GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 749
TO BE ANSWERED ON 07th FEBRUARY, 2025

Refurbished Medical Devices

749. Shri Vijayakumar Alias Vijay Vasanth:
Shri Manickam Tagore B:

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

(a) whether the Government has directed the Customs Department to halt the import of refurbished medical devices, if so, the details thereof and the reasons for not taking such a move earlier, given the known risks associated with these devices;
(b) the specific steps taken by the Government to ensure the availability of affordable and high-quality medical devices, especially for underserved regions, in the absence of refurbished imports;
(c) the detailed plan of the Government for providing support to local manufacturers to meet the growing demand for medical devices in the country;
(d) the measures that are in place to ensure that this does not lead to an increase in the prices of medical devices, thereby burdening patients and healthcare providers; and
(e) whether adequate checks are in place to monitor the quality and safety of domestically produced medical devices, if so, the details thereof and the manner in which the Government plans to maintain competitive pricing?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): The Central Drugs Standard Control Organisation (CDSCO) has informed that all medical devices are regulated by the Medical Devices Rules, 2017. As per Chapter V of the said rules, medical devices are imported in the country against a valid import licence issued by CDSCO. Under the said rules, there is no specific provision for regulation of refurbished medical devices. Any importer possessing a valid licence is permitted to import a medical device under the Drugs and Cosmetics Act, 1940.

(b) to (d): With a view to ensure the availability of affordable and high-quality medical devices, especially for underserved regions, Government has included four medical devices, namely Bare Metal Stents, Drug Eluting Stents including metallic ones and Bioresorbable Vascular

Scaffold / Biodegradable stents, Condoms and Intra Uterine Devices in Schedule-I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) and pursuant to the same, the National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals has fixed ceiling prices for the said medical devices. In addition to these, NPPA, *vide* its notification dated 16.8.2017 has fixed the ceiling prices for Orthopedic Knee Implants for knee replacement system. Presently, the ceiling prices of the Orthopedic Knee Implants are notified *vide* notification no. S.O. 3869(E), dated 10.9.2024.

Further, the Department of Health and Family Welfare, *vide* notification no. S.O. 648(E), dated 11.2.2020 has notified all medical devices intended for use in human beings or animals as 'drugs' under the Drugs and Cosmetics Act, 1940, with effect from 1.4.2020. Pursuant to the same, NPPA, *vide* notification no. S.O. 1232(E), dated 31.3.2020 has notified that all medical devices shall be governed under the provisions of DPCO, 2013, with effect from 1.4.2020.

Moreover, NPPA monitors the maximum retail prices of all non-scheduled medical devices and ensures that no manufacturer increases the maximum retail price of any medical device by more than 10% of the maximum retail prices during the preceding 12 months.

The Government has also taken several measures to encourage domestic manufacturing of high-end medical devices, with a view to reduce imports dependence and boost domestic manufacturing. The programmatic interventions for the same are as follows:

(i) Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of Medical Devices: This scheme has a financial outlay of ₹3,420 crore and a tenure from the financial year (FY) 2020-2021 to FY 2026-27. Under the scheme, selected companies are eligible for financial incentive at the rate of 5% of incremental sales of medical devices manufactured in India under the four target segments of (1) radiotherapy, (2) imaging devices, (3) anaesthesia, cardio-respiratory and critical care, (4) implants, for a period of five years. 19 Greenfield projects have so far been commissioned and production has started for 46 products, which include high-end medical devices such as linear accelerator, MRI machines, CT scans, mammograms, C-arms and ultrasound machines that were being imported. Applicants under the scheme have made cumulative sales ₹9,117.07 crore, including export sales worth ₹4,398.34 crore, till December 2024.

(ii) Scheme for Promotion of Medical Devices Parks: The scheme aims to provide easy access to world-class, common infrastructure facilities to medical device units located in parks. It has a financial outlay of ₹400 crore. Approvals for creation of common infrastructure facilities in the proposed medical device parks have been conveyed in respect of proposals received from the State Governments of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh.

(iii) Scheme for Strengthening Medical Device Industry: This scheme, with a financial outlay of ₹500 crore, has been launched on 8.11.2024, with a view to provide support in critical areas of the medical device industry, under the following five sub-schemes:

(1) Common Facilities for Medical Devices Clusters;
(2) Marginal Investment Scheme for Reducing Import Dependence;
(3) Capacity Building and Skill Development for Medical Devices;
(4) Medical Device Clinical Studies Support Scheme; and
(5) Medical Device Promotion Scheme.

(e): The Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare has informed that import of all classes of medical devices as well as manufacture of Class C and D medical devices is regulated by CDSCO, while manufacture of Class A and B medical devices is regulated by the State Licensing Authority (SLA) appointed by the State Governments concerned. However, the sale and distribution of all classes of medical devices are regulated by the SLAs concerned. For obtaining licence for import or manufacture of any medical device from CDSCO or SLA, the applicant is required to submit the details of design, specification, non-clinical as well as clinical data of safety and performance of the devices including regulatory status in other countries, etc. In case of medical devices, the quality, safety and performance data are evaluated by CDSCO in consultation with the Subject Expert Committee in the relevant therapeutic areas.

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