

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

LOK SABHA
UNSTARRED QUESTION No. 3581
TO BE ANSWERED ON THE 13TH MARCH 2026

Medical Devices Manufacturers

3581. Shri Appalanaidu Kaliseti:

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

- (a) the current number of licensed medical device manufacturers in the country along with production and export data during the last five years, State/UT-wise, year-wise and category-wise (Class A to D);
- (b) the domestic and FDI investment inflow in the medical devices sector since 2018, yearwise;
- (c) the details of incentives, capital grants and approvals provided under PLI Scheme and Promotion of Medical Device Parks Scheme, including the number of units supported and fund utilised;
- (d) whether the Government has made any assessment regarding self-reliance ratio of the country in critical medical devices such as diagnostic kits, ventilators, stents and implants and if so, the details thereof;
- (e) the steps taken to improve R&D, quality certification infrastructure and Micro, Small and Medium Enterprises (MSME) participation in the medical devices sector, including collaborations with academic or research institutions; and
- (f) whether the Government proposes to introduce new medical device clusters or technology platforms and if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): As per the information received from the Department of Health and Family Welfare, currently 4108 medical device manufacturers are licensed in the country. Out of 4108 medical device manufacturers, 2099 manufacturers are licensed for manufacture of Class A devices, 2560 manufacturers are licensed for manufacture of Class B devices, 1123 manufacturers are licensed for manufacture of Class C devices and 343 manufacturers are licensed for manufacture of Class D devices. Some manufacturers operate across multiple device classes. Production data is not maintained by Central Drugs Standard Control Organization (CDSCO) centrally.

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
2025-26 (up to December, 2025)	2,944
Total	20,658

Data regarding domestic investment in the medical device sector is not maintained centrally by any Ministry of the Government of India.

(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 4 target segments, for a period of five years. A total of 28 applicants have been approved and total incentive amount of ₹157.15 crore has been disbursed to seven applicants, till December 2025. So far, 24 greenfield projects have been commissioned, and production has started for 57 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 December 2025, cumulative eligible sales of Rs. 13,624.52 crore including exports sales worth Rs.6,425.48 crores have been made under the scheme.

The Scheme for Promotion of Medical Devices Parks aims to create common infrastructure and testing facilities for increased competitiveness and cost reduction of medical device units 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. Till date, a total amount of ₹210.00 crore has been disbursed to said three parks as grant-in-aid by the Government of India.

(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) above.

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) with an overall financial outlay of ₹5,000 crore. Under the scheme, seven Centres of Excellence (CoEs) have been set up, one at each of the seven National Institutes of Pharmaceutical Education and Research (NIPERs), with total budgetary support to the tune of ₹700 crore, for creating research infrastructure and promoting R&D in identified areas. Of these, the CoE at NIPER Ahmedabad is specializing in the area of Medical Device. Further, the scheme also provides for disbursement of financial assistance to support eligible research and development (R&D) projects of industry, start-ups and micro, small and medium enterprises (MSMEs) for R&D in identified priority areas which, inter-alia, include medical devices. The financial outlay for this component is ₹ 4,200 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 the 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.

(f): No plan is currently under consideration of the Department of Pharmaceuticals to introduce new medical device clusters or technology platforms.
