



Issue of high trade margins in essential medical devices

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The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP) fixes ceiling prices of formulations and medical devices included in the National List of Essential Medicines (NLEM) published by the Ministry of Health and Family Welfare and incorporated by the DoP in Schedule-I to the Drugs (Prices Control) Order, 2013 (DPCO, 2013). Coronary stents [Bare Metal Stents (BMS) and Drug Eluting Stents (DES)] are included in Schedule-I of the DPCO, 2013 and accordingly NPPA fixes their ceiling prices as per the provisions of DPCO, 2013. The present applicable ceiling price for BMS is ₹10,692.69 and for DES ₹38,933.14. The prices fixed under DPCO, 2013 are applicable across the country. All manufacturers, marketers and importers of stents are required to sell their products within such ceiling price (plus applicable Goods and Service Tax). Also, NPPA issued a notification dated 12.2.2018, requiring that institutions such as hospitals, nursing homes and clinics performing angioplasty procedures using coronary stents who bill patients directly, shall comply with the ceiling prices notified in the said notification. Further, the said notification also requires such institutions to specifically and separately mention in their estimate / proforma invoice / final billing, etc. the cost of the coronary stents, its category like bare-metal stent (BMS) or drug-eluting stent (DES), brand name, name of the manufacturer / importer / batch number / specifications and other details.

In addition, NPPA, in public interest, fixed and notified the ceiling prices for Orthopaedic Knee Implants for knee replacement system in August 2017 and which has been extended up to 15th November, 2026, or until further orders.

Further, during the COVID-19 pandemic, NPPA, in public interest, capped the trade margin on certain essential medical devices i.e. Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer, and Glucometer under the “Trade Margin Rationalisation” in accordance with the relevant provision of Drugs (Prices Control) Order (DPCO), 2013.

In case of non-scheduled formulations / medical devices, manufacturers are required to not increase the maximum retail price (MRP) of such formulations / medical devices by more than 10% of MRP during preceding 12 months. NPPA monitors the prices of both scheduled and non-scheduled formulations/medical devices and takes action in accordance with the provisions of DPCO, 2013 against companies that are found as overcharging consumers, based on references received regarding overcharging from any source, including Price Monitoring and Resource Units set up in States (including Maharashtra), State Drugs Controllers, samples purchased from open market, reports from market database and complaints lodged through grievance redressal channels.

There is no proposal of “One Nation, One Price” framework or nationwide price cap for essential medical devices currently under consideration of the Department.

This information was given by Minister of State for Chemicals and Fertilizers, Smt. Anupriya Patel, in a written reply in the Rajya Sabha today.

PC/PM

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