GOVERNMENT OF INDIA MINISTRY OF CHEMICALS & FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA UNSTARRED QUESTION NO. 2422 TO BE ANSWERED ON THE 17^{TH} DECEMBER, 2024

Domestic medical device industry

2422 Smt. Ranjeet Ranjan:

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

- (a) the details of import of various high-end medical devices in the country in the past five years, country-wise;
- (b) the measures taken by Government to promote domestic manufacturing of high-end medical devices:
- (c) whether Government has considered increasing the customs duty on finished medical devices as recommended by the Standing Committee to encourage local production; and
- (d) whether Government plans to establish additional central medical device testing laboratories to address the current shortfall?

ANSWER

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

(a): Department of Revenue has informed that there is no classification under the heading of "High End Medical Devices". However, 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

Source: DGCI&S, Ministry of Commerce and Industry

Between FY 2019-20 and FY 2023-24, the CAGR of imports in the said five segments is 8.79% and CAGR of exports is 13.35% which indicates that growth of exports during this period has been more compared to imports.

Country-wise imports and exports figures in respect of major countries as follows: -

Exports

(USD Million)

Major Country	F.Y. 2019-20	F.Y. 2020-21	FY 2021-22	FY 2022-23	FY2023-24
USA	521.85	600.01	631.48	714.12	714.30
Germany	123.74	133.7	127.29	176.63	199
China	130.27	133	146.94	144.574	166
Netherlands	33.78	43.87	93.68	110.44	145
Japan	30.63	27.21	31.84	38	42.17

Source: DGCI&S, Ministry of Commerce and Industry

(USD Million)

Major Country	F.Y. 2019-20	F.Y. 2020-21	FY 2021-22	FY 2022-23	FY2023-24
USA	1190.08	984.08	1464.73	1418	1519
CHINA	622.2	1110.92	1657.67	1246.82	1332
Germany	732.07	668.5	782.35	797.49	908
Netherlands	347.51	228.51	398	416	460
Japan	280.08	236.99	343.08	321.77	372

Source: DGCI&S, Ministry of Commerce and Industry

- (b): 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) Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices (PLI MD): The Union Cabinet approved proposal on 20.03.2020 with the objective of the Scheme to boost domestic manufacturing and attract large investments in the Medical Devices Sector. The production tenure of the scheme is from FY 2022-2023 to FY 2026-27 with total financial outlay of Rs. 3,420 crore. The scheme provides for financial incentive to selected companies at the rate of 5% on incremental sales of medical devices manufactured in India and covered under the four target segments of the scheme, for a period of five (5) years. 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.
- (ii) 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.
- (iii) 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-scheme of the scheme is as given below: -
 - (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
- (c) Department of Pharmaceuticals had recommended to increase the basic custom duty on 40 finished medical devices to Department of Revenue (DoR) but recommendation was not considered by DoR.

(d) As per information provided by Ministry of Health and Family Welfare, as on date they have notified six central medical device testing laboratories for testing of certain medical devices. In order to strengthen the government medical testing facilities in the country, Medical Device Rules, 2017 has been amended vide G.S.R 409E dated 02//06/2023 incorporating provisions for State Governments to notifying State Medical Device testing laboratories.
