

## is the price control of stents essential?

### What did the regulator do?

The National Pharmaceuticals Pricing Authority (NPPA), India's drug pricing regulator, has further brought down the cost of drug-eluting stents (DES) from Rs. 29,600 to Rs. 27,890, while marginally increasing the cost of bare-metal stents from Rs. 7,400 to Rs. 7,660.

The move comes a year after the NPPA slashed stent rates by nearly 85%. Price control, it said, "is necessary under the failed and exploitive market system characterised by exorbitant, irrational and restrictive trade margin."

The NPPA said it was "immediately necessary to fix the ceiling prices of coronary stents in order to protect public interest." Coronary stents are used to open narrowed arteries, reduce symptoms like chest pain and treat a heart attack.

### How will it help?

Doctors say the move will help more people opt for DES that are technologically better and more advanced. In just one year after price regulation, the use of bare-metal stents has been reduced by 30% and replaced by DES.

Bare-metal stents have a significantly higher rate of restenosis (the recurrence of abnormal narrowing of an artery or valve after corrective surgery) and the need for target vessel revascularisation or restoration of perfusion to a body part or organ that has suffered ischemia compared with all DES. "Affordability matters," NPPA Chairman Bhupendra Singh said.

The new order also allows transparency and better government control and audit ease. With this order, patients will have the option to get a stent and accessories from outside the establishment, and manufacturers are allowed only 8% trade margin. Also stents selling lower than the ceiling rates cannot go up in price now after the new order.

The Indian Medical Association has noted that "this is a bold move by the NPPA."

Dr. K.K. Aggarwal, immediate past president of the IMA, said: "Cardiac-related diseases are rising in India. Poor accessibility to quality health care and high pricing is a major deterrent for people seeking medical care. Price capping will minimise the expenditure in the health sector and allow more people to benefit from it."

Doctors also say the move sends a strong message to private players that profiteering at the cost of life is unacceptable. "This has also brought back attention to the needs of the patients and is now encouraging people to opt for better treatment plans and most importantly break the nexus of unethical pricing," Dr. Aggarwal noted.

The NPPA also decided against the request of multinational stent makers for a new category for advanced stents.

### Was there a need?

A core committee, which examined the issues relating to the essentiality of coronary stents, observed in its report to the government in April 2016 that there is a very high incidence of coronary artery disease (CAD) in India associated with high morbidity and mortality; and CAD has

become a major public health problem.

The NPPA held meetings with eminent cardiologists, who said the price cap had resulted in more angioplasties and fewer bypass surgeries. The NPPA also met stakeholders on February 5 and 8.

At a meeting held on February 13, the NPPA said it examined all available information/data of coronary stents supply chain and all relevant options for price fixation of coronary stents before announcing the new rates, which will be valid till March 13, 2019.

“This is being done to prevent the cardiac stents market from falling back to its old archaic state... and an extraordinary failed market system,” the NPPA noted.

### **What lies in store?**

Based on available data from official sources and manufacturers/importers, the NPPA is now analysing the trade margins in the cardiac guidewire/balloon catheter and guiding. The analysis by the authority notes that profit margins are as high as 400% in this area and thus may need government intervention for cost optimisation. The NPPA has sought comments and views of stakeholders in this matter.

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