

Report on Indian Economy and Biotech, Pharmaceutical, Medical Devices & Diagnostics Sector


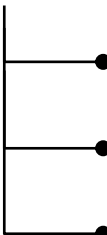





August 2021

Indian Economy

August 2021

Executive summary

Economic overview

Parameter/ indicator	Description	Source
Gross Value Added (GVA)  <div>  <ul style="list-style-type: none"> Agricultural Industry Services </div>	<ul style="list-style-type: none"> Post witnessing decline in the first two quarters of FY21, overall GVA grew by 1.0 percent in the third quarter, indicating a 'V' shaped recovery Despite COVID-19, the agriculture sector witnessed growth in the last three quarters. It grew by 3.9 percent in 3Q21, as compared to 3Q20 Manufacturing, construction and utilities sector registered growth during 3Q21, however, mining continues to be in the negative zone Apart from financial services (which grew by 6.6 percent in 3Q21), other two sectors i.e., trade, hotels and transportation, and public administration and defence, witnessed negative growth in the last three quarters of FY21 	Link
Index of Industrial Production (IIP) and employment 	<ul style="list-style-type: none"> After a huge decline in April 2020, IIP has continuously improved owing to pent up demand and increase in manufacturing output. However, it witnessed a decline in January 2021, owing to fall in output of mining, manufacturing and capital goods sectors Unemployment rate stands at 6.5 percent (as of March 2021), lower than pre-COVID-19 level 	Link
Inflation 	<ul style="list-style-type: none"> WPI and CPI inflation were highly volatile during 2020 and reached 4.2 percent and 5.1 percent, respectively by February 2021 	Link
Government's revenue and expenditure 	<ul style="list-style-type: none"> As of February 2021, the government's expenditure reached INR28.2 trillion as compared to total receipts of INR14.1 trillion, thereby creating a fiscal deficit of INR14.1 trillion 	Link
Trade, FDI and foreign exchange reserves 	<ul style="list-style-type: none"> In FY21 (till February 2021), India had a trade deficit of US\$7.8 billion While the country's foreign exchange reserves dipped a little to US\$579.3 billion (as of 2 April 2021), it became the fourth largest country during March 2021. In terms of FDI, the country reached US\$500 billion mark in September 2020 (from April 2000) 	Link
Business activity 	<ul style="list-style-type: none"> Increased government support has led to a rise in the new company registration by 37 percent in February 2021, as compared to previous year. In addition, there has been an upward movement in Nomura India Business Resumption Index indicating improved business activity 	Link

Key indicators – A snapshot (1/2)

Economic overview

Macroeconomic Indicator	4Q20	1Q21	2Q21	3Q21
Gross Value Added (GVA)	3.0	-22.4	-7.3	1.0
Agricultural	5.9	3.3	3.0	3.9
Mining and Quarrying	5.2	-18.0	-7.6	-5.9
Manufacturing	-1.4	-35.9	-1.5	1.6
Construction	-2.2	-49.4	-7.2	6.2
Electricity, Gas, water supply and utility services	4.5	-9.9	2.3	7.3
Trade, Hotels, Transport and Communication	2.6	-47.6	-15.3	-7.7
Financial, Real Estate and Professional Services	2.4	-5.4	-9.5	6.6
Public Administration, Defense and Other services	10.1	-9.7	-9.3	-1.5

Numbers are y-o-y percent change



- Though India's economy has witnessed recovery post the impact of pandemic, it's yet to reach the pre-COVID-19 levels
- The country's economy could rebound to 5.4 percent–13.7 percent growth in 2021, owing to improvement in business activities backed by COVID-19 vaccinations, government support, increased infrastructure spending and an improvement in consumption

Note: 1Q21 refers to Apr 2020 to Jun 2020; Percent change is calculated in comparison to figures from previous quarters; Quarterly WPI and CPI are calculated as an average of the three months; WPI and CPI inflation targets are considered as 5 percent and 4 percent respectively, with an allowed variance of 2 percent on either side

Macroeconomic Indicator	Unit	1Q21	2Q21	3Q21
Employment under MGNREGS	Million	62.7	-18.1	-13.2
Total GST collections	INR billion	-40.9	45.3	20.8
Foreign exchange reserves	US\$ million	4.3	9.3	6.1
Total receipts	INR trillion	-73.8	174.6	35.1
Total expenditure	INR trillion	42.2	-19.1	20.7
Foreign Direct Investment (FDI)	INR billion	-47.9	251.2	-9.37

Numbers are q-o-q percent change

Macroeconomic Indicator	Unit	1Q21	2Q21	3Q21
Unemployment Rate	Percent	18.5	7.5	7.5
WPI inflation percent (all commodities)	Percent	-2.3	0.5	1.4
CPI inflation percent (Combined)	Percent	6.2	6.9	6.4

Numbers are average of three months

Huge decline High growth
Legend: ← →

Key indicators – A snapshot (2/2)

Sectoral analysis

Sector	Indicator	Unit	1Q21	2Q21	3Q21
Services	PMI	Index	17.2	41.9	53.4
	Imports	US\$ billion	-14.6	1.7	4.7
	Exports		-8.4	0.8	3.4
Manufacturing	PMI	Index	35.1	51.6	57.2
	Imports	US\$ billion	-44.5	47.8	20.9
	Exports		-31.6	44.4	2.0

Index is average of three months; Import-export are in q-o-q percent change



- Services sector is witnessing recovery supported by securing of new work and growth in outstanding business
- Export business continues to be impacted owing to global COVID-19 restrictions, especially travel bans



- Manufacturing is getting back to normal owing to easing of COVID-19 restrictions, increased domestic as well as exports demand, and improved market conditions
- The sector is expected to grow in the near term, driven by favorable government reforms such as PLI scheme for 13 sectors, changes in FDI norms, and infrastructure development policies

Sector	Indicator	Unit	1Q21	2Q21	3Q21
Financial Services	UPI transactions	INR trillion	-8.5	45.4	30.0
	PE investments	US\$ million	194.3	-19.6	-9.6
Transport	Railway passengers booked	Million	-100.4	1,050.0	392.1
	Air passengers booked	Million	-93.6	282.3	111.1
	Air Freight Volume	'000 tonnes	-59.5	108.1	19.6
	Rail Freight Volume	Million tonnes	-24.4	20.7	15.1
	Fast tag collections	INR billion	-40.6	81.8	24.0
	E-way bills generated	Million	-51.3	106.6	18.5
Telecom and entertainment	Net wireless subscriber additions	Million	NA	NA	-35.0
	Monthly consumption of OTT Video	Billion minutes	15.4	4.3	5.3
Energy	Consumption of petroleum products	'000 tonnes	-22.6	11.4	19.2
	Consumption of natural gas	Million cubic meter	-17.5	16.5	0.5
	Electricity demand	Billion units	-4.8	14.9	-6.2
Automotive	Two-wheeler registrations	Thousand	-72.2	194.1	39.0
	Three-Wheeler Registration	Thousand	-91.1	300.0	32.1
	Commercial vehicle registration	Thousand	-92.6	514.3	68.6
	Passenger vehicle registration	Thousand	-76.2	238.9	52.6
Steel	Crude steel production	Million tonnes	-35.4	53.8	7.1
Cement	Cement production	Million tonnes	-39.1	30.5	15.1
Agriculture	Tractor sales	Thousand	10.3	47.4	9.9
	Fertilizer sales	Million tonnes	-11.3	33.6	-1.2
Mining and quarrying	Value of mineral production	INR billion	-44.3	-6.4	75.3
	Coal production	Million tonnes	-40.5	-5.3	38.6

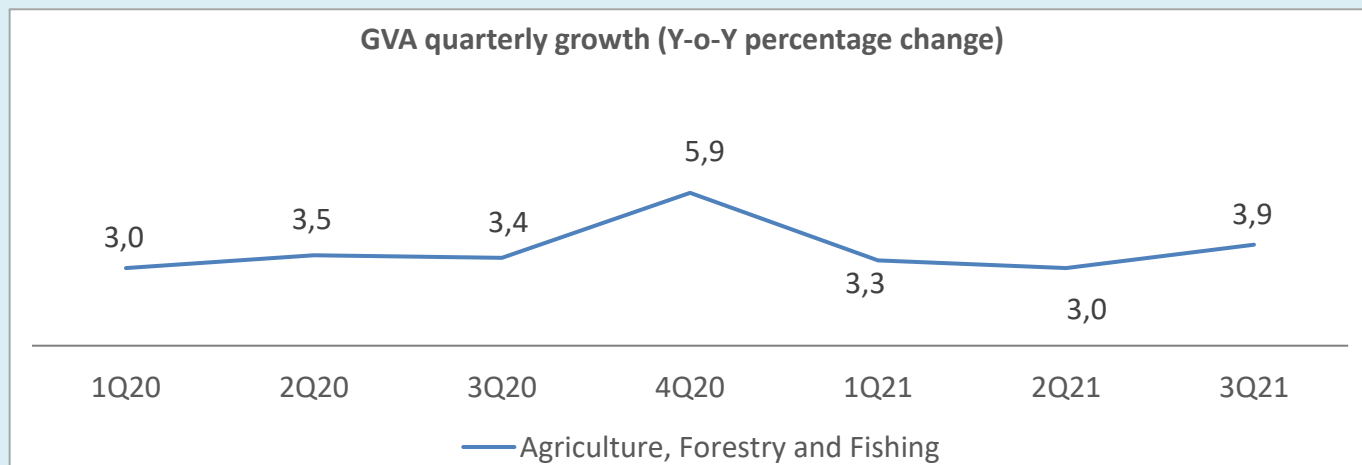
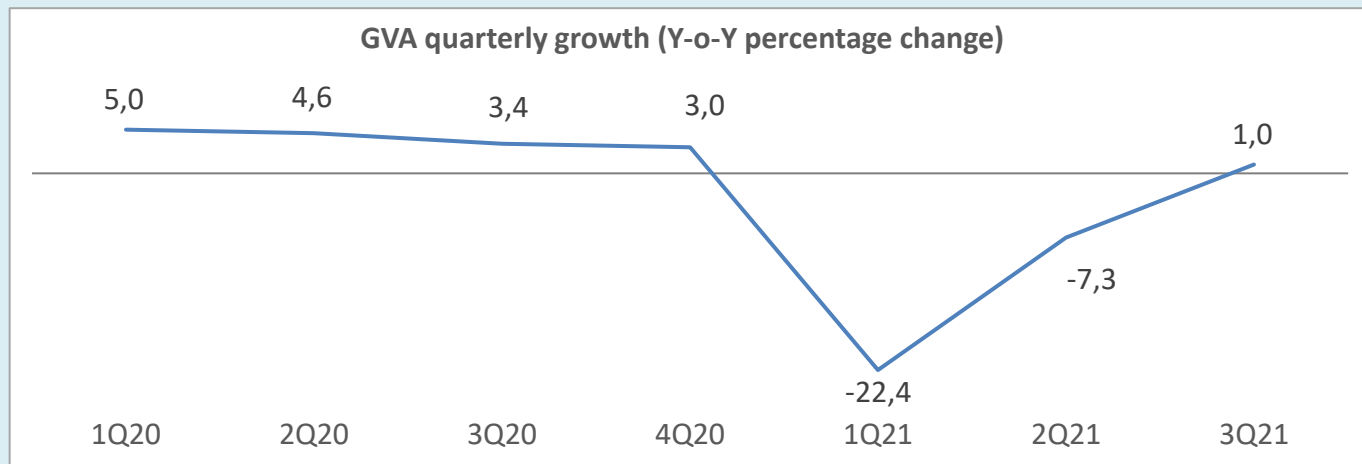
Numbers are q-o-q percent change

Note: 1Q21 refers to period from April 2020 to June 2020; Quarterly PMI calculations have been done by taking average of the values from the constituting months; PMI index above 50 has been considered positive and below 20 has been considered high negative

Huge decline High growth
Legend: ■ ← → ■

Economic overview

The GVA witnessed growth of 1.0 percent in 3Q21, as compared to a huge decline of 22.4 percent in 1Q21, which is expected to improve further by FY22. Agriculture sector continued its growth from the previous quarter owing to increased sowing of rabi crops



Key highlights

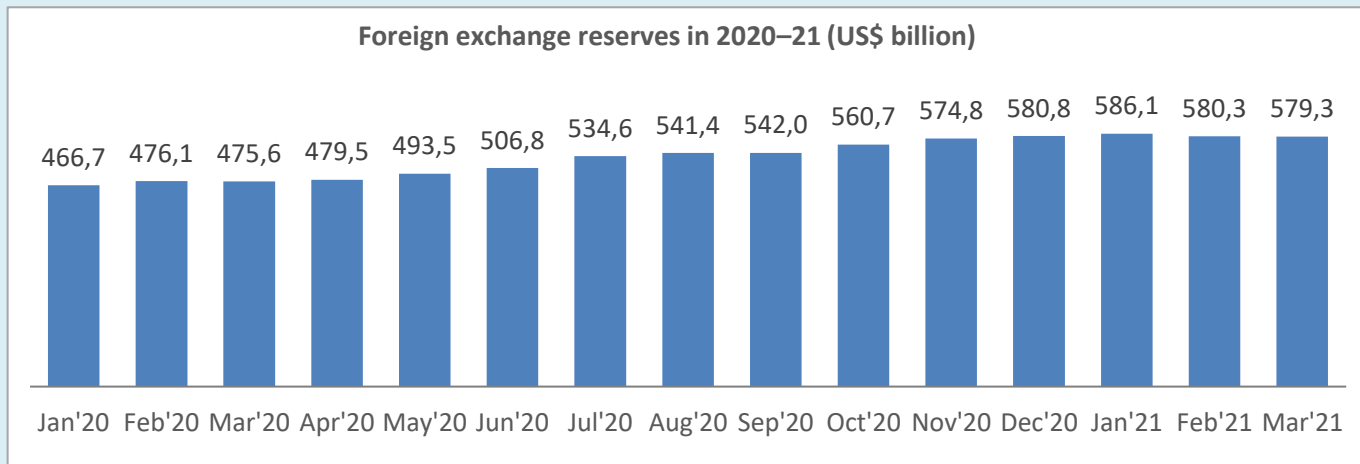
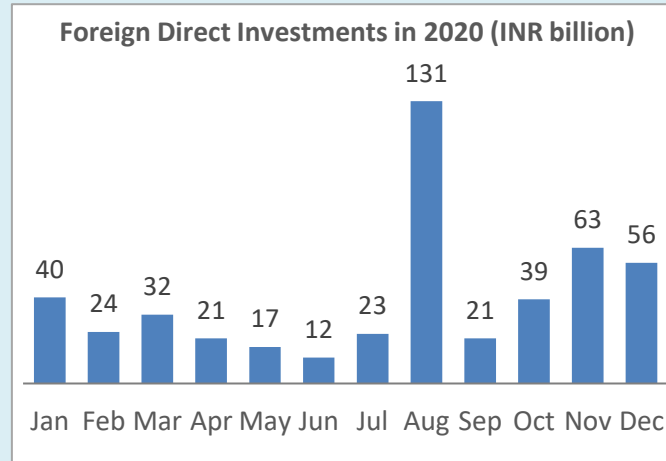
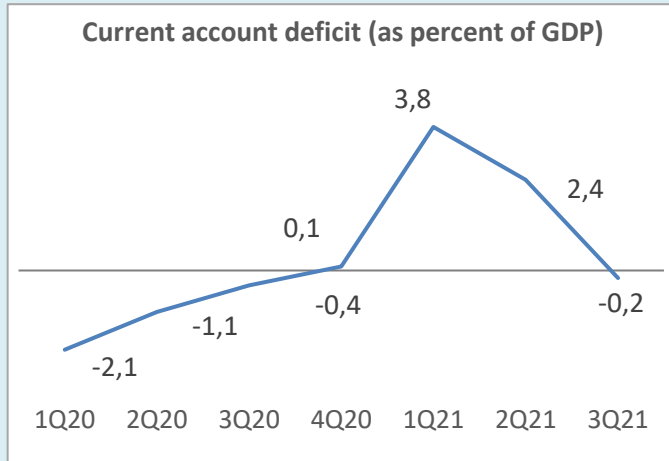
- The Gross Value Added (GVA) in 3Q21 saw a y-o-y growth of 1.0 percent, an improvement over the previous quarter, as five out of eight sectors recorded growth compared to just one sector in 1Q21
- The International Monetary Fund (IMF) projects that India will contract by 8.0 percent in FY21 and grow by 12.5 percent in FY22
- Agriculture sector witnessed a growth in 3Q21 on the back of growing production of crops, legumes and livestock products
 - Y-o-Y increase of 2.6 percent in sowing of rabi crops was seen till 8 January 2021, owing to increased planting of pulses, oilseeds and wheat
- Production of food grains is expected to grow by 2.0 percent in FY21 to 303 million tonnes

Note: FY21 represents time period of April 2020 to Mar 2021; 1Q21 represents period of April 2020 to June 2020

Source(s): "Estimates of Gross Domestic Product for the third Quarter", Ministry of Statistics & Programme Implementation, "Provisional Estimates of Annual National Income, 2019-20 and Quarterly Estimates (q4) of Gross Domestic Product", Ministry of Statistics & Programme Implementation, Farm sector maintains robust growth in Q2, GVA up 7.7% at current prices, Business Standard, 28 November 2020; India's food grain production to be an all-time high at 303 million tonnes, Times of India, 25 February 2021; Rabi sowing rises by 2.61%: Agriculture ministry, Economic Times, 8 January 2021; IMF projects India's growth rate to jump to impressive 12.5 per cent in 2021, The Indian Express, 7 April 2021; all accessed on 8 April 2021

Trade, FDI and Foreign exchange reserves

Post witnessing current account surplus in the first two quarters of FY21, India recorded a current account deficit of US\$1.7 billion in 3Q21. In March 2021 foreign exchange reserves dipped to US\$579.3 billion after reaching an all time high in January 2021



Foreign exchange reserves for Mar'21 are up to 2 April 2021;

Note: FY21 represents time period of April 2020 to Mar 2021; 1Q21 represents period of April 2020 to June 2020

Source(s): "Estimates of Gross Domestic Product for the third Quarter", Ministry of Statistics & Programme Implementation, "Provisional Estimates of Annual National Income, 2019-20 and Quarterly Estimates (q4) of Gross Domestic Product", Ministry of Statistics & Programme Implementation, Farm sector maintains robust growth in Q2, GVA up 7.7% at current prices, Business Standard, 28 November 2020; India's food grain production to be an all-time high at 303 million tonnes, Times of India, 25 February 2021; Rabi sowing rises by 2.61%: Agriculture ministry, Economic Times, 8 January 2021; IMF projects India's growth rate to jump to impressive 12.5 per cent in 2021, The Indian Express, 7 April 2021; all accessed on 8 April 2021

Key highlights

- India witnessed a current account surplus for three consecutive quarters till 2Q21 as trade improved. However, since October 2020, the country started witnessing a trade deficit
- India has a trade deficit of US\$7.8 billion in FY21 (till February 2021), with overall exports and imports estimated at US\$439.6 billion and US\$447.4 billion, respectively
- FDI inflow in the country grew during the September quarter and crossed US\$500 billion milestone, since April 2000
 - In the Union Budget 2021-22, FDI limits in insurance companies have been increased to 74 percent, from 49 percent
- In the week ended April 2, 2021, India's foreign exchange reserves dipped to US\$579.3 billion owing to decrease in Foreign Currency Assets (FCA)
 - Forex reserves of India reached to an all time high in Jan 2021, and stood as fourth largest reserve in the world as on March 5, 2021

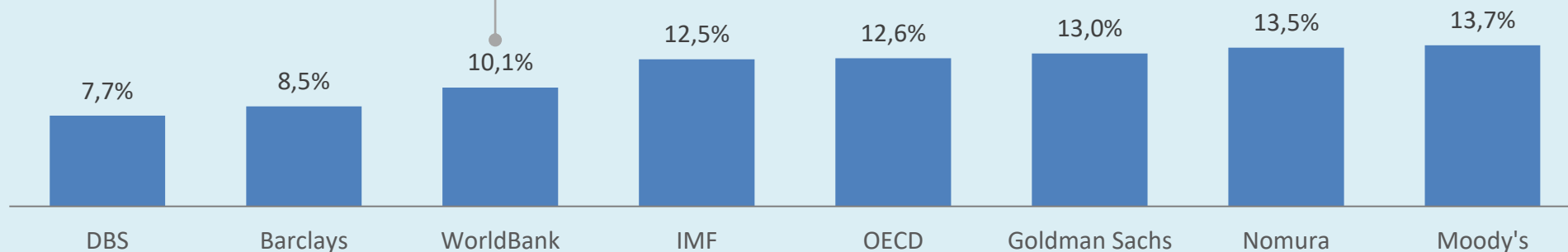
GDP forecasts for India

Analysts across all major financial institutions expect strong growth in the Indian economy during FY22. However, the projected growth rate varies considerably from 7.7–13.7 percent

Forecasted GDP growth in FY22 (percent)

- Strong pace of economic recovery and ongoing vaccination drive are likely to improve consumer spending and investments in the country

- Decline in new infection numbers, coupled with high recovery rates, is bending the pandemic curve, leading to further easing of restrictions on mobility
- Economic activity is expected to gradually gather momentum in the coming quarters
- However, slow credit intermediation is expected to impede recovery, owing to the already weakened financial sector



- IMF predicts strong economic recovery for the emerging and developing Asia economies driven by the removal of lockdowns and demand revival in the region

- Government stimulus measures/policies and increased expenditure on infrastructure development are likely to aid employment generation, and improve consumption
- Improvement in domestic and international demand since easing of lockdown restrictions and ongoing vaccination drive are likely to support economic recovery of the country

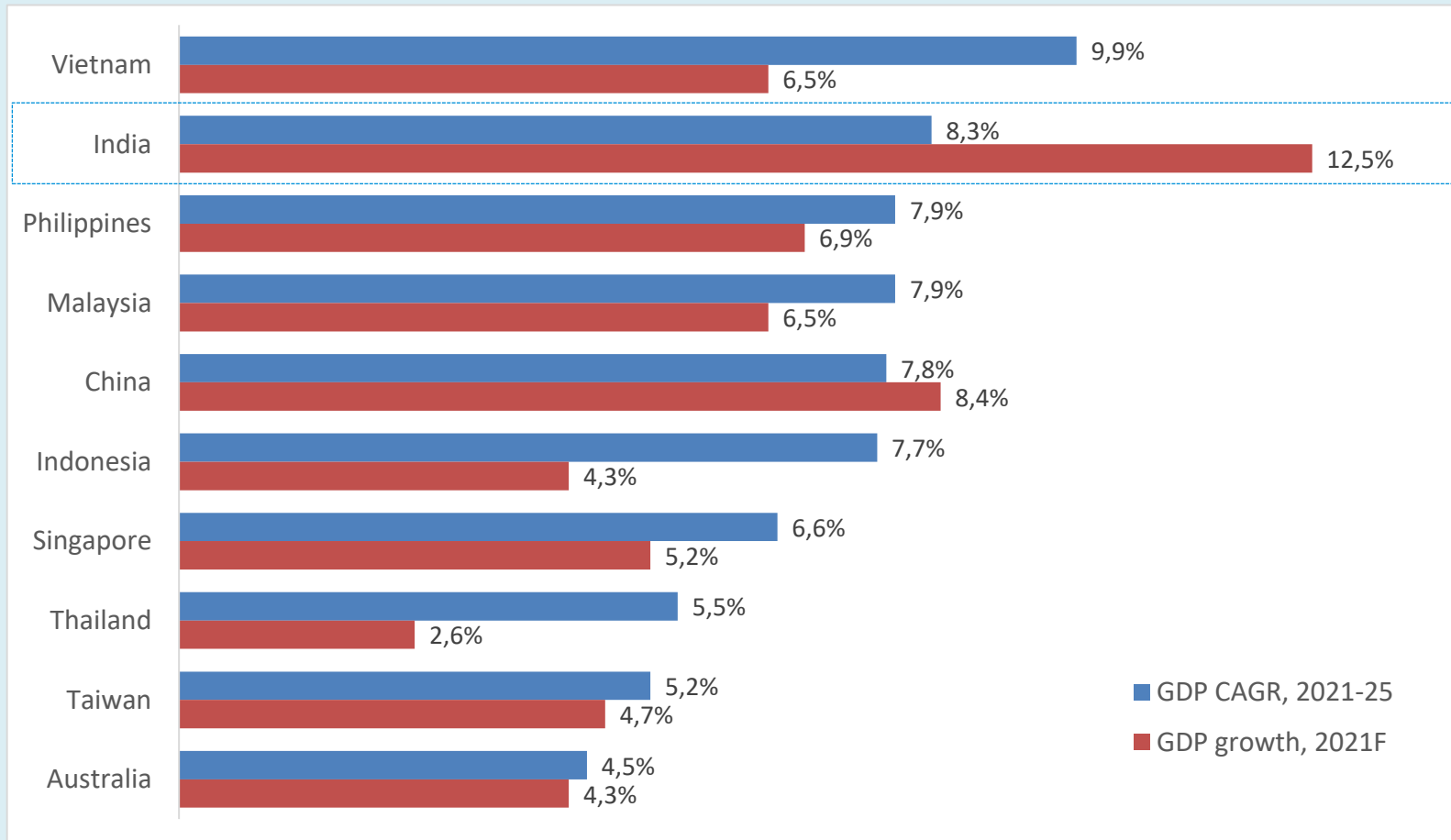
- GDP growth is projected to remain in the red in FY21, registering a net contraction of 10.3 percent and is expected to increase by 13.0 percent in FY22
- Availability of vaccines may help in faster recovery of consumer facing service sectors such as tourism and hospitality

Sources: "India 2021 Outlook", Goldman Sachs, 15 December 2020; "Moody's forecasts 7% GDP contraction for India in FY21; revises estimate to 13.7% growth in FY22", Business Today, 25 February 2021; "India may reclaim 'fastest-growing economy' tag in 2021-22: Report", India Today, 9 March 2021; "India's GDP to expand 0.8% in Q3, FY22 growth seen at 8.5%: Barclays", Business Today, 18 February 2021; "India's GDP growth estimated at 13.5% in FY22: Nomura", Hellenic Shipping news, 9 March 2021; "World Bank ups FY22 GDP growth projection for India by 4.7 percentage pts", Business Standard, 1 April 2021; "India 2021 Outlook: Normalisation underway, then recovery", DBS, 14 December 2020; all accessed on 6 April 2021;

India compared to peers – GDP growth

*With a growth rate of about 12.5 percent in 2021, the International Monetary Fund projects India as the fastest growing economy in 2021.
The country is expected to sustain a growth rate of 8.3 percent till 2025*

Forecasted GDP growth in 2021 and CAGR of GDP growth to 2025 (percent)



Vietnam is expected to grow at more than 9.0 percent till 2025, growing at a faster rate as compared to India and other peers

IMF forecasts India to be the fastest growing economy in 2021, with an estimated GDP growth rate of 12.5 percent, and 6.9 percent in 2022

Note: The average developing nation is expected to grow by about 5.0 percent in this calendar year while the world average will be close to 5.5 percent

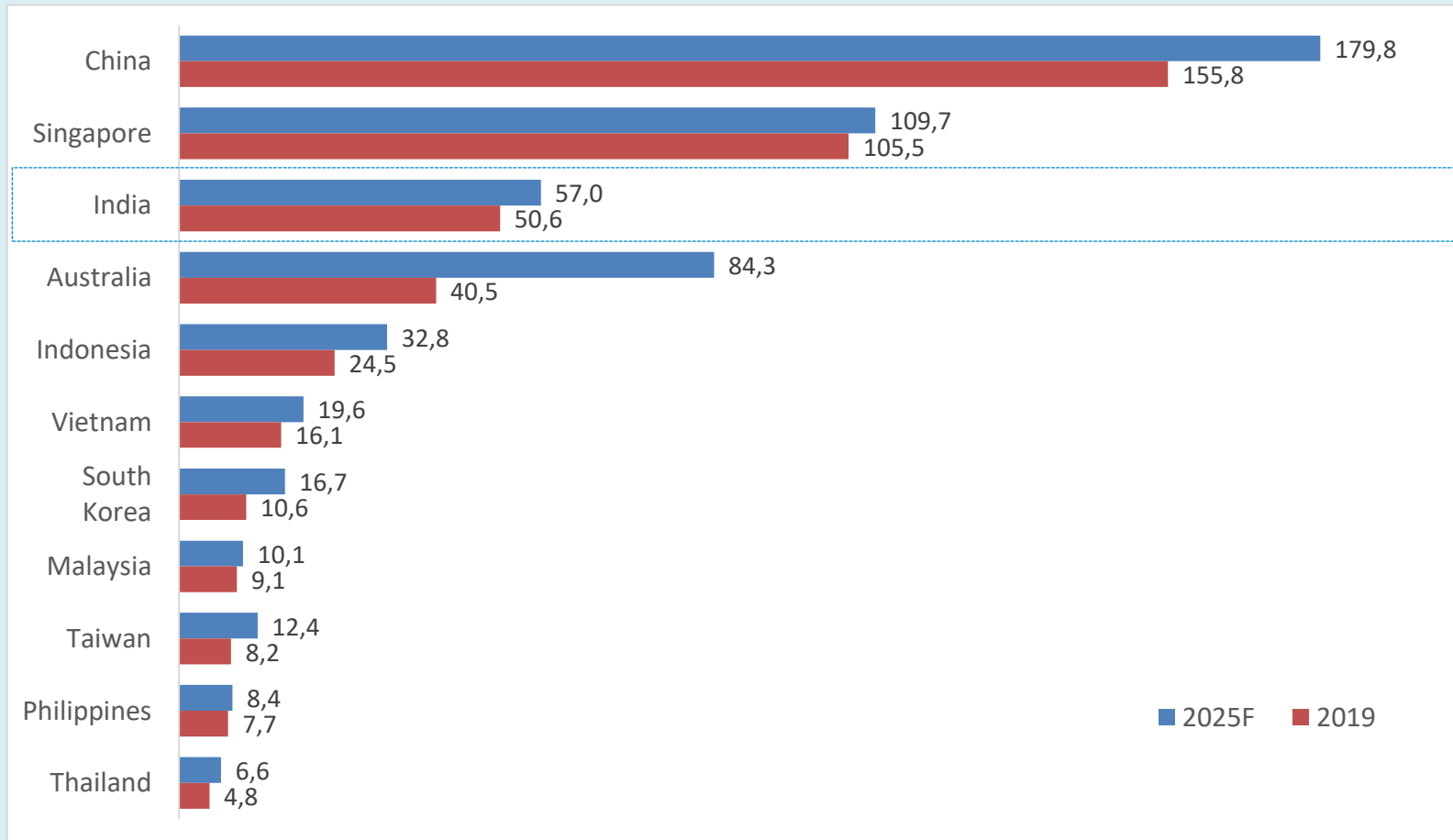
F indicates forecast

Sources: "Real GDP Growth", International Monetary Fund; "World Economic outlook update", IMF; accessed on 6 April 2021

India compared to peers – FDI inflows

In India, FDI through M&A and equity transactions in digital sectors and electronics manufacturing is expected to grow significantly in the near future

FDI inflows (US\$ billion)



As per a report by United Nations:

- In India, digital sectors such as IT, business process management, digital communication services and electronics manufacturing may register increase in FDI through acquisitions and equity transactions, and is expected to double by 2025
- Investment in pharmaceutical sector is forecasted to decline owing to local sourcing policies opted by European and the US pharmaceutical companies

F indicates forecast

Sources: "India's economy could prove to be most resilient in subregion over long term: UN", Money control, 29 December 2020; "FDI inflow data", EIU database; all accessed on 12 February 2021,

Biotechnology

August 2021

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Executive Summary



Executive summary

2. STRONG START-UP ECOSYSTEM

- India has a strong start-up ecosystem, originating from gradual improvements in the ease of doing business, proof-of-concept funds for start-ups and favourable government policies
- The biotechnology industry in India comprises >600 core biotech companies, >100 biotech incubators and >2700 biotech start-ups, which are estimated to reach 10,000 by 2024

1. GLOBAL POSITION

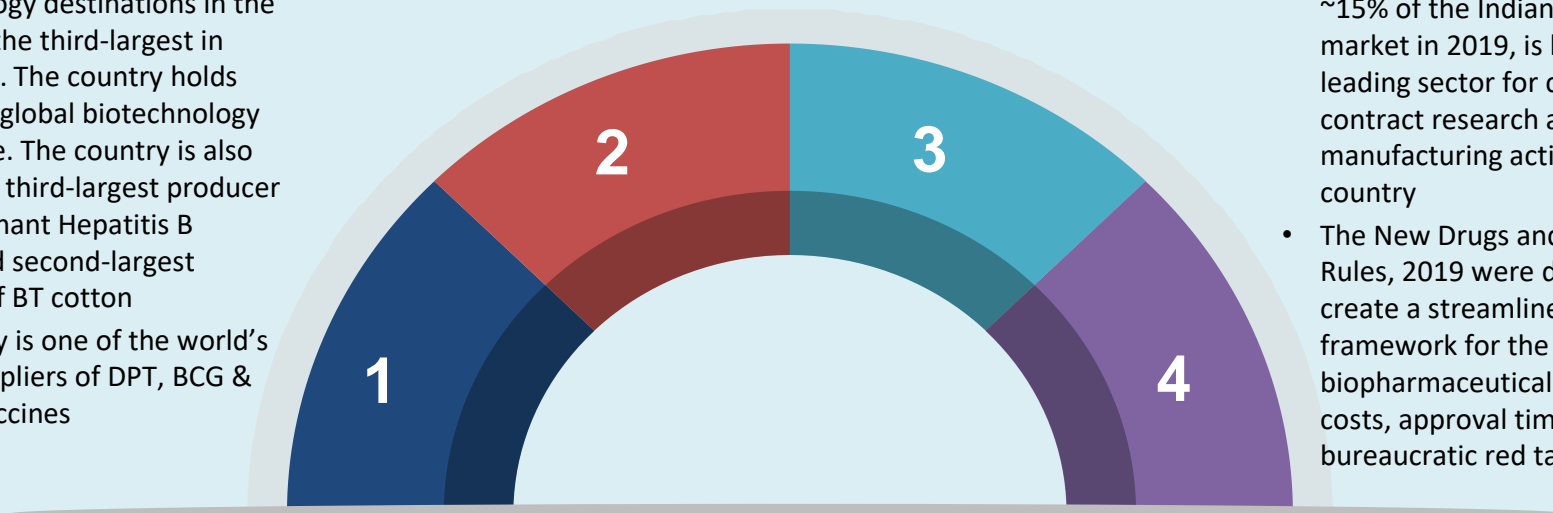
- India is among the top 12 biotechnology destinations in the world and the third-largest in Asia-Pacific. The country holds ~3% of the global biotechnology industry pie. The country is also the world's third-largest producer of recombinant Hepatitis B vaccine and second-largest producer of BT cotton
- The country is one of the world's leading suppliers of DPT, BCG & measles vaccines

3. STRONG GROWTH IN BIOPHARMACEUTICALS

- Biopharmaceutical is the largest segment that contributed ~58% to the Indian biotechnology market in 2019
- In June 2017, Department of Biotechnology, under the 'National Biopharma Mission', launched 'Industry-Academia Mission' to accelerate biopharmaceutical development in India

4. LEADING DESTINATION FOR CLINICAL TRIALS

- Bio-services, which accounted for ~15% of the Indian biotechnology market in 2019, is becoming a leading sector for clinical trials, contract research and manufacturing activities in the country
- The New Drugs and Clinical Trials Rules, 2019 were developed to create a streamlined legal framework for the biopharmaceutical market to reduce costs, approval timelines and cut bureaucratic red tape



Notes: BT Cotton: Genetically modified pest resistant plant cotton, DPT: diphtheria, pertussis, tetanus, BCG: Bacille Calmette-Guerin

Source: Global Bio-India 2019, Biotechnology Industry Research Assistance Council



Advantage India



Advantage India

1. Skilled human capital

- With a total population of 1.3 billion, 50% being under the age of 25, India has large pool of young and skilled workforce
- The government has come up with an industry-academia collaboration with the World Bank to accelerate discoveries and research for early-development of biopharmaceuticals

2. Infrastructure facilities

- Central and state governments have worked to set up several incubators and life science clusters across India.
- 9 DBT-supported biotech parks and 60 BIRAC-supported bio-incubators.
- Under the Union Budget 2021-22, the government announced plans to set up nine biosafety level-3 (BSL-3) laboratories through Pradhan Mantri Aatmanirbhar Swasth Bharat Yojana



4. Epidemiological factors

- Patient pool expected to increase over 20% in the next 10 years, mainly due to rise in population
- New diseases & lifestyle changes to boost demand for drugs and devices

3. Policy support

- 100% under automatic route for greenfield projects for pharmaceuticals
- While 74% is permitted under automatic route for brownfield projects, 100% under government route is permitted for brownfield investments
- Mission COVID Suraksha was announced by the Government of India to accelerate the development and production of indigenous COVID vaccines.
- 100% under automatic route is allowed for the manufacturing of medical devices



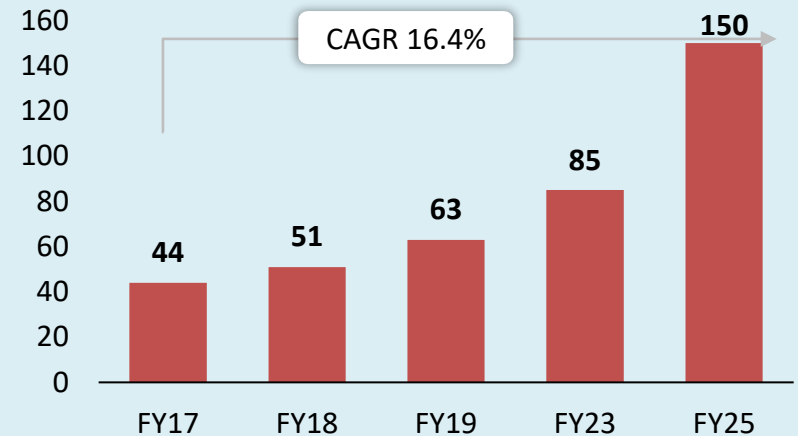
Market Overview



Biotechnology market

- The biotechnology sector in India is witnessing a strong growth trajectory and has proved to be highly inventive.
- India is among the top 12 biotechnology destinations in the world and the third-largest in Asia-Pacific.
- The Indian biotech industry holds 3% of the global market share
- The Indian biotechnology industry is likely to register a CAGR of 16.4% to reach US\$ 150 billion in 2025.
- By 2025, contribution of the Indian biotechnology industry in the global biotechnology market is expected to increase to ~19% from 3% in 2017.
- The biotechnology sector, mainly due to its multidisciplinary approach holds the potential to provide an array of solutions for challenges in sectors such as health, agriculture, environment, energy and industrial processes.
- The biotechnology industry consists of 2,700+ biotech start-ups and is expected to grow to 10,000 by 2024. In 2020, India had >2500+ biotech companies.
- India has 665, the highest number, of FDA-approved plants outside of the US; 44% global abbreviated new drug applications (ANDA) and >1400 manufacturing plants, which comply with WHO requirements

Indian biotechnology industry valuation (US\$ billion)



Indian bioeconomy at a glance(2020)

US\$ 12 billion

India's Biotech
Industry Revenue

1 million

India's Biotech
Workforce

2,500+

Biotech Companies in
India

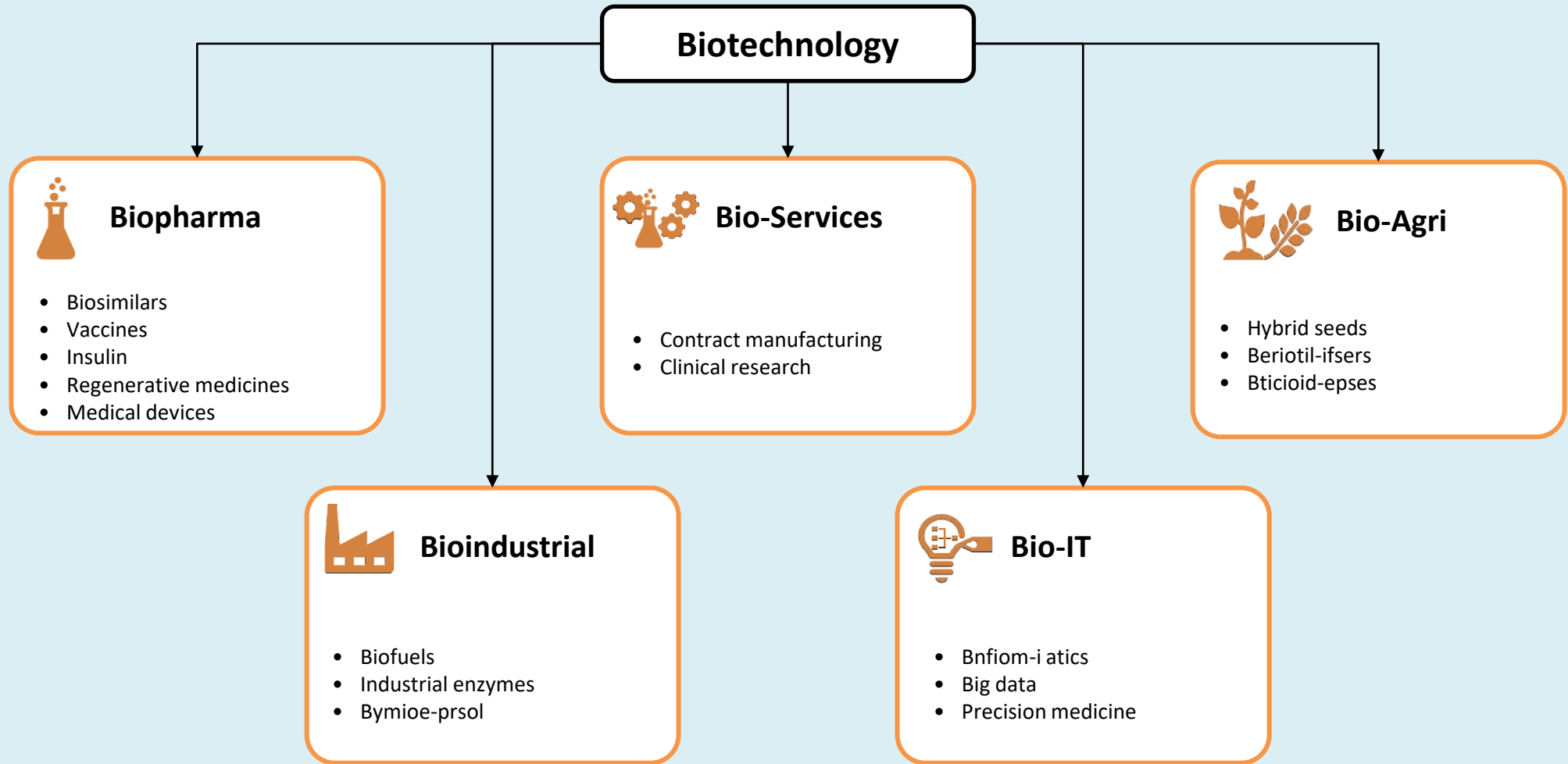
15,500+

Biotech Graduates
Every Year

Notes: FDA: Food and Drug Administration











Source: DPT-BIRAC, Association of Biotechnology Led Enterprises (ABLE)

Indian biotechnology sector is divided into five segments



Source: Association of Biotechnology Led Enterprises (ABLE)

Key players

	Biocon	Indian pharmaceutical company based in Bangalore that manufactures generic active pharmaceutical ingredients
	Serum Institute of India	Manufacturer of immuno-biologicals, which include Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps and Rubella vaccines
	Panacea Biotec Limited	Innovation-driven biotechnology company, undertaking research and development, manufacturing, sales, distribution and marketing of pharmaceuticals, vaccines and biosimilars
	Dr Reddy's Laboratory Limited	Integrated pharmaceutical company, providing affordable and innovative medicines
	Wockhardt	Global pharmaceutical and biotechnology organisation, manufacturing pharmaceuticals, biopharmaceutical formulations and active pharmaceutical ingredients
	Jubilant Life Sciences Co	Integrated global pharmaceutical and life sciences company, engaged in pharmaceuticals, life science ingredients, drug discovery solutions and India-branded pharmaceuticals
	AstraZeneca Pharma India Ltd.	Indian biopharmaceutical company based in Bengaluru that manufactures cardiovascular, renal and metabolic diseases, oncology, and respiratory medicines
	Bharat Serums and Vaccines Ltd	Indian pharmaceutical company based in Mumbai that manufactures plasma derivatives, monoclonals, fertility hormones, antitoxins, antifungals, anaesthetics, cardiovascular drugs and diagnostic products
	Indian Immunologicals Ltd	Indian biopharmaceutical company based in Hyderabad that manufactures animal and human vaccine including rabies, Hepatitis B, Diphtheria and Influenza vaccines
	Bharat Biotech	Indian biotechnology company based in Hyderabad that engages in drug discovery, drug development as well as manufactures vaccines, bio-therapeutics, pharmaceuticals and health care products

Note: News articles



Recent Trends and Strategies



National and international partnerships

Two PSUs ink pact with Covaxinmaker Bharat Biotech to manufacture COVID vaccines

In May 2021, Indian Immunologicals Limited (IIL) and Bharat Immunologicals and Biologicals Corporation (BIBCOL) inked technology transfer pacts with Bharat Biotech to develop the vaccine locally to boost India's vaccination drive.

The two PSUs plan to start the production of vaccines by September 2021.

Merck Sharp & Dohme (MSD) signs licensing pacts with 5 Indian drug firms for oral drug candidate for Covid-19

In April 2021, MSD, a drug firm, entered voluntary licensing agreements for investigational oral antiviral drug candidate 'molnupiravir', which is being studied for the treatment of Covid-19, with Indian drug firms—Sun Pharma, Cipla, Dr Reddy's, Emcure Pharma and Hetero Labs.

Bharat Biotech partners with Precisa Medicamentos to supply Covaxin in Brazil

In January 2021, Bharat Biotech signed an agreement with Precisa Medicamentos to supply Covaxin, a coronavirus vaccine, to Brazil.

Supplies to the private market would be based on receiving market authorisation from ANVISA—the Brazilian regulatory authority.

ZyCoV-D, DNA vaccine candidate against COVID-19

In January 2021, India's first indigenously developed DNA vaccine candidate against COVID-19, ZyCoV-D, by Zydus Cadila, has received approval by Drugs Controller General of India (DCGI), to conduct the Phase III clinical trials. The candidate has been supported by the National Biopharma Mission (NBM), under the sponsorship of BIRAC and the Department of Biotechnology, Government of India.

Indian SARS- CoV-2 Genomics Consortium

In December 2020, the government has launched the Indian SARS-CoV-2

Genomic Consortia (INSACOG),

comprising 10 labs across the country.

The purpose of INSACOG is to monitor the genomic variations in the SARS-CoV-2 on a regular basis through a multi- laboratory network.

Biotechnology University

In December 2020, the University of Edinburgh and Gujarat government signed an agreement to open a biotechnology university in the state by July 2021.

Notes: BIRAC: Biotechnology Industry Research Assistance Council

Source: Company website, news articles

Recent Developments

India allows 100% FDI under the automatic route (a non-resident or Indian company will not require any approval from the government) for greenfield pharmaceuticals and manufacturing medical devices.

2021

- **May 2021:** Under Atmanirbhar Bharat 3.0 (Atmanirbhar Bharat Abhiyaan or Self-reliant India campaign is the vision of new India envisaged by the Hon'ble Prime Minister Shri Narendra Modi, of which the primary aim of this package is to make the country independent and combating the competition in the global market. It is also helpful in filling the gap between demand and supply of essential goods and services in the present debilitating situation) Mission COVID Suraksha was announced by the Government of India to accelerate the development and production of indigenous COVID vaccines. To augment the capacity of indigenous production of Covaxin under the mission, the Department of Biotechnology, Government of India provided financial support in the form of a grant to vaccine manufacturing facilities for enhanced production capacities, which is expected to reach >10 crore doses per month by September 2021.
- **April 2021:** The Department of Biotechnology (DBT), Ministry of Science & Technology, approved additional funding towards clinical studies for India's 'first-of-its-kind' mRNA-based COVID-19 vaccine, HGC019, developed by Pune-based Gennova Biopharmaceuticals Ltd.
- **April 2021:** Drug Controller General Of India (DCGI) gave a restricted emergency use approval to the Zydus Cadila's 'Virafin' for treating patients with moderate COVID-19 symptoms. Virafin is a pegylated interferon alpha-2b (PegIFN), which when subcutaneously injected to the patient in the early stages of infection, resulted in their faster recovery.
- **April 2021:** The CSIR-CMERI, Durgapur, indigenously developed an 'oxygen enrichment technology', which may be effective for treating COVID-19 patients. The oxygen enrichment unit can deliver medical air in the range of up to 15 litres per minute, with oxygen purity of >90%.
- **March 2021:** Gland Pharma Ltd. announced that it will produce 252 million doses of the Sputnik V COVID-19 vaccine in the third quarter of 2021.

2020

- **November 2020:** Bharat Biotech plans to produce 10 types of vaccines including malaria and COVID-19—with a total investment of Rs. 300 crore (US\$ 40.54 million)—at its upcoming unit in Bhubaneswar, Odisha.

National Biopharma mission

		Developing Specific Products		
		Vaccines	Biosimilars	Medical devices
Strengthening Ecosystem	Facilities	GCLP lab for clinical immunogenicity, cell line repository, PDL+GMP	GLP lab for biologics, cell line repository, PDL+GMP	EMI/EMC testing facility, large animal testing facility, prototyping facilities
	Traditional research consortia	Viral repositories High throughput assays Animal models	Raw materials Novel biologics	
	Technology platforms	Animal models Novel assays	Novel cell lines development Indigenous manufacturing techniques	Core technology development
	Enhancing clinical trial capacity	Field site capacities for clinical trials	Hospital based clinical trial networks	Hospital based clinical trial networks
	Skill development	The mission engaged Biotech Consortium India Limited (BCIL) to organise a series of lecture-based workshops to facilitate skill development to build next-generation interdisciplinary skills for product innovations across the country		
	Technology transfer offices	Established 'Technology Transfer Offices' to support technology transfer and entrepreneurship		
		Affordable Products		

Notes: GCLP: Good clinical laboratory practice, GLP: Good laboratory practice, EMI: Electromagnetic interference, EMC: electromagnetic compatibility, PDL: preferred drug list, GMP: Good manufacturing practices

Source: Department of Biotechnology

State-specific policies

South	
Andhra Pradesh Biotechnology Policy 2015-2020	Development of several infrastructure projects and industrial parks
Karnataka Biotechnology Policy 2017-2022	Strengthening the ecosystem required for boosting start-ups, accessing funds for R&D and product development, developing attractive incentives for investors and providing mentorship for growth
Telangana Life Sciences Policy 2015-2020	Development of suitable infrastructure to attract life science companies and become a leading investment destination in the sector
North	
Uttarakhand Biotechnology Policy 2018-2023	Aims to attract new investments worth US\$709 million in the sector; generate employment opportunities for 5000 people by 2023
Himachal Pradesh Biotechnology Policy 2014	Aims to make Himachal a globally competitive destination for development of biotechnology products, processes and services
West	
Rajasthan Biotechnology Policy 2015	Aims to establish world-class research institutes and biomanufacturing infrastructure
Gujarat Biotechnology Policy 2016-2021	Aims to develop a robust biotechnology ecosystem in the state
East	
Assam Biotechnology Policy 2018-2022	Development of the biotechnology industry in Assam, following the growth of bio-agri segment in the state
Odisha Biotechnology Policy 2018	Aims to make Odisha one of the top biotech investment and innovation destinations in the country
Central	
Madhya Pradesh Biotechnology Policy 2003	Conservation and sustainable utilisation of bio-resources to promote socioeconomic growth in the state

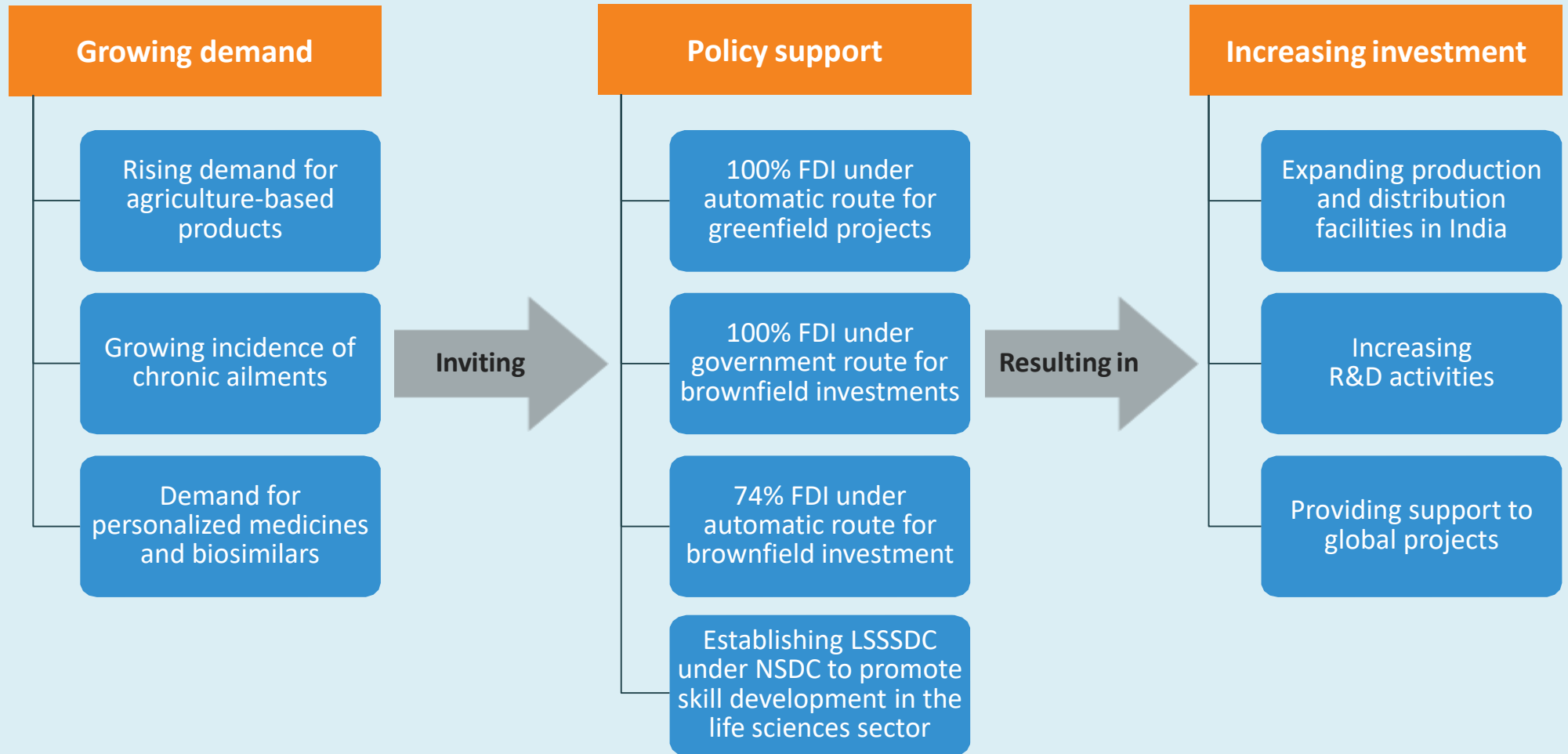
Source: State Government Website



Growth Drivers



Strong demand and policy support driving investments

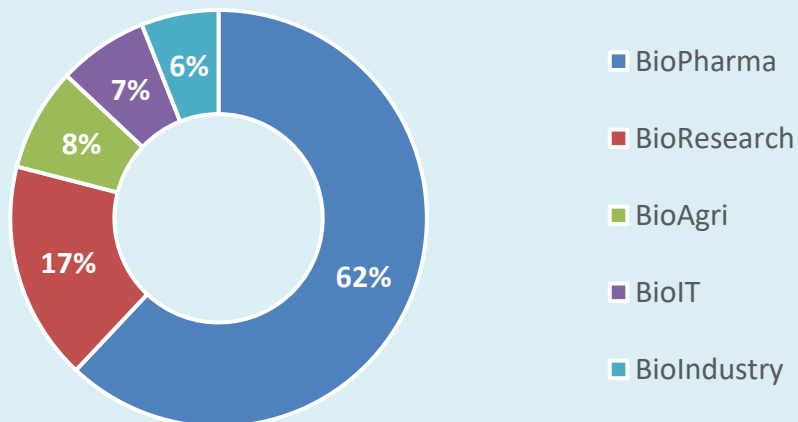


Notes: LSSSDC: Life Sciences Sector Skill Development Council, NSDC: National Skill Development Corporation, R&D - Research and Development
Source: Department of Biotechnology, Association of Biotechnology Led Enterprises (ABLE)

Ecosystem for start-ups

- The start-up ecosystem in India is strongly supported on the back of gradual improvements in the ease of doing business, proof-of-concept funds for start-ups and favorable government policies.
- BIRAC (Biotechnology Industrial Research Assistance Council), a public sector undertaking of DBT, partnered with innovative foundations and universities to focus on 'Make in India' and 'Start-up India' programmes.
- BIRAC established several industry-focussed schemes such as SBIRI, BIPP, Biotechnology Ignition Grant, BioNEST, SITARE, PACE, SIIP, SEED, LEAP and Fund of Funds-AcE. BIRAC has supported 50 bio-incubators for potential entrepreneurs.

Sector-wise representation of startups-2019 (%)



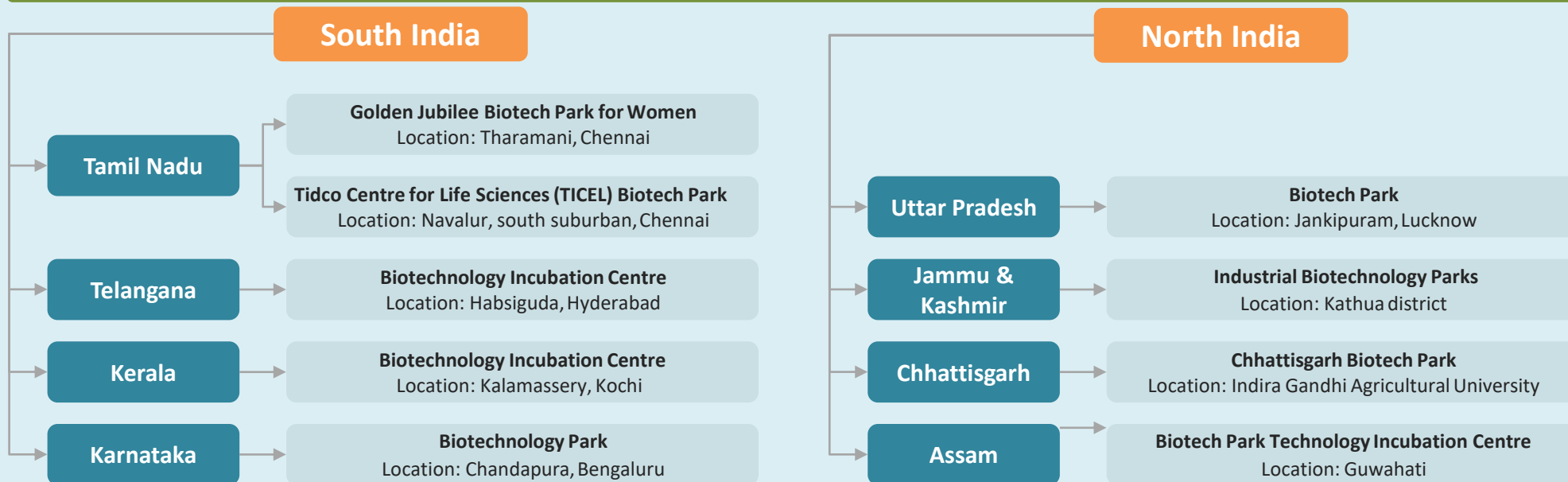
Source: BIRAC

BIRAC (Bio-Incubator)	
Incubators supported	60
Amount committed for BioNEST	US\$ 3.31 million
Incubation area supported	640,349 sq. ft.
Incubation supported	684
Resident incubatees supported	574
Non-resident incubatees supported	110
Total products/technologies commercialized	200
Total employment generated	3,500
Total IPs generated	250
Total trainings/workshops conducted	1,000

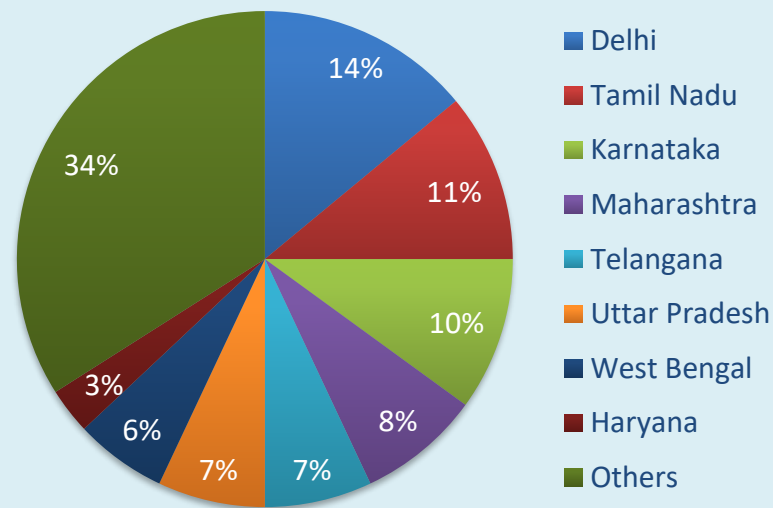
Biotech parks

"These parks are successful accelerating the commercialisation of new technologies, nurturing and maintaining emerging ventures and assisting new enterprises to forge appropriate linkages with other stakeholders of biotechnology sector including academia and the government."

- Secretary, DBT



State-wise Biotech Project Distribution








- Biotechnology parks and incubators are established across the country by the Department of Biotechnology (DBT), under the Ministry of Science and Technology, to translate research into products and services by providing necessary infrastructure support.
- These biotechnology parks offer facilities to scientists, and small and medium sized enterprises (SMEs) for technology incubation, technology demonstration and pilot plant studies to accelerate commercial development of biotechnology.
- The government, at present, supports nine biotechnology parks in various states, with the bulk being in the southern region

Opportunities



Opportunities in various segments

Under the Union Budget 2021-22, the government outlaid Rs. 1,660 crore (US\$ 227.94 million) for biotechnology research and development.

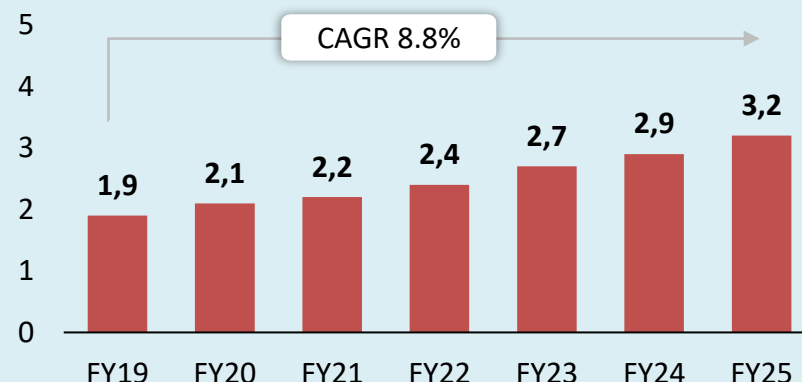
Bio-Services	Bioindustrials	Biopharma	Bio-Agri	Bio-IT
 <ul style="list-style-type: none"> India has potential for clinical trials due to a large and low-cost market Clinical trials in India are regulated by the Central Drug Standard Control Organisation, which has reduced approval time to about 30-90 days, giving opportunity for market growth The country also has the advantage of English-speaking researchers and required medical infrastructure to conduct medical research 	 <ul style="list-style-type: none"> Biofuels and bioenergy are considered alternative resources and are gaining popularity in India Rise in energy demand is leading to an increase in dependence on fossil fuel imports As a result, companies can develop a strategy to reduce import dependence through biofuels and bioenergy 	 <ul style="list-style-type: none"> The Indian biologics market is expected to register a CAGR of 22% from 2019 to 2025 to reach US\$ 12 billion by 2025. Growth of biologics provides opportunity for biosimilars in the market. India has availability of vast patient pool for various class of disease 	 <ul style="list-style-type: none"> India's Union budget 2021-22 states the government's plan to enhance farm productivity and focus on food security. This will likely increase the importance of bio-agriculture, which will enhance efficient food production. 	 <ul style="list-style-type: none"> Biotechnology has immense growth potential in the Bio-IT segment, given the rising need for technology to transform data generated by R&D institutes, clinics, hospitals, etc., into a defined format India's IT industry is witnessing substantial growth and has the requisite IT infrastructure to cater to the needs of the global Bio-IT industry

Source: Association of Biotechnology Led Enterprises (ABLE), Institute for Competitiveness

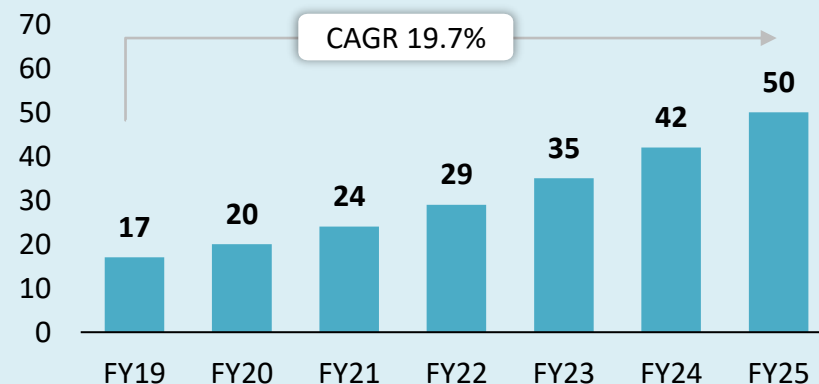
Key investment opportunities

- India is among the preferred destinations for clinical trials owing to a large patient pool, transformation of the healthcare market, well-educated physicians and cost competitiveness.
- The Union Ministry for Health and Family Welfare has reported new Drugs and Clinical Trials Rules, 2019, changing the regulatory landscape for approval of new drugs and conducting clinical trials in the country.
- The Indian Council of Medical Research (ICMR) has selected 12 institutes for clinical trial of the country's first indigenous COVID-19 vaccine.
- The Indian medical devices industry consists of MNCs and SMEs are expected to reach US\$ 50 billion by 2025 with domestic manufacturers accounting for ~65%.
- India is among the top 20 markets for medical devices in India and 4th largest in Asian markets.
- India has six medical device manufacturing clusters where efficient manufacturing is done at lower costs.
- On April 13, 2021, the Union Government approved to streamline and fast-track the regulatory system for COVID-19 vaccines that have been approved for restricted use by the US FDA, EMA, UK MHRA, PMDA Japan or those listed in WHO Emergency Use Listing (EUL). This decision is likely to facilitate quicker access to foreign vaccines by India and encourage imports, including imports of bulk drug materials, optimise utilisation of domestic fill and finish capacity, etc.; this will boost vaccine manufacturing capacity and total vaccine availability within the country.

Clinical trials market in India (US\$ billion)



Medical devices market in India (US\$ billion)



Note: US FDA - United States Food and Drug Administration, EMA - European Medicines Agency, UK MHRA – United Kingdom Medicines and Healthcare products Regulatory Agency, PMDA - Pharmaceuticals and Medical Devices Agency, Japan

Source: News Articles

Upcoming biotechnology projects in India

Upcoming Biotechnology Projects	State Presence	Cost of the Project (US\$ million)
Mangalapuram Bio 360 Life Sciences Park Project - Phase II	Kerala	56.56
Kupwara Biotechnology	Jammu & Kashmir	4.5

Source: NewsArticles

Ringier in 2020-21: After biosimilar foray into US, Europe, all eyes on how Indian pharma firms leverage investments

- It has been over a decade since Indian companies began looking at the biosimilar opportunity. It is not an easy space to be in and quite unlike their traditional stronghold of generics. However, it is a space that is linked to the nature of the future drugs -- today, as is often quoted by pharma experts, one in every three new drugs approved in the global markets is a biotech drug, especially in fields like cancer care.
- While in the Indian market, there are estimated over 50 (and counting) different biosimilars already, the big money lies in being able to launch these drugs in markets of Europe and the US. So far, hardly a couple of Indian companies have been able to do this. Much of this happened in the decade just concluded.
- **Intas Pharmaceuticals** became the first Indian company to get a biosimilar registered of the biotech drug Filgrastim under the brand Accofil in the EU in February 2015. It is now getting ready for more products and for foray into the US.
- It is, however, **Biocon**, along with **Mylan**, that during the decade emerged as a company that launched products in these markets, and even received a good response in the US. Biocon is looking forward to \$1 billion biologics (largely biosimilars) revenue by FY2022.
- Today, almost all the leading Indian pharma companies are into biosimilars space, with all having a biotech branch on their pharma tree. Other than Biocon and Intas, the big names include Dr Reddy's Laboratories, Zydus Cadila, Reliance Life Sciences, Emcure, Glenmark, Aurobindo, Lupin and Alkem Laboratories.



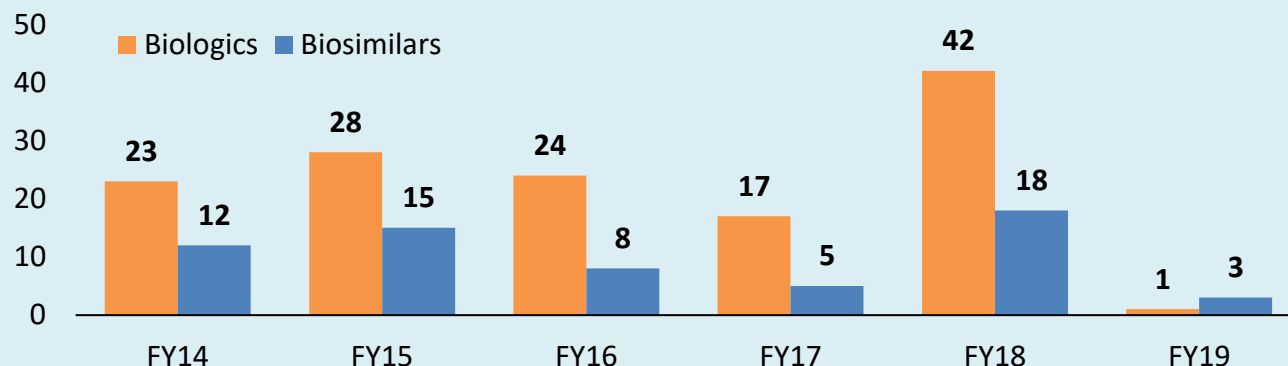
Source: News Articles

India: emerging hub for biologics and biosimilars

The global life sciences industry is shifting from chemical-based drug to biologics and biosimilars; India approved its first biosimilar as early as 2000

- India's first biosimilar was approved in 2000 for hepatitis B. In 2019, there were approximately >95 approved biosimilars.
- Biologics economy in India was valued at US\$ 7 billion in 2019 and is forecast to reach US\$ 12 billion by 2025.
- In India, the biologics segment is led by Biocon Ltd., and has commercialised the biosimilars Trastuzumab and Pegfilgrastim among others in partnership with Mylan.
- Other players in the space include Dr Reddy's Laboratories, Intas Pharmaceuticals, Zydus Cadila and Lupin.

Number of biologics and biosimilars approved in India



Drug name	Originator company	Originator companies	First Launched
bevacizumab	Dr Reddy's Laboratories Ltd.	Dr Reddy's Laboratories Ltd	19-Aug-19
trastuzumab	Dr Reddy's Laboratories Ltd	Dr Reddy's Laboratories Ltd	26-Jul-18
pegfilgrastim	Lupin Ltd	Lupin Ltd	25-Jul-18
pegfilgrastim	Biocon Ltd	Biocon Ltd; Mylan NV	30-Jun-18
adalimumab	Hetero Group	Hetero Group	03-Jan-18
bevacizumab	Biocon Ltd	Biocon Ltd; Mylan NV	23-Nov-17
bevacizumab	Zydus-Cadila Group	Zydus-Cadila Group	30-Sep-17

Source: Biologics Division, CDSCO, Association of Biotechnology Led Enterprises (ABLE)

Opportunity in Biopharma

2. VACCINES

- India exports vaccines to about 150 countries
- The country covers 40-70% of the World Health Organisation (WHO) demand for DPT (diphtheria, pertussis or whooping cough, and tetanus) and BCG (Bacille Calmette-guérin) vaccines against tuberculosis, followed by ~90% of its demand for the measles vaccine

1. BIOSIMILARS

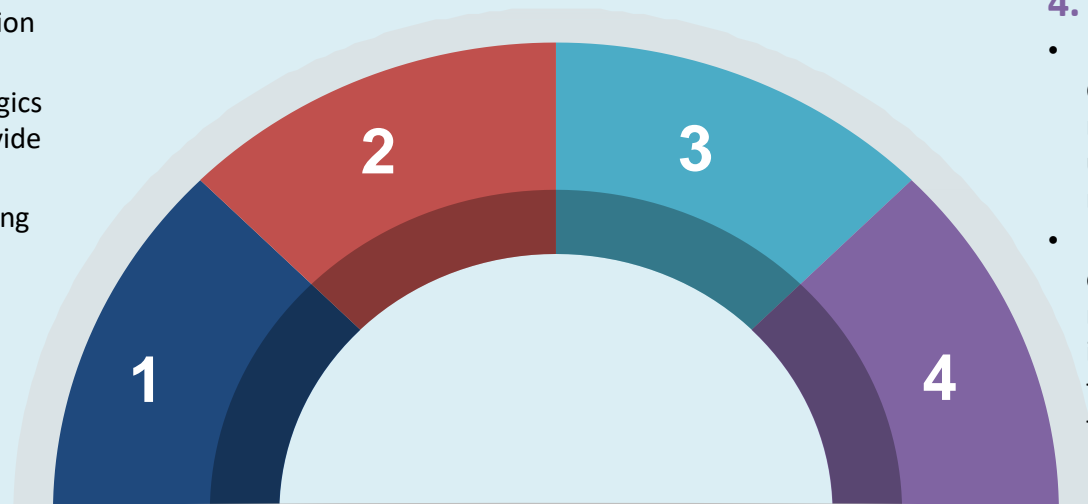
- India has >50 approved biosimilar products and the market is expected to reach US\$ 2.2 billion by 2025
- Expiry of ~US\$ 70 billion biologics drugs patent by 2020 will provide export opportunities
- Global companies are leveraging both generics to contain healthcare costs and Indian companies such as Biocon are positioning themselves to deliver affordable access to innovative and inclusive healthcare solutions

3. REGENERATIVE MEDICINE

- Several research institutes in India are investigating the use of stem cells to regenerate nerve, heart and adult muscle cells, and repair damaged bone tissues
- Rise in chronic disease incidences is driving the demand for regenerative medicine
- The Indian Council of Medical Research has issued the National Guideline for Stem Cell Research to promote clinical applications of stem cell research in ophthalmology, cardiology and spinal cord repair

4. INSULIN

- India is likely to witness >100 million diabetics by 2030. With rising number of patients, ~50% are undiagnosed, providing domestic market opportunity to the country
- Indian players are also creating opportunities in the international market. For example, Biologics and its partner Mylan N.V. launched their insulin glargine injection under the brand name Semglee in the US





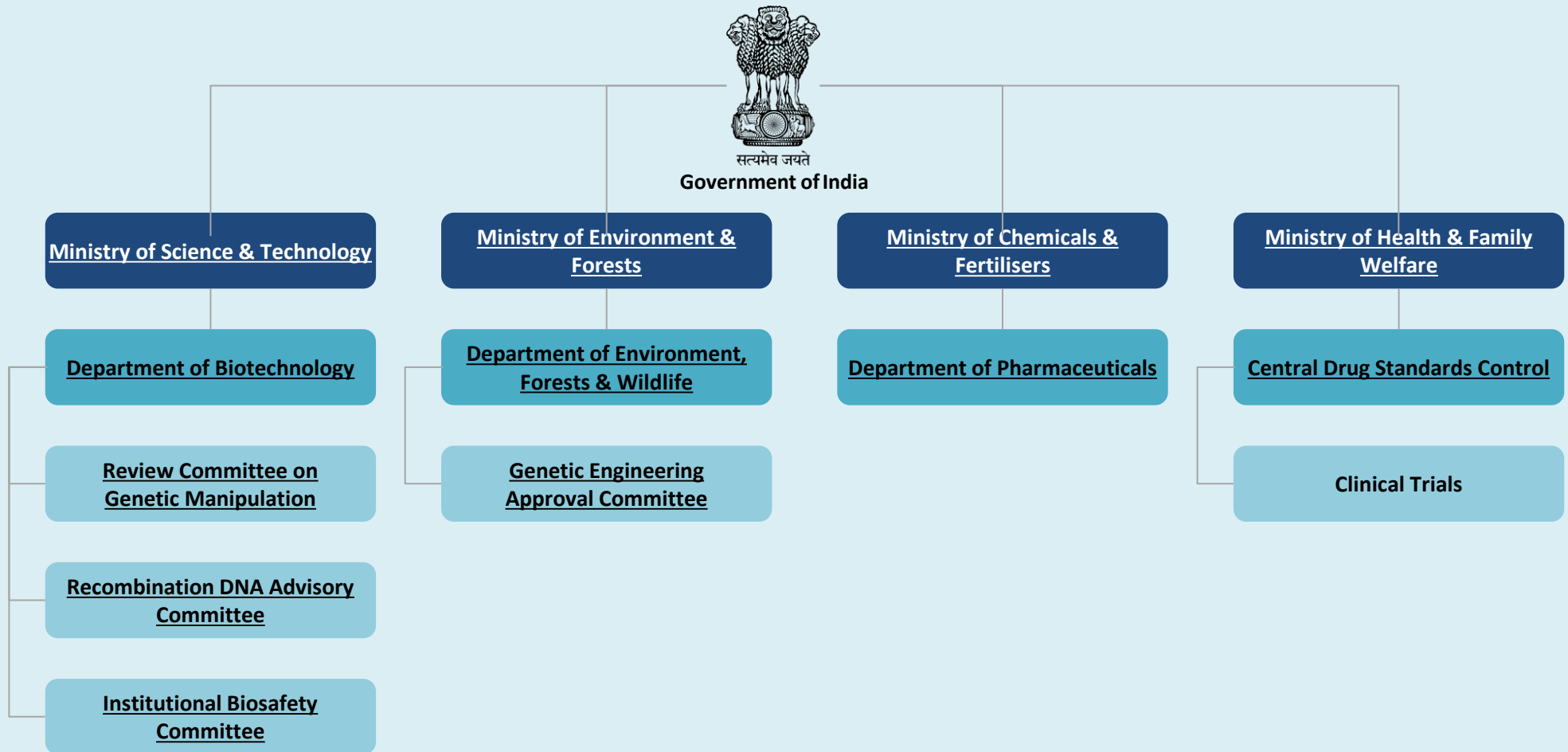
Key Industry Contacts



key industry organisations

	Agency	Contact Information
	Department of Biotechnology, Ministry of Science & Technology	6th-8th Floor, Block 2 CGO Complex, Lodhi Road New Delhi – 110 003.India Phone: 91-11-2436 2950 Website: www.dbtindia.gov.in
	Department of Science and Technology, Ministry of Science and Technology	Department of Science & Technology, Technology Bhavan, New Mehrauli Road, New Delhi-110016 Phone: +91-11-26562122/25/33/44, 26567373, 26962819 Fax +91-11-26863847, 26515637 Website: www.dst.gov.in
	Biotechnology Industry Research Assistance Council (BIRAC)	1st Floor ,MTNL Building ,9 , CGO Complex, Lodhi Road, New Delhi-110003 Website: www.birac.nic.in , E-mail address: birac.dbt@nic.in Phone: + 91-11-24389600 Fax: + 91-11-24389611
	Council of Scientific and Industrial Research (CSIR)	Council of Scientific and Industrial Research, Anusandhan Bhawan, 2 Rafi Ahmed Kidwai Marg, New Delhi - 110001 Phone: +91-11-23737889 Website: www.csir.res.in
	Association of Biotechnology Led Enterprises	# 123/C, 16th Main Road,5th Cross, 4th Block, Near Sony World showroom / Headstart school, Koramangala, Bangalore - 560034, India Phone: +91-80-41636853, Fax: +91-80-25633853 Website: www.ableindia.in , E-mail address: info@ableindia.org.in
	The Biotech Research Society, India	Biotechnology Division, NIIST, Industrial Estate P.O., Trivandrum 695019 Phone: +91-471-251 5279 Website: https://www.brsi.in/

Departments concerning biotech approvals





Indian Biotech Leaders



Top Biotechnology Companies in India 2021

Top 10 Biotechnology Companies In India In 2021

Biocon Ltd.

Serum Institute of India

Panacea Biotech Ltd.

Novo Nordisk

SIRO Clinpharm

Novozymes South Asia

Shantha Biotech

Indian Immunologicals

GlaxoSmithKline Pharmaceuticals Ltd.

Wockhardt Ltd.

1

Biocon Ltd



- Biocon is one of the largest biotechnology companies in India. The company focuses on continuous innovation in order to manufacture life-saving medicines at an affordable cost. This is evident from the humongous amount of ₹5,271 million spent on R&D activities in the previous year.
- Holding over 1220 patents, the company is working on its psoriasis biologic drug ALZUMAb™ in the fight against the global pandemic.

2

Serum Institute of India



- They manufacture highly specialized life saving biologicals like vaccines using cutting edge genetic and cell based technologies, antisera and other medical specialties
- Vaccines manufactured by them are accredited by the WHO, Geneva and are being used in around 170 countries
 - Serum Institute of India Pvt. Ltd. is now the world's largest vaccine manufacturer by number of doses produced and sold globally (more than 1.5 billion doses) which includes Polio vaccine as well as Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps and Rubella vaccines.

3

Panacea Biotech

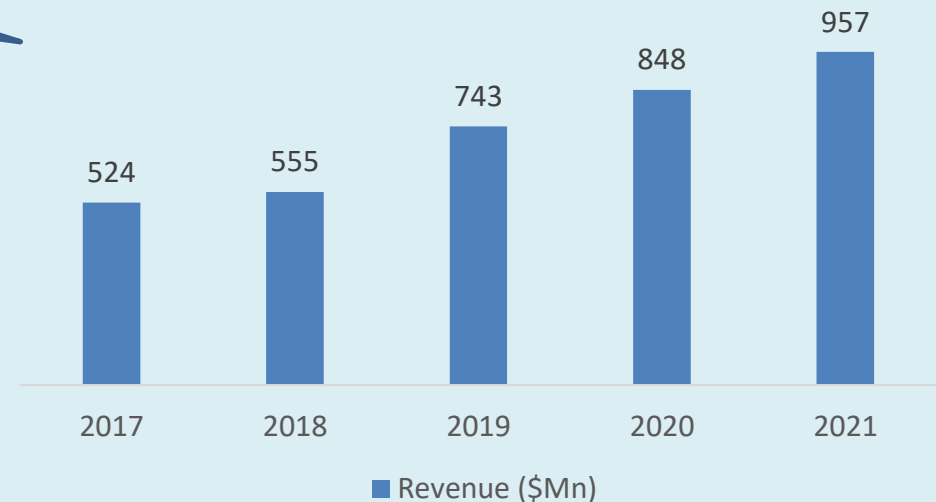


- It is an Innovation driven Biotechnology company doing Research and Development, Manufacturing, Sales, Distribution and Marketing of Pharmaceuticals, Vaccines and Biosimilars.
- Panacea Biotech is one of the largest Vaccine Manufacturing Company in India and is well acknowledged by the UN Health Agencies in partnering the Polio eradication initiative with supplies of millions of doses of WHO Pre-qualified Polio vaccine. As a sequel to the completion of full range of Oral polio vaccines (tOPV, mOPV1, mOPV3 & bOPV).

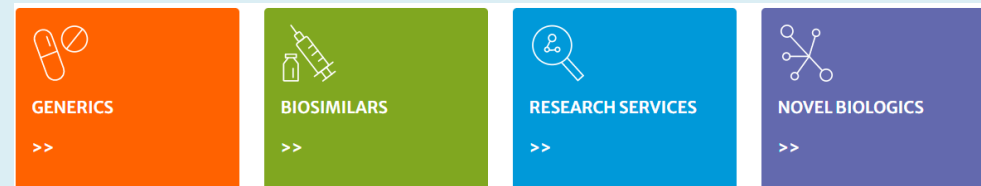
Crossed annual revenue turnover of US\$ 284million in the generics business.
 Started a clinical trial in India to study Itolizumab in treating moderate to severe patients with COVID-19 complications.
 Is the sixth-largest manufacturer of sodium bicarbonate worldwide.

- Biocon is fully integrated, innovation-led biopharmaceutical company, focussed on delivering affordable innovation. The company delivers innovative biopharmaceutical solutions.
- Biocon's global businesses – generics, biosimilars, research services and novel biologics research, develop and manufacture innovative biopharmaceutical medicines for unmet medical needs and branded formulations cater to the Indian market.
- Biocon's business strategy of delivering affordable innovation is well aligned with this emerging paradigm.
- Biocon's fully integrated business model spans the entire drug value chain, from pre-clinical discovery to clinical development and through to commercialisation.

Revenue (\$Mn)



Products/Services by Biocon

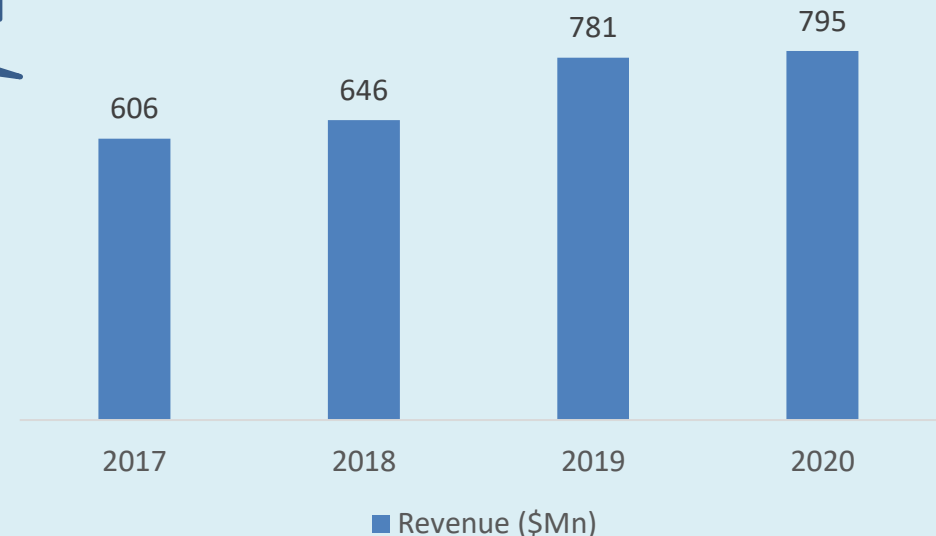


Serum Institute of India

One of India's top biotechnology company selling products in 140 countries worldwide
With more than 1.3 billion doses produced and sold globally

- Serum Institute of India is ranked as India's No. 1 biotechnology company, manufacturing highly specialised lifesaving biologicals like vaccines using cutting edge genetic and cell based technologies, antisera and other medical specialties.
- Serum Institute of India was founded in **1966 by Dr. Cyrus Poonawalla** with the aim of manufacturing life-saving **immuno-biologicals**, which were in shortage in the country and imported at high prices.
- Thereafter, several life-saving biologicals were manufactured at prices affordable to the common man and in abundance, with the result that the country was made self-sufficient for **Tetanus Anti-toxin and Anti-snake Venom serum, followed by DTP (Diphtheria, Tetanus and Pertussis) group of Vaccines and then later on MMR (Measles, Mumps and Rubella) group of vaccines**
- Serum Institute of India has set up the **Serum Bio Pharma Park**, India's first biotech special economic zone (SEZ).
- The Park is adjoining Serum Institute's existing manufacturing unit and is a sector-specific SEZ meant for biotechnology and pharmaceutical products.

Revenue (\$Mn)



Serum Institute could rake in at least \$1 billion by end of 2021 and overall revenue of \$4 billion through the Covid vaccine deals

Panacea Biotech

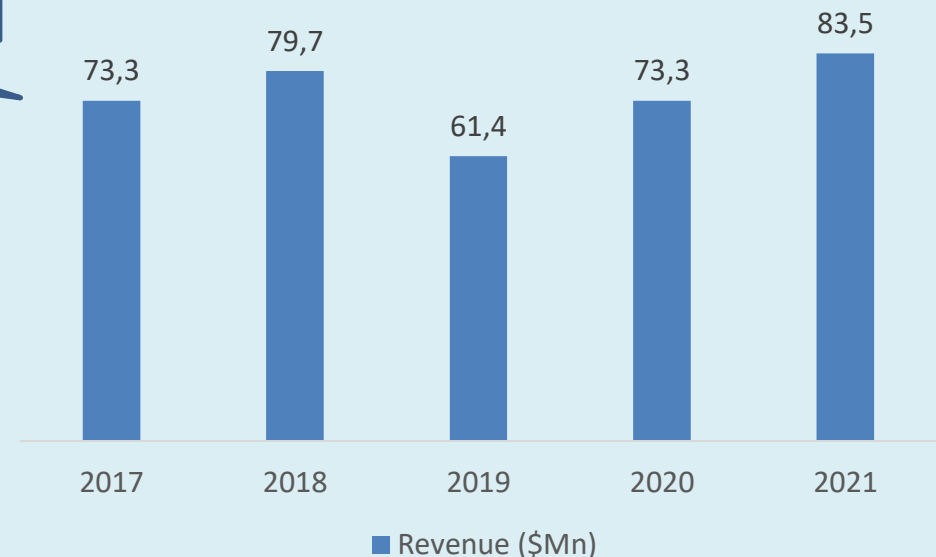
First company to develop fully liquid Pentavalent vaccine (DTwP+Hep B+Hib) Easy Five in 2005

The company registered growth of 44% in September 2019 compared with September 2018.

It has state-of-art production facilities at Baddi (Himachal Pradesh), Lalru (Punjab) and Delhi to manufacture tablets, capsules, ointments liquids, herbal formulations and vaccines.

- Panacea Biotech was established in **1984** under the name **Panacea Drugs Private Limited** and got publicly listed in **September 1995**
- The company does **research and development, manufacturing, sales, distribution and marketing** of **pharmaceuticals, vaccines** and **biosimilars**.
- The company's portfolio includes **prescription products** in niche therapeutic areas such as **pain management, diabetes & cardiovascular management, oncology, renal disease management, osteoporosis management, anti-tubercular, gastro-intestinal care products** and **vaccines**.
- The company **has developed four distinguished**, ultra-modern, state-of-art R&D centres in different locations, having internal capabilities for constant research, with over 300 highly professional and skilled scientists engaged in various aspects of research.
- As on 31st March 2011, the company had **filed over 1400 patent** applications in various parts of the world including India. Of these, **382 have been granted patent** and others are under various stages of examination or publication by the patent authorities.

Revenue (\$Mn)



Panacea Biotech and Refana collaborate to develop COVID-19 vaccine
Panacea transfers pharmaceuticals business to its wholly owned subsidiary 'Panacea Biotech Pharma Limited'

PE/VC Investors



PE/VC investments in pharma companies grow 3.5X in 2020, cross \$1 bn mark

- Private Equity (PE)/Venture Capital (VC) investments in pharmaceutical companies have grown by more than 3.5 times in 2020 and for the first time crossed \$1 billion to touch \$1.69 billion during January to September 2020.
- According to experts, the industry enjoys respect and enduring relationships among investors on the back of good exits.
- Fund managers said investors remained positive on the pharma manufacturing activity in India, which further strengthened during the Covid-19 period, on account of restrictions imposed on pharma imports from China.
- During January to September 2020, the sector attracted \$1.69 billion (in 19 deals) as compared to \$368 million, a year ago.
- Last year, as a whole, the sector attracted \$825 million across 18 deals, according to Venture Intelligence data.
- It may be noted, 2020 is a year in which healthcare & life sciences has taken centre stage due to the coronavirus (Covid-19) pandemic.

Carlyle

THE CARLYLE GROUP

Carlyle invested \$490 million in Piramal Pharma in 2020
Carlyle's also invested \$210 million in SeQuent Scientific in 2020

KKR

KKR

KKR invested \$414 million in JB Chemicals in 2020

ChrysCapital

CHRYSCAPITAL

ChrysCapital invested \$132 million in Intas Pharmaceuticals

Appendix



Glossary

- **CAGR:** Compound Annual Growth Rate
- **Capex:** Capital Expenditure
- **CENVAT:** Central Value-added Tax
- **EHTP:** Electronic Hardware Technology Park
- **EPCG:** Export Promotion Capital Goods Scheme
- **FDI:** Foreign Direct Investment
- **FY:** Indian Financial Year (April to March); So, FY10 implies April 2009 to March 2010
- **LCD:** Liquid Crystal Display
- **R&D:** Research and Development
- **US\$:** US Dollar
- Wherever applicable, numbers have been rounded off to the nearest whole number

Exchange rates

Exchange Rates (Fiscal Year)

Year	Rs. Equivalent of one US\$
2004-05	44.95
2005-06	44.28
2006-07	45.29
2007-08	40.24
2008-09	45.91
2009-10	47.42
2010-11	45.58
2011-12	47.95
2012-13	54.45
2013-14	60.50
2014-15	61.15
2015-16	65.46
2016-17	67.09
2017-18	64.45
2018-19	69.89
2019-20	70.49
2020-21	73.20

Exchange Rates (Calendar Year)

Year	Rs. Equivalent of one US\$
2005	44.11
2006	45.33
2007	41.29
2008	43.42
2009	48.35
2010	45.74
2011	46.67
2012	53.49
2013	58.63
2014	61.03
2015	64.15
2016	67.21
2017	65.12
2018	68.36
2019	69.89
2020	74.18
2021*	74.94

Note: As of April 2021

Source: Reserve Bank of India, Average for the year

Pharmaceuticals

August 2021

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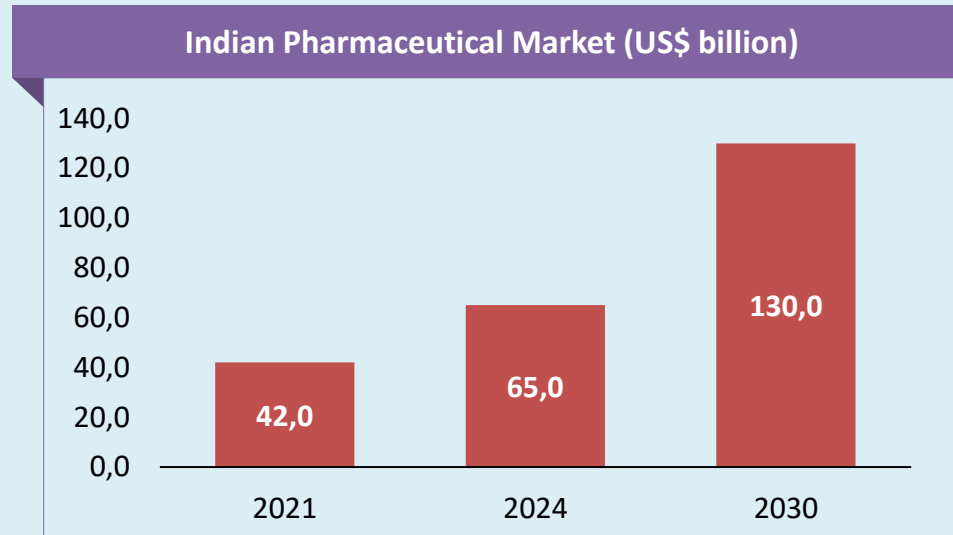
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Indian Pharmaceutical Market



Indian pharmaceuticals market

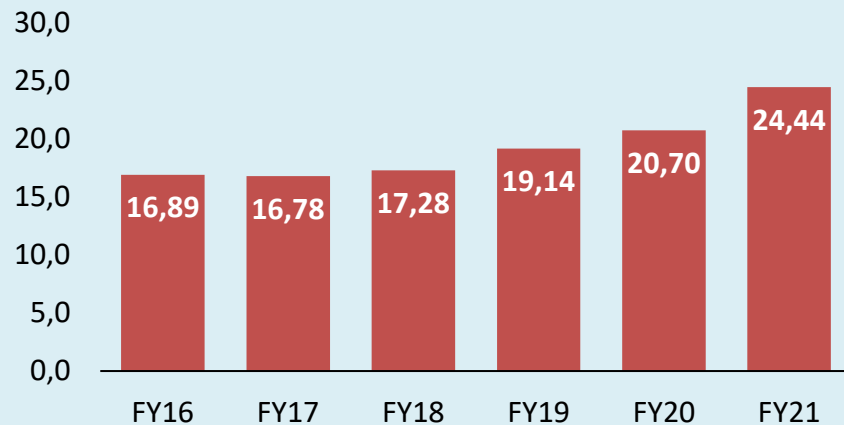


- Globally, India ranks 3rd in terms of pharmaceutical production by volume and 14th by value. The domestic pharmaceutical industry includes a network of 3,000 drug companies and ~10,500 manufacturing units.
- According to the Indian Economic Survey 2021, the domestic market is expected to grow 3x in the next decade. India's domestic pharmaceutical market is estimated at US\$ 42 billion in 2021 and likely to reach US\$ 65 billion by 2024 and further expand to reach ~US\$ 120-130 billion by 2030.
- The Ayurveda sector in India reached US\$ 4.4 billion by 2018 end and grow at 16% CAGR until 2025.
- In November 2020, Prime Minister Mr. Narendra Modi dedicated two future-ready national premier Ayurveda institutions to the country to mark celebrations of the '5th Ayurveda Day'. Also, World Health Organisation (WHO) announced the setting up of the Global Centre of Traditional Medicine in India.

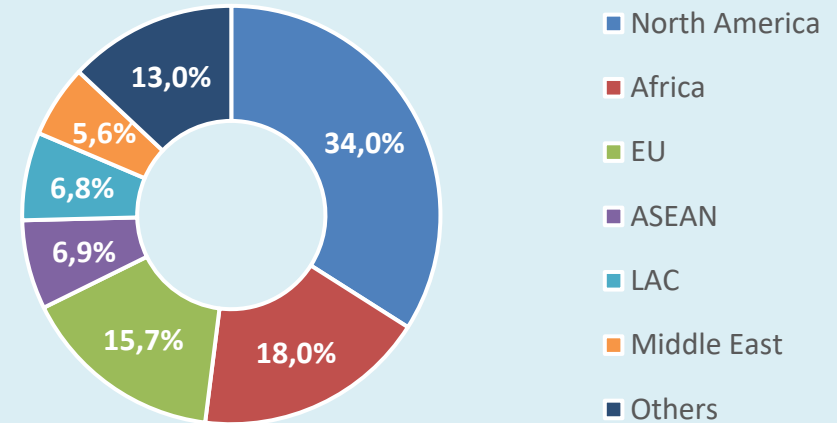
Source: Department of Pharmaceuticals, PwC, McKinsey, AIOCD AWACS, IQVIA, CII

Pharmaceuticals export to continue witnessing positive growth

Drugs & Pharmaceuticals Exports from India (US\$ billion)



Major Export Destinations in India's Pharma Export in FY20 (%)



- India is the world's largest provider of generic medicines; the country's generic drugs account for 20% of global generic drug exports (in terms of volumes). Indian drugs are exported to more than 200 countries in the world, with the US as the key market.
- Indian pharma companies are capitalising on export opportunities in regulated and semi-regulated markets.
- Exports of Indian pharmaceuticals, including bulk drugs, intermediates, drug formulations, biologicals, AYUSH & herbal products and surgical products, reached US\$ 16.28 billion in FY20. India's drugs and pharmaceuticals exports stood at US\$ 24.44 billion in FY21.
- The biggest export destination for Indian pharma product is the US. In FY20, 32.1% of India's pharma exports were to the North America, followed by 17.96% to Africa and 15.70% to the European Union.
- India's formulation surged 18% and the bulk drug exports rose 9% y-o-y in the first half of FY21, according to a report by Crisil.

Note: EU - European Union, ASEAN - Association of Southeast Asian Nations, LAC - Latin America and the Caribbean

Source: Department of Commerce India, Department of Pharmaceuticals, India Business News, Global Trade Atlas, KPMG US-India Dynamic June 2018, Pharmexcil



Trends in Pharmaceutical Market



Notable trends in the Indian pharmaceuticals sector

2. PRODUCT LAUNCH

- In May 2021, the Department of Science & Technology developed new multiplex RT-PCR kit with novel gene targets to facilitate detection across various mutant strains of COVID 19.
- In May 2021, a Bangalore-based start-up—PathShodh Healthcare—developed a novel, point-of-care Electrochemical ELISA test that enables fast and accurate estimation of antibody concentration of COVID-19 in clinical samples.
- In May 2021, Zydus Cadil launched a next-generation breast cancer drug—Trastuzumab Emtansine—at a fraction of its existing cost.
- In April 2021, the CSIR-CMERI, Durgapur, indigenously developed the technology of Oxygen Enrichment Unit (OEU). The unit can deliver medical air in the range of ~15 litres per minute, with oxygen purity of >90%. It transferred the technology to MSMEs—Conquerent Control Systems Pvt. Ltd., A B Elasto Products Pvt. Ltd. and Automation Engineers, Mech Air Industries and Auto Malleable.
- In February 2021, Glenmark Pharmaceuticals launched SUTIB, a generic version of Sunitinib oral capsules, for the treatment of kidney cancer and Natco Pharma launched Brivaracetam for the treatment of epilepsy in India.

1. INCREASING EXPORTS

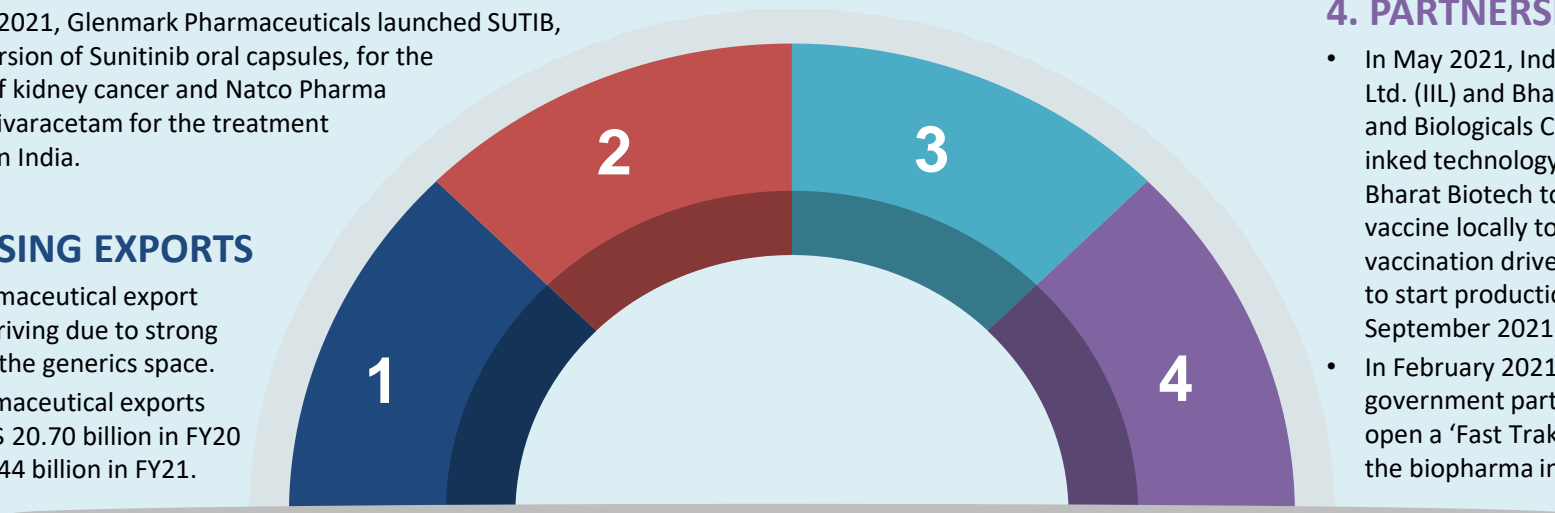
- India's pharmaceutical export market is thriving due to strong presence in the generics space.
- Indian pharmaceutical exports stood at US\$ 20.70 billion in FY20 and US\$ 24.44 billion in FY21.

3. EXPANSION

- In November 2020, Indian Immunologicals Ltd. commenced work on Rs. 75 crore (US\$ 10.17 million) viral antigen manufacturing facility in Genome Valley, Telangana, that will enhance its vaccine production capacity by 35% by October 2021.
- In December 2020, Lupin obtained clearance from the US health regulator to sell its generic penicillamine tablets—used for the treatment of Wilson's disease and cystinuria—in the US.
- In December 2020, Piramal Pharma Solutions announced plans to invest Rs. 235 crore (US\$ 32 million) to expand its facility in Michigan, US, with additional capacity and new capabilities for development and manufacturing of active pharmaceutical ingredients (APIs).

4. PARTNERSHIPS

- In May 2021, Indian Immunologicals Ltd. (IIL) and Bharat Immunologicals and Biologicals Corporation (BIBCOL) inked technology transfer pacts with Bharat Biotech to develop the vaccine locally to boost India's vaccination drive. The two PSUs plan to start production of vaccines by September 2021.
- In February 2021, the Telangana government partnered with Cytiva to open a 'Fast Trak' lab to strengthen the biopharma industry of the state



COVID-19 fightback from the Indian pharmaceuticals sector

2. R&D RELATED TO COVID-19

- In May 2021, the Government of India invited R&D proposals on critical components and innovations in oxygen concentrators by June 15, 2021.
- In May 2021, the Drugs Controller General of India cleared applications from five pharmaceutical companies to manufacture anti-fungal drug Amphotericin B used to treat mucormycosis or black fungus.
- In April 2021, the Department of Biotechnology, Ministry of Science & Technology, approved additional funding towards clinical studies for India's 'first-of-its-kind' mRNA-based COVID-19 vaccine, HGC019, developed by Pune-based Gennova Biopharmaceuticals Ltd

1. COLLABORATIONS

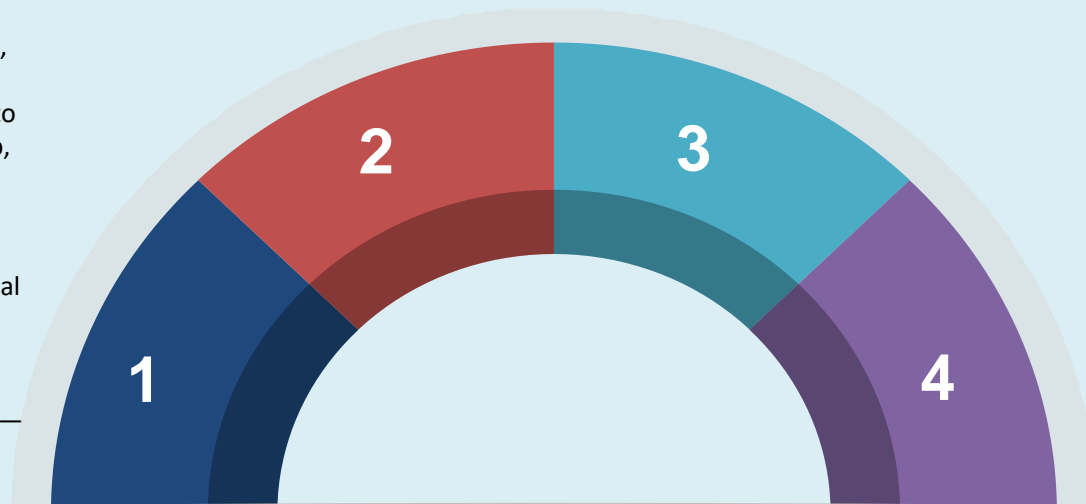
- In May 2021, Eli Lilly & Company issued non-exclusive voluntary licenses to pharmaceutical companies—Cipla Ltd., Lupin Ltd., Natco Pharma & Sun Pharmaceutical Industries Ltd.—to produce and distribute Baricitinib, a drug for treating COVID-19.
- In April 2021, MSD, a drug firm, entered voluntary licensing agreements for investigational oral antiviral drug candidate 'molnupiravir', which is being studied for the treatment of COVID-19, with Indian drug firms—Sun Pharma, Cipla, Dr Reddy's, Emcure Pharma and Hetero Labs

3. GOVERNMENT INITIATIVES

- In May 2021, under Atmanirbhar Bharat 3.0, Mission COVID Suraksha was announced by the Government of India to accelerate development and production of indigenous COVID vaccines. To augment the capacity of indigenous production of Covaxin under the mission, the Department of Biotechnology, Government of India, provided financial support in the form of a grant to vaccine manufacturing facilities for enhanced production capacities, which is expected to reach >10 crore doses per month by September 2021.
- In April 2021, the Union Government agreed/decided to streamline and fasttrack the regulatory system for COVID-19 vaccines that have been approved for restricted use by the US FDA, EMA, UK MHRA, PMDA Japan or those listed in the WHO Emergency Use Listing (EUL). This decision is likely to facilitate quicker access to foreign vaccines by India and encourage imports.

4. INDIAN PLAYERS GLOBAL EXPOSURE

- In February 2021, the Russian Ministry of Health allowed Glenmark Pharmaceuticals to market its novel fixed-dose combination nasal spray in Russia.
- In November 2020, Hetero Drugs, a Hyderabad-based pharmaceutical company, reached an agreement with the Russian Direct Investment Fund (RDIF) to produce >100 million doses per year of the RDIF's Sputnik V COVID19 vaccine in India.



States hosting key pharmaceutical ventures

- Sun Pharma's API manufacturing facility at Toansa, Malanpur, Guwahati, Ankleshwar, Panoli, Ahmednagar, Maduramthakam.

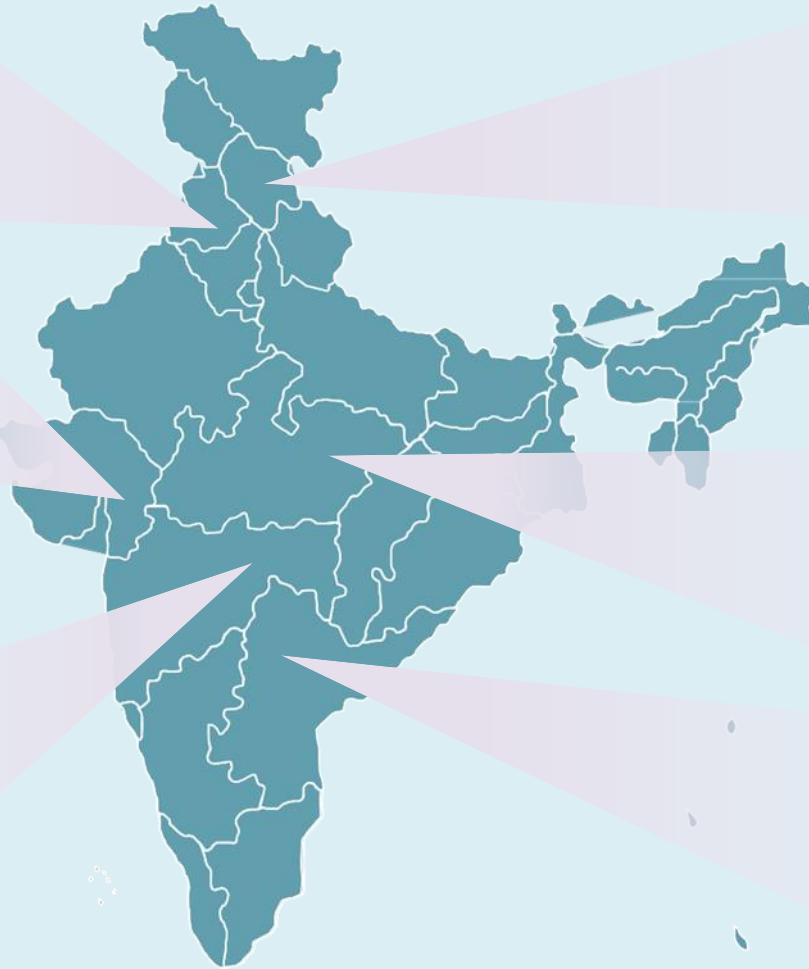
- Dholka in Gujarat houses a major manufacturing facility of Cadila, which spans over 100 acres.

- Lupin has an USFDA-approved plant at Tarapur, Maharashtra. The facility forms the core of Lupin's fermentation capabilities.

- Wockhardt's facility covers an area of 40,468 sq. meters in Baddi, Himachal Pradesh.
- Baddi is also home to Cipla's formulations manufacturing facility.

- Mandideep in Madhya Pradesh is the manufacturing hub for Lupin's cephalosporin and ACE-Inhibitors.
- Cipla has a formulations manufacturing plant at Indore.

- Piramal's USFDA-approved manufacturing plant in Hyderabad.
- GlaxoSmithKline has a major facility at Rajahmundry, Andhra Pradesh



Source: Company Website

Strategies adopted

2. DIFFERENTIATION

- Players in the sector are trying to strengthen their position in the market and expand themselves by investing heavily in R&D activities, such as: Dr Reddy's acquired OctoPlus N.V, a Netherlands-based company, to get access to the Poly LacticCo-Glycolic Acid (PLGA) technology for the formulation of complex injectables

1. COST LEADERSHIP

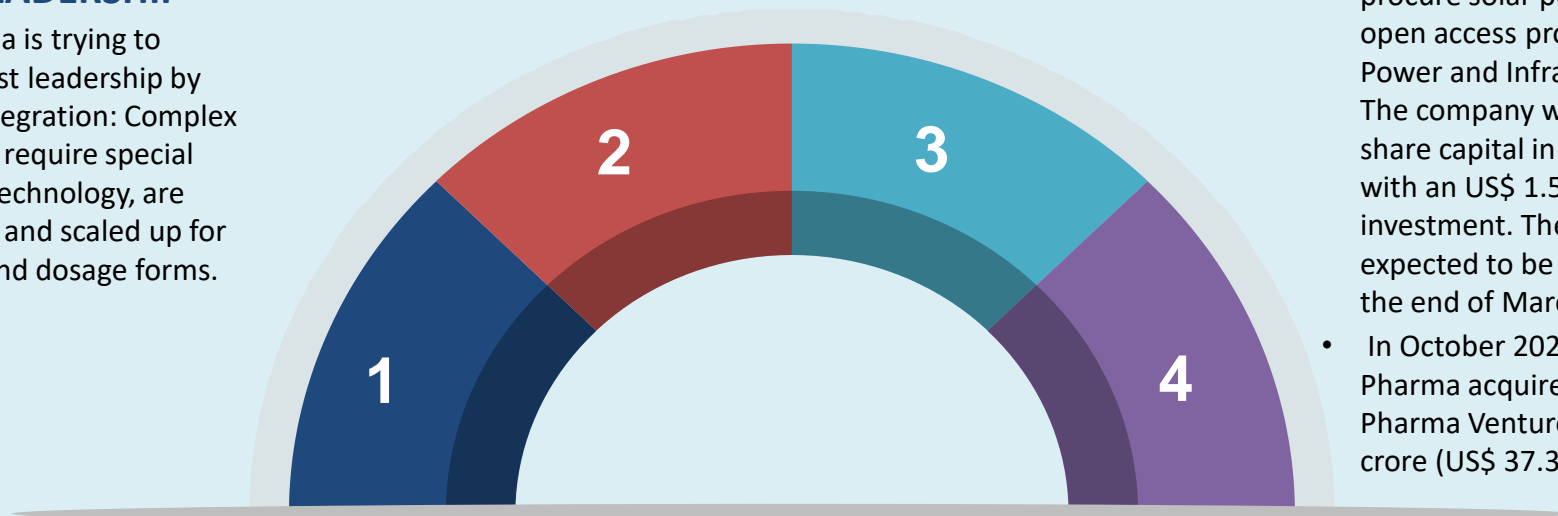
- Sun Pharma is trying to achieve cost leadership by Vertical Integration: Complex API, which require special skills and technology, are developed and scaled up for both API and dosage forms.

3. FOCUS ON NEW MARKETS

- Lupin is making road into new markets such as Latin America, Russia and other East European countries.
- Sun Pharma decided to focus on specialty and chronic therapies such as neurology, oncology, dermatology segments.
- India plans to set up a nearly Rs. 1 lakh crore (US\$ 1.3 billion) fund to provide boost to companies to manufacture pharmaceutical ingredients domestically.

4. M&A IN BIOTECH

- In February 2021, Aurobindo Pharma announced plans to procure solar power from two open access projects of NVNR Power and Infra in Hyderabad. The company will acquire 26% share capital in both companies with an US\$ 1.5 million investment. The acquisition is expected to be completed by the end of March 2021.
- In October 2020, Aurobindo Pharma acquired MViyeS Pharma Ventures for Rs. 274.22 crore (US\$ 37.30 million).



Notes: BT Cotton: Genetically modified pest resistant plant cotton, DPT: diphtheria, pertussis, tetanus, BCG: Bacille Calmette-Guerin

Source: Global Bio-India 2019, Biotechnology Industry Research Assistance Council



Growth Drivers



Supply-side drivers of Indian pharmaceuticals sector

1. Launch of patented drugs

- Following the introduction of product patents, several multinational companies are expected to launch patented drugs in India.
- Growth in the number of lifestyle diseases in India could boost the sale of drugs in this segment.
- High Court allowing to export patent drugs, to foreign players in the Indian market.

2. Launch of patented drugs

- Pharma companies have increased spending to tap rural markets and develop better medical infrastructure.
- Hospitals' market size is expected to increase by US\$ 200 billion by 2024.
- India's medical devices market stood at US\$ 10.36 billion in FY20. The market is expected to increase at a CAGR of 37% from 2020 to 2025 to reach US\$ 50 billion.



3. Scope in generics market

- India's generic drugs account for 20% of global exports in terms of volume, making it the largest provider of generic medicines globally. The generics drug market accounts for around 70% of the India pharmaceutical industry. India supplies >40% generics to the US market.

5. Patent Expiry

- About 120 drugs are expected to go off-patent over the next 10 years from 2020; with expected worldwide revenue between US\$ 80 to 250 billion.

4. Over-The-Counter (OTC) drugs

- India's OTC drugs market is estimated to have grown at a CAGR of 16.3% to US\$ 6.6 billion over 2008-16 and is further expected to grow on the account of increased penetration of chemists, especially in rural regions. The India OTC market was accounted at US\$ 4.61 billion in 2018 and is expected to reach US\$ 10.22 billion by 2024.

Notes: CAGR - Compound Annual Growth Rate

Source: BMI, India Biz, Nicholas Hall & Company, IQVIA

Demand drivers of Indian pharmaceuticals sector

2. ACCEPTABILITY

- Rising levels of education to increase acceptability of pharmaceuticals.
- Patients to show greater propensity to self-medicate, boosting the OTC market.
- Acceptance of biologics and preventive medicines to rise.
- Surge in medical tourism due to increased patient inflow from other countries.

1. ACCESSIBILITY

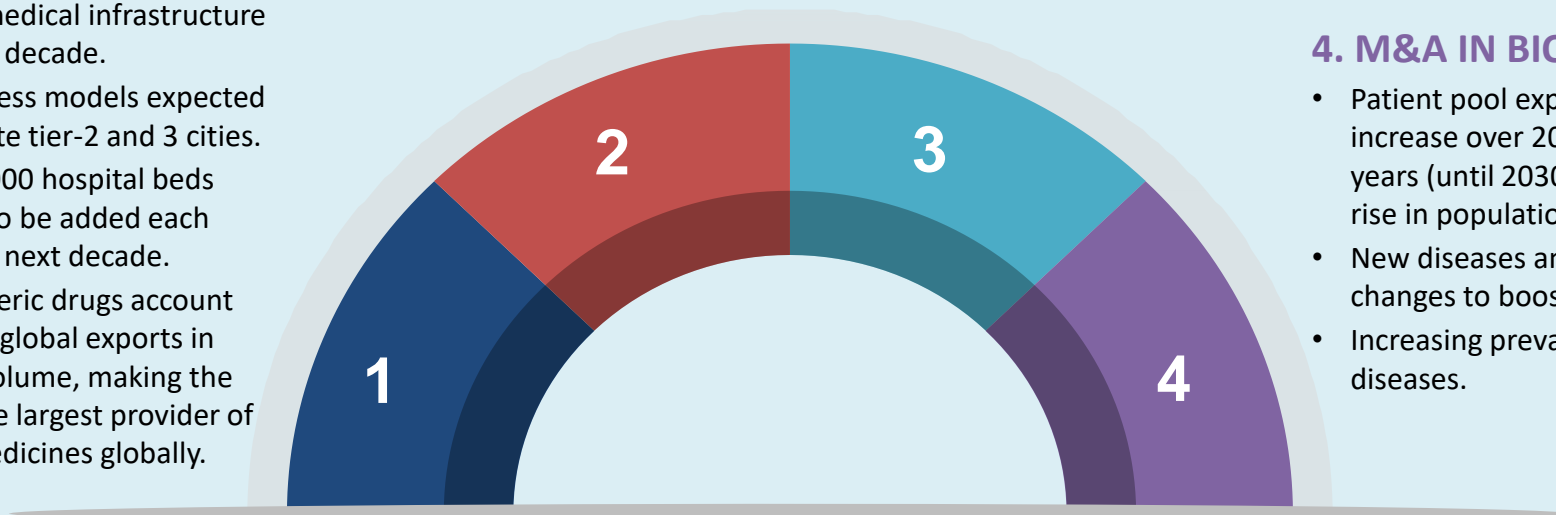
- As per Mckinsey's report (July 2019), > US\$ 200 billion to be spent on medical infrastructure in the next decade.
- New business models expected to penetrate tier-2 and 3 cities.
- Over 160,000 hospital beds expected to be added each year in the next decade.
- India's generic drugs account for 20% of global exports in terms of volume, making the country the largest provider of generic medicines globally.

3. PRADHAN MANTRI BHARTIYA JANAUSHADHI KENDRAS

- Over 650 million people expected to be covered by health insurance by 2020.
- The Government plans to provide free generic medicines to half the population at an estimated cost of US\$ 5.4 billion.
- Affordable medicines under Pradhan Mantri Bhartiya Janaushdhi Kendra's (PMBJKs) achieved an impressive sale of Rs. 100.40 crore (US\$ 14.24 million) in first two months of FY21.

4. M&A IN BIOTECH

- Patient pool expected to increase over 20% in the next 10 years (until 2030), mainly due to rise in population.
- New diseases and lifestyle changes to boost demand.
- Increasing prevalence of lifestyle diseases.



Note: RSBY - Rashtriya Swasthya Bima Yojna

Source: ICRA Report on Indian Pharmaceutical Sector, Pharmaceutical Industry: Developments in India- Deloitte, Mckinsey Pharma Report 2020

Policy Measures



Favourable policy measures support growth... (1/3)

1

Pharma Vision 2020

- Pharma Vision 2020 by the Government's Department of Pharmaceuticals aims to make India a major hub for end-to-end drug discovery.

2

National pharmaceuticals policy

- In 2017, the Department of Pharmaceuticals released a draft National Pharmaceutical Policy with the following objectives:
 - Make all essential drugs accessible to masses through affordable prices.
 - Provide the Indian pharmaceutical sector with a long-term stable policy environment.
 - Make India self sufficient in end-to-end domestic drug manufacturing.
 - Maintain world class quality for domestic consumption and exports.
 - Create a positive environment for research and development in the pharma sector.
- As per the new policy, the Department of Pharmaceuticals will have control over the National List of Essential Medicines (NLEM), which decides the drugs for which the Government of India can control the prices.
- In April 2021, National Pharmaceutical Pricing Authority (NPPA) fixed the price of 81 medicines, including off-patent anti-diabetic drugs, allowing due benefits of patent expiry to patients.

3

Support for technology upgrades and FDIs

- Government is planning to relax FDI norms in the pharmaceutical sector.
- In March 2017, the Government decided to create a digital platform to regulate and track the sale of quality drugs, and it can be used by people living in the country as well as abroad

Favourable policy measures support growth... (2/3)

4

Pharmaceutical Parks

- In January 2021, the central government announced to set up three bulk drug parks at a cost of Rs. 14,300 crore (US\$ 1,957 million) to manufacture chemical compounds or active pharmaceutical ingredients (APIs) for medicines and reduce imports from China.
- In February 2021, the Punjab government announced to establish three pharma parks in the state. Of these, a pharma park has been proposed at Bathinda, spread across ~1,300 acres area and project worth ~Rs. 1,800 crore (US\$ 245.58 million). Another medical park worth Rs. 180 crore (US\$ 24.56 million) has been proposed at Rajpura and the third project, a greenfield project, has been proposed at Wazirabad, Fatehgarh Sahib.

5

Production Linked Incentive

- In September 2020, the government announced production-linked incentive (PLI) scheme for the pharmaceutical industry worth Rs. 15,000 crore (US\$ 2.04 billion).

6

Union Budget 2021-22

- The Ministry of Health and Family Welfare has been allocated Rs. 73,932 crore (US\$ 10.35 billion) and the Department of Health Research has been allocated Rs. 2,663 crore (US\$ 365.68 million).
- The government allocated Rs. 37,130 crore (US\$ 5.10 billion) to the 'National Health Mission'.
- PM Aatmanirbhar Swasth Bharat Yojana was allocated Rs. 64,180 crore (US\$ 8.80 billion) over six years.
- The Ministry of AYUSH was allocated Rs. 2,970 crore (US\$ 407.84 million), up from Rs. 2,122 crore (US\$ 291.39 million).

Favourable policy measures support growth... (3/3)

7

Biotechnology Industry Research Assistance Council

- BIRAC has been established to promote research & innovation capabilities in India's biotech industry. The council will provide funding to biotech companies for technology & product development.
- BIRAC under Small Business Innovation Research Initiative (SBIRI) scheme supports innovations in biotechnology.

8

Biotechnology Based Programme for Women

- Programme on application of biotechnology for women was done to provide employment, skill development, awareness generation, health improvement & socio-economic upliftment of the women population.

9

National Biopharma Mission

- The Industry - Academia mission was launched in June 2017 to boost development of biopharmaceuticals in India.

10

National Commission for Homoeopathy (NCH) Bill, 2018

- In December 2018, the Government of India approved the National Commission for Homoeopathy, Bill, 2018 in order to have more transparency in the sector.



Top Pharma Companies



Top Pharma Companies in India 2021

Top 10 Indian Pharma Companies In India In 2021

Sun Pharmaceutical Industries

Divi's Laboratories Limited

Dr. Reddy's Laboratories

Cipla

Torrent Pharma

Lupin Pharmaceuticals

Cadila Healthcare limited

Aurobindo Pharma Limited

Intas Pharmaceuticals Limited

Glenmark Pharma Limited

1

Sun Pharmaceutical Industries

- Founded: 1983
- Owner: Dilip Shanghvi
- Headquarter: Goregaon, Mumbai
- Revenue: \$4.7 billion
- Sun Pharmaceutical Industries is the largest pharmaceutical company in India based on overall revenue. It is the fourth largest global specialty generic pharmaceutical company in the world. It also sells Carbamazepine, Etodolac, and Clorazepate as well as anti-cancer, steroids, peptides, sex hormones, and controlled substances



2

Divi's Laboratories

- Founded: 1990
- Owner: Murali Divi
- Headquarter: Hyderabad
- Revenue: \$780 million
- Divi's Laboratories Ltd. manufactures active pharmaceutical ingredients (APIs) and intermediates. This pharmaceutical company in India is engaged in the manufacture of leading generic compounds Nutraceutical ingredients and custom synthesis of APIs and intermediates for global innovator companies



3

Dr. Reddy's Laboratories

- Founded: 1984
- Owner: Dr. Kallam Anji Reddy
- Headquarter: Hyderabad
- Revenue: \$2.4 billion
- It is known for manufacturing wide range of pharmaceuticals in India and overseas. They have over 190 medications, 60 active pharmaceutical ingredients for drug manufacturers, diagnostics kits, critical care, and biotechnology products. It's notable products include Canagliflozin, Ramipril, Ibuprofen, Naproxen, Atorvastatin, Nizatidine, Naproxen Sodium, etc



Investments



Investments (1/2)

Production Linked Incentive (PLI) Scheme

- To achieve self-reliance and minimise import dependency in the country's essential bulk drugs, the Department of Pharmaceuticals initiated the PLI scheme to promote domestic manufacturing by setting up greenfield plants with minimum domestic value addition in four separate 'Target Segments' with a cumulative outlay of Rs. 6,940 crore (US\$ 951.27 million) from FY21 to FY30.
- Under 'Target Segment I', five applications with an investment of Rs. 3,761 crore (US\$ 515.52 million) have been approved.

Companies under Target Segment III (Key Chemical Synthesis Based KSMs/Drug Intermediates) are as follows:

Name of Approved Applicant	Committed Production Capacity (in MT)	Committed Investment (in Rs. crore)	Committed Investment (in US\$ million)
Natural Biogenex Private Limited	12	31.43	4.31
Natural Biogenex Private Limited	10	26.19	3.59
Natural Biogenex Private Limited	15	39.29	5.39
Symbiotec Pharmed Private Limited	15	5.00	0.69
Macleods Pharmaceutical Limited	200	198.36	27.19
Optimus Drugs Private Limited	200	35.00	4.80
Sudarshan Pharma Industries Limited	200	57.00	7.81
Optimus Drugs Private Limited	50	30.00	4.11

Source: BMI, Business Standard, DPIIT

Investments (2/2)

Companies under Target Segment II (Fermentation Based Niche KSMs/Drug Intermediates/APIs) are as follows:

Name of Approved Applicant	Committed Production Capacity (in MT)	Committed Investment (in Rs. crore)	Committed Investment (in US\$ million)
Saraca Laboratories Limited	3,000	50.0	6.85
Emmennar Pharma Private Limited	1,500	21.94	3.01
Hindys Lab Private Limited	3,000	37.60	5.15
Aarti Speciality Chemicals Limited	4,000	77.87	10.67
Meghmani LLP	13,500	55.06	7.55
Sadhana Nitro Chem Limited*	36,000	197.27	27.04

- Companies have agreed to invest Rs. 862.01 crore (US\$ 118.16 million) in these plants, resulting in ~1,763 employment opportunities. The government has approved a total of 19 applications totaling Rs. 4,623.01 crore (US\$ 633.68 million) in committed investment

Foreign direct investment (FDI)








- The Indian drugs and pharmaceuticals sector received cumulative FDI worth US\$ 17.75 billion between April 2000 and December 2020.

Source: BMI, Business Standard, DPIIT

Medical Devices

August 2021

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Executive Summary

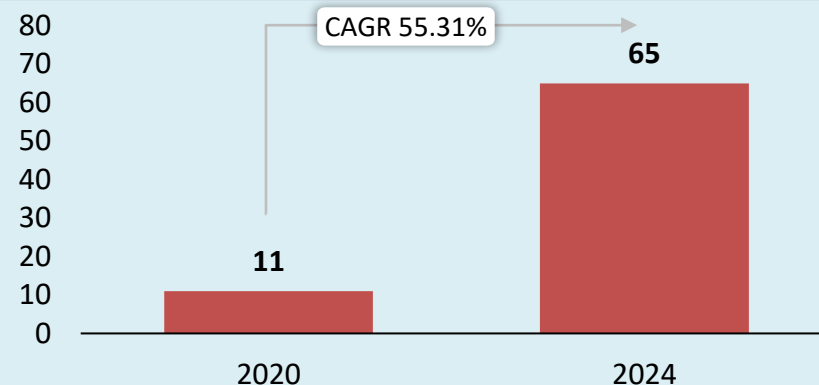


Executive summary

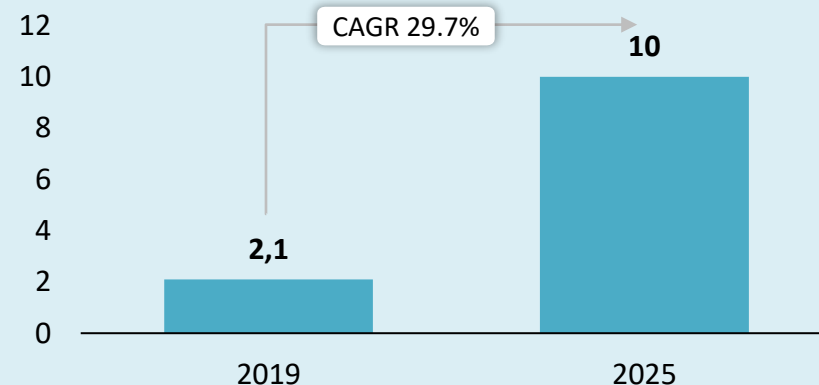
- India's medical devices market stood at US\$ 11 billion in 2020 and is expected to reach US\$ 65 billion in 2024.
- The FY22 medical devices market is expected to reach US\$ 11.86 billion.
- India has an overall 75-80% import dependency on medical devices, with export at Rs. 14,802 crore (US\$ 2.1 billion) in 2019 and is expected to rise at CARG of 29.7% to reach Rs. 70,490 (US\$ 10 billion) in 2025.
- The US, Germany, China, Brazil, Iran, etc., are a few key countries that import Indian medical devices.
- Gujarat, Maharashtra, Karnataka, Haryana, Andhra Pradesh, Telangana and Tamil Nadu are the manufacturing hubs for medical devices in India.
- In BioAsia 2021, key stakeholders in the panel discussion on medical technologies stated that India would become self-sufficient in the domestic medical devices manufacturing by 2025-26.
- Panel observed that the government is taking supportive measures such as promoting indigenous manufacturing of high-tech medical devices, production-linked incentive schemes (PLIs) on medical devices, boosting new medical devices park, etc., to boost overall growth of the domestic medical devices market in India.

Source: Government Website, WHO and AMTZ Report 'Medical Device - Manufacturing in India - A Sunrise 2017

Medical Devices Market in India (2020-24, in US\$ billion)



Medical Devices Export Market in India (2019-25, in US\$ billion)





Advantage India



Advantage India

2. OPPORTUNITIES IN EXPORT

- The Indian medical device is driven by 75-80% imports from countries such as the US, China and Germany.
- India and Russia have set the bilateral trade target at US\$ 30 billion by 2025. Trade is expected to increase by an additional US\$ 5 billion per annum, with opportunities in pharmaceuticals & medical devices, minerals, steel, and chemicals.
- Medical devices are a highly attractive export area for US firms.

1. INCREASING DEMAND

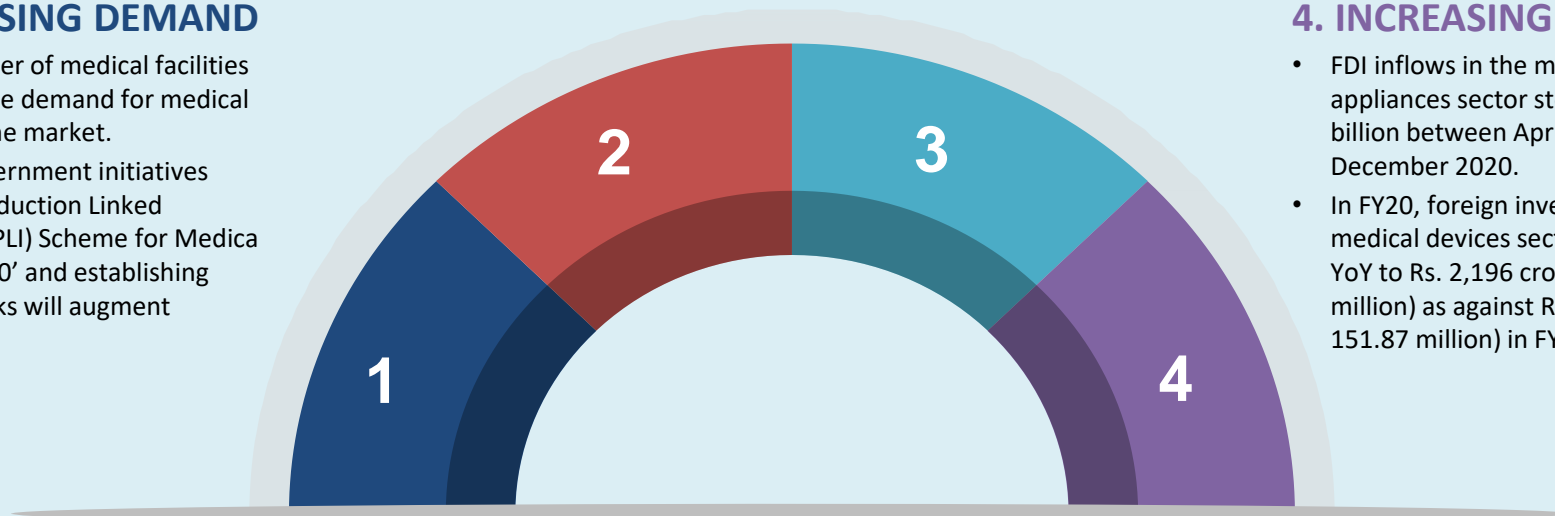
- Rising number of medical facilities will boost the demand for medical devices in the market.
- Various government initiatives such as 'Production Linked Incentives (PLI) Scheme for Medical Devices 2020' and establishing medical parks will augment demand

3. POLICY SUPPORT

- 100% FDI is allowed in the medical devices sector In India.
- Categories such as equipment and instruments, consumables and implants attract the most FDI.
- In order to expedite the clearance of medical devices such as nebulisers, oxygen concentrators and oxygen cannisters in April 2021, the government made it easier to import critical medical devices by easing the requirements for clearance under the Legal Metrology Act (Packaging Rules 2011).
- In February 2021, a production-linked incentive (PLI) scheme was announced with an outlay of Rs. 3,420 crore (US\$ 468.78 million) for FY21-FY28 for promotion of domestic manufacturing of medical devices.
- The Ministry of Chemicals and Fertilisers also approved nine projects including Siemens Healthcare and Wipro GE Healthcare

4. INCREASING INVESTMENT

- FDI inflows in the medical and surgical appliances sector stood at US\$ 2.18 billion between April 2000 and December 2020.
- In FY20, foreign investments in the medical devices sector increased 98% YoY to Rs. 2,196 crore (US\$ 301.01 million) as against Rs. 1,108 crore (US\$ 151.87 million) in FY19



Medical devices market is split into 4 key categories in India

Under the medical device and IVD regulations, the Health Ministry of India has divided medical devices into the following four categories:

CLASS B (LOW MODERATE RISK)

- Medical devices such as endoscopic forceps, vial adapters, suction cups and catheters, Sengstaken-Blakemore tube, feeding tubes, gastrointestinal tubes etc. are included in this category

CLASS C (MODERATE HIGH RISK)

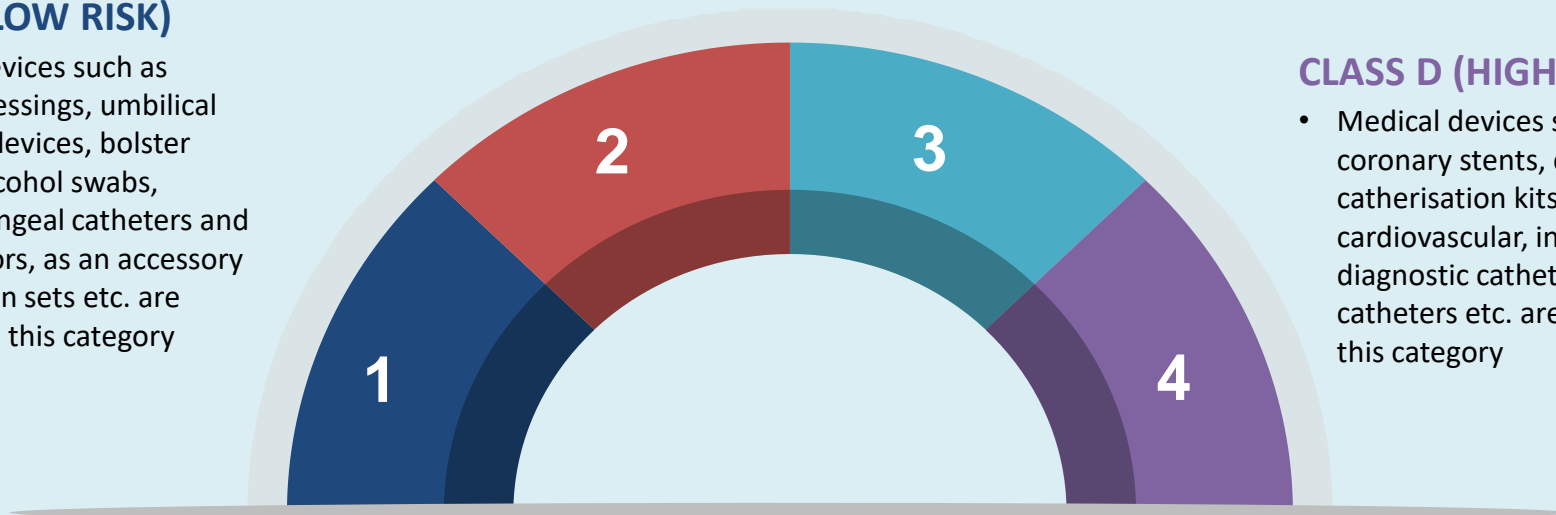
- Medical devices such as anesthesia conduction filter, introducer sheath, microcatheter, imaging catheter colonic stents, pancreatic instruments etc. are included in this category

CLASS A (LOW RISK)

- Medical devices such as surgical dressings, umbilical occlusion devices, bolster sutures, alcohol swabs, nasopharyngeal catheters and Y-connectors, as an accessory to perfusion sets etc. are included in this category

CLASS D (HIGH RISK)

- Medical devices such as coronary stents, cardiac catheterisation kits, cardiovascular, intravascular diagnostic catheters, occlusion catheters etc. are included in this category



Source: Drugs Controller General (India) Directorate General of Health Services 2017 notice

Policy Measures



India Medical Device Regulations

Medical Device Registration in India



Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India

- The **Central Drug Standards Control Organization (CDSCO)** is India's main regulatory body for pharmaceuticals and medical devices.
- **The Drug Controller General of India (DCGI)** is the key official within the CDSCO. The DCGI is responsible for the approval of the manufacturing of certain drugs (vaccines, large volume parenterals, blood products, r-DNA derived), specific medical devices, and new drugs.
- In India, the manufacturing, import, sale, and distribution of medical devices are regulated under **India's Drugs & Cosmetic Act and Rules (DCA)**.
- Under the Drugs and Cosmetics Act, the regulation of the manufacturing, sale, and distribution of drugs and devices is primarily the concern of state authorities. Central authorities are responsible for approving new drugs, controlling the quality of imported drugs, coordinating the activities of state organizations, and providing expert advice in order to bring about a uniformity in the enforcement of the Drugs and Cosmetics Act.

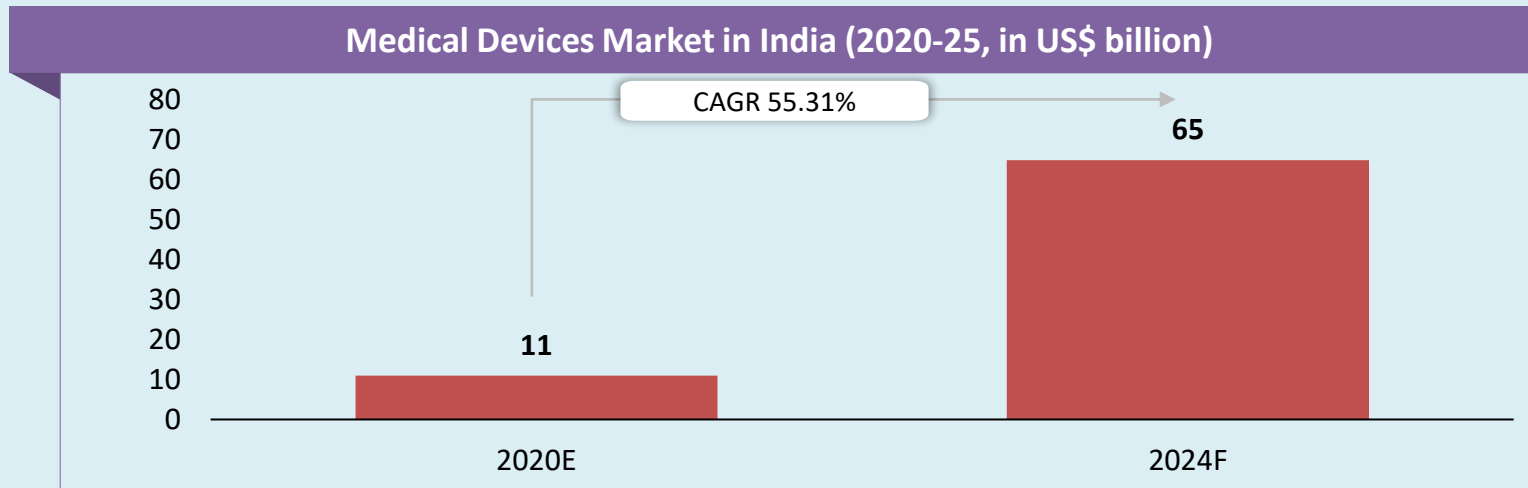
The Medical Devices Rules

- Medical devices and in vitro diagnostics (IVDs) in India are regulated under the Medical Device Rules that came into effect in 2018. Medical devices are categorized into Class A (low risk), Class B (low moderate risk), Class C (moderate high risk), or Class D (high risk) devices. IVDs are categorized separately using the same class names and risk levels from Class A to Class D.
- The Central Licensing Authority is the authoritative body that oversees the importation of all classes of medical devices; the manufacture of Class C and D medical devices; the clinical evaluation and approval of investigational medical devices; and the clinical evaluation and approval of new IVDs. The responsibility of overseeing the manufacture of Class A and B medical devices and the sale, stocking, exhibiting, and distribution of all classes of medical devices is delegated to state licensing authorities.

Growth Drivers



Growth in medical devices



- India's medical device market is the fourth-largest in Asia, following Japan, China and South Korea. However, it has the potential to surpass its peers in terms of size and scale; this based on the government's support the sector has received over the past several years.
- India's medical devices market stood at US\$ 11 billion in 2020 and is expected to reach US\$ 65 billion in 2024.
- The medical devices sector in India comprises large multinationals, small and mid-sized companies. This sector, which is growing faster amid the pandemic, offers great opportunities for domestic players, particularly engineering MSMEs, to further penetrate the global markets.
- The Government of India (GOI) has commenced various initiatives to strengthen the medical devices sector, with emphasis on research and development (R&D) and 100% FDI for medical devices to boost the market.
- India added significant production capacity for various critical care items such as PPE kits, surgical gloves, sanitisers and N95 masks, and emerged as a significant destination for manufacturing of healthcare products and services

Source: Government Website, News Articles



Medical Devices Manufacturers



List of medical devices manufacturers (1/2)

The Indian medical devices market comprises >800 manufacturers, of which 65% companies have a turnover of <Rs. 10 crore (US\$ 1.5 million), 25% companies have a turnover of Rs. 10-50 crore (US\$ 1.5-6 million) and 2% companies have a turnover of >Rs. 500 crore (US\$ 73 million).

List of Medical Devices Manufacturers in India

3M Corporation	ATLAS Surgical	Chemical Resources (Chereso)	GE Healthcare
3S Corporation	B Braun	Coral Laboratories Ltd.	Genex Pharma
Adonis Medical Systems Pvt. Ltd.	Banuline Pharma Pvt. Ltd.	Cura Healthcare Pvt. Ltd.	Gepach International
Aligens International	Bayer AG	Danaher Corp.	GOLDEN Nimbus INDIA Pvt. Ltd.
Ananta Medicare Ltd.	Bigtec Labs	Deluxe Scientific Surgico Pvt. Ltd.	GRIPORTHO Surgicals Pvt. Ltd.
Anchor Plus LLP	Becton Dickinson India	Dynamic Ortho Industries	GST Corporation Ltd.
Antila Life Sciences Pvt. Ltd.	Biocon	East African India Overseas	Gujarat HEALTH Care
Appaswami Associates	BIO Polymer Systems	Ethinext Pharma	Harsoria Healthcare Pvt. Ltd..
Arommac Industries	Biotrol Laboratories Pvt. Ltd.	Eucare Pharmaceuticals Pvt. Ltd.	Hexagon Nutrition Pvt. Ltd.
Arrow Medical Devices,	Boston Scientific Corp.	Fab Pharmaceuticals Pvt. Ltd.	Hindustan Syringes & Medical Devices Ltd.
Arthon Implants Pvt. Ltd.	Cachet Pharmaceuticals Pvt. Ltd.	Flagship Biotech International Pvt. Ltd.	Hiral Labs Ltd.
ASOJ Soft Caps Pvt. Ltd.	Caremax Healthcare	GANGAR Electronics	Hi-tech Medicare Devices Pvt. Ltd.

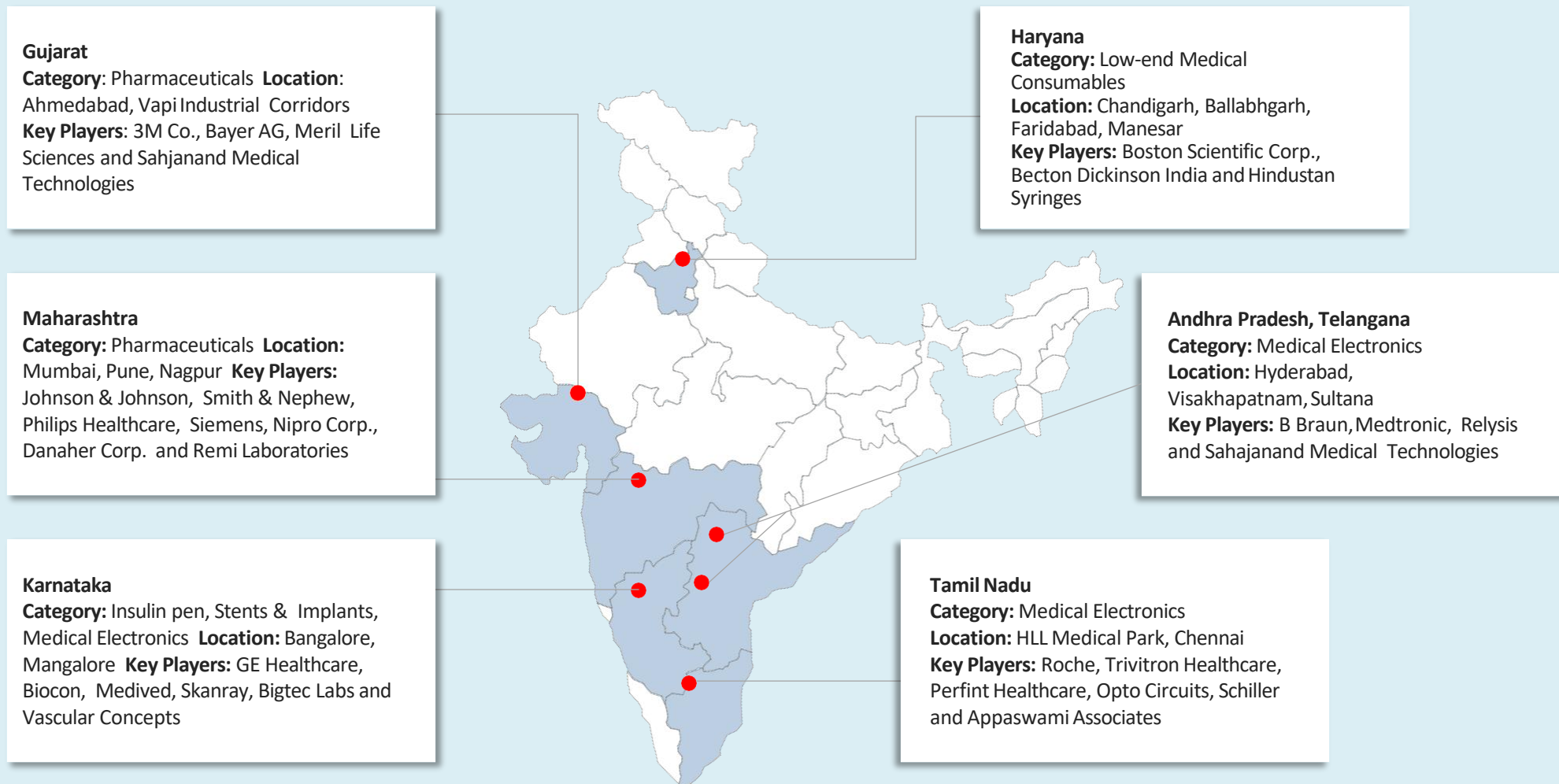
Source: Company Websites

List of medical devices manufacturers (2/2)

List of Medical Devices Manufacturers in India			
Hospi Line Equipment Pvt. Ltd.	MEDI Tech Devices Pvt. Ltd.	Mrk Healthcare Pvt. Ltd.	Palakkad Surgical Industries Pvt. Ltd.
Impact Labs Pvt. Ltd.	Medicare Hygiene Ltd.	Nandu Chemical Industries	Paramount Surgimed Ltd.
Jk Medirise	Meditek India	Nature's Global Service	Perfint Healthcare
Johnson & Johnson	Medived	Nebula Surgical Pvt. Ltd.	Pharmacrest Company Pvt. Ltd.
Johnson & Smit Co.	Medsorce Ozone Biomedicals	Nice Neotech Medical Systems Pvt. Ltd.	Pharmexcil
Kanam latex Industries Pvt. Ltd.	Medtronic	Nipro Corp	Philips Healthcare
Kenoor Organics Pvt. Ltd.	MEHTA Tubes Ltd.	NIRAJ Industries (P) Ltd.	Prasad Meditech
Lamar Healthcare Pvt. Ltd.	Meril Life Sciences	Nosch Labs Pvt. Ltd.	Preci Turn Pvt. Ltd.
Livealth Biopharma Pvt. Ltd.	Metal Gems	Nulife Global Medical Devices Pvt. Ltd.	Precision Coatings Pvt. Ltd.
MAESTROS Electronics & Telecommunications Systems Ltd.	Microtrack Surgicals	OM Surgical	Premium Serums & Vaccines Pvt. Ltd.
Magnatek Enterprises	Miracalus Pharma Pvt. Ltd.	Opto Circuits	Proactive Health Inc.
Magnus Analytics	Morepen Laboratories Ltd.	Ortho Care	Prognosys HEALTH Care

Source: Company Websites

Manufacturing cluster for medical devices



Source: WHO and AMTZ Report 'Medical Device - Manufacturing in India - A Sunrise 2017', Government Website

Growing number of hospitals & medical device rules to drive demand

3

Introduction of Medical Device (Amendment) Rules 2020

- In 2017, the Central Drugs Standard Control Organisation (CDSCO) published the 'Medical Devices Rules 2017', which came into effect in 2018 and comprised regulatory structures that were required to obtain registration and licence by importers and manufacturers of medical devices.
- In February 2020, two new amendments were introduced, i.e., a new chapter for registration of medical devices by their respective manufacturers and importers, and exemption of the 37 categories of already regulated or notified medical devices from the requirement of registration introduced by the new chapter

4

National Medical Devices Promotion Council

- In January 2020, the government set up a National Medical Devices Promotion Council to promote local manufacturing of highend medical devices and attract investments in the sector..
- The council will be headed by the secretary of the Department for Promotion of Industry & Internal Trade (DPIIT)

5

Revised Public Procurement Order (PPO)

- On March 25, 2021, the Department of Pharmaceuticals (DoP) released a revised notice on the Public Procurement Order (PPO), incorporating 19 medical devices in the revised guidelines of the PPO, which is expected to improve domestic medical devices manufacturing (and strengthen 'Make in India') and reduce import bills by ~Rs. 4,000 crore (US\$ 538.62 million)



Trends in Medical Devices Sector



Notable trends in the medical devices sector...(1/3)

1

Big Data

- Numerous companies have been utilising predictive analytics models by gathering key patient vital signs, along with other observations from devices, to make decisions about the overall health of patients
- For example, in 2019, Medtronic and IBM created a mobile personal assistant application that provides real-time glucose insights for individuals with diabetes. This management system helps understand the links between glucose readings, lifestyle choices and drug administration and thereby, aiding patients to make an informed decision about their medication

2

Robotics

- Selective Compliance Articulated Robot Arm (SCARA) robots can be easily mounted on a tabletop and fit well in small confined spaces; this is typical of a medical device manufacturing facility.
- In February 2021, Siemens Healthineers introduced Corindus, a robotic system, to drive cardiovascular interventions with robotic assistance in India.
- New Delhi-based SS Innovations, promoted by renowned robotic cardiothoracic surgeon Dr. Sudhir P Srivastava, will commercially launch India's first and cheapest robot surgical system in the next 4-6 months. The company plans to manufacture 100 units in 2021 of its new 'Mantra' multi-arm surgical robotics system, which was indigenously developed over the last three years, and sell >1,000 units in the next five years.

3

New Devices

- In April 2021, ResMed expanded 'AirView for Ventilation', a cloud-based remote monitoring and management platform in India, which allows healthcare professionals and physicians to leverage this digital respiratory monitoring solution to remotely track patients and provide better care.
- In February 2021, Apollo Hospitals Group collaborated with Anatomiz3D Medtech Pvt. Ltd. to build 3D-printing labs in various Apollo Hospitals in India, starting from Apollo Health City in Hyderabad.
- In February 2021, Siemens Healthineers got the Competition Commission of India's (CCI) nod to acquire 100% shares of Varian Medical Systems. The deal will put together the imaging equipment of Siemens Healthineers and oncology treatment solutions of Varian to enable a more innovative, reliable and comprehensive provider of oncology solutions

Notable trends in the medical devices sector...(2/3)

4

Start-ups

- The medical devices market is evolving at a fast pace on the back of constant innovations and research that are making medical devices affordable and accessible. Several Indian start-ups and SMEs have entered the medical devices market and are contributing with innovative solutions.
- With the entry of start-ups in this sector, new investments are being observed in the market.
- In April 2021, Anthill Ventures announced a collaboration with Kanfit3D (an Israeli health tech company) to help the company (Kanfit3D) expand in India and produce custom-made medical implants and market access to healthcare providers in the country

5

Wearables

- Wearables such as glucose monitors, exercise trackers and wearables for mental health are becoming popular among consumers in India because of their ease of usage
- In December 2020, Central Drugs Standard Control Organisation (CDSCO) has granted medical device registration to three wearable devices from GOQii, a California-based fitness technology company. These devices offer measurements of body temperature and a pulse oximeter, as well as of vitals such as electrocardiography (ECG), blood pressure and heart-rate.

6

Educational Programmes

- To fulfill the demand for trained professionals, several educational institutions are offering/introducing courses to provide training and research in the medical devices field.
 - National Institute of Pharmaceutical Education and Research introduced a course—Master in Technology in medical devices
 - IIT Hyderabad is offering Bachelor in Technology in biomedical engineering that will train students to design medical devices, develop 3D images and create bio-sensors on a chip

Note: AiMeD: Association of Indian Manufacturers of Medical Devices, PPE: Personal Protective Equipment, RT PCR: Reverse Transcription Polymerase Chain Reaction

Source: Government Website, News Articles

Notable trends in the medical devices sector...(3/3)

6

COVID-19

- According to AiMeD, before the outbreak of COVID-19, there were only 20 firms manufacturing 62 lakhs PPE kits per year, but within 2-3 months, the number of manufacturers listed with AiMeD increased to 140 with 25.55 crore annual capacity
- In May 2021, with joint efforts of the Defence Research and Development Organisation and Dr. Reddy's Laboratories an antiCOVID-19 drug called 2-deoxy-D-glucose (2-DG) is being developed. This drug is likely to expedite recovery.
- In April 2021, due to the unusual spike in covid infections and an increased number of patients requiring hospitalisation, the government allowed faster custom clearance for up to three months to import medical devices including nebulisers, oxygen concentrators, oxygen canister, cryogenic cylinders, oxygen generators and ventilators.
- Similarly, the number of Indian firms manufacturing ventilators increased from 8 to 17, mask manufacturers from 30 to 108, swab manufacturers from zero to five, sanitiser manufacturers from 35 to 49 and RT PCR kit manufacturer from zero to eight
- Hindustan Syringes and Medical Devices Ltd., the world's largest manufacturer of auto-disable syringes that are used for vaccination, plans to scale up production to 1 billion syringes a year (from 700 million) in the first-half of 2021, to push COVID-19 vaccination. In March 2021, the company announced its plan to produce 8,200 syringes per minute—40% more than its current capacity of 5,900 syringes per minute.
 - In April 2021, Hindustan Syringes and Medical Devices (HMD) announced to invest >Rs. 100 crore (US\$ 13.47 million) to increase its syringe production capacity from 2.5 billion to >3 billion syringes by the next quarter.
- In November 2020, the Engineering Exports Promotion Council India and National Institute of Design collaborated to promote and upgrade designs and technology for the medical devices industry, enabling it to meet the emerging needs of the country's health sector, particularly in the aftermath of COVID-19

Note: AiMeD: Association of Indian Manufacturers of Medical Devices, PPE: Personal Protective Equipment, RT PCR: Reverse Transcription Polymerase Chain Reaction

Source: Government Website, News Articles

Growing number of hospitals & medical device rules to drive demand

3

Introduction of Medical Device (Amendment) Rules 2020

- In 2017, the Central Drugs Standard Control Organisation (CDSCO) published the 'Medical Devices Rules 2017', which came into effect in 2018 and comprised regulatory structures that were required to obtain registration and licence by importers and manufacturers of medical devices.
- In February 2020, two new amendments were introduced, i.e., a new chapter for registration of medical devices by their respective manufacturers and importers, and exemption of the 37 categories of already regulated or notified medical devices from the requirement of registration introduced by the new chapter

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Top Medical Devices Companies



Top 10 Medical Devices Companies in India 2021

- The Indian Medical devices and equipment market is currently valued approximately at **8 Billion USD** and is having a rapid phase of improvement with an increase in **growth rate from 12% to 15% CAGR**.
- It has a CAGR value ranging around 5% for the global medical equipment industry. India is among the top 20 global medical devices market and the 4th largest in Asia after Japan, China, and South Korea.
- Imported products dominate the market by accommodating around 70% of the total available resources. They vary in both their intended use and indications for use.

Medical Devices Companies in India	Year of Estd.	ISIN	Market Value (\$Mn)
WIPRO GE PRIVATE HEALTH CARE	1945	INE075A01022	2253
POLY MEDICURE Ltd.	1995	INE205C01021	876
INDIA MEDTRONIC PRIVATE Ltd.	1979	IE00BTN1Y115	90.6
SIEMENS HEALTHCARE DIAGNOSTICS	2015	DE000SHL1006	34.3
OPTOCIRCUITS(INDIA) Ltd.	1991	INE808B01016	16
BECTON DICKINSON INDIA Ltd.	1897	US0758871091	9.7
MAESTROS MEDLINE SYSTEMS	1972	INE318N01011	4.4
TRANSASIA BIOMEDICALS	1979	INE321C01018	3.1
CURE SPECTS LASERS Ltd.	1995	INE730B01012	3.0
CENTENNIAL SURGICAL SUTURE Ltd.	1995	INE405H01018	2.9

Investments



Major investments in medical device sector (1/2)

- As of March 2021, 40 companies signed up to establish their facilities in the Medical Devices Park of Sultanpur, Telangana. In total, the park received a commitment of >Rs. 1200 crores (US\$ 165 million) with a potential to generate 6500 jobs.
- By 2022, the Gautam Budh Nagar, Noida, is expected to have Northern India's first medical tools and system manufacturing park. The park is likely to be developed in Sector 28 of the Yamuna Expressway Industrial Development Authority (YEIDA) Space by the Yamuna Expressway Authority. In March 2021, YEIDA is expected to introduce a mission scheme worth ~Rs. 5,000 crore (US\$ 685.35 million), of which Rs. 100 crore (US\$ 13.71 million) is likely to be funded by the central authorities.
- In February 2021, Punjab's Industry and Commerce Minister Mr. Sunder Sham Arora announced that a park for medical devices was proposed in Rajpura, Punjab, across an area of 210 acres, with an estimated project cost of ~ Rs. 180 crore (US\$ 24.67 million).
- In January 2021, Tamil Nadu government proposed to build a medical devices park (spanning 350 acres) near Oragadam in Kancheepuram district. The proposed cost for developing this project is Rs. 430 crore (US\$ 58.92 million).
- Hyderabad is emerging as a medical devices hub. Establishment of the country's largest medical devices park in Sultanpur (near Hyderabad) in 2017 has attracted >40 companies to set up units so far (as of 2020).
- To further incentivise investments in the manufacturing of medical devices, in May 2020, the Central Government of India announced incentivisation plans of at least Rs. 3,420 crore (US\$ 469.19 million) over a period of five years, and these funds will be offered to manufacturers only if they invest in set-ups to produce key medical devices.
- In May 2020, AiMeD (an Umbrella Association of Indian Manufacturers of Medical Devices) invited Japanese investors who were interested in setting-up a manufacturing base for medical devices (including medical electronics & IVD) in India. As a part of the initiative, India is targeting 1200 technical collaborations with Indian investors for JPY 600 billion (US\$ 5746.7 million) and above, 200 joint ventures with foreign investors for JPY 200 billion (US\$ 1903.8 million) and above and 50 MNCs for JPY 200 billion (US\$ \$ 1903.8 million) and above.







- In April 2021, the company announced that it has established a medical devices manufacturing plant in Visakhapatnam.
- In March 2021, Transasia Bio-Medical Ltd., a Mumbai-based in-vitro diagnostic company, announced plans to invest Rs. 150 crore (US\$ 21 million) to set up a manufacturing unit at the Medical Devices Park in Sultanpur, Telangana.
- The company plans to manufacture state-of-the-art high-technology analysers in the unit to address biochemistry, immunology, hematology, molecular testing in addition to COVID-19, HIV, dengue, and TB testing for domestic and export markets.



- In February 2021, Sunway Group, a Mumbai-based medium-sized pharmaceuticals company, signed a deal to acquire Inor Medical Products Ltd. (manufacture and seller of orthopaedic implants and instruments).
- As part of the contract, Sunway has also agreed to acquire Inor Medical's facility based in Valsad, Gujarat. The deal value of the transaction was not disclosed.

Source: Transasia Bio-medical Ltd. Website, News Articles

Major investments in medical device sector (2/2)

	<ul style="list-style-type: none"> • In March 2019, Sahajanand Medical Technologies (SMT), a manufacturer of coronary stent, announced an investment worth Rs. 250 crore (US\$ 34 million) to establish a stent manufacturing facility in Telangana. • This facility will be Asia's largest stent manufacturing facility with a capacity to produce one million stents and two million balloon catheters per year. • The facility is expected to be ready by 2020 and will generate employment for ~1,200-2,000 people
	<ul style="list-style-type: none"> • In April 2021, Medtronic inaugurated a Medtronic Engineering and Innovation Centre (MEIC) in Hyderabad to leverage India's large pool of diverse and qualified talent to accelerate its innovative work in the medical technology space in the country. • In August 2020, Medtronic, a global manufacturer of medical devices, announced an investment worth Rs. 1,200 crore (US\$ 163 million) to expand its R&D centre for medical device software and engineering solutions facility in Hyderabad, Telangana. • The facility will be Medtronic's largest R&D facility, outside of the US, generating ~1,000 jobs in the next five years. The investment is planned over the next five years and is aimed at making Hyderabad the hub for medical devices in India. • In February 2021, India Medtronic Private Limited introduced the TYRX Absorbable Antibacterial Envelope (TYRX Envelope), a single-use, absorbable antibacterial envelope equipped to stabilize an electronics system
	<ul style="list-style-type: none"> • In April 2021, Siemens Healthineers acquired Varian Medical Systems, Inc. to leverage Varian's AI-assisted analytics to advance development and implementation of data-driven precision care as well as redefine cancer detection, care delivery and post-treatment survivorship. • In October 2020, Siemens Healthineers, a global medical technology company, announced plans to invest Rs. 1,300 crore (US\$ 177 million) over the next five years in Bengaluru, Karnataka, to make India one of its four key digital innovation hubs worldwide. • The innovation hub will be housed in a new state-of-the-art campus that combines existing R&D centre and modern medical imaging factory. This hub will play a strategic role in developing software products and platforms for the company's three segments—imaging, diagnostics and advanced therapies.
	<ul style="list-style-type: none"> • Japan-headquartered Omron Healthcare, which established its Indian arm in 2010, is drawing growth plans for India that may include setting up a manufacturing unit in India and expanding its retail footprint. • By the end of 2021, the company plans to have 10 retail outlets in India and plans to create a centre in Warangal as part of its expansion into Southern India, where it anticipates a potential contribution of 40% of its sales in FY 2020. The company expects a Rs. 220 crore (US\$ 30 million) turnover in India during that period

Source: Transasisa Bio-medical Ltd. Website, News Articles

In-Vitro Diagnostics

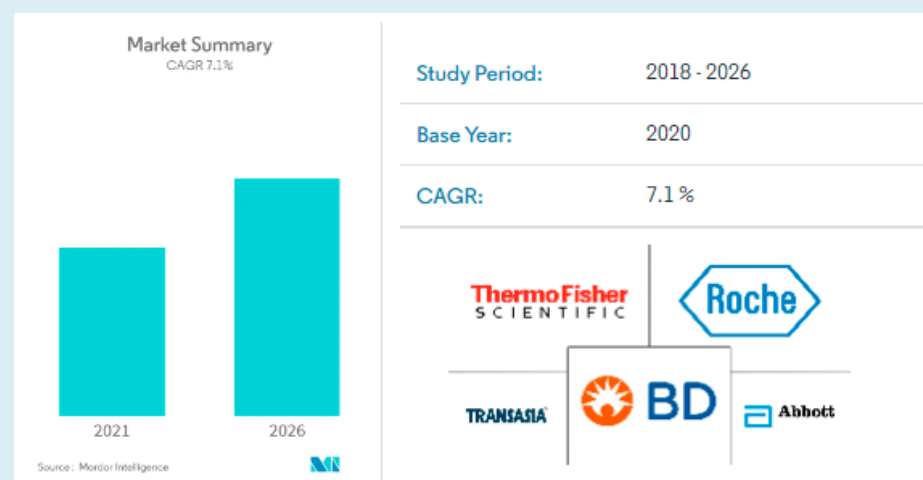
August 2021

India In-vitro Diagnostics Market

The India In-Vitro Diagnostics Market is Segmented into By Test Type (Clinical Chemistry, Molecular Diagnostics, Immunodiagnostics, Hematology, and Other Test Types), Product (Instruments, Reagents, and Other Products), Usability (Disposable IVD Devices and Reusable IVD Devices), Application (Infectious Disease, Diabetes, Cancer/Oncology, Cardiology, Autoimmune Disease, Nephrology, and Other Applications), and End User (Diagnostic Laboratories, Hospitals And Clinics, And Other End Users)

Market Overview

- India In-vitro diagnostics market estimated to be valued at USD 1255.18 million in 2020 and is expected to reach approximately USD 1990.99 million in 2026, registering a CAGR of nearly 7.10% during the forecast period.
- In the context of COVID-19, government organizations in various countries, research institutes, and many global and domestic companies are focusing on the launch of new products, which may contribute to the growth of the market studied. For instance, in July 2020, the Indian Institute of Technology (IIT), Delhi, launched a COVID-19 test kit and approved by the Indian Council of Medical Research (ICMR). In September 2020, the Central Drugs Standard Control Organization (CDSCO), which regulates pharmaceuticals and medical devices in India, approved the manufacture and sale of 'CoViDx One,' an RT-PCR test kit developed by Pune-based GenePath Diagnostics.
- The major factors that are driving the growth of the Indian in-vitro diagnostics market are the high prevalence of chronic diseases, increasing use of point-of-care (POC) diagnostics, and rising awareness and acceptance of personalized medicine and companion diagnostics. According to the GLOBOCAN factsheet, in 2020, the number of prevalent cancer cases in five years was found to be 2,720,251 among all age groups in India. Additionally, as per the International Agency for Research on Cancer (IARC), the incident cases in India are estimated to rise from 1.15 million in 2018 to 1.9 million in 2040. Similarly, according to the National Diabetes and Diabetic Retinopathy Survey report 2015-2019, there are 11.8% prevalent cases of diabetes in India. As diabetic is a major risk factor for many diseases it is expected to have significant growth of the market over the forecast period.
- Furthermore, emerging technological innovations in healthcare, such as bio-sensors, lab-on-a-chip, wearable devices, and POC diagnostics, are increasingly becoming an important part of the healthcare landscape. POC testing helps bring testing closer to the patients and obtain results quickly for the healthcare provider to expedite diagnoses and subsequent treatment. This is likely to increase the adoption of in-vitro diagnostics in India.
- However, stringent regulatory policies and lack of sufficient reimbursement policies are projected to hamper the market growth of in-vitro diagnostics market over forecast period.



Competitive Landscape- Indian Diagnostics Market

- The market studied is consolidated with the presence of a few major players. For the new entrants in the market, the barriers are high in this industry, and hence, few major market players hold the maximum market share.
- Some of the market players are Abbott Laboratories, Becton, Dickinson and Company, BioMérieux, Bio-Rad Laboratories Inc., Danaher Corporation, F. Hoffmann-La Roche AG, Qiagen NV, and Thermo Fisher Scientific.
- Companies are adopting various strategies such as collaborations, acquisitions, new launches to expand market position. For instance, in February 2018, Fujifilm Corp announced its foray into India's fragmented diagnostics market with the launch of a medical screening centre focusing on cancer screening in Bengaluru in collaboration with Dr Kutty's Healthcare

Major Players

- 1 Abbott Laboratories
- 2 Becton, Dickinson and Company
- 3 F. Hoffmann-La Roche AG
- 4 Transasia Bio-Medicals Ltd
- 5 Thermo Fisher Scientific

Market Concentration



Source: Mordor Intelligence



Recent Developments- Indian Diagnostics Market

In February 2021, Thermo Fisher Scientific Inc. set up a new state-of-the-art manufacturing facility in Bengaluru to produce COVID-19 testing kits and diagnostic solutions.

In September 2020, in collaboration with the Center for Cellular and Molecular Platforms and the Bangalore Life Science Cluster, the Indigenization of Diagnostics (InDx) was planning to build a robust supply chain network of Indian small and medium enterprises capable of the production of reagents.