Indian life sciences: Vision 2030
Expanding global relevance and driving domestic access

Executive summary

India's life sciences industry has traversed a successful journey in the past 50 years. From an era of import dependency in the pre-1970s, high-quality local players moved the country toward self-sufficiency in life sciences by the 1990s. Since then, world-class capabilities have helped the Indian industry build a strong global presence.

In this journey, the industry has achieved several successes and has contributed significantly to the Indian economy and healthcare outcomes, in both India and abroad. These include:

- **Significant contributions to the Indian economy:** The life sciences industry is now the third-largest contributor to reducing India's merchandise trade deficit. The industry generates around USD 10 billion of trade surplus every year, allowing it to neutralise around 4 to 5 per cent of total energy imports for India[1]. In addition, it also generates a significant number of jobs for India. Our estimates indicate that around 2.5 million people are currently employed by the industry (including some of the industries such as chemists, stockists, etc.).
- **Strong position in the global life sciences industry:** India has also been able to build a strong position across various segments of the market. In pharmaceuticals, India is now the eighth largest country by value globally with one of the highest growth rates[2]. It has also been able to build a strong position in key markets such as the US. In clinical trials, India continues to be one of the top 15 destinations globally based on the number of trials conducted between 2003 and 2013[3].
- **Contributions in driving access and affordability:** Indian industry has been a driver for access and affordability in life sciences. Indian drugs are available at an affordable price as compared to markets globally. Further, India is the primary supplier of essential medicines for numerous diseases, helping save millions of lives globally. India's contribution extends to developed markets such as the US as well, where through its position in the generics market, the industry is significantly reducing healthcare spend[4].
- **World-class capabilities across the value chain:** The life sciences industry has also built strong capabilities across all parts of the value chain. In manufacturing, India continues to have the highest number of FDA-approved

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[1] OPPI Annual Report 2013-14, Export Import Data Bank, Department of Commerce, Pharmexcil, IDMA report on "Journey towards Pharma 2020 & beyond", Team analysis

[2] United Nations Comtrade Database, Business Monitor International, Individual country industry associations, Team analysis

[3] PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2014

[4] Decision Resources' 2013 article on "Indian Generics Manufacturers penetration of US market", Team analysis

formulation plants outside the US[5]. In R&D and regulatory, Indian industry has accounted for 32 per cent of the ANDA filings last year, second only to the US at 44 per cent[6]. The industry is now also making some initial movement in the innovation space.

The journey so far has been a source of celebration, but the road ahead for the industry is challenging. There are some positive aspects that brighten the horizon (e.g., strengths that the industry can continue to leverage, and opportunities, if tapped, that could help the industry grow), but new challenges and discontinuities in the market continue to emerge. Three prominent challenges that the industry faces:

- **Changing market dynamics**: Changes in the market landscape are throwing up new challenges for the industry. For instance, sources of growth in the market continue to shift to areas where the industry does not have a strong presence today (e.g., emerging markets, complex generics)[7]. Prices and margins continue to be under pressure, driven by customer consolidation in developed markets and evolving regulations in few emerging markets. The dynamics of doing business are also undergoing a shift with the recent spate of mergers and acquisitions, increase in importance of scale, and changes in regulatory guidelines, requiring players to build new capabilities to succeed.
- **Dilution of some core drivers of success**: Much of the credit for India's success historically goes to the advantages that India offered in terms of affordable costs, reliability of supply, and its ability to release products rapidly in market. However, the reality is shifting. Cost position is under threat with players in developed markets becoming more competitive and players in developing markets moving up the value chain. Indian players are facing an increasing number of quality issues, especially for the US, which is affecting its supply reliability. Finally, recent changes in the regulatory landscape are also affecting the ability of Indian players to release products rapidly.
- **Gaps in the industry's competitive ability**: Changes in market dynamics are also accentuating gaps in the industry's competitiveness, which can have a considerable impact on the industry's ability to sustain its growth in the future. First, growing dependence on imports for KSM/intermediates is a cause of concern. It could lead to issues related to the availability of essential medicines in the country, impact the cost position and first-to-file capability of Indian players. Second, India's position in the innovation space continues to be nascent driven by gaps across the innovation ecosystem. Given that innovation

[5] US FDA website, Team analysis

[6] US FDA website, Team analysis

[7] Business Monitor International, Evaluate 2013

could represent the next wave of growth for the industry, a weak position in innovation would significantly impact growth outlook for the industry.

These challenges can drag down an industry with immense potential. Our estimates indicate that failing to address these issues could pull the growth rate down to 8 to 10 per cent over the coming years, also impacting the industry's ability to serve the local market and maintain its hard-earned global position. It is, therefore, important at this juncture for the industry and the government to come together and align on a common vision that would help the industry unlock its full potential.

In this context, we believe that the industry can aspire towards a vision of **"Expanding India's global leadership and relevance, while driving domestic access".** The industry can focus on three goals (Exhibit 1) to realise this vision.

EXHIBIT 1

Vision 2030 for the Indian life sciences industry



By achieving this vision, the industry will continue making significant contribution to the economy and healthcare outcomes:

- **Sustained economic contribution**: Under this vision, the industry will sustain its growth trajectory of 11 to 12 per cent and grow 7 to 8 times to a size of USD 190 billion to 200 billion by 2030. This growth will allow the industry to drive 5 to 6 times growth in trade balance contribution to around USD 55 billion to 60 billion by 2030[8]. This will help neutralise around 13 to 15 per cent

[8] Export Import Data Bank, Department of Commerce, Team analysis

of the estimated energy imports for India by 2030. The industry will also create nearly four million new jobs for the country over the next 15 years.

- **Becoming the world's largest and most reliable drug supplier**: The Indian life sciences industry can aspire to become the world's largest supplier of drugs globally by volume and third largest by value. This can be enabled by the leadership position that the industry can secure in the US, and in other emerging markets. Beyond value, the industry will also continue its contribution towards saving millions of lives by maintaining the supply of essential medicines and driving significant reduction in healthcare spend across major markets.
- **Providing every Indian access to high-quality, affordable drugs, and bringing the latest drugs to India**: The industry can work towards a goal of further deepening drug penetration in the Indian market. We believe that by adopting innovative models and government support, the industry can aspire to drive a 3–4 times increase in the number of treated patients across disease areas[9]. The industry can also continue to play a crucial role in ensuring the availability of new upcoming drugs to Indian patients.
- **Building a globally recognised position for India in the innovation space**: India could adopt an enterprise-led approach to drive innovation, given its strong and dynamic local industry. Under this approach, we believe that the industry can aspire to build a strong innovation pipeline (around 1 NME and 10–12 incremental innovation launches per year by 2030), drive significant economic upside (exports of around USD 16 billion to 18 billion by 2030)[10], and deliver better health outcomes for the country.

To achieve this vision, all the stakeholders have to act on their strengths and provide an enabling environment for the industry to grow. In particular, we believe that the industry could focus on six imperatives to enhance its competitiveness, deepen penetration in existing and new markets, and drive a common agenda to sustain growth:

- **Drive innovation at scale** by making "smart" choices on the portfolio, building new techno-commercial capabilities, and revamping the operating model (e.g., using new approaches such as adaptive trial design to optimise approach for development)
- **Expand presence in emerging markets** through a focused approach and by building a "global" supply chain and organisation (e.g., focus to build 1-2 "home markets" beyond India, re-configure the manufacturing network)

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[9] Decision Resources' PatientBase, WHO report on disease burden, IDF, Stakeholder interviews, Team analysis

[10] Evaluate (2013), Pharmexcil report on "505(b)(2) NDA: The Unexplored Opportunity" in 2009, Nature article on "How to improve R&D productivity" in 2010, Team analysis

- **Adopt innovative business models** to enable deeper penetration and access to drugs even in rural India (e.g., using technology to drive access and lower cost, providing integrated care for patients)
- **Upgrade quality systems and infrastructure, and enhance capabilities** to maintain India's image of a reliable, high-quality pharmaceuticals supplier (e.g., preventative culture, capability building in the front-line)
- **Build new-age capabilities to sustain cost and speed-to-market advantage** even across the newly emerging market segments (e.g., using automation and new technology to lower costs; embedding Quality by Design (QbD) to ensure "first time right" dossiers)
- **Collaborate more meaningfully within the industry** to support growth of the industry (e.g., capability building of quality teams across players)

The government could consider supporting this journey by creating a conducive environment for the industry to undertake the above actions. In particular, the government could look at four initiatives:

- **Build an enabling regulatory environment** to facilitate the "ease of doing business" by providing clarity on guidelines in a few areas (e.g., clinical trials, approval pathway for different product categories)
- **Help improve quality standards** by strengthening the capacity/capability of quality inspectors and harmonising the quality framework with global guidelines
- **Ensure India's self-sufficiency** by helping enhance competitiveness of the local API industry (e.g., by setting up a dedicated API/intermediate manufacturing cluster with resource sharing and incentives)
- **Create a conducive environment for innovation** by strengthening the local talent/research base (e.g., by reviewing the curriculum in the top 10 to 12 academic institutes) and enhancing incentives for investments in R&D

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Vision 2030 builds on the successful trajectory of the Indian life sciences industry. It lays out the path forward to unlock the industry's true potential. This can become a reality if all the stakeholders collaborate and build on the strengths that would help the sector achieve a higher trajectory.