Pharmaceuticals

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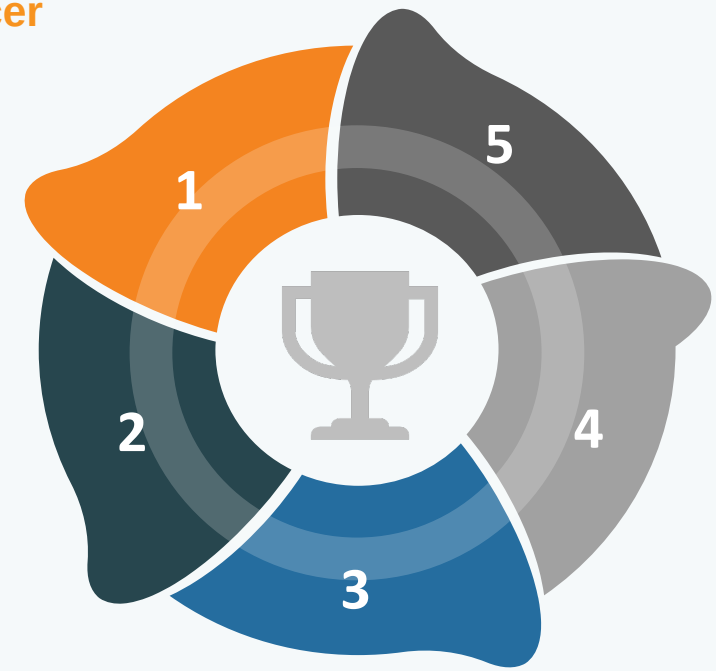
Executive summary

1. Leading pharma producer

- Indian pharmaceutical industry is expected to reach ~US$ 130 billion by 2030.
- India ranks 3rd worldwide for pharmaceutical production by volume and 14th by value. The country has an established domestic pharmaceutical industry, with a strong network of 3,000 drug companies and ~10,500 manufacturing units.

2. One of the highest exports

- Indian pharmaceutical exports stood at US$ 20.70 billion in FY20 and US$ 24.44 billion in FY21.



3. Among fastest growing industries

- Indian pharmaceutical sector is expected to grow at a CAGR of 22.4% in the near future and medical device market expected to grow US$ 25 billion by 2025. India is the second-largest contributor of global biotech and pharmaceutical workforce.

4. Rapidly growing healthcare sector

- Indian healthcare sector, one of the fastest growing sectors, is expected to cross US$ 372 billion by 2022.

5. Robust growth in biotech industry

- The Indian biotechnology industry was valued at US$ 64 billion in 2019 and is expected to reach US$ 150 billion by 2025.
- The biotechnology industry in India comprises ~600+ core biotechnology companies, ~2700+ biotech start-ups and ~100+ biotech incubators.

Note: *BIRAC - Biotechnology Industry Research Assistance Council*

Source: *[1] FICCI - Trends & Opportunities for Indian Pharma 2018, Pharmexcil*

Advantage India

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Advantage India

2. ECONOMIC DRIVERS

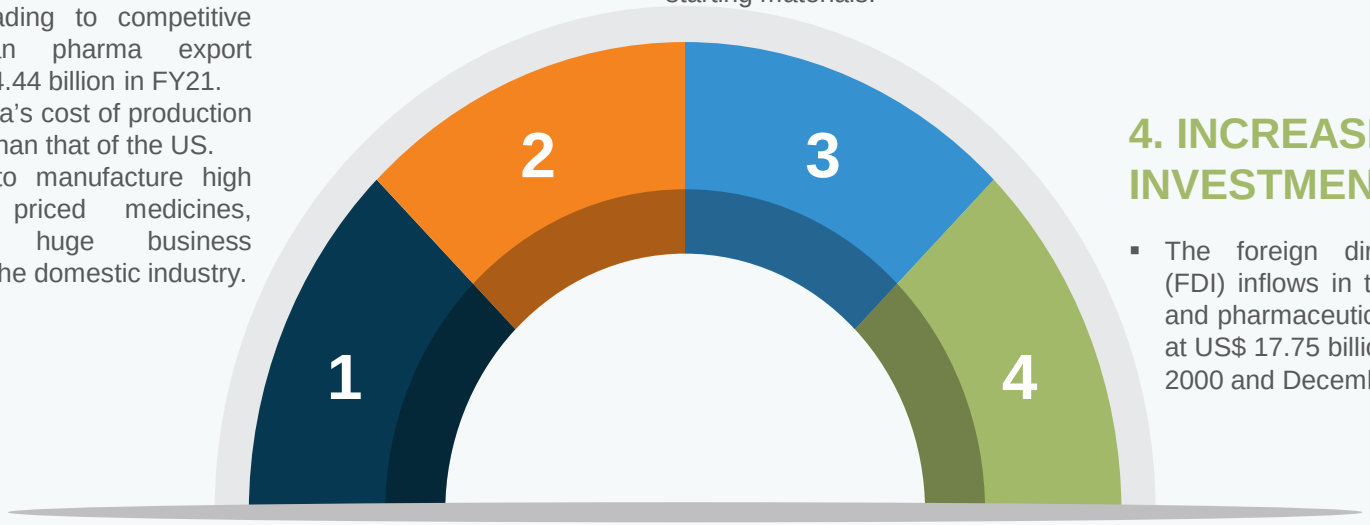
- Economic prosperity to improve drug affordability.
- Increasing penetration of health insurance to drive expenditure on medicine.
- With increasing penetration of pharmacies, especially in rural India, OTC drugs will be readily available.

1. COST EFFICIENCY

- Low cost of production and R&D boosts efficiency of Indian pharma companies, leading to competitive exports. Indian pharma export reached US$ 24.44 billion in FY21.
- As of 2019, India's cost of production is ~33% lower than that of the US.
- India's ability to manufacture high quality, low priced medicines, presents a huge business opportunity for the domestic industry.

3. POLICY SUPPORT

- In February 2021, the government approved a production-linked incentive (PLI) scheme for the pharmaceuticals sector from FY21 to FY29. The scheme is expected to attract investments of Rs. 15,000 crore (US$ 2.07 billion) into the sector. It is also expected to lead to incremental sales of Rs. 2,94,000 crore (US$ 40.63 billion) and exports of Rs.1,96,000 crore (US$ 40.63 billion) between FY23 and FY28.
- In June 2021, Finance Minister Ms. Nirmala Sitharaman announced an additional outlay of Rs. 197,000 crore (US $26,578.3 million) that will be utilised over five years for the pharmaceutical PLI scheme in 13 key sectors such as active pharmaceutical ingredients, drug intermediaries and key starting materials.



4. INCREASING INVESTMENTS

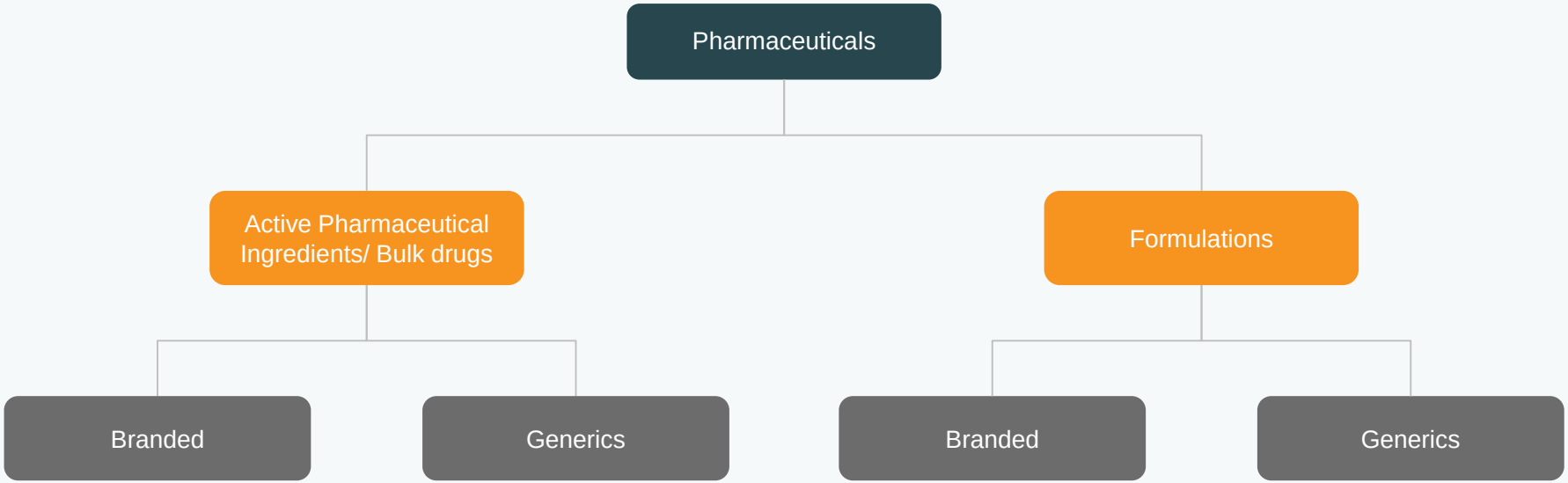
- The foreign direct investment (FDI) inflows in the Indian drugs and pharmaceuticals sector stood at US$ 17.75 billion between April 2000 and December 2020.

Market Overview

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Structure of pharmaceuticals sector in India



- Cardiovascular
- Anti-Diabetes
- Gastro-Intestinal
- Neurological

- Anti-infectives
- Respiratory
- Pain
- Gynecology

Source: *Dun and Bradstreet*

Evolution of the sector

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1970-90



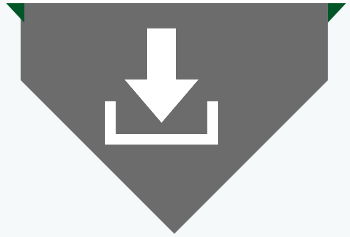
- Indian Patent Act passed in 1970.
- Several domestic companies start operations.
- Development of production infrastructure.
- Export initiatives were taken.

1990-2010



- Liberalised market.
- Indian companies increasingly launch operations in foreign countries.
- India a major destination for generic drug manufacturing.
- Approval of Patents (Amendment) Act 2005, which led to adoption of product patents in India.

2010-2013



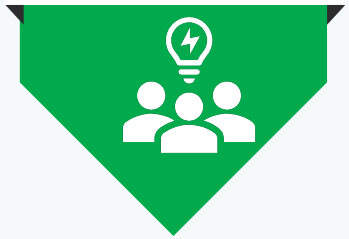
- Increased patent filings by pharma players.
- Likely adoption of newer sales models such as channel management, KAM and CSO.
- The National Pharmaceutical Pricing Policy, 2012 (NPPP-2012).
- 2013: New Drug Pricing Control Order issued by Directorate of Food and Drugs this will reduce the prices of drugs by 80%.

2013- 2015



- 2014: 100% FDI allowed in medical device industry. The investment will be routed through automatic route.
- Leading Indian pharma companies are raising funds aggressively to fund acquisition in domestic as well as international market to increase their product portfolios.
- 2015: India has 10,500 manufacturing units and over 3,000 pharma companies.
- National Health Policy Draft 2015 to increase expenditure in health care sector.
- Patent Act Amendment 2015, it includes amendments in Patent Act 2002.

2016 onwards



- In Union Budget, 2016, FDI increased to 74% in existing pharmaceutical companies and 100% for new projects.
- The Government of India unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments.

Note: *SAFTA - South Asian Free Trade Area, ASEAN - Association of Southeast Asian Nations*
Source: *TechSci Research*

Important segments in Indian pharmaceutical sector

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2. CONTRACT RESEARCH AND MANUFACTURING SERVICES (CRAMS)

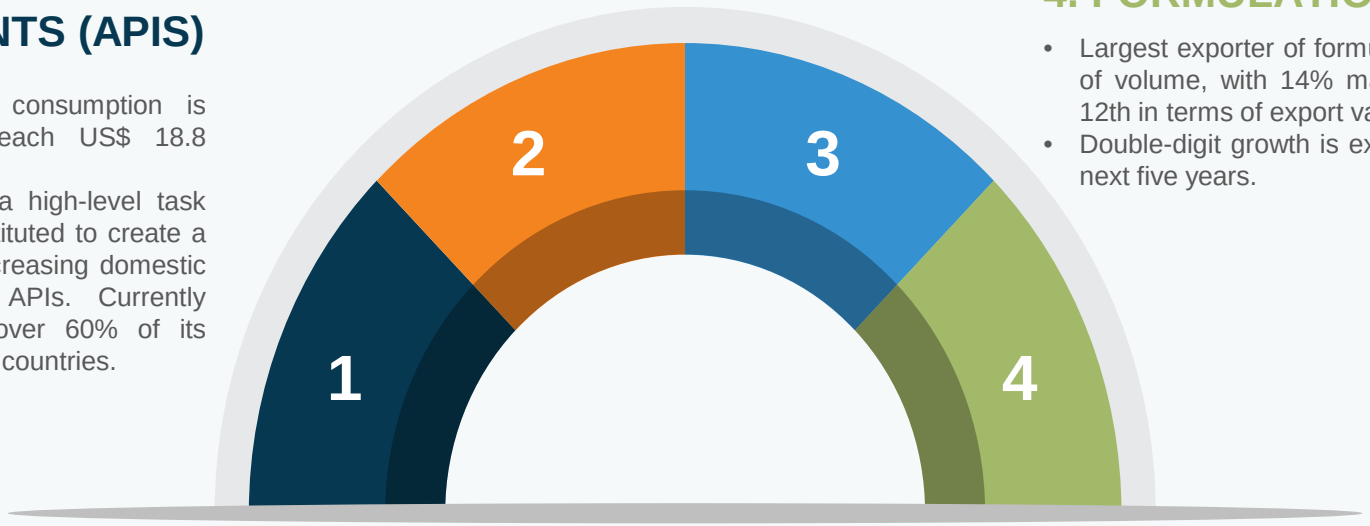
- Contract Research and Manufacturing Services (CRAMS).
- Fragmented market with more than 1,000 players.
- CRAMS industry has posted 48% CAGR between FY15-18 and expected to witness a strong growth over 25% over 2018-21.

3. BIOSIMILAR

- The Government plans to allocate US$ 70 million for local players to develop Biosimilar.
- The domestic market is expected to reach US$ 35 billion by 2030.

1. ACTIVE PHARMACEUTICAL INGREDIENTS (APIS)

- Domestic API consumption is expected to reach US$ 18.8 billion by FY22.
- In April 2019, a high-level task force was constituted to create a roadmap for increasing domestic production of APIs. Currently India imports over 60% of its APIs from other countries.

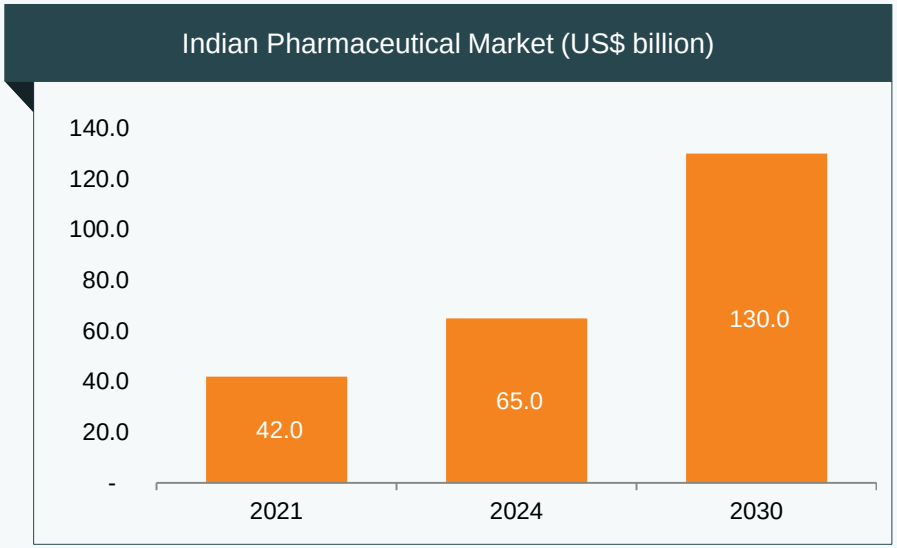


4. FORMULATIONS

- Largest exporter of formulations in terms of volume, with 14% market share and 12th in terms of export value.
- Double-digit growth is expected over the next five years.

Source: *[1] RNCOS, BMI, Datamonitor, Kemwell Biopharma, Chemical Pharmaceutical Generic Association, ICRA Report estimates, pharmanewsprwire.com*

Indian pharmaceuticals market



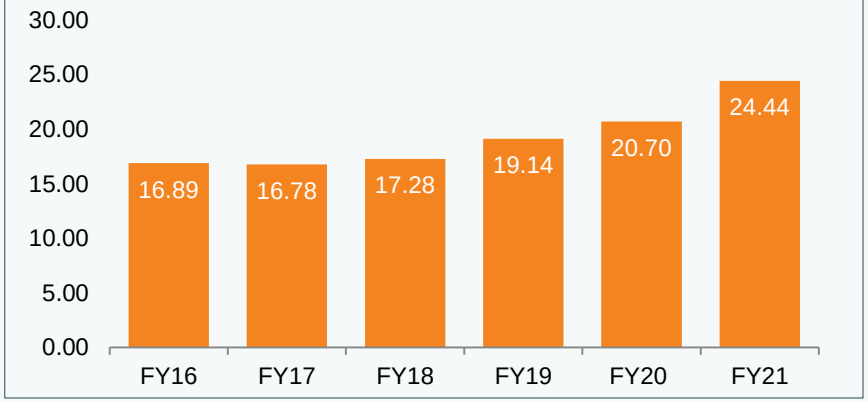
- Globally, India ranks 3rd in terms of pharmaceutical production by volume and 14th by value. The domestic pharmaceutical industry includes a network of 3,000 drug companies and ~10,500 manufacturing units.
- According to the Indian Economic Survey 2021, the domestic market is expected to grow 3x in 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*

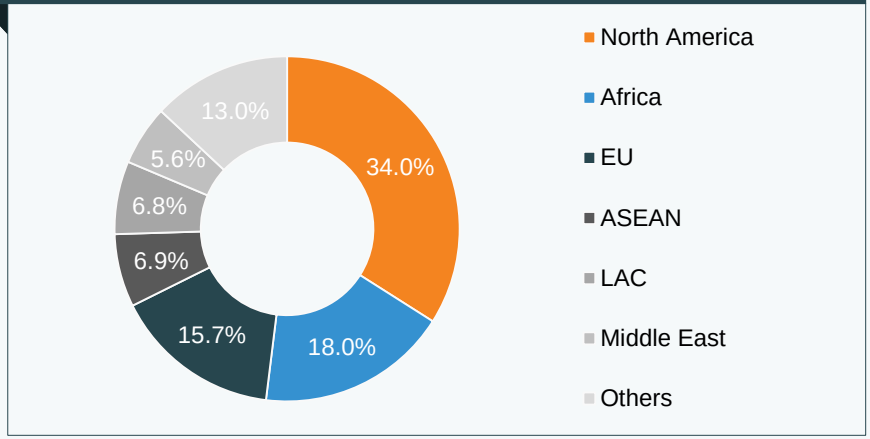
Pharmaceuticals export to continue witnessing positive growth

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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.
- India is the 12th largest exporter of medical goods in the world. The country's pharmaceutical sector contributes 6.6% to the total merchandise exports.
- 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.
- 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.
- As of May 2021, India supplied a total of 586.4 lakh COVID-19 vaccines, comprising grants (81.3 lakh), commercial exports (339.7 lakh) and exports under the COVAX platform (165.5 lakh), to 71 countries.

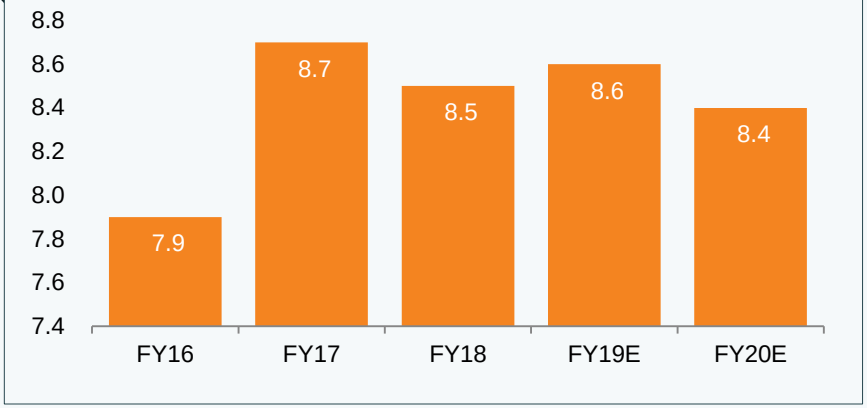
Note: *EU - European Union, ASEAN - Association of Southeast Asian Nations, LAC - Latin America and the Caribbean,*

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

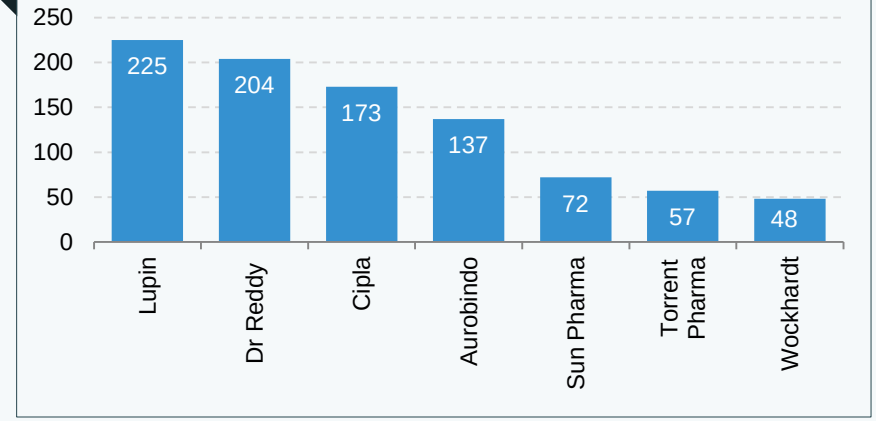
R&D spending in Indian pharmaceuticals

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R&D Investment by Indian Pharma Companies* (% of sales)



R&D spending by top pharma companies in FY20 (US$ million)



- The Indian pharmaceutical industry is now seeking to move up the global pharmaceutical value chain by investing in R&D for drug development, drug repurposing, process improvements and digital manufacturing.
- In FY20, the highest expenditure on R&D done by Lupin, followed by Dr. Reddy's.
- Sun Pharma's R&D plan includes developing more products through expanded R&D team for global markets, focussing on more complex products across multiple dosage forms and investments in speciality pipeline.
- As per the Union Budget 2021-22, Rs. 2,663 crore (US$ 365.68 million) has been set aside for research and Rs. 73,932 crore (US$ 10.35 billion) has been allocated for the Ministry of Health and Family Welfare.
- 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.

Note: **Top 10 companies as per research by HDFC Securities,*
Source: *Company website, CRISIL Research, HDFC Securities*

Recent Trends and Strategies

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Notable trends in the Indian pharmaceuticals sector

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2. PRODUCT LAUNCH

- In June 2021, Sun Pharmaceuticals acquired the patent license for Dapagliflozin from AstraZeneca. The company will be distributing and promoting the drug under the brand name 'Oxra'.
- In May 2021, Cipla launched a real-time COVID-19 detection kit 'ViraGen' that is based on multiplex polymerase chain reaction (PCR) technology.
- 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.

3. EXPANSION

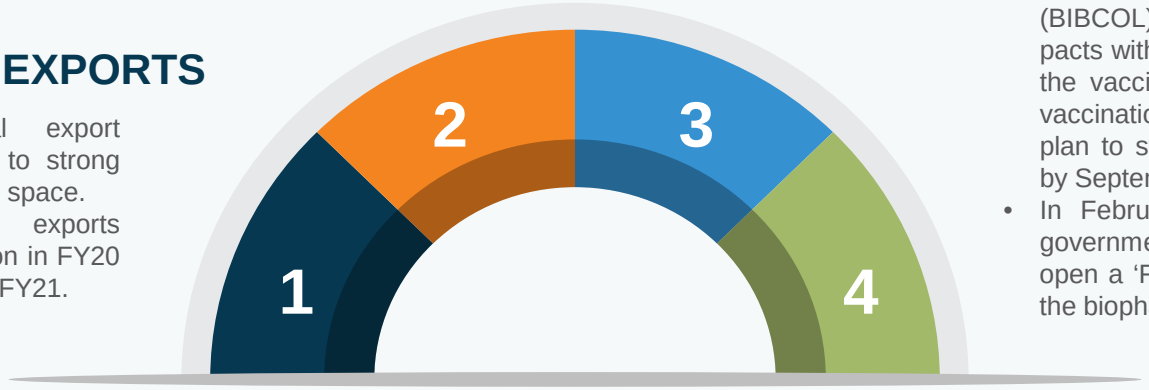
- In November 2020, Indian Immunologicals Ltd. commenced work on Rs. 75 crore (US$ 10.17 million) viral antigen manufacturing facility in Genome Valley, Telangana, that will enhance its vaccine production capacity by 35% by October 2021.
- In December 2020, Lupin obtained clearance from the US health 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.

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.



COVID-19 fightback from the Indian pharmaceuticals sector

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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, HGCO19, developed by Pune-based Gennova Biopharmaceuticals Ltd.

1. COLLABORATIONS

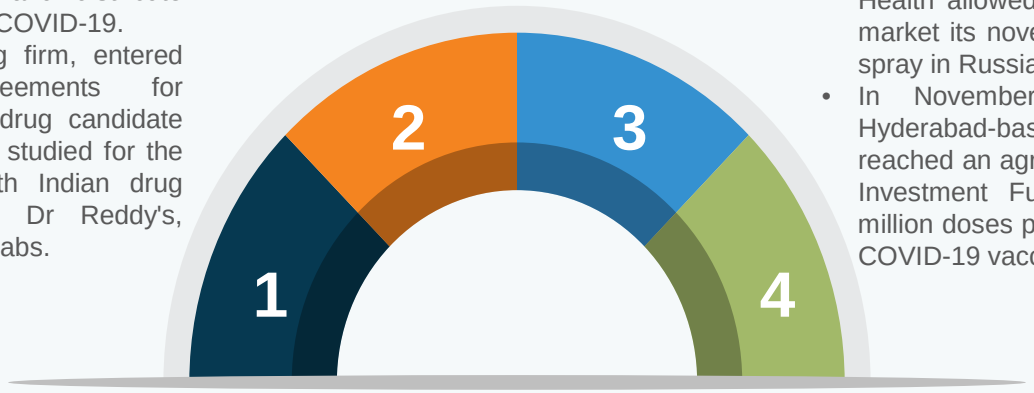
- In May 2021, Eli Lilly & Company issued non-exclusive voluntary licenses to pharmaceutical companies—Cipla Ltd., Lupin Ltd., Natco Pharma & Sun Pharmaceutical Industries Ltd.—to produce and distribute Baricitinib, a drug for treating COVID-19.
- In April 2021, MSD, a drug firm, entered voluntary licensing 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 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 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 COVID-19 vaccine in India.

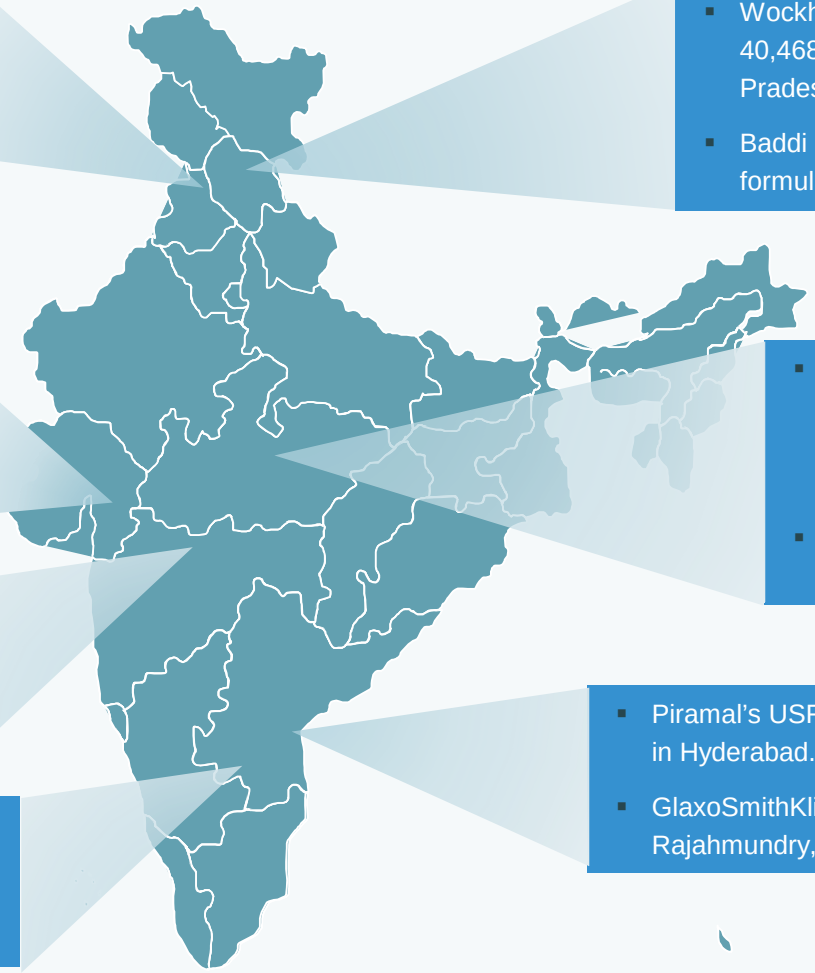


States hosting key pharmaceutical ventures

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

- 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.



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

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

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

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

- Key pharma companies and CMOs such as Mylan NV, Albany Molecular Research and Cambrex Corp. have manufacturing facilities in Telangana.

Source: *Company Website*

Strategies adopted

2. DIFFERENTIATION

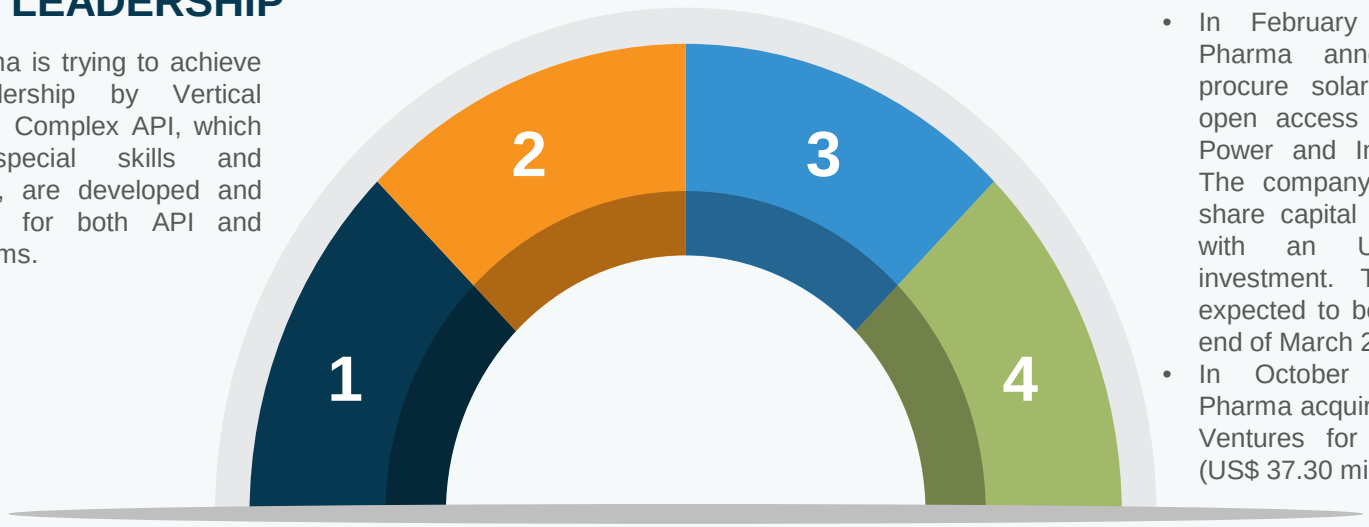
- Players in the sector are trying to strengthen their position in the market and expand themselves by investing heavily in R&D activities, such as: Dr Reddy's acquired OctoPlus N.V, a Netherlands-based company, to get access to the Poly Lactic-Co-Glycolic Acid (PLGA) technology for the formulation of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

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.

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.



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).

Growth Drivers

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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. Medical infrastructure

- 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.

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.

5. Patent Expiry

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

Notes: *CAGR - Compound Annual Growth Rate*

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

Demand drivers of Indian pharmaceuticals sector

2. ACCEPTABILITY

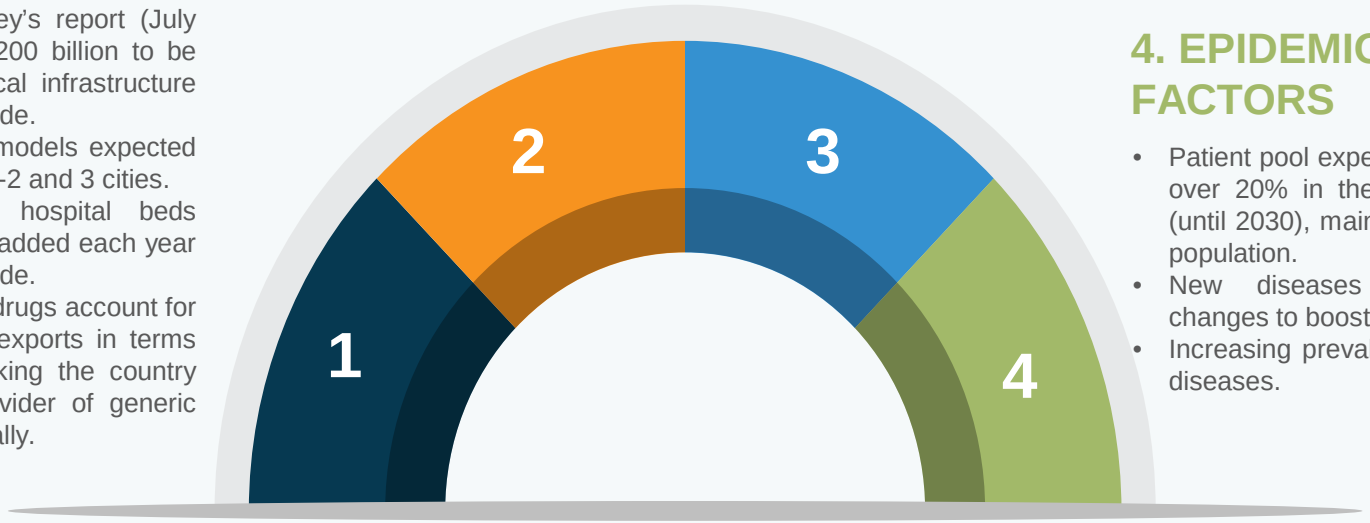
- Rising levels of education to increase acceptability of pharmaceuticals.
- Patients to show greater propensity to self-medicate, boosting the OTC market.
- Acceptance of biologics and preventive medicines to rise.
- Surge in medical tourism due to increased patient inflow from other countries.

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.

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.



4. EPIDEMIOLOGICAL FACTORS

- 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.

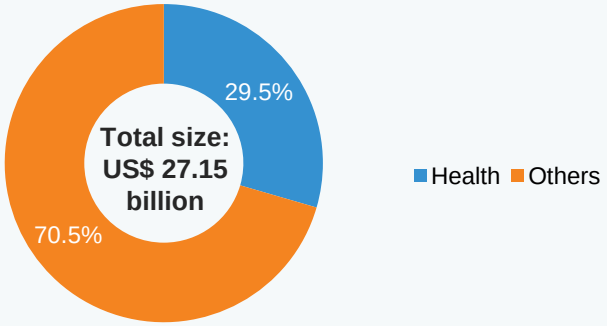
Note: *RSBY - Rashtriya Swasthya Bima Yojna*

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

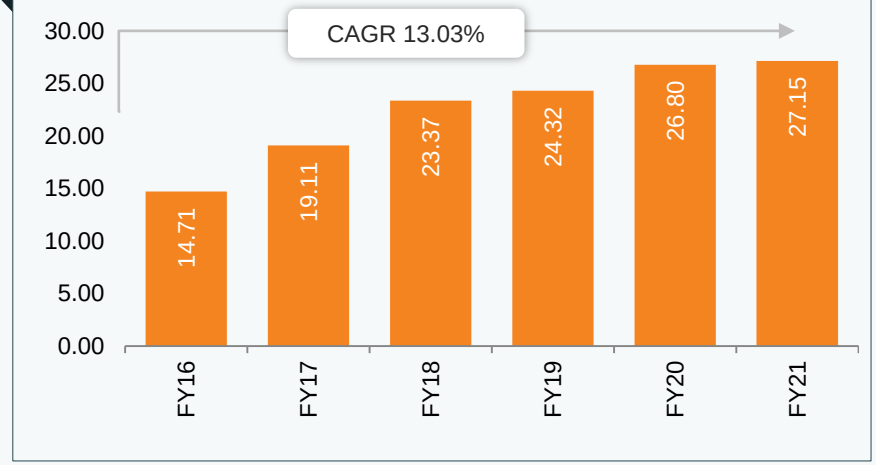
Growing health insurance

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Breakdown of non-life insurance market in India (FY21)



Gross Direct Premiums of Non-Life Insurers (US$ billion)



- Increasing penetration of non-life insurance including health insurance will drive the expansion of healthcare services and pharmaceutical market in India.
- A growing middle-class, coupled with rising burden of new diseases, is boosting the demand for health insurance coverage. With an increasing demand for affordable and quality healthcare, penetration of health insurance is poised to expand in the coming years.
- In FY21, gross written premiums in the health segment grew at 13.7% YoY to Rs. 58,584.36 crore (US$ 8.00 billion). The health segment has a 29.5% share in the total gross written premiums earned in the country.
- Another boost to the sector will be the National Health Protection Scheme under Ayushman Bharat, announced in the Union Budget 2018-19. The scheme was launched in September 2018.

Source: *IRDA, General Insurance Council, News Articles*

Favourable policy measures support growth… (1/3)

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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.

Source: *News Sources*

Favourable policy measures support growth… (2/3)

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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).

Source: *News Sources*

Favourable policy measures support growth… (3/3)

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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.

Source: *News Sources*

Investments (1/2)

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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.

- In June 2021, Finance Minister Ms. Nirmala Sitharaman announced an additional outlay of Rs. 197,000 crore (US$ 26.44 billion) that will be utilised over five years for the pharmaceutical PLI scheme in 13 key sectors such as active pharmaceutical ingredients, drug intermediaries and key starting materials.

- 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 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)
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 Pharmalab 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 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)
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*

Opportunities

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Opportunities abound in clinical trials and high-end drugs

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2. HIGH-END DRUGS

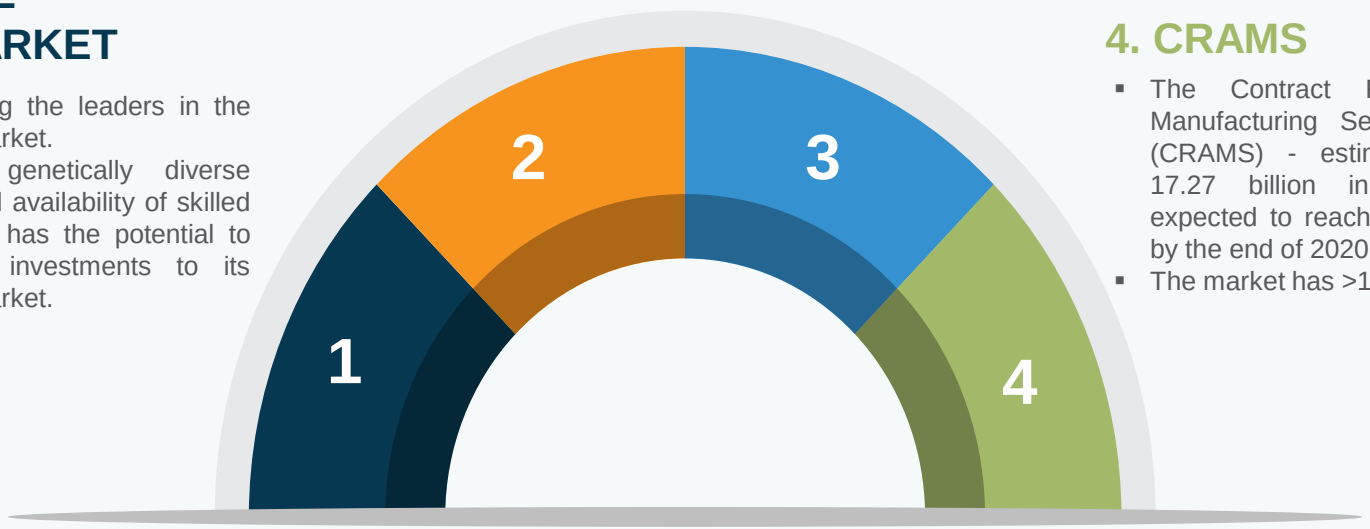
- Due to increasing population and income levels, demand for high-end drugs is expected to rise.
- Growing demand could open up the market for production of high-end drugs in India.

3. PENETRATION IN RURAL MARKET

- With 70% of India's population residing in rural areas, pharma companies have immense opportunities to tap this market.
- Demand for generic medicines in rural markets has seen a sharp growth. Various companies are investing in the distribution network in rural areas.

1. CLINICAL TRIALS MARKET

- India is among the leaders in the clinical trial market.
- Due to a genetically diverse population and availability of skilled doctors, India has the potential to attract huge investments to its clinical trial market.



4. CRAMS

- The Contract Research and Manufacturing Services industry (CRAMS) - estimated at US$ 17.27 billion in 2017-18, is expected to reach US$ 20 billion by the end of 2020.
- The market has >1,000 players.

Source: *BMI, Drug Controller General of India*

Key Industry Contacts

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Key industry contacts

Agency	Contact Information
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Organisation of Pharmaceutical Producers of India	Peninsula Chambers, Ground Floor, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013 Phone: 9122 24918123, 24912486, 66627007 Fax: 9122 24915168 E-mail: admin@indiaoppi.com Website: www.indiaoppi.com
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Bulk Drug Manufacturers Association	C-25, Industrial Estate, Sanath Nagar Hyderabad - 500018 Phone: 91 40 23703910/23706718 Fax: 91 40 23704804 E-mail: info@bdmai.org, bdma.hyd@gmail.com Website: www.bdmai.org

Appendix

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Glossary

- CRAMS: Contract Research and Manufacturing Services
- API: Active Pharmaceutical Ingredients
- FDI: Foreign Direct Investment
- GOI: Government of India
- Rs.: Indian Rupee
- US$: US Dollar
- BPL: Below Poverty Line
- RSBY: Rashtriya Swastha Bima Yojna
- ESIC: Employees State Insurance Corporation
- 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*	72.68

Note: *As of June 2021*
Source: *Reserve Bank of India, Average for the year*

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