

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

LOK SABHA
UNSTARRED QUESTION No. 50
TO BE ANSWERED ON THE 2nd FEBRUARY, 2024

Reduction on Import of APIs or Bulk Drugs

50. SHRI JAGDAMBIKA PAL:

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

- (a) whether the Government has taken any measures to decrease our reliance on the import of Active Pharmaceutical Ingredients (APIs) or Bulk Drugs in the country;
- (b) if so, the details thereof;
- (c) whether any initiatives have been undertaken by the Government to facilitate cost-effective production of bulk drugs in the country;
- (d) if so, the details thereof; and
- (e) the current status of the schemes or programmes implemented by the Government in pursuit of these objectives?

ANSWER

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

(a) to (e): (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) **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 tenure of the scheme is from FY 2020-2021 to 2029-30 with total financial outlay of ₹6,940 crores. The scheme provides for financial incentive on sales of 41 identified products for six (06) years. 48 projects have been approved under the scheme with a total committed investment of Rs. 3938.57 Crore, against which investment worth Rs 3062.69 cr has already been realized. 27 Projects have been commissioned so far. The envisioned production capacity under the scheme was 82,270 MT, out of which production capacity for 41881 MT has already been installed.

(ii) **Production Linked Incentive scheme for pharmaceuticals** - The total financial outlay of the scheme is Rs. 15,000 crore and the tenure of the scheme is from FY 2020-2021 to 2028-29. The scheme also provides for incentives on eligible sales of APIs/KSMs/DIs under category 2 of the scheme to the approved participants for a period of 6 years. 1962 APIs/KSMs/DIs are approved for manufacturing under the scheme.

(iii) The **scheme for Promotion of Bulk Drug Parks** has been started with the objective of providing easy access to Common Infrastructure Facilities (CIF) to bulk drug units located in the park, in order to significantly bring down the manufacturing cost of bulk drugs. The scheme has a financial outlay of Rs. 3,000 crores and the tenure is from FY 2020-2021 to FY 2024-25. The scheme 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. First instalment was released to Govt. of Gujarat, Himachal Pradesh and Andhra Pradesh, after the receipt of corresponding state shares in the state implementing agencies' accounts. The bulk drug parks with the CIF and subsidized power, water, land etc. is expected to optimize cost of manufacturing of bulk drugs in India.

(II): So far as regulatory measures are concerned, as informed by the Ministry of Health and Family Welfare and Central Drugs Standard Control Organisation (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.
