

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

RAJYA SABHA
UNSTARRED QUESTION No. 2270
TO BE ANSWERED ON THE 21ST MARCH, 2023

Production of high value pharmaceuticals and medical devices

2270 Dr. Dharmasthala Veerendra Heggade:

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

- (a) whether Government is focusing on production of high value pharmaceuticals and highend medical devices to reduce import dependency and if so, the details thereof;
- (b) whether Product Linked Incentive (PLI) Scheme for pharmaceuticals is crawling due to insufficient subsidy and many caveats for investment;
- (c) whether Government has released the first tranche of incentives under PLI Scheme for pharmaceuticals recently and if so, details thereof;
- (d) the financial outlay for PLI Scheme for Pharmaceuticals;
- (e) the Categories of products that are being supported, target Groups and selection criteria under the Scheme; and
- (f) the achievements of PLI for Bulk Drugs and Medical Devices?

ANSWER

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

(a): The Government of India has taken several measures to encourage domestic manufacturing of pharmaceutical drugs including bulk drugs and medical devices to reduce import dependence and to boost domestic manufacturing and attract large investments. The Programmatic interventions to support Pharma and Medical Devices Industries as on date are as follows;

- i. The *Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India*, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for financial incentive for 41 identified products.
- ii. *PLI 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 for manufacturing of identified products under three categories for a period of six years. This scheme also covers the APIs, other than those covered under the PLI scheme under Bulk Drugs as mentioned at Point (i).

- iii. *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.

FY 2022-23 is the first year of production for all the three PLI schemes, except fermentation-based products under PLI Scheme for Bulk Drugs, for which, FY 2023-24 is the first year of Production.

(b) to (d): The PLI scheme for Pharmaceuticals is not suffering due to insufficient subsidy and caveats for investment. As on 20.03.2023, *under the PLI scheme for Pharmaceuticals*, an incentive amount of Rs.363.87 Cr has been released under the scheme to 12 participant companies.

(e): The financial outlay for the PLI Scheme for Pharmaceuticals is Rs 15000 crore over the scheme tenure of 2020-21 to 2028-29. The details of categories of products that are being supported, target groups and selection criteria under these three PLI schemes are available in the Department website at <https://pharmaceuticals.gov.in/schemes> under the respective PLI scheme.

(f): *Under the PLI scheme for Bulk Drugs*, A total of 51 applications have been selected under the scheme. Out of these, 22 projects have already been commissioned with the installed capacity of 34,255 MT. As per the information submitted by the applicants on the sales for the period from April 2022 to December 2022, an investment of Rs.2018.58 Cr has been reported and a total sale of 3972.55 MT of 12 Bulk Drugs covered under the scheme, with a value of Rs.389.89 Cr has been reported. The details of Critical KSMs / DIs / APIs Ingredients approved under the PLI Scheme for Bulk Drugs are given at **Annexure-1**.

Under the PLI scheme for Medical Devices, a total of 60 applications (42 application of Category-A and 18 applications of Category-B) have been received out of which, 26 applications have been approved under the scheme. 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. 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-2**.

Annexure-1

Details of Critical KSMs / DIs /APIs Ingredients approved under PLI scheme for Promotion of Domestic Manufacturing of Critical KSMs / DIs / APIs in India

Sl. No.	Target Segment or Category of KSMs / DIs / APIs	Products approved under the PLI scheme
1.	Key Fermentation Based KSMs /Drug Intermediates	Penicillin G, 7 – ACA and Clavulanic Acid
2.	Fermentation Based Niche KSMs / Drug Intermediates / APIs	Betamethasone, Dexamethasone, Prednisolone, Rifampicin and Clindamycin Base.
3.	Key Chemical Synthesis Based KSMs/Drug Intermediates	1,1 Cyclohexane Diacetic Acid (CDA), Para amino phenol and Dicyandiamide (DCDA)
4.	Other Chemical Synthesis Based KSMs/Drug Intermediates/APIs	Meropenem, Atorvastatin, Olmesartan, Aspirin, Ritonavir, Lopinavir, Acyclovir, Carbamazepine, Oxcarbazepine, Vitamin B6, Valsartan, Losartan, Levofloxacin, Ofloxacin, Diclofenac Sodium, Carbidopa, Levodopa, Sulfadiazine, Ciprofloxacin, Vitamin B1, Telmisartan, Levetiracetam, Norfloxacin and Artesunate

Annexure-2**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
	40	Hip Implants

Target Segment	S.No.	Product / Name of the Medical Devices
4. All Implants including implantable electronic Devices	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 - All 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
