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

RAJYA SABHA
UNSTARRED QUESTION NO. 103
TO BE ANSWERED ON 11TH DECEMBER, 2018

FATALITIES CAUSED BY FAULTY HIP IMPLANTS

103. SHRI RIPUN BORA:

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

(a) whether it is a fact that faulty hip implants manufactured by a manufacturer had resulted in deaths and disability of several patients;

(b) if so, the number of deaths and disability caused due to the faulty hip implants and whether compensation has been paid to the victims; and

(c) whether Government was aware that the hip implants of the same manufacturer were recalled in the United States due to its faulty equipments and if so, the reasons why it was allowed to market the product in India?

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

(a) & (b): As per the information available with Central Drugs Standard Control Organisation (CDSCO), Ministry of Health and Family Welfare, 277 revision surgeries were undertaken because of disability due to faulty Articular Surface Replacement (ASR) Hip Implants manufactured by M/s DePuy International Limited, UK, (now M/s Johnson & Johnson Pvt. Ltd).

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.

(c): The product was recalled in the USA in August 2010. In India, the firm recalled it on 24.08.2010 and Central Drugs Standard Control Organisation (CDSCO) acknowledged their recall and no further import of the product was allowed.