

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:813

ANSWERED ON:24.07.2015

Medical Devices

Ahmed Shri Sultan ;Kesineni Shri Srinivas;Owaisi Shri Asaduddin;Reddy Shri Ch. Malla;Selvam Shri V. Panneer;Sundaram Shri P.R.

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

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

- (a) the quantum of medical device market in India along with the volume of imports therein during each of the last three years till date;
- (b) whether the Government has taken note of medical devices such as stents, catheters and orthopaedic implants being sold to the patients at high price in the country and if so, the details thereof;
- (c) whether the Government has asked the manufacturers of such medical devices to submit complete details of production and pricing of their products and if so, the details thereof;
- (d) the other measures being taken by the Government to monitor and regulate the high price of medical devices and protect the consumers being overcharged by the hospitals/companies for the same; and
- (e) the steps being taken by the Government to encourage domestic manufacturing of medical devices at cheaper/affordable costs?

Answer

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a): As per the data collected from the Department of Pharmaceuticals, the value of total sales of medical devices both indigenous and imported in 2013-14 is Rs.30,600 crore. The value of import of medical devices in the country during 2011-12, 2012-13 and 2013-14 is Rs.16,269 crore, 19,262 crore and 21,324 crore, respectively.

(b) to (d): The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals, has during a study regarding pricing of stents in the country, observed that bulk of the medical devices such as stents, catheters and orthopaedic implants, etc., consumed in the country, are imported and the difference between the landed cost and the Maximum Retail Price (MRP) thereof is very high. These medical devices fall under non-scheduled category under the Drugs Price Control Order, 2013, and as such, no ceiling price has been fixed for these medical devices. However, an increase of more than 10% in the MRP is not permitted in any medical device.

The NPPA has submitted a report to the Department of Pharmaceuticals on pricing of cardiac stents based on the available information and study conducted by National Health System Resource Centre (NHSRC).

(e): A Task Force constituted by the Department of Pharmaceuticals has made recommendations for creating an eco-system conducive for development of indigenous medical device industry. The Department of Industrial Policy and Promotion has permitted 100% Foreign Direct Investment (FDI) through automatic route both in the greenfield and brownfield medical device manufacturing companies.