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Govt plans medical device registry to help avoid repeat of J&J fiasco

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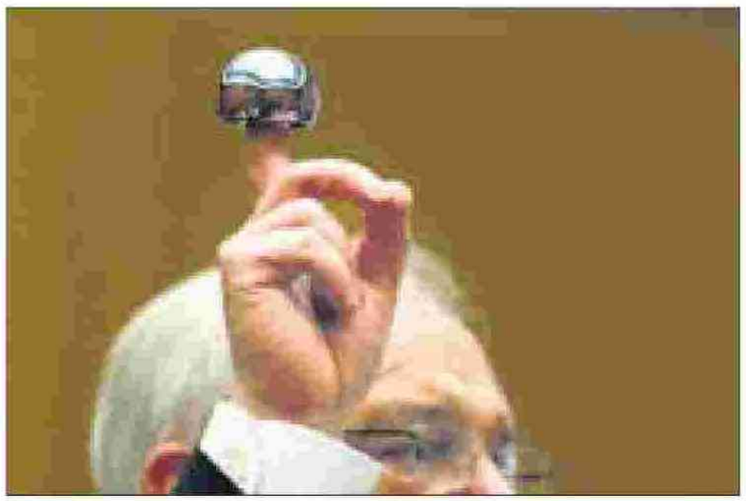

The move come in the wake of an investigation into hip implants manufactured by a J&J subsidiary that required some patients to undergo revision surgeries BLOOMBERG

NEW DELHI: An independent registry is in the offing to track implantable medical devices that could pose a risk to patients.

India's highest drug advisory board will take up a proposal for setting up a national registry for all implantable high-risk devices to protect patients in its next meeting, slated for November 27, according to two health ministry officials who asked not to be named.

The proposal is the result of a recent investigation by an expert committee on hip implants manufactured by a Johnson and Johnson (J&J) subsidiary that required some patients to undergo revision surgeries allegedly due to faulty designs.

The new registry being proposed will be on the lines of the UK's medicines and healthcare products regulatory agency (MHRA) and the Australian registry. "National registries are needed for all implantable devices to effectively study adverse effects associated with medical devices. This will protect patients and improve outcomes," said a senior official in the health ministry.

In the case of the J&J hip implant, the first warnings came from the National Joint Registry of England and Wales. In August 2010, the company voluntarily recalled articular surface replacement (ASR) implants worldwide after the England and Wales registry reported that 13% of patients with ASR implants ended up needing revision surgery.

In Australia, J&J's hip implant was withdrawn after an alert by the Australian Orthopaedics Association's joint replacement registry.

The Drug Technical Advisory Board (DTAB) will take up the proposal at its next meeting on November 27.

The registry aims to track the usage of high-risk medical devices, which, according to experts, would help prevent adverse events.

"This will help to issue warnings and alerts to the manufacturers and consumer in case of a device malfunction," said another official.

The official added: "Provisions may be introduced under the law to have legal backing for issuing alerts and warnings to a manufacturer. The registry will also help in providing a trend analysis of performance and usage of various medical devices in India annually."

As many as 4,700 patients in India had received ASR hip implants manufactured by J&J subsidiary DePuy Orthopaedics Inc between June 2004 and August 2010.

In 2017, the Union health ministry formed an expert committee headed by former dean of Maulana Azad Medical College Dr Arun Agarwal that found the ASR hip implants manufactured by DePuy International Ltd to be "faulty" and to have resulted in higher instances of revision surgeries globally, including in India.

According to officials at the drug regulatory authority, the new mechanism will avoid such situations

The committee had also suggested establishment of an independent registry for tracking use of high-risk medical devices by the health ministry.

The committee, after deliberations on the issues and review of the documents had found the firm to be "evasive" in providing the information regarding the design of the ASR, and patient details.