

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

LOK SABHA
STARRED QUESTION No. 204
TO BE ANSWERED ON THE 3rd December, 2019

Affordable Medical Devices

***204. SHRI MANOJ KOTAK:**

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

- (a) whether the Government has any plan to provide affordable medical devices/ equipments and surgical items in the country;
- (b) if so, the details thereof;
- (c) the steps taken by the Government to make surgical items affordable in the country;
- (d) whether the Department of Pharmaceuticals has launched any Umbrella Scheme in this regard; and
- (e) if so, the details thereof and the progress on the implementation of the scheme?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) to (e): A statement is laid on the Table of the House.

**STATEMENT REFFERED TO IN REPLY TO PARTS (a) TO (e) OF LOK SABHA
STARRED QUESTION NO. 204 FOR REPLY ON 03.12.2019**

(a), (b) & (c): Out of 24 notified/regulated medical devices listed as drugs by Ministry of Health and Family Welfare, 4 devices namely (i) Cardiac Stents, (ii) Drug Eluting Stents (iii) Condoms and (iv) Intra Uterine Devices have been included in the National List of Essential Medicines and are under price control in Schedule-I of the Drugs Prices Control Order, 2013 and ceiling prices have been fixed.

Price capping of Coronary Stents by the National Pharmaceutical Pricing Authority in 2017 and 2018 resulted in price reduction upto 85%. The price fixation of coronary stents has resulted in the annual notional saving of Rs.4,547 crores to the public.

Under para 19 of DPCO, 2013, Government fixed the ceiling prices of Orthopaedic Knee Implants for knee replacement vide notification dated 16th August, 2017. This has resulted in average price reduction of various type of Knee implant upto 69% resulting in annual notional savings of Rs.1,500 crore to the consumer.

The MRPs of remaining 20 medical devices, being non-scheduled category, are monitored by the National Pharmaceutical Pricing Authority to ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months.

NPPA so far has issued 27 demand notices to 23 Medical Device companies for violation of para 20 of DPCO,2013 for a total amount of Rs.185 crore (overcharge amount and interest) of which, an amount of Rs.25.50 crore has been recovered from the companies till 15.11.2019.

(d) & (e): With the objective to ensure drug security in the country by increasing the efficiency and competitiveness of domestic pharmaceutical industry the Department of Pharmaceuticals has prepared an umbrella scheme for Development of Pharmaceuticals Industry with the following sub-schemes: (a) Assistance to Bulk Drug Industry for Common Facility Centre; (b) Assistance to Medical Device Industry for Common Facility Centre; (c) Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS); (d) Assistance to Pharmaceutical Industry for Common Facilities; and (e) Pharmaceutical Promotion Development Scheme (PPDS). The said scheme is a Central Sector Scheme with a total financial outlay of Rs. 480 Crore.

Under the sub-scheme 'Assistance to Medical Device Industry for Common Facility Centre', financial assistance would be provided for creation of common facilities in any upcoming Medical Device Park promoted by State Governments/State Corporations. The Scheme would be implemented through a one-time grant-in-aid to be released to a

State Implementing Agency (SIA) set up for the purpose. Some of the indicative activities under the Common facilities include Component Testing Centre, Electro-magnetic interference laboratory, Biomaterial / Biocompatibility testing centre, Medical grade low vacuum moulding, Cabinet moulding injection moulding centers, 2D designing and printing for medical grade products, Sterilization and Toxicity testing centre, Radiation testing centre, etc. The maximum limit for the grant-in-aid under this category would be Rs. 25 Crore per Medical Device Park Common Facility Center (CFC) or 70% of the project cost of CFC whichever is less. So far, the following proposals have been received:

- i. **Andhra Pradesh Medtech Zone Ltd. (AMTZ)** for creation of CFC for Superconducting Magnetic Coils Testing & Research. AMTZ is an enterprise under the Government of Andhra Pradesh located at Visakhapatnam.
- ii. **Government of Telangana** for Biomaterials and biocompatibility testing lab, Electrical safety and reliability testing lab and Radiation testing lab. Govt. of Telangana is establishing a medical device park near Hyderabad at Sultanpur in Sangareddy district. The project is currently being executed by the Telangana State Industrial Infrastructure Corporation (TSIIC) which is the State Implementing Agency and has title over the land under construction.
- iii. **HLL Medipark Ltd. (HML)** for Rapid Prototyping Facility, State of Art Calibration Centre, Skill Development Centre and Common Logistics Centre. HML is developing a medical device park spread over 330 Acre in Kanchipuram district in Tamilnadu.
- iv. **Kerala State Industrial Development Corporation (KSIDC) in association with Sree Chitra Tirunal Institute of Medical Sciences and Technology** for Prototyping-Pilot Manufacturing & Incubation Centre, Medical Device Testing and Evaluation Centre, R&D Resource Centre, Knowledge Resource Centre & Large Animal Breeding Centre. The project will be based in Thiruvananthapuram, Kerala.

In-principle approval to all four proposals has been accorded by the Scheme Steering Committee (SSC) in 2019.

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