

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

LOK SABHA
UNSTARRED QUESTION No. 354
TO BE ANSWERED ON THE 3rd February, 2023

Active Pharmaceutical Ingredient

354. SHRI POCHA BRAHMANANDA REDDY:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) the quantum of Active Pharmaceutical Ingredient (API) manufactured at domestic level in the country;
- (b) whether there has been any change in the production after the introduction of Production Linked Incentive scheme for APIs;
- (c) if so, the details thereof and if not, the reasons therefor; and
- (d) the details of other steps taken/proposed to be taken to promote domestic manufacturing of APIs in the country?

ANSWER

**MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)**

(a): While the quantum of Active Pharmaceutical Ingredient (API) manufactured domestically is not available with the Department, however, the quantity and the value of Bulk Drugs and Drug Intermediates imported and exported during the last three years, which also gives an indication of the domestic manufacturing, are as under:

Year	Import		Export	
	Quantity (MT)	Value (In Rs Cr)	Quantity (MT)	Value (In Rs Cr)
2019-20	3,64,433	24,172	2,71,544	2,75,33
2020-21	3,90,476	28,529	3,24,331	3,28,57
2021-22	4,00,642	35,249	4,53,130	3,33,20
2022-23(upto November, 2022)	2,91,782	27,209	2,82,978	2,41,30

Source: DGCIS, Ministry of Commerce and Industry

(b) and (c): 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, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for the financial incentives for 41 identified products. Out of these, 21 projects have already been commissioned.

Under the Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of Bulk drugs, the current FY 22-23 is the first year of production for the chemical synthesis based Bulk drugs and FY 23-24 is the first year of production for fermentation based bulk drugs.

The PLI Scheme provides for submission of final estimates for sales in a FY by all PLI participants after the end of that Financial Year. Meanwhile, the details of production and sales as submitted by seven applicants for the first half year of the FY 22-23 for *seven APIs* viz., Para-Amino Phenol, Atorvastatin, Levofloxacin, Oxcarbazepine, etc, indicate a total sale quantity of 3,240.92 MT.

d. The other Programmatic interventions which are under implementation to support the industry for domestic manufacturing of APIs are as follows:

- i. Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentives to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. The eligible drugs under this scheme include APIs among other categories of pharmaceutical products.
- ii. Scheme for Promotion of Bulk Drug Parks, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance for creation of common infrastructure facilities to three States which have been selected under the scheme viz Gujarat, Himachal Pradesh and Andhra Pradesh. The industrial units setting up plants for APIs in these Parks are to be benefited from the common infrastructure developed under the scheme, in order to decrease the manufacturing cost and increase their competitiveness.

XXXXX