

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

RAJYA SABHA  
UNSTARRED QUESTION No. 3066  
TO BE ANSWERED ON THE 28<sup>TH</sup> MARCH, 2023

**Domestic manufacturing of APIs**

**3066 Shri M. Mohamed Abdulla:**

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

- (a) whether the Union Government is going to take any new steps to increase the domestic manufacturing of the Active Pharmaceutical Ingredients (APIs) and the details about the country's import of the API for the year 2022-23; and
- (b) whether the Union Government is going to introduce a draft of new Quality Control Orders (QCO) to the Active Pharmaceutical Ingredients imported from China and if so, the details thereof?

**ANSWER**

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

---

(a): The Indian Pharmaceutical industry is the 3rd largest in the world by volume. India is one of the major producers of Active Pharma Ingredients (API) or bulk drugs in the world. India exported Bulk Drugs/Drug Intermediates worth Rs. 33,320 crore in financial year 2021-22. However, the country also imports various Bulk Drugs/APIs for producing medicines from various countries and most of the imports of the Bulk Drugs/APIs being done in the country are because of economic considerations. India imported Rs. 35,249 crore worth APIs and Bulk drugs in 2021-22. The import value of APIs and Bulk Intermediates from April, 2022 to January, 2023 is Rs 30337 Cr. (source: DGCIS)

The Government of India has taken several measures to encourage domestic manufacturing of Active Pharmaceutical Ingredients (APIs). The Programmatic interventions for the same are as follows;

- i. 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 incentive for 41 identified products. A total of 51 applications have been selected under the scheme. Out of these, 22 projects have already been commissioned with the installed capacity of 34,255 MT.
- ii. PLI 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 incentive to 55 selected applicants for manufacturing of identified products under three categories for

a period of six years. This scheme also covers the APIs, other than those covered under the PLI scheme under Bulk Drugs as mentioned at Point (i).

- iii. Under the Scheme for Promotion of Bulk Drug Parks, proposals of Andhra Pradesh, Gujarat and Himachal Pradesh have been approved for financial support to facilitate setting up of three (3) Bulk Drug Parks in the country. The total financial outlay of the scheme is Rs. 3000 crore and the tenure of the Scheme is from 2020-21 to 2024-25. The financial assistance by the centre is subject to a maximum limit of Rs.1000 Crore per park or 70% of the project cost of CIF (90% in case of North Eastern States and Hilly States), whichever is less.

(b): As per the inputs received from Central Drug Standard Control Organization (CDSCO) under the Department of Health and Family Welfare, the import of Active Pharmaceutical Ingredients (APIs) is already regulated under the Drugs and Cosmetics Act, 1940 and Rules.

\*\*\*\*\*