

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

RAJYA SABHA
STARRED QUESTION No. 68
TO BE ANSWERED ON THE 8TH FEBRUARY, 2022

API Import from China

68 Shri G.C. Chandrashekhar:

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

- (a) whether it is a fact that Government is dependent on China for the supply of Active Pharmaceuticals Ingredients (API) for drug manufacturing;
- (b) if so, the details of total percentage imported from China and domestic production, in terms of value and quantity;
- (c) the contingency plan of Government in case of sudden dipping in the supply of APIs along with the quality check currently in place for API imported into the country and measures taken to avoid the dependency?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(Dr. MANSUKH MANDAVIYA)

(a) to (c): A statement is laid on the table of the house.

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 68 RAISED BY Shri G.C. CHANDRASHEKHAR, HON'BLE MEMBER OF PARLIAMENT TO BE ANSWERED ON 08.02.2022 REGARDING 'API IMPORT FROM CHINA'.

(a) to (c): The Indian Pharmaceutical industry is the 3rd largest in the world by volume. India exported pharmaceuticals worth Rs. 1,80,551 crore in the financial year 2020-21. India exported Bulk Drugs/ Drug Intermediates worth Rs.32,857 crore in financial year 2020-21. However, the country also imports various Bulk Drugs/ Active Pharmaceutical Ingredients (APIs) for producing medicines from various countries including China. The details of export and import of Bulk Drugs and Drug Intermediates of the country is given below:-

Export and Import of Bulk Drugs and Drug Intermediates						
Year	Export		Import			
	Quantity (MT)	Value (In Rs Cr)	Quantity (MT)	Value (In Rs Cr)	Value of imports from China (In Rs Cr)	Percentage of imports from China (In terms of value)
2018-19	3,66,616	27,346	3,45,944	24,850	16,777	67.5%
2019-20	2,71,544	27,533	3,64,433	24,172	16,443	68.02%
2020-21	3,24,331	32,857	3,90,476	28,529	19,403	68.01%
2021-22 (April to December 2021)	3,35,627	24,107	3,02,745	26,490	17,610	66.48%

Source: DGCIS, Ministry of Commerce and Industry.

2. Most of the imports of the Bulk Drug/APIs being done in the country are because of economic considerations and also, China is one of the largest producers of KSMs and API in the world. The Committee, constituted by Department of Pharmaceuticals, observed that there are 58 APIs, for which, dependency of the country on imports from China for these APIs varies from 50% to 100%.

3. The Government strives to minimize country's dependence on imports and to give fillip to indigenous manufacturing. In order to make the country Atmanirbhar in pharmaceuticals, the Department of Pharmaceuticals has launched 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. The total financial outlay of the scheme is Rs. 6,940 crore and the tenure from FY 2020-2021 to FY 2029-30. Another Production Linked Incentive Scheme for Pharmaceuticals has been launched with total financial outlay of Rs. 15,000 crore and tenure from FY 2020-2021 to FY 2028-29. The eligible drugs under this scheme include APIs among other categories of pharmaceutical products.

4. 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 Organisation (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.

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