Trends & Opportunities for Indian Pharma

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MESSAGE

With great pleasure I wish to congratulate the entire India Pharma fraternity on the release of the Knowledge Paper on : 'Trends & Opportunities for India Pharma'. I extend my best wishes and compliments on its release during the 3rd edition of International Exhibition and Conference on Pharmaceutical sector – "India Pharma 2018", scheduled to be held from 15-17 February, 2018 at Bangalore International Exhibition Centre, Bengaluru.

Indian Pharmaceutical industry has contributed immensely to the Make-in-India initiative over the last many years. The industry has showcased India's deep commitment to ensuring high quality, affordable and accessible medicines globally. I am sure the insights captured in this Knowledge Paper and the deliberations at the Conference would help the industry scale greater heights in the coming years.

Like previous years, I wish the Conference a grand success.

(AnanthKumar)

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Foreword

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 favourable market conditions over the last many years have ensured that India continues to be one of the most lucrative pharma markets in the world.

In the last couple of years, the industry has faced several challenges which have impacted our growth trajectory. Globally, several factors have had a severe impact on exports business. These include- higher level of customer consolidation, increased competition & number of products approvals, decreased value from new product launches and increased pricing control & protectionism. Even at home, growth in domestic market has slowed down. Even as we emerged from the transient impact of demonetisation, we have continued to face disruptions from evolving regulatory landscapes, alternate means of engaging with doctors & patients, and shift in balance of power towards pharmacists. Our strong position as a global supplier of high quality, affordable and accessible medicines has also been impacted due to recent compliance challenges and low productivities.

Does this indicate a dismal future for India pharma? Absolutely not. This transitionary phase offers us a timely opportunity to drive-out inefficiencies and build new-age capabilities. Data-and-technology-led innovations will provide us a growing set of levers to drive this transformation. We are confident that India pharma companies will emerge much stronger from this transitionary phase.

How do Indian pharmaceutical companies refine their strategy and re-orient their business model to embrace these challenges? What are the key imperatives for in the industry? How do the players go about building the next-age capabilities? These are some of the questions that still need to be answered. This whitepaper is a step towards answering some of these questions. Written in a shorter and more concise format, this white paper captures the key trends across the global & domestic markets and supply landscape, and the imperatives for the industry. It also lays out areas where support that the government and regulatory agencies need to provide to bring the industry back on the growth trajectory of the past.

Like previous years, McKinsey & Company has been our knowledge partner in this initiative. We thank them for their continued support to FICCI and commitment to the Indian pharmaceutical industry.

Pankaj Patel
Past President, FICCI

Foreword

The Indian pharmaceutical industry has contributed significantly to global healthcare by ensuring high quality, affordable and accessible medicines around the world. The industry has grown rapidly over the last decade and has been instrumental in driving generics penetration globally. Over the last 15 years, Indian companies have done well in the generic business and have built billion dollar organizations on the back of generics R&D.

India remains an attractive destination for generic R&D and manufacturing of pharmaceuticals owing to its strong capabilities across the value chain. While India is the third largest pharmaceutical market in the world by volume, but, the industry has been impacted by several challenges like the patent cliff, significant price erosion, consolidation at the distributors' level, increasing competition and increased regulatory scrutiny in global markets. However, we believe that Indian pharma industry owing to its strong fundamentals, can embrace these challenges and overcome this transient environment to reinvigorate the trajectory of strong growth. The first step is to acknowledge the forces at play and redefine our strategy and operating model to address them.

While many trends require us to innovate our practices, others require us to build on our strengths. It will be imperative for the Indian generic industry to transition itself to a specialty/innovation player or a strong biosimilar organization to drive value growth and address several growth challenges. Indian pharma companies also need to drive full compliance with the evolving regulatory guidelines by deploying global best-practices in an India-shop floor context. There needs to be renewed focus on operations excellence especially driven by new age technology and capabilities. Structural changes like achieving self-reliance on API are also more very important.

We are confident that Indian pharmaceutical companies will use this period to strengthen their fundamentals and build newer capabilities. This white paper is an attempt to guide the industry in that direction.

We are grateful to McKinsey & Company again for being our knowledge partner in this initiative, and for their continued support through various insights.

Glenn Saldanha
Chair FICCI Pharma Committee 2017

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The Indian pharmaceutical industry: An overview

The Indian pharmaceutical industry has contributed immensely not just to Indian but to global healthcare outcomes. India continues to play a material role in manufacturing various critical, high-quality and low-cost medicines for Indian and global markets. It supplies 50 to 60 percent of global demand for many vaccines (including ARVs), 40 percent of generics consumed in the US and 25 percent of all the medicines dispensed in the UK[1]. Over the last 5 years, 35 to 38 percent of total ANDAs approved (including 25 to 30 percent of total injectable ANDAs) have been filed from Indian sites[2]. Affordable anti-retroviral (ARV) drugs from India were a major factor in AIDS patients getting greater access to treatment. India supplies 60 percent of global ARV drugs and 30 percent of the annual UNICEF requirement[3].

However, over the last few quarters many Indian pharmaceutical companies (like other global peers) have registered much lower growth and profitability. Many have experienced significant value erosion, which to a large extent has posed a hindrance to industry's capacity expansion and R&D plans.

Even in these circumstances, the industry has grown in value with an average annual growth rate of ~6-7 percent over the last 5 years[4] . This has been driven by the following enabling factors:

- **Increasing demand in global markets:** Generic penetration in high value healthcare markets (e.g., US) has grown significantly, with India supplying 20+ percent of the generics demand in major geographies[5].
- **Stable growth in domestic market consumption:** India's pharmaceutical market has grown rapidly over the last decade. Despite recent headwinds, a stable growth of 5-7% was observed last year. India is likely to become one of the Top 3 pharma markets by 2030[6]
- **Low cost and at scale manufacturing capability in India:** India has the second highest number of US FDA approved facilities and labour costs in Indian have been lower than other manufacturing hubs by up to 40 percent[7].

While the headwinds are likely to continue for the next 2 to 3 years, Indian pharmaceutical companies need to adapt to the changing landscape, and emerge stronger.

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[1] Press search
[2] USFDA website
[3] "Quality Excellence: The next frontier for Indian pharma industry", IPA white paper, 2016
[4] Department of Commerce, AIOCD
[5] IBEF Pharmaceuticals, 2017
[6] AIOCD
[7] POBOS- McKinsey's proprietary pharma operations benchmarking

Global market dynamics & implications for India pharma

Even though companies anticipated a fair set of challenges in last few quarters, the sheer speed and impact of these has been overwhelming. Many leading generics players—in India and globally—shed up to 40 percent of their market capital in mere months due to a range of reasons[8]—from regulatory sanctions to litigation, impairment charges to generics market dynamics in the US, and raw material price volatility in China to evolving regulatory landscape in India, etc.

Various dynamics in international markets are eroding value from the generic value pools. These are:

- **Further consolidation among distributors and pharmacy chains:** This has continued to cause a steep fall in generic drug prices in the US—the largest healthcare market in the world.
- **Increased product approvals, and resultant competition in the generics space:** The number of filings and drug approvals is rising sharply, with an increasing number of Indian companies (e.g., accounting for around 40 percent of the ANDA approvals in 2017) vying for a share of the same pie[9]. This will keep up the competition (and consequently, price erosion) in the coming years.
- **Drop in new launch sales:** The average new launch sales per year has dropped due to lower value of drugs going off patent. This trend is also likely to sustain for the next couple of years.
- **Increasing price control and protectionism in various global markets:** Protectionism could significantly impact the value of exports, which contribute around half of India pharmaceutical industry's value.

Despite the likely severe impact of these factors in the short term, the industry could eventually be buoyed up by a sustainable cost advantage, a robust new product pipeline, completion of pricing corrections, the launch of next-gen assets and scaling up of the rest-of-world business. Technology and emerging business model innovations, too, could prompt a transformation.

In the coming year, we expect to see Indian pharmaceutical companies possibly adopting many of the following five priorities to capture the full potential of these opportunities:

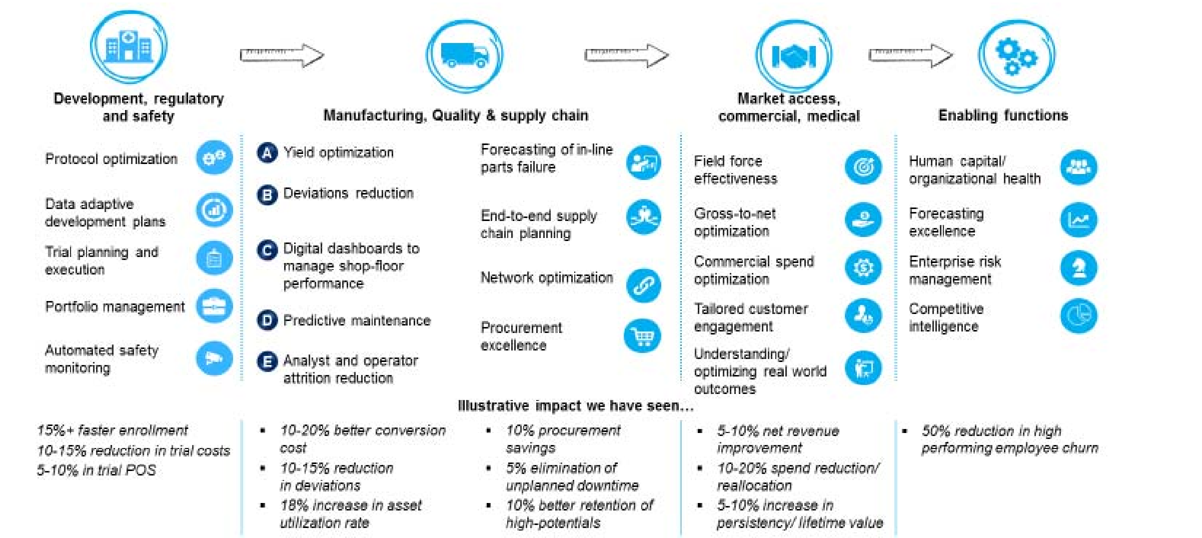
- **Driving Profitability and cost leadership through operational excellence:** Indian pharma manufacturers have been ceding ground on cost due to increasing complexity, remediation costs, additional controls, global supply market disruptions (particularly in China owing to environmental regulations), etc. To cope up with these margin pressures, the industry needs to improve manufacturing efficiencies across the network and drive cost excellence initiatives across the spend base. Some successful pharmaceutical companies have pruned their cost structures by approximately 10 percent in a relatively short span of time.
- **Focussing on strategic M&A for value buys:** The current operating environment could lead to several attractive opportunities through distressed divestitures and fewer strategic buyers with available cash at scale. Strategically pursuing and shaping deals could allow companies to make additions to the portfolio (products, business lines) that might support short-term top line buoyancy and create platforms for future strategic expansion.
- **Advancing the specialty / differentiated drugs business model:** While pharmaceutical companies could optimize the core generic portfolio across dosage forms, most have begun to embrace the "next-gen" specialty/differentiated assets portfolio. This will require purposefully reinventing the operating model for generics companies, pursuing a systematic portfolio and investment strategy

[8] Press search
[9] USFDA website

(using partnership, analytics, technology, etc.), strengthening development and launch processes (efficiency in trial design, setup and execution) and building new innovator-like functional strengths (pricing, launch, market access, regulatory, etc.).

- **Embracing Digital and advanced analytics for accelerated growth:** The recent technological shift has prompted the rapid rise of Advanced Analytics (AA), which is enabling companies to surface insights even with complex and unstructured data sets. Globally, in the pharma industry we have seen use cases of AA driving growth and productivity across the pharmaceuticals value chain including R&D (over 10 percent increase in clinical trial productivity), Manufacturing (more than 30 percent improvement in yields and throughput), Quality (over 15 percent reduced deviations), Supply Chain (over 20 percent increase in customer service levels), Sales (around 30 percent improvement in sales force conversion rate), etc[10]. In 2017, some India pharma companies experimented with AA through pilot scale test cases with promising results. We expect that they will advance the Digital and AA agenda on a larger scale in the years to come. (Exhibit 1)

Exhibit 1: Multiple Digital and Advanced Analytics applications in Pharma value chain



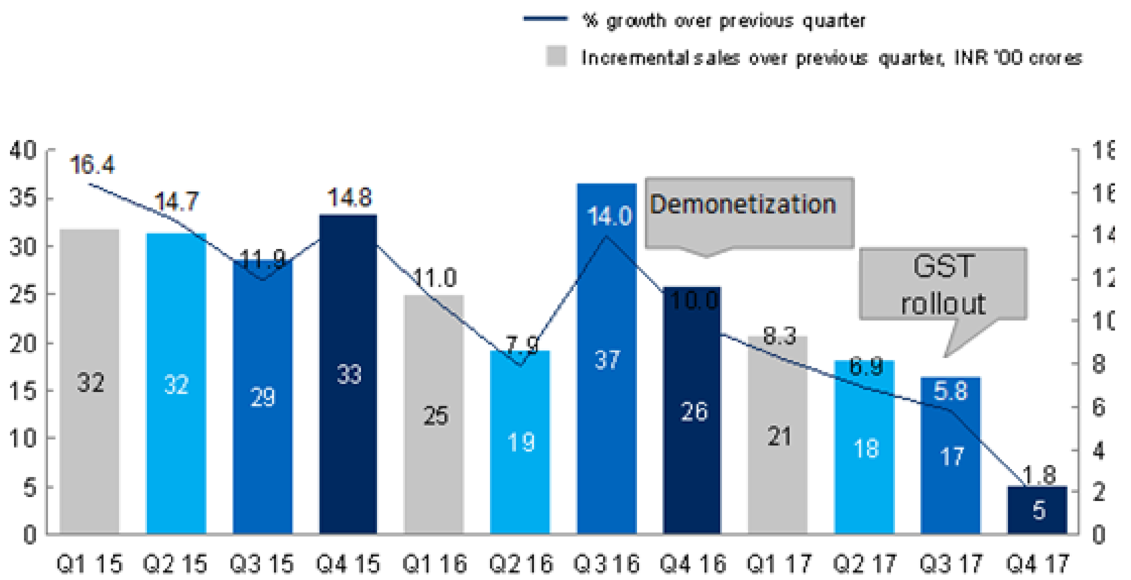
- **Organization and linking Talent to Value:** As portfolios become more complex, competition and regulatory scrutiny intensify, and external demand and supply situations tighten, companies will need to rethink how they organize for delivery. The capabilities in the Indian pharmaceutical industry will need to be upgraded to cope with the challenges ahead. Companies will need to follow a “Talent to Value” approach, linking business value to the most critical roles and then actively managing these roles. This is the right time to take a tough look at organization hierarchies and redesign for agility by de-layering and delegate decisions, and strengthening cross-functional interfaces to ensure collaboration in the most important areas.

[10] McKinsey analysis

India market dynamics & implications for India pharma

The growth rate for the Indian pharmaceutical market has slowed down consistently over the last five quarters—from 12-15 percent in 2015 to 5-6 percent in 2017[11](Exhibit 2). The market growth is driven largely by volume (2016-17 volume growth was 3-4 percent) with an average price increase of 1-2 percent[12].

Exhibit 2: Incremental growth in the Indian pharmaceutical market



Despite the slowing pace of growth, companies have continued to cater to healthcare needs, thereby enriching the quality of lives. Few recent entrants have rapidly achieved top line growth[13]. Institutions (both hospitals and government) have become much larger customers - Government expenditure on healthcare has increased from 22 Bn USD in 2012 to 53 Bn USD in 2016[14].

The volumes could possibly keep growing due to India's high disease burden, increasingly better access to healthcare (and hence better diagnosis rates) and greater affordability. But the market is also likely to be impacted in the near term due to several forces.

- **Evolving regulatory landscape:** The recently proposed pharma policy and several other interventions have an impact across the value chain- from development, manufacturing and supply chain to pricing and customer engagement. There is still potential to systematically strengthen and stabilize the Pharma policy of 2012, and improve the ease of doing business going forward. As the Government continues to play a more proactive role in shaping broader healthcare reforms, the industry environment could see some uncertainty in the near term.
- **Alternate means of engagement with doctors:** While doctors are likely to remain the single largest influencer of treatment and medicine choice, alternative means of engaging physicians could gradually become the norm. Doctors' behaviour is evolving with increasing time spent online to

[11] AIOCD
[12] AIOCD
[13] AIOCD
[14] Union Budget

gain information. Technology-based remote healthcare will continue to expand, significantly increasing the reach and influence of the doctors. The proposed UCPMP will also move to mandatory compliance with oversight.

- **Increased patient involvement:** As patients want to be more involved and empowered, their preferences will continue to influence healthcare choices. While this shift is visible across the country, with the trend being much stronger in metro cities –a recent survey in Gurgaon showed that over 60 percent of patients check their doctor / hospital choices on Google before deciding, and the prescribed products thereafter.
- **Greater role of pharmacists:** Pharmacists will grow more powerful (e.g., due to INN name) and the market may see another wave of consolidation giving rise to pharmacy chains. E-pharmacies will see a surge with easing regulation and increasing private investment in this space, causing a dramatic shift in generic brands and substitution ability.

The anticipation of these shifts, while causing some uncertainty, could also create various opportunities for pharmaceutical companies to grow by innovating on their business model.

- Companies could innovate the doctor engagement model by focusing on multiple touch points with doctors across the entire customer journey. Successful pharma companies globally have stitched together a partnership-led ecosystem to engage the physician, leveraging digital and other channels. The model could require fewer but more capable sales representatives, who can have scientific discussions with doctors and build a long-term relationship. Managing talent and attrition among the field force could become a key differentiator in the market.
- As patients become more involved in healthcare choices, companies may need to develop a new consumer engagement model, using digital as a systematic channel instead of an ad-hoc top-up. This can be a significant growth driver, helping to meet several needs in the market. For example, diabetes lifetime compliance is only 3 months in India. Engaging patients directly—for education, counselling or compliance support—could play an important role in therapy adoption and adherence. Targeted partnerships can also be explored with other players in the healthcare space.
- As pharmacists gain influence in final dispensing, strengthening channel management capabilities and resources to ensure availability can be a key differentiator for pharma companies. There is a need for a uniform quality standard in India, and building capabilities for pharmacists is crucial to enable them to play a greater role in the market.

Opportunities for India as a global supply destination

India's strong position as a pharma supplier rests on its ability to provide high quality medicines backed by strong innovation capabilities and a structural cost advantage.

The cost of manufacturing formulations in India remains 30-40 percent lower than other comparative manufacturing hubs such as China and Eastern Europe, notwithstanding low productivity levels[15]. This is driven by lower labour costs vis-à-vis other geographies[16]. Despite inflationary trends, India's labour cost advantage will sustain in the medium to long term, especially if Indian companies can improve productivity through operational excellence and digital initiatives.

The supply of local talent into the pharma industry (e.g., B.Pharm, M.Pharm, B.Sc.) is stronger than in countries such as China. Indian pharma companies are foraying into complex products (e.g., microspheres, liposomes, emulsions), building capabilities in R&D and the manufacturing of these products while still ensuring the required quality.

However, the industry is also facing several challenges in supplying to export markets, which must be addressed going forward.

- The increasing pricing pressure in the regulated market is squeezing margins and profitability. Key drivers include customer consolidation, greater competition in commoditized, easy-to-manufacture products with increased ANDA approvals, and a slowdown in new launches.
- Another key challenge stems from compliance issues affecting the reliability of supply. While many Indian companies have fared well in regulatory audits over the last year and seem to be emerging out of remediation, others continue to face challenges.
- India continues to rely on imports of key starting materials, intermediates and API's for, China with the share of dependence increasing over time. This potentially exposes us to raw material supply disruptions and pricing volatility.

There is an opportunity for India Pharma to drive growth by building on the cost advantage, and improving reliability of supply—major buying criteria for customers. Three priority areas thus emerge for Indian pharmaceutical companies:

- Build stronger quality systems and achieve full compliance
- Re-focus efforts on operational excellence
- Alternate sourcing and self-sufficiency in APIs / intermediates

These imperatives are inter-related—operational excellence is a strong enabler of quality and supply reliability. Analysis based on McKinsey's proprietary POBOS database of global pharmaceutical manufacturing sites shows that the sites with the best quality performance also often have the best operations performance.

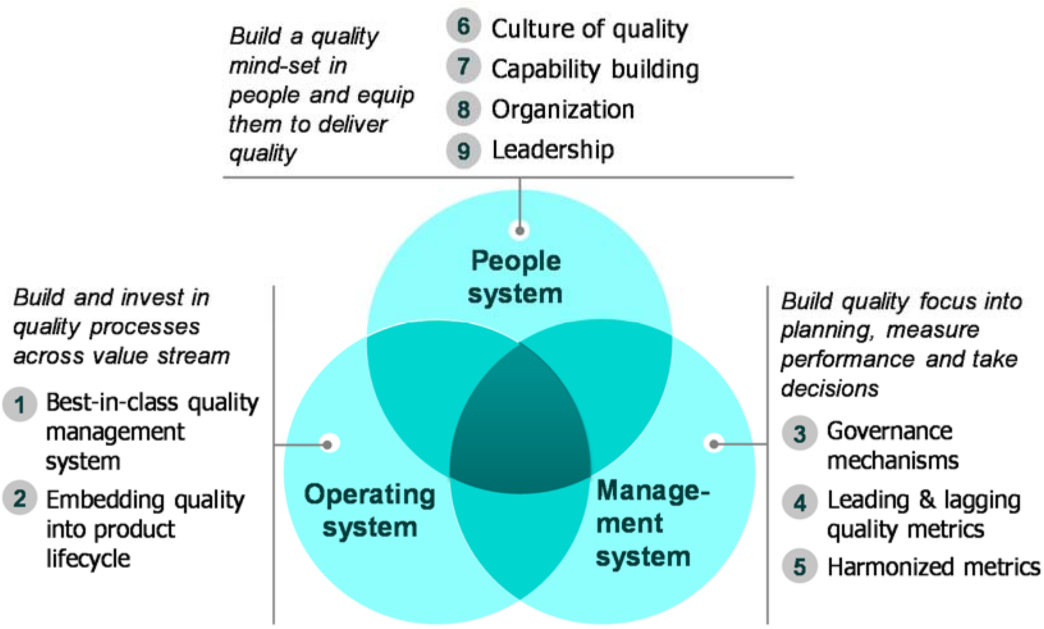
Institutionalizing quality and compliance excellence

The last few years have seen Indian pharmaceutical manufacturers experience intense regulatory scrutiny and numerous compliance challenges in meeting the evolving cGMP requirements. However, similar trends are seen at leading pharma companies in other major manufacturing hubs as well—

[15] POBOS- McKinsey's proprietary pharma operations benchmarking
[16] POBOS- McKinsey's proprietary pharma operations benchmarking

China, Europe, North America. Many global pharma companies have gone through a similar learning curve of multi-year and network-wide remediation.

Exhibit 3: Outstanding quality involves building quality in the organization's operating systems, management systems and people systems



Some Indian pharma companies have addressed the issues and built strong quality systems by deploying India-specific interventions in addition to global best practices. The interventions required span across 3 elements of a good quality system i.e., operating system, management system and the people system.

- **Expanding and upskilling the quality talent pool**: Building capabilities across all levels, particularly at the middle management layer; leveraging emerging technologies to build experiential training modules
- **Building a culture of Quality at the shop floor level**: Addressing India-specific cultural challenges and building an environment of ownership, openness and collaboration
- **Leveraging technology to fool-proof key processes and performance management systems**: Some Indian pharma companies are already looking to identify Quality Management System (QMS) risks and reducing OOS and deviations through the deployment of Advanced Analytics techniques.
- **Continuing to strengthen critical technical elements** of the QMS such as data reliability, good documentation practices, process validation and investigations.

Building operational excellence

While the overall cost of manufacturing in India is likely to remain competitive, productivity in Indian pharma sites continues to be 40-50 percent lower than the global median[17]. This presents a significant opportunity to drive efficiencies and offset some of the cost pressures.

While the traditional Lean applications continue to drive efficiencies, advances in availability of data coupled with disruptions in computational power and advanced analytics allow pharmaceutical companies to uncover new opportunities for performance improvements. While on average, the pharmaceutical industry lags advanced industries in the adoption of digital & advanced analytics,

[17] POBOS- McKinsey's proprietary pharma operations benchmarking

players who have merely piloted these applications have seen 10-30% improvement in conversion costs, deviations, yields and equipment efficiencies

Alternate sourcing and self-sufficiency in APIs / intermediates

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. Investing in next-generation APIs can help India pharma be at the forefront of these technologies and differentiate itself from other players. The industry could also explore alternate sourcing locations (such as Vietnam, Indonesia) while indigenous capabilities & capabilities ramp up.

The government can play a crucial role to help the industry achieve self-sufficiency in APIs / intermediates. It 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. It could further support 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 this area, or set up dedicated centres for such research.

☐ ☐ ☐

Amidst this challenging and transitionary period, we believe that greater opportunities will unfold in the future for the Indian Pharma sector. This will enable the sector to transcend greater heights, and cement India's position as a Pharma hub for the world in its true sense.

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About FICCI

Federation of Indian Chambers of Commerce and Industry

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 industrialization, 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.

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