



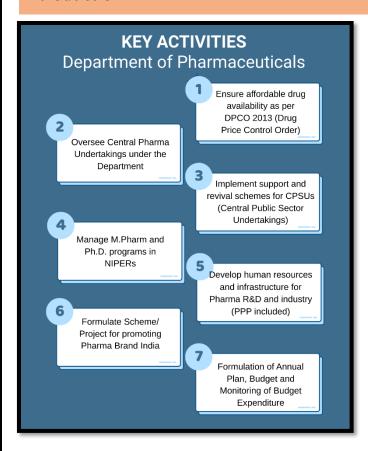
A Dose of Atmanirbhar Bharat

How Make in India is transforming India's Global Pharmaceutical Footprint

(Ministry of Chemicals and Fertilizers)

13th April, 2025

Introduction



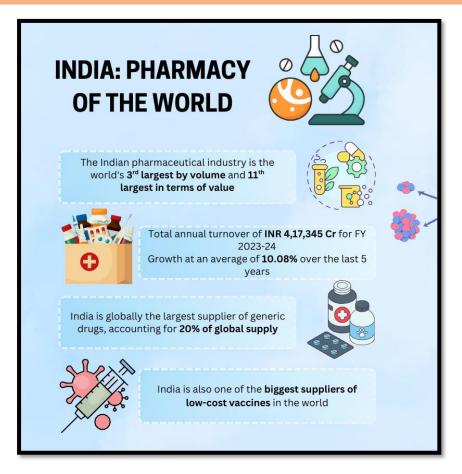
The Department of Pharmaceuticals, under the Ministry of Chemicals and Fertilizers, is responsible for matters related to the pricing and availability of affordable medicines, research and development and international obligations. With a vision to make India the world's largest provider of quality medicines at reasonable prices, the department's efforts align with the Make in India initiative. The Indian pharmaceutical industry continues to play a crucial role in manufacturing high-quality, cost-effective medicines for both domestic and global markets, marked by its dominance in branded generic medicines, competitive pricing, and a robust network of indigenous brands. ¹

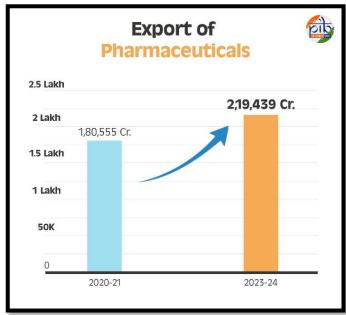
India has been UNICEF's largest vaccine supplier for the past six to seven years, contributing 55% to 60% of total volume procured contributing 99%, 52% and 45% of the WHO demand for DPT, BCG and the measles vaccines, respectively.²

¹ https://pharma-dept.gov.in/about-department

² https://www.ipa-india.org/wp-content/uploads/2025/02/bain reporthealing the world a roadmap for making india a global pharma exports hub.pdf page 20 & 21

Overview of the Indian Pharmaceutical Industry





³ https://pharma-dept.gov.in/sites/default/files/Final%20English%202024-25%20AR%20%281%29.pdf

34

⁴https://pharma-dept.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf (Pg 12 of PDF)

Medical Devices

India is one of the fastest growing markets in the global medical devices industry

Fourth largest medical device market in Asia, after Japan, China and South Korea

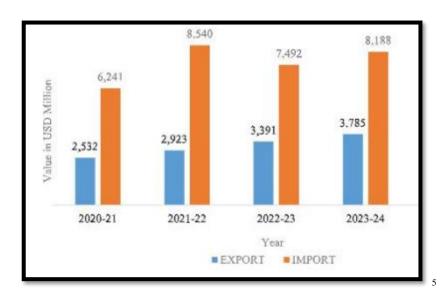
Among top 20 global medical device markets in the world

Begun exporting ventilators, personal protective equipment (PPEs), diagnostic kits, surgical gloves, coronary stents, radio-imaging equipment, body implants, etc.

The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector, particularly for prevention, diagnosis, treatment and management of all medical conditions and disabilities. The medical devices sector is a multi-disciplinary sector. Its constituent device categories are-

- a) electro-medical equipment
- b) implants
- c) consumables and disposables
- d) surgical instruments
- e) in vitro diagnostic reagents

Several segments of the medical device industry are highly capital-intensive, with a long gestation period, and require continuous induction of new technologies and the ongoing training of healthcare professionals to adapt to new technologies in the sector.



Export & Import of Medical Devices

 $^{^{5}\,\}underline{\text{https://pharma-dept.gov.in/sites/default/files/Final\%20English\%202024-25\%20AR\%20\%281\%29.pdf}$

Foreign Direct Investment

The Department of Pharmaceuticals considers FDI proposals falling under the Government approval route in pharmaceutical and meditech activities for approval or rejection as per FDI Policy.

In the financial year of 2024-25, from April 2024 to December 2024, FDI inflows (in both pharmaceuticals and medical devices) has been ₹11,888 Crore.

Further, the Department of Pharmaceuticals has approved 13 FDI proposals worth ₹7,246.40 Crore for brownfield projects during FY 2024-25.

FOREIGN DIRECT INVESTMENT The Indian pharmaceutical sector has emerged as a favourite destination for accounts for 3.78% of total foreign investors **FDI** inflows nationwide One of the top 10 sectors attracting foreign investments in India As per FDI Policy 2020, up **April 2000 to December** to 100 percent foreign 2024: investment is allowed Total FDI inflows: under the automatic route ₹1,68,974 crore (₹1,41,586 in meditech activities crore in pharmaceutical and ₹27,388 crore in meditech) In Pharmaceuticals, up to 100 percent FDI in greenfield projects and up to 74 percent FDI in brownfield projects is allowed under the automatic route Greenfield manufacturing projects involve the construction of

new facilities from the ground up Brownfield projects entail acquiring or leasing existing facilities to initiate production

6

Production Linked Incentive Scheme

The **Production Linked Incentive (PLI) Scheme**, launched in 2020 by the Government of India, is a transformative initiative aimed at boosting domestic manufacturing, attracting investments, reducing reliance on imports and increasing exports. Aligned with the vision of *Atmanirbhar Bharat* and the larger *Make in India initiative*, the scheme offers financial incentives based on production performance, encouraging companies to scale up operations, adopt advanced technologies, and improve global competitiveness.

For pharmaceuticals, the initiative aims to reduce import dependence on Key Starting Materials (KSMs), Drug Intermediates (DIs), and Active Pharmaceutical Ingredients (APIs), strengthening India's

⁶ https://pharma-dept.gov.in/sites/default/files/Final%20English%202024-25%20AR%20%281%29.pdf

manufacturing base. By promoting production and innovation, it boosts domestic capabilities and global competitiveness.

Overview of the PLI Schemes

The Department of Pharmaceuticals administers three PLI schemes as part of the Government of India's larger initiative to enhance manufacturing capabilities. These include:

- 1. PLI Scheme for Pharmaceuticals
- 2. PLI Scheme for promotion of domestic manufacturing of critical KSMs/DIs/APIs
- 3. PLI Scheme for promoting domestic manufacturing of Medical Devices⁷

PLI Scheme for Pharmaceuticals⁸

The PLI Scheme for Pharmaceuticals was approved by the Union Cabinet on 24 February 2021⁹, with a financial outlay of ₹15,000 crore and the production tenure from FY 2022-2023 to FY 2027-28, provides financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. Under this scheme, high value pharmaceutical products such as patented/off-patented drugs, biopharmaceuticals, complex generics, anti-cancer drugs, autoimmune drugs, among others, are manufactured. ¹⁰

Key Features of the Scheme:

The scheme supports the manufacturing of pharmaceutical goods under three categories:

- 1. Category 1: Biopharmaceuticals, complex generic drugs, patented drugs or those nearing patent expiry, gene therapy drugs, orphan drugs, and complex excipients.
- 2. Category 2: Active Pharmaceutical Ingredients (APIs), Key Starting Materials (KSMs), and Drug Intermediates (DIs).
- **3.** Category **3:** Repurposed drugs, autoimmune drugs, anti-cancer drugs, anti-diabetic drugs, cardiovascular drugs, and in-vitro diagnostic (IVD) devices ¹¹

PLI Scheme for KSMs, DIs, and APIs 12

⁷ https://pharma-dept.gov.in/sites/default/files/English%20version%20of%20Annual%20Report%202023-24.pdf

⁸ https://pib.gov.in/PressReleaseIframePage.aspx?PRID=2081491

⁹ https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1775321

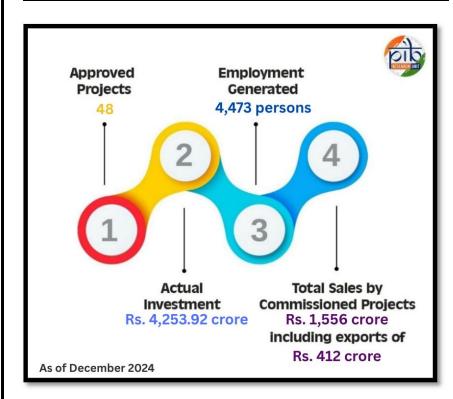
¹⁰ https://pib.gov.in/PressReleaselframePage.aspx?PRID=2081491

¹¹ https://pharma-dept.gov.in/sites/default/files/English%20version%20of%20Annual%20Report%202023-24.pdf

¹² https://static.pib.gov.in/WriteReadData/specificdocs/documents/2025/jan/doc202516481901.pdf

The PLI Scheme for KSMs, DIs, and APIs was launched on 20 March 2020, with a financial outlay of ₹6,940 crore for the period FY 2020-21 to FY 2029-30. The main objective of Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in India is to promote domestic manufacturing of 41 identified bulk drugs to address their high import dependence.

Achievements under the PLI Scheme for KSMs, DIs, and APIs



One of the significant achievements under the PLI scheme has been the surpassing of targeted investments. While the initial commitment was ₹3,938.57 crore, the actual realized investment has already reached ₹4,253.92 crore (as of December 2024).

Under the PLI scheme for Bulk Drugs, a total of **48 projects** have been selected under the scheme, of which 34 projects have been commissioned for 25 bulk drugs as of December 2024.

Notable Projects Under the PLI Scheme for Bulk Drugs

- Penicillin G Project (Kakinada, Andhra Pradesh): ₹1,910 crore investment; expected import substitution of ₹2,700 crore per annum.
- Clavulanic Acid Project (Nalagarh, Himachal Pradesh): ₹450 crore investment; expected import substitution of ₹600 crore per annum. 13

PLI Scheme for Medical Devices¹⁴

The **PLI Scheme for Medical Devices** was launched to support domestic manufacturing of high-end medical equipment and reduce reliance on imports. The scheme provides financial incentives to manufacturers in key segments such as radiology, imaging, cancer care, and implants. The period of the scheme is from financial year 2020-21 to financial year 2027-28 with total financial outlay of **Rs. 3,420**

¹³ https://static.pib.gov.in/WriteReadData/specificdocs/documents/2025/jan/doc202516481901.pdf

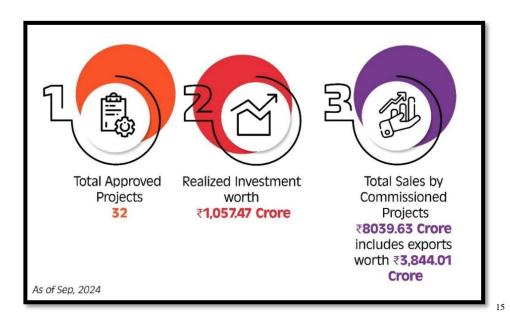
¹⁴ https://static.pib.gov.in/WriteReadData/specificdocs/documents/2025/jan/doc202516481901.pdf

crore. Under the scheme, financial incentive is given to selected companies, at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the target segments of the scheme, for a period of five years.

The details of incentive under the scheme are as follows:

Category of applicant	Incentive Period	Incentive rate
Category A	FY 2022-23 to FY 2026-27	5% limited to Rs.121 crore per
		applicant
Category B	FY 2022-23 to FY 2026-27	5% limited to Rs.40 crore per
		applicant

 $\underline{https://static.pib.gov.in/WriteReadData/specificdocs/documents/2025/jan/doc202516481901.pdf}$



Promotion of Bulk Drug Parks

Approved in March 2020, the Promotion of Bulk Drug Parks scheme (**FY 2020–21 to FY 2025–26**) aims to establish parks with world-class common infrastructure to reduce manufacturing costs and enhance self-reliance in bulk drugs. Proposals from **Gujarat**, **Himachal Pradesh**, and **Andhra Pradesh** were approved under the scheme. Financial assistance is capped at ₹1,000 crore per park or 70% of the project cost (90% for Northeastern and Hilly States), with a total outlay of ₹3,000 crore. ¹⁶

¹⁵ https://pib.gov.in/PressReleaselframePage.aspx?PRID=2081491

¹⁶ https://sansad.in/getFile/annex/266/AU1617 u1r6TL.pdf?source=pgars

Pradhan Mantri Bhartiya Janaushadhi Pariyojana

With an objective of making quality generic medicines available at affordable prices to all, **Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)** aims to ensure access to affordable, quality generic medicines across India.



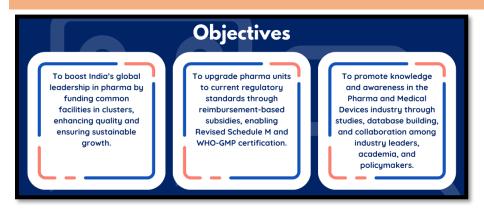


Some of the activities under this initiative include:

- Raising Awareness: Educating the public on the benefits of generic medicines, highlighting that
 affordability doesn't compromise quality and countering the belief that higher prices mean better
 efficacy.
- Encouraging Prescriptions of Generic Drugs: Promoting the use of generics by motivating healthcare professionals, especially in government hospitals, to prescribe cost-effective alternatives.
- Enhancing Accessibility: Ensuring the availability of essential generic medicines across therapeutic categories, with a focus on reaching underserved communities.¹⁷

As of April 8, 2025, there are a total of 15,479 Jan Aushadi Kendras across the country.

Strengthening of Pharmaceuticals Industry Scheme (SPI Scheme)



The SPI scheme is a Central Sector Scheme (CSS) with an outlay of **Rs.500 Cr** with the scheme period from FY 2021-22 to FY 2025-26. ¹⁸

¹⁷ https://pib.gov.in/PressReleasePage.aspx?PRID=2108862

¹⁸ https://sansad.in/getFile/loksabhaquestions/annex/183/AU1892 zKyymK.pdf?source=pqals

Conclusion:

India's pharmaceutical and medical devices sectors stand as a testament to the country's growing capabilities in science, innovation, and manufacturing. Through visionary initiatives like the **Production Linked Incentive (PLI) schemes and Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)**, the Department of Pharmaceuticals has not only bolstered domestic production but also ensured equitable access to affordable healthcare solutions. With its continued commitment to self-reliance under the Make in India vision, India is poised to solidify its position as a global hub for high-quality, cost-effective medicines and medical technologies, empowering both its citizens and contributing significantly to global health outcomes.

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Make in India (Pharmaceuticals) | Explainer | 08

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