Pricing reforms for drugs, med devices in the works

Centre forms committee, report likely in 3 months

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Soon, pricing regulations for drugs and medical devices in India may undergo reforms as the Centre appoints a committee to propose changes to the pricing framework.

Industry sources suggest that a new Drug (Prices Control) Order (DPCO) may be in the works, considering the current DPCO 2013 is already 11 years old.

Pricing regulations are periodically reviewed to ensure relevance for both the industry and consumers, said a source.

In a March notification, the Department of Pharmaceuticals (DoP) said that a committee is constituted for "reforms in the pricing framework for drugs and medical devices" with the approval of a "competent authority".

Business Standard has obtained a copy of the notification.

The committee will comprise three core members: Secretary, DoP; chairman, National Pharmaceutical Pricing Authority (NPPA); and senior economic advisor, DoP. Additionally, two special invitees from the industry will join — secretary-general of the Indian Pharmaceutical Alliance and chief executive officer of the Indian Drug Manufacturers Association (IDMA). The committee aims to submit its report within three months.

The DoP notification outlines that the committee will focus on "institutional reforms within the NPPA". It will strive to balance the price and availability of essential medicines, provide incentives to the industry for sustainable growth and exports, design a price moderation framework for emerging and precision therapies, and draft a new Drugs and Medical Devices (Control) Order to achieve these objectives.

Confirming the development, Viranchi Shah, national president, IDMA, said, "This is a regular exercise done periodically, and as a responsible industry, we will provide constructive inputs."

The pharmaceutical (pharma) industry expects the implementation of a new DPCO next year.

"The DPCO has been updated from time to time, and currently we are following the DPCO 2013. It is about time to review it. The pharma industry has made several representations to the Centre on issues it is currently facing, and these are likely to be discussed," the source said.For example, the industry feels that a mechanism of determining ceiling prices of scheduled drugs by working out the simple average of price to retailer in respect of all branded-generic and generic versions of that particular drug formulation having a market share of 1 per cent and above and then adding a notional retailer margin to it, is not a very efficient way.

The NPPA notifies the ceiling prices of drug formulations from time to time. The industry proposes that changes in pricing should be notified prospectively rather than retrospectively to avoid logistical challenges — calling back all stock in circulation, repackaging it with fresh prices, and then releasing it in the market. NPPA fixes prices for scheduled drugs in the National List of Essential Medicines and for non-scheduled drugs companies can take an annual rise of 10 per cent.

The industry feels the need to incentivise innovation and research and development (R&D) spending, suggesting that companies investing significantly in R&D should be allowed to price their innovative products at a premium.

While the industry values India's success as a global pharma giant with affordable pricing, it stresses the need for reforms.

Meanwhile, the medical devices industry in India seeks a separate regulator distinct from the pharma regulator.

Rajiv Nath, forum coordinator, Association of Indian Manufacturers of Medical Devices (AiMeD), proposes a separate regulatory framework and pricing mechanism for medical devices, distinct from drugs. He added, "Instead of price control, we have proposed price regulation based on trade margin monitoring and then a graded step-by-step non-disruptive regulatory rationalisation at the first point of entry of goods into the supply chain where goods and services tax is initially charged on overseas and Indian manufactured medical devices."

This could apply to imports and ex-factory prices. Indian manufacturers seek a level playing field with overseas manufacturers, distinguishing themselves from importers of foreign medical devices.

ILLUSTRATION: AJAY MOHANTY

TASK CUT OUT FOR PANEL

- Look at institutional reforms within the National Pharmaceutical Pricing Authority
- Balance price and availability of essential medicines
- Design a price moderation framework for medical devices
- Design a price moderation framework for emerging and precision therapies