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

LOK SABHA
STARRED QUESTION NO. 11
TO BE ANSWERED ON THE 21ST JUNE, 2019
CASES OF FAULTY IMPLANTS

***11. SHRI JANARDAN SINGH SIGRIWAL:**

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

(a) whether the Government has come across cases of faulty implants being supplied to Government hospitals by a multinational company and if so, the details thereof;

(b) whether a large number of implants done at major Government Hospitals have gone wrong and patients have to undergo revision surgery and if so, the details thereof and the reasons therefor;

(c) whether the Government is aware that the Security and Exchange Commission (SEC) of United States has slapped a huge penalty on a leading manufacturer of orthopedic implant devices for violating norms in India, China and Kuwait and if so, the reaction of the Government thereto;

(d) whether the Government has initiated any investigation in this regard and if so, the details thereof and if not, the reasons therefor; and

(e) the measures being taken by the Government to regulate the medical devices market in the country?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. HARSH VARDHAN)

(a) to (e): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 11* FOR 21ST JUNE, 2019

(a) The issue of adverse effects of the products requiring higher rate of revision surgeries in patients implanted with Articular Surface Replacement (ASR) hip implant imported by M/s DePuy Medical Private Limited (Now Johnson & Johnson) was reported to Central Drugs Standard Control Organisation (CDSCO), Ministry of Health and Family Welfare.

The Government had constituted a committee to examine the issues relating to faculty ASR Hip Implants. The Committee, after detailed examination of the issue, submitted its report to the Government, which accepted the recommendations with some modifications. Based on the accepted recommendations, the Government constituted a Central Expert Committee under the Chairmanship of Dr. R. K. Arya, Director, Sports Injury Centre, Safdarjung Hospital, New Delhi, inter-alia to determine the quantum of compensation.

The Ministry of Health & Family Welfare has also requested all the States/UTs to form State Level Committees to examine the claims of affected patients within their jurisdiction so that the process is less arduous for the patients.

A formula for determining compensation for the affected patients has also been formulated and placed in public domain. The affected patients can approach either the Central Expert Committee or State Level Committee as per their convenience.

M/s Johnson & Johnson Pvt. Ltd. has been asked to comply with the recommendations of the Committee and to pay the compensation as per the formula approved by the Government in the interest of the patients. However, M/s Johnson & Johnson Pvt. Ltd has challenged the expert committee report on payment of compensation before the Hon'ble High Court of Delhi.

(b) As per the records provided by M/s Johnson and Johnson, out of 4700 patients implanted with ASR hip implants, 292 patients have undergone revision surgery due to ASR hip implant.

(c) & (d) No complaint has been received by Government in this regard.

(e) The manufacture, sale and distribution of Medical Devices is regulated under Drugs and Cosmetics Act and Medical Device Rules, 2017. These rules were published by Government of India on 31st January, 2017 and became effective from 1st January 2018.

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