

INDIAN PHARMACEUTICALS ECOSYSTEM



INVEST INDIA.GOV.IN

Sunrise Sector of India : Pharmaceuticals

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Snapshot of Indian Pharmaceuticals Sector



Why India

Pharmaceuticals Ecosystem & Benefits in India



India Infrastructure

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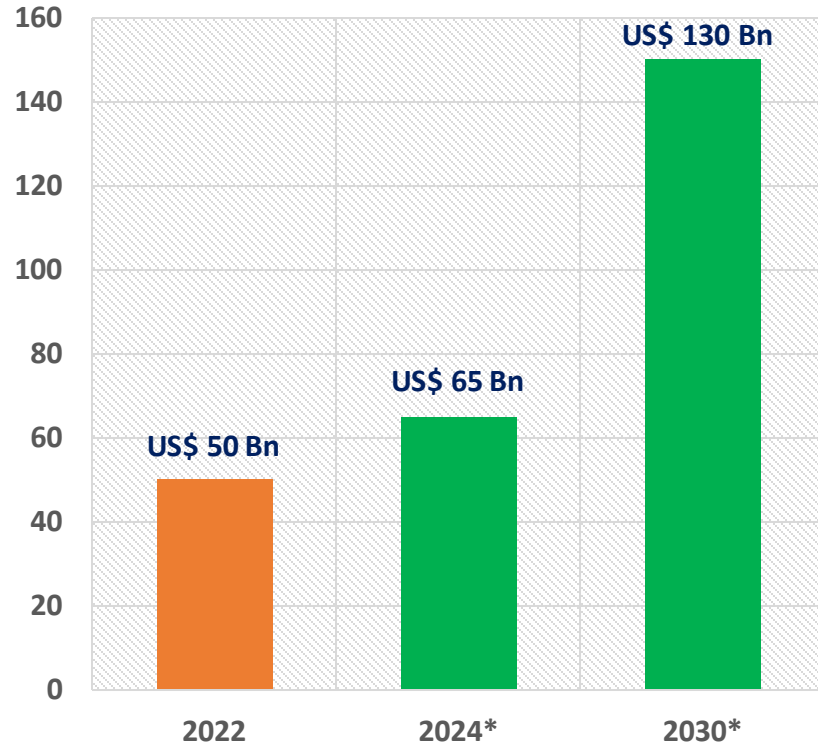


Invest India

Invest India Facilitation Services

SECTOR OVERVIEW- PHARMACEUTICALS

MARKET SIZE



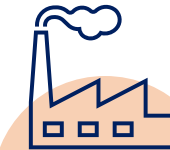
PHARMACY OF THE WORLD: GROWING AT A CAGR OF 12% BY 2030



PLI for domestic manufacturing of KSMs, APIs and Drug Intermediaries with a total committed investment of **US\$ 840 Mn.**



PLI for domestic manufacturing of high value pharmaceutical and biopharmaceutical products, with a financial outlay of **US\$ 1.83 Bn**



US\$ 363 Mn committed for infrastructure development for **3 Bulk Drug Parks** across India (**US\$ 121 Mn each**)

**INDIA AT
A GLANCE**

4%

Share in The Global
Pharmaceutical
Economy

3RD

Largest Destination for
Pharmaceutical
Production by Volume

8%

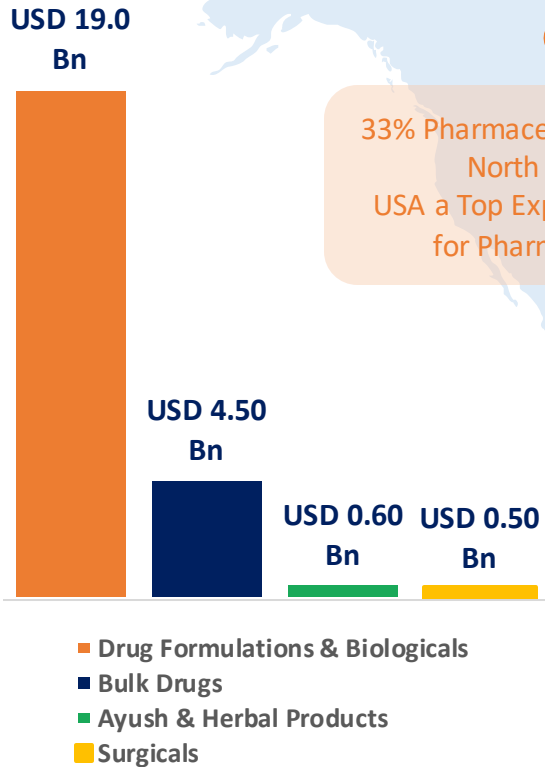
Share in the Global
API Manufacturing
Industry

20%

Share in Global
Supply of Generic
Medicines

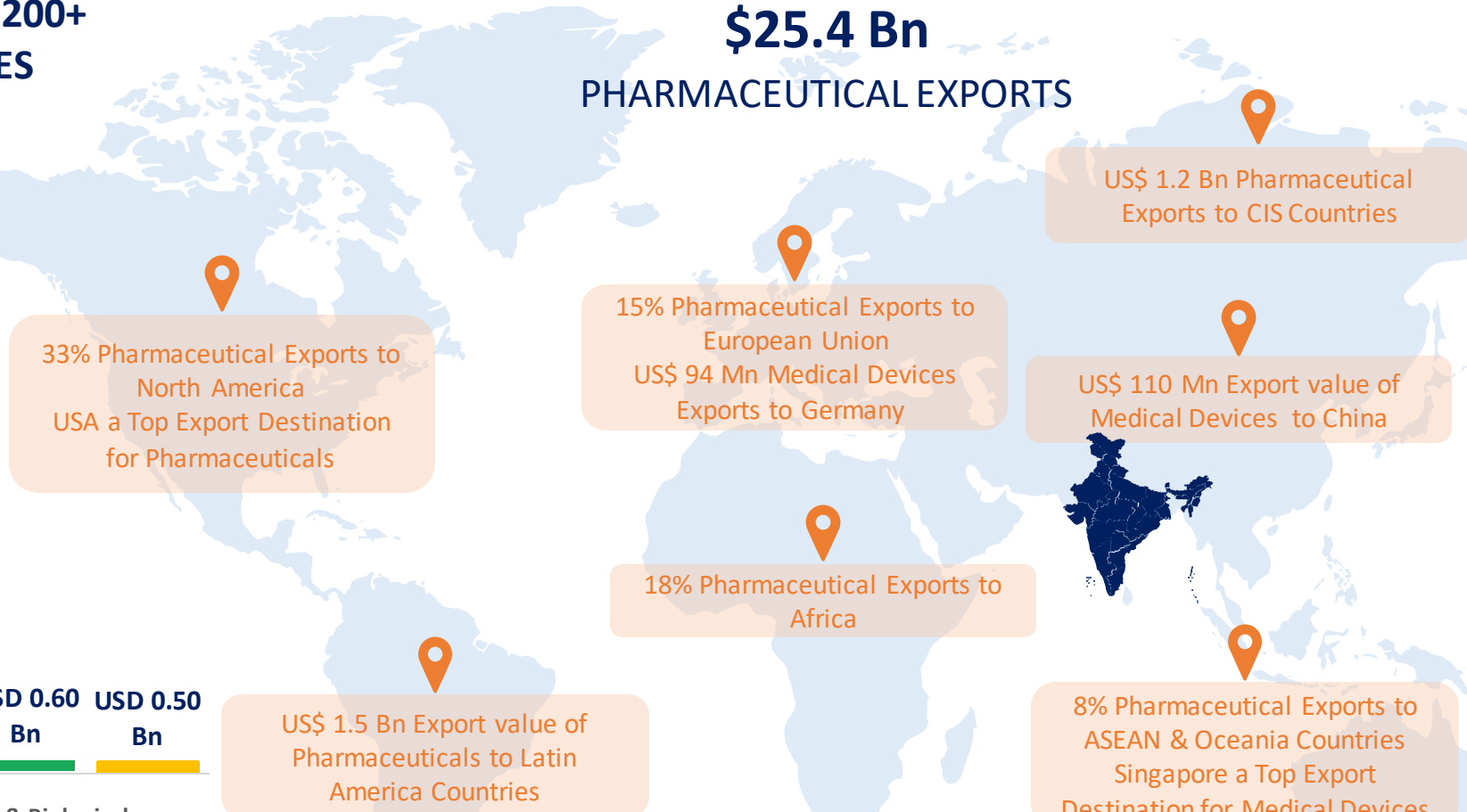
EXPORT POTENTIAL

EXPORTS TO 200+ COUNTRIES



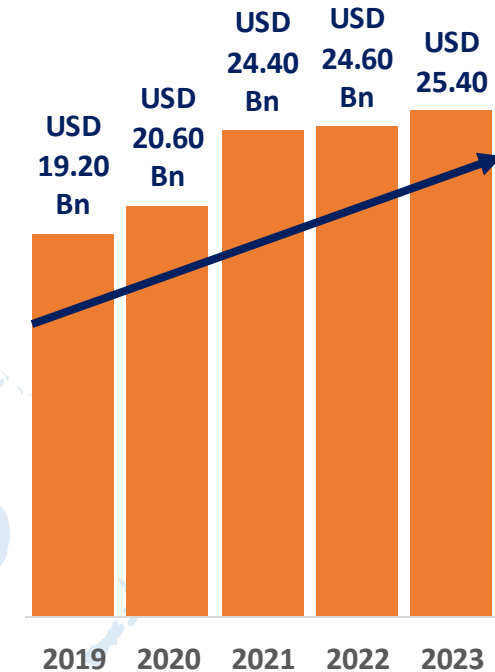
CATEGORY WISE EXPORTS

\$25.4 Bn PHARMACEUTICAL EXPORTS



8 INDIAN COMPANIES ARE AMONG THE TOP 20 GLOBAL GENERIC COMPANIES

32% INCREASE IN EXPORTS (2019 to 2023)



YOY EXPORTS GROWTH

INDIAN PHARMA INDUSTRY – CURRENT STATUS

Pharmacy of the World

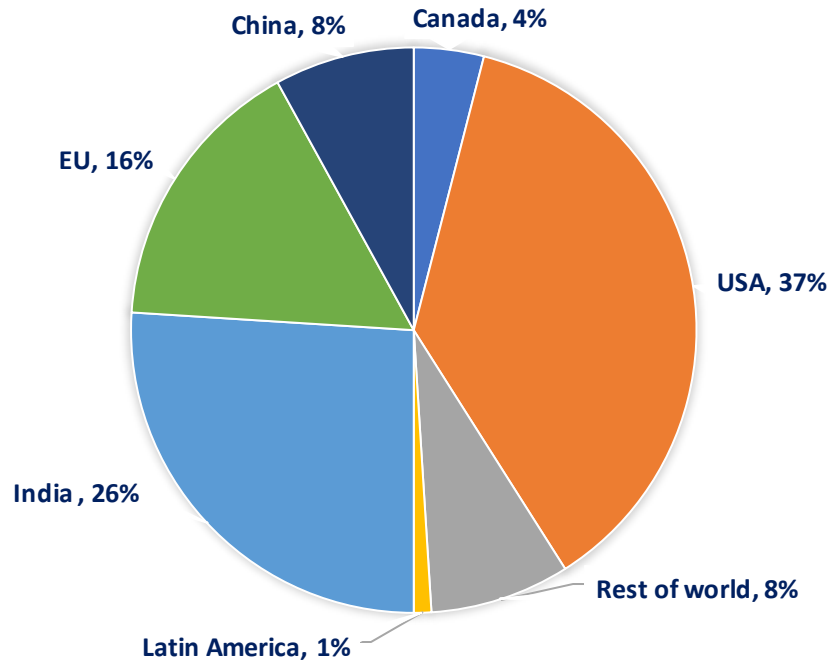
Exports to 200+ countries

3rd by Volume

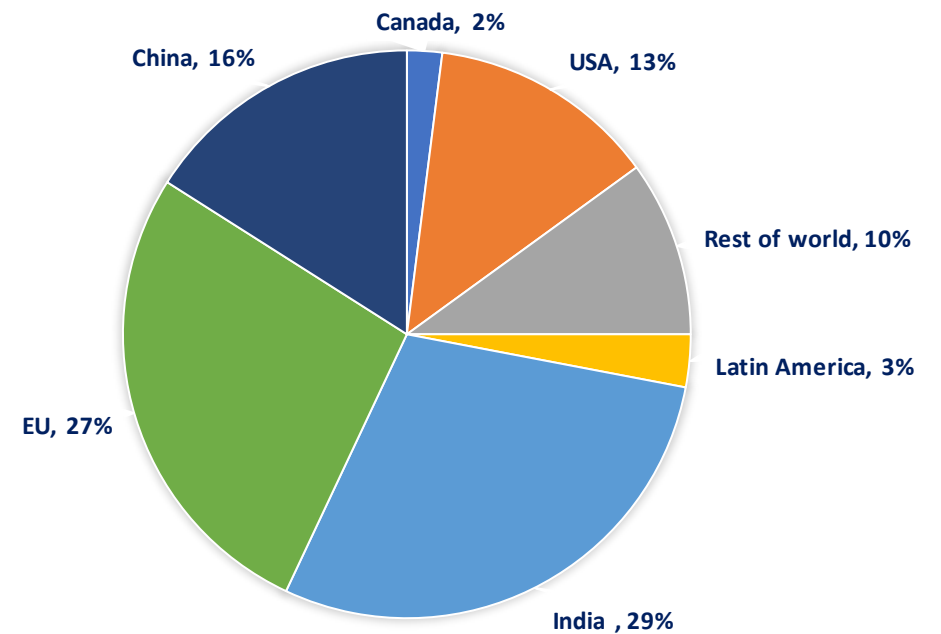
14th by Value

741 US-FDA approved plants (2021)

Manufacturing facilities in terms of:



Finished Dosage Forms (FDFs) for Generic Drugs



Active Pharmaceutical Ingredients (APIs) for Generic Drugs

KEY PHARMACEUTICALS PLAYERS IN INDIA



INDIA AS A PREFERRED R&D DESTINATION

Key R&D Centers from Different Countries in India:



R&D Centers in **Gurgaon and Hyderabad**, engaged in R&D in Gastrointestinal, Respiratory, Skin and Pain medications



Opened a **Lilly Capability Center in Bangalore** to focus on building unique drug development capabilities



Opened a **Pharmaceutical Development Centre in Mumbai**



R&D Centres in **Noida & Ambernath** in India



India hosts **one of the three Global Drug Development Centers in Hyderabad**



1 MILLION+

**INDIA'S STEM
WORKFORCE**



9

**BIOTECH
PARKS**



74+

BIO- INCUBATORS



FDI upto 100% under automatic route for Greenfield projects in Pharma



FDI upto 74% under automatic route & >74% to 100% under Govt. route allowed for Brownfield projects in Pharma



FDI upto 100% under automatic route (both Greenfield & Brownfield) for Medical Devices



Production Linked Incentive Scheme (PLI)

- Financial Incentives worth ~\$3 Bn to promote domestic production



Bulk Drugs Parks

- New Bulk Drugs Parks upcoming in Himachal Pradesh, Gujarat, & Andhra Pradesh to provide plug & play infrastructure



Strengthening of Pharmaceutical Industry (SPI)

- Strengthen the existing infrastructure facilities by providing Financial Assistance to Pharma clusters for creation of Common Facilities



New Drug and Clinical Trial Rules

- Streamlined regulatory approvals and clinical trials to create a robust Pharma ecosystem

PRODUCTION LINKED INCENTIVE (PLI) SCHEME



Scheme Outlay INR 6,940 Cr
PLI for Bulk Drugs



Scheme Outlay INR 15,000 Cr
PLI Scheme for Pharmaceuticals Manufacturing

The Indian pharmaceuticals market is supported by the following Production Linked Incentive Schemes to boost domestic manufacturing capacity, including high-value products across the global supply chain.

PLI SCHEME

PLI Scheme for Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) (PLI 1.0)

Production-Linked Incentive (PLI) Scheme for Pharmaceuticals (PLI 2.0)

PLI 1.0
SCHEME

55
Selected
Applicants

INR 16,199cr
Investment by the
selected Applicants as
on 31st January 2023

PLI 2.0
SCHEME

51
Projects selected for
notified 34 bulk
drugs

INR 2019 cr
Investment by the
selected Applicants as
on 31st January 2023

PLI 1.0: BULK DRUGS

PLI for KSMs, APIs and Drug Intermediaries with a total financial outlay of **US\$ 840 Mn.**

OBJECTIVES

- Enhance the production capacity of bulk drugs in India.
- Promote the development of a competitive and self-reliant pharmaceutical industry.
- Reduce the import dependence on bulk drugs and APIs.
- Generate employment opportunities and boost the overall economy.

KEY FEATURES

- Financial incentives provided to eligible applicants based on the incremental sales of APIs.
- The incentive structure encourages the establishment of greenfield projects and the expansion of existing manufacturing units.
- PLI scheme provides a competitive advantage and increases profitability.
- Long-term benefits include technology upgradation, quality enhancement, and reduction in import costs.

IMPACT & STATUS

- **51 Applicants** approved for production of **35 categories of bulk drugs**, with a committed investment of **US\$ 516 Mn.**
 - **22** projects commissioned, **4 led by MSMEs.**
 - Out of the 51 approved applicants, **15 projects belong to MSMEs.**
 - **US\$ 36 Mn** invested by MSMEs.
- Investments worth **US\$ 219 Mn** actualized, generating an **employment for 1700+ individuals.**

PLI 2.0: PHARMACEUTICALS

PLI for high value pharmaceutical and biopharmaceutical products, with a financial outlay of **US\$ 1.83 Bn**

OBJECTIVES

- Enhance the production capacity and competitiveness of the Indian pharmaceutical industry.
- Encourage domestic manufacturing of critical drugs, APIs, and medical devices.
- Reduce import dependency and make quality medicines more affordable and accessible.
- Promote research and development, technology upgradation, and innovation.

KEY FEATURES

- Different incentive rates for different categories, such as complex generics, biopharmaceuticals, and patented drugs, APIs, in-vitro diagnostic devices.
- Incentivizes the establishment of greenfield projects and the expansion of existing manufacturing units.
- Long-term benefits include increased employment, improved quality standards, and reduced healthcare costs.

IMPACT & STATUS

- **55 applicants** approved across three categories.
 - 11 applicants under Category A, 9 applicants under Category B, 35 applicants under Category C.
 - 5 Medical Devices Companies (Category C).
- Investments worth **US\$ 1.9 Bn** actualized, generating an **employment for 23000+ individuals**.
- **Incentives worth US\$ 20.5 Mn released by D/o Pharmaceuticals.**

FOREIGN DIRECT INVESTMENTS (FDI)

FDI
OPPORTUNITIES

API, Bulk Drugs, Finished
Drug Formulations

Research, Development
& Innovation

Herbal Medicines

Vaccines and Biosimilars

CROs/CMOs/CDMOs

Bio-Pharma Raw
Materials

\$21.23 Bn

FDI in Pharmaceuticals
(Apr2000 to Dec 2022)

100% FDI UNDER AUTOMATIC ROUTE FOR GREENFIELD PROJECTS

74% FDI UNDER AUTOMATIC ROUTE & UPTO 100% UNDER GOVERNMENT ROUTE FOR BROWNFIELD PROJECTS



India hosts **one of the
three Global Drug
Development Centers** in
Hyderabad



R&D Centers in **Gurgaon
and Hyderabad**,
researching on
**Gastrointestinal,
Respiratory, Skin and
Pain medications**



Opened a **Lilly
Capability Center** in
Bangalore to focus on
building unique **drug
development
capabilities**



R&D Centers in **Noida &
Ambarnath** in India



Opened a
**Pharmaceutical
Development Centre** in
Mumbai



Global R&D Centre in
Chennai, employing
more than **150+**
employees

KEY PHARMACEUTICAL CLUSTERS

NORTHERN ZONE

Clusters: Baddi, Patnagar, Haridwar, and NCR

Institutes: NIPER-Mohali, NIPER Raebareli and CRI Kasauli

Companies: Panacea Biotech, Mankind Pharma, Eli Lilly, Teva, J&J, Abbott

WESTERN ZONE

Clusters: Ahmedabad, Ankleshwar, Vapi, Baroda, Aurangabad, Mumbai, Pune, and Goa

Institutes: NIPER- Ahmedabad, WHO Global Centre for Traditional Medicines (TBP)

Companies: Zydus Cadilla, Sun Pharma, Amneal, Cipla, Lupin, Merck, J&J, Sanofi, Pfizer

EASTERN ZONE

Clusters: Sikkim and Assam, Orissa, West Bengal, Bihar

Institutes: NIPER Guwahati, NIPER Kolkata, NIPER Hajipur

Companies: IPCA, Lupin and Hetero

CENTRAL ZONE

Clusters: Indore, Pithampur and Gwalior

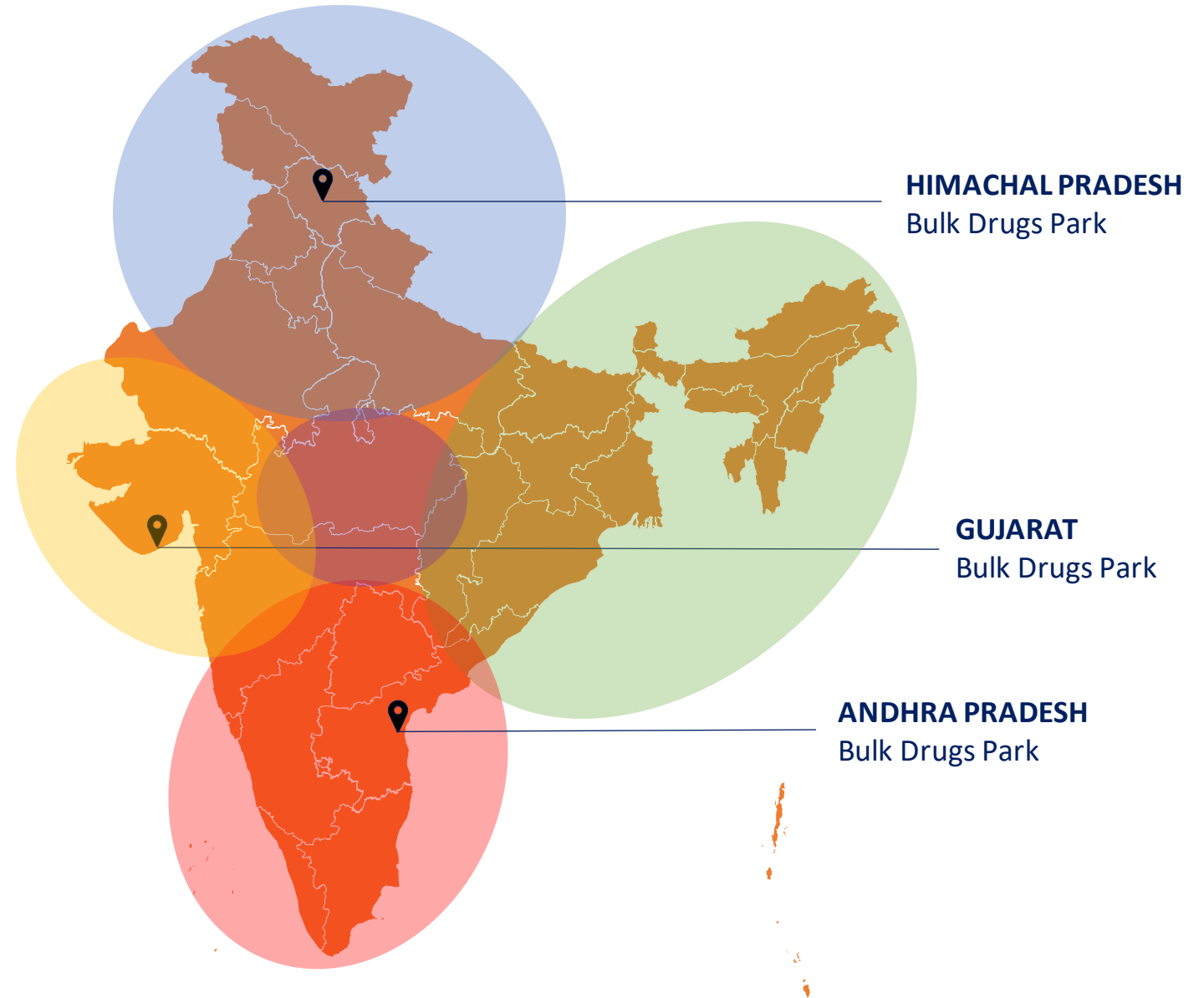
Companies: Ajanta, Piramal, Viatrix/Mylan

SOUTHERN ZONE

Clusters: Hyderabad, Visakhapatnam, Bangalore, Mangalore, Mysore, Chennai, and Pondicherry.

Institutes: NIPER Hyderabad, IISC Bengaluru, IIT Palakkad

Companies: Dr. Reddy's Laboratories, Aurobindo Pharma, Roche, Eisai Pharmaceuticals, Novartis, Pfizer



Invest India is the National Investment Promotion & Facilitation Agency under the Government of India



Pre-Investment Stage

- 1 Opportunity Assessment
- 2 Market Strategy
- 3 Policy Guidance
- 4 Subsidy / Incentive Advisory

Fact-based Inputs for
Strategy Formulation

Investment Execution

- 1 JV & Strategic Partner Research
- 2 Corporate & Industry Associations
- 3 Site Identification
- 4 Entry Route Advisory
- 5 Regulatory Clearances

Comprehensive
Facilitation

Long Term Partnership

- 1 Policy Advocacy
- 2 Issue Redressal
- 3 Expansion Support

Ensure Ease of Doing
Business



THANK YOU



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& FACILITATION AGENCY

Write to us at:
pharma@investindia.org.in



@investindia



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investindiaofficial



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Precision medicine

- India with its 1.3 billion population and disease burden of both noncommunicable and communicable disease offers unique opportunity for Precision Medicine investments. Rapid Strides have been made by GOI in digitization of health including National Digital Health Mission , National Health Policy etc. The Department of Biotechnology has initiated the Genome India project (GIP) which aims at collecting 10,000 genetic samples from citizens across India to build a reference genome. These projects with Public private partnerships (PPP) & sustained investments can help accelerate innovations to create new business opportunities.

Artificial intelligence

- Strategic use of data, AI and ML in Indian Pharmaceutical Industry can help unlock enhanced production efficiency, inventory management and replenishment processes. Big strides are being made by Global & Indian MNC's by investing in AI for efficient drug discovery, development , diagnostic assessment & predict epidemic outbreaks as part of future innovation for access to better healthcare.

Bio-pharmaceuticals

- The Indian biopharmaceutical industry is emerging with high-quality, affordable biosimilars entering the developed market unlocking new value chains. Indian biopharmaceutical industry consists of highly skilled & experienced workforce who serve as a strong support system for the business process. INR 15,000 Mn under the Innovate in India (i3) program has been sanctioned by GOI for capability building & industry – academic collaboration to set Indian Bio-pharmaceutical division on high Growth Trajectory.

Cell Gene Therapy

- While the Cell Gene Therapy Market is in nascent Stage in India, growing investments in biotech startups is likely to change this landscape making CAR-T therapies affordable in India complemented by new policy being developed by Indian Government to spur research in gene therapy. Multiple Indian companies are building new R&D centre to fuel growth in this division .



Biotech startup partnerships for cell/gene therapy development in India (As of Aug 16, 2022)

Date Announced	Deal type	Company	Investors	Investment Amount	Leading Pipeline Molecule	Indication
08-08-2022	Venture Financing (Series A Funding)	Eyestem	Biological E / Alkem / NATCO / Kemwell Biopharma	\$6.4M	Eyecyte-RPE (Cell therapy – Preclinical)	Dry AMD
21-06-2022	Venture Financing (Series A Funding)	Immuneel Therapeutics	Eight Roads Ventures / True North / F-Prime Capital	\$15M	IMN-003A (Gene-modified cell therapy – Phase II)	B-Cell Acute Lymphocytic Leukemia; B-Cell Non-Hodgkin Lymphoma
19-11-2021	Minority Acquisition	ImmunoACT	Laurus Labs	\$7M	HCAR19 (Gene-modified cell therapy – Phase I)	B-Cell Acute Lymphocytic Leukemia