



Extension of PLI Scheme to API

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The Department of Pharmaceuticals has received representations from the approved applicants under 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) in India (commonly known as “PLI Scheme for Bulk Drugs”) regarding the extension of scheme tenure. In this regard, the Government has decided not to give extension to the said scheme as it will result in an unfair benefit to non-performers and thereby, will be against the interest of those beneficiaries those have made efforts to meet the timelines.

i. India's dependence on imported APIs, particularly from a single source country, has posed supply chain vulnerability risks for domestic drug manufacturing. The COVID-19 pandemic further highlighted the risks associated with excessive dependence on imports for critical APIs and KSMs, which had the potential to disrupt domestic pharmaceutical production and thereby affect health security.

ii. In this regard, the Government has proactively notified 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) In India (also known PLI scheme for bulk drugs) with a budgetary outlay of ₹6,940 crore, specifically to address this structural vulnerability by incentivizing domestic manufacturing of 41 identified critical APIs/ KSMs that were previously largely imported.

iii. With respect to the State of Maharashtra specifically, it may be noted that 3 projects have been approved under the PLI Scheme for Bulk Drugs in the State, with an investment of ₹159 crore as of December 2025. Under these projects, domestic manufacturing capacity of approximately 17,680 MT per annum has already been established, contributing significantly to the State's API manufacturing base and thereby reducing import vulnerability for critical drug inputs. At the national level, as of December 2025, 38 projects covering 28 notified products have been commissioned under the Scheme, resulting in establishment of domestic manufacturing capacity of approximately 56,800 MT per annum, progressively reducing dependence on single-source imports.

With a view to strengthening the domestic biopharmaceutical sector and enhancing global competitiveness in biologics and bio-similars, the Government has announced the Biopharma SHAKTI scheme with an outlay of ₹10,000 crore over five years with an objective to build a globally competitive domestic ecosystem for biologics and bio-similars to support affordable healthcare in India and enable India to emerge as a global biopharma manufacturing and innovation hub. By supporting research and development, strengthening clinical trial infrastructure and promoting collaboration between academia, research institutions and industry, the Scheme seeks to encourage domestic innovation and manufacturing capabilities in the biopharmaceutical sector.

The Scheme for "Promotion of Research and Innovation in Pharma MedTech sector (PRIP)" has been launched by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers with the goal of transforming India into a global powerhouse for R&D in the Pharma MedTech sector. The scheme has a total financial outlay of ₹5000 crores, which includes ₹700 crores to establish Centers of Excellence (CoEs) at seven National Institutes of Pharmaceutical Education & Research (NIPERs), and ₹4200 crores to accelerate investments in the R&D ecosystem within the sector.

Department of Science and Technology (DST), through the "Therapeutic Chemicals" program of Technology Translation and Innovation (TTI) Division, is pursuing to have self-reliance in health care sector. As a top-down approach, DST has created 5 clusters ((i) Chennai Tirupati Bengaluru Cluster (ii) Hyderabad Cluster (iii) Mumbai Pune Cluster (iv) Dehradun Himachal Cluster (v) Kolkata Guwahati Cluster) under this initiative of "Therapeutic Chemicals" program for the development of KSMs, Intermediates and raw materials. This cluster is expected to collaborate with relevant industry for their inputs to identify the priority chemicals and also for commercialization of the identified chemicals for which the feasibility report is under process.

Rationalization of import duties is undertaken during the Annual Budget exercise or through specific notifications based on representations from stakeholders and recommendations from relevant technical bodies. Such decisions involve an assessment of the balance between providing affordable access to advanced medical equipment, such as cancer radiation technology, and encouraging domestic value addition. Matters relating to customs duties on imported medical equipment, including advanced cancer radiation equipment, are reviewed by the Government from time to time in consultation with the concerned Ministries/Departments, taking into account various relevant factors such as domestic manufacturing capacity, public health considerations and revenue implications.

This information was given by Minister of State for Chemicals and Fertilizers, Smt. Anupriya Patel, in a written reply in the Lok Sabha today.

PC/PM

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