

STATE PANELS TO TRACK HIP IMPLANT PATIENTS

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The Ministry of Health and Family Welfare has said that State-level committees consisting of two orthopaedic surgeons or physical medical rehabilitation experts and one radiologist from government hospital, a representative from the Central Drugs Standard Control Organisation (CDSCO) and drug controller of respective States should be formed to identify patients who have received the faulty hip implant by pharmaceutical giant Johnson & Johnson.

The notification made public on Tuesday also said States should advertise widely to reach out to the patients.

“The committee [of the Ministry which submitted its report recently] has recommended, among other things, the constitution of [a] Central Expert Committee and Regional Expert Committees for determining the exact quantum of compensation after taking into account the minimum amount of 20 lakh,” the notification stated.

The compensation amount will be further calculated based on other factors such as the degree of disability and loss of wages.

“Patients can now reach out directly to the committees”, Drug Controller General of India (DCGI), Dr. S. Eswara Reddy told *The Hindu*, adding that more and more patients should now come forward. J&J’s Articular Surface Replacement (ASR) hip implant manufactured by its subsidiary DePuy Orthopaedics was recalled globally in 2010 after reports of it leaching metals and causing severe pain, fluid accumulation, and metal poisoning in patients. However, till date, only 1080 patients have reached out to the ASR helpline set up by the pharma company for guidance on revision surgeries and reimbursement process and 275 have undergone revision surgeries.

In 2011, the Maharashtra Food and Drug Administration (FDA) first initiated action against the pharmaceutical giant by registering an FIR at the Mahim police station in Mumbai and also alerted the DCGI.

“The police and the DCGI turned a blind eye to the matter,” said Dombivali resident Vijay Vojhala who underwent a hip implant surgery in 2008.

“I approached the Maharashtra government too but did not get any response”, he said.

Soon after the surgery, the implant caused him severe pain. Tests revealed extremely high levels of cobalt and chromium deposits in the body. In 2012, Mr. Vojhala underwent a revision surgery funded by the pharmaceutical company. “The onus of ensuring that the affected patients come forward for compensation was on the government. But all the authorities have been grossly negligent,” he said.

Dr. Reddy said a lot of work was done over the years which finally culminated in the report submitted to the Health Ministry. “It would be wrong to say that the DCGI had not acted”, he claimed.

Former FDA commissioner Mahesh Zagade who filed the FIR said the police initially were very active in the investigation. “I made my staff available for the investigating police officers as the case was not like other routine police matters. The company had approached the court to quash the FIR but they never got an order in their favour,” Mr. Zagade told *The Hindu*, adding that he later pushed for a CBI inquiry as well. “I feel that the DCGI was extremely slow in pursuing the case”, he said. After Mr. Zagade’s transfer in 2014, the FDA has seen three commissioners but the case lost its pace. The current commissioner Pallavi Darade said there is no action pending with the FDA.

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