

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

LOK SABHA
UNSTARRED QUESTION No. 304
TO BE ANSWERED ON THE 3rd February, 2023

Supply of Active Pharmaceuticals Ingredients

**304. MS. RAMYA HARIDAS:
SHRI UDAY PRATAP SINGH:
SHRI BRIJENDRA SINGH:**

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

- (a) whether it is a fact that Government is depended on China for the supply of Active Pharmaceuticals Ingredients (API) for drug manufacturing;
- (b) if so, the details thereof along with the ratio of API import from China and domestic production, in terms of value and quantity;
- (c) whether the Government has any contingency plan in case of sudden dip in the supply of APIs along with the quality check put in place for API imported into the country;
- (d) the measures taken/proposed to be taken to avoid such dependency on China for supply of APIs;
- (e) the details of API imported by India, country-wise; and
- (f) whether the Government is taking steps to expand the volume of 'Made in India' APIs to reduce reliance on imports, especially from China and if so, the details thereof?

ANSWER

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

(a) to (b) and (e): The Indian pharmaceutical industry is the world's 3rd largest by volume and 14th largest in terms of value. Over the last 30 years, the Indian Pharmaceutical Industry has become a leader in the manufacture of high quality generic drugs at competitive prices. India exported pharmaceuticals worth Rs. 1,75,040 crore in the financial year 2021-22, including Bulk Drugs/ Drug Intermediates.

Also, 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 including China, because of economic considerations.

Department does not maintain the details of domestic production of the APIs. However, the details of APIs (Bulk Drug and Drug Intermediates) imported from China & from other countries from 2019-20 to 2022-23 (upto November, 2022) and details of Imports (by value) of APIs (Bulk Drug and Drug Intermediates) from 25 countries in FY 21-22 is given at **Annexure**.

(c): As per the information received from the CDSCO under DoHFW, the Indian pharmaceutical producers make an assessment of the imports needs and keeps adequate stocks of APIs in emergencies as has been observed during the times of COVID. Further, the import of drugs is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made there under. For import of any drug, including bulk drug (API), the overseas manufacturing sites and the drugs are required to be registered and import license is required to be obtained in accordance with provisions of the said Act and Rules. All the imported drugs are required to comply with standards mentioned under Second Schedule of the Drugs & Cosmetics Act 1940. Further, for quality check of drugs, sampling is carried out based on defined risk based criteria for imported consignments, at Port offices of Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare. As and when issue regarding quality of imported drug is received, action is taken by CDSCO in accordance with the provisions of said Act and Rules.

(d) & (f): In order to make the country Atmanirbhar in the manufacturing of APIs, the Department of Pharmaceuticals has taken several measures. The Programmatic interventions which are under implementation to support the industry for domestic manufacturing of APIs are as follows:

- i. 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, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, the financial incentives are to be provided for 41 identified products. Out of these, 21 projects have already been commissioned.
- ii. 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.
- iii. 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 will get benefitted from the common infrastructure developed under the scheme, which will decrease the manufacturing cost and increase their competitiveness.

1. Details of APIs (Bulk Drug and Drug Intermediates) imported from China & from other countries from 2019-20 to 2022-23 (upto November, 2022)

Year	Total Import		Import from China	
	Quantity of Import (MT)	Value of Import (In Rs Cr)	Quantity of import from China (MT)	Value of import from China (In Rs Cr)
2019-20	3,64,433	24,172	2,20,875	16,443
2020-21	3,90,476	28,529	2,56,609	19,403
2021-22	4,00,642	35,249	2,64,582	23,273
2022-23 (upto November, 2022)	2,91,782	27,209	1,92,808	18,973

Source: DGCIS, Ministry of Commerce and Industry.

2. Details of Imports (by value) of APIs (Bulk Drug and Drug Intermediates) from top 25 countries in FY 21-22

S. No	COUNTRIES	2021-22 (Rs. in crore)
1	CHINA PRP	23273.02
2	USA	3096.81
3	SINGAPORE	964.28
4	ITALY	830.04
5	SPAIN	618.46
6	KOREA RP	560.33
7	JAPAN	555.42
8	GERMANY	549.71
9	HONG KONG	492.87
10	SLOVENIA	388.99
11	AUSTRIA	374.64
12	FRANCE	351.15
13	DENMARK	345.11
14	SWITZERLAND	272.85
15	NETHERLAND	268.91
16	BELGIUM	266.23
17	INDONESIA	235.29
18	TAIWAN	227.77
19	UK	212.91
20	HUNGARY	212.22
21	MALAYSIA	200.84
22	MEXICO	177.59
23	CZECH REPUBLIC	120.09
24	UAE	68.14
25	CANADA	50.63

Source: DGCIS, Ministry of Commerce and Industry