Government plugs-in all loopholes on MedTech price labeling

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New Delhi: In a significant move aimed at curbing prevalent malpractices related to MRP and over-invoicing via the "Institutional Consumer" route while boosting domestic manufacturing, the Government has plugged in loopholes related to labelling requirements of imported medical devices. It has been alleged that the loopholes had been used in the past to evade taxes, hype up the MRP while eroding the competitiveness of domestically manufactured medical devices.

The Government in a letter to domestic medical device manufacturers' apex body AiMeD has clarified that all imported (and indigenous) devices, irrespective of being notified as 'Drugs or Not" will have to comply with all labeling requirements as per the existing Legal Metrology (Packaged Commodities) Rules, 2011 in addition to compliance with GSR 629 (E) which was issued on June 23rd, 2017. The Government has also plugged in loopholes which were used in the past by certain hospitals to 'buy cheap, sell dear' by taking advantage of their status as "Institutional Consumer".

The Association of Indian Medical Device Industry (AiMeD) has lauded the move as a significant step towards consumer protection and a big boost for domestic manufacturers “The directives will help curb marketing malpractices, over invoicing and boost the competitiveness of domestic medical device,” mentioned Mr Rajiv Nath, Forum Coordinator, AiMeD.

It may be noted that confusion had arisen due to ambiguities in the wordings of GSR 629 issued recently by the Ministry of Consumer Affairs, GoI which gave the impression that labeling requirement was mandatory for only those 23 medical devices which had been notified as drugs. Another confusion was related to the labeling requirement of devices purchased by Institutional Consumers. These ambiguities and loopholes had in the past given rise to marketing malpractices where importers would import devices without putting the unit MRP on unit packages and would later mark up the unit price while selling it to Institutional Consumers like hospitals, though hospitals in practice would be paying much less than the marked up MRP but would charge the hyped up price from consumers/patients.This practice gave big margins to hospitals but exploited consumers/patients.

Another fallout of this malpractice was that institutional buyers discriminated against domestic manufacturers as unlike importers/foreign suppliers, the domestic manufacturer was unable to supply them with marked up labels as they have to strictly comply with labelling requirement.

The Ministry of Consumer Affairs has now amended the very definition of ‘Institutional Consumer’ which now means the institution that buys packaged commodities bearing a declaration ‘not for retail sale’, directly from the manufacturer or from an importer or from wholesale dealer for use by that institution and nor for commercial or trade purposes.”

The government has further clarified that “all such medical devices, which are eventually hospital billed to the patients, even if they are initially supplied to the hospital directly, are covered under these rules and hospitals cannot claim the status of institutional consumers.”

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