GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO.1146
TO BE ANSWERED ON 28TH JUNE, 2019

MEDICAL EQUIPMENTS MARKET

1146. SHRI SANJAY HARIBHAU JADHAV:
SHRI KRUPAL BALAJI TUMANE:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) the size of medical equipments market in India and the quantum of medical equipments imported during each of the last three years and till date;

(b) whether the Government is aware that medical equipments like stents, catheters and bone implants are being sold at higher rates to patients in the country and if so, the details thereof and the reasons therefor;

(c) whether the Government has asked the manufacturers of such medical equipments to submit the complete details of production and rate fixation of their products and if so, the details thereof;

(d) the measures being taken by the Government to monitor and regularize the prices of medical equipments and to protect the customers being overcharged by hospitals/companies; and

(e) the steps being taken by the Government to promote domestic manufacturing of medical equipments at affordable price?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a): Central Drugs Standard Control Organisation (CDSCO) under Ministry of Health and Family Welfare regulates the quality, safety and performance of notified category of medical devices under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder.

As per the data received from port offices of CDSCO, value of import of medical devices during last 3 years is below:

Year	**2016-17**	**2017-18**	**2018-19**	**2019- till 24.06.19**
Value in Crore Rupees	4372.61	3615.13	5210.26	2611.57

(b): National Pharmaceuticals Pricing Authority (NPPA) under the Ministry of Chemicals & Fertilizers had fixed ceiling prices of Bare Metal and Drug Eluting Cardiac Stents (scheduled medical device) in February 2017. NPPA had also fixed ceiling prices of Orthopedic Implants for Knee Replacement System (non-scheduled medical device) in August 2017 in extraordinary circumstances in the larger public interest.

NPPA is monitoring implementation of ceiling pries of Cardiac Stents and Knee Implants across the country. In this regard, no complaint of overcharging has been received so far. As regard Catheters (non-scheduled medical device), NPPA has not fixed its ceiling price. However, NPPA monitors price movement of Catheters so that no manufacturer can increase the price more that 10% in preceding twelve months.

(c): NPPA collected costing data from importers/manufactures of Cardiac Stents and Knee Implants at the time of fixing their ceiling prices. With regard to Catheters, NPPA has collected MRP details from importers/manufactures of Catheters to monitor the price increase.

(d): The Government controls price of only medical devices declared as essential drugs. Out of 23 Medical Devices notified as "Drugs" under Drugs & Cosmetics Act only three devices namely 'Condom', 'IUD containing copper' & 'coronary Stents' have been included in the National List of Essential Medicines-2015 (NLEM-2015) and therefore included in Schedule-I of Drugs (Price Control) Order, 2013 (DPCO, 2013) and are under price control.

Knee Implant, though not included in Schedule I of DPCO, has also been given a price cap under Paragraph of 19 of DPCO. No price cap has been fixed on rest of the notified devices as they come under non-scheduled category. However, manufactures are not allowed to increase the price of non-scheduled drugs more than 10% per annum under DPCO. NPPA continuously monitors market prices of all drugs and notified medical devices.

(e): Realizing the needs of medical devices sector, the Government has operationalized a sub-scheme namely development of Common Facility Centre for Medical Devices (DCFC-MD). It aims to provide financial assistance to upcoming medical device parks for creation of Common Facility Centre (CFC). This move is expected to bring down the manufacturing cost of indigenous medical devices, thus making them competitive and boost 'Make in India'. Further, pursuant to the Public Procurement (Preference to Make in India) Order, 2017, D/o Pharmaceuticals has issued guidelines for implementation of this order on 18.05.2018. Further D/o Pharmaceuticals vide Office Memorandum dated 16.10.2018 has amended the guidelines clarifying that USFDA/CE certifications etc. shall not be mandatory for those medical devices for which Bureau of India Standards (BIS) standards exist. This move is also expected to boost manufacturing of indigenous medical devices.

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