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

LOK SABHA
UNSTARRED QUESTION NO. 1031
TO BE ANSWERED ON 08TH FEBRUARY, 2019

MEDICAL IMPLANTS

1031. DR. KAMBHAMPATI HARIBABU:

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

(a) whether the Government has made it mandatory for hospitals, which are dealing in medical implants, to report cases to Medical Device Adverse Event (MDAE), maintained by the Indian Pharmacopoeia Commission (IPC) and if so, the details thereof;

(b) the details of action taken on MDAE reports during the last four years; and

(c) whether the Government has provisions in place to compensate the affected patients and if so, the details thereof along with the patients compensated during the last four years, State-wise?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a): Realizing the need for having a system to monitor the safety of medical devices by monitoring and reporting of adverse events/side effects, 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. However, IPC collects such reports on voluntary basis.

Further, there is provision, under the Medical Devices Rules, 2017, stipulating that subsequent to approval of a medical device, the applicant is required to submit Periodic Safety Update Reports (PSURs) to Central Drugs Standard Control Organisation (CDSCO).

(b): Medical device alerts are issued on the website of CDSCO wherein 11 alerts have been issued in public interest till date.

(c): Import, sale and manufacture of notified medical devices are regulated as drugs under the provisions of the Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2017. However, there is no specific provision in the said Act and Rules for compensation to a victim after a device has been found faulty.

However as per Section 27 of the said Act, any drug deemed to be adulterated under section 17A or spurious under section 17B, when used by any person for, or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of section 320 of the Indian Penal Code, solely on account of such drug being adulterated or spurious or not being of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to a term of life and with fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more, provided that the fine imposed on and released from the person convicted shall be paid, by way of compensation, to the affected party.