



Price Control of Medical Devices

What is the issue?

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It is alarming and worrying when a couple of top **stent makers** decide to withdraw some products from the country — a move, they say, is in response to the Government's price control efforts.

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What prompted this issue?

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- A stand-off between the Government and industry is not without precedent - price control on medicines is an example.

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- But medical devices have come into the Government's price net for the first time.

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- With data from the National Pharmaceutical Pricing Authority (NPPA) revealing exorbitant distribution margins exercised each time a stent changed hands before it reached the patient at an **inflated price**, the case for a crackdown was made.

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- It all started with the National Pharmaceutical Pricing Authority (**NPPA**) **announcing a price ceiling for stents** in mid-February.

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- The government brought stents under **the National List of Essential Medicines** and effected a sharp cut in prices.

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- While the price of a bare metal stent was capped at Rs 7,260 (as against a starting market price of Rs 25,000), that of the drug-eluting and the biodegradable ones, which cost up to Rs 2 lakh, was capped at Rs 29,600 apiece.

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- The decision, which was in accordance with a Delhi High Court order seeking action, was evidently a popular move. But the companies begged to differ.

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What the manufacturing companies say?

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- Three multinational stent manufacturing companies have **sought to withdraw their cutting edge stents from the Indian market**, stirring concern about the long-term impact of such an exodus on patient care in India.
- The companies, as well as several hospital administrators, argued that as the government's price control order treated all drug-eluting stents as equivalent, disregarding differences, it should not in principle have any objection to companies withdrawing some stents and maintaining a steady supply of others.

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How the Government responded?

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Stung by this withdrawal, the government has **invoked an emergency clause** in the Drug Price Control Order (2013) and has asked the manufacturers **to maintain uninterrupted supply** of all types of stents.

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What are the implications?

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- It was feared that while complying with the government diktat making it mandatory for hospitals to bill stents separately from surgical procedures, **hospitals would simply charge more for other services.**
- In any case, there was no way the government could monitor this.

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- But the bigger problem was about the ***scarcity of quality stents***.
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- When the price cap was announced, some doctors did say that in the absence of quality products, patients needing critical care would have to compromise by using inferior Chinese stents.
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- Reports suggest Chinese stents are gaining massively from the gap created by the shortage of stents from the US.
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What is the way ahead?

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- **Price control is a poor policy choice.** At the very best it provides some temporary relief and only helps in creating a grey market.
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- Invoking an emergency clause to ask companies to maintain supply of stents is a desperate solution.
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- **Differential pricing has to be the answer** when it comes to the entry of the latest technology into India.
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- The health ministry needs to outline guidelines for the use of stents and commission an independent comparative study of Indian and foreign stents to establish what is safe and revolutionary and call the bluff of pretenders.
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- And on prices, NPPA and industry need to discuss methods to bring in good, effective products at affordable prices through better sourcing and financing support for patients.
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Source: Business Line & Business Standard

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