

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

**LOK SABHA  
UNSTARRED QUESTION NO. 1110  
TO BE ANSWERED ON 08<sup>TH</sup> FEBRUARY, 2019**

**CDSKO REPORT ON FAULTY HIP IMPLANTS**

**1110. SHRI JAGDAMBIKA PAL:**

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

- (a) whether the Government has received any report from the Central Drugs Standard Control Organisation (CDSKO) on the issue of faulty ASR Hip Implants and if so, the salient findings and recommendations thereof;
- (b) whether the Government has accepted and acted upon the recommendations of the said report and if so, the details thereof and if not, the reasons therefor;
- (c) whether all of the affected patients in India have received compensation from Johnson & Johnson and if so, the details thereof and if not, the reasons therefor;
- (d) whether consultations were held with patients while deciding the formula, if so, the details thereof along with the basis of deciding on a formula for payment of compensation; and
- (e) whether the Government is proposing to take criminal action against Johnson & Johnson and if so, the details thereof and if not, the reasons therefor?

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

(a) to (e): The Government had constituted a committee to examine the issues relating to faulty Articular Surface Replacement (ASR) Hip Implants. The committee, after detailed examination of the issue, submitted its report. Specific recommendations of the Committee include:

- I. Compensation to ASR patients by the firm.
- II. Constitution of Central Expert Committee and Regional Expert Committees.
- III. Extension of ASR Reimbursement Program by the firm.
- IV. Health assessment of the patients.
- V. Patient awareness.
- VI. Medical Management to patients by the firm.

The Government 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 (**Annexure**). The affected patients can approach either the Central Expert Committee or State Level Committee as per their convenience.

Subsequently, the Central Expert Committee has invited the affected patients/their representatives/stakeholders in the meeting and given audience to those present in the meeting.

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.

Formula for determining compensation for the affected patients.

$$\frac{B \times R \times F}{99.37} + \text{Rs 10 lakh towards non-pecuniary damages.}$$

B is the base amount i.e., Rupees Twenty Lakh (Rs 20,00,000)

R is the Risk Factor-Disability

F is the Age Factor

Risk Factor (R)

Percentage Disability	Risk factor to be assigned
20% - 30%	1
30% - 40%	1.5
40% - 50%	2
50% & above	2.5

Age Factor (F)

Age	Factor
16	228.54
17	227.49
18	226.38
19	225.22
20	224.00
21	222.71
22	221.37
23	219.95
24	218.47
25	216.91
26	215.28
27	213.57
28	211.79
29	209.92

30	207.98
31	205.95
32	203.85
33	201.66
34	199.40
35	197.06
36	194.64
37	192.14
38	189.56
39	186.90
40	184.17
41	181.37
42	178.49
43	175.54
44	172.52
45	169.44
46	166.29
47	163.07
48	159.80
49	156.47
50	153.09
51	149.67
52	146.20
53	142.68
54	139.13
55	135.56
56	131.95

57	128.33
58	124.70
59	121.05
60	117.41
61	113.77
62	110.14
63	106.52
64	102.93
65 & more	99.37

For easy understanding of the patients, illustrative cases of the amount of compensation payable to the patients with ASR Hip implant with disability in relation to their Age and Percentage Disability would work out as below:

Age	Age Factor as per Clinical Trial Formula	Compensation Amount (in lakhs) for Disability 20-30% (Risk Factor 1)	Compensation Amount (in lakhs) for Disability 30-40% (Risk Factor 1.5)	Compensation Amount (in lakhs) for Disability 40-50% (Risk Factor 2)	Compensation Amount (in lakhs) for Disability 50% above (Risk Factor 2.5)
20	224.00	55.08	77.63	100.17	122.71
25	216.91	53.66	75.49	97.31	119.14
30	207.98	51.86	72.79	93.72	114.65
35	197.06	49.66	69.49	89.32	109.15
40	184.17	47.07	65.60	84.14	102.67
45	169.44	44.10	61.15	78.21	95.26
50	153.09	40.81	56.22	71.62	87.03
55	135.56	37.28	50.93	64.57	78.21
60	117.41	33.63	45.45	57.26	69.08
65 & above	99.37	30.00	40.00	50.00	60.00