

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

LOK SABHA
UNSTARRED QUESTION NO. 3700
TO BE ANSWERED ON 11th August, 2023

Import of Refurbished Medical Devices

3700. SHRI M.K. RAGHAVAN:

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

- (a) whether the Government has observed large scale import of refurbished medical devices into India and if so, the details thereof;
- (b) whether import of such refurbished medical devices have caused threat to lives of our citizens in the country and if so, the details thereof along with the steps taken/proposed to be taken by the Government to prevent such imports;
- (c) the steps measures taken/proposed to be taken by the Government to promote aatmanirbharata in medical devices sector in the country;
- (d) whether the Government has observed that certain tender norms for procuring assisted robotic technologies for medical surgery favours import over indigenization; and
- (e) if so, the details thereof and the steps taken/ proposed to be taken by the Government to prevent the same?

ANSWER

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

(a): As a Regulator, CDSCO issues import licences to the importers. The Export/Import data as maintained by DGCIS includes the import of Finished products, refurbished items and parts of medical devices.

(b): Ministry of Environment, Forest and Climate Change has notified Hazardous and other Wastes (Management and Transboundary Movement) Second Amendment Rules, 2022 on 23rd December 2022 wherein High End and High Value Used Medical Equipment other than Used Critical Care Medical Equipment is included in Part "B" of Schedule III of Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016. Directorate General of Health Services (DGHS) forwarded the list of High End and High Value used Medical Equipment other than Critical care Medical Equipment and MoEFCC on 19.06.2023 allowed 50 High End and High Value used Medical Equipment other than Critical care Medical Equipment to be imported by actual user or by original Equipment Manufacturers (OEM) or Indian Subsidiary of OEM or Trader on behalf of actual user for re-use.

However, for licensed products, IPC runs Materiovigilance Programme of India (MvPI) with the aim to generate indigenous adverse event data (with the use of medical devices) from

Indian population and recommend/communicate regulatory measures to be taken by CDSCO to ensure the safety of medical devices.

(c): The Government of India has taken several measures to encourage domestic manufacturing of Medical Devices. The steps taken to support Medical Devices Industries are as under:-

- i. Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices (PLI MD) with total financial outlay of Rs. 3,420 crore and tenure from FY 2020-2021 to FY 2027-28. The financial incentive is to be given to selected companies at the rate of 5% on incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. 26 participants have been approved under the scheme
- ii. Production Linked Incentive Scheme for Pharmaceuticals has been launched with total financial outlay of Rs. 15,000 crore and tenure from FY 2020-2021 to FY 2028-29. The scheme covers the In-Vitro Diagnostic (IVD) devices under product Category 3. Total 55 participants have been approved under the scheme, out of which 5 participants are selected for In-Vitro Diagnostic (IVD).
- iii. The scheme *Promotion of Medical Devices Parks*, with a total financial outlay of Rs. 400 crore and the tenure from FY 2020-2021 to FY 2024-2025, provides for the maximum financial assistance of Rs. 100 crore each to 4 selected States/Union Territories for creation of Common Infrastructure Facilities in the upcoming Medical Devices Parks. Under the scheme, final approval for financial assistance of Rs. 100 crore each, has been given to the States of Himachal Pradesh, Madhya Pradesh, Tamil Nadu, and Uttar Pradesh.
- iv. The scheme Assistance to Medical Device Clusters for Common Facilities (AMD-CF) provides for financial incentive to Medical devices clusters to develop common infrastructure facilities like Medical devices testing labs, E-waste treatment facility, logistic centers. The scheme also provides for financial assistance to National or State level Government or Private institutions interested to establish or strengthen testing facilities for medical devices.
- v. To attract investments in Medical Devices sector, the Government has allowed 100% FDI under automatic route
- vi. In addition, the Department has recently notified National Medical Devices Policy, 2023 and has set up Export Promotion Council for Medical Devices.

(d) & (e): Based on revised Public Procurement (Preference to Make in India) Order issued by DPIIT dated 16.09.2020, DoP also revised its PPO guidelines on 16.02.2021 giving preference to Class-I Local supplier & Class-II Local supplier, having local content equal to or more than 50% & having local content more than 25% but less than 50% respectively, in Public Procurement.
