

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

RAJYA SABHA
STARRED QUESTION No. 1464
TO BE ANSWERED ON 20th December, 2022

Medical devices sector

1464 Dr. Dharmasthala Veerendra Heggade:

Will the **Minister of Chemicals and Fertilizers** be pleased to state:

- (a) current market size of medical devices sector and number of domestic medical device manufacturers in the country;
- (b) steps taken to build an ecosystem for innovation in medical devices and drugs, thereby enhancing the industry-academia linkages;
- (c) whether India's import of medical devices is staggering at almost 80 per cent and if so, steps taken to reduce import dependence on medical devices;
- (d) present status of Production Linked Incentive Scheme in manufacturing of medical devices; and
- (e) whether all devices required for critical care are categorized as 'Scheduled Medical Devices' and brought under the National List of Essential Medicines?

ANSWER

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

(a): Indian medical devices' market stood at USD 11 billion in 2020 as per Industry sources. The number of domestic medical device manufacturers is not available right now with the Department. As per the provisions of Medical Devices Rules, 2017 of Ministry of Health and Family Welfare, the medical devices are being brought under regulations (class A and B Medical Devices w.e.f 1.10.2022 and class C and D Medical Devices w.e.f 1.10.2023).

(b): There are seven National Institutes of Pharmaceutical Education and Research (NIPERs) under the Department. Besides conducting academic courses for the pharma and medtech sector, these institutes facilitate strong industry-academia linkages to build an ecosystem for innovation and research.

(c) and (d): The Government has taken several measures to encourage domestic manufacturing of medical devices and reduce import dependence and the programmatic interventions are as follows:

- i. Under the scheme "*Assistance to Medical Device Industry for Common Facility Centres*", assistance was provided for establishment of common facility of Super conducting magnetic coil testing and research facility at Andhra Pradesh Medtech Zone Ltd. (AMTZ), Andhra Pradesh with a project cost of Rs.25 Cr.

- ii. Under the scheme “*Promotion of Medical Devices Parks*”, final approval has been given to the States of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh for establishment of common facilities in the Medical Device Parks being developed by these 4 States.
- iii. Under the *Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices*, with a financial outlay of Rs. 3,420 Cr and with the tenure from FY 2020-21 to FY 2027-28, financial incentives will be given to selected companies for manufacturing of medical devices covered under the four Target segments of the scheme, for a period of five (5) years. Under the scheme, a total of 42 applications have been received. So far, 21 applicants (including 10 MSME) have been approved and out of this, 13 applicants have commissioned their projects.
- iv. Under the *Production Linked Incentive (PLI) scheme for Pharmaceuticals*, with the tenure from FY 2020-2021 to 2028-29 and incentives for a period of six years, five (5) industry applicants have been selected for manufacturing In-vitro diagnostic medical devices.
- v. under the Pradhan Mantri Bharatiya Jan Aushadhi Pariyojana, efforts are made to make available 240 types of surgical supplies in over 8900 Jan Aushadhi Kendras at highly affordable prices.

(e): The mandate of revision of National List of Essential Medicines (NLEM) is with Ministry of Health and Family Welfare (MoHFW). Four 4 devices (Bare metal stents, drug eluting stents, condoms and intra uterine devices) have been included in the National List of Essential Medicines 2022 issued by MoHFW. Accordingly, NPPA under the Department of Pharmaceuticals, notified these 4 devices in revised Schedule-I of the DPCO, 2013 vide S.O. No. 5249(E) dated 11th November 2022.
