

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

LOK SABHA  
UNSTARRED QUESTION No. 4395  
TO BE ANSWERED ON THE 23<sup>rd</sup> March, 2021

**Production and Import of APIs**

**4395. SHRI P.P. CHAUDHARY:  
SHRI FEROZE VARUN GANDHI:  
SHRI KAUSHAL KISHORE:**

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

- (a) the details of Chemicals and their ingredients, like APIs, which are produced in India and which are imported;
- (b) the details of Indian currency spent on the import of these chemicals and ingredients;
- (c) the details of Indian manufacturers which were affected due to disruption caused by the global pandemic in the logistics and supply chains;
- (d) whether any policy/scheme has been formulated to increase or facilitate production of the imported chemicals and their ingredients in the country to ensure safety of chemical products and adequate quantity for Indian market consumption; and
- (e) if so, the details thereof?

**ANSWER**

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

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(a): As per Central Drugs Standard Control Organisation (CDSCO), the manufacture, sale and distribution of the drugs is regulated under Drugs and Cosmetics Act and rules there under. As per the said rules, the manufacturing licence for manufacturing of drugs is issued by state licensing authorities. CDSCO has no data regarding details of APIs manufactured in India. So far as import is concerned, as per the data available from port offices of CDSCO more than 700 APIs of various therapeutic categories such as Antibiotics, Vitamins, Hormones, Antiviral, Anti-TB, Anticonvulsant, Analgesic, Antipyretic, Antidiabetic, Cardiovascular etc. have been imported into country.

(b): As per the available data received from the various port offices of CDSCO, the details of value imports of various Bulk Drugs / Active Pharmaceutical Ingredients (APIs) during the last three years is as under:

<b>Year</b>	<b>Value (in Cr.)</b>
2018	7066
2019	8247
2020	8857

(c): As per National Pharmaceutical Pricing Authority (NPPA), at the onset of the pandemic there was an apprehension that supplies of essential APIs/KSMs from China might be disrupted. However, the NPPA did not receive any reference regarding shortage of medicines in the country in the ongoing pandemic.

(d) & (e): The Department of Pharmaceuticals has recently launched following three schemes for promoting domestic manufacturing of Pharmaceutical drugs including bulk drugs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries:-

**(I) 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:** Under the scheme, financial incentive will be given for manufacturing of 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). Incentives for incremental sales will be given to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 6,940 crore and the tenure of the scheme is from FY 2020-2021 to 2029-30.

**(II) Scheme for Promotion of Bulk Drug Parks:** This scheme provides for grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total financial outlay of the Scheme is Rs. 3000 crore and the tenure of the Scheme is from FY 2020-21 to 2024-25.

The above two schemes were notified on 21.07.2020 in the Gazette of India and the detailed guidelines of these schemes are available on the website of the Department of Pharmaceuticals i.e. <http://pharmaceuticals.gov.in>.

**(III) Production Linked Incentive Scheme for Pharmaceuticals:** The Union Cabinet recently approved Production Linked Incentive scheme for Pharmaceuticals with the objective to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains. The total financial outlay of the scheme is Rs. 15,000 crore and three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sales. The tenure of the scheme is from FY 2020-2021 to 2028-29. The scheme has been notified on 3.3.2021 in the Gazette of India.

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