

No. 29/MISC/03/2018-DC (388)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Medical Device Division)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 30 NOV 2018

To

All State/UT Drug Controllers,

Subject: Formula for grant of compensation to the patients who were implanted with ASR Hip and constitution of the State Level Committee-reg

Sir/Madam,

This is to inform you that the Central Expert Committee constituted by the Ministry of Health & Family Welfare had finalised a formula for grant of compensation to the patients who were implanted with ASR Hip. This formula was sent to the Ministry of Health & Family Welfare for their approval.

Now, the Ministry of Health & Family Welfare had approved the formula and the same is enclosed for your reference and further action in the matter.

That the Ministry of Health & Family Welfare vide letter X.11035/25/2015-DFQC dated 30.08.2018 and this office vide letter No. 29/MISC/03/2018-DC (389) dated 28.09.2018 has already requested you to ensure the formation of Central Level Committee and get the matter advertised in the newspapers. Also vide letter No. F. No. DCGI/Legal/Misc-68/2018-DC dated 09.11.2018, a copy of the draft advertisement for publication in newspaper was forwarded to you.

You are further requested to ensure that the State level Committee are constituted in your respective State/UT to examine the documents as received from the patients and also the patients as well as the advertisement is issued. The State/UTs where the State Level Committees have already been constituted may apprise the Central Expert Committee (through email at legalcell@cdsco.nic.in or by post at Legal Cell, CDSCO, FDA Bhawan, Kotla Road, New Delhi-110002)

about the cases received so far. With respect to the modalities of the examination of the patient and their documents, a detailed format is enclosed herewith for the ready reference of State Level Committee.

It is important to mention herein that as per the recommendations approved by the Central Government, the final report with respect to each individual patient has to be submitted to the Central Expert Committee within a period of 60 days from the date of receipt of the application by the State Level Committee.

Yours,



(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Enclosures:

- 1) Formula as approved
- 2) Modalities including undertaking

Copy to:

Principal/ Health Secretaries of all States/UTs

Brief Procedure for State Level Committee

State Level Expert Committee shall evaluate the Patient and ascertain:

If, ASR metal on metal hip replacement from DePuy International Ltd (Now Johnson and Johnson) is actually implanted & if, yes date of implantation vide document (discharge sheet etc) with implant stickers.

- A. If revision surgery is done.....
 - a. The date of revision surgery.
 - b. The percentage disabilities vide the certificate no..... dated & issued as per rule is..... % by competent authorities (As guided by Ministry of Social justice and Empowerment)
- B. If the revision surgery is not done.
 - a. The result of blood evaluation for metal ion toxicity i.e. levels of Cobalt, Chromium by Accredited path. Lab.
 - b. MRI (Metal Artefact reduction technique)
 - c. Based on (a) & (b) above whether condition of patient requires revision surgery or need to be kept under follow up observation.

After ascertaining the above facts the State Level Expert Committee shall furnish its report to Central Level Expert Committee in following Performa.

I. If revision surgery is undertaken:

Mr/Mrs 'XYZ' was implanted ASR Hip (metal on metal) Implant of DePuy International Ltd (Now Johnson and Johnson).

- a. On date..... when his/her age was..... vide document.....
- b. And he /she has undergone revision surgery on date..... when his / her age was (vide document like discharge sheet etc).

c. And his/her verified percentage disability as on date is.....
%.

Submitted the verified copies of all relevant documents along with this.

Signature of Member Secretary

Date : -

II. If revision surgery is not undertaken:

The report shall be given in following format

Mr / Mrs'XYZ' was implanted with ASR Hip(metal on metal) Implant of DePuy International Ltd (Now Johnson and Johnson)ondated& his Clinical Examination of blood, X-ray & MRI suggest revision surgery/ does not suggestrevision surgery at this stage but follow up at six monthly interval is advised.

Signature of Member Secretary

Date : -

Undertaking

I, Mr/Mrs.....S/o or D/o resident of.....Aadhar card/ voter card
No..... hereby submitting self-attested true copies of document which are authentic.
I undertake to submit the original documents for verification to State level
Committee/Central Expert Committee whenever required. In case the documents are
found to be fabricated/tampered with, I undertake to bear the legal responsibility of
the same.

The formula for the payment of compensation to the ASR patients is as mentioned herein below:

$$\frac{B \times R \times F}{99.37}$$

+

Rupees Ten lakhs (Rs 10,00,000) towards non-pecuniary damages

B is the base amount that is Rupees Twenty Lakhs (Rs 20,00,000)

R is the Risk Factor-Disability as per **Annexure A**

F is the Age Factor as per **Annexure B**

The Government of India, MoHFW has approved the formula for determining the compensation.

Annexure A

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

Annexure B

Factor (F) for calculating the amount of compensation

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