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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.
   - India is the largest producer of vaccines worldwide, accounting for ~60% of the total vaccines, as of 2021.

2. **One of the highest exports**

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.
   - The Indian pharmaceutical industry has been generating a trade surplus of ~US$ 11 billion each year, since 2019.

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*
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 drugs and pharmaceuticals exports reached US$ 5.78 billion between April 2021 and June 2021.
- 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 reached US$130 million between April 2021 and June 2021.
- PharmEasy received US$ 300 million in July 2021 from its existing investors after acquiring Thyrocare, the diagnostic firm. These funds will be utilised to continue Thyrocare’s acquisition process. After the transaction is completed, the online pharmacy plans to float the company on the Indian Stock Exchange.
Market Overview
Structure of pharmaceuticals sector in India

**Source:** Dun and Bradstreet

- **Active Pharmaceutical Ingredients/ Bulk drugs**
  - Branded
  - Generics

- **Formulations**
  - Branded
    - Cardiovascular
    - Anti-Diabetes
    - Gastro-Intestinal
    - Neurological
  - Generics
    - Anti-infectives
    - Respiratory
    - Pain
    - Gynecology
Evolution of the sector

1970-90
- 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.
- 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.

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
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.

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%.

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

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.
- In 2021, the government had approved a US$ 955 million production-linked incentive (PLI) scheme to encourage domestic production of important starting materials, pharmacological intermediates and APIs.
Global, 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.

In terms of overall volume, the Indian pharmaceutical market increased by ~14.1% in June 2021.

As of August 2021, CARE Ratings expect India’s pharmaceutical business to develop at an annual rate of ~11% over the next two years to reach more than US$ 60 billion in value.

In the global pharmaceuticals sector, India is a significant and rising player. India is the world’s largest supplier of generic medications, accounting for 20% of the worldwide supply by volume and supplying about 60% of the global vaccination demand. The Indian pharmaceutical sector is worth US$ 42 billion and ranks 3rd in terms of volume and 13th in terms of value worldwide.

In August 2021, the Indian pharmaceutical market increased at 17.7% annually, up from 13.7% in July 2020.

According to India Ratings & Research, the Indian pharmaceutical market revenue is expected to be over 12% Y-o-Y in FY22.

Source: Department of Pharmaceuticals, PwC, McKinsey, AIOCD AWACS, IQVIA, CII
Pharmaceuticals export to continue witnessing positive growth

- 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.
- In FY21, North America was the largest market for India’s pharma exports with a 34% share and exports to the U.S., Canada and Mexico recorded a growth of 12.6%, 30% and 21.4%, respectively.
- 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.
- According to a report released in September 2021 by the global consulting firm Kearney in collaboration with the Confederation of Indian Industry (CII), India’s vaccines industry could grow from US$ 2 billion to US$ 5 billion in the next decade, as new Indian and global pharmaceutical companies have started including vaccines as a key part of their portfolios.
- India could restart deliveries of COVID-19 shots to global vaccine-sharing platform COVAX in November-December 2021 for the first time since April 2021. The World Health Organization (WHO), which co-leads COVAX, has been pushing India to resume supplies for the programme, particularly after it sent ~4 million doses to neighbours and allies in October 2021.

**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

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

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<tr>
<td>FY17</td>
<td>16.78</td>
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<tr>
<td>FY21</td>
<td>24.44</td>
</tr>
<tr>
<td>FY22 (until May 2021)</td>
<td>3.8</td>
</tr>
</tbody>
</table>

**Major Export Destinations in India’s Pharma Export in FY20 (%)**

- North America: 34.0%
- Europe (EU): 13.0%
- ASEAN: 18.0%
- LAC: 6.9%
- Middle East: 15.7%
- Africa: 6.8%
- Others: 6.9%

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- North America: 34.0%
- Europe (EU): 13.0%
- ASEAN: 18.0%
- LAC: 6.9%
- Middle East: 15.7%
- Africa: 6.8%
- Others: 6.9%
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.

In July 2021, Delhi Pharmaceutical Sciences and Research University (DPSRU) collaborated with All India Institute of Ayurveda (AIIA) to focus on assessment of application of ayurvedic and medicinal plant-based drugs in modern medicines.

The Import Bank of India (India Exim Bank), in collaboration with the Japan Bank for International Cooperation (JBIC) and the Pharmaceutical Export Promotion Council of India (Pharmexcil), organised a roundtable with Indian COVID vaccine manufacturers (current and potential) in September 2021 to discuss their various financing needs and options.

Note: *Top 10 companies as per research by HDFC Securities,
Source: Company website, CRISIL Research, HDFC Securities
Recent Trends and Strategies
Notable trends in the Indian pharmaceuticals sector

2. PRODUCT LAUNCH

- In November 2021, Sun Pharmaceuticals announced that it is gearing up to introduce Merck Sharpe Dohme (MSD) and Ridgeback’s molnupiravir under the brand name Molxvir in India. DCGI is currently reviewing clinical data of molnupiravir for treatment of COVID-19 among adults in the country.
- In August 2021, Alkem Laboratories introduced Famotidine and Ibuprofen tablets to treat osteoarthritis and rheumatoid arthritis symptoms in the US.
- 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, 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 Cadila launched a next-generation breast cancer drug—Trastuzumab Emtansine—at a fraction of its existing cost.
- In September 2021, BDR Pharmaceuticals launched a generic drug Cabozantinib, which is used to treat a variety of cancers. The medicine will soon be available in India.

3. EXPANSION

- In November 2021, Medikabazaar, a B2B health-tech platform, announced expansion of its warehousing capacity across India to strengthen the supply chain infrastructure. The health-tech firm has set up >45 fulfillment centres across the country to cater to the surge in customer base demands with a target to increase accessibility and faster availability of medical supplies and equipment across India by augmenting supply chain efficiencies.
- In July 2021, Generic Health (an Australia-based subsidiary of Lupin Limited) signed an agreement with Southern Cross Pharma Pty Ltd. (SCP). Under this deal, Lupin will acquire 100% shares of SCP. The acquisition is expected to further strengthen Lupin’s foothold in Australia.
- 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.

4. PARTNERSHIPS

- In November 2021, Cadila Healthcare Ltd. (CHL) entered into a manufacturing license and technology transfer agreement for its plasmid DNA-based COVID-19 (ZyCoV-D) vaccine with Korea-based Enzymchem Lifesciences (Enzymchem).
- In November 2021, ScholarRx, a mission-driven organization, announced a new partnership with AMSA International, the Asian Medical Students’ Association (AMSA) International, which promotes the interest and welfare of medical students in the Asia-Pacific region.

1. INCREASING EXPORTS

- India’s pharmaceutical export market is thriving due to strong presence in the generics space.
1. COLLABORATIONS

• In August 2021, Glenmark collaborated with SaNOtize to introduce spray for COVID-19 treatment in India and other Asian markets.
• In July 2021, five of India’s largest pharmaceutical companies participated in an outpatient trial of the investigational oral antiviral medication, Molnupiravir, to treat moderate COVID-19.
• In July 2021, BDR Pharmaceuticals joined forces with Defence Research and Development Organisation (DRDO) to manufacture COVID-19 drugs in India.

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.

3. GOVERNMENT INITIATIVES

• In November 2021, PM Mr. Narendra Modi inaugurated the first Global Innovation Summit of the pharmaceuticals sector. The summit will have 12 sessions and over 40 national and international speakers deliberating on a range of subjects including regulatory environment, funding for innovation, industry-academia collaboration and innovation infrastructure.
• 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 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

- 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.
- Key pharma companies and CMOs such as Mylan NV, Albany Molecular Research and Cambrex Corp. have manufacturing facilities in Telangana.
- 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 Lactic-Co-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 MVy-eS 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 earnouts in June 2021.
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.
   - According to Sagacious IP, in terms of patents filed by Indian companies, India ranks among the top 10 countries in healthcare and pharmaceutical sectors. The number of patents filed by Indian firms increased to 7,399 in 2020 from 2,548 in 2015.

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 stood at US$7.62 billion in 2021 and is estimated to grow at a CAGR of 19.4% to reach US$18.49 billion in 2026, driven by a shift in consumer attitudes towards self-medication, product advancements towards self-medication, product advancements and pharmaceutical preferences for OTC drugs over prescription drugs.

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

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.

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 Janaushadhi Kendra's (PMBJKs) achieved an impressive sale of Rs. 100.40 crore (US$ 14.24 million) in first two months of FY21.

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
Growing health insurance

- 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)

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.

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.

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
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.

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.

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).
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<th>Description</th>
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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)

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:

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Source: BMI, Business Standard, DPIIT
Investments (2/2)

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

<table>
<thead>
<tr>
<th>Name of Approved Applicant</th>
<th>Committed Production Capacity (in MT)</th>
<th>Committed Investment (in Rs. crore)</th>
<th>Committed Investment (in US$ million)</th>
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</thead>
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<tr>
<td>Saraca Laboratories Limited</td>
<td>3,000</td>
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<td>Aarti Speciality Chemicals Limited</td>
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<td>Meghmani LLP</td>
<td>13,500</td>
<td>55.06</td>
<td>7.55</td>
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<td>Sadhana Nitro Chem Limited*</td>
<td>36,000</td>
<td>197.27</td>
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</table>

- 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 FDIs worth US$ 18.12 billion between April 2000 and June 2021.
  - The foreign direct investment (FDI) inflows in the Indian drugs and pharmaceuticals sector jumped to US$130 million between April 2021 and June 2021.
- In September 2021, Schott, a pharmaceutical glass manufacturing company, stated that it will invest US$ 82 million to expand its tubing facility in Jambusar, Gujarat.

Source: BMI, Business Standard, DPIIT
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

- 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

<table>
<thead>
<tr>
<th>Agency</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Indian Pharmaceutical Association</td>
<td>Kalina, Santacruz (E), Mumbai - 400 098</td>
</tr>
<tr>
<td></td>
<td>Phone: 91-22-2667 1072, Fax: 91 22 2667 0744</td>
</tr>
<tr>
<td></td>
<td>E-mail: <a href="mailto:ipacentre@ipapharma.org">ipacentre@ipapharma.org</a>, Website: <a href="http://www.ipapharma.org">www.ipapharma.org</a></td>
</tr>
<tr>
<td>Organisation of Pharmaceutical Producers of</td>
<td>Peninsula Chambers, Ground Floor,</td>
</tr>
<tr>
<td>India</td>
<td>Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400 013</td>
</tr>
<tr>
<td></td>
<td>Phone: 9122 24918123, 24912486, 66627007, Fax: 9122 24915168</td>
</tr>
<tr>
<td></td>
<td>E-mail: <a href="mailto:admin@indiaoppi.com">admin@indiaoppi.com</a>, Website: <a href="http://www.indiaoppi.com">www.indiaoppi.com</a></td>
</tr>
<tr>
<td>Indian Drug Manufacturers' Association</td>
<td>102-B, Poonam Chambers, Dr A.B. Road</td>
</tr>
<tr>
<td></td>
<td>Worli, Mumbai - 400 018, Phone: 91-22-2494 4624/2497 4308, Fax: 9122 24950723</td>
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<td>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></td>
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<tr>
<td>Bulk Drug Manufacturers Association</td>
<td>C-25, Industrial Estate, Sanath Nagar</td>
</tr>
<tr>
<td></td>
<td>Hyderabad - 500018, Phone: 91 40 23703910/23706718</td>
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<td>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></td>
</tr>
<tr>
<td></td>
<td>Website: <a href="http://www.bdmai.org">www.bdmai.org</a></td>
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</table>
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)

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### Exchange Rates (Calendar Year)

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