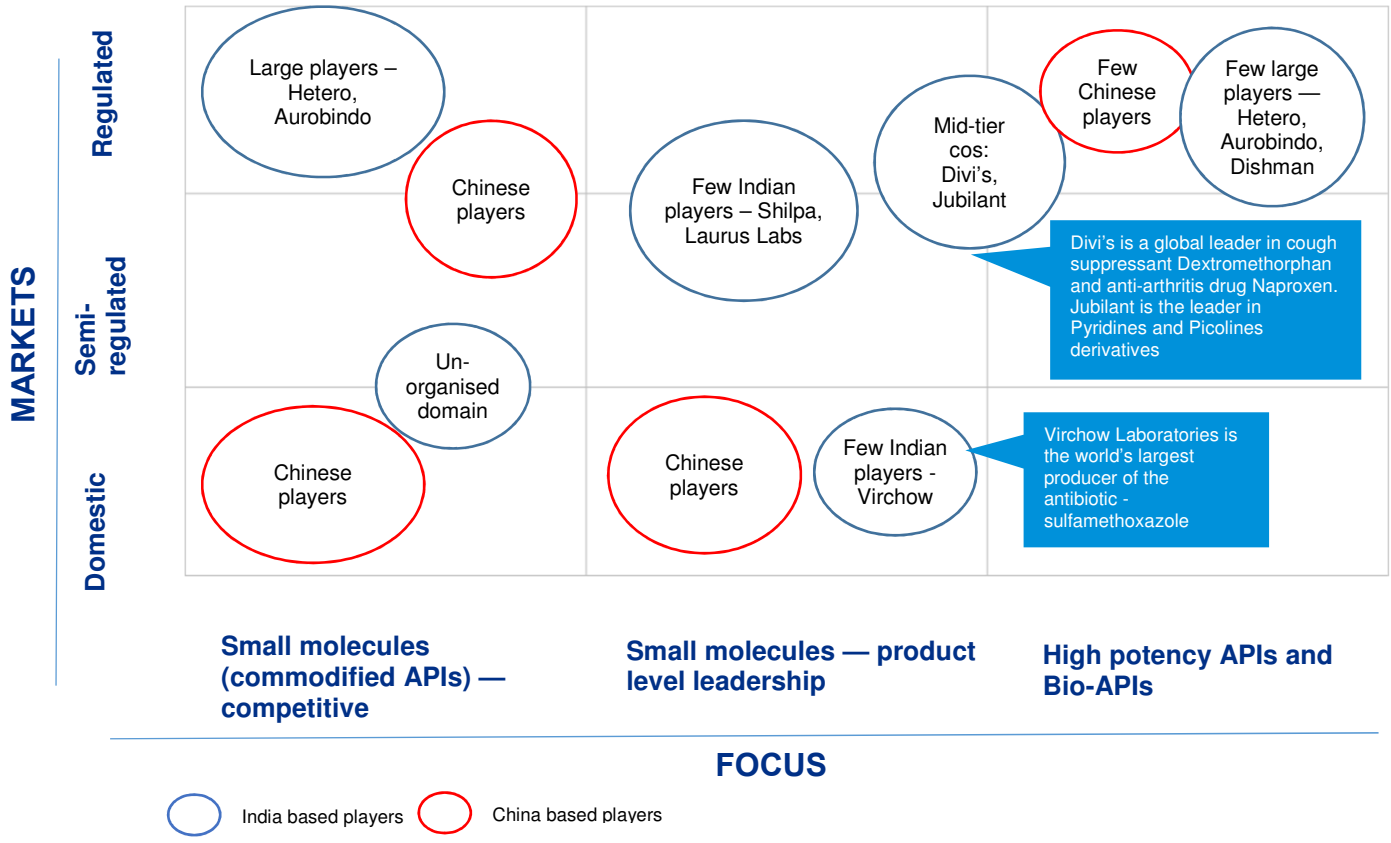
Sources: 1 - Source: Bulk drugs, Crisil, accessed October 2017

To remain competitive, India's bulk drug industry is gradually moving from commoditised APIs to speciality APIs

Commoditised versus speciality APIs

- Stronger chemistry skills have enabled bulk drug manufacturers move up the value chain by enabling the manufacture of complex molecules and their export to regulated markets
- Major Indian pharmaceutical companies still produce APIs in-house for their important speciality products, and have basically out-sourced 'commoditised' APIs to China
- China has captured the market in 'low-margin and high-volume commoditised' APIs due to its large scale of operations, low cost of utilities and favourable Government support.

Presence of Indian and Chinese bulk drug manufacturers* (illustrative)



Note* - List not exhaustive

Source: KPMG in India analysis, 2017

Challenges impacting India's bulk drugs industry

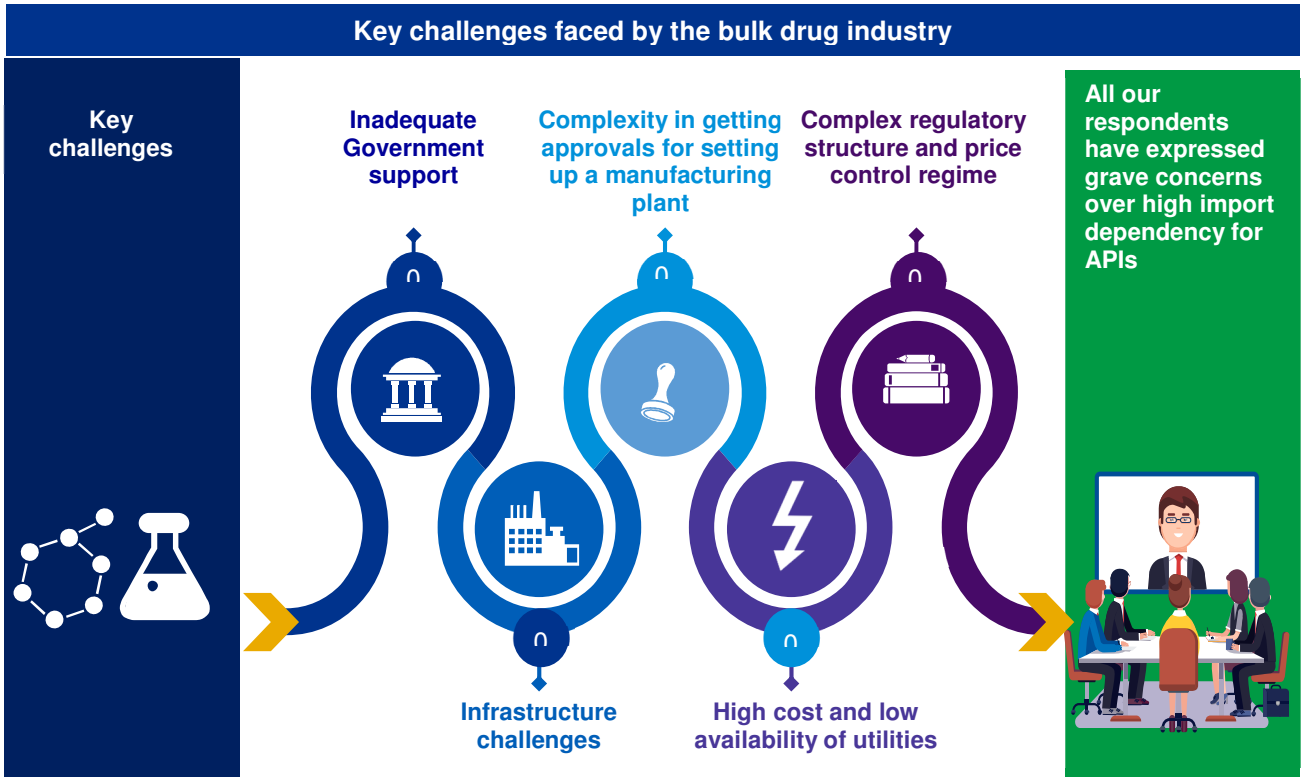
Although significant opportunities exist in bulk drugs, India needs to address the current industry challenges

To reach its true potential, the bulk drug industry needs to outline a clear road map with defined action points and milestones. Furthermore, the efforts need support from key stakeholders through well-coordinated and timely execution of the agreed action plan. Like any other industry, a bulk drugs market also requires a conducive ecosystem to grow and sustain, and both the Government and private sector need to work in tandem to develop a long-term plan, defining their responsibilities and working towards a common vision of reviving this industry

Unless a clearly laid out plan with defined roles, responsibilities and timelines is implemented, the bulk drugs industry would continue to face challenges

The 'Make in India' initiative is likely to provide a good platform for the growth of the bulk drug industry; in order to optimally use the support provided by this initiative, business environment-related challenges (such as land acquisition, ease of doing business, taxation and operating infrastructure), need to be acknowledged and then solved by the respective stakeholders.

Key challenges have been identified on the basis of discussion with industry leaders and KPMG in India research



Inadequate government support

- **Lack of proactive steps**: Lack of proactive steps by the Government in the area of API focused clusters, large chemical parks etc
- **Inadequate financing options and tax incentives:** Loans at relatively low interest rates, tax benefits, subsidies and duty breaks for bulk drugs manufacturing units are currently not given by the Government.

Infrastructure challenges

- **Inadequate emphasis on API focused cluster development:** A sector as technical as bulk drugs requires quick access to low-cost raw material, skilled manpower, waste management systems, R&D support in its vicinity. There are a few pharma and chemical clusters in India such as Ramky Pharma city, Atchutapuram pharma cluster in Andhra Pradesh, Lote Parshuram in Maharashtra. Baddi in Himachal Pradesh and Jadcherla in Telangana are focused on formulations. However, currently there are no API focused cluster in India.
- **Sub-optimal infrastructure:** The country has sub-optimal infrastructure with respect to laboratory space, sea ports, roads and cargo zones at airports for the import and export of bulk drug products.

Complex approval process for setting up a manufacturing plant

- **Lengthy approval timelines**: The approval timelines are lengthy (takes about two–three years) and voluminous (about 20–25 approvals) with multiple stakeholders. For example, the approval timeline from the Pollution Control Board ranges between two–nine months, and has been identified as one of the biggest impediments in the approval process
- **Overlapping procedures**: In many cases, multiple agencies / ministries are involved in the grant of a single approval, which may require similar set of documentation to be submitted at these agencies, leading to unnecessary paperwork.
- **Lack of clear set of guidelines**: Most of the states do not have a clear set of guidelines available online, leading to ambiguity regarding the approval process for setting up of a pharmaceutical manufacturing plant.
- **Non-existence of a single-window clearance mechanism**: Involvement of several authorities like the State Pollution Board, State Industrial Development Corporation, Directorate of Industrial Safety and Hazards, and District Industrial Centre results in lack of co-ordination between various departments, making the process of getting approvals cumbersome and time consuming.

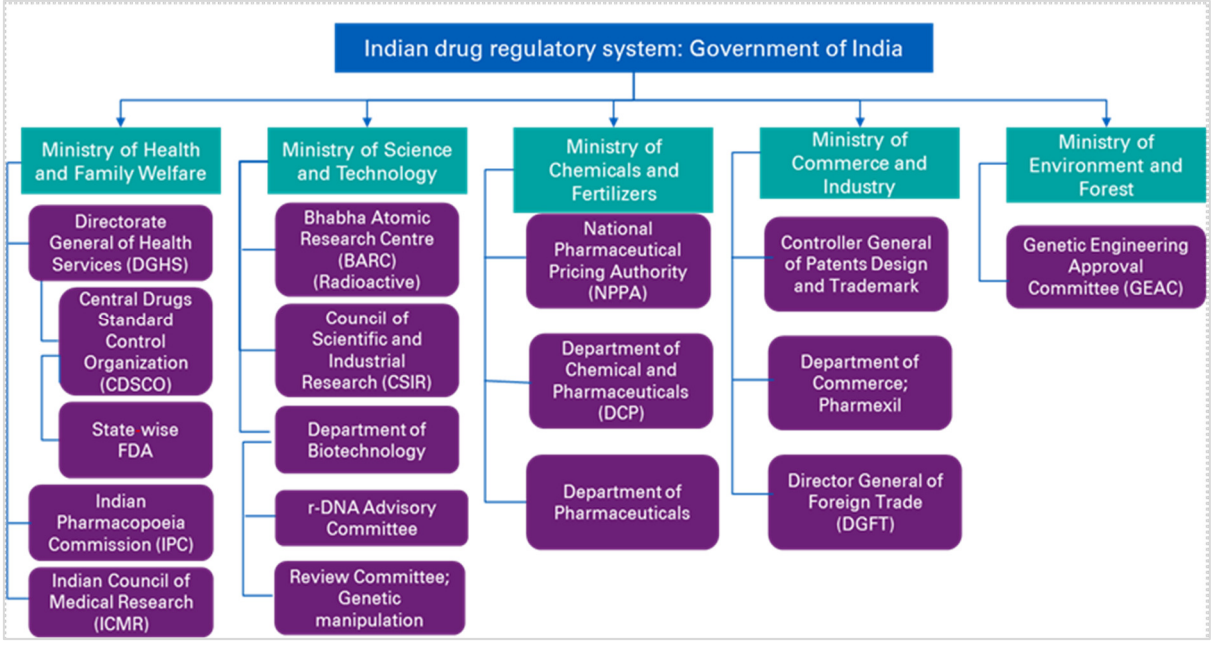
High cost and poor availability of utilities

- **Rising electricity cost**: Industrial electricity tariffs in India has seen a sharp increase in the last decade. An upward price pressure is expected to continue due to rapid increase in demand and volatility in raw material prices.
- **Under-supply of electricity**: Under-supply of electricity is a challenge for the industry in many states
- Other utilities which contribute significantly to production costs, such as steam, brine, chilled water, hot water and hot oil, are relatively costlier in India as compared to that of other countries, such as China.

Complex regulatory and tax structure; and price control

- **Multiple regulatory bodies:** There are multiple regulatory bodies which, directly or indirectly, frame rules and guidelines for the pharmaceutical and bulk drug industries. This multiplicity, at the policy-making level can result in inefficiencies in the allocation of resources and often creates a divided agenda. The challenges pertaining to regulations, at times, can take longer to resolve due to multiple decision makers; this eventually hurts the industry
- **Complex tax structure:** Historically, the pharmaceutical and bulk drug industry was burdened with multiple taxes at the central, state and municipal levels. After implementation of GST, the tax structure is expected to be simplified
- **Increasing price control:** In 2013, the Department of Pharmaceuticals (DoP) published the Drug Price Control Order (DPCO) 2013, which increased the number of medicines on the NLEM from 74 to 348, and imposed price ceilings on 652 formulations.[1] Currently, there are 376 drugs[2] in NLEM 2015 and price ceiling applies to 660 formulations.[3] This price control is adversely impacting the bulk drug industry as it doesn't allow an increase in selling price linked to the rising cost of production; this has also led to a gradual erosion of bulk drug manufacturing units as pharma players prefer to source low cost APIs from China.
- In 2013, when the number of drugs under the ambit of price control increased, the API import volume from China also increased 11 per cent over 2012 levels indicating a direct correlation between price control and API import.[4]

Multiplicity in the Indian drug regulatory system



Source: KPMG in India analysis 2017

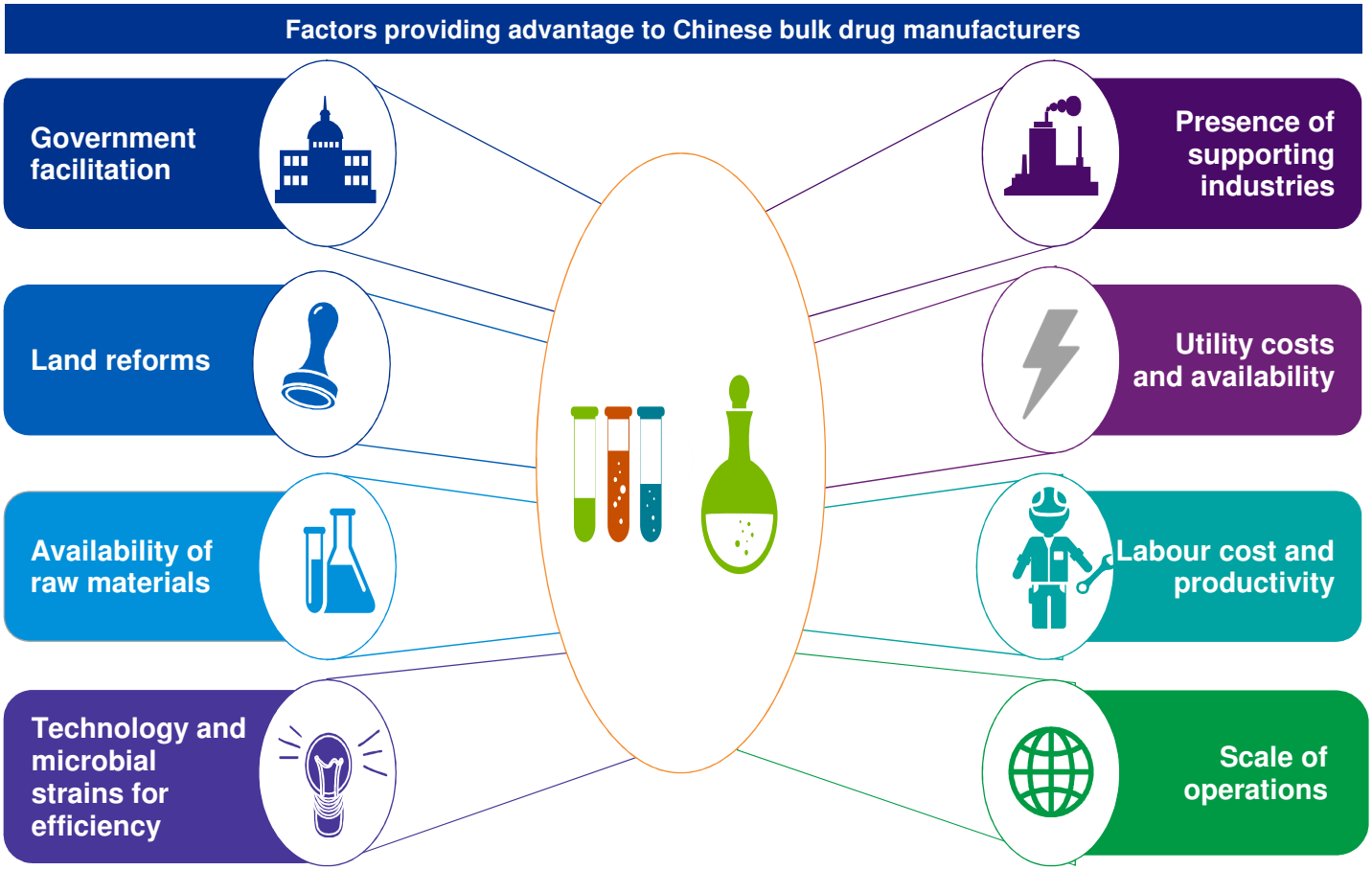
Source: 1 - Rise in Price of Drugs, Press Information Bureau, Government of India, Ministry of Chemicals and Fertilizers, August 2013; 2- Report of the Core-Committee for Revision of National List of Essential Medicines November 2015, CDSCO; 3- Revised ceiling price (WPI) of scheduled formulations of Scheduled-I under Drug, DPCO, April 2017; 4 – KPMG in India analysis 2017

Comparative study of India and China

A number of factors have helped China gain advantage over India in the bulk drug manufacturing sector

China has made its presence felt in the bulk drug market; supported by low cost of utilities, access to labour and greater government support, Chinese manufacturers also have the advantage of significant scale of operations, leading to much lower cost of bulk drugs.

The dependence on China is clearly visible in basic intermediates and bulk drugs, especially fermentation based drugs, where imports from China have led to a gradual erosion of India's manufacturing capacity of many bulk drugs.



Source: Interviews with industry leaders and KPMG in India analysis 2017

With Government support, Chinese manufacturers are gaining strength in bulk drug exports to regulated markets where India was traditionally a stronger player

China is increasing focus on regulated markets

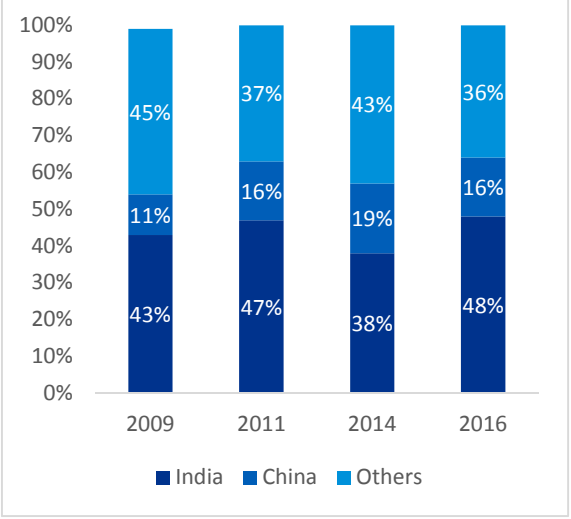
- China ranks first in the production of several intermediates and APIs such as penicillins, vitamins, antipyretic, analgesics among others. It also holds a significant share of featured APIs such as prils, statins and sartans in the world
- China's share of DMF filings in the U.S. has steadily increased since 2009, indicating a renewed focus by Chinese manufacturers to upgrade to global quality standards
- Chinese players are making progress by entering into strategic partnerships with major innovators and generic western companies and expanding into the finished dosage market. They are also developing newer molecules and making investments in equipment, management and staffing. These steps, collectively, indicate their desire to upgrade to international quality standards and boost API exports to regulated markets as well[1]
- According to the China Chamber of Commerce for Export and Import of Medicine and Health Products, China exported biologics worth USD2.7 billion to 174 countries in 2015.[2]

Regulatory changes in China to strengthen quality

The Chinese regulatory system is continuously evolving to keep up with the standards of EU, the U.S. and Japan. For gaining strength in exports to the regulatory markets, the following regulatory reforms are being implemented[3,4]:

- The China Food and Drug Administration (CFDA) has demanded generic drug manufacturers to start drug consistency research on quality and efficacy against the innovator drug to be completed by the end of 2018, which would then prevent quality variation amongst approved drugs in China
- Self-inspection of clinical data by applicants, contract research organisations (CROs) and clinical sites began in July 2015; cases where disclosures were unauthentic and incomplete were disapproved or investigated by the CFDA. Furthermore, for more new drug applications (NDAs), applicants are now required to submit clinical trial self-inspection report for further review by the CFDA

Although India leads the number of DMF filings, China is narrowing down the existing gap



Note – Data analysed for type II and type IV DMFs

Source: "Drug Master Files (DMFs)", FDA website, accessed October 2017; Agenda for the Pharmaceutical Industry in India, KPMG in India, Feb 2015

- In addition, China has joined the International Council for Harmonisation (ICH) as its eighth regulatory member with an aim to implement technical standards and guidelines to promote global public health. India has joined as a observer in ICH in 2015,
- The local new drug innovators in China can now hold marketing authorisation independently, allowing them to transfer manufacturing to an established player having a validated manufacturing process
- In 2017, the CFDA announced its plan to replace the current good manufacturing practice (GMP) five-year certification with a dynamic unannounced inspection system
- These reforms are likely to upgrade the pharmaceutical industry in China by bringing the marketed products up to global standards in terms of efficacy, safety and quality. Furthermore, additional steps are being taken to make the review and approval process more transparent, improving the overall quality image of pharmaceuticals made in China.

Source: 1- China joins ICH as full regulatory member, pledges to implement guidelines, FDA News, 23 June 2017; 2. Is a wave of GMP exports in our future, Pharma Focus Asia, 2017; 3. An overview of major reforms in China's regulatory environment, TOPRA, July/August 2017; 4. New guidelines to make China a more drug-friendly market, BioPharma Dive, 03 April 2017

Government initiatives in the form of ease of doing business, infrastructure building, and fiscal and tax incentives have helped China gain advantage over India in the bulk drug manufacturing sector

Government facilitation

Ease of doing business

— Historically, India has ranked lower in World Bank's ease of doing business (Eodb) rankings, indicating a complex unfriendly business environment. However, with many positive initiatives taken by the current Government, India jumped 30 spots to reach the 100th rank amongst 190 countries in 'Doing business: 2018' report.[1] China (78th rank) still is more favorably placed than India[1]

— The number of procedures to obtain a construction permit; time required to register land; number of steps involved in paying taxes; and time to export are high in India as compared to that in China

Expenditure on infrastructure and investment gaps

— China spends approximately five times more on infrastructure as compared to India.[1] Moreover, the gap in annual need for infrastructure is only 10 per cent in China as against 95 per cent in India.[2]

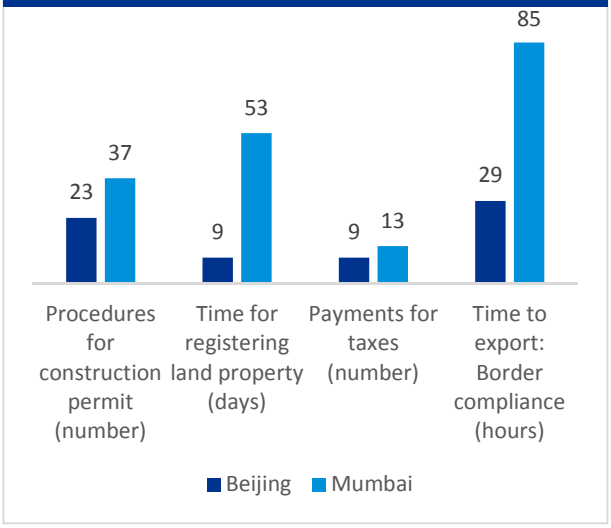
Fiscal and tax incentives

— In 2016, the lending interest rate in China was 4.35 per cent as compared to 9.68 per cent in India[3]. Furthermore, the Chinese Government provides subsidised debt, tax and duty breaks on capital equipment

— Lower corporate tax rate of 25 per cent in China vis-à-vis 30 per cent in India[4]

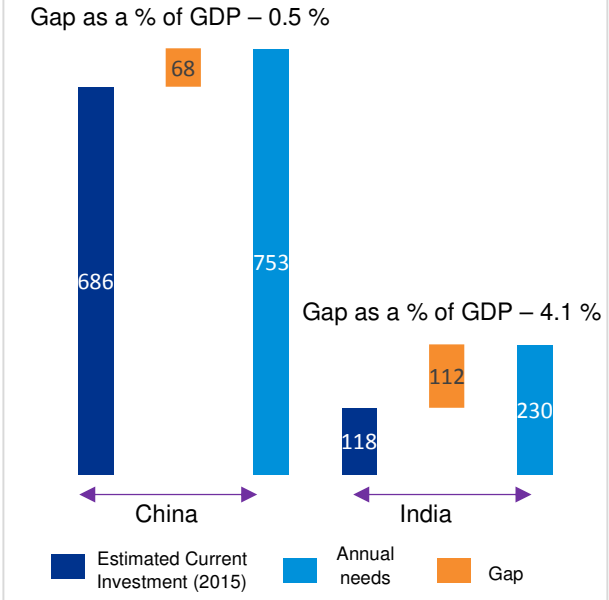
— Establishment of special economic zones (SEZs) in Shenzhen, Zhuhai, Xiamen, Shantou, and Hainan are driving investments in the Chinese manufacturing segment

Few 'ease of doing business' parameters (data June 2017)



Source: Doing business, The World Bank website, accessed November 2017

Estimated infrastructure investments and gaps, 2016–20 (in USD billion, 2015 prices)



Note: The gap as a % of GDP is based on the annual average of projected GDP from 2016 to 2020
Source: Meeting Asia's infrastructure needs, Asian Development Bank, March 2017

Source: 1 - Doing Business 2018: Reforming to create jobs, World Bank Group, 2017; 2 - Meeting Asia's infrastructure needs, Asian Development Bank, March 2017; 3- Lending interest rate (%), World Bank website, accessed November 2017; 4 - Corporate tax rates table, KPMG Global website, accessed November 2017

Easier land availability, investment in technology and presence of supporting industries have provided China an edge over India in setting up and running its bulk drug manufacturing industry

Land reforms

Ease in land procurement

— Since 1983, China has implemented several land policy reforms to enhance efficiency, rationalise land allocation and improve land management[1]

— India faces a challenge in the absence of a uniform land acquisition policy and inconsistent enforcement, leading to less availability of land for industrial development. The number of departments to be visited, as well as the number of visits to each department, makes the land acquisition process complex and time consuming. High costs and high transaction fees add to the overall burden of acquiring land

— India ranks low on various parameters of the World Bank's assessment of industrial land acquisition. India's score is low in strength of lease rights, access to land information, time to lease private and public land.

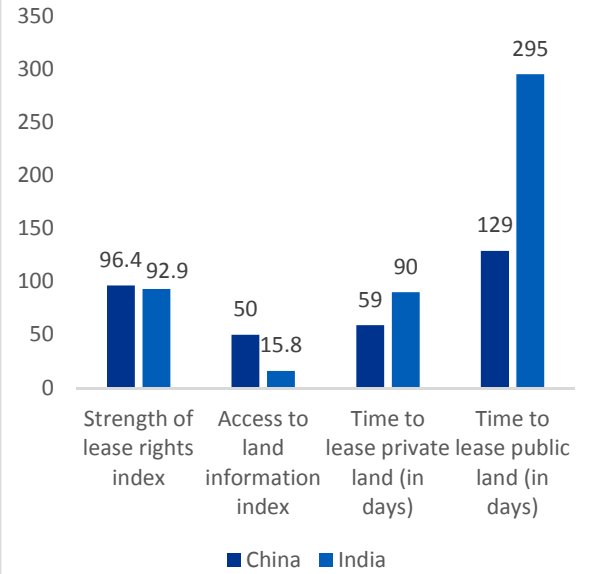
Availability of raw materials

— China has rich natural resources; for example, limestone is found in abundance in Inner Mongolia which is harnessed by bulk drug manufacturers to produce dicyandiamide (DCDA). Similarly, China has abundant maize starch, which is used in fermentation plants as a source of carbohydrate.

Technology and conversion efficiencies

— China has invested significantly to improve technological capabilities, especially in fermentation processes

Procuring industrial land



Note: Strength of lease rights index (0-100): compares economies on the security of legal rights they offer to investors interested in leasing industrial land; Access to land information index (0-100): compares economies on the ease of access to land-related information through the countries' land administration systems including land registries, cadastres and land information systems.
Source: Accessing Industrial Land, The World Bank website accessed November 2017

Presence of supporting industries

— The focus on producing basic chemicals which are the building blocks of bulk drugs is high in China as compared to India

— In China, attractive tax incentives are available to chemical manufacturers, which have enabled the industry to flourish.

Source: 1 - Planning For Human Development – Lessons from the Asian Experience, World Bank, 2014

Lower cost of utilities have given China the much-needed cost advantage over India

Utility costs and availability

Utility cost is the single-largest contributor to operating cost in a bulk drug plant. The largest contributor in utilities is electricity followed by steam.

Availability of electricity

— China is the highest electricity-producing country in the world. It has invested significantly in its power generation facilities over the last 10 years[1] and its power generation capacity has doubled since 2004

— China's power generation capacity is also 4.2 times higher than India.[1]

Electricity price

— The Chinese Government had subsidised electricity and steam before 2008 due to abundant availability and limited demand. However, after 2008, increase in demand of electricity and relatively faster increase in coal prices has led to a steady rise in electricity prices

— In India, the power situation improved in mid-2000s as the Government subsidised electricity costs and implemented certain reforms such as setting up of power exchanges to determine availability of merchant power

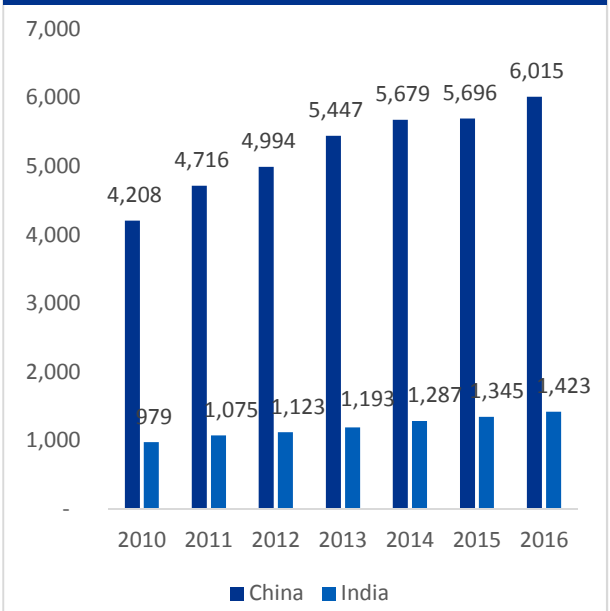
— These factors led to the narrowing of electricity price gap between China and India, compared to the gap that existed in the early 2000s.

Other utilities

— Other utilities which contribute significantly to production costs, such as steam, brine, chilled water, hot water and hot oil, are more easily available in China

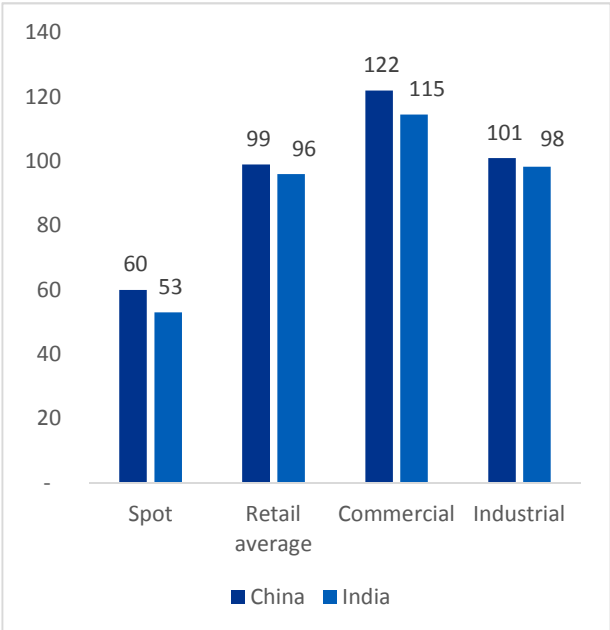
— The availability of subsidised steam, which is a byproduct of electricity in China, has helped manufacturers further reduce costs

Electricity production (TWh)



Source: Electricity production, Enerdata, 2016

Electricity price attractiveness (USD / MWH 2014)



Source: India and China, Climatescope website, accessed November 2017

Source: 1 - Electricity production, Enerdata, 2016

Chinese labour cost was relatively cheap in the last decade, however it is now at 2-2.5X of India. Despite this, China is able to supply low cost APIs due to several other factors

Labour cost and productivity

Labour cost

— Over several decades and up until 2007, China has fared better than India in terms of lower compensation cost which helped Chinese manufacturers keep the cost of production low.[1] However, after 2007, a shift in demographics and economic changes have escalated wages in China to a level much higher than those in India

Labour productivity

— China's labour cost has increased over the years; however, productivity has seen a steady rise

— China's labour productivity is nearly 1.5 times[2] higher than India's. Better quality infrastructure, superior production techniques and skill development has helped Chinese workers produce more output than that of an average Indian worker.

Scale of operations

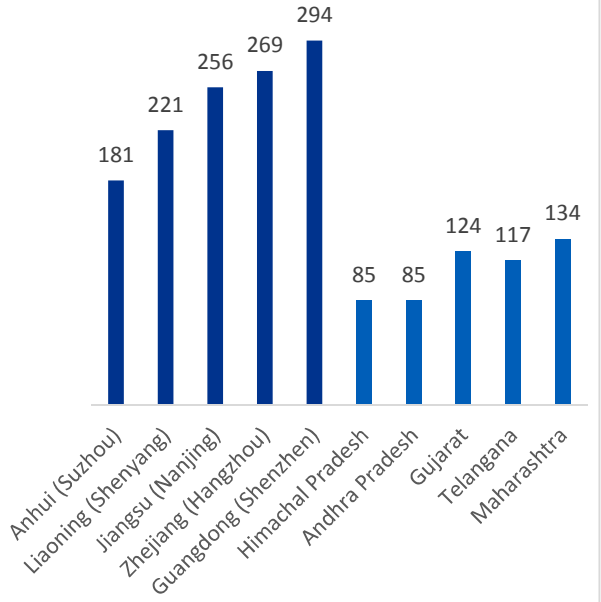
Large size of SEZs in China

— While India lagged behind China in terms of matching the scale of manufacturing capacities, the latter has effectively mastered the art of exploiting economies of scale as evidenced by the sheer size of their SEZs

— Even though the Indian Government has approved 423 SEZs for various industries, of which around 14 are pharmaceutical/biotechnology focused (operational)[3], the size of these SEZs remains a vital consideration. The average size of an SEZ in India is about 300 hectare — less than 1 per cent of the average size of an SEZ in China.[4] This has resulted in higher scale of manufacturing; China has also effectively exploited synergies in several mega parks with common facilities for effluent treatment, laboratories, R&D etc

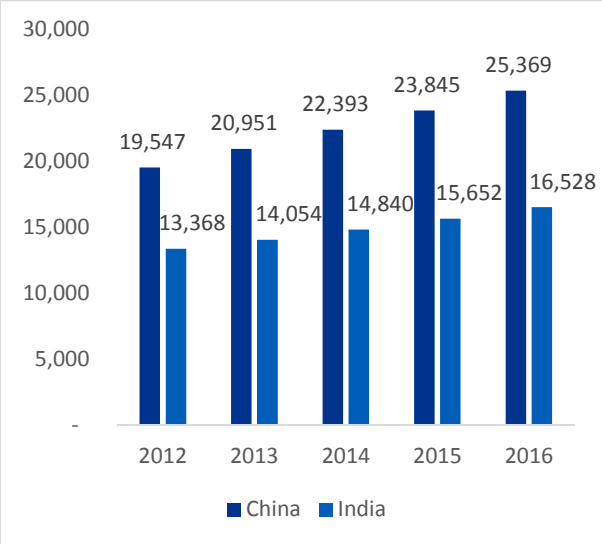
— In India, the Government's role in nurturing SEZs is limited to allotment of land, whereas their counterpart in China develops and nurtures the zones with fiscal and tax incentives as well

Monthly minimum wage rate in key Chinese provinces and Indian states during 2016–17 (in USD)



Note: China's monthly minimum Wage is for 2016–17; India's monthly minimum wage rate is for April 2017; yearly average currency exchange rates for Yuan is 6.91 and Indian Rupees is 69.95 for 2016; for Indian states, the average of unskilled, semi-skilled and skilled has been used
Source: Salaries – Minimum wage — China and India, Wage indicator foundation website, accessed November 2017

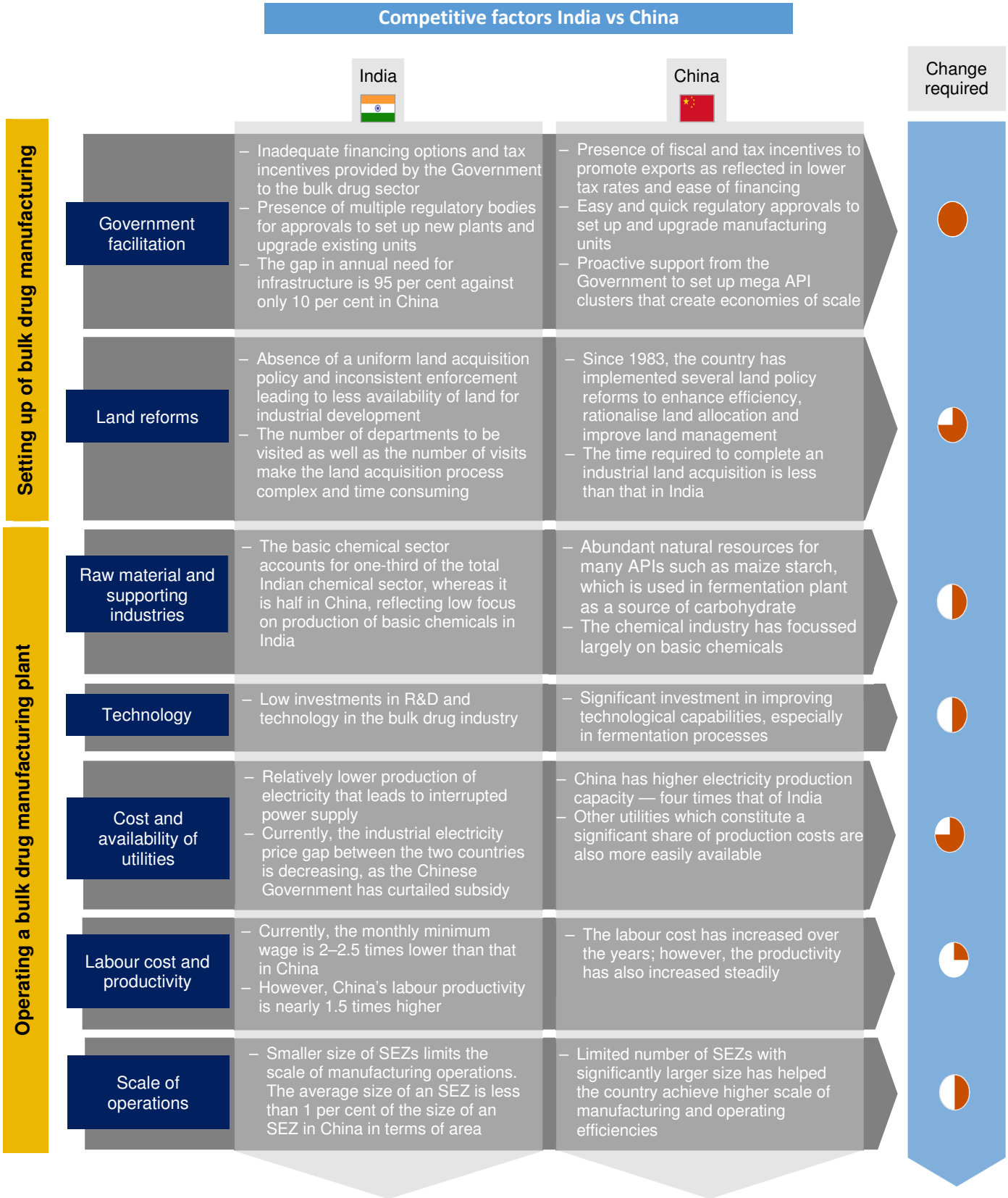
Labour productivity — Output per worker (GDP constant 2011 international USD in PPP)



Source: Key Indicators of the Labour Market, International Labour Organization, 2017

Source: 1 - International comparison of hourly compensation costs in manufacturing, The Conference board, 2015; 2 - Key Indicators of the Labour Market, International Labour Organization, 2017; 3 - Approved and operational SEZs in India, Special Economic Zones in India, Department of Commerce, 2017; 4 - India: SEZs as an Export Promotion Strategy: Can India Recreate China's Success Story?, AFG Venture group, 2007

It is now imperative for India to address the key factors impacting the growth and competitiveness of the bulk drug industry



Source: KPMG in India analysis, 2017

Steps taken and planned by the Government

While a lot of positive steps has been taken by the Government, the bulk drug industry is yet to receive focused attention to alleviate bottlenecks

The Government of India has taken many positive steps for the life sciences sector under the 'Make in India' campaign. These steps have improved ease of doing business in the country. However, the bulk drug industry is yet to receive the attention in needs to achieve self sufficiency

Key steps proposed and taken in life sciences sector

FDI policy
Under the automatic route, 100 per cent and 74 per cent FDI is allowed in greenfield and brownfield pharmaceutical projects, respectively[1]

Pharma city in Telangana
The Telangana Government has launched one of the world's largest pharma cities covering over 15,000 acres[3] and housing the entire range of manufacturing units across formulations, bulk drugs, as well as R&D facilities

New Drugs & Cosmetics Act
The Government is working towards drafting the new Drugs & Cosmetics Act[5] to improve the EoDB for the pharmaceutical industry

Industry–academia collaboration
The Government has approved a programme for the development of bio pharmaceuticals through industry–academia collaboration

GST implementation
Goods and Services Tax (GST) has been implemented from 1 July 2017, and is expected to eliminate the cascading effect of taxes[7] and other anomalies of the current indirect tax structure

New policy for clinical trials
The Government is working towards drafting new rules to facilitate drugs and clinical trials[2]

New IPR policy
The country launched the new IPR policy[4] in May 2016 to foster innovation, and increase predictability, clarity and transparency

Draft pharma policy, 2017
In August 2017, the Central Government presented a new draft national pharmaceutical policy[6] to make essential drugs accessible at affordable prices, provide a stable policy environment, achieve self-sufficiency in drug manufacturing, ensure quality drugs and create a favourable environment for R&D

Implementation of UCPMP
The Government is now planning to implement a mandatory[8] code that is expected to replace the current voluntary uniform code of pharmaceutical marketing practices (UCPMP) for increased adherence and governance

Source: 1 - Allowing 74 Per Cent FDI in Pharma Sector, Press Information Bureau, Government of India; July 2016; 2 - Indian govt working with stakeholders to devise new rules for clinical trials, The Hindu, 20 May 2017; 3 - Land allotment for Pharma City soon, The Hindu, August 2017; 4 - Cabinet approves National Intellectual Property Rights Policy, , Press Information Bureau, Government of India, MAY 2016; 5 - Union Health Ministry to give Drugs and Cosmetics Act a makeover, Indiatoday, June 2016; 6 - National Pharma Policy draft aims to boost domestic manufacturing of drugs, BioSpectrum India, August 2017; 7 - GST roll-out – Complete transformation of the Indirect Taxation Landscape, Press Information Bureau, Government of India, June 2017; 8 - Code to ban bribes from companies to doctors in final stages, Times of India, July 2017

The Katoch Committee formed in 2013 submitted its recommendations in 2015. The recommendations were well received by industry; however these are pending implementation

In order to reduce dependence on API imports from China, the Government of India is exploring ways to boost infrastructure and reduce cost of production. In 2013, the Government set up the 'Katoch Committee', headed by Dr. V.M. Katoch (former Secretary, Department of Health Research), with an aim to design and formulate long-term policies and strategies that could boost the local manufacturing of APIs in the country.[1] In February 2015, the committee submitted its report, consisting of recommendations such as providing land to manufacturers at concessional rates, setting up bulk drug parks and easing regulations. Some of the key recommendations of the committee include:

Infrastructure[2]

– Basic infrastructure such as land, water and electricity, and common leading facilities such as effluent treatment plants (ETPs), captive power plants, steam and testing facilities, may be provided at a reasonable cost. There is a need to establish mega parks for API or bulk drug manufacturing

– The bulk drug industry is known as one of the major polluting industries; lack of capital intensive technology and high cost of pollution control measures make it absolutely necessary to implement proper rules and regulations to arrest pollution level and achieve high-quality output

Financing[2]

– There is a need to set up two fully financed API intermediate clusters (one focussed on fermentation and other on APIs), while other clusters could be set up in five–six states at a later stage. Financial support from the Government in the form of dedicated equity funds for the development of these clusters could be provided. Furthermore, cluster developers and cluster participants could be provided tax-free status for 15 years

– Provisions for easy soft loans through interest subvention up to 7.5 per cent, and capex loan for API manufacturers could be made available. In addition, income tax rebates can be doubled from the existing 200 per cent to 400 per cent for upgrading the existing R&D facilities to encourage new development

Infrastructure

- Mega parks
- Land, water and electricity
- Advanced lab infrastructure
- API clusters
- Revival of PSUs

Financing

- Soft loans
- Capex loans
- Income tax rebates
- R&D investments
- Tax-free status for cluster developers
- FDI investments

Regulatory approvals

- Pollution checks and regulations
- Single-window clearance
- Monthly inspections of manufacturing facilities

Awards / recognitions

- Innovation awards
- Patent protection

– Creation of advanced testing lab infrastructure at all Indian airports / ports can facilitate easier foreign trade

– Provisions for incentives can be made for manufacturers allowing them to set up large plants and import technology, reducing the cost of production, while service tax could be reduced on clinical trials to develop drugs in India

Source: 1- Salient features of Katoch Committee recommendations, Government of India, 24 September 2015; 2- Bulk Drugs and Katoch Committee Recommendations, GKToday, 30 May 2017

Regulatory approvals

- The synergy between the DoP and other important Government departments could be leveraged by having all units co-located at one site, also ensuring single-window clearance to manufacturers and making other support facilities easily available to them
- Gujarat, Andhra Pradesh, Tamil Nadu and Odisha, with the requisite facilities and systems in place, could come forward to participate in this sector. Moreover, these states may also establish their own manufacturing zones and facilities
- The revival of public sector units (PSUs) for manufacturing selected and essential drugs (e.g., penicillin and paracetamol) and vaccines

Awards / recognitions

- Promotion of innovative ideas and products, awards to scientists for contributions made to the industry, and patent protection of innovations could be undertaken to prompt further innovation in the sector. In addition, facilitating industry–academia interaction, import duty exemption, and other tax benefits and incentives for the development of improved products / competitive technologies is imperative.

Status of implementation

In 2015, the Katoch Committee suggested several measures such as infrastructure development, easy financing, streamlining regulations and awards to strengthen the bulk drug sector in the country. However, two years later, the implementation of these recommendations is still pending.

In 2017, the Department of Pharmaceuticals[1] said that the implementation of the Katoch committee recommendations in a fixed timeframe is not tenable. The Government is looking into the issue of duty structure, assistance to bulk drug parks and interest rate support to the industry and is trying to obtain necessary approvals for providing funds. As per the decision taken by the higher levels in the Government, an umbrella scheme is being prepared under which assistance to the bulk drug industry for common facilitation will be a sub scheme

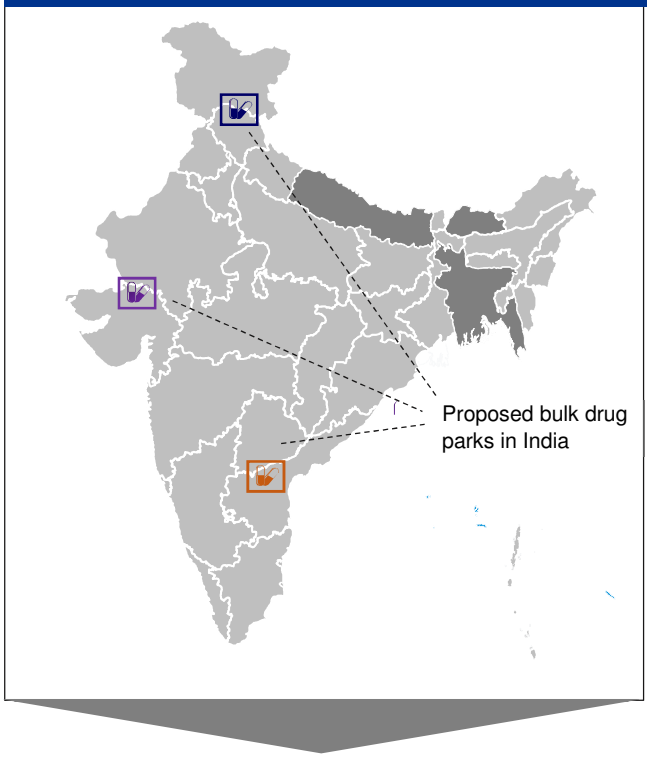
Source: 1- Bulk drug parks: Still waiting for financial backing, The Indian express, June 2017

Deliberating on the Katoch Committee recommendations, the DoP decided that financial assistance of INR200 crore can be given to develop a common facility at bulk drug parks

Despite the fact that over two years have passed since the Katoch Committee recommendations, financial approvals are yet to come by for the establishment of bulk drug parks

- After examining the recommendations, the central Government recommended a financial assistance of INR200 crore each at the three proposed bulk drug parks in Andhra Pradesh, Gujarat and Himachal Pradesh through public–private partnership (PPP) model[1]
- Since then, negligible progress has been made and the scheme has failed to take off due to lack of financial assistance
- In June 2017, the DoP decided that financial assistance (yet to be approved) can be given on the condition that each concerned state Government set up a park and put in the requisition for funds[2]
- Further, a few private domestic pharmaceutical companies are not keen to manufacture APIs as they anticipate that China can further bring down the prices of APIs making their business unviable. Another concern for India's pharmaceutical industry is the uncertainty over the price control regime.

Proposed bulk drug parks in India



Bulk drug park in Himachal Pradesh[3]

In March 2017, the Government of Himachal Pradesh identified 133 acres of land in Nalagarh Industrial Area to set up a centrally sponsored bulk drug park

Bulk drug park in Gujarat[4]

In October 2016, the central Government's proposal was accepted by the Government of Gujarat to set up three industrial parks for manufacturing medical devices, formulations and bulk drugs

Bulk drug park in Andhra Pradesh[5]

In April 2016, the Government of Andhra Pradesh announced its readiness to allot 500 acre of land at Visakhapatnam to set up a bulk drug park

Source: 1 - Government may provide Rs 200 crore each for three new bulk drug parks, The Economic Times, April 2016; 2 - Bulk drug parks: Still waiting for financial backing, Indian Express, June 2017; 3 - Land for bulk drug park identified in Nalagarh, Tribune India, March 2017 ; 4 - Gujarat accepts centre's proposal to set up three pharma parks, Financial Express, October 2016; 5 - AP govt ready to give 500 acres for bulk drugs park: Naidu, The Times of India, April 2016

The recently released draft pharma policy 2017 suggests many steps to encourage thorough indigenous drug manufacturing including that of APIs and their precursor intermediates

The proposed policy highlights India's high dependence on imported raw materials and intermediates from one or two countries as a major area of concern. To encourage thorough indigenous drug manufacturing including that of APIs and their precursor intermediates, the following steps are mentioned in the policy —

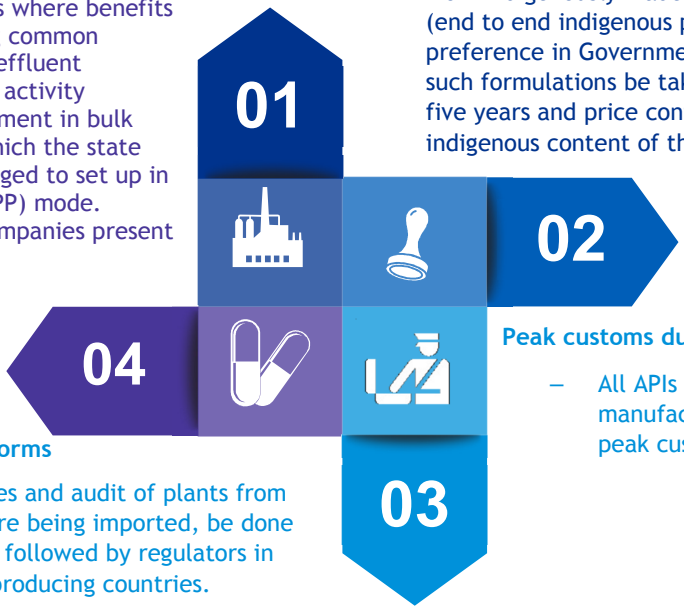
Proposed recommendations in the draft pharma policy 2017

Establish bulk drug parks

- Enabling environment will be created for setting up mega bulk drug parks where benefits of scale can be availed by using common facilities for pollution control, effluent treatment or any such common activity provided by the central Government in bulk drug / pharmaceutical parks which the state Governments would be encouraged to set up in a public-private partnership (PPP) mode. Single-window clearance for companies present in bulk drug parks.

Preference in Government procurement

- It is proposed that the formulations manufactured from indigenously made API and its intermediates (end to end indigenous production) be given preference in Government procurements. Moreover, such formulations be taken out of price control for five years and price control be linked to the indigenous content of the formulations.



Peak customs duty on imports

- All APIs which can be indigenously manufactured should be imported at peak customs duty.

Stringent import quality norms

- Foreign registration fees and audit of plants from where intermediates are being imported, be done according to standards followed by regulators in large pharmaceutical producing countries.

Source: Draft Pharma Policy 2017, Department of Pharma, 2017

The Katoch Committee suggested, inter-alia, the creation of mega bulk drug parks in its report released in February 2015. However, these recommendations are yet to be implemented. Creation of bulk drug parks is not a panacea to the challenge of dependence on imports. Unless the underlying drivers related to making indigenously manufactured APIs competitive are addressed, APIs manufactured in India are likely to remain costlier when compared to those manufactured in China, thereby negating the incentive to manufacture in India. Speedier environmental clearances, removing onerous taxes in the manufacturing processes and strengthening the supply chain need to be undertaken simultaneously.

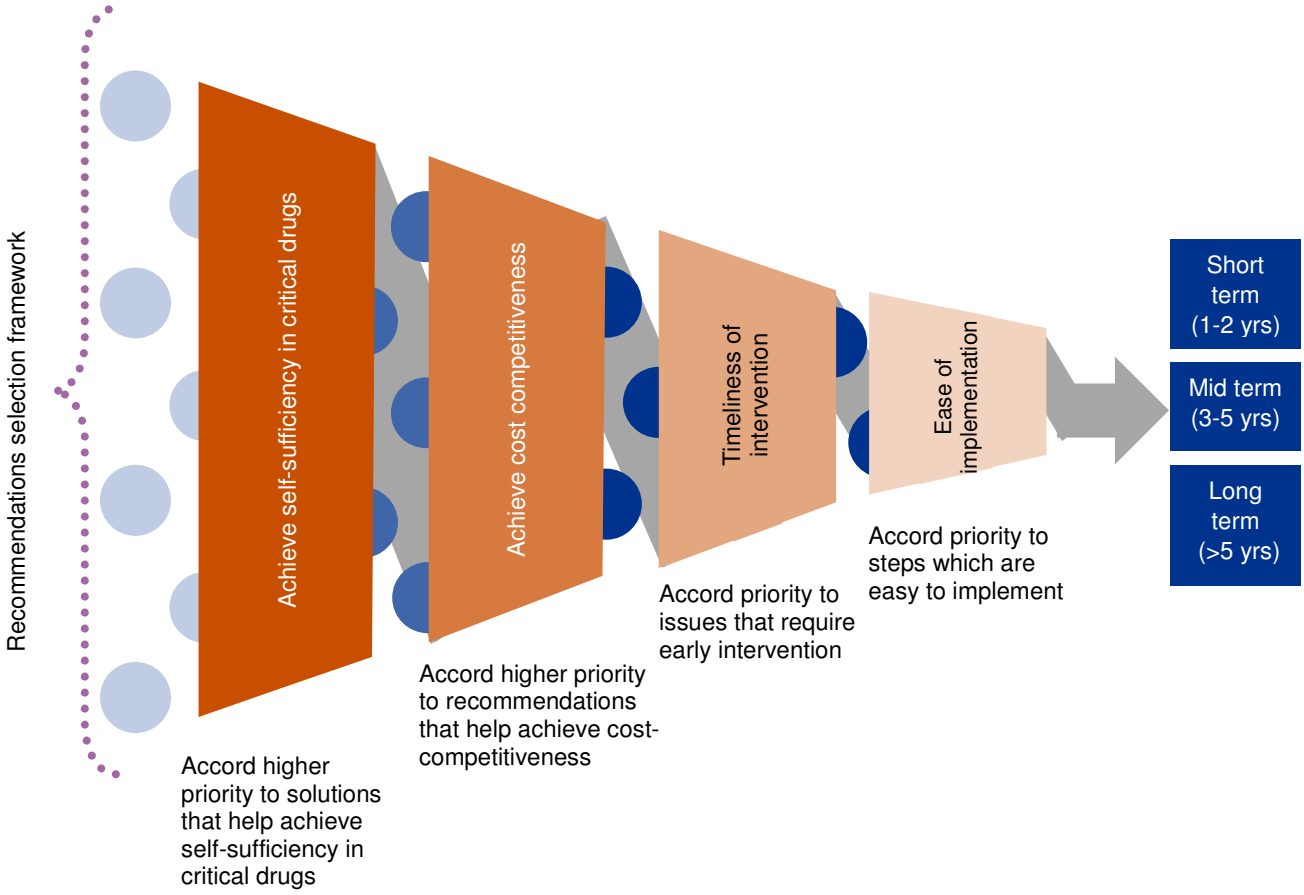
Preference to be given to indigenously manufactured APIs (Government procurement)

Unless the cost of indigenously manufactured APIs are significantly lower than those imported, the net price to consumers may actually be higher, since these would be outside the purview of price control. The price differential of final products manufactured with indigenously manufactured APIs and those with imported APIs would have to be determined to understand whether this move can finally result in making drugs more affordable.

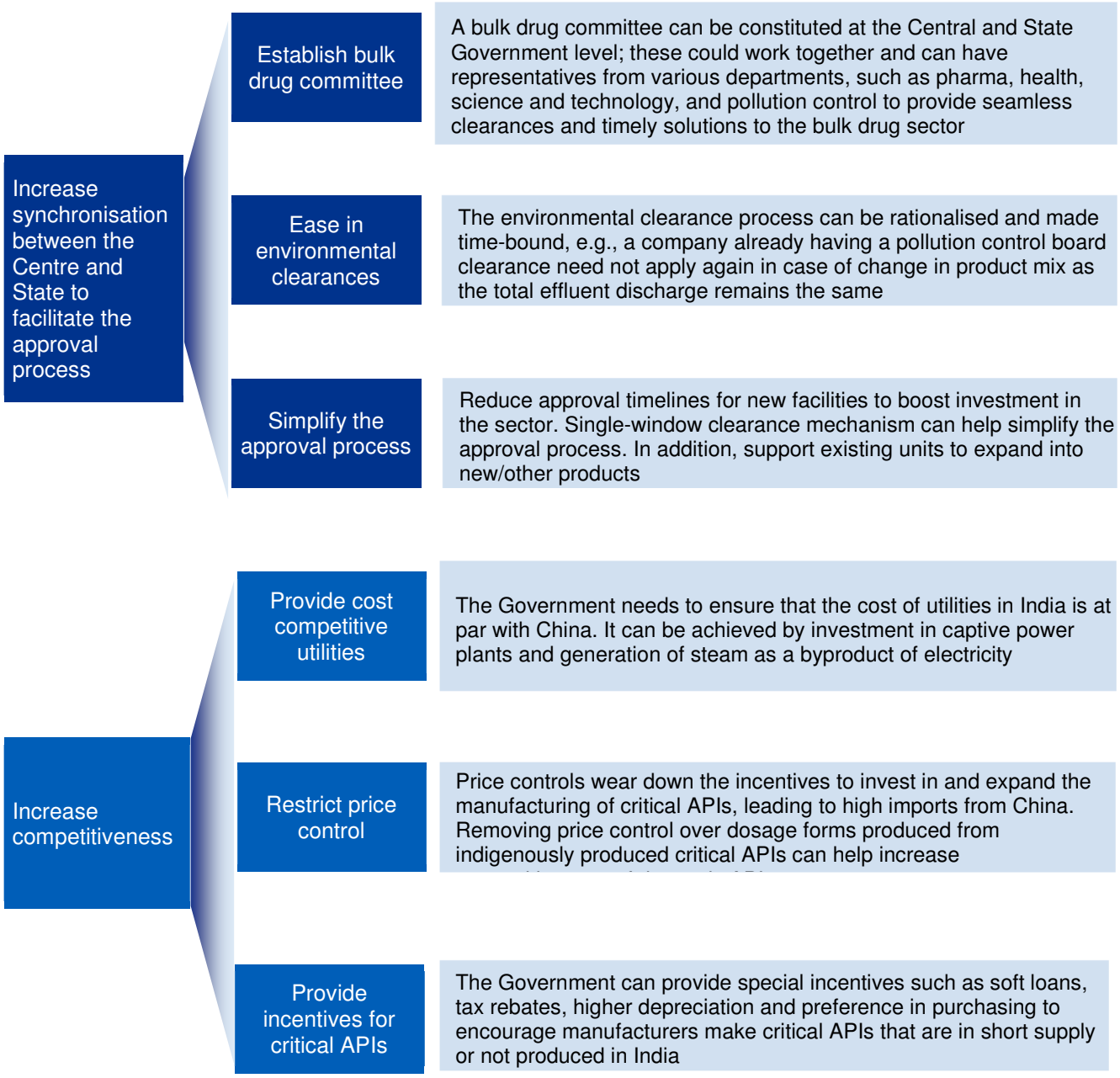
Proposed recommendations

A structured approach to be followed to help prioritise the recommendations made in order to help achieve self-sufficiency

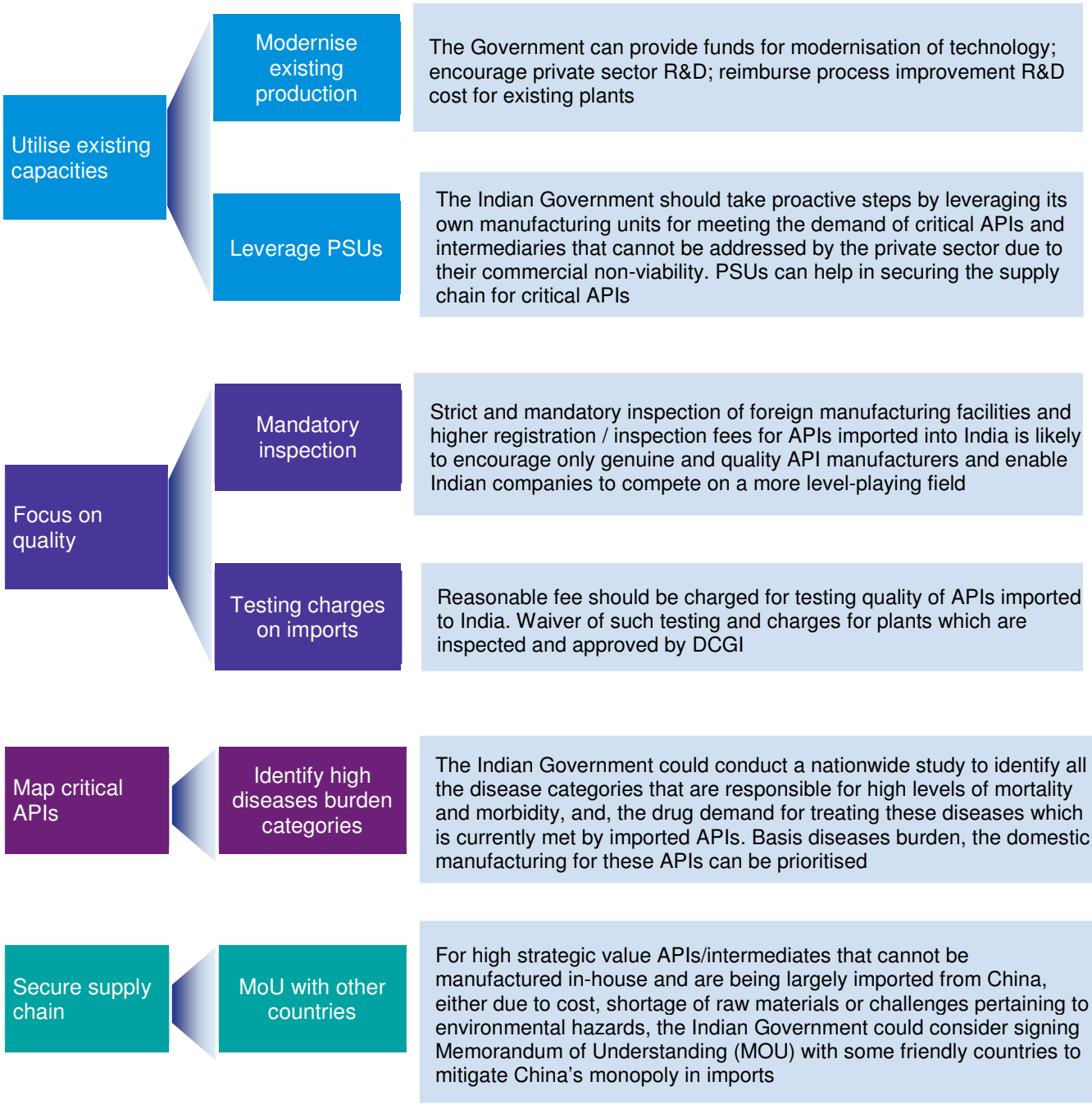
In line with views emanating from interviews with stakeholders, the following recommendation framework has been identified to develop short-, mid- and long-term recommendations. Factors such as securing supply of critical drugs, creating cost competitiveness, mitigating current industry challenges and ease of implementation were key considerations while drafting these recommendations.



Short-term recommendation 1: Ease the approval process and increase competitiveness to revive bulk drug manufacturing in India



Short term recommendation 2: Utilise existing capacities, focus on quality, identify critical APIs and secure supply chain are some short-term measures that need to be carried out

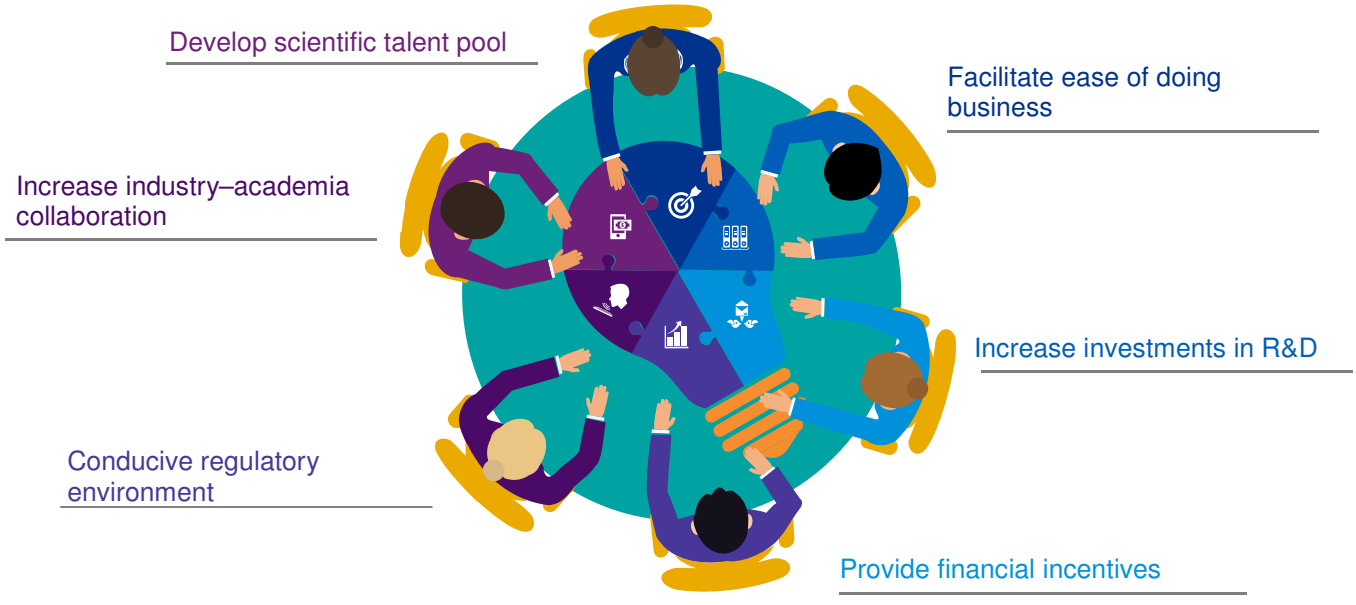


Mid-term recommendation 1: To nurture entrepreneurship in the bulk drug industry, a conducive ecosystem of policies, regulations and financial incentives needs to be established

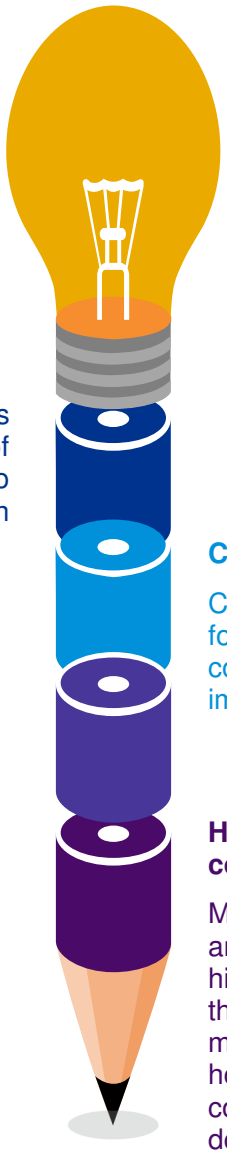
India needs a holistic and conducive ecosystem to capitalise on the full potential of its bulk drug manufacturing capabilities. Following are the steps / policy changes recommended — for the Government and industry to take into account to build a conducive environment:

- **Facilitate 'ease of doing business'**: Ease of doing business has improved by great measure in recent years. However, more needs to be done in a shorter span of time for us to catch up with other competing countries
- **Increase investments in R&D**: Create an innovation fund for targeted R&D in key technologies, such as fermentation, chiral chemistry, and bio-catalysis, where India lags currently. The industry also needs to increase investment in R&D and quality of manufacturing to comply with global regulatory standards and be at with competition
- **Provide financial incentives**: Provide financial incentives (such as 15-year tax holiday for cluster developers), land and infrastructure facilities at concessional rates, cheaper utilities, interest subsidies on bank loans, income tax benefit of 10 years for each launched product and export rebates
- **Conducive regulatory environment[1]:** Build transparent and comprehensive regulations to enable faster approvals; improve IP protection; pricing regulation and faster environmental clearances. In addition, an effective quality control system could be set up at all levels in India to promote strict quality adherence, reducing concerns related to Indian products
- **Increase collaborations between academia and industry**: Offer grants to academic institutions, and set up dedicated research centres to achieve process innovation and lower environmental impact technologies that industry can use. Infuse the culture of transparency to build trust between academia and industry
- **Develop scientific talent pool**: The Government can grant fellowships and provide targeted training programmes to talented researchers and students from leading academic institutes. These training programmes can be created with greater focus on basic chemical industry.
- **Government grants for R&D**: the Government needs to provide special grants to the bulk drug industry to encourage R&D.

Conducive ecosystem for bulk drug manufacturers



Mid-term recommendation 2: Declare API as a strategic sector, encourage reverse brain drain and capacity creation abroad



Declare API as a strategic sector

Declare API as a strategic sector as it has a direct bearing on the health security of the nation. Provide special budgets to achieve and maintain self-sufficiency in critical APIs

Encourage reverse brain drain

Increase reverse brain drain for Indian scientists by providing them soft loans, R&D labs, land at concessional rates, comparable salaries and research grants

Capacity creation abroad

Create production capacities abroad for critical APIs and manufacture cost competitive products which can be imported at nil import duty.

Higher incentives for manufacturing complex APIs

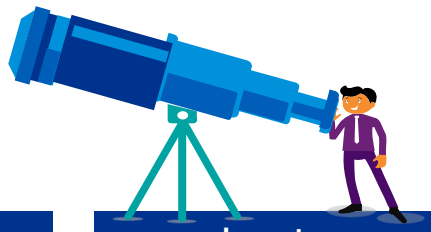
Manufacturers of complex APIs such as anti-cancer products could be entitled to higher incentives. Manufacturers of these products from their basic stage may be given star status similar to export houses. Indigenous manufacturer of complex APIs who export APIs or dosage forms made using their APIs should get higher export incentives; in short, incentivise innovation

Long-term recommendation: to achieve cost competence and self-sufficiency, India needs robust cluster development

A cluster development approach, including setting up bulk drug parks, could help reduce the country's API import burden substantially; increase the responsiveness of the bulk drug sector to market challenges; and facilitate the adoption of global best practices and latest technologies.

Setting up bulk drug manufacturing parks would provide the following advantages:

- **Economies of scale**: Bringing various manufacturers, raw material suppliers, technology providers, logistic providers, etc., under one roof along with a set of common infrastructure facilities would help bulk drug manufacturers, especially the SMEs gain access to common facilities and enhance their scale of production manifold
- **Distribution of fixed costs amongst large number of beneficiaries:** Government support and common infrastructure facilities such as common ETPs, testing facilities, captive power plants, etc., would help reduce the fixed cost burden on manufacturers
- **Maintaining ecological balance:** Pollution caused during drug manufacturing is one of the major areas of concerns. However, large scale effluent treatment plants using latest technology would help effectively treat pollutants generated during the drug manufacturing process, thus minimising the harmful impact on the environment
- **Increasing cost competitiveness and attracting FDI:** Setting up bulk drug parks where various stakeholders across the drug manufacturing value chain would be operating together, could help significantly bring down cost of production. In addition Government subsidies and tax breaks could help increase competitiveness of Indian bulk drugs at a global level, thus increasing the attractiveness of bulk drug manufacturers among investors.



Timelines for establishment of bulk drug parks

Short term

- **Location assessment and land acquisition:** Selection of an appropriate location that provides easy access to raw materials and is suited for bulk drug manufacturing (near airports and ports) and appropriation of enough land for setting up new plants
- **Single-window clearance:** Provide clearances with minimum delay by placing officials of concerned departments within the park
- **Finance and subsidies:** Offer funding support, availability of finance at cheaper rates, and tax breaks and subsidies to attract private players.

Medium term

- **Infrastructure development:** Build necessary infrastructure such as common ETPs, testing facilities, captive power plants, storage and roads
- **Research and development (R&D):** Set up R&D centres to facilitate drug manufacturing and develop new technologies for pollution control
- **Policy reforms:** Introduce policy reforms such as exclusion of formulations produced by using indigenous APIs and relaxation of price controls
- **Dedicated investment fund:** Set up a professionally managed, dedicated equity fund for the promotion of API manufacturing, and creation of cluster and individual unit infrastructure.

Long term

- **Achieve self-sufficiency:** Create a holistic ecosystem where India's pharmaceutical industry becomes self-sufficient
- **Promotion of industry–academia collaboration:** Establish colleges inside the park that offer specialised courses in drug production
- **Skill development and training:** Establish training infrastructure and institutes, offering industry-specific training at the drug parks
- **Focus on innovation:** Incentivise bulk drug manufacturers for process innovations and reward adoption of key technologies in fermentation, bio catalysis, etc.

Appendix

Abbreviations

API	Active pharmaceutical ingredient	**ICH**	International council for harmonisation
CAGR	Compound annual growth rate	**IDPL**	Indian Drugs and Pharmaceuticals Limited
CFDA	China Food and Drug Administration	**IPR**	Intellectual property right
CIS	Commonwealth of Independent States	**Kgs**	Kilograms
DCDA	Dicyandiamide	**MNC**	Multinational corporation
DCGI	Drug Controller General of India	**MOU**	Memorandum of Understanding
DMF	Drug master file	**MSME**	Micro, Small and Medium Enterprises
DoP	Department of Pharmaceuticals	**NCD**	Non-communicable disease
DPCO	Drug price control order	**NLEM**	National list of essential medicines
EoDB	Ease of doing business	**PPP**	Public–private partnership
ETP	Effluent Treatment Plant	**PSU**	Public sector undertaking
EU	European Union	**R&D**	Research and development
FDA	Food and Drug Administration	**SEZ**	Special economic zone
FDI	Foreign direct investment	**SME**	Small and Medium Enterprises
FY	Financial year	**U.S.**	United States
GDP	Gross domestic product	**UCPMP**	Uniform code of pharmaceutical marketing practices
GMP	Good manufacturing practice	**USD**	United States dollar
GST	Goods and Services Tax		

Research methodology

This thought leadership paper is the result of a study undertaken over a ten–week period by a KPMG in India team that worked closely with CII National Committee of Pharmaceuticals and its members. The scope and methodology of the study was as follows:

Acknowledgements

We are grateful for the efforts and guidance of the following people and acknowledge their contribution:

Interviews conducted with senior leaders of the following API industries:

- Cadila Pharmaceuticals Ltd.
- Eisai Pharmaceuticals India Pvt Ltd.
- Fresenius Kabi Oncology Ltd
- Lupin Ltd.
- Mylan Laboratories Ltd.
- Takeda Pharmaceutical Co Ltd

Report preparation team

- CII National Committee of Pharmaceuticals 2017-18
- KPMG in India Life Sciences team

Confederation of Indian Industry

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the development of India, partnering industry, Government, and civil society, through advisory and consultative processes.

CII is a non-government, not-for-profit, industry-led and industry-managed organization, playing a proactive role in India's development process. Founded in 1895, India's premier business association has over 8,500 members, from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 200,000 enterprises from around 250 national and regional sectoral industry bodies.

CII charts change by working closely with Government on policy issues, interfacing with thought leaders, and enhancing efficiency, competitiveness and business opportunities for industry through a range of specialized services and strategic global linkages. It also provides a platform for consensus-building and networking on key issues.

Extending its agenda beyond business, CII assists industry to identify and execute corporate citizenship programmes. Partnerships with civil society organizations carry forward corporate initiatives for integrated and inclusive development across diverse domains including affirmative action, healthcare, education, livelihood, diversity management, skill development, empowerment of women, and water, to name a few.

As a developmental institution working towards India's overall growth with a special focus on India@75 in 2022, the CII theme for 2017-18, **India@75: Inclusive. Ahead. Responsible** emphasizes Industry's role in partnering Government to accelerate India's growth and development. The focus will be on key enablers such as job creation; skill development and training; affirmative action; women parity; new models of development; sustainability; corporate social responsibility, governance and transparency.

With 67 offices, including 9 Centres of Excellence, in India, and 11 overseas offices in Australia, Bahrain, China, Egypt, France, Germany, Iran, Singapore, South Africa, UK, and USA, as well as institutional partnerships with 344 counterpart organizations in 129 countries, CII serves as a reference point for Indian industry and the international business community.

Confederation of Indian Industry

The Mantosh Sondhi Centre

23, Institutional Area, Lodi Road, New Delhi – 110 003 (India)

T: 91 11 45771000 / 24629994-7 • F: 91 11 24626149

E: info@cii.in • W: www.cii.in

Follow us on :

 facebook.com/followcii

 twitter.com/followcii

 www.mycii.in

Reach us via our Membership Helpline: 00-91-124-4592966 / 00-91-99104 46244

CII Helpline Toll free No: 1800-103-1244