

**GOVERNMENT OF INDIA  
CHEMICALS AND FERTILIZERS  
LOK SABHA**

UNSTARRED QUESTION NO:3566

ANSWERED ON:11.08.2015

Prices of Medical Devices

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

- (a) whether it is a fact that huge difference exist between import cost and Maximum Retail Price (MRP) of medical devices like cardiac stent, eluting stent implants/orthopaedic Implant etc.;
- (b) if so, the reasons therefor and the steps being taken/proposed to be taken by the Government in this regard;
- (c) whether the Government proposes to create an autonomous body on the line of Telecom Regulatory Authority of India (TRAI)/National Medical Devices Authority (NDMA) to control/reduce the prices of the said life saving devices including stents and if so, the achievement made so far;
- (d) whether the Government also proposes to take action/impose penalty on the manufacturers/sellers who are charging exorbitant prices of these devices/violating the rules/norms prescribed by the Government;
- (e) if so, the details thereof and the number of such complaints received in this regard and the action taken thereon so far; and
- (f) whether the Government proposes to include number of medical devices under the Drug (Price Control) Order, 2013 and if so, the details thereof and if not, the reasons therefor?

**Answer**

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS ( SHRI HANSRAJ GANGA RAM AHIR )

(a to e) : Cardiac Stents, Drug Eluting Stents, Implant / Orthopaedic Implants are notified as 'drugs' under section 3(b) (iv) of the Drugs & Cosmetics Act, 1940 and Rules made thereunder. These devices are not included in the National List of Essential Medicines (NLEM) 2011 which is incorporated in the Schedule-I to the Drugs (Price Control) Order, (DPCO) 2013 for the purpose of price control. Accordingly, no ceiling price has been fixed for these devices under DPCO, 2013. DPCO, 2013 provides that manufacturers / importers / distributors shall not increase the MRP of non-scheduled formulations including medical devices, more than ten percent of MRP during preceding twelve months. Manufacturers/ importers/ distributors of medical devices, regulated as drugs, have been asked to provide information for monitoring of price movement as non-scheduled formulations under provisions of DPCO, 2013. The draft National Medical Device Policy, 2015 is under examination.

(f): Ministry of Health and Family Welfare has constituted an expert core committee to review and recommend the revision of National List of Essential Medicines (NLEM)-2011 in the context of contemporary knowledge of use of therapeutic products."

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