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

STARRED QUESTION NO:457
ANSWERED ON:24.04.2015
SAFETY AND QUALITY OF MEDICAL DEVICES EQUIPMENT
Singh Deo Shri Kalikesh Narayan;Venkatesh Babu Shri T.G.

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

(a) the estimated quantity/value of medical devices and equipment being marketed along with the quantum of imports in the country during each of the last three years;

(b) the details of the norms and standards laid down and infrastructure created by the Government to ensure safety and quality of medical devices/equipment in the country;

(c) whether the Government has put in place any vigilance mechanism and adverse event reporting system to keep a track on safety records of medical devices/ equipment in the country, if so, the details thereof and if not, the reasons therefor;

(d) whether the Government proposes to implement a materio vigilance programme and set up a `track and trace` mechanism to ensure the safety and quality of medical devices/equipment in the country and if so, the details thereof; and

(e) the measures being taken by the Government to indigenise the medical device sector?

## Answer

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

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 457 FOR 24 APRIL, 2015

(a) : The Department of Pharmaceuticals has informed that 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) : Only 14 categories of medical devices notified under the provisions of Drugs & Cosmetics Act. 1940 and Rules made thereunder are regulated as drugs by Central Drugs Standard Control Organization (CDSCO). The norms and standards for these notified devices are prescribed under the provisions of the said Act & and Rules. CDSCO has a separate Division dealing with the notified medical devices under the provisions of Drugs & Cosmetics Act & Rules. As per the Notification GSR 690(E) dated 25.09.2014, medical devices in India are required to conform to the Indian Standards laid down from time to time by the Bureau of Indian Standards.

(c) & (d): As a component the Pharmacovigilance Programme of India (PvPI), a Materio-vigilance Programme has been approved by the Ministry of Health and Family Welfare. This programme is for monitoring the adverse events associated with medical devices; creating awareness amongst health care professionals about the importance of reporting of adverse events associated with the medical device in India; and monitoring the benefit-risk profile of medical devices, etc.

At present, there is no proposal for introduction of the Track and Trace mechanism for medical devices and medical equipment marketed in the country.

(e) : A Task Force constituted by the Department of Pharmaceuticals has made recommendations for creating an eco-system conducive for the 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 devices manufacturing companies.