

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

LOK SABHA
UNSTARRED QUESTION NO. 1142
TO BE ANSWERED ON THE 8TH DECEMBER 2023

Import of Bulk Drugs or APIs

**1142. SHRIMATI GODDETI MADHAVI:
SHRI MARGANI BHARAT:
SHRI N. REDDEPPA:
SHRI POCHA BRAHMANANDA REDDY:**

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

- (a) whether the Government has taken/proposes to take steps to tackle India's reliance on China for APIs and other pharma products in view of the recent Ministry data showing the import of bulk drugs or APIs and drug intermediates (materials produced during API synthesis) from China which has increased from 20 per cent from FY 21 to Rs. 23,273 crore in FY 22 constituting 66 per cent of India's total imports of medical products worth Rs. 35,249 crore in that fiscal;
- (b) if so, the details thereof;
- (c) whether the Government is aware that Andhra Pradesh, a hub for drug manufacturing, also produces innovator and biosimilar drugs for the US and EU with over 26 drugs for these foreign markets having their APIs manufactured in the State;
- (d) if so, the details thereof;
- (e) whether the Union Government has any plan on extending financial assistance to the State of Andhra Pradesh to further manufacture these APIs, to increase India's domestic manufacturing; and
- (f) if so, the details thereof?

ANSWER

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

(a) & (b) Yes, Sir. Country imports various Bulk Drugs/ APIs for producing medicines from various countries including China. 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 APIs in the world. The quantity and the value of Bulk Drug and Drug Intermediates imported from other countries including China during the last two years is as under: -

Year	Imports from all countries		Imports from China	
	Quantity (MT)	Value (In Rs Cr)	Quantity (MT)	Value (In Rs Cr)
2021-22	400642	35,249	264582	23,273
2022-23	402111	36,229	300120	25,551

However, it is also needs to be mentioned that Indian has exported Bulk Drug and Drug Intermediates worth Rs 37,853 Cr. in FY 2022-23.

(I) The Government strives to minimize country's dependence on imports and to give fillip to indigenous manufacturing. In order to make the country self-reliant in APIs and drug intermediates, the Department of Pharmaceuticals is implementing the following three schemes:

(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, under which financial incentive is given for manufacturing of 41 identified products. A total of 48 applications have been selected under the scheme. Out of these, 27 projects have already been commissioned with the installed capacity of 41,881 MT.

(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 incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. The eligible products under the scheme cover APIs/KSMs/Dis, except for the 41 eligible products already covered under the "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India".

(iii) The 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 to three States for establishing Bulk Drug Parks. The Department had received proposals from 13 States. After evaluation of the proposals as per prescribed criteria, the approval was accorded to the proposal of setting up Bulk Drug Parks in the states of Andhra Pradesh, Gujarat and Himachal Pradesh.

(II) So far as regulatory measures are concerned, as informed by the Ministry of Health and Family Welfare and CDSCO, the following steps have been taken to encourage indigenous manufacturing of drugs: The Drugs Rules, 1945 was amended vide G.S.R. 1337 (E), Dated 27 October, 2017 providing that drugs manufacturing license, sale license and approval of drug testing laboratory shall remain valid, if licensee deposits a license retention fee as prescribed, before the expiry of a period of every succeeding five years from the date of its issue, unless it is suspended or cancelled by the licensing authority. The Drugs Rules, 1945 were amended vide Notification No. G.S.R. 1193 (E) dated 12.12.2018 wherein application fees were increased for grant of import Registration Certificate as well as fees for Overseas inspection.

(c) & (d): As per the information provided by CDSCO under the M/o Health and Family Welfare, there is no unit in Andhra Pradesh manufacturing and marketing innovator and biosimilar drugs.

(e) & (f): Under the Scheme for Promotion of Bulk Drug Parks, Rs. 1000 Cr have been sanctioned for Government of Andhra Pradesh, out of which first instalment of Rs. 225 Cr has been released.