



# **Realising “Make in India”– Journey to become the most preferred manufacturer of high quality affordable medicines**



अनंत कुमार  
ANANTH KUMAR  
ಅನಂತ ಕುಮಾರ್



रसायन एवं उर्वरक मंत्री  
भारत सरकार  
MINISTER FOR  
CHEMICALS & FERTILIZERS  
GOVERNMENT OF INDIA



**MESSAGE**

It is a matter of great pleasure to share my blessings and good wishes with the Pharmaceutical fraternity through this message for the Knowledge paper titled: **'Realising Make in India – Journey to become the most preferred manufacturer of high quality affordable medicines'** centered around the theme: **'Make in India – Are we on track'**. I express my best compliments on release of the Knowledge paper during the **"India Pharma-2016 Conference"**, an International Exhibition and Conference on Pharmaceutical sector scheduled from January 7 – 9, 2016 at BIEC, Bengaluru.

Over the last decade, Indian Pharmaceutical sector has created a leading position for itself and is one of the fastest and the most accessible markets globally. I am sure this Knowledge paper would be a positive step towards strengthening our manufacturing setup by building the make in India brand; also thinking of new ideas and use of technology across multiple domains.

I am confident that the deliberations from the event would help strengthen India's position in the Pharmaceutical manufacturing landscape and help to achieve the desired growth.

I wish the Conference a grand success.

  
(Ananth Kumar)

20 December, 2015

---

Office : Room No. 316, Shastri Bhawan, Dr. Rajendra Prasad Road, New Delhi-110 001 Tel.: 23383559, 23386519 Fax : 23384020  
Resi. : 26, Tughlak Crescent, New Delhi-110 011 Tel. : +91-11-23794754, Fax : +91-11-23012791  
Bengaluru : 15th Cross, 2nd Block, Jayanagar, South End Circle, Bengaluru-560 011  
Telefax : (080) 26560286, 26571188 e-mail : ananthkumardelhioffice@gmail.com, www.ananth.org



# Foreword

Indian pharmaceutical industry is already at the forefront of the Make-in-India initiative. Most of our domestic demand for drugs is fulfilled by medicines that are made in India. The pharma sector has come a long way, from import-dependence before the 1970s to today where India is reputed for a deep knowledge base in pharmaceuticals that differentiates it from other low-cost suppliers of pharmaceuticals. India's pharmaceuticals industry has been growing rapidly, nearly doubling in the last five years. India has also demonstrated a deep commitment to ensuring affordable and accessible medicines globally.

How can we take Indian pharma industry to the next S-curve of growth? What are the opportunities and challenges in front of us? How do we address them? The FICCI report, "Indian life sciences: Vision 2030—Expanding global relevance and driving domestic access" (June 2015) laid out three goals to realise this vision – (i) Become the world's largest and most reliable drug supplier, (ii) Provide access to affordable, quality drugs for every Indian and bring the latest drugs to Indian market, and (iii) Establish a globally recognised presence for the Indian industry in pharma innovation. Given the government's recent efforts to promote "Make in India", the first pillar takes on added significance, and we are eager to make it a reality. This report is a step in this direction of making India achieve a strong position in both developed and emerging markets through leadership in cost, quality and development excellence. It provides a quick recap of the achievements of the Indian pharma industry and identifies its strengths, opportunities and challenges in achieving the Make-in-India vision. Finally, it also provides suggestions to various stakeholders on their role in making India the most preferred manufacturer of high quality affordable medicines.

We are grateful to McKinsey & Company for again being a Knowledge Partner to this initiative and for their continued support through insights and analytics.



**Mr. Pankaj Patel**

Senior Vice President, FICCI & Chair, Pharma Committee



# Contents

Executive summary .....	9
The Pharmaceutical Industry in India: Successful and promising .....	15
Steady domestic and global demand for products .....	15
Strong position in infrastructure and capabilities.....	16
Policy efforts to ease business .....	18
Road Ahead: Areas of opportunity .....	23
Formulations manufacturing.....	23
Bulk drug manufacturing.....	24
Indigenous vaccines manufacturing.....	25
Contract manufacturing .....	26
Road Ahead: Multiple challenges to overcome.....	29
Growing dependence on external markets for raw materials.....	29
Challenged cost-competitiveness in traditional generic formulations .....	29
Competition in complex generics and new technology ...	30
Quality issues affecting supply reliability .....	30
Strengthening execution of govERNMENT policies .....	31
Making it happen: Imperatives to achieve Make-in-India ambition .....	35
Role of industry .....	35
Role of government bodies .....	37
Role of regulators .....	39
Role of other stakeholders .....	40
Acknowledgements.....	43
FICCI Lifesciences Team .....	45
About FICCI.....	46





# Executive summary

Indian pharmaceuticals industry is globally respected and is one of the most successful industries in India. It has contributed immensely to India's healthcare outcomes and economy

World-class capabilities and market conditions ensure that India continues to be one of the most lucrative pharma markets in the world. This strong market presence rests on three crucial pillars:

- **Steady domestic and global demand for products:** Affordability and accessibility of India pharma products has improved in domestic as well as international markets
- **Strong position in infrastructure and capabilities:** India has been able to build strong capabilities across the value chain
- **Policy efforts to ease business:** The Indian government has taken various steps to ease administrative and regulatory procedures for pharma companies

The pharmaceutical industry has been one of the success stories for India in the last two decades. Many opportunities continue to exist in the core businesses as well as new businesses that present a favourable outlook for the industry over the next 10-15 years. These are:

- **Formulations manufacturing:** Indian pharmaceutical industry can aspire to deepen its presence in global markets as well as build a stronger presence in key emerging markets to create a platform for sustained growth in formulations manufacturing
- **Bulk drug manufacturing:** Given the increasing competition from China which has led to a stagnated growth in bulk drug manufacturing, the industry should focus on self-sufficiency in API for the domestic market
- **Indigenous vaccines manufacturing:** India has scope and demand for indigenous vaccines, both existing and new players can capture this opportunity in vaccines manufacturing
- **Contract manufacturing:** With increasing pressures on managing costs and shortening time to market globally, Indian Contract Research and Manufacturing Services (CRAMS) companies have an opportunity to be viewed as strategic partners to global pharma companies rather than transactional suppliers

The journey so far has been a source of celebration, but the road ahead for the industry is challenging. Certain headwinds are challenging the growth trajectory of the industry. The prominent challenges that the industry faces are:

- **Growing dependence on external markets for raw materials:** The sector continues to rely on imports of key starting materials, intermediates and API; with the share of dependence increasing over time
- **Challenged cost-competitiveness in traditional generic formulations:** India's ability to sustain its cost-competitiveness in traditional generic formulations is being challenged for many reasons - high levels of commoditization, increasing customer consolidation, pricing regulations, increasing global competition and productivity boosts from players in developed markets to match India's conversion costs
- **Competition in complex generics and new technology:** While India has made substantial headway in the last few years, it is still behind in operational maturity in this space, particularly as compared to China and South Korea
- **Quality issues affecting supply reliability:** In the last 2 to 3 years, Indian pharmaceutical companies (like their global peers) have faced increasing number of quality-related issues especially for the US market. These challenges have been driven by continuously evolving regulator expectations and risk-based inspection planning model
- **Strengthening execution of government policies:** While a lot of good policies are in pipeline, if not executed on time would lead to high opportunity cost. There exists opportunity to strengthen dialog between government and industry for feedback on current policies. It is important for the government and industry to work together and resolve these issues in a timely manner

As the challenges to sustainable growth of the industry are quite critical, it requires a set of concerted actions from all stakeholders.

- **Role of industry:** The industry needs to take lead in tackling the imminent challenges facing the Indian pharmaceutical space. The effort must begin by upgrading quality systems, infrastructure and enhancing capabilities through a holistic approach to fundamentally transform the quality systems. Next, it is crucial to build a globally recognised position for India in the innovation space and build new-age capabilities to sustain competitiveness and speed to market advantage. There is need to collaborate more meaningfully within the industry to support growth and industry evolution

- **Role of government bodies:** The government will continue to play a critical role in helping the pharmaceutical industry to achieve the full potential of Make-in-India. Potential interventions could include strengthening the current business environment to facilitate “ease of doing business”. The government must identify strategic priorities for the sector and provide holistic support through joint interactions with the industry. Lastly, there is need to build more transparency and predictability in the regulatory regime which can help facilitate ease of doing business, and attract further investment in the sector while safeguarding needs and interests of all stakeholders

- **Role of regulators:** The role of regulators to ensure safety, reliability and efficiency of the industry is very crucial. Periodic review of guidelines to maintain the thrust on quality, continued efforts to strengthen regulatory infrastructure and facilitating the ease of attaining regulatory approvals are important steps in this direction


- **Role of other stakeholders:**

Healthcare professionals should proactively participate and shape development of new medicines. They are also the custodians of professional practices in the frontend of the pharma industry. Forums of healthcare professionals can also continue to play a significant role in shaping the healthcare policies of the country

Academia can also play a major role in fostering research and collaboration with the industry. Academia can complement industry’s efforts by focusing on areas that are relevant from patient servicing point of view. There is a need to create forums that can improve transparency and collaboration between academia and the industry

Driven by the entrepreneurial zeal of the industry and a supportive government, the industry is well positioned to achieve the Make-in-India vision. It will require all stakeholders to come together and tap into the opportunities provided by the domestic and global markets.





# **The Pharmaceutical Industry in India: Successful and promising**





# The Pharmaceutical Industry in India: Successful and promising

Indian pharmaceuticals industry is globally respected and is one of the most successful industries in India. It has contributed immensely to Indian's healthcare outcomes and economy. In addition to helping ensure affordable and accessible medicines in the far reaches of India, it also generates employment, directly or indirectly hiring around 2.5 million people.

The industry has nearly doubled in the last five years - from around USD 17 billion to 18 billion in 2008–09 to USD 30 billion in 2014–15, and is likely to grow at 13 to 14 per cent to rank third largest in the world by 2030, valued at USD 200 billion. Much of this growth comes from rapid growth in exports—India's pharma sector is the fourth-largest exporter of goods in India (rising from sixth place in 2008–09) and accounts for 5 per cent of all merchandise exports<sup>1</sup>.

Bulk drug exports accounted for about 25 per cent of total exports in the pharmaceutical industry in 2013–14<sup>2</sup>. Although the domestic formulations market recorded the lowest growth rate in the last 5 years in 2013–14 due to various externalities, the growth of the domestic formulations market is expected to remain strong. Contract Research and Manufacturing Services (CRAMS) and the Biotech Industry are two fast growing segments in the pharmaceutical and biotechnology industry. India is among the top 12 biotech destinations in the world<sup>3</sup> and ranks second in Asia, after China.

World-class capabilities and market conditions ensure that India continues to be one of the most lucrative pharma markets in the world. This strong market presence rests on three crucial pillars: steady demand, relevant capabilities, and an ecosystem conducive to growth.

## STEADY DOMESTIC AND GLOBAL DEMAND FOR PRODUCTS

Affordability and accessibility of India pharma products has improved in domestic as well as international markets. The industry's strong initiatives to drive access and

---

<sup>1</sup> Domestic market at consumer price level; Includes other pharmaceuticals segments such as Clinical Research, beyond pharmaceuticals; OPPI Annual Report 2013–14, Export Import Data Bank, Department of Commerce, Pharmexcil, IDMA report on "Journey towards Pharma 2020 & beyond", McKinsey analysis

<sup>2</sup> Pharmexcil – India's Pharmaceutical exports 2014

<sup>3</sup> ASSOCHAM The Indian Pharmaceutical Industry Report 2015



awareness across all regions of the country has resulted in around 50 per cent higher drug penetration in rural India. India continues to be the primary supplier of essential medications for numerous disease areas worldwide, helping save millions of lives every year (Exhibit 1).

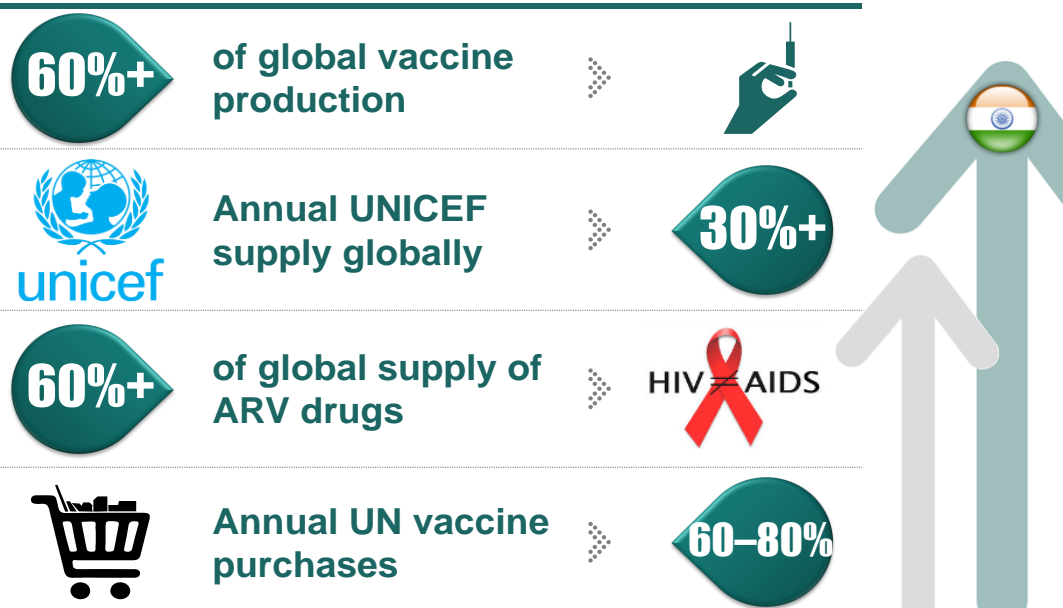
## STRONG POSITION IN INFRASTRUCTURE AND CAPABILITIES

India's strong capabilities across the value chain are critical for successfully serving global pharmaceutical markets. Here, too, India is well positioned:

- It has strong capabilities in generics R&D. For the last five years, India bagged around 1/3<sup>rd</sup> of the total ANDA filings and approximately 45 per cent of DMFs<sup>4</sup> filed with the USFDA
- India has the largest number of FDA-approved pharmaceutical manufacturing plants outside the USA located in India (Exhibit 2)

### EXHIBIT 1

#### Indian industry's contribution to drug access, both in India and globally



SOURCE: Press Information Bureau; "Affordable Efficacious Medicines – All Roads Lead to India" report by IDMA; "Vaccines Market in India" report by Netherlands Office of Science and Technology

<sup>4</sup> US FDA website



## EXHIBIT 2

### Strength of Indian industry's capabilities in Manufacturing and R&D

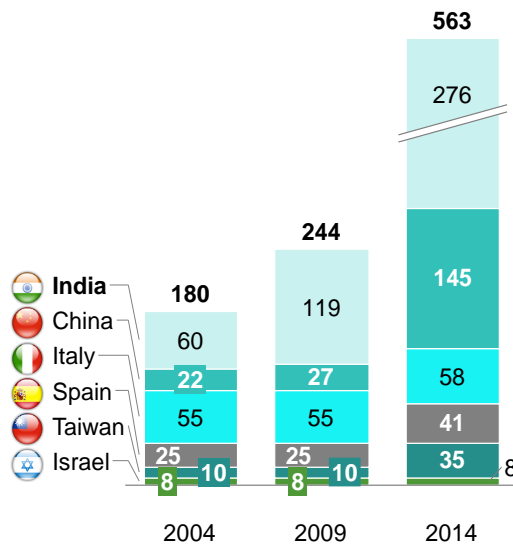
India has the most number of FDA-approved plants outside of the US ...



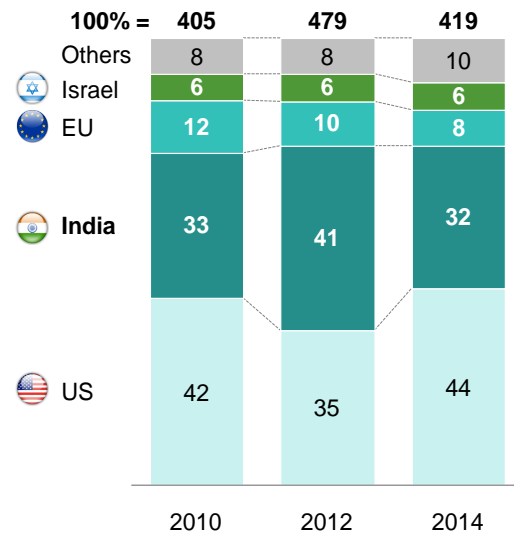
... and also has the 2<sup>nd</sup> largest share of ANDA approvals after the US



Number



Percent



SOURCE: US FDA website; team analysis

- India is also known for innovation, with 60+ biosimilars<sup>5</sup> approved for marketing (30 active substances<sup>6</sup>) and an additional 30+ in the pipeline. In addition two new medical entities (NMEs) have been developed and launched till date
- India ranks among the preferred clinical-trial destinations in the world. Although there has been a decline in the number of clinical trials approved by Drug Controller General of India (DCGI) in recent years, several initiatives to bring back the growth are underway
- Multiple mergers and acquisitions in India have seen Indian companies acquire multi-national corporations (MNCs) to get a firm foothold in global markets
- Production costs for commodity generics continue to be low in India—the country ranks lowest in conversion costs, 50 per cent lower than the US or UK and other developed countries (Exhibit 3)

<sup>5</sup> FirstWord Pharma biosimilar Index, McKinsey Biosimilar Interest Group

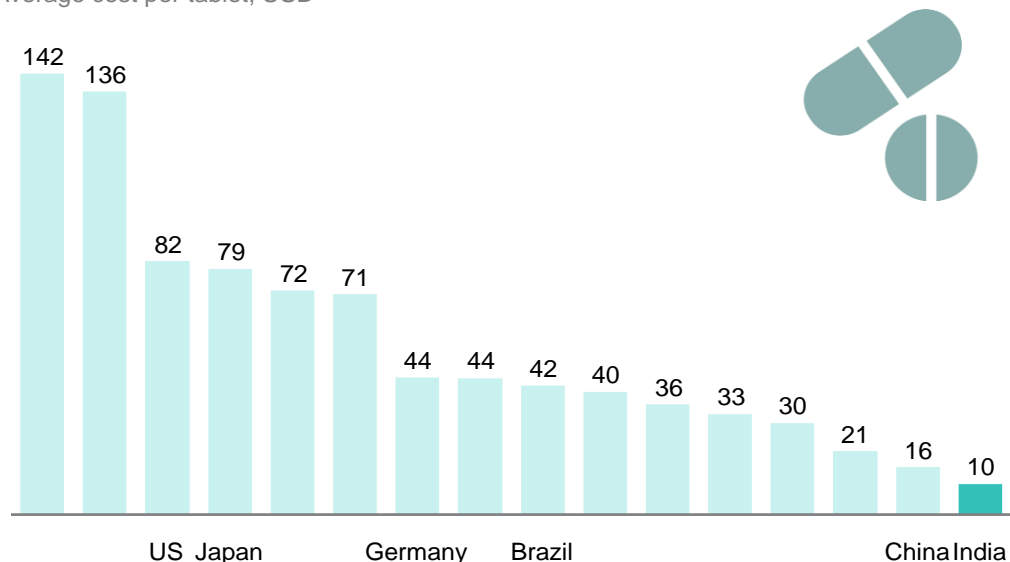
<sup>6</sup> CDSCO data listed by GaBi Online

## EXHIBIT 3

### Indian companies have been among the most cost competitive

#### Unit conversion costs of the most competitive plants in countries

Average cost per tablet, USD



SOURCE: McKinsey

## POLICY EFFORTS TO EASE BUSINESS

The Indian government has taken various steps to ease administrative and regulatory procedures for pharma companies. These are in various stages of implementation and include<sup>7</sup>:

- 100 per cent Foreign Direct Investment (FDI) is allowed under the automatic route for greenfield projects. For brownfield project investments, up to 100 per cent FDI is permitted under the government route on a case-to-case basis
- Under the National Institute of Pharmaceutical Education & Research (Amendment) Act, 2007, the Government has taken steps to nurture and promote pharmaceutical education & research at post graduate level. National Institute of Pharmaceutical Education and Research (NIPER) at Mohali is a premier institute in the field of Pharmaceuticals with fully equipped facilities. Further, six new National Institutes of Pharmaceutical Education and Research (NIPER) were opened in 2007. Recently, three new NIPERs have been proposed in the states of Maharashtra, Rajasthan and Chattisgarh

<sup>7</sup> Department of Pharmaceuticals website, CDSCO, Make In India – Pharmaceuticals website

- Mega parks and clusters to provide shared services and infrastructure reducing costs; supported by area-based incentives from the government. An exclusive pharma zone is coming up on about 11,000 acres near Rangareddy district of Telangana with an in-house pharmaceutical university and research facility. Over 2000 acres for this pharma city has already been acquired<sup>8</sup>. The State Government has further allotted 400 acres on the outskirts of Hyderabad for an advanced 'Smart Health City'
- The government has announced elimination of the need to repeat pre-clinical or toxicological studies on animals for new drugs already approved outside India for importing or manufacturing them in the country unless some specific concerns are raised
- The government provides financial benefits for R&D efforts. A 100 per cent deduction is available for qualifying expenditures paid out or expended in scientific research and a weighted deduction of 200 per cent is available for scientific research on in-house R&D expenditure. There is also a provision allowing 125 per cent deduction on amounts paid to approve third-party R&D contractors. Duty free import of Pharmaceuticals reference standards is allowed
- A number of export benefits under Focus product scheme, Special focus product scheme, Focus market scheme and Export promotion capital goods scheme have been envisaged
- The government has set up an effective control system to monitor the quality of pharmaceuticals at all the levels in India through various agencies/ bodies. Efforts are underway to digitalize the procedures. Some of them include online clinical trial application and monitoring system, software system for monitoring and disposal of applications for import licence for test and analysis, etc.

□ □ □

Pharmaceutical industry has been one of the success stories for India in the last two decades. Many opportunities continue to exist in the core businesses (formulations and bulk drugs) as well as new businesses (e.g., complex generics) that present a favourable outlook for the industry over the next 10-15 years.

---

<sup>8</sup> Telangana Industrial Infrastructure Corporation (TSIIC) Press release



## Road Ahead: Areas of opportunity





# Road Ahead: Areas of opportunity

India is already an attractive destination for the manufacturing of pharmaceuticals owing to its strong capabilities across the value chain. Going forward, pharmaceuticals manufacturing in India has multiple opportunities for growth across formulations, bulk drugs, indigenous vaccines manufacturing and contract manufacturing.

## FORMULATIONS MANUFACTURING

Indian pharmaceutical industry can aspire to deepen its presence in global markets, e.g., In the US, by expanding its value share from the current 10 per cent to around 25 per cent by 2030<sup>9</sup>. India's pharma sector could also build a stronger presence in key emerging markets to create a platform for sustained growth. To drive this growth, pharma manufacturers can continue to expand their existing facilities and also diversify to manufacture new drug forms at lower costs. Key opportunities include:

- **Upgrading and expanding current manufacturing facilities:** Most companies are over-dependent on one or two manufacturing units to cater to key growth markets. This results in high complexity at those sites, high utilisation levels, and increased exposure to operating risk (quality, service levels, employee workload, etc.). Companies should continue to invest in expanding their manufacturing footprint and build adequate redundancy to mitigate supply chain risks and build capacity for future growth
- **Scaling capabilities and infrastructure for manufacturing new drug forms:** Several companies are investing in building manufacturing capabilities in biosimilars. There also seems to be a shift in strategy toward more complex products (Exhibit 4). Pharmaceutical manufacturers should focus on developing scale and capabilities in these areas to build a strong cost and capacity position vis-à-vis global competitors
- **Low-cost manufacturing of branded drugs and repurposing of formulations:** Several Indian generics companies have launched efforts to develop incremental innovation (505b2) drugs and NMEs. These programs will be the growth vehicles for Indian pharma companies particularly in the high value branded pharmaceutical markets. Building the backend for these drugs will also

---

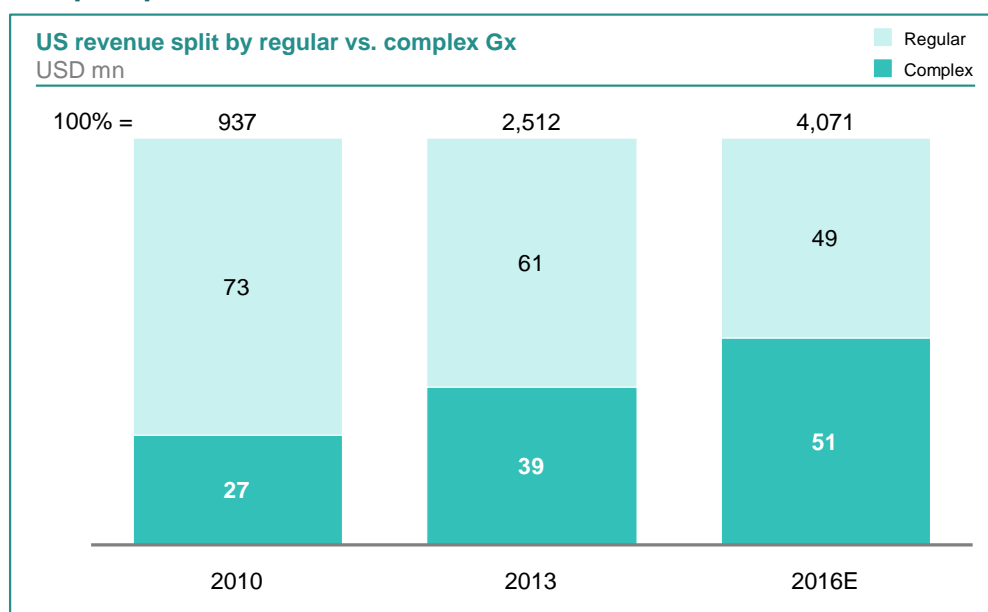
<sup>9</sup> FICCI "Indian life sciences: Vision 2030 Expanding global relevance and driving domestic access" Report

require Indian pharmaceuticals companies to upgrade their workforce and manufacturing capabilities. In due course, India could also attract global pharmaceutical companies to shift manufacturing of their high value branded drugs to India

With years of experience and expertise behind them, Indian manufacturers can easily take lead in formulations repurposing. The area offers unique advantages of shorter cycle times, lower development costs and higher success rates. There is potential to partner as development or manufacturing partner to global pharmaceutical companies.

#### EXHIBIT 4

### Indian manufacturers have now started to shift to more complex products



SOURCE: PHAST; Analyst reports; McKinsey analysis

### BULK DRUG MANUFACTURING

Bulk drug exports from India continue to be strong and are driving growth. They are estimated to have grown from USD 3.7 billion in 2008–09 to an estimated USD 3.9 billion<sup>10</sup> in 2013–14. The bulk drug exports have shifted in favour of regulated markets (49 per cent share in 2013–14<sup>11</sup>) and is expected to continue in this

<sup>10</sup> Pharmexcil – India's Pharmaceutical exports 2014

<sup>11</sup> ASSOCHAM The Indian Pharmaceutical Industry Report 2015



direction. However, there has been an increasing competition from China which has led to a stagnated growth in this space.

For the next horizon of growth, the industry should focus on self-sufficiency in API for the domestic market. India imported APIs and other raw materials worth USD 3.9 billion in 2014-15 which is 5 times the imports in 2004-05 (USD 800 million)<sup>12</sup>. With almost 80 per cent of its bulk drugs imports coming from China, there is an urgent need to bring about self-sufficiency in API sourcing.

While there are many pharma clusters, notably in Hyderabad which can be used to set up new facilities and augment existing ones, the government should continue to incentivize state-run and private bulk drug manufacturers. The government is proposing incentives such as land at concessional rates, tax holidays, soft loans, setting up of mega pharma parks and allocation of power at concessional rates to help revive investment in the sector.

## **INDIGENOUS VACCINES MANUFACTURING**

Indian vaccine manufacturers have emerged as significant players in the global market. India has been a major supplier of basic Expanded Programme on Immunization (EPI) vaccines to the UNICEF. The industry is now able to produce new and more complex vaccines such as the meningitis, Haemophilus influenzae Type B, pneumococcal conjugate vaccines, rotavirus vaccines and influenza A (H1N1) vaccines.

India has scope and demand for indigenous vaccines, both existing and new players can capture this opportunity in vaccines manufacturing. Of the 31 vaccines listed by the World Health Organisation, India manufactures 20, which means there is scope for more players to enter the manufacturing space<sup>13</sup>. Introduction of four new vaccines in the Universal Immunization Program (UIP) in 2014 is further expected to promote investment and R&D in vaccines in India.

Even as new initiatives to ensure self-sufficiency are being deliberated upon, effective implementation of policies and supportive interventions to cushion risks taken by the industry can help make the sector attractive. While Indian companies are researching next generation vaccines, collaborating with multi-national

---

<sup>12</sup> Ministry of Commerce & Industry, India

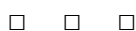
<sup>13</sup> WHO website

companies could speed up efforts. In-licensing deals are yet another way to boost indigenous vaccine development.

## CONTRACT MANUFACTURING

The global contract manufacturing services market is estimated at USD 58 billion in 2014, with the Indian sector valued at around USD 5.3 billion<sup>14</sup>. This indicates a vast growth opportunity. The Indian contract manufacturing services sector (CRAMS) has been growing and is further projected to grow at a rate three times higher than that of the global market—18 per cent CAGR till 2018<sup>15</sup>. Contract manufacturing contributes to up to 60 per cent of formulations and bulk drug manufacturing and continues to present itself as a significant growth opportunity.

With increasing pressures on managing costs and shortening time to market globally, Indian CRAMS companies with product mix skewed towards high-end research, biologics and complex technology services at low cost and abundant pool of skilled professionals are preferred players. They now need to be viewed as strategic partners rather than transactional suppliers. With strategic partnerships, their range of services can be expanded to include new drug forms, including biologics and parenteral drugs.



Indian pharmaceutical industry has multiple opportunities to tap into. However, certain headwinds are challenging the growth trajectory of the industry. It is important for all stakeholders to acknowledge and prepare to proactively address them in the near-term.

---

<sup>14</sup> Indian Drug Manufacturers' Association (IDMA)

<sup>15</sup> ASSOCHAM The Indian Pharmaceutical Industry Report 2015

**Road Ahead: Multiple  
challenges to overcome**





# Road Ahead: Multiple challenges to overcome

While Indian pharmaceutical industry is poised for future growth, certain challenges need to be addressed to de-risk the growth trajectory and provide future impetus. The ecosystem comprising of pharmaceutical players, industry associations, policy maker and regulators will need to play their part to address these challenges.

## GROWING DEPENDENCE ON EXTERNAL MARKETS FOR RAW MATERIALS

Sector continues to rely on imports of key starting materials, intermediates and API; with the share of dependence increasing over time. China alone accounts for more than 80 per cent of India's API imports; driven by low costs, almost 50 to 60 per cent lower than indigenous prices. This dependence impacts supply chain flexibility and control cost for formulation manufacturers. Also, lack of control of supply chain can impact ability to reliably service other markets.

## CHALLENGED COST-COMPETITIVENESS IN TRADITIONAL GENERIC FORMULATIONS

India's ability to sustain its cost-competitiveness in traditional generic formulations is being challenged for many reasons:

- **High levels of commoditization:** Portfolio of products getting commoditised with high competition at the product or SKU level. Moreover, proliferation of SKUs/products has made supply chains increasingly complex (as indicated by the number of SKUs, line changes overs, new launches, etc.), further affecting productivity and costs
- **Increasing customer consolidation:** Customers have consolidated at a rapid pace in developed markets increasing pressure on prices. In the US, the share of the top three buyers has risen from around 50 per cent to over 80 per cent in the past 5 years<sup>16</sup>
- **Pricing regulations:** Many more markets are coming under price regulation, thereby putting further pressure on margins

---

<sup>16</sup> Company annual report filings (10K), press releases and investor presentations

- **Increasing global competition:** Chinese players are expanding downstream, from APIs to formulations. Of the top 15 Chinese players in API, 14 are now present in formulations. The Chinese manufacturers, traditionally state owned enterprises enjoy 15-17 per cent drawback duty on exports<sup>17</sup> and tax incentives that help cover a part of their operating costs
- **Players in developed markets are boosting productivity** to match India's conversion costs. This along with the perceived quality advantage and proximity to global customers is making them relatively more reliable

## COMPETITION IN COMPLEX GENERICS AND NEW TECHNOLOGY

Countries like China and South Korea have had many more approvals and evolved manufacturing capability for complex molecules and new technology. While India has made substantial headway in the last few years, it is still behind in operational maturity in this space. The South Korean government's investment in current biosimilars development reached around 35 per cent of total R&D costs in 2012<sup>18</sup>. To gain competitive advantage in this space, India must invest in developing or acquiring the desired set of capabilities including R&D and manufacturing. However, these investments could result in substantial increase in per unit costs in the short term.

## QUALITY ISSUES AFFECTING SUPPLY RELIABILITY

In the last 2 to 3 years, Indian pharmaceutical companies (like their global peers) have faced increasing number of quality-related issues especially for the US market. The number of warning letters, import alerts, 483 observations and product recalls has gone up proportionately to the extent of approvals and exports. These issues have not only impacted the near-term performance (e.g., upto 20 per cent drop in sales and market cap, delay or revoking of new product approvals), but also may have some effect on the reliable supplier image of the Indian industry.

These Quality challenges are driven by:

- **Continuously evolving regulator expectations:** Regulators such as USFDA are focusing on improving fundamental Quality systems and procedures across the enterprise rather than addressing individual site-level observations

---

<sup>17</sup> Research and Information System for Developing Countries (ris.org)

<sup>18</sup> Korea Food & Drug Administration Database

- **Risk-based inspection planning model:** Firms with high export volumes and/or compliance deviations continue to experience closer and more frequent regulatory scrutiny

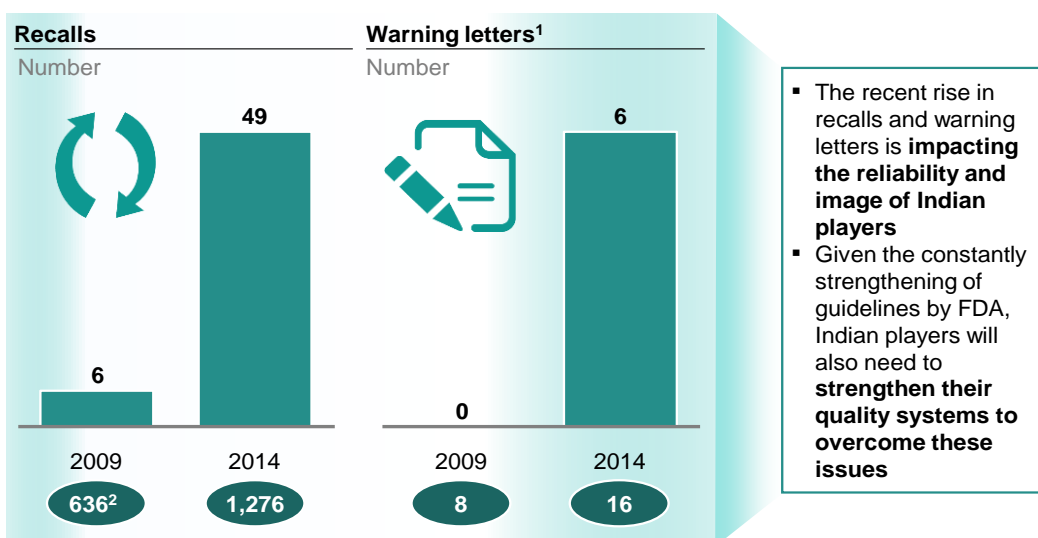
Regulators are emphasizing the importance of Quality-oriented culture as a leading indicator of quality and compliance gaps. Recent FDA draft guidelines on metrics includes certain metrics tracking Quality culture.

The Indian Pharmaceutical industry in response is fundamentally upgrading their Quality management systems and investing to build a culture of Quality that spans from the top management to the shopfloor operations. However given the scale of regulatory expectations and complex nature of these issues, the journey to Quality excellence may be long.

## EXHIBIT 5

### The Indian industry is facing increasing quality-related issues, which are impacting its high quality, reliable supplier image

xx Global numbers



<sup>1</sup> Accounts only for warning letters issued by the Office of Manufacturing and Product Quality


<sup>2</sup> Excluding the exception recalls of Advantage dose

SOURCE: US FDA website and databases; Gold Sheet; FiercePharma; FDAzilla; Press search

## STRENGTHENING EXECUTION OF GOVERNMENT POLICIES

Over the last five years, a lot of initiatives have been taken by the government to boost the Indian pharma industry. While some of these policies have progressed in the right direction, there is scope to expedite implementation for some of them and fine-tune others based on feedback from the industry.





**Need to enhance pace of implementation of policies:** While a lot of good policies are in pipeline, if not executed on time would lead to high opportunity cost, e.g., one window clearances, Pharma parks/clusters, etc.

**Opportunity to strengthen dialog between government and industry for feedback on current policies:** There are areas where regulators, government and industry have had different opinions and managing them well is critical for industry growth. While many government policies have been welcomed as-is by the industry, others such as NPPP 2012 have received mixed feedback. It is important for the government and industry to work together and resolve these issues in a timely manner.

□ □ □

While opportunities for the Indian pharmaceutical industry are immense, there are critical challenges to sustainable growth of the industry. The next section provides suggestions to different stakeholders on the role they can play to overcome these challenges.



**Making it happen:  
Imperatives to achieve Make-  
in-India ambition**





# Making it happen: Imperatives to achieve Make-in-India ambition

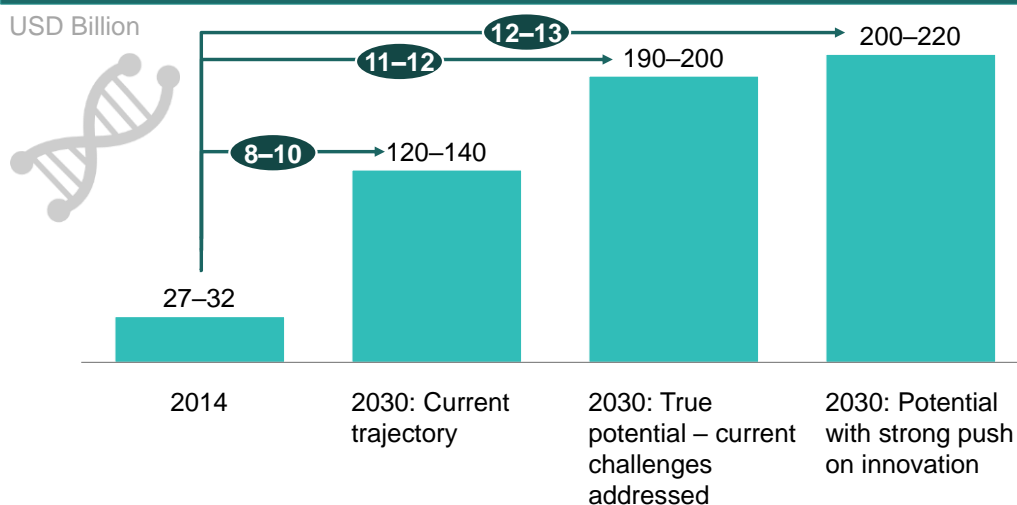
Indian pharmaceutical industry can continue to contribute in a big way to the economy and healthcare outcomes, both in India and abroad. Industry could ramp up its trade balance contribution by five times to create a trade surplus of about USD 55 to 60 billion for the country by 2030<sup>19</sup>. The industry could also continue to drive significant job creation and generate nearly 4 million additional jobs over the next 15 years. This will require a set of concerted actions from all stakeholders including the industry, industry associations, policy making government bodies as well as regulatory authorities.

## EXHIBIT 6

**Indian industry<sup>1</sup> can grow 7–8 times to reach a size of USD 200–210 billion by 2030**

xx % CAGR

### Indian life sciences industry 2013–2030



**There is a risk of industry losing ~40% of this growth, if players and the government do not take corrective actions to address current challenges**

<sup>1</sup> Industry – NOT Indian market  
SOURCE: Export Import Bank of India; team analysis

## ROLE OF INDUSTRY

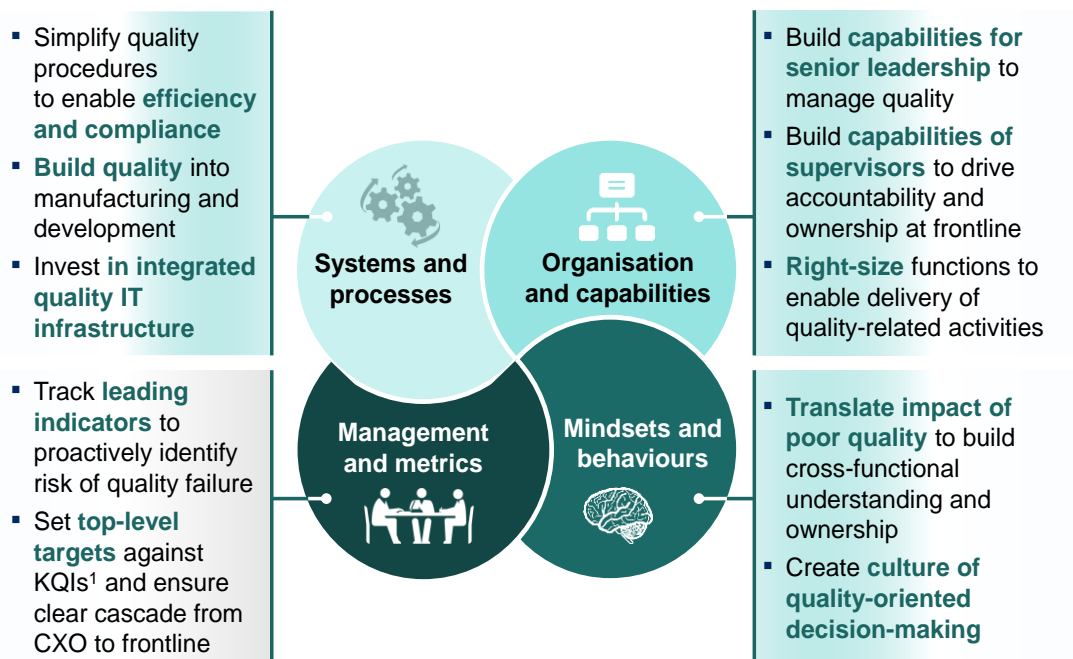
- **Upgrade quality systems, infrastructure and enhance capabilities to maintain India's image of a reliable, high-quality supplier:** Overcoming the recent quality

<sup>19</sup> FICCI "Indian life sciences: Vision 2030 Expanding global relevance and driving domestic access" Report

issues would be a key focus for the industry to maintain its image and global market position. Players will need to adopt a holistic approach to fundamentally transform their quality systems across four dimensions (Exhibit 7). This approach will help players to drive sustainable improvement in quality standards, by not only strengthening core processes, but also by improving quality-related capabilities, mind-sets and performance management systems across the organisation to institutionalise the improvement

## EXHIBIT 7

### A holistic approach to transform quality systems



<sup>1</sup> Key Quality Indicators

SOURCE: Stakeholder interviews; team analysis

- **Building a globally recognised position for India in the innovation space:**  
Building a strong position in innovation segment will be a key component of India's growth in the pharmaceutical industry. While other countries that have successfully built presence in innovation space have adopted two types of approaches, India could adopt an enterprise-driven approach to innovation as laid out in the India Lifesciences Vision 2030 report
- **Build new-age capabilities to sustain competitiveness and speed to market advantage:** As described earlier, the Indian industry's core advantages of low cost position and fast speed to market face the threat of growing global competition and changes in the local market landscape. Players in this context will need to build new sets of capabilities in manufacturing to sustain their

competitive advantage. For example, players could explore four types of interventions:

- Systematically explore and adopt new technologies. Here players can consider automation of end-end manufacturing processes to lower costs and improve compliance (e.g., automatic storage and retrieval systems, automatic weight control in tablet compression). Players can also consider piloting and adopting other new technologies (e.g., using alternate energy sources to lower costs, taking lead in adopting continuous manufacturing systems, etc.)
  - Adopt a “total cost of ownership” approach to work with suppliers in a “win-win” fashion and identify joint cost-improvement opportunities, e.g., optimising API specification while maintaining quality standards
  - Continuously review and optimise production processes to improve productivity (e.g., reduce cycle times, increase batch sizes) and yields, rather than sticking to the processes developed the first time
  - Adopt a focused approach to build scale and global leadership in volumes for select products, rather than focusing on a fragmented production base across multiple products and SKUs
- **Collaborate more meaningfully within the industry to support growth and industry evolution:** The level of collaboration amongst players in the pharmaceuticals industry has historically been quite low. However, there are recent examples of certain players taking lead in transforming the industry. The Quality Forum of India Pharmaceutical Alliance (IPA) is developing the roadmap for quality transformation for the Indian pharmaceutical industry. Going forward, industry could collaborate more to address the growing scale of challenges in the market

## ROLE OF GOVERNMENT BODIES

The government will continue to play a critical role in helping the pharmaceutical industry to achieve the full potential of Make-in-India. Potential interventions could include:

- **Strengthening the current business environment to facilitate “ease of doing business”:** Government should continue to support in maintaining the industry’s cost leadership in the global market. This could be done through export incentives, easier duty structures, concentrated pharma parks/cities, etc. Moreover, the government should continue to encourage new players to setup

base in India with advanced technical knowhow. This would involve expediting initiatives such as bringing in transparency on regulatory approvals required and single window clearances. Through vehicles such as 'Invest in India' government can pro-actively reach out to potential investors and promote the Indian pharmaceutical space

- **Identifying strategic priorities for the sector and provide holistic support:**  
Through joint interactions with the industry, the government should identify major priorities where industry has been seeking support. One of these is to ensure India's self-sufficiency by helping enhance competitiveness of the local API industry. Ensuring India's self-sufficiency in API/intermediates will be critical to maintain the competitiveness of Indian players and to ensure supply security for the local market. The government could consider following initiatives to help India achieve self-sufficiency in this area
  - **Setting up dedicated manufacturing clusters for the industry:** The government could explore setting up three to five dedicated clusters across the country for the API/ intermediate industry. These clusters could offer benefits such as subsidised land and utilities, common resources for effluent treatment, quality assurance, etc. to help improve cost competitiveness of Indian players
  - **Invest in building capabilities in complex or difficult to make APIs:** Investing in next-generation APIs can help the Indian industry to be at the forefront of these technologies and differentiate itself from other players. The government could support this by offering additional incentives to players for R&D investments in these areas. It could also offer grants to academic institutions and public sector undertakings to invest in such areas, or set up dedicated centres for such research

Another area can be creating an enabling environment to drive innovation. Players would need to ramp up their R&D investment by about 140 per cent<sup>20</sup> over the coming years to build a credible presence in the innovation space. Given the scale and the long gestation period for these investments, players will struggle to find this investment independently. Government could consider providing an impetus to enable this by raising the level of incentive offered on R&D investments to the industry. This increase would take the overall government's share on R&D from current 25 per cent to about 35 per cent, at

---

<sup>20</sup> FICCI "Indian life sciences: Vision 2030 Expanding global relevance and driving domestic access" Report

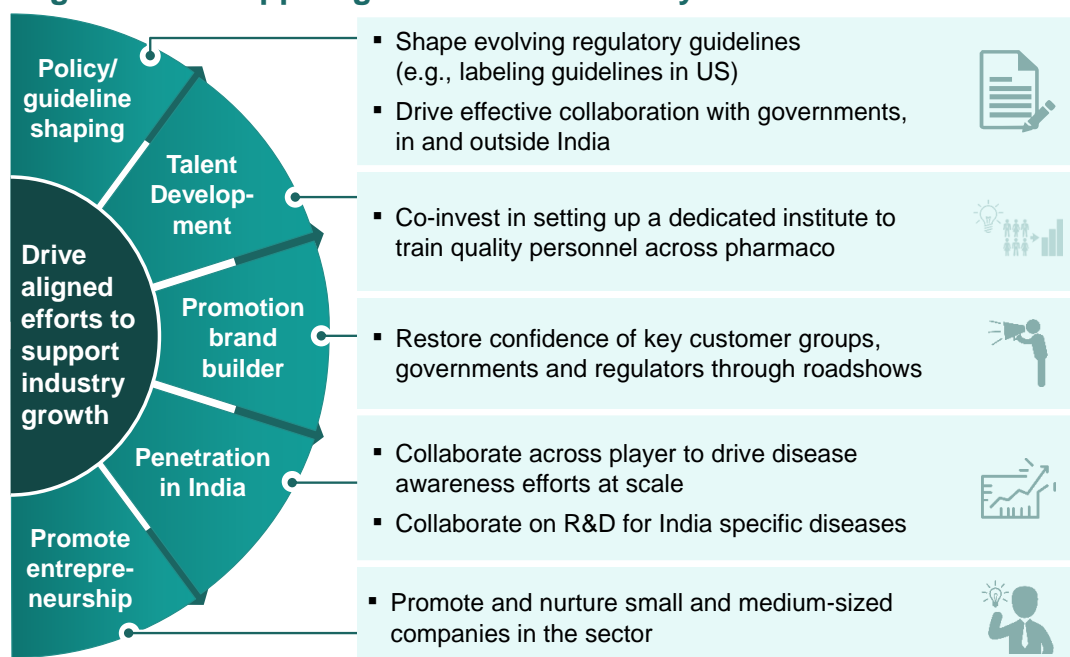


par with markets such as US (at 41 per cent) and EU (at 35 per cent)<sup>21</sup>. The government is already taking steps in this direction. Dedicated venture capital funding to support innovation projects is planned. The responsibility of selection of high-potential project would lie with the private sector

- **Help build transparency and predictability of regulations:** Government has made various policy interventions some of which have come as received mixed feedback from various stakeholders e.g., revision in clinical trial operating guidelines, regulation on prices for essential drugs etc. Today India is one of the most affordable and accessible pharmaceutical markets. Building more transparency and predictability in the regulatory regime can help facilitate ease of doing business, and attract further investment in the sector while safeguarding needs and interests of all stakeholders

## EXHIBIT 8

### Potential areas for collaboration across players to drive common agenda and support growth of the industry



SOURCE: Stakeholder interviews; team analysis

## ROLE OF REGULATORS

With the projected growth in scale, complexity and global relevance of the Indian pharmaceutical industry in the next 10-15 years, role of regulators in ensuring

<sup>21</sup> Based on data from The New England Journal of Medicine '14, GoI Union Budget '15

safety, reliability and efficiency of the industry will be very crucial. This would involve:

- **Periodic review of guidelines to maintain the thrust on quality:** FDA has already announced shift towards guidelines laid out by WHO criteria. This will need to be evolved periodically to ensure consistency with global standards. The government has also offered support to the industry, particularly the small and medium-sized companies with financial and technical assistance
- **Continue to strengthen regulatory infrastructure:** FDA is already gearing up to have 1000+ audit inspectors over next 2-5 years. Similar scales ups are planned for various state units as well. DCGI office is also taking steps towards simplification of filings and licencing through advanced IT systems. They are also looking to leverage technology in strengthening the pharmacovigilance infrastructure to ensure ease of reporting, and ensuring resolution of repeat issues
- **Facilitate ease of attaining regulatory approvals:** To build an enabling regulatory environment in India, the regulators could consider providing further clarity on regulatory requirements in a few areas. For instance, making compensation and operating guidelines for clinical trials more comprehensible; increasing transparency on requirements and criteria for evaluation for approval of different product categories such as NMEs, Biologics, etc.

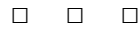
## ROLE OF OTHER STAKEHOLDERS

Healthcare professionals should proactively participate and shape development of new medicines. Given they are closest to the patients, their patient specific insights at early stages of drug development can improve chances of commercial success.

Healthcare professionals are also the custodians of professional practices in the frontend of the pharma industry. Forums of healthcare professionals (e.g., FOGSI) can also continue to play a significant role in shaping the healthcare policies of the country.

Academia can also play a major role in fostering research in collaboration with the industry. While there are 200+ academic institution facilitating research, rate of commercialisation continues to be lower than desired. Academia can complement industry's efforts by focusing on areas that are relevant from patient servicing point of view which the industry can eventually commercialise. There is a need to create forums that can improve transparency and collaboration between academia and the industry.





Driven by the entrepreneurial zeal of the industry and a supportive government, the industry is well positioned to achieve the Make-in-India vision. It will require all stakeholders to come together and tap into the opportunities provided by the domestic and global markets.



# Acknowledgements

## Government

### Representative

Ministry of Health and Family Welfare

### Representative

Department of Pharmaceuticals

### Representative

Ministry of Commerce

### Representative

Central Drugs Standard Control Organisation (CDSCO)

## Industry

### Mr. Pankaj R Patel

Senior Vice President, FICCI and Chairman & Mg. Director  
Zydus Cadila Healthcare Limited

### Dr. Habil Khorakiwala

Chair- FICCI Lifesciences Council, Past President FICCI and Founder Chairman Wockhardt Group

### Mr. Cyrus Karkaria

Chair, FICCI Biotech Committee and President (Biotech)  
Lupin Ltd.

### Mr. Rehan Khan

Co-Chair, FICCI Pharma Committee and Managing Director  
Abbott India Ltd

### Mr. Aditya Vijay Berlia

Co-Chair, FICCI Pharma Committee and Member Management Board  
Apeejay Styra Group

### Dr. Hemanth Nandigala

Co-Chair, FICCI Biotech Committee and Executive Director  
Virchow Biotech

### Dr. Surinder Kher

Managing Director  
Ecron Acunova Ltd

### Mr. Tabrez Ahmad

Secretary General  
OPPI

### Mr. Manoj Kamra

Vice President- Corporate Affairs  
Zydus Cadila Healthcare Ltd.

### Mr. Anurag Khara

Senior Vice President- Corporate Affairs  
Glenmark Pharmaceuticals Ltd.

### Dr. Saurendra Das

Executive Director  
Excel Life Sciences Pvt Ltd.

### Dr. Akhilesh Sharma

Chief Medical Officer & Global Head, Global Medical Affairs,  
Dr.Reddy's Laboratories Ltd.

### Dr. Rustom Mody

Sr. Vice President – Head R&D, Biotechnology Division  
Lupin Ltd.

### Mr. CV Venkataraman

Director- Corporate Services  
Lupin Ltd.



## FICCI Lifesciences Team

**Ms. Shobha Mishra Ghosh**

Senior Director

FICCI

**Ms. Swati Aggarwal**

Consultant

FICCI

**Ms. Geetika Mehrotra**

Assistant Director

FICCI

## About FICCI

Established in 1927, FICCI is the largest and oldest apex business organisation in India. Its history is closely interwoven with India's struggle for independence, its industrialisation, and its emergence as one of the most rapidly growing global economies.

A non-government, not-for-profit organisation, FICCI is the voice of India's business and industry. From influencing policy to encouraging debate, engaging with policy makers and civil society, FICCI articulates the views and concerns of industry. It serves its members from the Indian private and public corporate sectors and multinational companies, drawing its strength from diverse regional chambers of commerce and industry across states, reaching out to over 2,50,000 companies.

FICCI provides a platform for networking and consensus building within and across sectors and is the first port of call for Indian industry, policy makers and the international business community.

### Contact us:

FICCI, Federation House

Tansen Marg, New Delhi- 110 001

Tel: 011 23728760 – 70 (Ext. 355/438)

Fax: 011 233 0714, 011 2372 1504

Email: [lifesciences@ficci.com](mailto:lifesciences@ficci.com)



