

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

LOK SABHA
UNSTARRED QUESTION NO. 1483
TO BE ANSWERED ON 10th February, 2023

Import of High end Scan Machines

1483. SHRI D.M. KATHIR ANAND:

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

- (a) whether the Government has taken any proactive steps to increase and facilitate the import of high end scan machines including the CT Scan and MRI Scan equipments from foreign countries;
- (b) if so, the details thereof;
- (c) the total number of scan machines and medical equipments imported in the last five years, year-wise origin, country-wise and the expenditure incurred for the same;
- (d) whether the Government has taken adequate measures to ensure the indigenous production and supply of high-end medical equipments and scan machines;
- (e) if so, the details thereof; and
- (f) the steps taken/proposed to be taken by the Government to establish medical equipments manufacturing hub for high-end medical equipments including the CT and MRI scan machines in the country including in Tamil Nadu?

ANSWER

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

(a), (b), (d), (e): The Government has taken various measures including *Production Linked Incentive (PLI) scheme for Medical Devices* to strengthen the domestic manufacturing capacity to ensure the indigenous production and supply of the Medical Devices, including the CT Scan and MRI Scan equipments and the same is placed at Annexure-1. Under the PLI Scheme for Medical devices, four (4) applicants are approved for manufacturing of CT Scan and three (3) applicants are approved for MRI Scan equipment respectively.

(c): As per the data available with DoC, the details of import of medical electronic equipment which is inclusive of scan machines, along with details of top six countries of import, are given at **Annexure-2**.

(f): Under the scheme for Promotion of Medical Devices Parks, the Government provides support to the four States of Himachal Pradesh, Madhya Pradesh, Tamil Nadu and Uttar Pradesh, for creation of the world class common infrastructure facilities in the Medical Devices Parks, being developed by them. So far, first instalment of Rs.30 Cr is released to all these four states.

Measures taken to encourage domestic manufacturing of medical devices

- 100% FDI through automatic route is allowed in the medical devices sector
- In 2019, under the Department of Pharmaceutical's sub-scheme named "***Assistance to Medical Device industry for Common Facility Centre***", financial assistance of Rs 25 crore was approved to the Andhra Pradesh MedTech Zone (AMTZ) for setting up a common infrastructure of a superconducting magnetic coil testing facility.
- In 2020, revised scheme named "***Scheme for Promotion of Medical Device Parks***" was launched. Under this scheme, financing support of Rs 100 crore each has been approved for creation of common facilities in four medical devices parks coming up in **Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh**, which are being developed by these State Governments. This is an infrastructure support scheme wherein the common facilities will be accessed by the industrial units in the parks. These parks will come up as manufacturing hubs and provide enabling ecosystem dedicated solely for medical devices. The expected date of completion of the Parks is June, 2024. As per scheme guidelines, first tranche of grant-in-aid of Rs. 30 crore each has been released to the four States.
- Further in 2020, a scheme named "***Production Linked Incentive Scheme for Medical devices***" was introduced. The scheme has a financial outlay of Rs. 3,420 crores, over a period of FY 2020-21 to FY 2027-28. The objective of the scheme is to support the domestic manufacturing of certain identified high-technology medical devices through incentivizing domestic manufacturers. The identified medical devices under the scheme are Cancer Care /Radiotherapy medical devices; Radiology & Imaging medical devices (both ionizing and non-ionizing radiation products) and nuclear imaging devices; Anesthetics & Cardio-Respiratory medical devices including catheters of Cardio Respiratory Category and Renal Care Medical Devices; and all Implants including implantable electronic devices like Cochlear implants and pacemakers. Four (4) applicants are approved for manufacturing of CT Scan and 3 applicants are approved for MRI Scan equipments respectively.
- The Department for Promotion of Industry and Internal Trade (DPIIT) brought out the policy of "***Public Procurement (Preference to Make in India) in 2017***" and designated the Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions related to medical devices. DoP thereafter laid out the definition of Class-I, Class-II and Non-Local supplier under the said Policy. Initiatives have been taken under the policy to give preference to domestic manufacturers in public procurement of medical devices done by the hospitals of the Central Government. The Public Procurement (Preference to Make in India) policy is an important pillar of the Atmanirbhar Bharat program.
- The ***Medical Devices Rules, 2017*** were notified under the Drugs and Cosmetics Act, 1940 by the Department of Health and Family Welfare. These rules lay out the regulatory framework for medical devices in terms of their quality, safety and efficacy. This expanded the regulatory oversight to the entire gamut of devices and classified them into four categories based on the level of risk associated with the medical devices. Class A and B Medical Devices (Low risk and medium risk) are brought into licensing under MDR 2017 from October 2022 onwards and remaining Class C and D medical devices will be brought under compulsory licensing from October 2023 onwards.

Annexure II

Value of import of medical electronic equipment (USD Million)				
F.Y. 2017-18	F.Y. 2018-19	F.Y. 2019-20	F.Y. 2020-21	FY 2021-22
3266.99	3676.74	3646.53	3568.64	5441

Source: EEPC, India

Top countries for import of medical electronic equipment (USD Million)			
S.No	Country	2020-21	2021-22
1	China	768.44	1377
2	USA	547.9	818.6
3	Germany	493.7	593.7
4	Singapore	367.4	532.9
5	Japan	195.3	281.2
6	Malaysia	25.21	31.58

Source: EEPC, India
