

No.31026/21/2020-MD  
Government of India  
Ministry of Chemicals & Fertilizers  
Department of Pharmaceuticals

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Shastri Bhawan, New Delhi  
Dated the 19<sup>th</sup> December, 2023

**CORRIGENDUM/ADDENDUM**

**Subject:** - Modifications in the guidelines of Production Linked Incentive (PLI) Scheme for promoting domestic manufacturing of Medical Devices (PLI - MD) to **invite applications for the eligible products as per Annexure-1A for Category-B applicants**– reg.

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Department of Pharmaceuticals issued guidelines of the PLI Scheme for Medical Devices on 27.07.2020, which got revised on 29.10.2020, 18.08.2022 and on 25.02.2023, As per guidelines dated 25.02.2023, 4<sup>th</sup> round of applications were invited under the scheme.

2. Based on the arising needs and subsequent to the decision of the Empowered Committee (competent authority) in its meeting on 09.06.2023, following amendments in Annexure-1 and Annexure-1A of the PLI MD guidelines dated 25.02.2023 are hereby notified: -

**I. Annexure-1:** "Category A" applicants allowed to apply for the product target segments under the scheme -

Sl. No.	Name of the segment	Indicative eligible products in the PLI MD guidelines dated 25.02.2023	Amended indicative eligible products in the PLI MD guidelines dated 19.12.2023
1	Cancer care / Radiotherapy medical devices	Rotational Cobalt Machine, Linear Accelerator (LINAC)	Rotational Cobalt Machine, Linear Accelerator (LINAC)
2	Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices	CT Scan, MRI, Ultrasonography, X-ray equipment, C-arm, Cath-Lab, Mammography, Collimator, Flat Panel Detector, Surgical X-Ray C-Arm, Fixed LF and HF X-Ray Products, X-Ray Panels, MRI Coils and Monitor	CT Scan, MRI, Ultrasonography, X-ray equipment, C-arm, Cath-Lab, Mammography, Surgical X-Ray C-Arm, Fixed LF and HF X-Ray Products, X-Ray Panels and MRI Coils
3	Anesthetics & CardioRespiratory medical devices including Catheters of Cardio Respiratory Category &	Dialyzer, Anesthesia Unit Ventilators, Patient monitoring system, Anaesthesia Kits, Masks —Anaesthesia, Anesthesia Workstation, Automated External Defibrillators (AEDs), ECG, Syringe Pump, Defibrillators, Stress Test System and Oxygen	Dialyzer, Anesthesia Unit Ventilators, Patient monitoring system, Anaesthesia Kits, Masks —Anaesthesia, Anesthesia Workstation, Automated External Defibrillators (AEDs), ECG, Syringe Pump, Defibrillators, Stress Test

	Renal Care Medical Devices	Concentrator, Dialysis Machine, Peritoneal Dialysis kits, Fistula, Blood Line, Haemodialysis Catheter, Transducer Protector, Anaesthesia Unit Gas Scavengers, Anaesthesia Unit Vaporizers, Bi-Phasic Defibrillators, Infusion pumps - Syringe and Volumetric, Intensive Care Ventilators, Emergency Ventilators (Portable Ventilators), High Flow Oxygen Devices, Multi-parameter Monitor, Suction Machine.	System, Oxygen Concentrator, Dialysis Machine, Peritoneal Dialysis kits, Fistula, Blood Line, Haemodialysis Catheter, Transducer Protector, Anaesthesia Unit Gas Scavengers, Anaesthesia Unit Vaporizers, Bi-Phasic Defibrillators, Infusion pumps - Syringe and Volumetric, Intensive Care Ventilators, Emergency Ventilators (Portable Ventilators), High Flow Oxygen Devices, Multi-parameter Monitor, Suction Machine.
4	All Implants including implantable electronic devices	Heart Valves, Stents, PTCA Balloon Dilatation Catheter, Heart Occluders, PTCA Balloon Catheter, Hip Implants, Knee Implant and Trauma Implant, Drug Eluting Stents and Drug Eluting Balloons.	Heart Valves, Stents, PTCA Balloon Dilatation Catheter, Heart Occluders, PTCA Balloon Catheter, Hip Implants, Knee Implant, Trauma Implant, Drug Eluting Stents and Drug Eluting Balloons.

**II. Anneure-1A:** "Category B" applicants allowed to apply for the product target segments under the scheme

Sl. No.	Name of the Segment	Indicative eligible products in the PLI MD guidelines dated 25.02.2023	Amended indicative eligible products in the PLI MD guidelines dated 19.12.2023
1	Cancer care / Radiotherapy medical devices	Brachytherapy Systems, Radiotherapy Simulation Systems, Workstations-Radiotherapy Planning, Proton therapy system and other products* in this target segment.	Brachytherapy Systems, Radiotherapy Simulation Systems, Workstations-Radiotherapy Planning, Proton therapy system, Cryoablation Unit, Cryoprobe, Cryotherapy, HDR Brachytherapy, Holium LASER system with MOSES Technology, Holmium Laser 100W, Hyperthermic Intra Vesicular Therapy, Vaccum Assisted Breast Biopsy Machine and other products* in this target segment.

2	Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices	Cyclotrons, Positron Emission Tomography (PET), Systems, Single photon emission tomography (SPECT), X-Ray Tube and other products* in this target segment.	Cyclotrons, Positron Emission Tomography (PET), Systems, Single photon emission tomography (SPECT), X-Ray Tube, Collimator, Monitor, Flat Panel Detector, 3T Digital PET/MR, Biplane DSA, Cone Beam Computed Tomography, CR System, Dedicated Solid- state cardiac SPECT Camera, Densitometer with computer, DEXA Scan, DEXA Scanner (BMD), Dual Particle Cyclotron, ECHO and USG Machine, Elbow & Ankle Arthroscopy, Fibro Scan, FNIRS ( Functional Near Infra-Red Spectroscopy) System, Gamma Camera, Handheld ICG Fluorescence Imaging System (Burns and Plastic Surgery Block), Intraoperative Imaging and TTFM for CT Surgery, IVUS, Metaphase Finder System with Fluorescence, Orthopantomogram (OPG) unit, Transcranial Doppler, PET CT and other products* in this target segment.
3	Anesthetics & Cardio Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices	Needles-Anesthesia, Syringes-Anesthesia, Biopsy Kits Renal, Dialyser reprocessing system, Lithotripters Extracorporeal -Renal and other products* in this target segment.	Needles-Anesthesia, Syringes-Anesthesia, Biopsy Kits Renal, Dialyser reprocessing system, Lithotripters Extracorporeal -Renal, Activated Clotting Time Machine, Continuous Glucose Monitoring System, Apheresis Machine, Cardiopulmonary Bypass Machine, CRRT Machine, Cystoscope paediatric cystoscope, Dual action Ultrasonic plus Pneumatic lithotripter, Electrical Impedance Tomography, Electro Physiology (EP) System, Endoscopic Saphenous Vein Harvesting (EVH) System, ESWL, Excimer Coronary laser Atherectomy System- ih Catheter (50), FFR Machine (Fractional Flow Reserve), Flexible cysto-nephoscopy, Floppy wire with extra support 0 Coronary Angioplasty, Flow Track Cardiac Output Monitoring, Hemodynamic Recorded for Cardio Vascular lab, Impella, Intra-aortic balloon pump (IABP), Kidney Transporter with 05



			<p>sets of Expendables with Each Equipment, Laparoscopic Surgery Set with High-Definition camera, Laparoscopic Surgery Set with Hysteroscope &amp; Resectoscope with High-Definition Camera &amp; Monitor, Minimally Invasive Cardiac Instruments, Non-Invasive Jugular Oximetry Monitor, Paediatric Bronchoscope Set, Paediatric cystoscope and resectoscope set/Cystoscope &amp; Resectoscope — Paediatric, Paediatric laparoscopy set, Paediatric High Resolution Fibre Flexible Bronchoscope with recorder and Screen Display, PCNL set, Rapid Blood/Fluid Flow warmer, Rigid Bronchoscope, Rigid Thoracoscope (VATS), Sanders Jet Ventilator for Emergency Airway, T Piece Resuscitator, Trans Oesophageal Echo Cardiograph, Transcutaneous Oxygen Monitor, Uretero-roscope-Adult, Uretero-roscope-Paediatric, Vacuum Assist Drainage Controller Device, VAP Care System, Video Assisted Thoracic Surgery (VATS) and Minimally Invasive Cardiac Surgery instrument set, Video bronchoscope with mobility of tip in four directions and other products* in this target segment..</p>
4	<p>All Implants including implantable electronic devices</p>	<p>Cochlear Implants, Spinal and neuro-surgical implants, Urogynecologic Surgical Mesh Implants, Hernia Surgical Mesh Implants, Cerebral Spinal Fluid (CSF) Shunt Systems, Implanted Pacemakers, insulin pump, implanted neuro-stimulated device like Deep Brain Stimulator, Intraocular lenses and other products* in this target segment.</p>	<p>Cochlear Implants, Spinal and neuro-surgical implants, Urogynecologic Surgical Mesh Implants, Hernia Surgical Mesh Implants, Cerebral Spinal Fluid (CSF) Shunt Systems, Implanted Pacemakers, insulin pump, implanted neuro-stimulated device like Deep Brain Stimulator, Intraocular lenses, Bi- Ventricular Pacemaker with Quadripolar LV Lead, Expandable Corpectomy device, MRI Conditional Automatic Implantable Cardioverter Defibrillator (AICD), MRI Conditional Cardiac Resynchronisation Therapy - Pacing (CRT-P) and other products* in this target segment.</p>

\*Other products – For products not specifically mentioned in the table above the Technical Committee shall decide whether such products shall be considered eligible under the target segments. Further, any product which is listed in Annexure 1 (Category A) will not be considered under 'other products' above.

**Note:** A key component which constitutes major part of the finished medical device (such as Rotating Anode Tube, Stationary Anode Tube, MRI Magnet, Flat Panel Detector and similar components), and has a distinct HS code for itself, will be considered as included in the corresponding target segment.

If the selected applicants of Category-A withdraw or get rejected with the approval of the Empowered Committee, the products applied by those applicants withdrawn or rejected (if there are no other applicants for same products as approved in earlier rounds), shall automatically be included under Annexure1A and may be made available for Category B applicants to apply.

3. All other clauses in the PLI MD guidelines dated 25.02.2023 remain the same.
4. This issues with the approval of the competent authority.



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To

- Director NIC, DoP – Requested to upload the same in DoP Website.
- Shri. Varun Mahajan, IFCI Ltd.- for further action.