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

LOK SABHA
STARRED QUESTION NO.74
TO BE ANSWERED ON THE 14TH DEEMBER, 2018
FAULTY MEDICAL IMPLANTS

***74. DR. KAMBHAMPATI HARIBABU:**

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

(a) whether the Government has taken cognizance of the increasing faulty medical implants in the country and if so, the details thereof;

(b) the steps being taken to hold the manufacturers and importers accountable for faulty medical implants; and

(c) the details of regulatory conditions in place to safeguard the concerns of the patients?

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 LOK SABHA STARRED QUESTION NO.74* FOR 14TH DECEMBER, 2018

(a) & (b): The Central Government through the Central Drugs Standard Control Organisation (CDSCO), takes cognizance of faulty notified medical implants for corrective action under the Drugs & Cosmetics Act, 1940 and Rules thereunder as and when such reports are received. The Government has not received any such report that there is an increase in faulty medical implants in the country.

(c): To have comprehensive regulatory provisions for import, manufacture, sale and distribution of medical devices based on risk based criteria, Government has notified the Medical Devices Rules, 2017 which became effective from 01 January 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, efficacy 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.

Further, Ministry of Health and Family Welfare has approved the commencement of "Materiovigilance Programme of India (MvPI)" with Indian Pharmacopoeia Commission, 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.

Under the Medical Device Rules, there is also 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 is required to immediately initiate procedures to withdraw the medical device in question from the market and patients.

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