

# Pharmaceuticals



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# Executive summary

## 1. Leading pharma producer

- According to a recent EY FICCI report, as there has been a growing consensus over providing new innovative therapies to patients, Indian pharmaceutical market is estimated to touch US\$ 130 billion in value by the end of 2030. Meanwhile, the global market size of pharmaceutical products is estimated to cross over the US\$ 1 trillion mark in 2023.
- 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

- India's drugs and pharmaceuticals exports stood at Rs. 2,08,231 crore (US\$ 25.3 billion) for FY23, as per the data by Pharmexcil.
- According to the Government data, the Indian pharmaceutical industry is worth approximately US\$ 50 billion with over US\$ 25 billion of the value coming from exports.
- About 20% of the global exports in generic drugs are met by India.



## 3. Among fastest growing industries

- The Indian pharmaceutical industry has seen a massive expansion over the last few years and is expected to reach about 13% of the size of the global pharma market while enhancing its quality, affordability, and innovation.
- 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.
- Drugs and pharmaceuticals have recorded a positive growth of 2.97% between April 2022-January 2023.

## 5. Robust growth in biotech industry

- India is among the top 12 destinations for biotechnology worldwide and 3rd largest destination for biotechnology in Asia Pacific. In 2022, India's biotechnology industry has crossed US\$ 80.12 billion, growing 14% from the previous year.

## 4. Rapidly growing healthcare sector

- Healthcare sector in India is expected to reach a size of US\$ 50 billion by 2025.

*Note: BIRAC - Biotechnology Industry Research Assistance Council*

*Source: News Articles, Make in India, Press Information Bureau*



## 2. ECONOMIC DRIVERS

- On December 21, 2020, a MoU was signed between Tata Memorial Centre of India and Vietnam National Cancer Hospital to promote exchanges in the areas of training and scientific research, health care services, collaboration in diagnosis and treatment for cancer patients.
- The total market size of the Indian Pharma Industry is expected to reach US\$ 130 billion by 2030.

## 1. COST EFFICIENCY

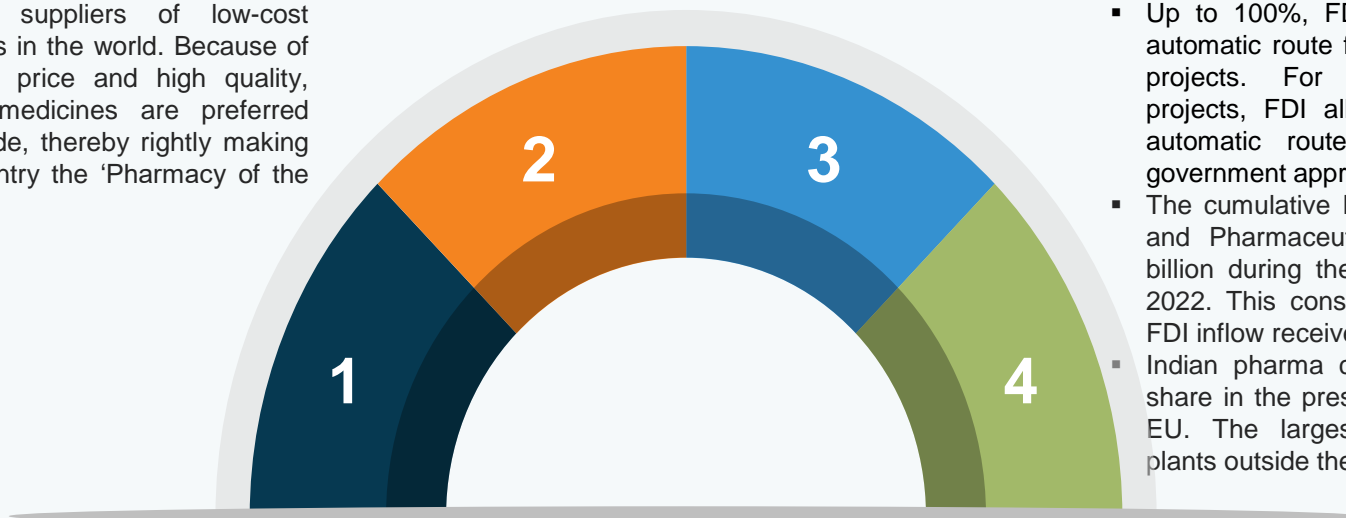
- Access to affordable HIV treatment from India is one of the greatest success stories in medicine. India is one of the biggest suppliers of low-cost vaccines in the world. Because of the low price and high quality, Indian medicines are preferred worldwide, thereby rightly making the country the 'Pharmacy of the World'.

## 3. POLICY SUPPORT

- The Union Cabinet, on April 26, 2023, approved the National Medical Devices Policy, 2023. The National Medical Devices Policy, 2023 is expected to facilitate an orderly growth of the medical device sector to meet the public health objectives of access, affordability, quality and innovation.
- Strengthening of Pharmaceutical Industry (SPI): The Ministry's scheme "Strengthening of Pharmaceutical Industry (SPI) with a total financial outlay of Rs. 500 crore (US\$ 60.6 million) extends support required to existing pharma clusters and MSMEs across the country to improve their productivity, quality and sustainability.
- Pradhan Mantri Bhartiya Jan Aushadhi Kendras (PMBJKs): The Government has set a target to increase the number of PMBJKs to 10,500 by the end of March 2025. Product basket of PMBJP comprises of 1,451 drugs and 240 surgical instruments.

## 4. INCREASING INVESTMENTS

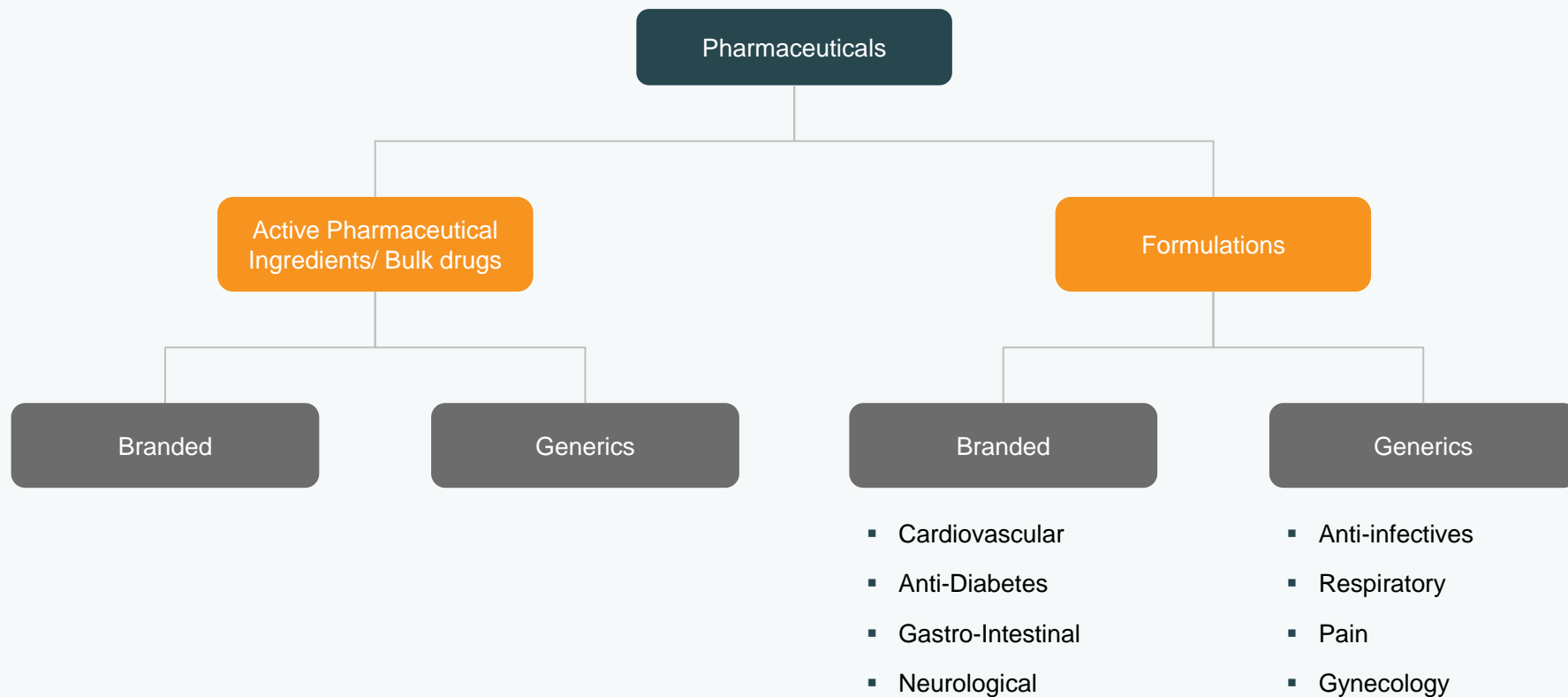
- Up to 100%, FDI has been allowed through automatic route for Greenfield pharmaceuticals projects. For Brownfield pharmaceuticals projects, FDI allowed is up to 74% through automatic route and beyond that through government approval.
- The cumulative FDI equity inflow in the Drugs and Pharmaceuticals industry is US\$ 21.22 billion during the period April 2000-December 2022. This constitutes almost 3% of the total FDI inflow received across sectors.
- Indian pharma companies have a substantial share in the prescription market in the US and EU. The largest number of FDA-approved plants outside the US is in India.



Source: Make in India, Department of Pharmaceuticals, DPIIT

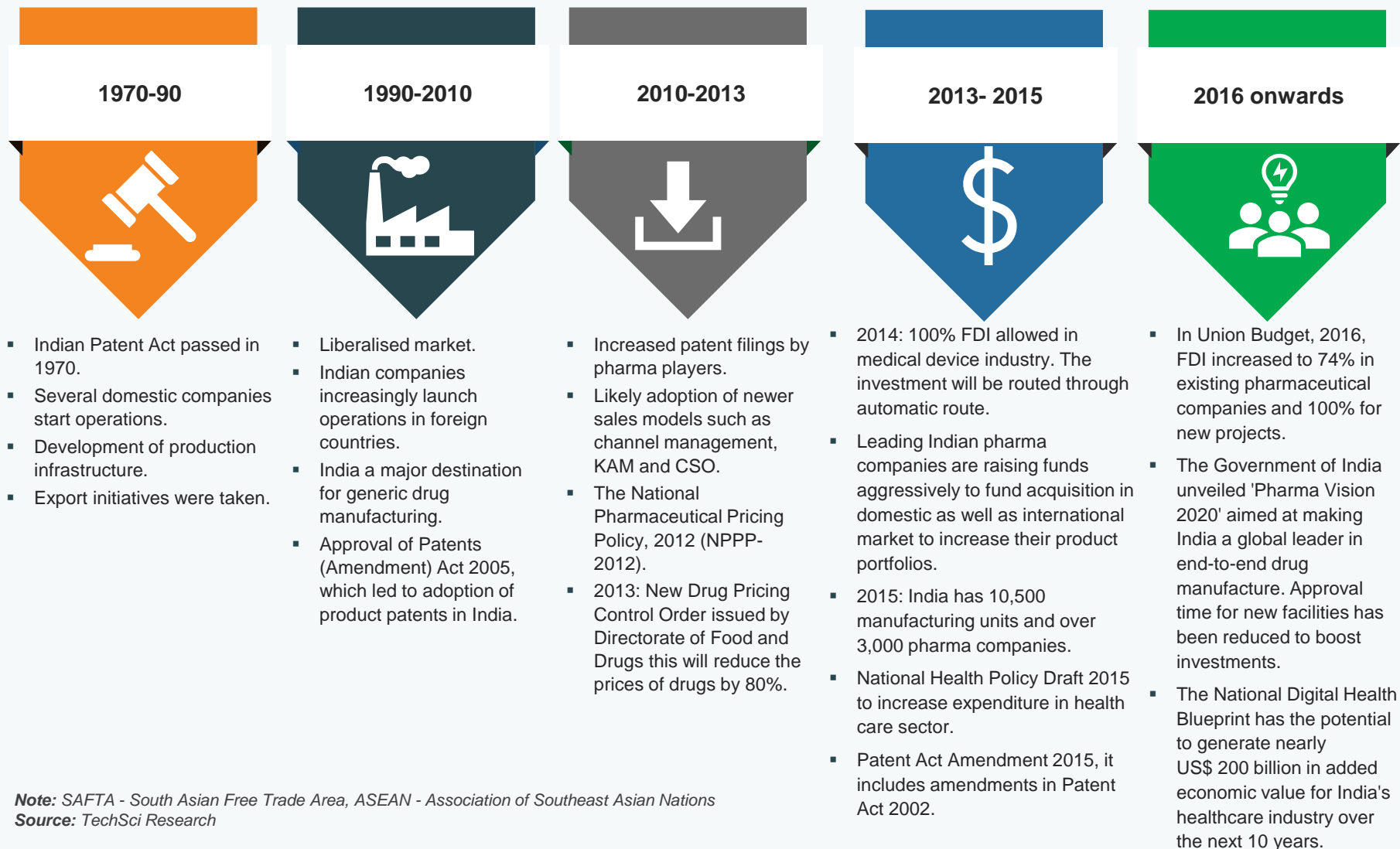


# Structure of pharmaceuticals sector in India



Source: Dun and Bradstreet

# Evolution of the sector



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

**Source:** TechSci Research

# Important segments in Indian pharmaceutical sector

## 2. CONTRACT RESEARCH AND MANUFACTURING SERVICES (CRAMS)

- Contract research and manufacturing services (CRAMS) is one of the fastest growing segments in the pharmaceutical and biotechnology industry. The pharmaceutical market uses outsourcing services from providers in the form of contract research organizations (CROs) and contract manufacturing organizations (CMOs).

## 1. ACTIVE PHARMACEUTICAL INGREDIENTS (APIS)

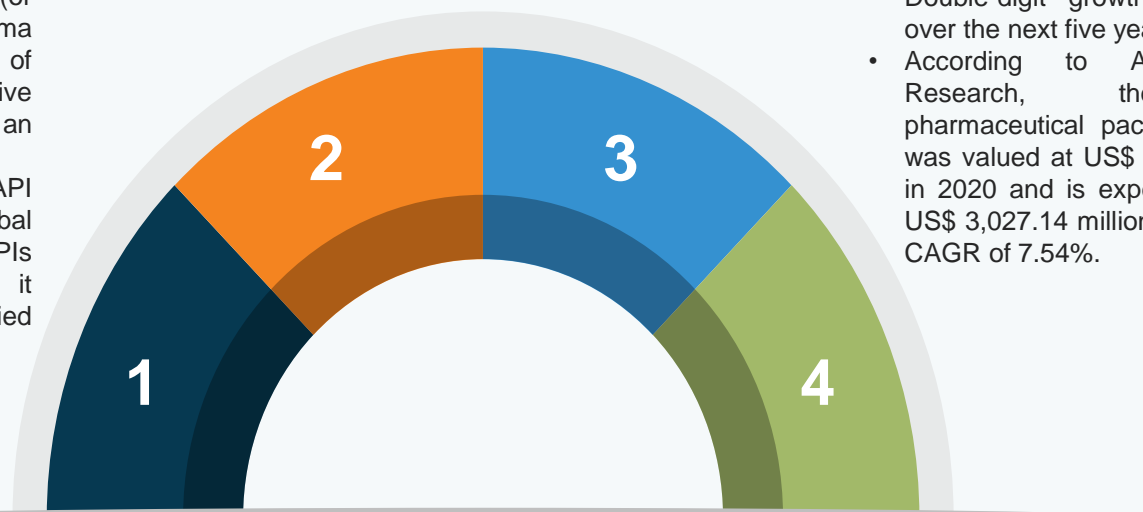
- Active Pharmaceutical Ingredient (or API) is a crucial segment of the pharma industry, contributing to around 35% of the market. API is the biologically active component of a drug that causes an intended medical effect.
- India is the 3rd largest producer of API accounting for an 8% share of the Global API Industry. About 500+ different APIs are manufactured in India, and it contributes 57% of APIs to prequalified list of the WHO.

## 3. BIOSIMILAR

- The biosimilars market in India is estimated to grow at a compounded annual growth rate (CAGR) of 22% to become US\$ 12 billion by 2025. This would represent almost 20% of the total pharmaceutical market in India.

## 4. FORMULATIONS

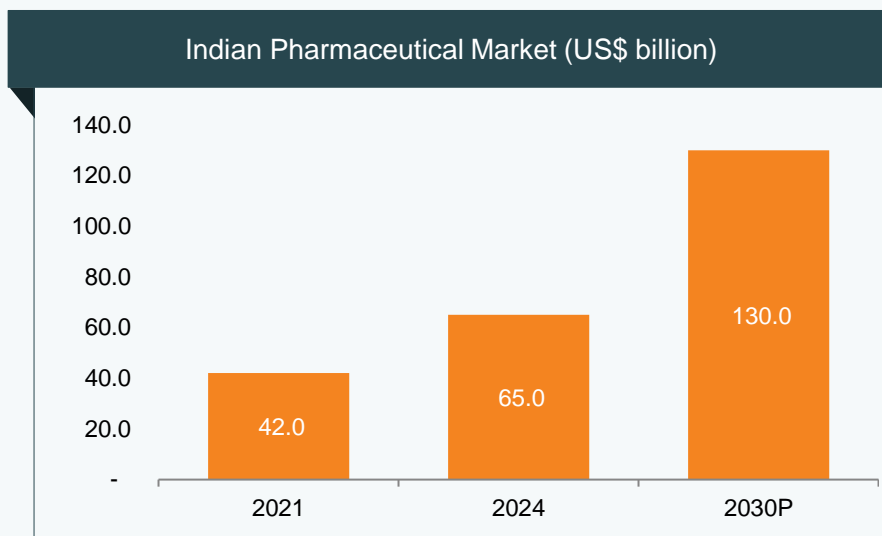
- Largest exporter of formulations in terms of volume, with 14% market share and 12th in terms of export value.
- Double-digit growth is expected over the next five years.
- According to Allied Market Research, the Indian pharmaceutical packaging market was valued at US\$ 1,434.1 million in 2020 and is expected to reach US\$ 3,027.14 million by 2030, at a CAGR of 7.54%.



**Note:** CAGR- Compounded Annual Growth Rate

**Source:** News Articles, Invest India, Make in India

# Indian pharmaceuticals market



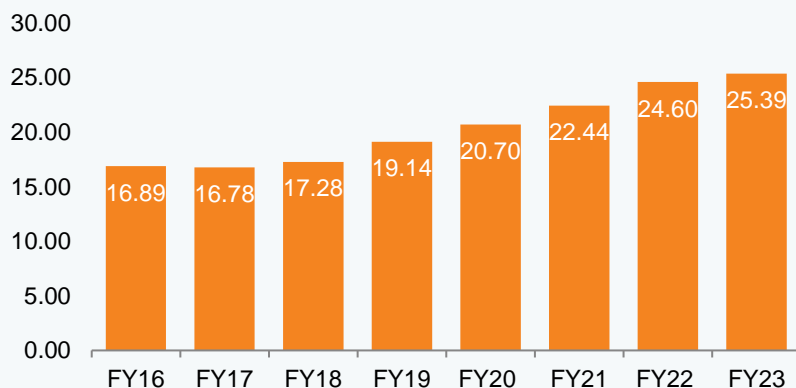
- Indian pharmaceutical industry is known for its generic medicines and low-cost vaccines globally. Transformed over the years as a vibrant sector, presently Indian pharma ranks third in pharmaceutical production by volume. The Pharmaceutical industry in India is the third largest in the world in terms of volume and 14th largest in terms of value. The pharma sector currently contributes to around 1.72% of the country's GDP.
- Major Segments of the Pharmaceutical Industry are Generic drugs, OTC Medicines and API/Bulk Drugs, Vaccines, Contract Research & Manufacturing, Biosimilars & Biologics.
- Market size of India pharmaceuticals industry is expected to reach US\$ 65 billion by 2024, and ~US\$ 130 billion by 2030.
- India is 3rd largest market for APIs globally, 8% share in the Global API Industry, 500+ different APIs are manufactured in India, and it contributes 57% of APIs to prequalified list of the WHO.
- Pharmaceutical is one of the top ten attractive sectors for foreign investment in India. The pharmaceutical exports from India reach more than 200 nations around the world, including highly regulated markets of the USA, West Europe, Japan, and Australia.
- India supplied around 45 tonnes and 400 million tablets of hydroxychloroquine to around 114 countries globally.
- The current market size of the medical devices sector in India is estimated to be US\$ 11 billion and its share in the global medical device market is estimated to be 1.5%.

*Note: P-Projected*

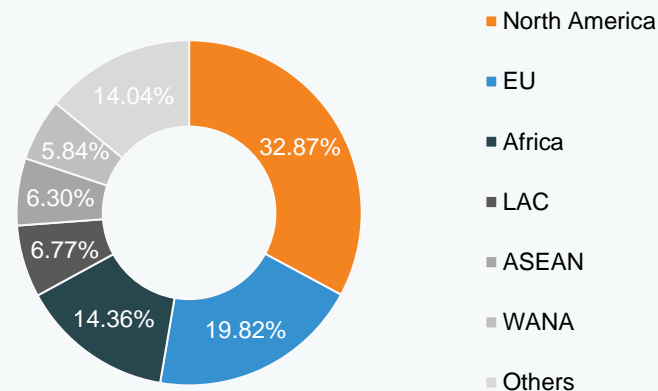
*Source: Department of Pharmaceuticals, Make in India, Invest India*

# Pharmaceuticals export to continue witnessing positive growth

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



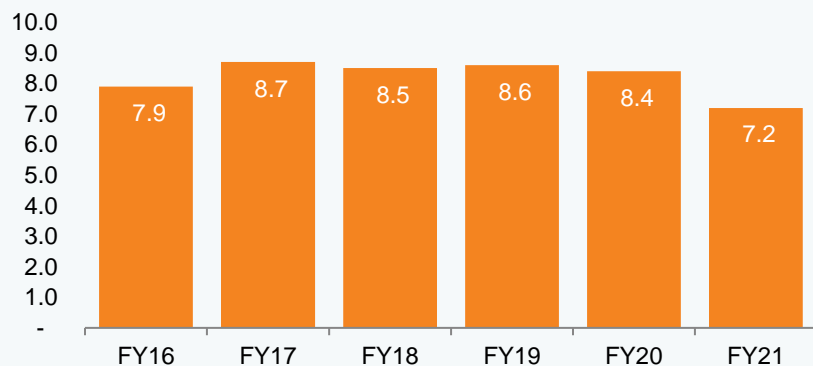
Major Export Destinations in India's Pharma Export in FY21 (%)



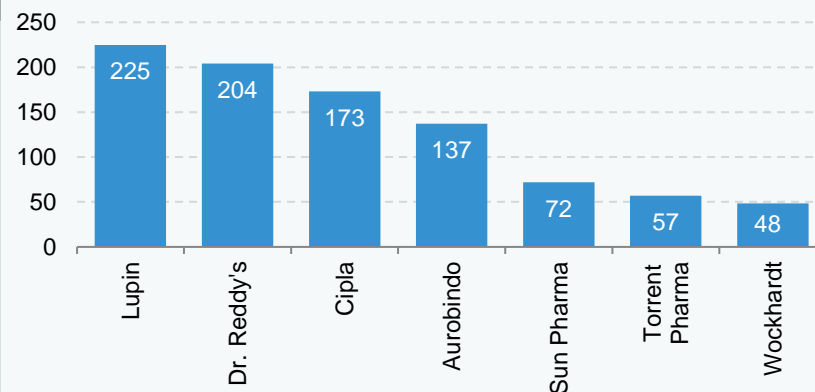
- Indian pharmaceutical industry is known for its generic medicines and low-cost vaccines globally. Transformed over the years as a vibrant sector, presently Indian Pharma ranks third in pharmaceutical production by volume. Indian drugs are exported to more than 200 countries in the world, with the US as the key market.
- Exports of Drugs & Pharmaceuticals was estimated to be at US\$ 2.48 billion in March, 2023 and shared 6.47% of the total exports of the month.
- About 20% of the global exports in generic drugs are met by India.
- The medical devices sector to grow from the current US\$ 11 billion to US\$ 50 billion in the next few years.
- Building on the outstanding performance in the previous FY21, Indian pharmaceutical exports once again registered a healthy performance in 2021-22. The pharma exports in 2021-22 sustained positive growth despite the global trade disruptions and drop in demand for COVID-related medicines.
- The Indian vaccine industry developed Covid vaccine with indigenous technology in collaboration with India's research institutions like Indian Council of Medical Research (ICMR) and the National Institute of Virology (NIV) within shortest time on par with highly developed countries like America and EU. India provided 115 million doses of vaccines to more than 97 countries.
- India's pharmaceutical exports have increased 138% in April-October 2022-23 compared to the same period of 2013-14.

# R&D spending in Indian pharmaceuticals

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



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



- The biotechnology and pharmaceutical sectors have showcased resilience and grit in the face of the pandemic, continuously evolving and innovating for better outcomes. The industry has witnessed innovation in the fields of new vaccine technology and treatment methods as well as in the R&D that goes behind making these vaccines and treatments.
- Utilizing modern technologies to manufacture pharmaceuticals, improve scientific procedures, and identify novel treatment approaches is fast catching on.
- India is making an effort to build a policy framework that incorporates intellectual property and technology commercialization, government procurement, scientific research, education, and skill development, as well as ease of doing business, regulatory legislation, and tax and financial incentives, these regulatory adjustments will open the door for further private sector investment in pharmaceutical R&D.
- The Union Budget 2023 aims to provide stimulus towards innovation with the announcement of the promotion of research and innovation programme in pharmaceuticals through Centres of Excellence.
- For innovation in the pharmaceutical sector, through centres of excellence, a new initiative to encourage pharmaceutical research and innovation will be implemented. The government persuades business to spend money on R&D in a few chosen priority fields. At the grassroots level, government has also announced on building 157 nursing colleges in co-location with government medical colleges.
- The government would also facilitate select ICMR labs with facilities like research by both public and private medical collage faculty's alongside, private sector R&D teams.

# Recent Trends and Strategies



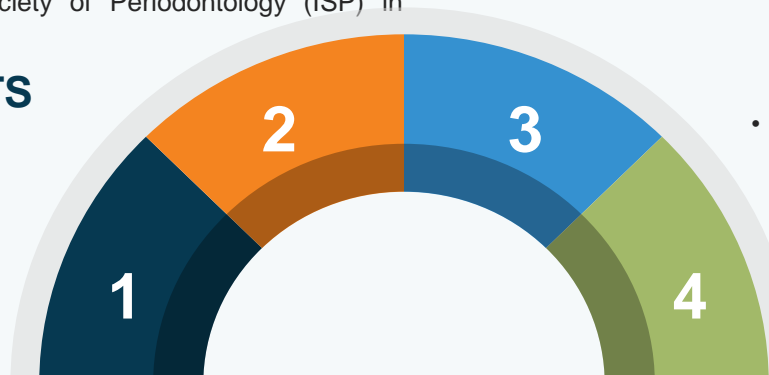
# Notable trends in the Indian pharmaceuticals sector

## 2. PRODUCT LAUNCH

- Emcure Pharmaceuticals Limited (EPL) becomes the first ever company to launch Orofer FCM 750, a new extension of its parenteral iron brand containing Ferric carboxymaltose (FCM). The dose is suitable for the majority of Indian patients with iron deficiency and iron deficiency anemia.
- Glenmark Pharmaceuticals Ltd. (Glenmark), an innovation-driven, global pharmaceutical company, is the first to launch a unique I.V. injection formulation, Akynzeo I.V., in India for the prevention of chemotherapy-induced nausea and vomiting (CINV), under an exclusive licensing agreement with Helsinn, a Swiss biopharma group company.
- Entod Pharmaceuticals has recently launched its new ocular aesthetic range focused on improving eye comfort and enhancing the aesthetics of the eyes.
- BDR Pharmaceutical has launched the first generic apalutamide (brand name Apatide) in India to treat both metastatic castration sensitive prostate cancer as well as non-metastatic castration resistant prostate cancer. The product will be available across India.
- Anglo French Drugs & Industries Limited (AFDIL), a 99-year-old organization in the pharmaceutical sector, announced that it has entered into the fertility space with the launch of the LYBER range.
- Eli Lilly introduces Ramiven in India, for certain high-risk early breast cancer patients in November 2022.
- ICPA Health Products Ltd (ICPA), a leading pharma company in the oral healthcare segment, has launched its latest product – Heximetro at the annual conference of the Indian Society of Periodontology (ISP) in November 2022.

## 1. INCREASING EXPORTS

- About 20% of the global exports in generic drugs are met by India.
- Exports of Drugs & Pharmaceuticals was estimated to be at US\$ 2.48 billion in March, 2023 and shared 6.47% of the total exports of the month.



## 3. EXPANSION

- In October 2022, Lupin signed an agreement to acquire two inhalation brands from Sunovion Pharmaceuticals Inc.
- Glenmark became the first Indian pharmaceutical company to launch Indacaterol + Mometasone fixed-Dose combination drug for Asthma.
- In April 2022, Dr. Reddy's Laboratories Ltd. inked a pact with MediCane Health to announce the launch of medical cannabis products in Germany.

## 4. PARTNERSHIPS

- Japanese companies have been invited to invest in the Indian Pharmaceutical and Medical Device Industry. The cooperation between Pharmaceutical Traders Association and Japan Federation of Medical Devices Associations of the two countries can contribute to stabilize the global supply-chain especially of APIs and Medical Devices.
- An investment announcement came from Mumbai-based Jupiter Lifeline Hospitals Limited to set up a state-of-the-art neuro rehabilitation centre with 100 inpatient beds in the UK for patients with stroke, traumatic brain injury, and neurological disorders.
- Microlabs, an Indian pharmaceuticals company has committed an investment of US\$ 10.84 million (£10 million) to expand in the UK, besides Qure AI Technologies' investment of US\$ 6.51 million (£6 million).
- The representatives of Ahmedabad's Kusum Dhirajlal Hospital a multispeciality charitable hospital along with the British multinational medical equipment maker, Smith & Nephew Plc, met Johnson in Ahmedabad to showcase the hospital's capabilities of robotic surgeries and held discussions on the possible future technological tie-ups.

# COVID-19 fightback from the Indian pharmaceuticals sector

## 2. R&D RELATED TO COVID-19

- In light of the COVID-19 pandemic, Department of Biotechnology and Biotechnology Industry Research Assistance Council (BIRAC) launched the 'DBT-BIRAC COVID-19 Research Consortium' as part of the comprehensive efforts to facilitate development of indigenous research solutions to tackle COVID-19.
- *Mission COVID Suraksha- the Indian COVID-19 vaccine development Mission*: 'Mission COVID Suraksha- The Indian COVID-19 Vaccine Development Mission', was announced as part of the third stimulus package, Atmanirbhar Bharat 3.0, for promoting research and development of Indian COVID-19 vaccines.

## 1. COLLABORATIONS

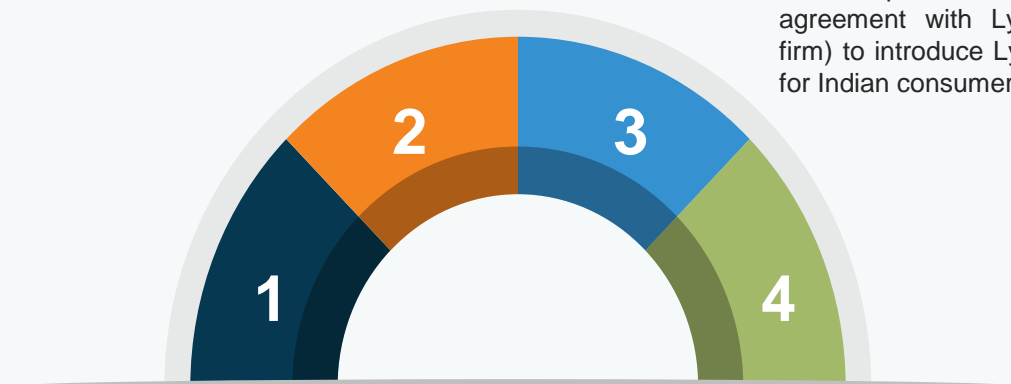
- Under the Ind-CEPI Mission, Financial support is being provided for 'Global Chikungunya Vaccine Clinical Development Program' (GCCDP), a collaboration between Bharat Biotech International Limited (BBIL) and the International Vaccine Institute (IVI) to advance the development of a novel inactivated vaccine candidate for Chikungunya (CHIKV), BBV87.

## 3. GOVERNMENT INITIATIVES

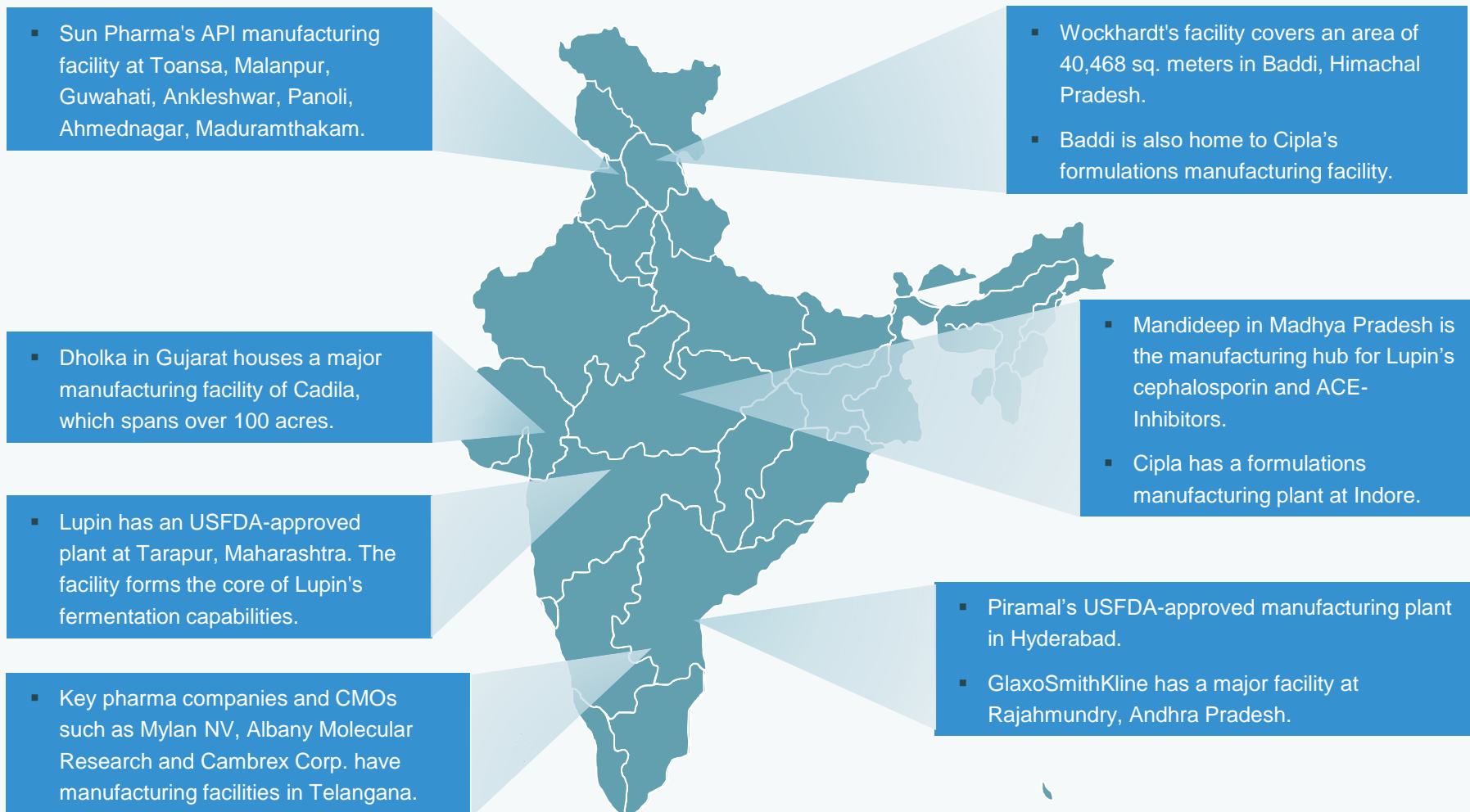
- The Department of Biotechnology (DBT), initiated the implementation of the Ind-CEPI Mission entitled "Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development aligned with the global initiative of the Coalition for Epidemic Preparedness Innovations (CEPI)".
- The Mission is focused on strengthening infrastructure for development of vaccines for emerging infectious diseases of epidemic potential through academia-industry interface; enabling skill development and capacity building activities.

## 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 August 2021, Uniza Group, an Ahmedabad-based pharmaceutical firm, signed an agreement with Lysulin Inc. (an US-based firm) to introduce Lysulin, a nutritional product for Indian consumers.



# States hosting key pharmaceutical ventures



Source: Company Website

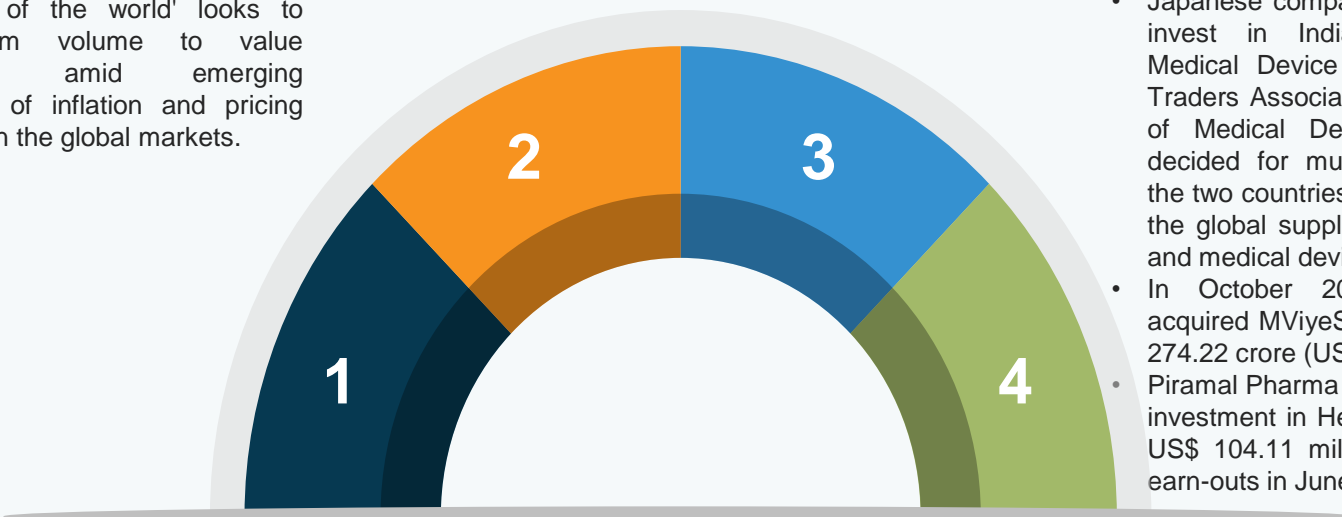
# Strategies adopted

## 2. DIFFERENTIATION

- R&D investment, market competitiveness, regulatory scrutiny, and domestic price regulations are expected to shape the growth of generics and injectable products in the pharmaceutical industry in 2023.
- The industry believes that in view of India's G20 Presidency, digital health innovation, achieving universal health coverage, improving healthcare infrastructure and delivery will continue to be the key driving factors in 2023.

## 1. COST LEADERSHIP

- Reinvent and innovate will be the key mantra for the Indian pharma industry in the New Year as the 'pharmacy of the world' looks to move from volume to value leadership, amid emerging challenges of inflation and pricing pressures in the global markets.



## 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

- Sun Pharmaceutical Industries Limited announced the successful completion of its acquisition of Concert Pharmaceuticals, Inc. on March 6, 2023, a late-stage clinical biopharmaceutical company that is developing deuruxolitinib, a novel, deuterated, oral JAK1/2 inhibitor, for the potential treatment of adult patients with moderate to severe alopecia areata.
- Japanese companies have been invited to invest in Indian Pharmaceutical and Medical Device Industry. Pharmaceutical Traders Association and Japan Federation of Medical Devices Associations have decided for mutual cooperation between the two countries can contribute to stabilize the global supply-chain especially of APIs and medical devices.
- In October 2020, Aurobindo Pharma acquired MViyeS Pharma Ventures for Rs. 274.22 crore (US\$ 37.30 million).
- Piramal Pharma Ltd. agreed to buy a 100% investment in Hemmo Pharmaceuticals for US\$ 104.11 million in cash up front and earn-outs in June 2021.



# 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

- The presence of a skilled workforce as well as high managerial and technical competence is a source of attraction for private players. Pharma companies have already increased spending in the country to tap rural markets and develop better infrastructure.
- *Promotion of Medical Devices Parks:* Objective of the scheme is Creation of world class infrastructure facilities in order to make Indian medical device industry a global leader.



## 3. Scope in generics market

- India has the second-highest number of US FDA approved plants outside the US and is the largest provider of generic drugs globally.
- About 20% of the global exports in generic drugs are met by India.

## 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.

## 4. Over-The-Counter (OTC) drugs

- The Union government, in 2022, has proposed to introduce over-the-counter (OTC) drugs in India through an amendment in the Drugs and Cosmetics Rules and allow their sale in the retail market without doctors' prescription.
- A draft notification issued by the Union health ministry has proposed that the 16 drugs, which include common antipyretic medicine such as paracetamol 500 mg, some laxatives, nasal decongestants and topical antifungal creams be included in the OTC drug category.

# Demand drivers of Indian pharmaceuticals sector

## 2. ACCEPTABILITY

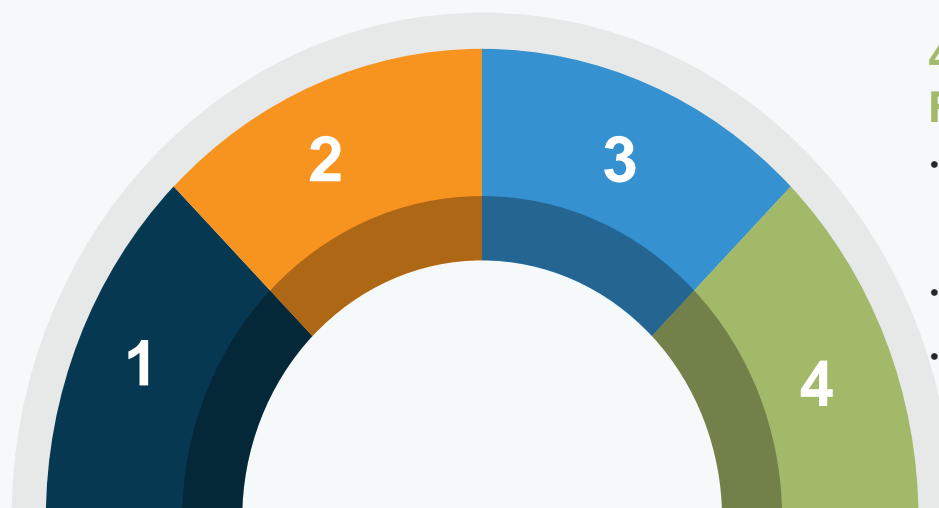
- Rising levels of education to increase acceptability of pharmaceuticals.
- Patients to show greater propensity to self-medicate, boosting the OTC market.
- Acceptance of biologics and preventive medicines to rise.
- Surge in medical tourism due to increased patient inflow from other countries.

## 3. PRADHAN MANTRI BHARTIYA JANAUSHADHI KENDRAS

- As of May 19, 2023, the total number of Jan Aushadhi Kendras in the country are 9,442.
- 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

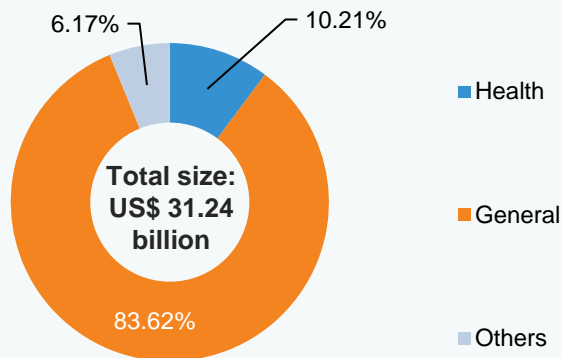
- Patient pool expected to increase over 20% in the next 10 years (until 2030), mainly due to rise in population.
- New diseases and lifestyle changes to boost demand.
- Increasing prevalence of lifestyle diseases.

*Note: RSBY - Rashtriya Swasthya Bima Yojna*

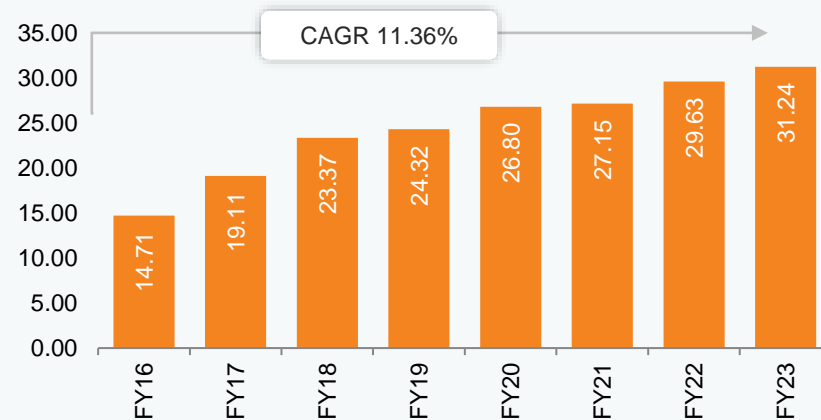
*Source: ICRA Report on Indian Pharmaceutical Sector, Pharmaceutical Industry: Developments in India- Deloitte, Mckinsey Pharma Report 2020*

# Growing health insurance

Breakdown of non-life insurance market in India (FY23)



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



- At present, there is a rise in the demand for healthcare insurance among the masses due to increasing medical costs. This, coupled with the growing geriatric population, represents one of the key factors offering a favorable market outlook in India.
- Besides this, the Government of India is launching various schemes, such as the Pradhan Mantri Jan Aarogya Yojana (PM-JAY), Ayushman Bharat Yojana, Pradhan Mantri Suraksha Bima Yojana, and Aam Aadmi Bima Yojana (AABY) to provide health insurance to the economically weaker section of the country. They are also providing comprehensive healthcare facilities to central government pensioners and officials under the Central Government Health Scheme (CGHS) in the country.
- COVID-19 Insurance Policy:** COVID-19 insurance, like many other life insurance products, provides financial protection against the most terrifying human life event: death. In light of this, the Insurance Regulatory Development Authority of India (IRDAI) has authorised two basic COVID-19 Health Insurance policies, Corona Kavach and Corona Rakshak, to help consumers protect themselves from the financial burden of COVID-19 medical bills.

Source: News Articles

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

1

## Strengthening of Pharmaceutical Industry (SPI)

The Ministry's scheme "Strengthening of Pharmaceutical Industry (SPI)" with a total financial outlay of US\$ 60.9 million (Rs. 500 crore) extends support required to existing pharma clusters and MSMEs across the country to improve their productivity, quality and sustainability.

2

## Scheme for Development of Pharma industry – Umbrella Scheme

- The Department of Pharmaceuticals has prepared an Umbrella Scheme namely 'Scheme for Development of Pharma industry'. Which comprises of the following sub schemes:
  - Assistance to Bulk Drug Industry for Common Facilitation Centres
  - Assistance to Medical Device Industry for Common Facilitation Centres
  - Assistance to Pharmaceutical Industry (CDP-PS)
  - Pharmaceutical Promotion and Development Scheme (PPDS)
  - Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

3

## Support for technology upgrades and FDIs

- Ayushman Bharat Digital Mission (ABDM): Under the ABDM, citizens will be able to create their ABHA (Ayushman Bharat Health Account) numbers, to which their digital health records can be linked. This will enable creation of longitudinal health records for individuals across various healthcare providers and improve clinical decision making by healthcare providers.
- The pilot of ABDM is completed in the six Union Territories of Ladakh, Chandigarh, Dadra & Nagar Haveli and Daman & Diu, Puducherry, Andaman and Nicobar Islands and Lakshadweep with successful demonstration of technology platform developed by the NHA.
- During the pilot, digital sandbox was created in which more than 774 partner solutions are undergoing integration. As on May 21, 2023, 394,287,830 Ayushman Bharat Health Accounts have been created and 185,500 doctors and 206,966 health facilities have been registered in ABDM.

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

## 4

### Promotion of Medical Devices Parks

- Objective of the scheme is Creation of world class infrastructure facilities in order to make Indian medical device industry a global leader.
- Easy access to standard testing and infrastructure facilities through creation of world class Common Infrastructure Facilities for increased competitiveness will result into significant reduction of the cost of production of medical devices leading to better availability and affordability of medical devices in the domestic market.

## 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).
- The production-linked incentive (PLI) scheme was introduced to encourage Indian manufacturers to produce critical key starting materials (KSMs), drug intermediates (DIs) and active pharmaceutical ingredients (APIs). To support this, the government granted funds worth US\$ 932.66 million.

## 6

### Union Budget 2023-24

- A mission to eliminate sickle cell anemia by 2047 will be launched. It would involve raising awareness, conducting a comprehensive screening of seven crore individuals in the impacted tribal regions between the ages of 0 and 40, and providing counselling through coordinated efforts.
- The government would also facilitate select ICMR labs with facilities like research by both public and private medical collage faculty's alongside, private sector R&D teams.
- For innovation in the pharmaceutical sector, through centres of excellence, a new initiative to encourage pharmaceutical research and innovation will be implemented. The government persuades business to spend money on R&D in a few chosen priority fields. At the grassroots level, government has also announced on building 157 nursing colleges in co-location with government medical colleges.

*Source: News Sources, Invest India, Union Budget 2023-24*

# 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.

Source: News Sources

# 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.
- 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.
- In September 2021, the Indian government contributed US\$ 4 billion to the pharmaceutical and medical industries.
- As of August 31, 2021, the PLI scheme received a good response from the industry with a total of 278 applications. This is likely to benefit 55 manufacturers.

**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 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 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)

- Up to 100%, FDI has been allowed through automatic route for Greenfield pharmaceuticals projects. For Brownfield pharmaceuticals projects, FDI allowed is up to 74% through automatic route and beyond that through government approval.
- The cumulative FDI equity inflow in the Drugs and Pharmaceuticals industry is US\$ 21.22 billion during the period April 2000-December 2022. This constitutes almost 3% of the total FDI inflow received across sectors.

Source: BMI, Business Standard, DPIIT

# Opportunities



OPPORTUNITIES

# Opportunities abound in clinical trials and high-end drugs

## 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.

## 1. CLINICAL TRIALS MARKET

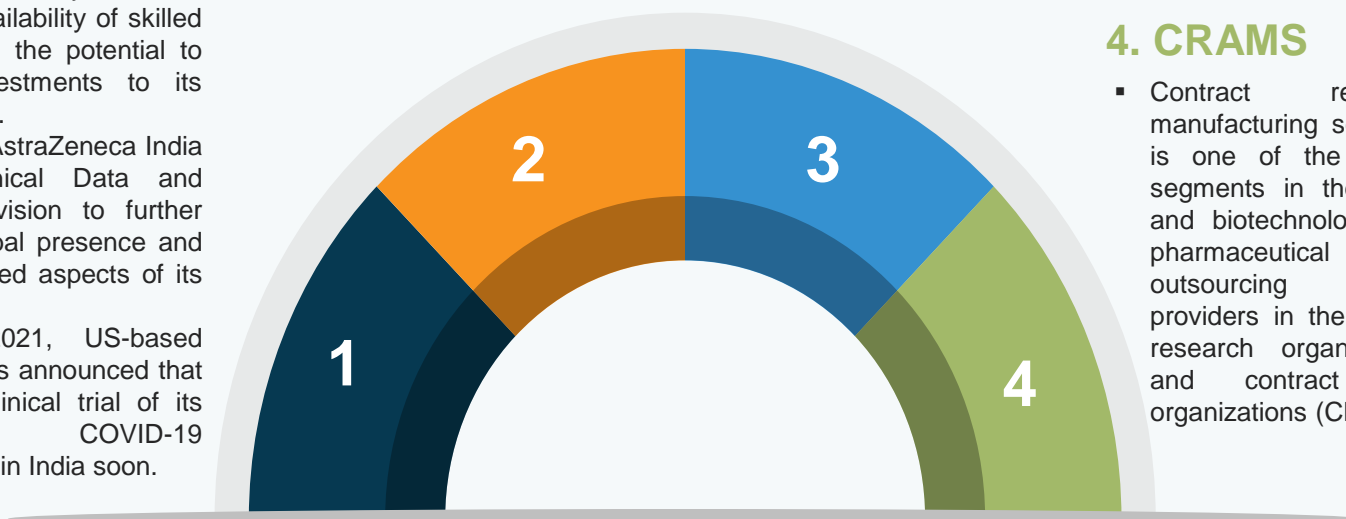
- India is among the leaders in the clinical trial market.
- Due to a genetically diverse population and availability of skilled doctors, India has the potential to attract huge investments to its clinical trial market.
- In October 2021, AstraZeneca India launched a Clinical Data and Insights (CDI) division to further strengthen its global presence and manage data-related aspects of its clinical trials.
- In November 2021, US-based Akston Biosciences announced that it will start the clinical trial of its second-generation COVID-19 vaccine 'AKS-452' in India soon.

## 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.

## 4. CRAMS

- Contract research and manufacturing services (CRAMS) is one of the fastest growing segments in the pharmaceutical and biotechnology industry. The pharmaceutical market uses outsourcing services from providers in the form of contract research organizations (CROs) and contract manufacturing organizations (CMOs).



Source: BMI, Drug Controller General of India

# Key Industry Contacts



# Key industry contacts

	Agency	Contact Information
	The Indian Pharmaceutical Association	Kalina, Santacruz (E), Mumbai - 400 098 Phone: 91-22-2667 1072 Fax: 91 22 2667 0744 E-mail: <a href="mailto:ipacentre@ipapharma.org">ipacentre@ipapharma.org</a> Website: <a href="http://www.ipapharma.org">www.ipapharma.org</a>
	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: <a href="mailto:admin@indiaoppi.com">admin@indiaoppi.com</a> Website: <a href="http://www.indiaoppi.com">www.indiaoppi.com</a>
	Indian Drug Manufacturers' Association	102-B, Poonam Chambers, Dr A.B. Road Worli, Mumbai - 400 018 Phone: 91-22-2494 4624/2497 4308 Fax: 9122 24950723 E-mail: <a href="mailto:admin@idmaindia.com">admin@idmaindia.com</a>   <a href="mailto:accounts@idmaindia.com">accounts@idmaindia.com</a> Website: <a href="http://www.idma-assn.org">www.idma-assn.org</a>
	Bulk Drug Manufacturers Association	C-25, Industrial Estate, Sanath Nagar Hyderabad - 500018 Phone: 91 40 23703910/23706718 Fax: 91 40 23704804 E-mail: <a href="mailto:info@bdmai.org">info@bdmai.org</a> , <a href="mailto:bdma.hyd@gmail.com">bdma.hyd@gmail.com</a> Website: <a href="http://www.bdmai.org">www.bdmai.org</a>



# 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
2021-22	74.42
2022-23	78.60

**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	73.93
2022	79.82
2023*	82.74

*Note: \*- Until May 2023*

*Source: Foreign Exchange Dealers' Association of India*

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