

Govt may cap orthopaedic implant prices

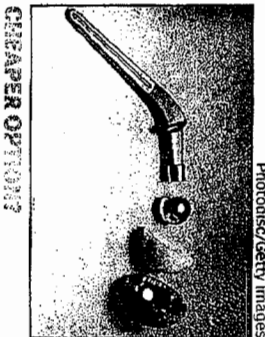
Rupali Mukherjee
@timesgroup.com

Mumbai: Soon, there may be ceiling prices, fixed by the government, on orthopaedic implants. Alarmed with the sharp spike in prices of orthopaedic implants, drug pricing regulator National Pharmaceutical Pricing Authority (NPPA) has directed manufacturers—such as Johnson & Johnson (J&J), Zimmer and Stryker—to submit details of production and pricing of their products, including those for knee and hip. At present there are no price caps on these medical devices. The companies will also need to submit the increase in prices effected by them over the last three years, the NPPA communication on June 17 said.

Sources said that the gov-

ernment has initiated the process of setting ceiling prices for exorbitantly-priced medical devices like cardiac stents and implants. It also wants to ensure that the price increase in devices is less than 10% annually, as these are regulated as 'drugs' under the Drugs and Cosmetic Act. (All non-scheduled drugs—prices of which are not controlled—are allowed an annual increase of 10% under the Drug Price Control Order, 2013). Hip and knee implants cost around Rs50,000 to Rs90,000 on an average, depending on the type of implant used.

This is the second time that the NPPA has asked medical device manufacturers to submit data like the maximum retail price (MRP) and landed cost (cost at which imported). In an



earlier communication sent out in May this year, it had sought details acting on "media reports highlighting the exorbitant prices and huge margins". Since most of these devices are imported into the country, their prices are already high, and they go up further with the duties levied on them. The cost to patient is high as these are sold at a huge margin. Worse, the pricing structure is opaque with companies not submitting the pricing details to the regulator, and there is no method of determining the margin charged by the distributor or hospital.

When contacted, a J&J executive said they would be submitting the pricing data again, though they had sent it earlier too. Last year, a Maharashtra Food and Drug Administration report to the government said that drug-eluting stents were sold with huge mark-ups, sometimes nearly double the landed cost. The government seems to be serious in monitoring the prices of these vital devices as it had issued show-cause notices to companies for not having revealed prices earlier this year.

In another development, the NPPA has asked 19 drug companies to register for an online database, which is a pre-requisite for price fixation in respect of scheduled drugs and new drugs, and for monitoring production and availability of scheduled formulations. The companies include Wockhard, IPCA Labs, British Biologics, Danone, Dabur India, Indoco Remedies and Alkem Laboratories.

Last September, the NPPA had asked all pharma companies to register online with the Integrated Pharmaceutical Database Management System (IPDMS). With the transition from DPCO 1995, which followed cost-based mechanism for price fixation, to the DPCO 2013, which follows market-based mechanism for price fixation, reference data and source of market-based data has assumed critical importance, an analyst said.

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