

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

LOK SABHA
UNSTARRED QUESTION No.3680
TO BE ANSWERED ON THE 10th December, 2019

Bulk Drug Manufacturer

**3680. SHRI CHANDRA SEKHAR SAHU:
SHRI CHIRAG KUMAR PASWAN:
DR. PRITAM GOPINATHRAO MUNDE:**

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

- (a) whether India was the World's leading Bulk drug manufacturer till about 10 years back and if so, the details thereof;
- (b) whether presently a very large percentage of bulk drug requirements are sourced from China;
- (c) if so, the details thereof and the percentage of drugs out of the total requirement imported from China during the last three years, year-wise;
- (d) whether the experts has expressed their concerns over the security risk and financial stress of the manufacturers of the country;
- (e) if so, the details thereof and the action taken by the Government thereon;
- (f) whether the Government proposes to revive the drug sector and introduce a bulk drug policy in the country;
- (g) if so, the details thereof along with the proposals for setting up of Bulk Drug Units across the country including Jamui in Bihar; and
- (h) the time by which a final decision is likely to be taken in this regard along with the present status thereof?

ANSWER

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

(a) to (c): India has been importing Bulk Drugs/Active Pharmaceutical Ingredients (APIs) which are required for the manufacture of certain drugs in the country. Many bulk drugs are imported from China, for manufacturing of medicine. As per available data from the various Port Offices of Central Drugs Standard Control Organization (CDSCO), the details of the percentage of bulk drugs imported from China are as under.

Year	Percentage (in terms of value)
2016	56.62%
2017	68.62%
2018	66.53%

(d) to (h): The Government, taking into account the drug security of the country, had set up a high level Committee on 8th October, 2013 headed by Dr. V. M. Katoch, the then

Secretary, Department of Health Research, which had the mandate to carefully study the whole issue of APIs of critical importance by identifying important APIs and then working out a package of interventions/concessions required to build domestic production capabilities and examine the cost implications. The Committee has since submitted its recommendations. The recommendations were examined and it was decided to finance common facilities in bulk drug parks which would reduce the cost of production and in turn it would reduce the cost of medicines which would be available to the patients. Department of Pharmaceuticals approved the 'Scheme for Development of Pharmaceutical Industry' in May 2018 which has 'Assistance to Bulk Drug Industry for Common Facility Centre' as one of its sub-schemes. No separate bulk drug policy is proposed.

Under the scheme 'Assistance to Bulk Drug Industry for Common Facility Centre', financial assistance would be provided for creation of common facilities in any upcoming Bulk Drug Park promoted by State Governments/State Corporations. The Scheme would be implemented through a one-time grant-in-aid to be released to a State Implementing Agency (SIA) set up for the purpose. Some of the indicative activities under the Common facilities include Effluent Treatment Plants, Captive Power Plants, Steam and Cooling systems, Incubation facilities, Common logistic facilities, Advance common testing Centre, Regulatory awareness facilitation Centre and Emergency Response Centre. The maximum limit for the grant-in-aid under this category would be Rs. 100 Crore per Bulk Drug Park CFC or 70% of the project cost of CFC whichever is less. So far, the following proposals have been received under this scheme:

a) Andhra Pradesh Economic Cities Promotional Corporation Limited, Andhra Pradesh for financial assistance to common facilities an Integrated Pharma Cluster to cater the needs of especially MSME segment at Orvakal of Kurnool District of Andhra Pradesh in 1000 acres.

b) AIDC Ltd., Assam for creation of Common Facilities at proposed bulk drug park in Sipajhar, Darrang district nearby Guwahati. The project will be implemented by the AIDC Ltd., a Government of Assam Undertaking Organization

c) Telangana State industrial Infrastructure Corporation Ltd. (TSIIC), Telangana for development of Zero Liquid Discharge (ZLD) based common effluent treatment plant in Hyderabad Pharma City.

d) Himachal Pradesh State Industrial Development Corporation Limited, Solan, Himachal Pradesh for setting up of Bulk Drug/API park in Baddi/Nalagarh, area. In-principle approval has been accorded to all the four proposals.

No proposal has been received from Jamui in Bihar.
