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Med devices like stents, implants set to come under price control

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The objective of the new policy is to strengthen the Make In India drive by reducing dependence on imports and setting up a strong base for medical devices, especially those with critical implications

Mumbai: Faced with complaints of overpricing of medical devices like cardiac stents and implants, the government seems to be finally getting its act together.

According to a government official, in a string of measures to regulate the industry under the Draft National Medical Device Policy, it has recommended creating an autonomous body — the National Medical Devices Authority (NDMA) — pricing control for medical devices by including them under the Essential Commodities Act and, most importantly, floating a separate pricing division in the drug pricing regulator, NPPA.

Significantly, the draft says the government may announce a separate policy for regulating prices of identified medical devices and implement it through a separate medical devices control order. Currently, prices of medicines are notified through the Drug Prices Control Order, by the department of pharmaceuticals.

The NMDA may be headed by an officer of the rank of additional secretary/joint secretary and include a member secretary (rank of joint secretary), two medical practitioners, two medical device technologists or scientists and the secretary general of Quality Council of India (ex-officio).

In a patient-friendly measure, the draft mentions adopting policies on efficacy and safety testing, and quality control through a 'Made in India' marking (BIS) specific to medical devices in line with global standards.

In fact, the objective of the National Medical Device Policy 2015 is "strengthening the Make in India drive by reducing dependence on imports and setting up a strong base for medical devices, especially those with critical implications in terms of affordability and availability of patients".

Medical devices, which are classified as equipment, implants and disposables, are mainly import driven, with nearly 70-80% high-end devices and equipment brought into the country, while the domestic industry manufactures disposables and medical supplies. "Lack of national regulation helped the MNCs in doing business in this sector," it says.

Incidentally, the Drugs and Cosmetics (Amendment) Bill, 2015, for providing regulation on medical devices is also in the legislative process.

Over the last few months, there have been complaints about overcharging, with regulators investigating cases where patients have coughed up almost three to four times the landed cost (price at which these are imported) for certain devices like cardiac stents and, hence, sold with huge mark-ups of 250-400%.

The draft policy, which has been put up on the department of pharmaceuticals (DoP) website and communicated to industry bodies and chambers, seeks comments within six weeks, after which a final note will be prepared for Cabinet approval.

When contacted, AIMED (Association of Indian Medical Devices Industry) forum coordinator, Rajiv Nath said: "It (the draft) contains mostly very good content and is on the lines of our recommendations, but it does need some fine-tuning for ensuring more clarity of direction."

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