GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 338
TO BE ANSWERED ON 06th FEBRUARY, 2024

Import of medical devices

338 Shri V. Vijayasai Reddy:

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

(a) whether it is a fact that we are importing 80-85 per cent of medical devices by spending nearly ₹ 50,000 crores annually;
(b) whether it is also a fact that there is a need for huge R&D in the country to bring down import of medical devices and become net exporter in the coming years; and
(c) the manner in which Government is planning to adopt technologies such as cloud computing, robotic process automation to boost Atmanirbharta to quicken the process of manufacturing and take the country as one of the top 5 manufacturers of medical devices?

ANSWER

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

(a): The value of imports and exports of Medical Devices is given below:

(Values in USD million)

Imports			**Exports**		
2020-21	**2021-22**	**2022-23**	**2020-21**	**2021-22**	**2022-23**
6242	8540	7492	2532	2923	3391

The Government of India has taken several measures to encourage domestic manufacturing of high end medical devices to reduce imports dependence and to boost domestic manufacturing. The programmatic interventions for the same are as follows:

i. *Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of Medical Devices (PLI MD)* with total financial outlay of Rs. 3,420 crore and tenure from FY 2020-2021 to FY 2027-28. The financial incentive is to be given 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. The four target segments are – (I) Radiotherapy, (II) Imaging Devices, (III) Anaesthesia, Cardio-respiratory & Critical Care, (IV) Implants. 26 participants have been approved under the scheme.
ii. *Production Linked Incentive (PLI) scheme for Pharmaceuticals*, with a financial outlay of Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for

financial incentive to 55 selected applicants, which includes 5 selected applicants of In-Vitro Diagnostics (IVD) devices. The incentive period under the scheme is for six years.

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 Himachal Pradesh, Madhya Pradesh, Tamil Nadu, and Uttar Pradesh.

(b) & (c): Yes, realizing this need, Department has taken steps to promote R& D in the Medical Device sector:

(i) The Department has notified *National Policy on Research & Development and Innovation in Pharma-MediTech Sector* in India on 18.08.2023 to promote R&D in the pharmaceuticals and medical devices and create an ecosystem for innovation.
(ii) The Department has also framed a scheme for *Promotion of Research & Innovation in Pharma-MediTech sector (PRIP)* with an outlay of Rs. 5000 Crore for a period of 5 years i.e., 2023-24 to 2027-28, which has been notified on 17.08.2023 with the objective of transforming Pharma Medi-Tech sector from cost-based to innovation-based sector by strengthening research infrastructure in the country.
(iii) The Department of Pharmaceuticals has also introduced a scheme for "*Human Resource Development in the Medical Device Sector*" to fill the existing gap in the education and research in the Medical Devices Sector and to ensure quality teaching, training and nurturing excellence in Med-tech education. The scheme has an outlay of Rs. 480 Cr over three years., i.e. 2023-24,2024-25, 2025-26. The scheme aims to generate a critical mass of trained human resources to meet the requirement of rapidly innovating multidisciplinary areas of Medi-tech and to create an R&D ecosystem for the Medical Device Sector.

Also, ICMR has set up Medical Device & Diagnostic Mission Secretariat (MDMS) under Division of Development Research at its headquarters which has adopted a multi-pronged approach to foster indigenous innovation in Meditech space. More information on MDMS activities can be accessed from: https://mdms.icmr.org.in/

Further, under the guidance of NITI Aayog, ICMR in collaboration with Central Drugs Standard Control Organization (CDSCO) has launched '*MedTech Mitra*' initiative for providing strategic handholding support to MedTech innovators for clinical evaluation, regulatory facilitation and uptake of new products. More information on this initiative can be accessed from: https://medtechmitra.icmr.org.in/

ICMR has released "*Ethical guidelines for application of Artificial Intelligence in Biomedical Research and Healthcare*" to ensure ethical conduct and address emerging ethical challenges in the field of Artificial Intelligence (AI) in biomedical research and healthcare including meditech sector. https://main.icmr.nic.in/sites/default/files/upload_documents/Ethical_Guidelines_AI_Healthcare_2023.pdf .

CSIR has implemented a Mission Mode Project on '*Medical Instruments and Devices*' with an aim to take lead in the manufacturing of high-end medical devices in the

country. The prototypes of the following functional devices/products/implants have been developed under this Project:

- Plasmonic photothermal based sterilization device for surgical instruments;
- Dialysis machine for haemodialysis of chronic kidney disease patients;
- Diagnostic system for detection of circulating tumor cells using optical fiber sensor;
- Robotic gait trainer system for rehabilitation of spinal cord injury patients (ROBOG);
- Bio-mechatronic orthotic device for rehabilitation of motor disorders (BioMOD);
- Actuated exoskeleton-based rehabilitation device for human hand impairment (AEROH);
- Advanced closed loop control system for electric tricycle for outdoor mobility of differently abled persons (e-Assist Tricycle);
- Vascular sclerotherapy guidance and assistance tools for clinical diagnostics and treatment of venous malformations (Vascu-Guide);
- Thermal imaging based non-invasive technique for diagnosis of musculoskeletal disorders (MSD);
- Dristiscope – An operating microscope for ophthalmic applications;
- IoT-enabled smart Colposcope device for examination of pre-stage cervical cancer;
- Development of additive manufactured pelvis revision surgery implants;
- Biomaterials for Implants Technologies for Dental and Musculoskeletal Reconstruction; and
- Surface modification of Ti-alloy implants with bioactive, antibacterial & anticorrosive properties.

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