

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

LOK SABHA
STARRED QUESTION NO. *446
TO BE ANSWERED ON 27th March, 2018

Medical Device Industry

*446. SHRI RAM CHARITRA NISHAD:

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

- (a) whether the medical device industry has demanded that it be regulated by the Government as self regulation does not work;
- (b) if so, the details thereof;
- (c) whether it is true that hospitals were effectively forcing the manufacturers to mark extremely high MRPs to boost their profit margins and if so, the details thereof;
- (d) whether the domestic medical device industry has been urging for a cap on trade margins for more than a year; and
- (e) if so, the details thereof;

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
AND PARLIAMENTARY AFFAIRS (SHRI ANANTH KUMAR)**

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

**Statement referred to in reply to LOK SABHA STARRED QUESTION
No. 446 to be answered on the 27TH MARCH, 2018 regarding Medical
Device Industry**

(a) & (b): No specific demand from medical device industry for regulation by the Government for failure of self-regulation has been received. However, Medical Technology Association of India (MTAI), one of the medical device industry representative bodies, made a proposal to the Government in August, 2017 that the total trade margins for medical devices should not exceed 35%-50% of MRP excluding taxes.

(c): There is no information/report of hospitals forcing manufacturers to mark high MRPs. However, based on complaints and media reports on overpricing and inflated bills to the patients by some hospitals, National Pharmaceutical Pricing Authority (NPPA) had asked for details of billing from the hospitals under the provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013). Based on the data submitted by the hospitals, NPPA has found that the highest margin (difference of amount billed for the formulation by the hospitals and the price at which they were procured expressed in percentage terms) available to the hospitals on scheduled medicines, non-scheduled medicines, consumables and non-scheduled medical devices were 357%, 1192%, 1737% and 1271% respectively. NPPA's report prepared on the basis of information submitted by these hospitals is available under the "What's New" link of website of NPPA. (www.nppaindia.nic.in).

(d) & (e): In various interactions with the Government, medical device industry associations have not, in general, opposed the proposal of capping of trade margins on medical devices. To make notified medical devices affordable and accessible, Government has various options including that of fixing trade margins. Monitoring the prices of essential medicines and devices is an ongoing process and Government, in extraordinary circumstances such as market failure or excessive profiteering can fix the ceiling prices of any formulation or notified medical device, in public interest.

XXXX