



The best prescription for the global medicine space

The Indian pharmaceuticals sector is the third-largest market globally in terms of volume and the 13th largest in terms of value.¹ It has witnessed steady growth on the back of increasing export opportunities in the generic medicine space and a large domestic market, to reach revenues of US\$37 billion in FY18^{2,3}. With a strong network of 3,000+ companies and 10,500+ manufacturing units,² India is expected to clock up revenues of US\$55 billion in FY20² to become one of the leading pharmaceuticals markets globally. Key Indian players in the sector include Sun Pharma, Cipla, Lupin, Dr. Reddy's, Aurobindo Pharma, Zydus Cadila and Glenmark Pharmaceuticals.

India's major role in driving better health outcomes through its world-class formulation development capabilities and its low-cost structures has catapulted the country to become the leader in the global, generic medicine space. It exports around 50% of its total pharmaceutical production to 200+ countries and accounts for 20% of the world's generic drug exports (in terms of volume).² Major export markets (FY18) are North America (31%), Africa (19%) and the European Union (16%) (IBEF Pharmaceuticals, August 2019 Report).

INDIA PHARMACEUTICALS SECTOR: HIGHLIGHTS

- Indian players account for eight out of the top 20 global generic companies (FY18)³
- Highest US Food and Drug Administration (USFDA)-approved generic drug facilities outside the USA
- Accounted for approximately 50% of USFDA-approved generic drugs in 2018⁴
- Supplies 40% of US generic medicine demand³
- Supplies 25% of all medicines consumed in the UK³
- Supplies 60% of global antiretroviral drugs used to combat AIDS³
- 60,000+ generic brands in 60 therapeutic categories⁵

KEY POLICY INITIATIVES

The Indian government has been at the forefront of supporting the pharmaceuticals sector's growth. It has undertaken various initiatives, including a reduction in approval timelines for new facilities, a proposal for single-window clearance for biosafety products and the liberalization of foreign direct investment

¹ Pharmaceutical Industry: Analysis and Scope of Partnership between India and Germany, December 2018 by Economic & Commercial Wing – Consulate General of India, Frankfurt

² Indian Pharmaceuticals – A formula for success, <https://www.investindia.gov.in/sector/pharmaceuticals>

³ Sector Highlights: Pharmaceuticals, <http://www.makeinindia.com/article/-/v/sector-highlights-pharmaceuticals>

⁴ ANDAs remain pillar of Indian pharma, www.nishithdesai.com, 2 January 2019

⁵ Indian pharmaceutical market, strong the weight of generics, www.pharmaworldmagazine.com

(FDI) norms, etc. to increase the attractiveness of the Indian market. It has also recently introduced *New Drug and Clinical Trial Rules, 2019*, which aims at promoting clinical research through a transparent and faster approval process. These new rules are expected to encourage local drug development and will help in getting early access to high-impact medicines for better patient care.

The Government of India, in order to boost local manufacturing, has recently slashed corporate income tax rates to historic, low levels. This is expected to provide the necessary thrust for increased investments in the local manufacturing of pharmaceuticals. The reduction can help India to enhance exports-led growth and will provide Indian players with increased ammunition to compete with global pharmaceuticals companies.

FOREIGN INVESTMENTS

Low manufacturing costs, the availability of skilled manpower, socioeconomic changes, significant domestic market opportunities and a liberalized FDI regime (100% in greenfield projects and 74% in brownfield projects under the automatic route) have translated into growing interest in the Indian market from global players. The Indian pharmaceuticals sector attracted FDI inflows of US\$16.2 billion between April 2000 and June 2019² with key global players, including Mylan Laboratories, Amneal Pharmaceuticals, Abbott, Johnson & Johnson, GlaxoSmithKline, Novartis, Pfizer, Sanofi and AstraZeneca, operating in the Indian market.

Recent marquee foreign investments include (VCCEdge):

- US-based Baxter International's acquisition of Claris Injectables for US\$625 million
- China-based Shanghai Fosun Pharmaceutical Group's acquisition of Gland Pharma for US\$1,091 million
- Sweden-based Recipharm AB's acquisition of Nitin Lifesciences for US\$103 million and Kemwell Biopharma's contract development and manufacturing organization (CDMO) business for US\$205 million
- US-based Abbott's acquisition of healthcare solutions business (domestic formulations) of Piramal Healthcare for US\$3,720 million

Recent engagements in the cross-border space involving Oaklins' Indian team include:

- Advising Germany-based Dr. Willmar Schwabe on its acquisition of Sanat Products, a leading manufacturer of herbal extracts and phytopharmaceutical products
- Advising a leading domestic intellectual property (IP)-driven active pharmaceutical ingredient (API) manufacturer for a full sale to global strategics and large, private-equity funds

OPPORTUNITIES IN THE INDIAN MARKET

- **New manufacturing units (formulations, APIs and intermediates)**—The availability of skilled labor, considerable opportunities in the domestic market and liberalized FDI and taxation regimes provide a perfectly blended opportunity to set up new manufacturing facilities.
- **Contract research and manufacturing services (CRAMS)**—India, through its high number of manufacturing facilities approved by various global pharmaceuticals authorities, presents a great platform for global companies to outsource manufacturing activities for affordable and quality products accepted across various geographies. The availability of laboratories and of skilled manpower, including a high density of PhD students and scientists, act as major drivers for outsourcing research and development (R&D) activities at an affordable cost. In FY18, revenue from CRAMS was estimated at approximately US\$17 billion.
- **Clinical trials**—The recent introduction of globally competitive clinical trial rules, combined with a genetically diverse population and a skilled doctor pool, signifies the Indian market's potential to offer the best opportunities for conducting clinical trials. The United States National Library of Medicine's database of global clinical studies reported that India engaged in 3,618 clinical trials between March 2018 and February 2019, most of which were conducted for global players.
- **IP protection**—The Government of India, to provide Indian patients with better access to blockbuster life-saving drugs and encourage global majors to participate in the Indian market, has enacted patent laws that allow exclusivity in the marketing and distribution of such drugs.



GLOBAL PRESENCE

Indian companies, in their quest to achieve scale and category leadership in niche therapies, have been on a constant lookout for quality manufacturing assets as well as complex generic brands and product portfolios. These help Indian players get access to newer markets and approved manufacturing facilities, diversify into newer therapeutic categories, and allow scope for further value addition and expansion of product portfolios in existing markets and categories.

Key outbound transactions include (VCCEdge):

- Aurobindo Pharma's acquisition of the dermatology business and generic US oral solids portfolio of Sandoz (a division of Switzerland-based Novartis) for US\$900 million (the largest outbound pharmaceuticals acquisition by an Indian company) (announced but not closed)
- Lupin's acquisition of US-based Symbiomix Therapeutics LLC for US\$150 million to expand its branded women's health specialty business
- Piramal Enterprises' acquisition of the spasticity and pain management portfolio of UK-based Mallinckrodt Pharmaceuticals for US\$203 million
- Aurobindo Pharma's acquisition of Portugal-based Generis Farmaceutica SA for US\$143 million to become the leading generics group in Portugal with the ability to service European markets with a low lead time
- Lupin's acquisition of US-based Gavis Pharmaceuticals for US\$880 million to broaden offerings in dermatology, controlled-substance products and other high-value and niche generics
- Strides' acquisition of the generic pharmaceuticals business of South-Africa-based Aspen Pharmacare in Australia for US\$300 million to become one of the top three generic pharmaceutical suppliers in Australia and among the top 10 pharmaceutical companies in the country.

CONCLUSION

The Indian pharmaceuticals sector has been a standout performer in India's growth story. It has grown consistently, navigating through regulatory and other challenges. With increased R&D expenditure from major players and proposed new drug launches making their impact, coupled with government-sponsored healthcare schemes and a liberalized regulatory regime, the pharmaceuticals sector is expected to move towards an even higher growth trajectory.



