



Indian Pharmaceutical Industry Outlook

18 September 2019

INDUSTRY OUTLOOK

Indian pharmaceutical sector industry supplies over 50 per cent of global demand for various vaccines, 40 per cent of generic demand in the US and 25 per cent of all medicine in UK¹. India enjoys an important position in the global pharmaceuticals sector. Presently over 80 per cent of the antiretroviral drugs used globally to combat AIDS (Acquired Immune Deficiency Syndrome) are supplied by Indian pharmaceutical firms².

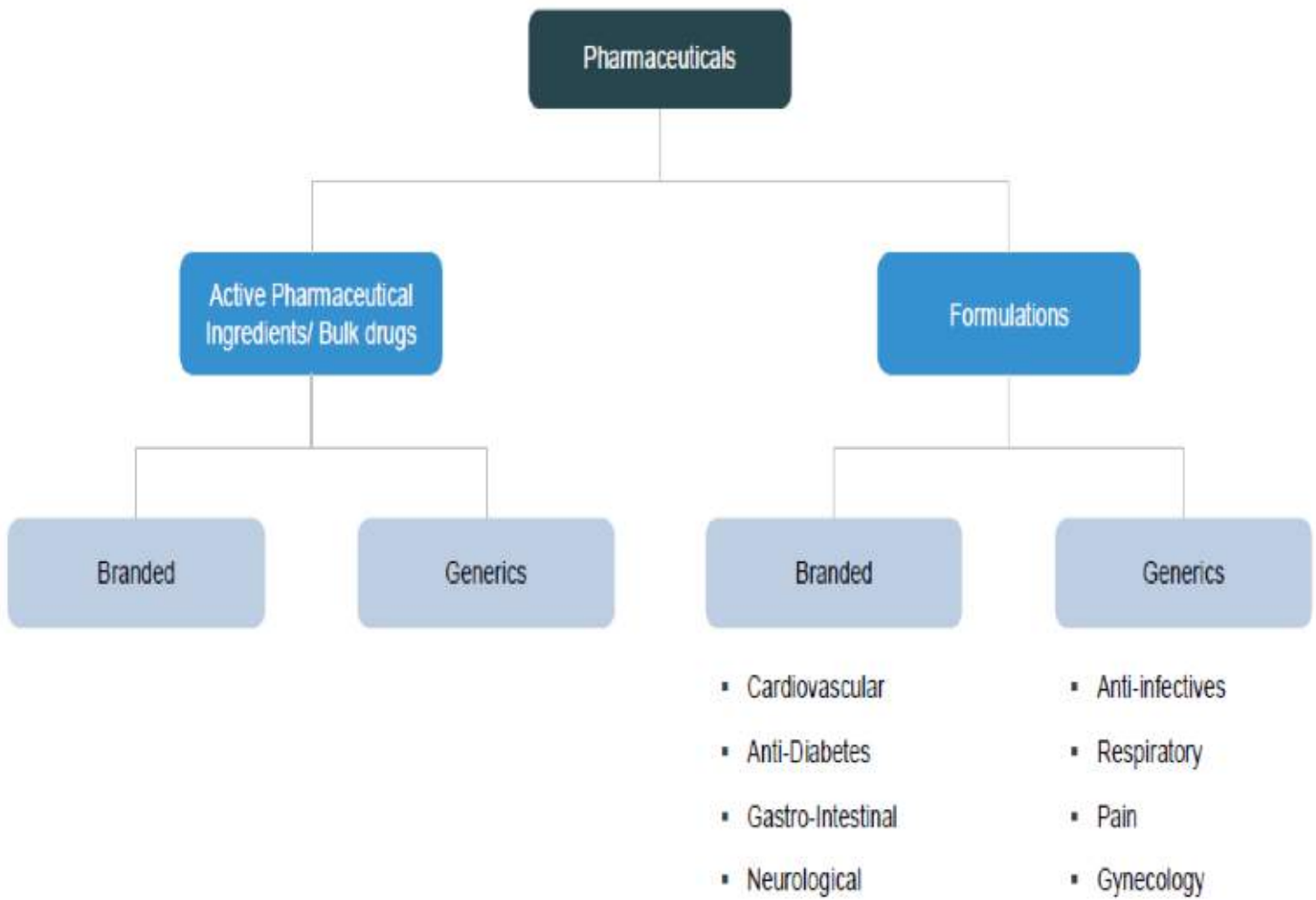
The industry is typically involved in four types of businesses- marketing of generic medicines, marketing of branded generic medicines, marketing of innovator medicines, and manufacture and supply of active pharmaceutical ingredients which are used as ingredients in medicines as well as finished formulations³.

The industry has played a key role in driving better health outcomes across the world through its affordable and high-quality generics drugs. Increased accessibility to affordable drugs has been one of the key enablers for lowering the disease burden in India. India's per person disease burden measured as Disability Adjusted Life Years (DALYs) dropped by 36 percent between 1990 and 2016 after adjusting for changes in the population age structure.

India accounts for 60 percent of global vaccine production, contributing 40 to 70 percent of the World Health Organisation (WHO) demand for Diphtheria, Tetanus and Pertussis (DPT) and Bacillus Calmette–Guérin (BCG) vaccines, and 90 percent of the WHO demand for the measles vaccine⁴. Estimates suggest that one in every three pills consumed in the United States is produced by an Indian generics manufacturer⁵. In the UK, approximately 25 percent of the medicines used are made in India⁶.

The Indian pharmaceutical industry is experiencing amalgamations and collaborations (such as licensing, co-development, joint distribution and joint ventures). Domestic manufacturers are looking to tap into international generic market with high margins. The Abbreviated New Drug Applications (ANDA) to the US FDA is also increasing. The Industry is witnessing a paradigm shift as the focus is shifting from the manufacturing of generic drugs to drug discovery and development.

Chart 1: Structure of Pharmaceutical Sector in India



Source: 'Pharmaceuticals' (January 2019) India Brand Equity Foundation Report.



Evolution of Indian Pharmaceutical Industry

- Approval of Patents (Amendment) Act 2005, which led to adoption of product patents in India.
- Indian Patent Act passed in 1970.
- Several domestic companies start operations.
- In 2013, New Drug Pricing Control Order issued by Directorate of Food and Drugs this will reduce the prices of drugs by 80 per cent.
- In 2014, 100 per cent FDI allowed in medical device industry. The investment will be routed through automatic route.
- In 2015, India has 10,500 manufacturing units and over 3,000 pharma companies.
- National Health Policy Draft 2015 to increase expenditure in health care sector.
- Patent Act Amendment 2015, it includes amendments in Patent Act 2002.
- In Union Budget, 2016, FDI increased to 74 per cent in existing pharmaceutical companies.
- The Government of India unveiled 'PharmaVision 2020' aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments.

Table 1:A Snapshot of Indian Pharmaceutical Industry

SI No.	Characteristics	Details/Description
1	Leading Pharma Producer	Indian Pharmaceutical Industry supplies over 50 per cent of global demand for various vaccines, 40 per cent of generic demand in the US and 25 per cent of all medicine in UK.
2	Growing Industry	India's pharmaceutical industry is expected to expand at a CAGR of 22.4 per cent over 2015-20 to reach USD 55 billion.
3	Rapidly Growing Healthcare Sector	Indian healthcare sector, one of the fastest growing sectors, is expected to cross USD 372 billion by 2022.
4	High Potential Generics market	The domestic generics market is expected to reach USD 27.9 billion by 2020. India's generics market has immense potential for growth. Indian pharmaceutical companies received at least 300 generic drug approvals in US during 2017 and the market is expected to reach USD 88 billion by 2021.
5	Robust growth in Bio-tech Industry	By 2024-25, India's Bio-tech industry is estimated to increase to USD 100 billion.

Source: 'Pharmaceuticals Industry' (January 2019) India Brand Equity Foundation.

Table 2: Important Segments in Indian Pharmaceutical Sector

SI No.	Segments	Details/Description
1	Active Pharmaceuticals Ingredients (APIs)	Domestic API consumption is expected to reach USD 18.8 billion by FY22.
2	Formulations	India is the largest exporters of formulations in terms of volume, with 14 per cent market share and 12 th in terms of export value. Drug formulation exports (including biologicals) from India reached USD 12.91 billion during FY18 and USD 9.28 billion between Apr-November 2018.
3	Contract Research and Manufacturing Services (CRAMS)	Fragmented market with more than 1000 players. Manufacturing of drugs and medicines have become the point of active debate owing to their very nature that attract stringent regulations from policymakers and close scrutiny from industry watchdogs. The industry regulators worldwide such as the USFDA, MHRA-UK, TGA-Australia, MCCSOUTH Africa have been consistently tightening the legal and ethical norms for end-to-end operations in the manufacture of drugs, patents, clinical trials and research in this field. Consequently, MNCs in this industry which is essentially knowledge-based and knowhow driven, have found it more advantageous to move out of their parent countries. Complete operations or part of it such as R&D or manufacturing were shifted out to low-cost destinations, such as India, in order to remain profitable. 1
4	Biosimilar	The domestic market is expected to reach USD 40 billion by 2030.

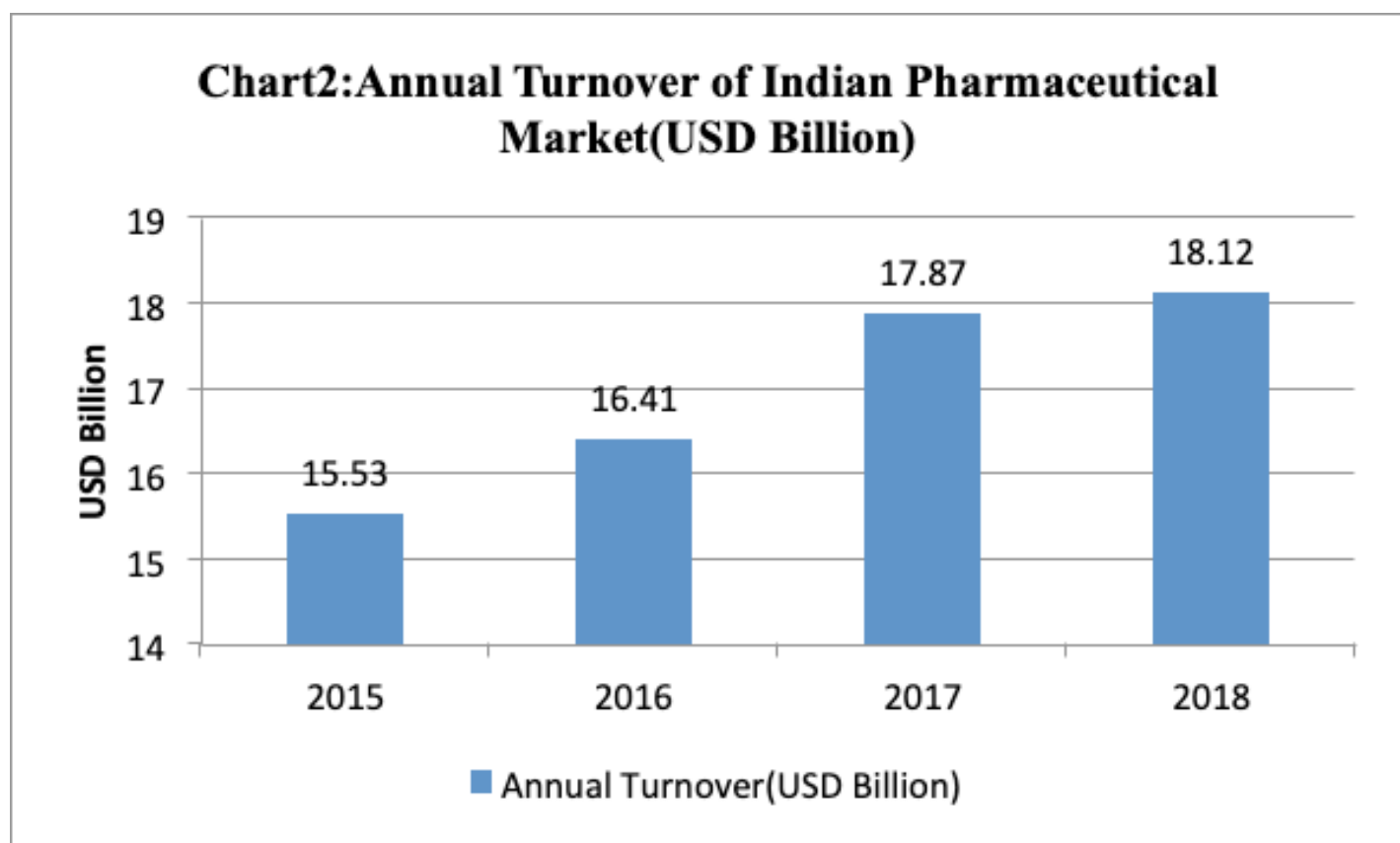
Source: 'Pharmaceuticals'(January 2019) India Brand Equity Foundation.

MARKET SIZE

India's domestic Pharmaceutical market turnover reached INR 129,015 crore in 2018(USD 18.12 billion) from INR 116,389 crore (USD 17.87 billion) in 2017. Medicine spending in India is projected to grow 9-12 per cent over the next five years, leading India to become one of the top ten countries in terms of medicine spending. India's cost of production is much lower compared to US and Europe, which gives India a competitive advantage. The country's pharmaceutical industry is expected to expand at a CAGR of 22.4 per cent over 2015–20 to reach US\$ 55 billion. Pharmaceutical exports include bulk drugs, intermediates, drug formulations, biologicals, Ayush & herbal products and surgicals. Indian pharmaceuticals sector has attracted FDI worth USD 15.72 billion between April 2000 and March 2018.

Indian companies received 304 Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (USFDA) in 2017. The country accounts for around 30 per cent (by volume) and about 10 per cent (value) in the US\$ 70-80 billion US generics market.

India's biotechnology industry comprising bio-pharmaceuticals, bio-services, bio-agriculture, bio-industry and bioinformatics is expected grow at an average growth rate of around 30 per cent a year and reach US\$ 100 billion by 2025.



Source:'Pharmaceuticals' (January 2019) India Brand Equity Foundation.

In 2018, generic drugs form the largest segment of the Indian pharmaceutical sector with seventy per cent market share. Over the Counter (OTC) medicines and patented drugs constitute 21 per cent and 9 per cent, respectively. Based on moving annual turnover, Anti-infectives, cardiac, Gastro intestinal had the biggest market share in the Indian pharma market in 2017.

GROWTH DRIVERS

- Potential breakthroughs in next generation innovative products.
- Growth in the US market by driving higher Abbreviated New Drug Application (ANDA) share in molecules going off patent, and potential ease in price erosion.
- Increased growth in large underpenetrated market such as Japan and China.

Table 3: Indian pharma industry could grow to USD 120-130 billion by 2030

Year	Projected Size (USD Billion)
2018	38
2030(Base Case)	80-90
2030 (Aspirational Case)	120-130

Source: 'The Indian Pharmaceutical Industry-The Way Forward' (June 2019)

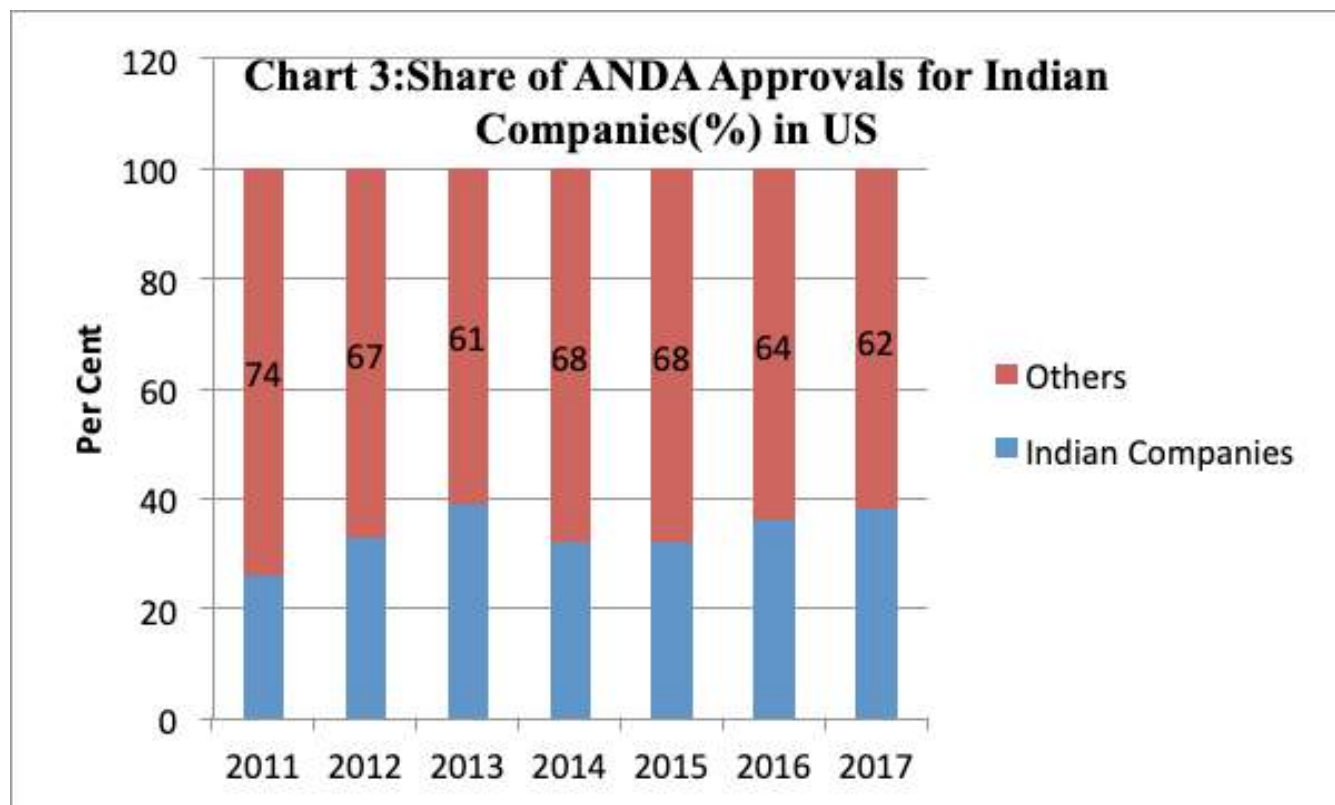
IPA India <https://www.ipa-india.org/static-files/pdf/publications/position-papers/2019/ipa-way-forward.pdf>

According to IPA India, the pharmaceutical Industry can work towards four primary goals as part of this vision as follows:

- Accelerate the goal of universal health care across India and the world by providing access to high-quality affordable drugs: Keeping in line with the Government of India's vision of providing universal healthcare for India, the industry can support this goal by providing access to quality medicines at affordable prices. In India, as more and more patients come under treatment, this could help reduce the disease burden substantially. The aspiration could be to make the DALY (Disability Adjusted Life Years) in India and other emerging markets comparable to the developed economies such as the US and UK by 2030.
- Emerge as an innovation leader to build a globally recognized position for India: the industry can aspire to build a strong innovation pipeline (with three to five new molecular entities launched or in late clinical trial phases and 10–12 incremental innovation launches per year by 2030).
- Opportunities as drug sales worth USD 251 billion going off-patent: Patents for branded molecules with cumulative global sales of over USD 251 billion are expected to expire between 2018 and 2024⁹. The Indian generics industry can benefit substantially from the patent cliff, given an increased Abbreviated New Drug Application (ANDA) share¹⁰. According to an IQVIA report, Indian pharma companies received more than 300 approvals in 2017 to launch generic drugs in the US. The clearances came despite regulatory pressure from the US Food and Drug Administration (FDA), and unprecedented warning letters issued to the pharma companies' facilities¹¹.

Indian Players in US Generics Market

The US market continues to see entry of two to three new Indian players year after year, and these companies are expected to further drive the share of Indian players in overall ANDA approvals. Large Indian companies like Mankind and few Indian CDMOs are also planning to enter the US market.



Source: 'US Generics Market-Evolution of Indian Players'(February 2019) IQVIA <https://www.iqvia.com/-/media/iqvia/pdfs/ap-location-site/india/us-generics-market-evolution-of-indian-players.pdf>

While the number of ANDA filings continues to remain strong for large Indian players, they have now begun transitioning the US business to specialty / complex generics where competition is relatively lower. Indian players are also taking the acquisition route to gain access to manufacturing units or proprietary therapies. Most of the large Indian players that have a significant presence in the US market have invested in acquiring companies with focus on niche therapies (complex generics).



Table 4:Key Acquisitions by Indian Players

Sl No.	Company	Target	Access /Therapeutic Skill	Specialty/Complex/Generic
1	Dr. Reddy's	Habitrol (Brand acquired from Novartis)	OTC - Transdermal	Complex
2	Aurobindo	Acquired 4 brands from TL Pharmaceutical Sandoz International	Biosimilar Dermatology and Oral Solids	Complex Complex+Generic
3	Cipla	Invagen	Cardio, Anti-Infectives,CNS, Anti-Inflammatory and Anti Depressants	Complex
4	Glenmark	Uno Ciclo (Brand acquired from Institute Biochimico) Bouwer Bartlett	Hormonal Contraceptive Dermatology	Complex Complex
5	Lupin	Symbiomix Therapeutics Gavis Pharma Celon InspiRX Laboratories Grin	Women health Controlled Substances, Derma and Gastro Respiratory Respiratory Ophthalmology	Complex Complex Complex Complex Complex

Source: Crunchbase, VCEdge 'US Generics Market-Evolution of Indian Players'(February 2019) IQVIA <https://www.iqvia.com/-/media/iqvia/pdfs/ap-location-site/india/us-generics-market-evolution-of-indian-players.pdf>

Co-development arrangements between Indian and multinational pharmaceutical companies

The Indian pharmaceutical market is witnessing a rise in collaborations with global companies such as Glenmark Pharmaceuticals, GlaxoSmithKline (“GSK”), Merck and Eli Lilly. In 2018, within a span of a month, Glenmark announced an exclusive licensing agreement with Australian company Seqirus for an allergy drug and another with Chinese biopharmaceutical firm Harbour Biomed for its oncology molecule. Piramal Life Science Ltd (PLS) and Eli Lilly and Company have signed a landmark new drug development collaboration. Ranbaxy and GSK have launched Research team to advance into preclinical investigation in the chronic obstructive pulmonary disease (COPD) and other anti-infectives therapeutic areas¹².

Pharmaceuticals Export Scenario

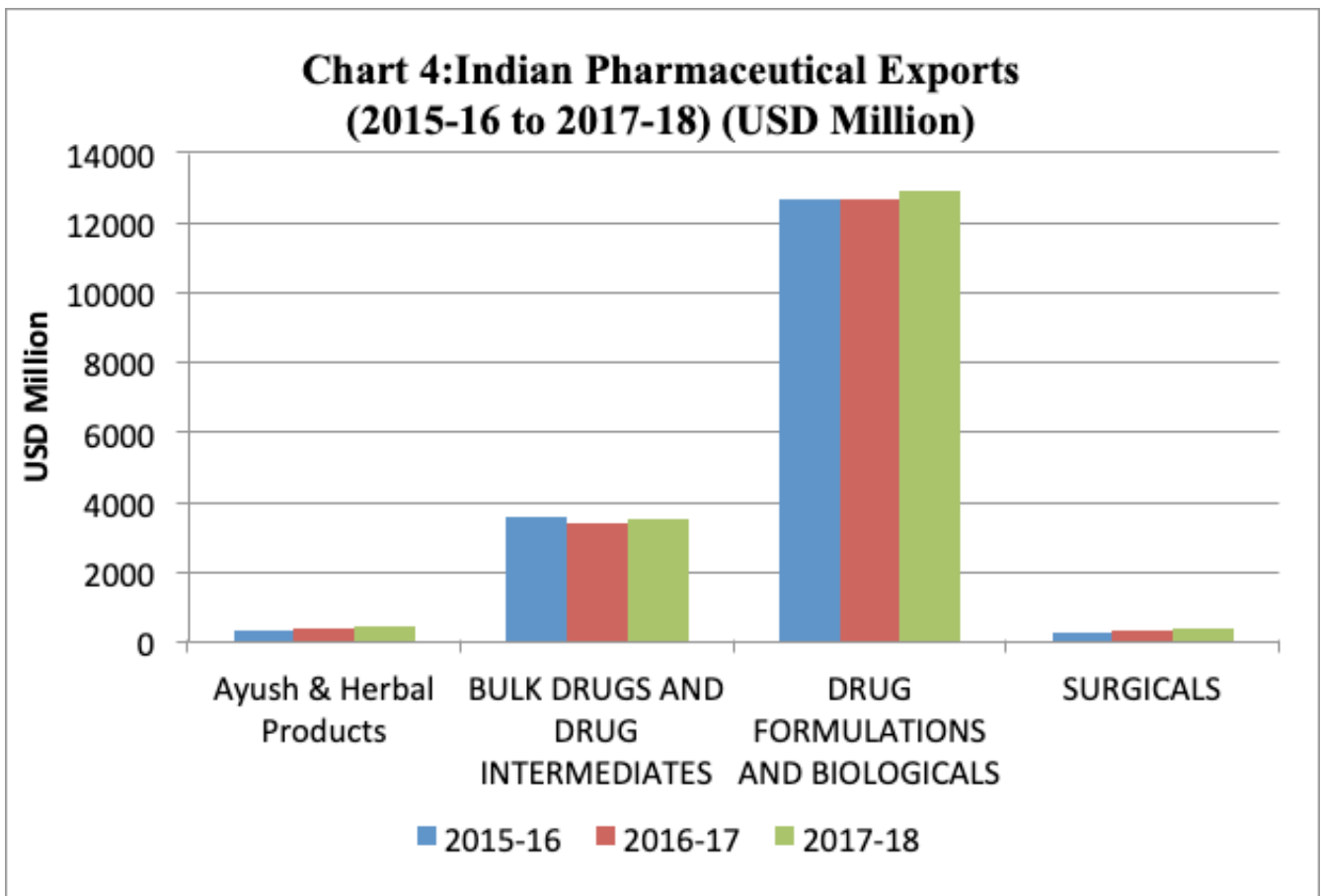
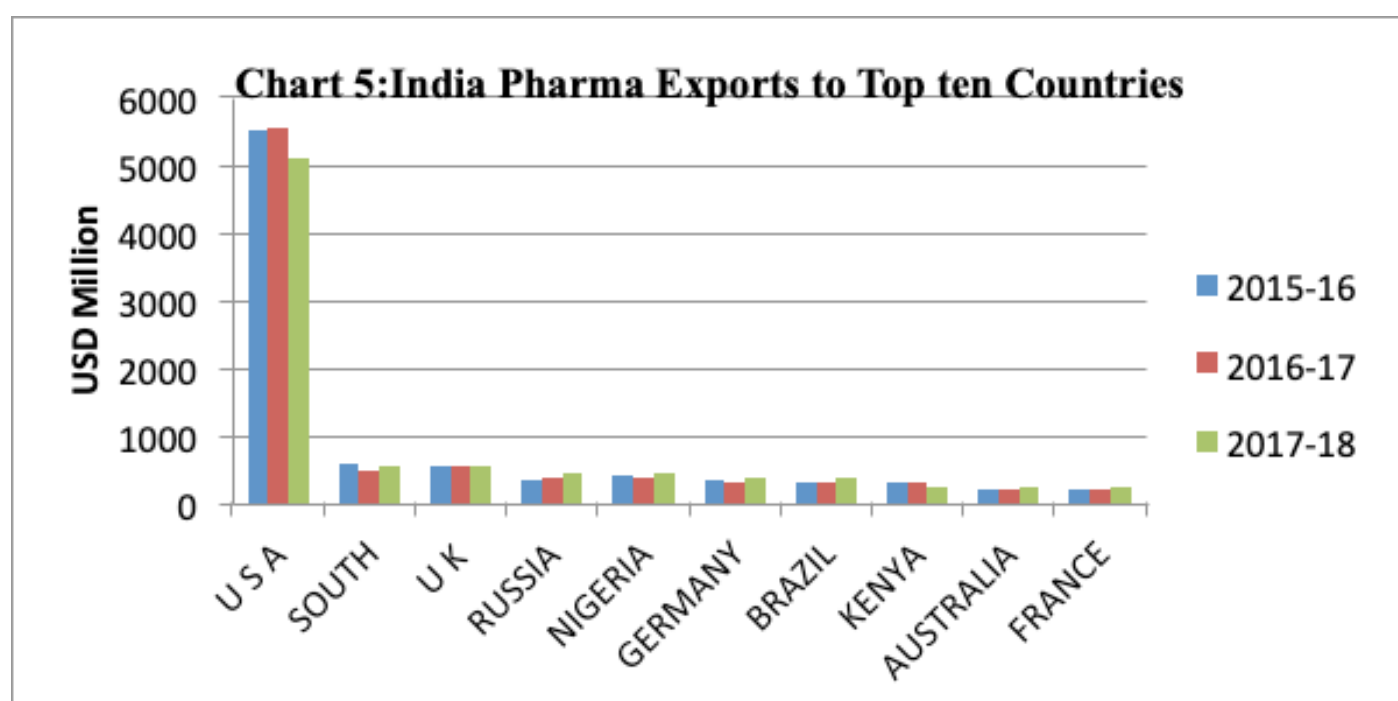


Table 5: India's Pharma Exports to Top Ten Countries (USD Million)

Rank	Country	2015-16	2016-17	2017-18
1	U S A	5513.78	5563.54	5116.32
2	SOUTH AFRICA	605.27	484.89	582.99
3	U K	563.76	549.81	556.7
4	RUSSIA	373.76	383.46	468.74
5	NIGERIA	436.61	397.99	466.67
6	GERMANY	347.65	333.3	388.43
7	BRAZIL	326.17	337.37	383.72
8	KENYA	332.48	325.43	254.62
9	AUSTRALIA	232.78	236.87	253.8
10	FRANCE	231.76	208.87	251.44
Total Of top Ten		8964.04	8821.53	8723.43
Grand Total		16912	16785	17275.8

Source: Ministry of Commerce and Industry, DGCIS.



Source: DGCIS and Ministry of Commerce and Industry <https://commerce.gov.in/InnerContent.aspx?Id=506>

INVESTMENTS AND RECENT DEVELOPMENTS

The Union Cabinet has given its nod for the amendment of the existing Foreign Direct Investment (FDI) policy in the pharmaceutical sector in order to allow FDI up to 100 per cent under the automatic route for manufacturing of medical devices subject to certain conditions.

The drugs and pharmaceuticals sector attracted cumulative FDI inflows worth US\$ 15.98 billion between April 2000 and March 2019, according to data released by the Department of Industrial Policy and Promotion (DIPP). Some of the recent developments/investments in the Indian pharmaceutical sector are as follows¹³:

- Between Jul-Sep 2018, Indian pharma sector witnessed 39 Private Equity (PE) investment deals worth US\$ 217 million.
- Investment (as % of sales) in research & development by Indian pharma companies increased from 5.3 per cent in FY12 to 8.5 per cent in FY18.
- In 2017, Indian pharmaceutical sector witnessed 46 merger & acquisition (M&A) deals worth US\$ 1.47 billion
- The exports of Indian pharmaceutical industry to the US will get a boost, as branded drugs worth US\$ 55 billion will become off-patent during 2017-2019.

Table 6: Investments in the Drugs and Pharmaceutical Industry (INR Million)

Year	Project Completed
2011-12	65,448.90
2012-13	42,988.30
2013-14	19,205.90
2014-15	14,864.30
2015-16	27,099.60
2016-17	30,328.00
2017-18	24,600.00

Source: Bulk Drug Manufacturers Association of India <http://bdmai.org/indian-pharma-market/>



Table 7: FDI Equity inflows during FY18-19 in Drugs and Pharma Industry(in INR Crore) [April 2018 to March 2019]

Period (Year/Month)	FDI Equity inflows(in INR Crore)
April 2018	35,104
May 2018	30,479
June 2018	19,597
July 2018	19,025
August 2018	17,441
September 2018	33,472
October 2018	34,595
November 2018	12,495
December 2018	31,056
January 2019	31,181
February 2019	20,404
March 2019	25,019

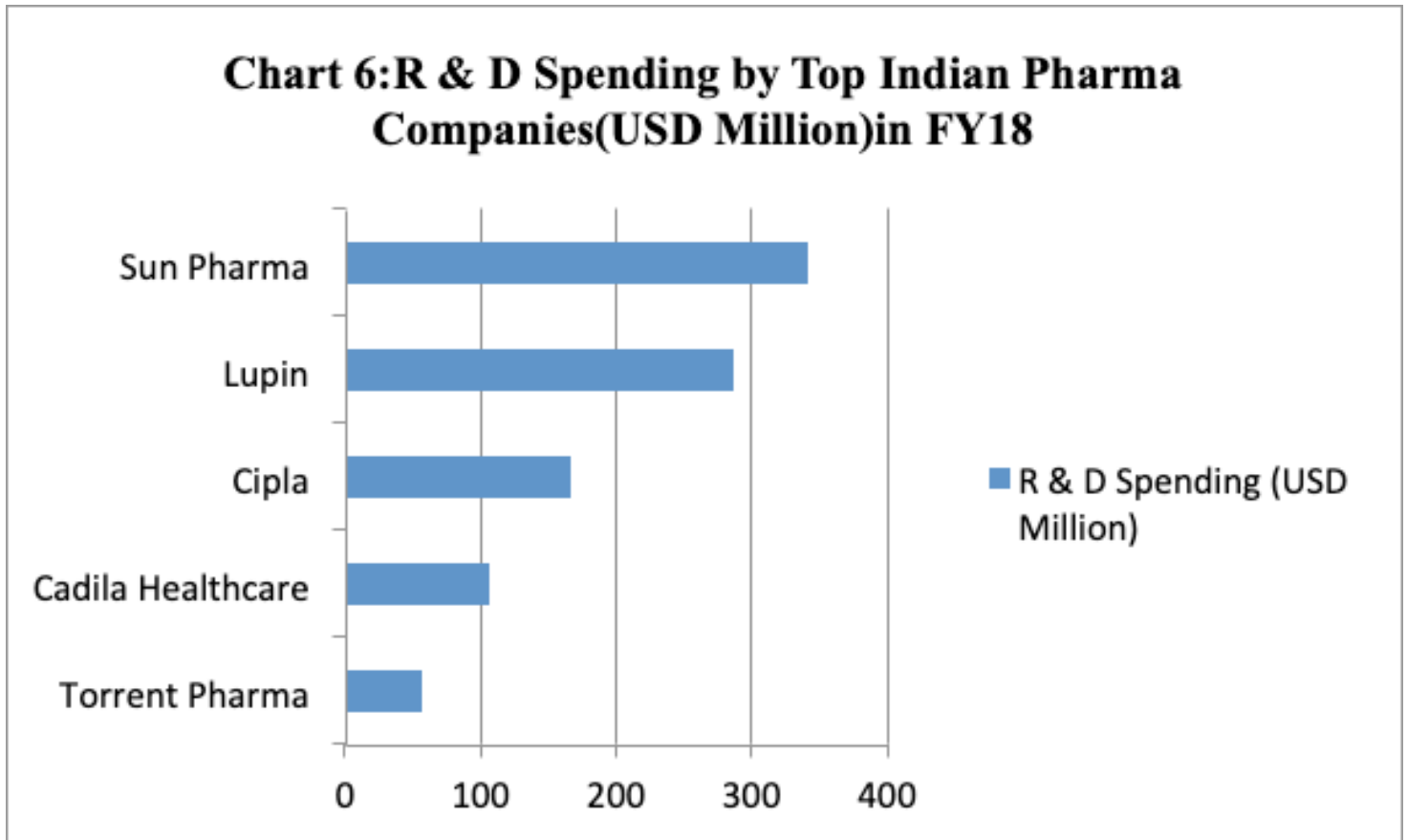
Source: 'Industry blames policies, USFDA probes for 73% drop in Pharma FDI'(9 June 2019) Business Standard
https://www.business-standard.com/article/economy-policy/industry-blames-policies-usfda-probes-for-73-drop-in-pharma-fdi-119060900353_1.html

GOVERNMENT INITIATIVES

Some of the initiatives taken by the government to promote the pharmaceutical sector in India are as follows:

- In October 2018, the Uttar Pradesh Government announced that it will set up six pharma parks in the state and has received investment commitments of more than Rs 5,000-6,000 crore (US\$ 712-855 million) for the same.
- The National Health Protection Scheme is largest government funded healthcare programme in the world, which is expected to benefit 100 million poor families in the country by providing a cover of up to Rs 5 lakh (US\$ 7,723.2) per family per year for secondary and tertiary care hospitalisation. The programme was announced in Union Budget 2018-19.
- In March 2018, the Drug Controller General of India (DCGI) announced its plans to start a single-window facility to provide consents, approvals and other information. The move is aimed at giving a push to the Make in India initiative.
- The Government of India is planning to set up an electronic platform to regulate online pharmacies under a new policy, in order to stop any misuse due to easy availability.
- The Government of India unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments.
- The government introduced mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority to deal with the issue of affordability and availability of medicines.

Research and Development (R & D) Spending in Indian Pharma



Source: 'Pharmaceuticals' (January 2019) India Brand Equity Foundation.

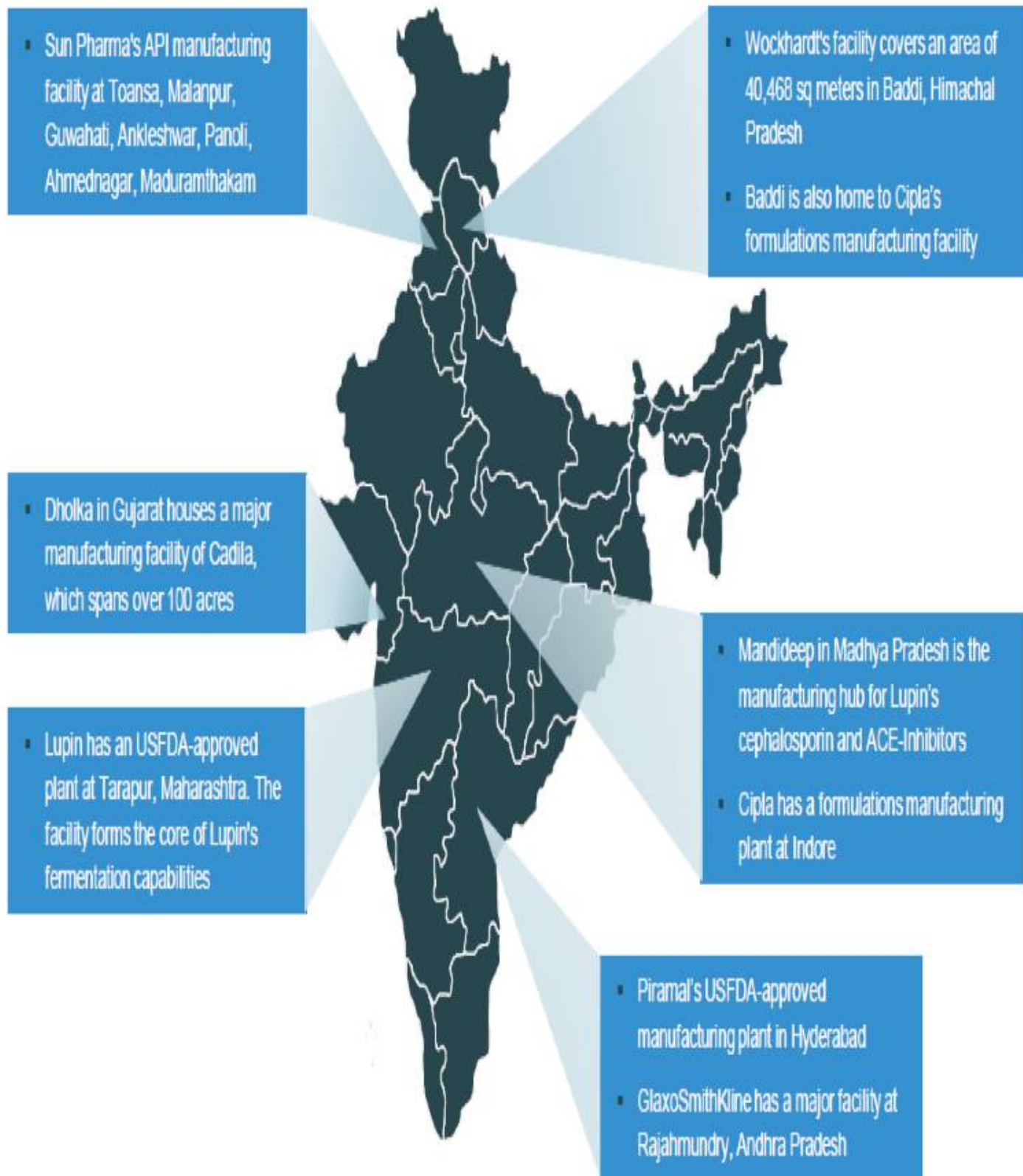
Every year pests and diseases destroys on an average 15%-25% of food produced by the farmers. Due to the continuous increase in population, the demand for food grains is increasing at a faster pace as compared to its production. This therefore necessitates putting more thrust on the use of crop protection methods. Indian agrochemicals market will be driven by the growth in herbicides and fungicide. Contrary to global trends where herbicides form the largest share in use, the Indian agrochemicals industry is dominated by the growing use of insecticides given India is a tropical country marked by insect and fungi attacks. However, the use of herbicides has been increasing due to shortages of farm labour and concerns about the affordability of labour costs. India's exportables of agrichemicals are far outweighs the importables, hence greater attention and incentives to this sector would enhance its export potential further. Further, between 2017 to 2022, patents of 26 pesticides are expected to expire. This provides significant export opportunities for Indian companies. Growth in horticulture and floriculture industries would also be conducive for the growth of the agrochemical industry.

Table 8: Government Initiatives for Pharmaceutical Industry

Sl No.	Policy Measures	Details
1	Pharma Vision 2020	Pharma Vision 2020 aims to make India a major hub for end-to-end drug discovery.
2	Reduction in approval time for new facilities	Steps taken to reduce approval time for new facilities.
3	Pharmaceutical Parks	<p>Government plans to open Mega Pharmaceutical Parks to reduce industry's dependency on raw material imports.</p> <p>The Uttar Pradesh government plans to open six pharma parks across the state with an investment commitment of INR 5,000-6,000 crore from domestic and multinational pharma companies like Mylan, GE, Pfizer, Sanofi along with domestic players.¹</p> <p>The Government is setting up six pharma parks in Noida, Bundelkhand, Ghaziabad, Gorakhpur, Lucknow, Allahabad.</p>
4	National Commission for Homeopathy (NCH) Bill 2018	In December 2018, the Government of India approved the draft National Commission for Homeopathy, Bill, 2018 in order to have more transparency in the sector.
5	National Biopharma Mission	The industry-academia mission was launched in June 2017 to boost development of biopharmaceuticals in India.

Source: 'Pharmaceuticals' (January 2019) India Brand Equity Foundation.





Source: 'Pharmaceuticals' (January 2019) India Brand Equity Foundation.

INDUSTRY RISK

Since the pharmaceutical industry operates in the sensitive health sector, there are a plethora of laws that regulate it. India introduced a patent protection regime in 2005 to protect both process as well as product innovation. India now also has its own competition law to address anti-trust issues which arise in course of day to day operation of the industry as well as owing to the numerous collaborations which the Industry is witnessing. Though in case of pharmaceutical industry, FDI is allowed up to 100 per cent, permission from the Department of Pharmaceuticals is required to buy more than 74 per cent shareholding in existing companies. Domestic pharmaceutical companies witnessed muted growth over last two years due to many factors including new pricing policy and ban on Fixed Dose Drug Combinations (FDCs), demonetisation, GST implementation, weak seasonality etc. Domestic formulation and medical device segments are not attractive for investors due to policy uncertainty, regulatory challenges and pricing cap on medical devices and formulations. FDI equity inflows into India's Drugs & Pharma industry dropped by 73 per cent to USD 266 million between April 2018-March 2019 from USD 1,010 million in the corresponding period of the previous year. Medical devices also declined by USD 66 million by December 2018¹⁵. Price control on drugs and devices acted as an impediment according to experts. On the pharmaceutical front, foreign companies are not looking to buy generic drugmakers who make similar versions of an original drug. Instead, they are looking for companies making new biosimilar drugs. They are also looking for bulk drug or API plants to reduce their dependence on China.

THE WAY FORWARD

The Indian pharmaceutical industry is poised for growth. Even at current rates of seven to eight percent CAGR, the industry's annual revenues can grow to about USD 80 to 90 billion by 2030. However, it could also set bold aspirations of eleven to twelve percent CAGR, and grow to annual revenues of about ~USD 65 billion by 2024 and about ~USD 120 to 130 billion by 2030. In June 2019 quarter remains bullish for major pharma companies, and the first-quarter FY20 revenues of ten leading pharma firms increased by 13.3 per cent from the year-ago quarter. Channel and distribution partners in the US have been consolidating, leading to some easing in pricing. Besides, Indian pharma companies are trying to sweeten the revenue pie by rolling out new drug application products in the US. Much of the future recovery would depend on the consolidation in the US and other overseas businesses, which is likely to be slow. Besides, since drug development and launches differ from company to company, that would be a key factor to watch out for from an investment perspective¹⁶. The remedy that the pharmaceutical and medical devices industry needs is consistent and remunerative policies where companies and investors can make long-hauls plan for India.

FOOTNOTES

1. 'Indian Pharmaceutical Industry'(July 2019) India Brand Equity Foundation (IBEF).
2. *ibid*.
3. 'The Indian Pharmaceutical Industry (February 2019) Nishith Desai Associates http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/The-Indian-Pharmaceutical-Industry.pdf
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