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CORONARY STENTS' PRICE CAPPED

Patients welcome move, industry not so much

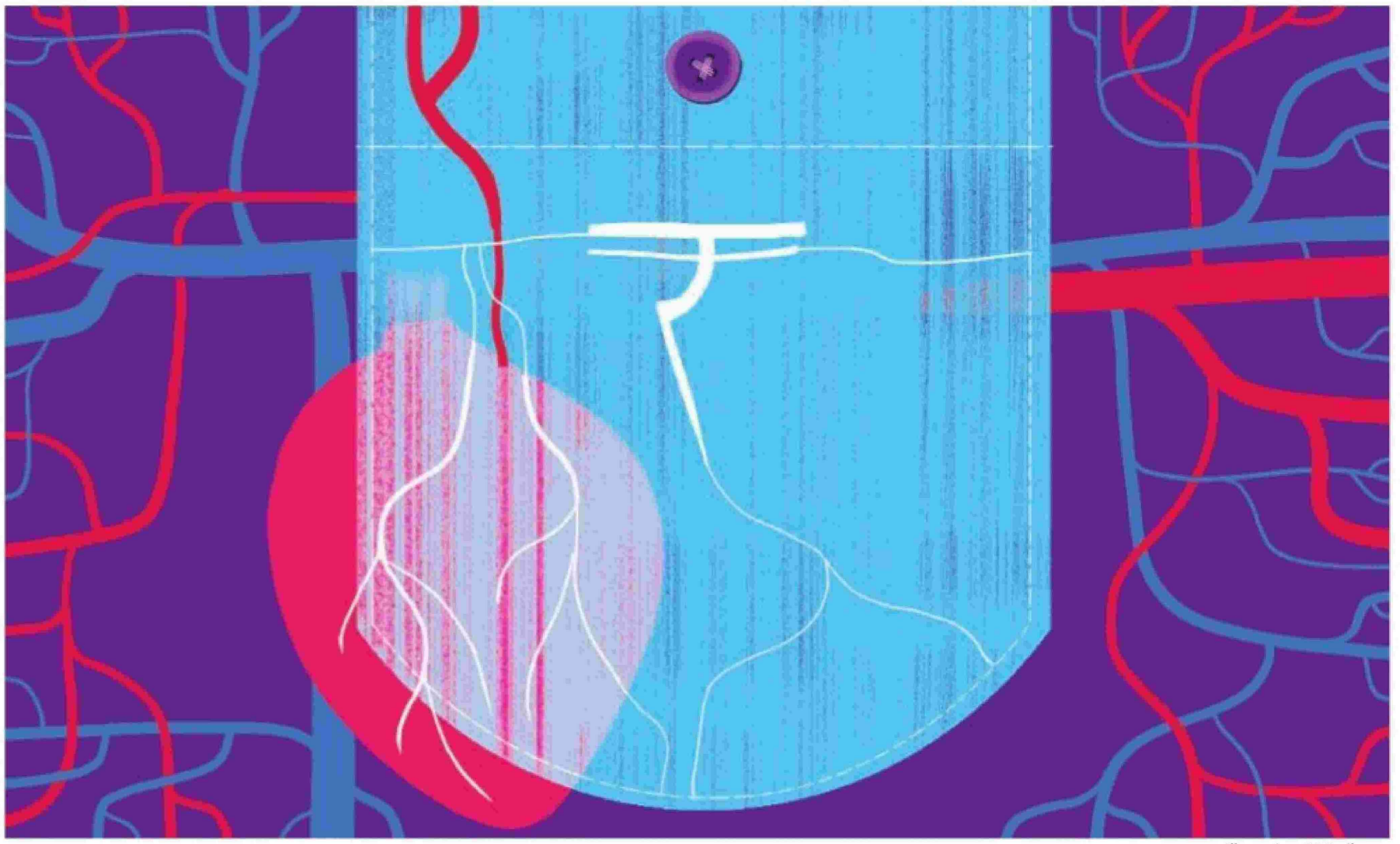

Illustration: C R Sasikumar

With the burden of diabetes and hypertension rising in the country, the NPPA move has been welcomed by activists. However, the industry says it will deprive patients of latest tech advancements

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THE NOTIFICATION by the National Pharmaceutical Pricing Authority (NPPA) on February 13 capping the price of coronary stents at a level up to 40 per cent lower than their existing market rates has brought the curtains down on a long-winded saga that started with the inclusion of these devices in the National List of Essential Medicines in July last year.

Here's all you would want to know about the decision; why it was taken and what it means for patients and the industry, which predictably has not taken the news too kindly.

What is the price ceiling fixed for coronary stents?

The notification categorises stents into two kinds: Bare metal stents (BMS) and drug-eluting stents. A stent is a tube-shaped device that, when inserted into a blocked blood vessel, can help clear the blockage, sometimes through physical means but often through the drugs it gives out at a slow rate. The price cap for BMS is Rs 7,260 while that for a drug-eluting stent is Rs 29,600. This is about 40 per cent lower than the existing prices with the range currently at Rs 25,000-Rs 1,50,000. Industry sources say that 35 per cent of the products are available at the lower end of the spectrum.

Does this also include imported stents?

The notification makes no distinction whatsoever on whether a stent is branded or unbranded, manufactured locally or abroad. So long as it is being sold in the country, no stent can cost more than Rs 29,600 though there is room for addition of local taxes, VAT, etc. "The ceiling price for a pack of coronary stents shall be arrived at by the concerned manufacturer/importer in accordance with the ceiling price specified in column (4) of the above table as per the provisions under DPCO, 2013," reads the notification making it clear that imported stents, too, are within its ambit. It also makes it clear that while manufacturers currently selling at prices higher than the cap will have to bring down prices, those selling at lower than the ceiling prices will have to maintain the existing MRP.

Does it only apply to stent manufacturers/marketers/importers?

It does not. The notification clearly takes into account the fact that a stent will have to be put in by a hospital set-up and the product is usually billed by institutions rather than the people selling them. Institutions such as hospitals, nursing homes and clinics performing cardiac procedures using coronary stents and billing directly to patients also will have to comply with the price ceilings. "Institutions such as hospitals/nursing homes/clinics utilising coronary stents shall specifically and separately mention the cost of the coronary stent along with its brand name, name of the manufacturer/importer/batch no. and other details, if any, in their billing to the patients or their representatives," says the notification.

What is the size of the Indian stent market?

Industry estimates suggest that the market is worth $500 million. It is expected to grow many times in the coming days thanks to the huge burden of diabetes and hypertension in the Indian population. That in fact is also the reason why it is the first item outside of drugs to be treated as such and brought under price control. The core committee that examined the pros and cons of bringing coronary stents under price control in its report to the government last year cited the high incidence of coronary artery disease (CAD) in India describing it as a "major public health problem". Percutaneous coronary intervention which is the term used for the procedure by which a coronary stent is inserted, is an important treatment option for CAD. That is why stents were ruled to be "essential" for public health, a criterion that is key to the price control principle.

What regulatory changes allowed stents to be brought under price control?

In July 2016, the Ministry of Health and Family Welfare included coronary stents in the National List of Essential Medicines, 2015 (NLEM, 2015). Subsequently on December 21, 2016, the Department of Pharmaceuticals incorporated coronary stents at number 31 of Schedule I of the Drug Prices Control Order, 2013 effectively giving it the status of a "scheduled formulation" as defined in the Drug Price Control Order 2013. The aim of DPCO, 2013, issued under Section 3 of Essential Commodities Act, 1955, is to ensure that essential drugs are available to all at affordable prices.

How was the ceiling price calculated?

According to the National Pharmaceutical Pricing Policy 2012, the price ceiling of any commodity is taken as the simple average of all brands of that particular product that have a market share of at least 1 per cent. During the time when the price cap was being arrived at, there were demands from the industry that the "generation" of the stent be taken into account while formulating the cap. Some of the criteria that decide the "generation" of a stent are whether it is made of metal or polymer, whether it has drug eluting properties or not, and also the design. Thinner the stent, more sophisticated and expensive it is supposed to be. The thickness may vary from 70 to 150 micron. A committee was formed under a joint secretary in the health ministry to look at the options of categorisation. However in the end distinction was made only on the basis of whether it gives out a drug or not.

How has the industry reacted to this order?

The industry has been very unhappy with the price cap and the fact that there were just two categories into which the entire gamut of coronary stents were put. There have been dire predictions of patients being deprived of the latest technological advancements.

"The medical technology industry is disappointed with this outcome. The industry was expecting a reasonable price along with rational differentiation in drug eluting stents, to recognise innovation. Additionally, since this order is being enforced from immediate effect without provision of a transitory period, Indian stents industry is going to face enormous operational challenges in the coming time," said CII medical technology division chairman Himanshu Baid in a statement.

Health activists welcomed the move. "We are pleased that the NPPA took note of the extraordinary circumstances in respect of the unmet health need and the prevailing conditions of extreme overpricing of stents and exploitation of patients. We strongly support the use of Paragraph 19 of the DPCO to set right the balance in favour of the public interest," said Malini Aisola of the All India Drug Action network.