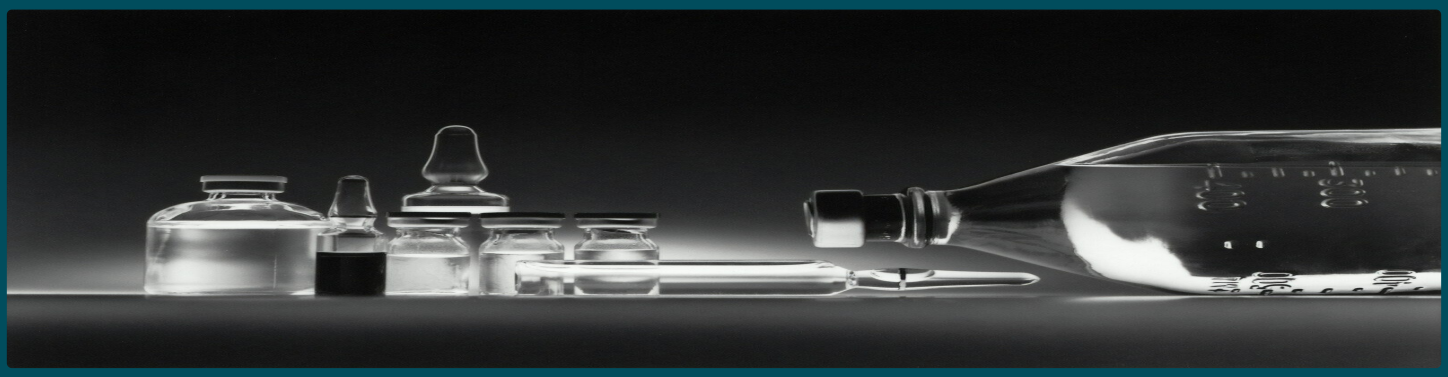
INDIALAW



REGULATORY

Regulating the Price of Health: A Legal Analysis of India’s 2026 Drug Ceiling Price Notification

AUTHOR Aditi Rana, Tanvi Dalvi

PUBLISHED 15 April 2026

Overview

On March 25, 2026, the National Pharmaceutical Pricing Authority (NPPA), operating under the aegis of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals), Government of India, issued Statutory Order S.O. 1575(E) pursuant to the powers vested under Paragraphs 4, 6, 10, 11, 14, 16, 17, and 18 of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The said order notifies revised ceiling prices for 767 scheduled pharmaceutical formulations, operative with effect from April 1, 2026, and supersedes all prior pricing orders issued in relation to the listed formulations.

The revision is anchored on the annual Wholesale Price Index (WPI) adjustment mechanism embedded within the DPCO, 2013 framework. For the year 2025 over 2024, the applicable WPI increase stands at 0.64956% representing a marginal index?linked revision in prices for the relevant period, reflecting near-flat inflation in pharmaceutical input costs during the reference period.

Legal and Regulatory Basis

The DPCO, 2013, enacted under the Essential Commodities Act, 1955, empowers the NPPA to regulate and enforce ceiling prices for scheduled formulations. The WPI-linked revision mechanism, governed by Paragraph 16(2) of the DPCO, 2013, provides a transparent, index-based methodology for periodic price adjustments. The present order, read with S.O. No. 1394(E) dated May 30, 2013, and S.O. 5249(E) dated November 11, 2022, operates as a comprehensive supersession of the pricing framework previously notified for all 767 formulations listed therein.

The ceiling prices notified herein are exclusive of Goods and Services Tax (GST), which may be added by manufacturers only if it has been actually paid or is payable to the Government on the ceiling price in question. This distinction carries material compliance significance for pricing and invoicing purposes across the pharmaceutical supply chain.

Scope and Coverage of the Order

The revised schedule encompasses a broad spectrum of essential medicines spanning multiple therapeutic categories, including antibiotics (such as Amoxicillin, Azithromycin, Ceftriaxone, and Vancomycin), antiretroviral agents (including Dolutegravir, Efavirenz, Tenofovir combinations, and Zidovudine), oncological agents (including Paclitaxel, Rituximab, Trastuzumab, and Imatinib), cardiovascular formulations, vaccines, anaesthetics, anti-diabetic agents, and psychiatric medications.

The price range within the schedule is extensive. Commonplace formulations such as Paracetamol 500mg Tablet are capped at Rs. 0.93 per unit, whereas high-cost biologics such as Trastuzumab Injection (440mg/50mL) are subject to a ceiling of Rs. 56,039.24 per vial. The order further makes specific provisions for proportionate pricing of Enoxaparin Injection at varying strengths (applying the ratio of Rs. 114.68 per 0.10 mL), Paclitaxel Injection at a ratio of Rs. 220.61 per mL, and Budesonide Respirator Solutions for nebulizer use.

Compliance Obligations for Manufacturers and Retailers

The order imposes immediate and enforceable obligations upon all manufacturers of scheduled formulations. Any manufacturer presently selling, whether under a branded or generic label, at a price exceeding the newly notified ceiling (inclusive of applicable GST) is mandated to revise its Maximum Retail Price (MRP) downward with immediate effect. Conversely, manufacturers whose existing MRP falls below the revised ceiling are accorded the discretion, though not the obligation, to revise their MRP upward within the permissible WPI-linked limit, in accordance with Paragraph 16(2) of the DPCO, 2013.

From a procedural standpoint, manufacturers are required to submit an updated price list in Form-V to the NPPA through the Integrated Pharmaceutical Database Management System (IPDMS) from the date of notification, with a concurrent copy to the State Drug Controller and to dealers. Any upward revision carried out under this order must be reported to the Government in Form-II within fifteen days of such revision. Failure to file such information shall be construed as a non-revision of MRP, and the concerned manufacturer shall be liable to deposit all amounts overcharged, together with interest thereon, from the date of overcharging.

Retailers and dealers are equally bound by Paragraph 24(4) of the DPCO, 2013 to display the price list furnished by manufacturers in a conspicuous part of their business premises, ensuring accessibility to any person wishing to consult the

same. Furthermore, manufacturers intending to discontinue production of any listed scheduled formulation are required to notify the NPPA in Form-IV, at least six months prior to the intended date of discontinuation.

Consequences of Non-Compliance

Non-compliance with the ceiling prices and ancillary conditions prescribed under this order attracts significant legal consequences. Under the combined operation of the DPCO, 2013 and the Essential Commodities Act, 1955, manufacturers found to be overcharging are liable to deposit the excess amount along with applicable interest. The NPPA retains authority to initiate enforcement proceedings, issue show-cause notices, and pursue recovery actions against defaulting entities.

Conclusion and Advisory Observations

The issuance of S.O. 1575(E) is a routine yet consequential exercise of the NPPA's statutory mandate to ensure the affordability of essential medicines for the Indian population. The exceptionally low WPI adjustment of 0.64956% effectively renders prices stable for the coming fiscal year, providing limited headroom for manufacturers whilst sustaining access to critical therapies.

Related Practice Areas

Regulatory & Compliance Advisory