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

# LOK SABHA UNSTARRED QUESTION No. 3014 TO BE ANSWERED ON THE 13<sup>th</sup> DECEMBER, 2024

#### **Medical Device Industry**

3014. Dr. Mohammad Jawed:

Shri K Sudhakaran:

Dr. Amar Singh:

Dr. Shashi Tharoor:

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

- (a) the details of import of various high-end medical devices indicating it as a percentage of total Medical devices sale in the country in the past five years, country-wise;
- (b) whether the import of high-end devices has risen between 2019-20 and 2022-23, if so, the reasons for such an increase, despite production-linked incentives being in place;
- (c) the steps taken by the Government to promote the domestic medical devices sector;
- (d) whether the Government plans to decrease the GST on medical devices and increase the import duty on finished medical devices, which is lower than the import duty on raw materials or manufacturing components, to promote the domestic medical devices sector, if so, the details thereof and if not, the reasons therefor;
- (e) whether the Government plans to establish additional central medical device testing laboratories to address the current shortfall; and
- (f) the steps taken by the Government to adopt advanced technologies such as cloud computing and robotic process automation to enhance the process of domestic manufacturing in the country?

#### **ANSWER**

## THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a) & (b): As per DGCI&S, Ministry of Commerce and Industry, Import-Export data in respect of five segments (Consumables & Disposables, Electro-Medical Equip, Implants, In-Vitro Diagnostics, Surgical Instruments) of medical devices for last five years is as follows:

(USD Million)

	F.Y. 2019-20	F.Y. 2020-21	FY 2021-22	FY 2022-23	FY 2023-24
Export	2293	2532	2923	3391	3785
Import	5845	6242	8540	7492	8188

Between FY 2019-20 and FY 2022-23, the CAGR of imports in the said five segments is 8.63% and CAGR of exports is 13.93 % which indicates that growth of exports during this period has been more compared to imports.

FY 2022-23 was the first year of performance under the PLI Scheme for promoting domestic manufacturing of medical devices. Since then the cumulative sales made by the applicants

under the scheme is Rs 8039.63 crore (which includes exports worth Rs 3,844.01 crore) up to September, 2024.

- (c): Apart from the Production Linked Incentive Scheme for promoting domestic manufacturing of medical devices, Government of India has taken several measures to encourage domestic manufacturing of medical devices to reduce import dependence and to boost domestic manufacturing and attract large investments.
- (i) Scheme for Promotion of Medical Devices Parks: The scheme "Promotion of Medical Device Parks" was approved on 20th March, 2020 for providing easy access to world class common infrastructure facilities to medical device units located in the parks. The total financial outlay of the scheme is Rs. 400 crore and the implementation period is from FY 2020-2021 to FY 2024-2025. Under the scheme, Department had received proposals from 16 States. After evaluation of the proposals, Govt. of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh were conveyed final approval for creation of common infrastructure facilities in the proposed medical device parks in these four states.

#### (ii) Scheme for Strengthening Medical Device Industry:

In order to provide support in critical areas of the medical device industry, covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure and industry promotion, a new scheme "Strengthening of Medical Device Industry" with five sub-schemes has been launched on 8.11.2024 with financial outlay of Rs. 500 crore. Sub-schemes under the scheme are as follows:-

- (i) Common Facilities for Medical Devices Clusters
- (ii) Marginal Investment Scheme for Reducing Import Dependence
- (iii) Capacity Building and Skill Development for Medical Devices
- (iv) Medical Device Clinical Studies Support Scheme
- (v) Medical Device Promotion Scheme
- (d): As per Department of Revenue, the GST rates and exemptions are prescribed on the recommendations of the GST Council which consists of representation from both Union and State/UT Governments. There is no such recommendation of the GST Council.
- (e): The Ministry of Health and Family Welfare has informed that they have notified six central medical device testing laboratories for testing of certain medical devices. Further, in order to strengthen the government medical device testing facilities in the country, Medical Devices Rules 2017 has been amended vide G.S.R 409(E) dated 02/06/2023 incorporating provisions for State Governments to notifying State Medical Device testing laboratories.
- (f): The adoption of suitable technology by the domestic manufacturers of medical devices supported under the schemes of the department is as per their own choice. The guidelines for the PLI scheme promoting domestic manufacturing of medical devices allow investment in IT and ITES infrastructure related to manufacturing to be admissible for meeting the investment target.

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