

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

RAJYA SABHA
UNSTARRED QUESTION No. 2267
TO BE ANSWERED ON THE 21ST MARCH, 2023

Reducing dependency on medical devices

2267 # Shri Neeraj Dangi:

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

- (a) whether the country currently imports medical equipments, especially high-end equipments, if so, the details thereof;
- (b) whether Government has any plan to promote domestic manufacturing of medical devices;
- (c) if so, the details of the amount allocated by Government for such scheme during the last two years and in the current year; and
- (d) the details of the targets set by Government to reduce dependency of medical equipments?

ANSWER

**MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)**

(a): Yes Sir, the country currently imports medical equipment including high end equipment and the details of imports for last two FYs are given below:

S. NO.	Segment	Imports F.Y. 2021-22(in USD Million) *
1	Consumables & Disposables	1624
2	Surgical Instruments	169
3	Electronics Equipment	5441
4	Implants	423
5	IVD Reagents	883
	TOTAL	8540

***Source: DGCIS**

(b) to (d): The Government of India has taken several measures to encourage domestic manufacturing of Medical Devices to reduce import dependence and to establish a dominant position in the global market. The Programmatic interventions to support Pharma Industries as on date are as follows:

- i. *PLI Scheme for Promoting Domestic Manufacturing of Medical Devices* with total financial outlay of Rs. 3,420 crore and tenure from FY 2020-2021 to FY 2027-28, provides 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. Under the scheme, a total of 60 applications (42 applications of Category-A and 18 applications of Category-B) have been received out of which, 26 applications have been approved, with a committed investment of Rs. 1,205.52 cr. As per the information submitted by the applicants on the sales for the period from April 2022 to December 2022, an investment of Rs.714 Cr has been reported. Fourteen projects have been commissioned so far. Under the scheme, domestic manufacturing of high-end medical devices has started which include Linear Accelerator, MRI Scan, CT-Scan, Mammogram, C-Arm, MRI Coils, high end X-ray tubes, etc and the details of the approved medical devices under the PLI scheme is attached at **Annexure**.

- ii. *Production Linked Incentive Scheme for Pharmaceuticals*, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants which also covers five (5) applicants under Group – C category, to manufacture In-Vitro Diagnostic (IVD) medical devices. The incentive period under the scheme is for six years and a total 457 IVD products has been approved under the scheme.
- iii. The scheme *Promotion of Medical Devices Parks*, with a total financial outlay of Rs. 400 crore and the tenure from FY 2020-2021 to FY 2024-2025, provides for the maximum financial assistance of Rs. 100 crore each to 4 selected States/Union Territories for creation of Common Infrastructure Facilities in the upcoming Medical Devices Parks. Under the scheme, final approval for financial assistance of Rs. 100 crore each, has been given to the States of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh.
- iv. Under the major non-schematic intervention, in order to attract investments in Medical Devices sector, the Government has allowed 100% FDI under automatic route

FY 2022-23 is the first year of production for the above two PLI schemes. In FY 20-21 and FY 21-22, an amount of Rs.2.0 Cr and Rs.3.31 Cr had been allotted towards PMA charges under PLI scheme for Medical Devices; Similarly, an amount of Rs.3.0 Cr had been allocated under PLI scheme for Pharmaceuticals in FY 21-22 towards PMA Charges. In current FY of 22-23, an amount of Rs.21.56 Cr and Rs.694.2 Cr have been allocated for PLI scheme for Medical Devices and Pharmaceuticals respectively.

Under the Medical Devices Parks Scheme, Rs. 21.05 Cr and Rs.137.02 cr were allocated in FY 20-21 and FY 21-22 respectively and first instalment of Rs.30 Cr per park had been released in FY 21-22. In current FY 22-23, a provision of 0.9 Cr has been made towards PMA charges.

Details of the Medical Devices, Category –A applicant product being manufacturing under PLI schemes

Target Segment	S.No.	Product / Name of the Medical Devices
1. Cancer care / Radiotherapy medical devices	1	Rotational Cobalt Machine
	2	Linear Accelerator (LINAC)
2. Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices	3	CT Scan
	4	MRI
	5	MRI Coils
	6	Ultrasonography / Ultrasound Products
	7	Mammography
	8	X-ray equipment
	9	X- Ray including Fixed Line Frequency (LF) and High Frequency (HF) X-Ray Product
	10	C-arm/ Surgical X-Ray C-Arm
	11	Cath-Lab
	12	Collimators
	13	Flat Panel Detector
	14	Monitors
3. Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices	15	Anesthesia Workstation
	16	Anesthesia Unit Gas Scavengers
	17	Anesthesia Kits
	18	Masks –Anesthesia
	19	Anesthesia Unit Vaporizers
	20	Anesthesia Unit Ventilators
	21	Dialyzer
	22	Dialysis Machine
	23	Haemodialysis Catheter
	24	Peritoneal Dialysis Kits
	25	Oxygen Concentrators
	26	High Flow Oxygen Devices
	27	Intensive Care Ventilators
	28	Emergency Ventilators
	29	ECG
	30	Patient Monitoring System / Patient Monitors
	31	Multi-Parameter Monitor
	32	Syringe Pump / Infusion pumps - Syringe and Volumetric
	33	Defibrillators / Automated External Defibrillators (AED)
	34	Bi-Phasic Defibrillators
	35	Stress Test System
36	Fistula	
37	Blood Line	
38	Transducer Protector	
39	Suction Machine	

Target Segment	S.No.	Product / Name of the Medical Devices
4. All Implants including implantable electronic Devices	40	Hip Implants
	41	Knee implants
	42	Trauma Implants
	43	PTCA Balloon Dilation Catheter / PTCA Balloon Catheter/Drug Eluting Balloons
	44	Heart Valves
	45	Heart Occluders
	46	Stents/Drug Eluting Stents

Details of the Medical Devices, Category –B applicant product being manufacturing under PLI schemes

S. No.	Target Segment	Product / Name of the Medical Devices
1	2 - Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices	Anode Can
2		Anode Outer Sealling Ring
3		Anode Shield
4		B18x center section
5		Casting Housing Assembly
6		Cathode Can BULGED Machined
7		Cathode Can BULGED Machined
8		Cathode Can Machined 743708
9		Collar
10		Cover
11		FABR Housing Anode End Std
12		FABR Housing Cathode End Std
13		Housing / Center section SAPPHIRE
14		Housing Aluminium 4131Z
15		Housing anode and SAPPHIRE III
16		Housing anode and SAPPHIRE III
17		Housing B-130,180 Degree
18		Housing B-130,180 Degree
19		Housing Center B-240
20		Housing Diamond Emerald Metric 90 DEG
21		Kovar Bushing
22		Ring Sealing Cathode inner
23		Sealing Ring
24		Shield Cathode
25		Shield Cathode
26		Support Cathode
27	3 - Anesthetics & Cardio-Respiratory Medical Devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices	Amplatz Dilator / Kit & Mini Amplatz Dilator / Kit
28		Automatic Blood Pressure Monitor
29		Biopsy Kits-Renal
30		Braided Shaft Catheter (Ureteral Access Sheath)
31		Chiba Needle
32		Cysto Catheter /Kit
33		Dialyser Reprocessing System
34		Double J Stent /Kit (Long Term)
35		Double J Stent/Kit (Short Term)
36		Dual Lumen Ureteral Catheter
37		Endopyelotomy Stent / Kit
38		Evacuator
39		Fascial Dilator/Set
40		Filiform Self Dilator

41		Hydrophilic (Nano Glidewire) Guidewire
42		Incontinence Sling-AQUA
43		IP Needle
44		IUI Catheter / Kit
45		Malecot Catheter / Kit
46		Meatal Dilator
47		Mono J Stent / Kit
48		Nephrostomy Balloon Dilator
49		Nottingham One Step Dilator
50		PCN Catheter / Kit (Abscess Drainage Catheter / Kit)
51		Penile Clamp
52		Perk Basket
53		PTFE Guidewire
54		Re Entry Malecot Catheter / Kit
55		S Curve Urethral Dilator / Set
56		Screw Dilator
57		SS Guidewire
58		Stone Basket - X Circle
59		Stone Basket- G Paw
60		Stone Basket Helical
61		Stone Basket –Segura
62		Stone Basket -Zero Tip
63		Stone Grasper
64		Stonestop -Retrieval Coil
65		Striped Guidewire
66		Striped Guidewire with Hydrophilic Tip
67		Suction And Irrigation System
68		Suprapubic Catheter / Kit
69		Thulium Fiber Laser & Laser Probes
70		Turp Loop/Cutting Electrodes
71		Ureteral Balloon Dilator
72		Ureteral Catheter
73		Ureteral Dilator / Set
74		Urethral Dilator / Set
75		Urethral Stent
76		URS Forceps
77		Endoscopes With Flexible / Fixed Shaft
78	4 - AII Implants including Implantable Electronic Devices	Carotid Stent
79		Cerebral Spinal Fluid Shunt System (CSF)
80		Embolic liquid
81		Endocutter
82		Flow diverter implants
83		Hemostates
84		Hernia Surgical Mesh Implants

85		Intracranial Stent
86		Intrasaccular Device
87		Linear Cutter
88		Linear Stapler
89		Litigation Clip
90		Peripheral Stent
91		Trocar
