

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

RAJYA SABHA
UNSTARRED QUESTION NO.187
TO BE ANSWERED ON 22nd July, 2025

Promotion of Domestic Manufacturing of APIs

187 Smt. Ranjeet Ranjan:

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

- (a) whether Government is aware that our country relies on China for a significant share of its pharmaceutical imports, particularly Active Pharmaceutical Ingredients (APIs), and whether this dependency has increased or decreased since 2014;
- (b) the key steps taken by Government to promote domestic manufacturing of APIs and reduce import dependency;
- (c) whether Government intends to impose import duties or trade restrictions on Chinese APIs to encourage local production;
- (d) whether quality standards are in place for imported APIs, and if so, the mechanisms for their enforcement; and
- (e) the financial or policy incentives currently being offered by Government to domestic manufacturers of APIs?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): With a view to avoid disruption in supply of critical APIs (used to make critical drugs for which there are no alternatives) by reducing excessive dependence on a single source, Government constituted a committee on drug security in the year 2020, under the chairpersonship of Joint Drugs Controller (India) and representatives from relevant Departments, expert agencies and industry. The committee identified critical APIs on which the country was highly dependent on imports from China and, based on its recommendations, 41 products were identified for manufacturing under the Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India (also known as “PLI Scheme for Bulk Drugs”).

The scheme, which has a total budgetary outlay of ₹6,940 crore, aims to avoid disruption in supply of critical active pharmaceutical ingredients (APIs) used to make critical drugs for which there are no alternatives by reducing supply disruption risk due to excessive dependence on single source. Products notified and approved under the scheme prior to commencement of production under the PLI scheme were primarily imported. As of March 2025, against an investment commitment of ₹3,938.5 crore over the period of six years, investment of ₹4,570 crore has already been made under the scheme. As a result of the scheme, cumulative sales of ₹1,817 crore have been reported over the period from the beginning of the scheme till March 2025, including exports of ₹455 crore, thereby avoiding imports worth

₹1,362 crore and creation of domestic manufacturing capacity for 25 identified KSMs/DIs/APIs.

(b): The key steps taken by the Government to promote domestic manufacturing of APIs and reduce import dependency are the following:

- (i) *PLI Scheme for Bulk Drugs*: Details are given in the reply to part (a).
- (ii) *PLI Scheme for Pharmaceuticals*: This PLI scheme, whose production-linked incentive period began in FY2022-23 and which has a total budgetary outlay of ₹15,000 crore, aims 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 and incentivises production of, among others, APIs/DIs/KSMs other than those notified under the PLI Scheme for Bulk Drugs. It has enabled enhanced investment and production in eligible products. Till March 2025, total domestic sales of API and DIs, worth ₹22,658 crore, have been made under the scheme, which includes sales of over 190 APIs and DIs that were manufactured domestically for the first time.
- (iii) *Scheme for Promotion of Bulk Drugs Parks*: Under the scheme, which has a total budgetary outlay of ₹3,000 crore, three parks have been approved and are at various stages of development in the States of Andhra Pradesh, Gujarat and Himachal Pradesh, through their respective State Implementing Agencies. The total project cost of these is over ₹ 6,300 crore, with Central assistance to the tune of ₹1,000 crore each for creation of common infrastructure facilities. These parks would offer land and utilities such as power, water, effluent treatment plant, steam, solid waste management, warehouse facilities at a subsidised rate. The State Implementing Agencies of the three States are also offering fiscal incentives in the form of capital subsidy on fixed capital investment, interest subsidy, State Goods and Services Tax reimbursement, exemption of stamp duty and registration charges, etc. Further, the scheme provides that applicants for allotment of land in the parks to set up units for manufacturing products prioritised in the PLI Scheme for Bulk Drugs will have priority in land allotment.

(c): The Directorate General of Trade Remedies, an attached office of the Department of Commerce, conducts various investigations {anti-dumping/safeguard (quantitative restrictions) /countervailing} under the Customs Tariff Act, 1975 and the rules made thereunder, based on a duly substantiated application filed by the domestic industry alleging dumping of goods into the country causing injury to it. Further, under the Foreign Trade Policy issued by the Department of Commerce, the Directorate General of Foreign Trade, an attached office of the said Department, may impose "prohibition" or "restriction" for preventing sudden increases in imports from causing serious injury to domestic producers or to relieve producers who have suffered such injury. As and when proposals are received from domestic industry for imposition of import duties or trade restrictions, including in respect of APIs imported from China, the same are considered in accordance with the aforesaid provisions.

(d): The Department of Health and Family Welfare has informed that the Central Drugs Standard Control Organisation (CDSCO) issues the Registration Certificate and Import License for the import of APIs. As part of the regulatory process, CDSCO reviews the chemistry, manufacturing and controls data, stability data, certificate of analysis, etc., as per the provision of the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945 made thereunder. Further, import consignments are examined on random basis to verify compliance with the provision of the said Act and rules.

(e): Under the PLI Scheme for Bulk Drugs, production-linked financial incentive is provided on eligible sales of identified products over a period of six years, at the rates given below:

- (i) For fermentation-based products, incentive for the period from FY2023-24 to FY2026-27 is 20%, for FY 2027-28 is 15% and for FY2028-29 is 5%.
- (ii) For chemical synthesis-based products, incentive for the period from FY2022-23 to FY2027-28 is 10%.

Further, under the PLI Scheme for Pharmaceuticals, production-linked financial incentive is provided to selected participants on incremental sales at rates of 10% for FYs 2022-23 to 2025-26, 8% for FY2026-27 and 6% for FY2027-28.

Under the two PLI schemes, total financial incentive of ₹1,008.15 crore has so far been disbursed.
