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

LOK SABHA
UNSTARRED QUESTION NO. 1056
TO BE ANSWERED ON 08TH FEBRUARY, 2019

CASE OF FAULTY IMPLANTS

1056. SHRI MANSHANKAR NINAMA:
DR. RAMESH POKHRIYAL "NISHANK":

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 it is a fact that 02 out of every 10 implants done at All India Institute of Medical Sciences, New Delhi have gone wrong and patients have to come for revision surgery and if so, the details thereof and the reasons therefor;

(c) whether the Government has taken note of the fact that the Securities and Exchange Commission (SEC), the top financial regulator in the United States has slapped a huge fine/penalty on a leading manufacturer of orthopaedic implant devices for violating its corruption norms in India, China and Kuwait and if so, the details thereof;

(d) whether the Government has initiated any investigation into the matter 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 which has so far remained unregulated and if so, the details thereof?

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

(a): The issue of adverse effects of the product requiring higher rate of revision surgeries in patients implanted with the 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 faulty 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 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 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): No.

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

(e): Medical devices are regulated as drugs notified under section 3 (b) (iv) of the Drugs & Cosmetics Act 1940 from time to time. Such medical devices are regulated under the said Act and Medical Devices Rules, 2017 made thereunder. At present, 23 Medical Devices are regulated under the provisions of said Act.

Further vide Gazette notification S.O. 5980(E), dated 03.12.2018, in pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, have specified the following 04 more devices intended for use in human beings as drugs with effect from the 1st day of January, 2020:

(i) Nebulizer;

(ii) Blood Pressure Monitoring Devices;

(iii) Digital Thermometer; and

(iv) Glucometer