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

LOK SABHA
UNSTARRED QUESTION NO. 4185
TO BE ANSWERED ON 13TH DECEMBER, 2019

DEATH FROM FAULTY IMPLANTS

4185. MS. RAMYA HARIDAS:
SHRI MARGANI BHARAT:
DR. SHRIKANT EKNATH SHINDE:

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

(a) whether the 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 the attention of the Government 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 if so, the details thereof;

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

(d) whether it is true that the Government has set up a Committee to look into the side effects of medical devices and if so, the details thereof;

(e) the manner in which the Government imposes penalties on manufacturers of medical devices without incorporating it in the Drugs and Cosmetics Act; and

(f) the steps taken to amend the Drugs and Cosmetics Act for this purpose?

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

(a): The Government has not received such reports.

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(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.

(d): No.

(e) & (f): Notified medical devices are regulated under Drugs & Cosmetics Act, 1940 and Medical Device Rules, 2017 thereunder. The Act provides for penalties in case of violation of its provisions.

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