

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

LOK SABHA
UNSTARRED QUESTION No. 2331
TO BE ANSWERED ON THE 09th MARCH, 2021

Affordable Medical Devices

**2331. SHRI RAJENDRA DHEDYA GAVIT:
SHRI SUDHAKAR TUKARAM SHRANGARE:
SHRI SUDHEER GUPTA:
SHRI SHRIRANG APPA BARNE:
SHRI RANJEETSINGH HINDURAO NAIK NIMBALKAR:
SHRI BIDYUT BARAN MAHATO:
SHRI SANJAY SADASHIVRAO MANDLIK:
SHRI SHIVAKUMAR C. UDASI:
SHRI CHANDRA SEKHAR SAHU:**

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

- (a) whether the Government has been encouraging the domestic manufacturing of affordable medical devices, bulk drugs and pharmaceuticals under its 'Make in India' initiative and if so, the details thereof;
- (b) the extent to which such policies and schemes has boosted India's affordable generics and medical devices sector;
- (c) the details of the contribution of the country's export of affordable generics and medical devices;
- (d) whether Indian pharma market is expected to grow to US\$ 130 billion by 2030;
- (e) if so, the details of the steps taken by the Government to achieve the growth targets of the country; and
- (f) the details of employment opportunities likely to be increased in this sector by 2030?

ANSWER

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

(a) & (b): Yes Sir, the Government is encouraging the domestic manufacturing of affordable medical devices, bulk drugs and pharmaceuticals under its 'Make in India' initiative. The Department of Pharmaceuticals has recently launched following two schemes for Medical Devices Sector:

- i. **Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices:** The Scheme has been approved by the Government of India on 20th March, 2020. The revised guidelines for implementation of the scheme has been issued on 29.10.2020. The Scheme is applicable only to the Greenfield projects and intends to boost domestic manufacturing and attract large investments in the Medical Devices

Sector. Under the Scheme, financial incentive will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. The tenure of the scheme is from FY 2020-21 to FY 2027-28. The total financial outlay of the Scheme is Rs. 3,420 crore. The scheme is under implementation.

- ii. **Promotion of Medical Device Parks:** Recognizing the need for higher levels of investments for the creation of testing and laboratory facilities, this Scheme has been approved by the Government of India on 20th March 2020. The parks will provide common testing and laboratory facilities / centre at one place reducing the manufacturing cost significantly and will help in creating a robust ecosystem for medical device manufacturing in the country. The total financial outlay of the scheme is Rs. 400 crore. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025. Financial assistance to a selected Medical Device Park would be 70% of the project cost of common infrastructure facilities. 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. Maximum assistance under the scheme for one Medical Device Park would be limited to Rs. 100 crore. The scheme is under implementation.

Also, the Department of Pharmaceuticals has recently launched following three schemes for promoting domestic manufacturing of critical KSMs/Drug Intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs:

- 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 is given for manufacturing of 41 eligible products under the four Target Segments viz.:
 - a. Fermentation based KSMs/Drug Intermediates.
 - b. Fermentation based niche KSMs/Drug Intermediates /APIs.
 - c. Key Chemical Synthesis based KSMs/Drug Intermediates.
 - d. Other Chemical Synthesis based KSMs/Drug Intermediates/APIs.

Incentives for incremental sales will be given to selected participants for a period of 6 years. The total outlay of the scheme is Rs. 6,940 crore.

- ii. **Scheme for Promotion of Bulk Drug Parks:** To provide 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 size of the Scheme is Rs. 3000 crore and the tenure of the Scheme will be five years (2020-21 to 2024-25).
- iii. **Production Linked Incentive Scheme for Pharmaceuticals:** The Union Cabinet in its meeting on 24.02.2021 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 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 will be from FY 2020-2021 to 2028-29. The Scheme has been notified on 03.03.2021 in the Gazette of India.

(c): The details of generics exports are as follows:

India's Generic Pharma exports US \$ Million				
Category	2017-18	2018-19	2019-20	2020-21 (April-December)
Drug Formulations (Generics)	12900.28	14368.65	15811.24	13966.85

India's Medical Device exports US \$ Million				
Category	2017-18	2018-19	2019-20	2020-21 (April-November)
Medical Devices	1868.05	2138.14	2292.87	1549.89

(d): As per economic survey 2020-21, the Pharma Sector is expected to grow to about US \$ 120-130 billion by 2030.

(e): The Department of Pharmaceuticals has launched following three schemes to achieve the growth targets of the country:

- 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
- ii. Promotion of Bulk Drug Parks
- iii. Production Linked Incentive Scheme for Pharmaceuticals

(f): Approximately, 2 lakh jobs, direct and indirect, are likely to be created through industry promotion schemes of the Department by 2030.
