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

LOK SABHA
UNSTARRED QUESTION NO. 2911
TO BE ANSWERED ON 28TH DECEMBER, 2018

MEDICAL EQUIPMENT

2911. SHRI K. ASHOK KUMAR:
SHRI KODIKUNNIL SURESH:
SHRI A.P. JITHENDER REDDY:

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

(a) whether the Government is aware of the reports in media by the International Consortium of Investigative Journalists (ICIJ) about large scale anomalies in AIIMS with regard to Medical Devices Adverse Event (MDAE) report and if so, the details thereof and reaction of the Government thereto;

(b) whether the Government maintains a public database of medical devices that have been recalled by companies due to technical problems and if so, the details thereof and the steps taken against those medical device manufacturers;

(c) the details of medical device malfunctioning, or adverse reports, as received by the Indian Pharmacopoeia Commission, Company-wise and device-wise;

(d) whether the Government has any proposal to conduct an investigation in the matter or constitute a high level committee to ascertain facts and if so, the details thereof;

(e) whether the Government intends to take steps to ensure that the medical professional performing or recommending an implant surgery does not have stake in the medical device they are recommending, if so, the details thereof; and

(f) whether the Government has taken any steps to regulate the medical devices market which so far remained unregulated and if so, the details thereof and if not, the reasons therefor?

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

(a): The Government is aware of the reports in media by the International Consortium of Investigative Journalists (ICIJ). In this regard, the "Materiovigilance Programme of India (MvPI)" is run by Indian Pharmacopoeia Commission under the Ministry of Health & Family Welfare for strengthening the medical devices safety and performance.

(b): The Government of India has notified the Medical Device Rules 2017 which are effective from 01.01.2018**.** Under the Medical Device Rules, there is a provision for recall of medical devices. If a manufacturer or importer considers or has reason to believe that a medical device is likely to pose a risk to the health of patients, the manufacturer/importer shall immediately initiate procedures to withdraw the medical device in question from the market and the patients. The information received from manufacturers is analysed by Central Drugs Standard Control Organisation (CDSCO) and Medical Device alerts are issued by CDSCO on its website i.e. www.cdsco.gov.in.

(c): 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 details of reports received under Materiovigilance Programme of India company-wise and device-wise are attached as **Annexure.**

(d): The Government had constituted a committee to examine the issues relating to faulty Articular Surface Replacement (ASR) hip implants which gave specific and general recommendations to strengthen the regulatory system regarding materiovigilance, registry and recall mechanism of medical devices.

(e) & (f): The Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare regulates the safety, efficacy and quality of notified medical devices under the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder.

Medical Devices Rules, 2017 have been implemented with effect from 01.01.2018 which have comprehensive provisions for regulation of manufacture, import, sale and distribution of medical devices covered under the said Act to ensure their quality. More than 350 medical devices and more than 250 in- vitro diagnostics have been brought under regulation.

ANNEXURE

Device category	Manufacturer
Intra-Uterine Contraceptive Devices	Bayer India, Thane
Catheters	BL Lifesciences Pvt Ltd, New Delhi
	Covidien Manufacturing Solutions
	Cook India, Chennai
	Others (Delux surgicals,Klarvoyant Biogenic Pvt. Ltd, Cordis Corporation, etc)
Intra-Venous Cannula	Vygon India, Gurugram
	(Lamed, Rompson, Polymedicare etc.)
Cardiac Stent	Abbott Vascular, Mumbai
	Terumo India Pvt Ltd, Gurugram
	Cook India, Chennai
	Boston Scientific Corporation, Gurugram
Orthopaedic implant	Johnson & Johnson Pvt. Ltd., Mumbai
	Zimmer Biomet, Gurugram
Hernia Graft	Cook Biotech Inc.
Heart valve	St. Jude Medical India Pvt. Ltd., New Delhi
Others (Gloves, BP Apparatus, Dressing material etc.)	Others (Bapuji Surgicals, Jam Healthcare, Ethicon,Smith and Nephew Ltd etc)