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Boosting Domestic Manufacturing in Pharmaceuticals: An Evaluation of the PLI Scheme's Effectiveness

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Abstract

The Production Linked Incentive (PLI) scheme, introduced by the Department of Pharmaceuticals, aims to strengthen domestic manufacturing in India's pharmaceutical sector by providing financial incentives to key segments, including Key Starting Materials (KSMs), Drug Intermediates (DIs), Active Pharmaceutical Ingredients (APIs), medical devices, and pharmaceutical drugs/Bulk drugs. This paper evaluates the scheme's effectiveness across three critical sectors: KSMs/DIs and APIs, medical devices, and pharmaceutical drugs. It examines how the PLI scheme addresses India's heavy reliance on imports, enhances production capacity, and fosters self-reliance. The study analyses the impact of the scheme on domestic supply chain resilience, cost competitiveness, and innovation in manufacturing. By assessing key performance indicators such as output growth, investment inflows, and export potential, the paper provides insights into the overall effectiveness of the PLI scheme. The findings underscore the scheme's role in positioning India as a global pharmaceutical manufacturing hub while contributing to economic growth and healthcare security.

Keywords: *Production Linked Incentive (PLI) Scheme, Pharmaceuticals, Bulk Drugs, Foreign Direct Investment (FDI), Medical Devices, Domestic Supply Chain, Self-Reliant India, Active Pharmaceutical Ingredients (APIs), Employments.*

1. Introduction

1.1 What is PLI Scheme?

PLI Scheme refers to Production Linked Incentive Scheme, "In order to boost domestic manufacturing and cut down on import bills, the central government in 20thMarch, 2020 introduced a scheme that aims to give manufacturing companies financial incentives (4% to 6%) on incremental sales from products manufactured in domestic units. Apart from inviting foreign companies to set production units in India, the scheme also aims to encourage local companies to set up or expand existing domestic manufacturing units.

The base year of the PLI Scheme is 2019-20 and notified date of the scheme is 1st April 2020. Financial Incentives applicable from 1St Aug 2020.

1.2 What was the need of PLI Scheme?

During the COVID-19 pandemic, it was clearly visible that most of the countries around the world including India were overly dependent on a single country for import of electronic hardware, components, Key Starting Materials (KSMs), Drug Intermediates (DIs), Active Pharmaceutical Ingredients (APIs), medical devices. Sudden events can cause a large-scale shortage of electronic components, medicines, raw material and disrupt domestic manufacturing. It is important to promote indigenous production and reduce dependency on a single market or geographical region. The PLI Scheme was launched by the government amidst the COVID-19 Pandemic to reinforce the manufacturing sector and supply chain in the country. The PLI scheme is expected to have a cascading effect on the country's MSME ecosystem.

1.3 Which sectors are covered under PLI Scheme?

When this PLI Scheme was launched in March 2020, Initially, there were 3 critically important manufacturing sectors covered under this scheme and later on in November 2020, 10 more sectors were notified and after that in September2021, Drones and its Drone Components under Ministry of Civil Aviation also added.

So as on today, there are 14 important sectors under PLI Scheme for boosting domestics manufacturing in Indian.

Sr. No.	Name of Manufacturing Sector
	March 2020
1	Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs)
2	Large Scale Electronics Manufacturing
3	Manufacturing of Medical Devices
	November 2020
4	Telecom and Networking Products
5	Specialty Steel Products
6	Advance Chemistry Cell (ACC) Battery
7	Textile Products (Man-made Fibers and Technical Fibers)
8	White Goods (ACs and LEDs)
9	Products of Information Technology and Electronic items
10	Components of Auto & Automobiles
11	Pharmaceutical Drugs
12	Food Products
13	High-efficiency Solar PV Modules

	September 2021
14	Drones and Drone Components

The Production Linked Incentive (PLI) scheme is formulated to be make effective by certain industries and various departments for each sector with the twin objectives of increasing the India's production capabilities and merchandise export from Indian economy.

1.4 What are the objectives of PLI Scheme?

For a USD 5 trillion economy, our manufacturing sector has to grow in double digits on a sustained basis. Our manufacturing companies need to become an integral part of global supply chains, possess core competence and cutting-edge technology. To achieve all of the above, PLI schemes to create manufacturing global champions for an **Atmanirbhar Bharat** have been announced for 13 sectors. For this, the government has committed nearly Rs.1.97 lakh crores, over 5 years starting FY 2021-22(announced in union budget on 1st February, 2021).

The key objectives of the Production Linked Incentive (PLI) Scheme in India are as follows:

1. Boost Domestic Manufacturing.
2. Attract investments in key sectors and cutting-edge technology
3. Reduce Import Dependency.
4. Promote Export Competitiveness among the manufacturers in the global market attract investment.
5. Encourage Technological Upgradation.
6. Create Employment Opportunities.
7. Develop National Supply Chains.
8. Enhance Self-Reliance (Atmanirbhar Bharat).
9. Fiscal Consolidation through improvement in Current Account Deficit (CAD).

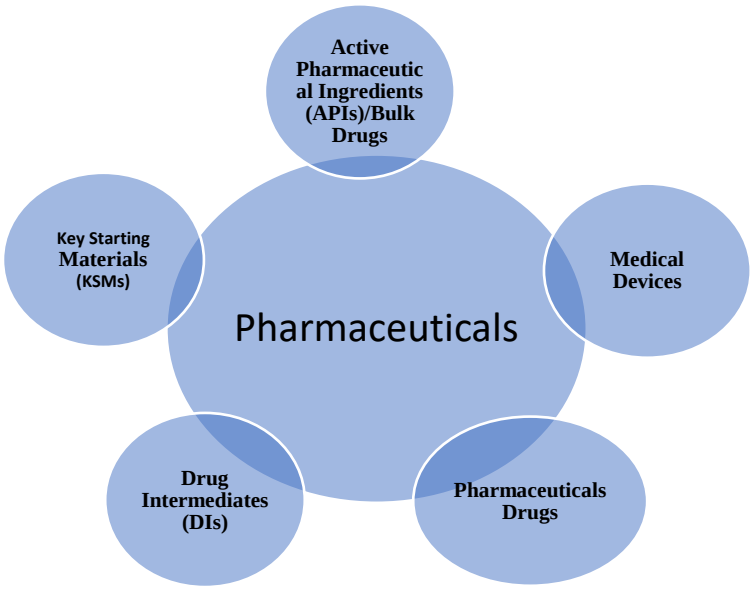
These objectives align with the Indian government's vision of transforming India into a global manufacturing hub while ensuring economic growth and development.

2. Production Linked Incentive (PLI) Scheme: - A need of the hour for boosting domestic pharmaceutical manufacturing in India.

The Production Linked Incentive (PLI) Scheme is vital for enhancing India's domestic pharmaceutical manufacturing, especially in the wake of the COVID-19 pandemic, which exposed the nation's dependency on imports for critical drug components like Key Starting Materials (KSMs), Drug Intermediates (DIs), and Active Pharmaceutical Ingredients (APIs). By providing financial incentives for increased local production, the PLI scheme aims to strengthen India's supply chain, foster innovation, and promote self-reliance. It encourages investment in advanced manufacturing technologies, reducing vulnerabilities in essential drug production while positioning India as a global leader in pharmaceuticals.

2.1 What are the components of Pharmaceuticals?

Pharmaceuticals are composed of various components, including Key Starting Materials (KSMs) like Basic raw materials for drug synthesis, Drug Intermediates (DIs) such as Intermediate products in the manufacturing process, Active Pharmaceutical Ingredients (APIs)/Bulk Drugs i.e. the active substances in drugs, Medical Devices i.e. Instruments used in healthcare, Pharmaceutical Drugs: Finished products containing APIs and other components.



2.2 Important Sectors under Department of Pharmaceuticals, Ministry of Chemical and Fertiliser.

Out of the 14 manufacturing sectors mentioned above, there are 3 sectors which are solely responsible for boosting domestic manufacturing in Pharmaceuticals in India. These are as under: -

Sr. No.	Manufacturing Sector	Brief Description
1	**Key Starting Materials (KSMs)/ Drug Intermediates(DIs) and Active Pharmaceutical Ingredients (APIs)**	Focuses on enhancing the production of essential pharmaceutical ingredients/Bulk Drugs (APIs) in India to reduce dependence on imports.
2	**Manufacturing of Medical Devices**	Aims to promote the manufacturing of medical devices and equipment within India to meet domestic demand and increase exports.
3	**Pharmaceutical Drugs**	Includes the manufacturing of pharmaceutical drugs and formulations. Aims to make India a global pharmaceutical hub.

2.3 Schemes wise description and other important information:

A. Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the Country.

Indian pharmaceutical industry is the 3rd largest in the world by volume and 14th largest in terms of value. India contributes 3.5% of total drugs and medicines exported globally. However, despite these achievements, India is significantly dependent on import of some of the basic raw materials, viz., bulk drugs that are used to produce the finished dosage formulations. India imports bulk drugs largely for economic considerations. Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during FY 2018-19. There are 53 APIs for which the country is heavily dependent on imports.

Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) are called bulk drugs. These are the main ingredients of a drug or medicine. The bulk drug is the key source to provide therapeutic effects or intended pharmacological activity. They are produced in large quantities and are used to manufacture the final pharmaceutical products, or formulations.

Sr.No.	Description	
1	**Objective of Scheme**	➢ The scheme intends to boost domestic manufacturing of identified KSMs, Drug Intermediates and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs. ➢ The scheme is applicable only for Greenfield projects.
2	**Date of Notification**	21st July 2020
3	**Base Year**	FY 2019-20
4	**Tenure of the Scheme**:	The tenure of the scheme is from FY 2020-21 to FY 2029-30.
5	**Financial Outlay**	Rs. 6940 Crore
6	**Quantum of Incentives**	➢ Four Target Segments covering 41 products. ➢ Financial incentive under the scheme shall be provided on sales of 41 identified products for six (06) years at the rates given below: - (i) For fermentation-based products, incentive for FY 2023-24 to FY 2026-27 would be 20%, incentive for 2027-28 would be 15% and incentive for 2028-29 would be 5%. (ii) For chemical synthesis-based products, incentive for FY 2022-23 to FY 2027-28 would be 10%.

Target Segment No.	Description (Total 41Products)
Target Segment 1	Fermentation based KSMs/Drug Intermediates (04)
Target Segment 2	Fermentation based niche KSMs/Drug Intermediates/APIs (10)
Target Segment 3	Key Chemical Synthesis based KSMs/Drug Intermediates (04)
Target Segment 4	Other Chemical Synthesis based KSMs/Drug Intermediates/APIs (23)

B. Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices.

Domestic medical devices market in India is heavily dependent on imports which contribute to more than 85% of the market. The medical devices manufacturing sector faces in India lack of a level playing field vis-à-vis competing economies. The medical devices manufacturing sector suffers from a considerable cost of manufacturing disability, among other things.

Sr.No.	Description	
1	**Objective of Scheme**	➢ The Scheme intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. ➢ The scheme is applicable only for Greenfield projects.
2	**Date of Notification**	21st July 2020
3	**Base Year**	FY 2019-20
4	**Tenure of the Scheme**	From FY 2020-21 to FY 2026-27.
5	**Financial Outlay**	Rs. 3420 Crore
6	**Quantum of Incentives**	Under the Scheme, financial incentive shall be given to selected companies at the rate of 5% of incremental sales (over Base Year) of goods manufactured in India and covered under Target segments, for a period of five (5) years i.e. from FY 2021-22 to FY 2025-26.

Target Segment No.	Description of Medical Devices covered under Target Segment
Target Segment 1	Cancer care/Radiotherapy medical devices.
Target Segment 2	Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices.
Target Segment 3	Anesthetics& Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices.
Target Segment 4	All Implants including implantable electronic devices like Cochlear Implants and Pacemakers.

C. Production Linked Incentive (PLI) scheme for Pharmaceuticals Drugs.

The objective of the scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains.

Sr.No.	Description	
1	**Objective of Scheme**	The scheme aims to boost India's pharmaceutical manufacturing, promote high-value products, and create global champions through innovation.
2	**Date of Notification**	3rd March 2021
3	**Base Year**	FY 2019-20
4	**Tenure of the Scheme**	FY 2020-21 to FY 2026-27. The duration of the scheme will be from FY 2020-21 to FY 2028-29. This will include the period for processing of applications (FY 2020-21). Optional gestation period of one year (FY 2021-22), Incentive for 6 years and FY 2028-29 for disbursal of incentive for sales of FY 2027-28. The incentives will be paid for a maximum period of 6 years for each participant.
5	**Financial Outlay**	Rs. 15000 Crore
6	**Quantum of Incentives**	The total quantum of incentive Rs 15,000 crore. The incentive allocation in as under:- (a) For Group A manufacturers: Rs 11000 (b) For Group B manufacturers: Rs 2250 (c) For Group C manufacturers: Rs 1750 **Rate of Incentive: -** ➢ The rate of incentive on incremental sales (over base year) of pharmaceutical goods covered under Category 1 & 2 will be 10% for FY 2022-23 to FY 2025-26, 8% for 2026-27 and 6% for 2027-28. ➢ The rate of incentive on incremental sales (over base year) of for pharmaceutical goods covered under Category-3 will be 5% for FY 2022-23 to FY 2025-26, 4% for 2026-27 and 3% for 2027-28.

Target Groups: The manufacturers of pharmaceutical goods registered in India will be grouped based on their Global Manufacturing Revenue (GMR) in FY 2019-20.

Target Groups	Applicants having GMR (Rs. Crore)
Group A	More than or equal to Rs 5000.
Group B	More than Rs.500 to less than Rs 5000.
Group C	Less than Rs 500. (Within group C, a sub-group for MSME industry will be made).

Category of Goods: The scheme shall cover pharmaceutical Drugs under three (03) categories as mentioned below:

Categories	Descriptions
Category I	Biopharmaceuticals, Complex generic drugs etc.
Category II	APIs/KSMs/DIs (Bulk Drugs).
Category III	Not covered under Cat I & II like Repurposed drugs, auto immune drugs, Anti-Cancer Drugs etc.

3. Literature Review

The Indian government's Production Linked Incentive (PLI) scheme, launched under the "Atmanirbhar Bharat" (Self-Reliant India) initiative, is a strategic intervention aimed at boosting domestic manufacturing, reducing import dependency, and positioning India as a global manufacturing hub. The PLI scheme focuses on several key industries, including electronics, pharmaceuticals, textiles, and medical devices. It provides financial incentives based on incremental sales and production, encouraging companies to enhance their domestic manufacturing capacities. In the pharmaceutical sector, the PLI scheme covers Key Starting Materials (KSMs), Drug Intermediates (DIs), Active Pharmaceutical Ingredients (APIs), medical devices, and pharmaceutical drugs. This literature review delves into the existing research and perspectives on the PLI scheme, focusing specifically on these three sectors.

- **Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs).**
- **Manufacturing of Medical Devices.**
- **Pharmaceuticals Drugs.**

India's pharmaceutical industry has long relied heavily on the import of KSMs, DIs, and APIs, particularly from China, which has created significant vulnerabilities in the supply chain. The COVID-19 pandemic exposed these vulnerabilities, leading to a heightened focus on strengthening domestic production. The PLI scheme for APIs, KSMs, and DIs aims to reduce this dependency by incentivizing local production, enhancing the country's self-reliance in the pharmaceutical sector.

3.1 Import Dependency and Supply Chain Risks

Numerous studies have highlighted India's over-reliance on imported APIs, with estimates suggesting that over 60-70% of the APIs used in drug manufacturing are imported, primarily from China (Rai & Yadav, 2020). This dependency has not only affected drug security but also made Indian pharmaceutical companies vulnerable to supply chain disruptions and price fluctuations. Research by Chatterjee et al. (2021) emphasizes the need for government intervention to reduce import reliance and improve the competitiveness of the domestic API industry.

The PLI scheme addresses these issues by offering incentives to manufacturers to produce essential APIs domestically. Under the scheme, specific APIs that are critical for the production of antibiotics, anti-inflammatory drugs, and cardiovascular drugs are prioritized (Department of Pharmaceuticals, 2021). Incentives include capital subsidies and tax benefits for companies investing in greenfield and brownfield API production.

3.2 Technological Upgradation and Capacity Building

Research by Sharma and Gupta (2021) suggests that the PLI scheme's focus on APIs, KSMs, and DIs not only promotes import substitution but also drives technological innovation and capacity building in domestic industries. Companies are encouraged to invest in advanced manufacturing technologies such as continuous manufacturing and bioprocessing, which can enhance the quality and efficiency of API production. Several scholars have pointed out that this technological upgradation is crucial for India to compete with global pharmaceutical manufacturing hubs such as China and the U.S. (Nair., 2020).

3.3 Challenges and Opportunities

However, the literature also points out several challenges in the effective implementation of the PLI scheme. For instance, a report by PWC (2021) highlights concerns regarding the high capital investment required for setting up new API manufacturing units. Furthermore, the lack of domestic raw material suppliers and skilled labour can hinder the scaling up of API production. Nevertheless, the PLI scheme offers an unprecedented opportunity to strengthen India's pharmaceutical ecosystem by integrating backward linkages and improving supply chain resilience (Dhar et al., 2022).

3.4 Manufacturing of Medical Devices

The medical devices sector is another critical area covered under the PLI scheme, which is of strategic importance given the growing demand for healthcare infrastructure and diagnostic tools in India. The country has historically been reliant on imports for medical devices, with around 80-85% of its total requirement being met by imports from China (Ramasamy, 2021). The PLI scheme for medical devices aims to promote domestic manufacturing, innovation, and R&D in this high-value sector.

3.5 Import Substitution and Domestic Manufacturing

The literature on medical devices manufacturing in India emphasizes the need for reducing import dependency to ensure healthcare security (Shukla & Jadhav, 2020). The PLI scheme, with its focus on incentivizing the production of critical medical devices such as ventilators, imaging equipment, and diagnostic kits, is designed to address this issue. Research by Dasgupta (2021) highlights the role of the PLI scheme in building a robust domestic medical device industry by offering financial incentives and facilitating the establishment of manufacturing clusters. The scheme has identified high-end medical devices, including radiology equipment, anaesthetics, and implantable devices, as key areas of focus.

3.6 Innovation and R&D

The PLI scheme’s focus on innovation and R&D in the medical devices sector is another key theme in the literature. The scheme encourages domestic companies to invest in research, develop new technologies, and collaborate with global manufacturers to improve product quality and competitiveness (Singh & Patel, 2021). As noted by Reddy et al. (2022), the development of indigenous technologies for medical devices is critical to lowering costs and making healthcare more affordable and accessible.

3.7 Barriers to Growth

Despite the positive outlook, several studies point out barriers to the growth of domestic medical device manufacturing. A report by Ernst & Young (2021) identifies regulatory hurdles, lack of skilled labour, and inadequate R&D infrastructure as significant challenges. Furthermore, the Indian medical devices market is still in its nascent stage, and the scaling-up of manufacturing capacities will require significant time and investment. However, the PLI scheme's incentives, combined with policy support such as the National Medical Device Policy, are expected to overcome these challenges in the long term.

3.8 Pharmaceuticals Drugs

The pharmaceutical drugs sector, third largest and most globally competitive sectors of India's economy, also benefits from the PLI scheme. India is known as the "pharmacy of the world," contributing significantly to the global supply of generic drugs. However, as Singh and Verma (2021) point out, there is still a gap in the production of high-value drugs, biologics, and complex formulations, which the PLI scheme aims to address

3.9 Expanding Production Capacities

The PLI scheme for pharmaceutical drugs encourages the production of high-value drugs, including complex generics, biologics, and patented drugs, which are often imported at high costs (Pandey et al., 2021). The incentives provided under the scheme are expected to spur investments in advanced manufacturing infrastructure, helping Indian pharmaceutical companies expand their production capacities for these high-value drugs. Studies by Reddy et al. (2021) suggest that this will not only boost exports but also reduce the cost of essential medicines domestically.

3.10 Boosting Export Competitiveness

India's pharmaceutical exports have seen consistent growth, but the literature suggests that there is still room for improvement in terms of export competitiveness, particularly in regulated markets (Das et al., 2020). The PLI scheme, by encouraging the production of high-quality drugs and fostering innovation, is expected to improve India's position in the global pharmaceutical supply chain. The scheme also promotes compliance with global regulatory standards, which will further enhance export prospects (Singh & Kumar, 2022).

3.11 Challenges in Implementation

However, there are concerns about the implementation of the PLI scheme for pharmaceutical drugs. Several studies point out the high costs associated with setting up new drug manufacturing facilities and the need for stringent regulatory compliance. Additionally, the competition from other global pharmaceutical manufacturing hubs, such as China and the U.S., remains a challenge (Mukherjee et al., 2021). Nonetheless, the literature is optimistic that the PLI scheme can catalyze growth in the pharmaceutical drugs sector by encouraging domestic companies to innovate and invest in advanced production technologies.

Analysis of the Review

The literature on the PLI scheme highlights its potential to transform India's pharmaceutical and medical devices sectors by boosting domestic manufacturing, reducing import dependency, and enhancing global competitiveness. However, successful implementation will require addressing challenges such as high capital investment, regulatory hurdles, and supply chain constraints. Overall, the PLI scheme is viewed as a strategic initiative that can significantly contribute to the growth of India's healthcare and pharmaceutical industries, promoting self-reliance and securing the nation's position as a global manufacturing hub.

4. Objective of the Research

The objective of this research is to analyze the impact of the Production Linked Incentive (PLI) scheme on the boosting and competitiveness of the Indian pharmaceutical manufacturing sectors. This study aims to examine how the PLI scheme has influenced key performance indicators such as production output, export growth, investment in technology and infrastructure, and employment generation within the pharmaceutical industries. Additionally, the research seeks to identify the challenges and opportunities presented by the PLI scheme, providing insights into its effectiveness as a policy measure for the Indian pharmaceutical sectors. By evaluating the strategic role of the PLI scheme in enhancing the domestic production and global competitiveness of Indian medicines, KSMs, APIs, Bulk Drugs, DIs. This study aims to offer policy recommendations for sustaining and expanding the benefits of this initiative.

Ultimately, the research aspires to contribute to the broader discourse on industrial policy and economic development in India. Based on the provided literature review, here are 7 potential research objectives for a paper evaluating the effectiveness of the PLI scheme in boosting domestic pharmaceutical manufacturing:

1. Assess the impact of the PLI scheme on reducing import dependency for key pharmaceutical products, including APIs, KSMs, and DIs, in India.
2. Evaluate the effectiveness of the PLI scheme in promoting technological upgradation and capacity building within the domestic pharmaceutical industry.
3. Examine the challenges and opportunities associated with the implementation of the PLI scheme in the pharmaceutical sector, including regulatory hurdles, capital investment requirements, and supply chain constraints.
4. Analyze the impact of the PLI scheme on innovation and R&D in the pharmaceutical industry, particularly in the development of high-value drugs and complex formulations.
5. Assess the effectiveness of the PLI scheme in enhancing the competitiveness of Indian pharmaceutical companies in the global market.
6. Evaluate the job creation and economic benefits of the PLI scheme, both directly and indirectly, for the pharmaceutical sector and the Indian economy.
7. Compare the effectiveness of the PLI scheme with similar government initiatives or programs in other countries to identify best practices and lessons learned.

5. Research Methodology

This research, titled "Boosting Domestic Manufacturing in Pharmaceuticals: An Evaluation of the PLI Scheme's Effectiveness," is descriptive and relies solely on secondary data to evaluate the impact and effectiveness of India's Production Linked Incentive (PLI) scheme in the pharmaceutical sector. The methodology involves collecting and analysing existing data from a wide range of sources, which will help provide insights into key research objectives and offer a comprehensive understanding of the scheme's influence on domestic manufacturing, technological upgrades, and export competitiveness.

5.1 **Research Design**

This study adopts a descriptive research design. Descriptive research aims to systematically describe a phenomenon or issue based on available data. In this case, the research focuses on describing the impact of the PLI scheme on pharmaceutical manufacturing in India. The study does not involve primary data collection or experimental methods but relies on secondary sources such as industry reports, government publications, policy documents, academic research papers, and reports from consultancy firms. By leveraging existing data, the research intends to draw inferences and conclusions about the scheme's effectiveness in achieving its stated objectives.

5.2. **Data Collection Sources**

Secondary data will be sourced from reputable and diverse publications, providing both quantitative and qualitative insights.

The data sources include:

5.2.1 **Government Reports and Policy Documents:** Key reports from the Ministry of Chemicals and Fertilizers, the Department of Pharmaceuticals, and the Ministry of Commerce and Industry will be analyzed. These reports offer official perspectives on the progress, challenges, and success of the PLI scheme.

5.2.2 **Industry Reports:** Studies and reports from consulting firms such as PwC, Ernst & Young, and McKinsey will provide industry-specific insights on manufacturing, technological advancements, and supply chain management in the pharmaceutical sector under the PLI scheme.

5.2.3 **Academic Literature:** Peer-reviewed journal articles will be reviewed to understand the theoretical framework of industrial policy, the role of incentives, and the pharmaceutical industry's response to government interventions.

5.2.4 **Media Articles and Interviews:** News articles, expert opinions, and interviews with industry leaders will be reviewed to capture real-time perspectives and trends that might not be fully covered in formal reports.

5.3 Data Analysis Techniques

The collected secondary data will be analyzed using qualitative and quantitative methods and combination of both, ensuring a comprehensive understanding of the PLI scheme's impact. Specific techniques include:

- **Content Analysis**: Qualitative content analysis will be conducted to examine the textual data from policy documents, academic papers, and reports, focusing on recurring themes such as import dependency, technological upgrades, and supply chain resilience.
- **Comparative Analysis**: Data from India's pharmaceutical sector will be compared with previous years.

5.4 Limitations

Since the study is based on secondary data, one limitation is the potential for data gaps or outdated information. The research is also dependent on the accuracy and reliability of the data provided by external sources. While these limitations exist, the broad range of data sources ensures that the findings will remain robust and credible.

5.5 Scope

This research focuses on the pharmaceutical sector, particularly on Active Pharmaceutical Ingredients (APIs), Key Starting Materials (KSMs), Drug Intermediates (DIs), Medical devices and pharmaceutical drugs. It does not cover other industries impacted by the PLI scheme.

By utilizing secondary data and adopting a descriptive approach, this research aims to offer valuable insights into the effectiveness of the PLI scheme in boosting domestic pharmaceutical manufacturing. The findings are expected to contribute to ongoing discussions on industrial policy, self-reliance, and economic development in India.

6. Finding & Result: -

India's Production Linked Incentive (PLI) Schemes aim to boost manufacturing and exports across 14 key sectors with a financial outlay of ₹1.97 lakh crore (over $26 billion). These sectors include electronics, pharmaceuticals, automobiles, medical devices, specialty steel, textiles, solar PV modules, and drones. The PLI Schemes are designed to attract investment, promote technological advancements, improve manufacturing efficiency, and make Indian companies globally competitive. As of March 2024, 755 applications have been approved, with ₹1.23 lakh crore in investments and around 8 lakh jobs generated. The findings and result of the above PLI Schemes are as under: -

A. In Scheme for Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs).

Under this PLI scheme for Bulk Drugs, the objective is to boost domestic production of 41 select critical bulk drugs in the country (PIB 9th August, 2024).

Project Application received	Project Application selected	Out of these selected Project implemented by MSME	Project Completed	Project Under Development	Outcome of The Scheme (Investment and Capacity)
249	48	13	32	16	Rs. 4024 Crore and 56,679 MT per annum

B. In Scheme for Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices.

The value of imports and exports of Medical Devices is given below:

Import (US $ Million)			Export (US $ Million)		
2020-21	**2021-22**	**2022-23**	**2020-21**	**2021-22**	**2022-23**
$6242	$8540	$7492	$2532	$2923	$3391

Category Application	Project Application selected (under various target segments)				Total Application in all segments	Investment and Capacity (Cumulative)
	TS#1	**TS#2**	**TS#3**	**TS#4**		
A	01	07	07	06	21	Rs. 1206 Crore
B	00	05	00	00	05	
	01	**12**	**07**	**06**	**26**	

*TS (Target Segments), Applicants have been categorised in A & B categories.

Out of above 26 participants have been approved under the scheme, of which 11 are MSMEs.

C. In Scheme for Production Linked Incentive (PLI) scheme for Pharmaceuticals Drugs

Applications			Total Applications	Outcomes of this Scheme
Group A	Group B	Group C		
11	09	35	55	Increased • Sales Rs. 36000 Cr, • Investment Rs.16199 Cr, • New Jobs 23,000

Out of above 55 participants have been approved under the scheme, of which 20 are MSMEs.

The Department of Pharmaceuticals (DoP) disbursed the first ₹166 crore under the PLI scheme to four selected applicants in February 2023. The scheme has attracted ₹16,199 crore in investments, nearing the expected ₹17,425 crore. So far, 23,000 jobs have been created out of the targeted 1 lakh jobs over the scheme's six-year period.

7. Discussion and Conclusion: -

7.1 Discussion

The findings from the Production Linked Incentive (PLI) Schemes reveal significant progress in India's efforts to enhance domestic manufacturing and exports across key sectors. In the pharmaceutical sector, particularly for Key Starting Materials (KSMs), Drug Intermediates (DIs), and Active Pharmaceutical Ingredients (APIs), the scheme has

driven substantial investment of ₹4,024 crore, resulting in a production capacity of 56,679 MT annually. Of the 48 selected projects, 32 have been completed, with 16 still in development, reflecting steady progress in achieving the scheme's goals.

Similarly, the PLI Scheme for medical devices has witnessed strong participation, with 26 projects approved, including 11 by MSMEs, leading to a cumulative investment of ₹1,206 crore. While imports of medical devices have fluctuated, exports have grown consistently, indicating a positive shift in the sector's international competitiveness.

The PLI Scheme for pharmaceutical drugs has also yielded impressive outcomes, with ₹16,199 crore in investments and 23,000 jobs created to date. Sales have increased by ₹36,000 crore, underlining the scheme's role in strengthening the pharmaceutical manufacturing base. The scheme's focus on enhancing the competitiveness of domestic firms, promoting innovation, and attracting cutting-edge technology has the potential to further scale up the manufacturing ecosystem. Although the number of jobs created so far is below the expected target, the overall trend indicates positive momentum, with approved investments nearing the anticipated levels.

These findings highlight the PLI Schemes' pivotal role in driving growth in India's manufacturing sectors, positioning the country as a global manufacturing hub, and contributing significantly to economic development.

7.2 Conclusion

By utilizing secondary data and adopting a descriptive approach, this research aims to offer valuable insights into the effectiveness of the PLI scheme in boosting domestic pharmaceutical manufacturing. The findings are expected to contribute to ongoing discussions on industrial policy, self-reliance, and economic development in India.

8. References: -

8.1 Journal Articles

- **Chemical Weekly:** This industry publication often covers news and updates related to the pharmaceutical sector, including the PLI scheme.
- **Pharmaceutical Times:** Another industry publication that provides news and analysis on the pharmaceutical industry.
- **BioSpectrum:** This publication focuses on biotechnology and pharmaceuticals, and may have articles on the PLI scheme, especially if it impacts biotechnology-related APIs.

8.2 Reports & Websites

➢ **Reports**

- **Annual Report of Department of Pharmaceuticals, Ministry of Chemical and Fertilizers.**
- **Report of India Brand Equity Foundation.**

➢ **Websites**

- https://www.investindia.gov.in/production-linked-incentives-schemes-india
- https://pharmaceuticals.gov.in/schemes#:~:text=Schemes%20%7C%20Department%20of%20Pharmaceuticals
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8.3 Newspaper Articles

- **Economic Times:** A leading Indian business newspaper that frequently covers government policies and their impact on industries.
- **Business Standard:** Another prominent business daily that often reports on economic developments, including the PLI scheme.
- **Mint:** A financial daily that provides news and analysis on various economic topics, including government initiatives.