GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
STARRED QUESTION NO.196
TO BE ANSWERED ON THE 1st JANUARY, 2019
REGULATORTY FRAMEWORK TO CHECK MEDICAL IMPLANTS

***196. SHRI ANAND SHARMA:**

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

(a) whether Government is aware of rising number of adverse events including deaths from faulty implants of medical devices which include breast and knee implants, pelvic meshes, coronary stents and pacemakers, if so, the details thereof;

(b) whether Government's attention has also been drawn to a corrupt nexus between hospitals, doctors, global pharma majors and manufacturers of medical devices resulting in unregulated sale and implants of medical devices in the country; and

(c) whether Government proposes to bring in a legislation to put in place a regulatory framework on implants of medical devices to check its rampant abuse?

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

(a) to (c) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 196* FOR 1st JANUARY, 2019

(a) The Government has not received such reports that there is rising number of adverse events including deaths from faulty implants of medical devices.

Adverse reactions/malfunctioning in medical devices may happen due to various reasons like improper usage, improper size, electrical and mechanical problems and defective medical devices. It may or may not be related to the device.

The Central Drugs Standard Control Organisation (CDSCO), under the Ministry of Health and Family Welfare, regulates the import, sale and manufacturing of notified medical devices including breast and knee implants, pelvic meshes, coronary stents under the provisions of Drugs and Cosmetics Act, 1940 and Medical Device Rules, 2017 thereunder. More than 350 medical devices and more than 250 in- vitro diagnostics have been brought under regulation. Under these rules, import of all classes of Medical Devices as well as manufacture of Class C & D Medical Devices are regulated by CDSCO, while manufacture of Class A & B Medical devices are regulated by the concerned State Licensing Authorities (SLA) appointed by the State Governments.

Further, Ministry of Health and Family Welfare has approved the commencement of "Materiovigilance Programme of India (MvPI)" with Indian Pharmacopoeia Commission (IPC), Ghaziabad as the National Coordinating Centre having dedicated functional Medical Device Adverse Event Monitoring Centres (MDMCs) all over the country. All the Adverse Drugs Reaction Monitoring Centres (AMCs) under Pharmacovigilance Programme of India (PvPI) have also been entrusted to report adverse events due to the use of medical devices.

(b) & (c): To have comprehensive regulatory provisions for import, manufacture, sale and distribution of medical devices based on risk based criteria, the Government of India has notified the Medical Device, Rules 2017 which have become effective from 01.01.2018. For import or manufacture of any medical device, the applicant is required to submit details of design, specification, non-clinical as well as clinical data of safety and performance of the devices. In case of new Medical Devices, the safety, quality and performance data are evaluated by CDSCO in consultation with the Subject Expert Committee in the relevant therapeutic areas. Under the said rules, there are provisions that subsequent to approval of a medical device, the applicant is required to closely monitor the device for its clinical safety. The applicant is required to submit Periodic Safety Update Reports (PSURs) to CDSCO.

The Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) announced by the Department of Pharmaceuticals in December, 2014 which is in operation since 01.01.2015 for voluntary adoption by pharma industry provides that the manufacturers should not use any unethical practices for luring doctors to boost sales of their products.

Further, Clause 6.8 (Code of Conduct for doctors in their relationship with pharmaceutical and allied health sector industry) of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prohibits doctors from taking gifts, travel facilities, hospitality or monetary grants from pharmaceutical and allied health sector industry. The said regulation empowers the Medical Council of India and respective State Medical Councils to award punishment to a doctor against any act in violation of code of Ethics.

****