

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

**LOK SABHA  
UNSTARRED QUESTION NO. 2908  
TO BE ANSWERED ON 28<sup>TH</sup> DECEMBER, 2018**

**FAULTY HIP IMPLANTS**

**2908. SHRI P. NAGARAJAN:  
SHRI MUTHAMSETTI SRINIVASA RAO (AVANTHI):  
SHRI RAJESH KUMAR DIWAKER:  
DR. C. GOPALAKRISHNAN:  
SHRI KIRTI VARDHAN SINGH:**

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

- (a) whether the Government is aware of the faulty Hip-implants cases which has led to unbearable suffering to the patients;
- (b) if so, the details thereof indicating the name of the company which supplied this faulty hip-implants in India;
- (c) the total number of patients affected/suffered by the faulty hip implants, State/UT-wise;
- (d) whether the Government has constituted an expert group/Committee to investigate the matter in this regard and if so, the details and findings thereof along with the amount of compensations proposed to be given to each patient; and
- (e) whether the Government has imposed any penalty on the company who produced faulty hip implants and if so, the details thereof?

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

(a) & (b): Yes. 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 by the said firm.

(c): As per the information provided by the firm, 1058 patients were registered on Johnson & Johnson Helpline, out of which, 277 patients had undergone revision surgeries. Among the 277 patients, 250 were Indian patients. The State/UT-wise data of these patients is attached as **Annexure**.

(d) & (e): 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.

Further, in response to the reports of adverse events and recalls, the Import license of M/s. DePuy Medical Private Limited (Now Johnson & Johnson) was cancelled under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder.

**ANNEXURE**

<b>S.NO.</b>	<b>State Wise</b>	<b>Numbers</b>
1	Andhra Pradesh	9
2	Assam	1
3	Arunachal Pradesh	1
4	Chattisgarh	1
5	Gujarat	17
6	Haryana	11
7	Himachal Pradesh	2
8	Jammu and Kashmir	1
9	Jharkhand	4
10	Karnataka	14
11	Kerala	13
12	Madhya Pradesh	4
13	Maharashtra	65
14	Manipur	1
15	Meghalaya	1
16	New Delhi	7
17	Orissa	2
18	Punjab	8
19	Rajasthan	6
20	Sri Lanka	1
21	Tamil Nadu	39
22	Telangana	5
23	Tripura	1
24	Uttar Pradesh	24
25	Uttarakhand	2
26	Uttranchal Pradesh	1
27	West Bengal	9