

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

**LOK SABHA
UNSTARRED QUESTION No. 2126
TO BE ANSWERED ON THE 01st AUGUST 2025**

Medical Devices

2126. Shri Sribharat Mathukumilli:

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

- (a) current number of licensed medical device manufacturers in the country alongwith production and export data for the past five years, year-wise, category-wise (Class A to D) and State/UT-wise;
- (b) the investment inflow (domestic and FDI) in the medical devices sector since 2018, yearwise;
- (c) the details of incentives, capital grants and approvals provided under PLI Scheme and the Promotion of Medical Device Parks Scheme, including the number of units supported and fund utilisation thereunder;
- (d) whether the Government has undertaken any assessment of India's self-reliance ratio in critical medical devices (e.g., ventilators, stents, implants) and if so, the findings thereof;
- (e) the steps taken to improve R&D, quality certification infrastructure and MSME participation in the medical devices sector, including collaborations with academic or research institutions; and
- (f) whether the Government plans to introduce new medical device clusters or technology platforms, if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): According to the Department of Health and Family Welfare, as per data available on the online portal of the Central Drugs Standard Control Organisation, currently 3,351 medical device manufacturers are licensed in the country, out of which 1,721 are licensed for manufacture of Class A devices, 2,099 for Class B devices, 971 for Class C devices and 304 for Class D devices. Production data of all the licensed medical devices manufacturers, risk-class-wise export data and State- and Union territory-wise export data is not available.

Details of medical devices exported to various countries during the last five years, as per data maintained by the Directorate General of Commercial Intelligence and Statistics, is as follows:

(In million US\$)						
S. No.	Segment	Financial year (FY) 2020-21	FY 2021-22	FY 2022-23	FY 2023-24	FY 2024-25
1	Consumables and disposables	1,290	1,378	1,605	1,752	1,863
2	Surgical instruments	54	71	72	79	86
3	Electromedical equipment	985	1,163	1,335	1,472	1,483
4	Implants	99	135	188	266	350
5	<i>In vitro</i> diagnostic reagents	104	176	191	216	232
Total		2,532	2,923	3,391	3,785	4,014

(b): The financial-year-wise inflow of foreign direct investment (FDI) into the medical device sector for the period since FY2018-19, as per data from the Department for Promotion of Industry and Internal Trade, is as under:

Financial year	FDI inflows (in crore ₹)
2018-19	1,108
2019-20	2,196
2020-21	511
2021-22	1,545
2022-23	3,123
2023-24	3,978
2024-25	5,253
Total	17,714

(c): The Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices aims to promote domestic manufacturing of medical devices by attracting large investments for creation of domestic manufacturing capacity and incentivising domestic production. It has a total budgetary outlay of ₹3,420 crore and a five-year performance-linked incentive period from FY2022-23 to FY2026-27. Under the scheme, selected companies are eligible for financial incentive for incremental sales of domestically manufactured medical devices in the radiotherapy, imaging device, anaesthesia, cardio-respiratory and critical care and implant device segments, for a period of five years. A total of 31 applicants have been approved and total incentive amount of ₹133.95 crore has been disbursed to seven applicants, till June 2025. So far, 21 greenfield projects have been commissioned, and production has started for 54 products, which include high-end medical devices on which the country has been import-dependent, such as linear accelerators, MRI, Ultrasound, CT scans, Mammograms, C-Arm and X-ray machines. Till March 2025, cumulative eligible sales ₹10,413.40 crore have been achieved under the scheme, including exports worth ₹5,002 crore.

The Scheme for Promotion of Medical Devices Parks aims to create common infrastructure and testing facilities for increased competitiveness and cost reduction through optimisation of resources and economies of scale, thereby leading to better availability and affordability of medical devices in the domestic market. Under the scheme, three parks have been approved and are at an advanced stage of development in Greater Noida (Uttar Pradesh), Ujjain (Madhya Pradesh) and Kanchipuram (Tamil Nadu). The total project cost of these parks is over ₹871.11 crore, with Central assistance to the tune of ₹100 crore each, for creation of common infrastructure facilities, which is expected to enhance industry's competitiveness and

reduce production costs through optimisation of resources and economies of scale. Till June 2025, a total amount of ₹180 crore has been disbursed to said three parks as grant-in-aid by the Government of India, out of which an amount of ₹127.87 crore has been utilised.

(d) and (e): No data regarding such a ratio is maintained by the Government. However, in line with the vision of Atmanirbhar Bharat, Government from time to time has assessed dependence on imports in the medical device sector and has taken steps to improve R&D, quality certification infrastructure and MSME participation in the medical devices sector, including collaborations with academic and research institutions.

In 2020, assessing that the domestic medical devices market was heavily dependent on imports, which contributed to more than 85% of the market, Government launched the PLI Scheme for Promoting Domestic Manufacturing of Medical Devices and the Scheme for Promotion of Medical Devices Parks, details of which are given in the reply to part (c).

Subsequently, Government announced the National Medical Devices Policy, 2023 as a holistic policy framework to accelerate growth of the sector with a patient-centric approach to meet the evolving healthcare needs of patients. Pursuant to the policy, the following actions, among others, have been undertaken:

- (i) Domestic manufacturing of medical devices has been promoted under the PLI Scheme for Promoting Domestic Manufacturing of Medical Devices.
- (ii) Common infrastructure and testing facilities have been approved and are at various stages of implementation under the Scheme for Promotion of Medical Devices Parks.
- (iii) The Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) scheme has been launched with an outlay of ₹ 5,000 crore to transform India's Pharma MedTech sector from cost- to innovation-based growth by strengthening research and to promote industry-academia linkage for research and development in priority areas that include medical devices. Under this, a Centre for Excellence in medical devices has been established at the National Institute of Pharmaceutical Education and Research, Ahmedabad with an outlay of ₹100 crore. Further, the scheme also provides financial assistance to industry, startups and micro, small and medium enterprises (MSMEs) for research and development in identified priority areas, which include medical devices. The medical device priority area includes, among other medical devices, artificial intelligence / machine learning based medical devices with software development, software as medical device, software in medical device, medical diagnostics and screening devices with genetic technology, robotic medical devices for surgical procedures and medical devices with telemedicine facilities. Such medical devices may also use new technology platforms. The financial outlay for this component is ₹ 4,250 crore.
- (iv) The Scheme for Strengthening Medical Device Industry has been launched with a financial outlay of ₹500 crore to provide support in manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure and industry promotion. Under its Common Facilities for Medical Devices Clusters sub-scheme, financial assistance of up to ₹20 crore is provided for creating common infrastructure facilities and up to ₹5 crore for establishing testing facilities.
- (v) Action is being pursued in respect of the six focus areas of the policy, namely, regulatory streamlining, enabling of infrastructure, facilitating of research and development and innovation, attracting investments in the sector, human resources development and brand positioning and awareness creation.

In November 2024, assessing that the dependence on imports continues to be about 70%, Government has launched the Scheme for Strengthening Medical Device Industry, with financial outlay of ₹500 crore and provision for support in critical areas as aforesaid.

(f): No plan is currently under consideration to introduce new medical device clusters. With regard to technology platforms, clause (iv) of the reply to parts (d) and (e) may be referred to.
