

No.X.11035/25/2015-DFQC
Government of India
Ministry of Health & Family Welfare
Department of Health & Family Welfare
(Drugs Regulation Section)

NirmanBhavan, New Delhi
Dated the 30th August, 2018

To

Principal / Health Secretaries of all States/UTs

Subject: Faulty ASR Hip Implant manufactured by M/s DePuy international Limited U.K.

Sir / Madam,

I am directed to say that the Ministry of Health & 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.

2. The committee, after detailed examination of the issues submitted its report alongwith its final recommendation. A copy of the report is **enclosed**.

3. The report of the committee has been examined in this Ministry and accepted with some modifications. A brief note bringing out the modifications subject to which the recommendations of the committee have been accepted is also **enclosed**.

4. As can be seen from the attached documents, action by State Governments / UT Administrations is required on the following points:

- a. **Constitution of State Level Committee:** The Committee should comprise the following:
 - a) Two Orthopaedic Surgeons / Physical Medical Rehabilitation (PMR) experts from Govt. Medical College and Hospital.
 - b) One Radiologist from the Govt. Medical College and Hospital.
 - c) CDSCO Zonal/Sub Zonal Office representative

d) Drugs Controller of respective state as Member Secretary.

- b. **Paper advertisement:** Advertisements are to be brought out by respective State Governments / UT Administrations in newspapers so that affected patients can approach the State Level Committee or the concerned State Drugs Controller, who would be the Member Secretary of the Committee, or the Central Expert Committee.
5. In view of the above, you are requested to take appropriate action in terms of the preceding para immediately so that affected patients can get relief.

Encl: A/a

Yours faithfully,

Signature valid

Digitally signed by R.G. Singh
GOPAL SINGH
Date: 2018.08.27 20:03:55 IST
Reason: Approved

(R.G. Singh)

Under Secretary to the Govt. of India
Tele: 23063019

**Brief Note on modifications in the recommendations of the Committee
as accepted by the Government**

The Committee has recommended, amongst other things, the constitution of Central Expert Committee and Regional Expert Committees for determining the exact quantum of compensation after taking into account the minimum amount of Rs.20 lakhs.

3. The Government has accepted the recommendations of the Committee with certain 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 as under:

Sr. 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 Govt. Medical College and Hospital.
 - b) One Radiologist from the Govt. 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.

5. Apart from the modifications which have been specifically brought out above, all other recommendations of the committee have been accepted.
