

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

UNSTARRED QUESTION NO:1451

ANSWERED ON:02.12.2014

OVERCHARGING OF MEDICAL DEVICES

Chavan Shri Ashok Shankarrao;Kirtikar Shri Gajanan Chandrakant

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

- (a) whether the Government is aware that huge difference exist between import cost and MRP of medical devices like drug eluting stents, orthopaedic implants;
- (b) if so, whether these medical devices are not included under the Drug (Price Control) Order, 2013 and if so, the details thereof and the reasons therefor;
- (c) whether Food and Drug Administration of Maharashtra had carried out a detailed investigation into over- charging of various medical devices and submitted the report to the National Pharmaceutical Pricing Authority (NPPA);
- (d) if so, whether any action has been taken by the NPPA in this regard; and
- (e) if so, the details thereof and if not, the reasons therefor and the corrective steps taken/being taken by the Government in this regard?

Answer

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

- (a) Information is being collected and will be laid on the table of the House.
- (b) National Pharmaceutical Pricing Authority (NPPA) is authorised to monitor the cost and sale of only those medical devices which are considered as drugs as per the provisions of the Drug & Cosmetics Act. Two medical devices notified as drugs namely condom and IUD containing copper are included in the First Schedule of the said Order based on the National List of Essential Medicines, 2011 and their prices have been fixed by NPPA as per the provisions of DPCO, 2013.
- (c) to (e) NPPA vide its letter dated 08.10.2014 has informed the Food and Drug Administration of Maharashtra that a high level Core Committee has been constituted under the Chairmanship of Dr. V.M. Katoch, Secretary, Department of Health Research, Government of India and Director General, ICMR for revision of NLEM-2011, by the Ministry of Health & Family Welfare. Further, NPPA has undertaken a detailed study of the drugs already included in NLEM-2011 and to identify drugs that require inclusion so as to ensure that all lifesaving and essential drugs of mass consumption are included for safeguarding the public interest. In this regard, FDA, Maharashtra has been requested to provide necessary input for revision of the recommendation made by them for inclusion of 14 medical devices under drug price control for examination in the context of the ongoing exercise for revision of NLEM, which is being carried out by the Ministry of Health & Family Welfare.