

**GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS AND FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

RAJYA SABHA  
STARRED QUESTION No. 169  
TO BE ANSWERED ON 19<sup>th</sup> December, 2023

**PLI Schemes in pharmaceutical sector**

**169 Shri Ayodhya Rami Reddy Alla:**

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

- (a) whether the Production Linked Incentive (PLI) schemes strike a balance between incentivizing generic drug manufacturing, which is critical for accessibility, and encouraging the development and production of innovative and high-value pharmaceutical products;
- (b) whether the PLI schemes in the pharmaceutical sector contribute to fostering innovation, improving production capacities, and enhancing the global competitiveness of the industry; and
- (c) the mechanisms for monitoring and ensuring compliance with the objectives of the PLI schemes, particularly concerning the timely execution of investments, research and development activities and production targets?

**ANSWER**

**MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS  
(Dr. MANSUKH MANDAVIYA)**

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(a) to (c): A Statement is laid on the Table of the House.

**Statement referred to in reply to the RAJYA SABHA STARRED Q.NO. 169 (4<sup>th</sup> POSITION) for answer on 19.12.2023 raised by Shri Ayodhya Rami Reddy Alla regarding PLI Schemes in pharmaceutical sector**

(a) to (c): India is the 3rd largest producer of pharmaceuticals by volume and the largest supplier of generic medicines with 20 percent share of the global supplies. India produces more than 60,000 generic drugs across 60 therapeutic categories and has the maximum number of US FDA approved plants outside the United States. India is also the largest supplier of low-cost vaccines to the world.

The Government of India is implementing the Production Linked Incentive (PLI) Scheme for Pharmaceuticals with a financial outlay of Rs. 15,000 crores. The objective of the scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector.

Under the scheme, financial incentive is provided for production of identified products under three product categories. Category 1 includes drugs such as - bio-pharmaceuticals, complex generics, patented drugs or drugs nearing patent expiry, orphan drugs etc., Category-2 includes active pharmaceutical ingredients, key starting materials, drug intermediates etc., and Category-3 includes auto-immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs, anti-retroviral drugs, In-vitro devices etc.

Under the PLI Scheme for Pharmaceuticals, 362 patented drugs or drugs nearing patent expiry have been approved for manufacturing. Also, 281 complex generics have been approved for manufacturing. Under the scheme, incentive is being provided both for manufacturing of generic drugs and for manufacturing high value products like bio-pharmaceuticals, 119 of which have been approved under the scheme.

In the PLI scheme for Pharmaceuticals, the investment committed by the selected applicants was Rs 17,275 cr, against which investment worth Rs 25,813 cr has already been realized. The cumulative sales made by the applicants under the scheme is Rs 1,16,121 cr. (including exports worth Rs. 75,141 cr.)

Another PLI scheme being implemented by the Department of Pharmaceuticals is the Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) (PLI scheme for Bulk Drugs). The scheme intends to boost domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector, thereby reducing India's import dependence of the critical APIs. The scheme has a financial outlay of Rs. 6,940 crores and the tenure of the scheme is from FY 2020-2021 to FY 2029-30. The scheme provides for financial incentive for production of 41 products and 48 projects have been approved under this scheme. The investment committed by the selected applicants was Rs 3938.57 cr, against which investment worth Rs 3062.69 cr has already been realized. The envisioned production capacity under the scheme was 82,270 MT, out of which production capacity for 41881 MT has already been installed.

For better monitoring Project Management Agencies (PMAs) have been selected under both the PLI Schemes. The PMAs are responsible for providing secretarial, managerial and

implementation support. The PMAs conduct verification of investment and sales of approved participants for deciding eligibility to receive incentive. The Department regularly reviews the PLI schemes by seeking periodical information through the PMAs and conducts meetings with the PMAs and the applicants.

Under PLI Scheme for Pharmaceuticals, Scheme Selection and Steering Committee under the Chairmanship of Secretary, Department of Pharmaceuticals regularly monitors implementation of the Scheme. Under PLI Scheme for Bulk Drugs, an Empowered Committee (EC) under the Chairmanship of CEO, Niti Aayog conducts periodic review of the projects under the Scheme. Further, an Empowered Group of Secretaries (EGoS) under the chairmanship of Cabinet Secretary undertakes periodic review of various PLI schemes. The PLI schemes of the Department of Pharmaceuticals are also reviewed from time to time by the Minister for Chemicals and Fertilizers.

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