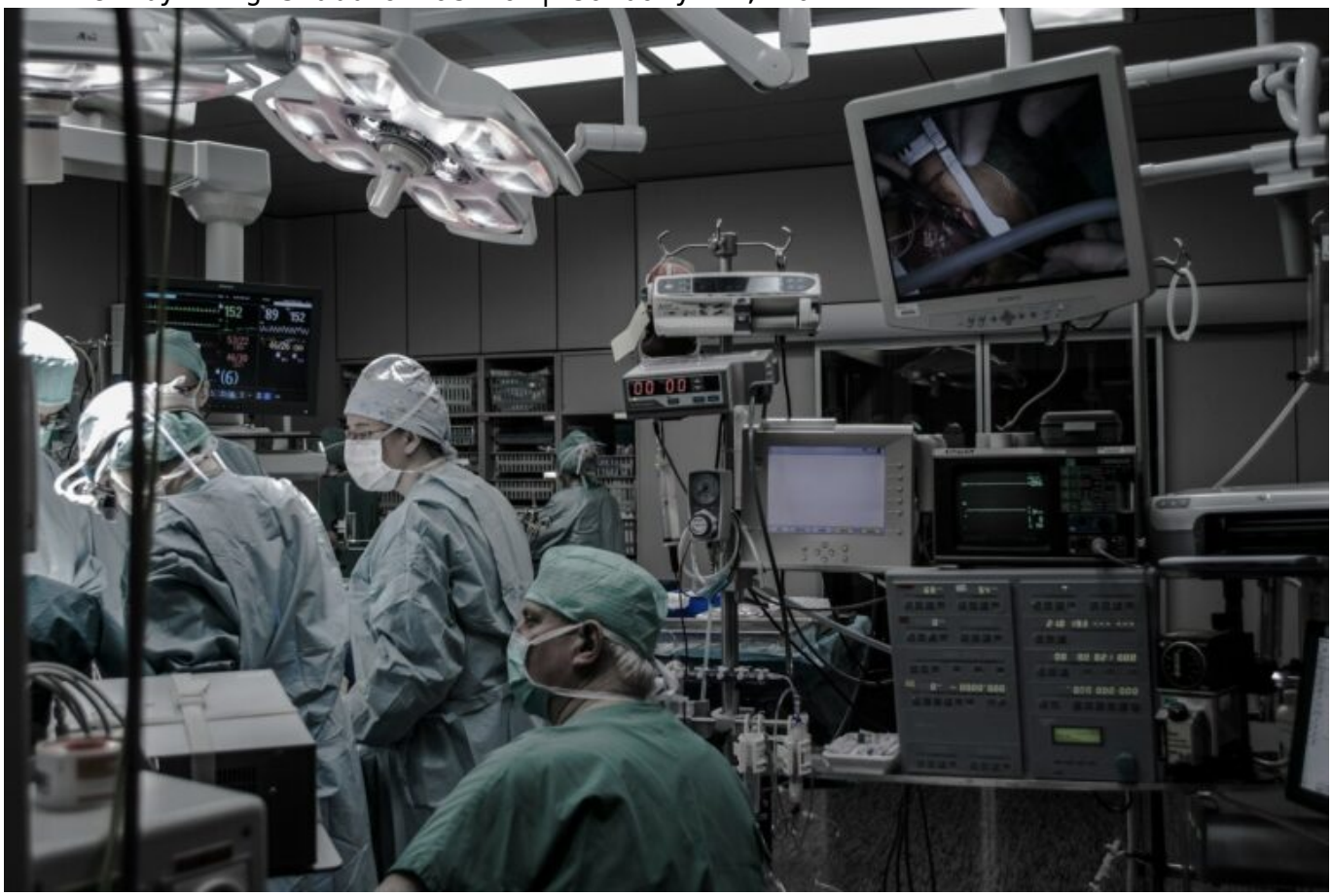
Shaping India's Healthcare Destiny: The Pioneering Impact of PLI Schemes in Pharmaceuticals and Medical Devices

written by King Stubb & Kasiva | January 17, 2024



Introduction

In a defining moment for India's healthcare landscape, the Government, led by the visionary Dr. Mansukh Mandaviya, Union Minister of Health & Family Welfare is making a monumental step to diminish the country's reliance on imported pharmaceuticals and medical devices. The release of Rs. 166 Crores in incentives under the Product Linked Incentive (PLI) scheme for Pharmaceuticals marks a pivotal juncture in the nation's journey towards Aatmanirbharta, or self-sufficiency.[1] This article explores the developments, achievements, and legal implications of these transformative initiatives, and the profound impact on the healthcare sector.

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The Vision and Focus

Dr. Mansukh Mandaviya's emphasis on high-value pharmaceuticals and cutting-edge medical devices highlights a strategic approach to fortifying an indigenous healthcare ecosystem. The focal point on diminishing import dependency resonates with the overarching national objective of fostering economic resilience while ensuring the availability of critical healthcare products.[2]

PLI Scheme for Pharmaceuticals: A Comprehensive Insight

The PLI scheme for pharmaceuticals, inaugurated in 2021 with a financial outlay of Rs. 15,000 Crores over six years, encompasses three pivotal categories of products:

- Category 1: Encompassing biopharmaceuticals, complex generic drugs, patented drugs, cell-based or gene therapy drugs, orphan drugs, special empty capsules, and complex excipients.
- Category 2: Focused on bulk drugs, excluding those notified under the "PLI Scheme for Bulk Drugs."
- Category 3: Encompassing drugs not included in Category 1 and Category 2, such as repurposed drugs, auto-immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs, anti-retroviral drugs, and in vitro diagnostic devices.

Incentives and Achievements

The incentives provided under the PLI scheme are tied to incremental sales, with rates ranging from 10% to 3% over the years. In the first year of implementation (2022-2023), the scheme has surpassed expectations, garnering an investment of Rs. 16,199 Crores, exceeding the anticipated investment of Rs. 17,425 Crores. Notably, 23,000 jobs have been generated, surpassing the projected employment figure of 1 lakh over the scheme period.

Legal Implications

The disbursement of incentives to selected participants involves a meticulous evaluation process. The Rs. 544 Crore incentive claim from 15 applicants underscores the legal intricacies surrounding claims, evaluations, and disbursements. The transparency and fairness of this process are imperative to ensuring the success and credibility of the PLI scheme.

PLI Schemes for Bulk Drugs and Medical Devices

PLI Scheme for Bulk Drugs

With a financial outlay of Rs. 6940 Crores, this scheme aims to boost the domestic production of 41 critical bulk drugs. Out of the committed investment of Rs. 4,138 Crores, Rs. 2019 Crores have been reported in the first year. Notably, 51 projects have been selected for the 34 notified bulk drugs, with 22 projects commissioned to date.[3]

Further, the Incentive rates for fermentation-based products are 20%, and for chemical-based products, they are 10% for the initial four years, tapering off in subsequent years. Approximately 1900 individuals have found employment under the scheme, emphasizing its positive impact on job creation.

PLI Scheme for Medical Devices

With a financial outlay of Rs. 3,420 Crores, this scheme focuses on establishing domestic manufacturing capabilities for high-end medical

devices[4] in four target segments, including cancer care, radiology, anaesthetics, and implants.

Furthermore, against a committed investment of Rs. 1059 Crores over five years, an investment of Rs. 714 Crores has been reported in the first year. Fourteen projects have already been commissioned for 34 products, including high-end devices such as CT scans, MRI coils, and intensive care ventilators. About 2900 individuals have found employment under the scheme, signalling a positive trajectory in the medical device manufacturing sector.[5]

Legal Framework and Compliance

The success of these PLI schemes hinges on adherence to regulatory frameworks, ensuring that participants comply with stipulated guidelines and standards. A robust legal framework is essential to monitor and regulate the implementation of these schemes.

The legal procedures surrounding incentive claims demand transparency, fairness, and adherence to predefined criteria. The Department of Pharmaceuticals' careful evaluation of claims from applicants like Dr. Reddy's Laboratories Limited, Biocon Limited, Strides Pharma Science Limited, and Premier Medical Corporation Private Limited sets a precedent for the scrutiny and disbursement process.

Future Outlook and Global Implications

The PLI schemes are poised to have a substantial economic impact, not only by reducing import dependency but also by stimulating domestic production, attracting investments, and generating employment.

India's focus on high-value pharmaceuticals and advanced medical devices positions it as a global contender in the healthcare sector. The success of these schemes could elevate India's status as a reliable and competitive player in the international market.

Conclusion

The PLI schemes for pharmaceuticals, bulk drugs, and medical devices signify a momentous leap towards healthcare self-sufficiency in India. Dr. Mansukh Mandaviya's vision and the government's steadfast efforts have laid the foundation for a thriving indigenous healthcare industry. As a legal professional and author, it is crucial to recognize the legal intricacies, transparency, and compliance that underpin the success of these schemes. The journey towards Aatmanirbharta in healthcare is not just a national aspiration but also a testament to India's commitment to global health and economic resilience.

FAQs

What is the primary focus of India's PLI schemes in the pharmaceutical and medical device sectors?

The primary focus of India's PLI schemes is to reduce import dependency by emphasizing the production of high-value pharmaceuticals and advanced medical devices, fostering economic resilience and self-sufficiency.

What are the key achievements of the PLI scheme for pharmaceuticals in its first year of implementation?

In the first year (2022-2023), the PLI scheme for pharmaceuticals has exceeded expectations, garnering an investment of Rs. 16,199 Crores against the anticipated Rs. 17,425 Crores. Additionally, 23,000 jobs have been created, surpassing the projected employment figure of 1 lakh over the scheme period.

How has the PLI scheme for medical devices contributed to India's healthcare landscape?

The PLI scheme for medical devices, with a focus on cancer care, radiology, anaesthetics, and implants, has reported an investment of Rs. 714 Crores in its first year against the committed Rs. 1059 Crores over five years. It has already commissioned 14 projects for 34 products, showcasing a positive trajectory in high-end medical device manufacturing and generating employment for about 2900 individuals.

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[1] https://www.makeinindia.com/schemes-manufacturing-medical-devices

[2]https://pharmaceuticals.gov.in/sites/default/files/Gazette%20notification%20of%20Medical%20Device%20schemes.pdf

[3]https://pib.gov.in/PressReleasePage.aspx?PRID=1901121#:~:text=Under%20the%20PLI%20scheme%20for%20Medical%20Devices%20with%20a%20financial,Cancer%20care%2FRadiotherapy%20medical%20devices

[4]https://pharmaceuticals.gov.in/sites/default/files/Gazette%20notification%20of%20Medical%20Device%20schemes_1.pdf

[5]https://pib.gov.in/PressReleasePage.aspx?PRID=1901121#:~:text=Under%20the%20PLI%20scheme%20for%20Medical%20Devices%20with%20a%20financial,Cancer%20care%2FRadiotherapy%20medical%20devices