



ABSTRACT

Faulty ASR Hip Implant manufactured by M/s. DePuy International Limited U.K –
Constitution of State Level Committee – Orders - Issued.

HEALTH AND FAMILY WELFARE (M1) DEPARTMENT

G.O (Ms.) No.551

Dated: 29.11.2018

விளம்பி – கார்த்திகை – 13
திருவள்ளூர்வராண்டு 2049

Read:

1. From the Under Secretary to Government of India, Ministry of Health and Family Welfare, New Delhi letter No.11035/25/2015-DFQC dated 30.08.2018.
2. From the Drugs Controller General (I), Government of India, Ministry of Health and Family Welfare Department, New Delhi, letter No.29/Misc./03/ 2018-DC, dated 28.09.2018.

ORDER:

In the letter first read above, the Under Secretary to Government of India, Ministry of Health and Family Welfare Department has stated that the Ministry of Health and Family Welfare, Government of India, had constituted an Expert Committee under the Chairmanship of Dr. Arun Kumar Aggarwal, Ex-Dean and Professor of ENT, Maulana Azad Medical College, New Delhi to examine the issues relating to faulty ASR Hip Implants manufactured by M/s. DePuy International Limited, U.K. The committee, after detailed examination of the issues submitted its report alongwith its final recommendation. The report of the committee has been examined in the Ministry of Health and Family Welfare Department, New Delhi and accepted with some modifications. The recommendations which have been accepted after certain modifications are as under:-

- a. State Level Committees, instead of Regional Committees, should be formed to enable hassle-free access to the patients as they can easily approach the State Level Committee in their respective States. The patients can also be given preference to approach either of the two committees.

b. The eligibility criteria for compensation as accepted is an under:-

Sl.No.	Category of Patient	Eligibility to make application to the State Level/Central Expert Committee
1.	Patients implanted with ASR and no revision surgery performed or recommended to perform	Eligible
2.	Patients implanted with ASR and one revision surgery performed but no disability	Eligible
3.	Patients implanted with ASR and one revision surgery performed and suffering with disability	Eligible
4.	Patients implanted with ASR and more than one revision surgery performed and suffering with disability	Eligible
5.	Patients implanted with ASR and suffering with any other systemic disorder where the causality is established	Eligible

And

6. First Surgery of ASR must be performed in India on or after the year 2006; Patient must be implanted with ASR within 10 years from the date of first surgery; or
 7. Patients who have been implanted with ASR between 10 to 15 years from the date of first surgery and is symptomatic.
- c. Determining the quantum of compensation, as admissible under appropriate law, by the Central Expert Committee:

The Central Committee shall review the report of the State Level Committee and also other documents submitted by the patients. Quantum of the compensation will be determined by the Central Expert Committee based on the following.

- i. Base amount of Rs.20 Lakh
- ii. Degree of disability

- iii. Patient suffering on account of monetary loss due to loss of wages and other losses
- iv. Percentage Disability of the patients
- d. Paper advertisement: Advertisements in newspapers are to be brought out by respective State Governments. Affected patients may approach concerned State Drugs Controller, who can be Member Secretary of State Level Committee.
- e. Composition of Central Expert Committee & State Level Committee:
 - (i) The Central Expert Committee shall comprise of the following:
 - (a) Head of the Department, Orthopaedic / Physical Medical Rehabilitation (PMR) expert of a Tertiary Government Medical College and Hospital who will act as the Chairman;
 - (b) Two Orthopaedic Surgeons / Physical Medical Rehabilitation (PMR) experts from Government Medical College and Hospital;
 - (c) One Clinical Pharmacologist;
 - (d) One Legal Expert;
 - (ii) State Level Committee would comprise of the following:
 - (a) Two Orthopaedic Surgeons / Physical Medical Rehabilitation (PMR) experts from Government Medical College and Hospital.
 - (b) One Radiologist from the Government Medical College and Hospital.
 - (c) CDSCO Zonal / Sub Zonal Office representative
 - (d) Drugs Controller of respective state as Member Secretary
- f. Procedure for making application:

Patients would approach either Central Expert Committee or State Level Committee as per their convenience. The Central Expert Committee with the assistance of State Level Committee will arrive at the exact amount of the compensation, as admissible under appropriate law, which will be communicated to Central Drugs Standard Control Organization (CDSCO). CDSCO will pass an order for grant for compensation.

2. The Under Secretary to Government of India, Ministry of Health and Family Welfare Department has therefore requested all the States/UTs to constitute the State Level Committee to enable the affected patients relating to faulty ASR Hip Implants manufactured by M/s. DePuy International Limited, U.K.

3. The Government of Tamil Nadu, accordingly constitute a State Level Committee with the following members to examine the issues of the affected patients relating to faulty ASR Hip Implants of M/s. DePuy International Limited, U.K.

i)	Thiru. K. Sivabalan, Director of Drugs Control, Chennai	Member Secretary
ii)	Dr. Dheen Md. Ismail HOD of Orthopedic Surgery, Madras Medical College, Chennai	Member
iii)	Dr. C. Ramesh Director, Institute of Physical Medical Rehabilitation, KK Nagar, Chennai	Member
iv)	Dr. R. Ravi HoD of Radiology, Madras Medical College, Chennai	Member
v)	Ms. Shanthi Gunashekarani, Deputy Drugs Controller (I)	Member

(BY ORDER OF THE GOVERNOR)

J. RADHAKRISHNAN,
PRINCIPAL SECRETARY TO GOVERNMENT.

To
The Secretary, Government of India, Ministry of Health and Family Welfare,
Nirman Bhavan, New Delhi.
The Drugs Controller General, Government of India, DGHS,
Ministry of Health and Family Welfare Department,
CDSCO, FDA Bhawan, Kotla Road, New Delhi-110 002.
The Director of Medical Education, Chennai-10.
The Director of Drugs Control, Chennai-6.
All the Members of the Committee (through Director of Drugs Control)

Copy to:-

The Health and Family Welfare (Data Cell) Department, Chennai-9

SF/SC

// FORWARDED / BY ORDER //

[Handwritten Signature]
30/11/81
SECTION OFFICER