GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

LOK SABHA UNSTARRED QUESTION No. 436 TO BE ANSWERED ON THE 19th November, 2019

API from China

436. MS. MALA ROY:

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

- (a) whether it is true that the 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
- (c) the contingency plan of the 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?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI D. V. SADANANDA GOWDA)

(a) & (b): Yes, Sir. The country imports Bulk Drugs/Active Pharmaceutical Ingredients (APIs) for producing medicines including certain essential medicines.

The details of India's imports of Bulk Drugs, Drug Intermediates from China are as under:

Years	Total import (US \$ mn)	Imports from China (US\$ mn)	Percent of Import from China
2016-17	2738.46	1826.34	66.69%
2017-18	2993.25	2055.94	68.36%
2018-19	3560.35	2405.42	67.56%

(Source: DGCIS Kolkata)

(c): The imports from China are due to economic considerations, however, there are other sources like United States, Italy, Singapore, Hong Kong etc. from which Bulk drugs/APIs can be imported during contingencies. The policies formulated by Government from time to time are designed to minimize country's dependence on imports and to give fillip to indigenous manufacturing. In this direction, the Department of Pharmaceuticals has formulated a Scheme namely 'Assistance to Bulk Drug Industry for Common Facility Centre' for providing assistance to Bulk Drug Industry for Common Facility Centre in any upcoming bulk drug park promoted by State Governments/State Corporations. An Inter-Ministerial Task Force was also constituted under the

Chairmanship of the Minister of State (Chemicals & Fertilizers) on 18.04.2018 to formulate a roadmap for the enhanced production of Active Pharmaceutical Ingredients (APIs) in the country.

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 site and the drug are required to be registered and import license is required to be obtained in accordance with provisions of said Act and Rules. As and when issue regarding quality of imported drug is received, action is taken in accordance with the provisions of said Act and Rules.

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