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Price caps on implants, stents may be replaced by margin restrictions

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NEW DELHI: The government is planning to control prices of medical devices by restricting their trade margins, a departure from the existing mechanism of capping prices, two people aware of the matter said.

There has been more or less a consensus among government think tank NITI Aayog, health ministry, department of pharmaceuticals and the department of industrial policy & promotion on regulating trade margins on medical devices, the people said, requesting anonymity.

Once the new mechanism is decided, it will apply to devices such as cardiac stents and knee implants, prices of which were slashed by as much as 85% using powers under the Drugs Price Control Order (DPCO), 2013. The move had drawn severe criticism from the medical devices industry, which claimed that the government move would curb innovation. There are three separate formulae under consideration and one of the three will be decided for calculation of maximum retail price (MRP) in the next few days.

One view is that trade margins should be calculated from the import price itself. It means that the MRP should be decided by adding the landed cost to the percentage of the trade margin. The percentage will be decided by the government. There is another view that many expenditures are incurred by the importing companies including clinical education on deployment and therefore the trade margins should start from the first point of sale that is the stockist. In this case, MRP will be decided by adding the price at the first point of sale (stockist) to the percentage of the trade margins.

A third view is that the companies may be allowed to separately show the mark up over and above the landed cost. The companies will therefore arrive at the MRP by adding the landed cost to mark up due to services and percentage of trade margins.

"Out of three mechanisms, one will be chosen and once it's done medical devices will come out of the ambit of DPCO," said one of the two cited above.

As of now, 23 medical devices have been notified as drugs and are regulated under the Drugs and Cosmetics Act. Of these, only four — cardiac stents, drug-eluting stents, condoms and intra-uterine devices — have been included in the National List of Essential Medicines (NLEM) and are therefore subjected to notified price ceilings. Last year, knee implants were brought under price control under para 19 of the Drugs (Price Control) Order, 2013. The remaining medical devices are not under any form of price regulation.

Govt's prescription

- The government wants to impose curbs on trade margins for medical devices such as cardiac stents, knee implants
- Move would be a departure from the current practice of DPCO setting price caps
- The debate between the govt and the medical devices lobby and firms is on the location of the first point of sale
- At present, 23 medical devices are regulated by the Drugs and Cosmetics Act

- Of these, only cardiac stents, drug eluting stents, condoms and intra-uterine devices are on the National List of Essential Medicines and hence subjected to price ceilings