DEPARTMENT OF PHARMACEUTICALS AMENDS THE DRUGS (PRICES CONTROL) ORDER, 2013

The Drugs (Prices Control) Order, 2013 ("**DPCO 2013**") is the principal legal framework governing the regulation of drug prices in India. It empowers the Central Government, acting through the National Pharmaceutical Pricing Authority (NPPA), to fix and revise the ceiling prices of scheduled formulations specified in the First Schedule to the DPCO 2013, determine the retail prices of new drugs, and monitor the prices of non-scheduled formulations. DPCO 2013 also imposes compliance obligations on manufacturers, including requirements relating to applications for price fixation, the display and dissemination of price lists, and the maintenance of records and furnishing of information. In addition, it provides for the recovery of amounts overcharged, together with applicable interest, where manufacturers sell scheduled formulations at prices exceeding the notified ceiling price. On June 30, 2026, the Ministry of Chemicals and Fertilizers, issued Notification No. S.O. 3516(E), notifying the Drugs (Prices Control) Amendment Order, 2026 ("**Amendment Order**"), further amending the DPCO 2013.

The key changes introduced by the Amendment Order are as follows:

- Paragraph 11(3) of the DPCO 2013 empowered the Government to fix and notify a separate ceiling price or retail price for injections, inhalations, or any other medicine for which the dosage form or strength or both were not specified in Schedule-I of the DPCO 2013. The Amendment Order has substituted Paragraph 11(3) to broaden this power to any drug for which a ceiling price or retail price has already been fixed, thereby removing the limitation to unspecified dosage forms or strengths. The Government may now fix and notify a separate ceiling price or retail price, upon an application made by the manufacturer or otherwise, for such drug with a specified therapeutic rationale, considering the type of packaging, pack size, dosage compliance or content in the pack, in the unit dosage, conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act, 1940 and the rules made thereunder.

- Further, under Paragraph 14(2) of the DPCO 2013, where any manufacturer sold a scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the Government, the manufacturer was liable to deposit the overcharged amount along with interest thereon from the date of such overcharging, without any qualification or limitation on the scope of such liability. The Amendment Order has inserted a proviso in Paragraph 14(2), whereby, in respect of scheduled formulations produced or available in the market prior to the notification of a ceiling price, where the manufacturer demonstrates compliance with Paragraph 24 and such other guidelines as may be issued by the Government, the overcharging liability shall be restricted to the quantity of stock traded through the distributor or retailer found to have effected such overcharging.

- Paragraph 15(2) of the DPCO 2013 required every existing manufacturer launching a "new drug" under DPCO 2013 — that is, a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines — to apply for prior price approval from the Government in Form-I of the DPCO 2013. The Amendment Order inserts two provisos to Paragraph 15(2), under which an existing manufacturer launching the same new drug within twelve months of the retail price being fixed of such new drug is no longer required to apply for price fixation afresh, and is instead only required to intimate the details of such launch in the newly inserted Form-IA under Schedule-II, within one month of the launch.

- Correspondingly, under Paragraph 15(5) of the DPCO 2013, where an existing manufacturer of a scheduled formulation failed to apply for prior approval of the price of a new drug in Form-I, such manufacturer was liable to deposit the overcharged amount over and above the price fixed and notified by the Government, along with interest from the date of launch of the new drug, in addition to the penalty. The Amendment Order has substituted Paragraph 15(5) to align the obligation with the revised Paragraph 15(2), wherein an existing manufacturer of a scheduled formulation fails to adhere to sub-paragraph (2) which now encompasses both the prior price approval application requirement and/or the new intimation route under Form-IA, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the Government, if any, together with interest thereon from the date of launch of the new drug, in addition to the penalty.

- Additionally, Paragraph 15(6) of the DPCO 2013 provided that no existing manufacturer of a scheduled formulation could sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government, and a manufacturer found to have sold the new drug at a price exceeding the retail price was liable to deposit the overcharged amount along with interest from the date of overcharge, in addition to the penalty. The Amendment Order has substituted Paragraph 15(6) to introduce a twelve-month look-back: no existing manufacturer of a scheduled formulation shall now launch such new drug at a price higher than the latest retail price (plus applicable local taxes) fixed by the Government for such new drug during the preceding twelve months. Where the manufacturer is found to have sold such new drug at a price exceeding the notified retail price, it shall be liable to deposit the overcharged amount along with interest from the date of overcharge, in addition to the applicable penalty.

- Paragraph 24(1) of the DPCO 2013 contained a proviso permitting manufacturers a forty-five-day window to bring down the maximum retail price of pre-existing stock to the ceiling price following a price notification. The Amendment Order inserts another proviso, noting that if the manufacturer furnishes the prescribed documentary evidence, upon demand, demonstrating sufficient efforts to disseminate a notified price revision to all stakeholders,

then the overcharged amount for such manufacturer shall be calculated solely on the stock handled by each retailer, distributor, or stockist found selling the formulation above the ceiling price (plus local taxes as applicable) pertaining to that batch.

- Further, under Paragraph 24(3) of the DPCO 2013, every manufacturer was required to issue a price list and supplementary price list, if required, in Form V to the dealers, State Drugs Controllers and the Government, indicating reference to the relevant price fixation or revision. The Amendment Order has substituted Paragraph 24(3) to introduce Form-VI as an additional permissible format alongside Form V, and to remove dealers from the list of specified recipients, thereby limiting the obligation to the issuance of price lists to the State Drugs Controllers and the Government only.

- Paragraph 29 of the DPCO 2013 earlier required manufacturers to maintain sales records relating to active pharmaceutical ingredients, bulk drugs and formulations, without specifying any minimum retention period. The Amendment Order now requires every manufacturer to maintain such records, along with any other records directed by the Government, for a period of not less than seven financial years immediately preceding the current financial year and further provides that where any proceeding has been initiated or is pending against the manufacturer under the DPCO 2013, such records must continue to be maintained until the final disposal of that proceeding.

Read more:
https://egazette.gov.in/WriteReadData/2026/273983.pdf

Luthra and Luthra
LAW OFFICES INDIA

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The Team



PRADNESH WARKE
Partner
Email – p.warke@luthra.com



PRAGNA YENDURI
Associate
Email – syenduri@luthra.com



TANAY JHA
Associate
Email – t.jha@luthra.com

NEW DELHI
1st and 9th Floors, Ashoka Estate, 24,
Barakhamba Road, New Delhi - 110 001
T: +91 11 4121 5100
F: +91 11 2372 3909
E: delhi@luthra.com

MUMBAI
20th Floor, Indiabulls Finance Center,
Tower 2 Unit A2, Elphinstone Road,
Senapati Bapat Marg, Mumbai - 400 013
T: +91 22 4354 7000
E: mumbai@luthra.com

BENGALURU
3rd Floor, Onyx Centre, No. 5, Museum Road,
Bengaluru - 560 001
T: +91 80 4112 2800 / +91 80 4165 9245
F: +91 80 4112 2332
E: bengaluru@luthra.com

HYDERABAD
Serene Towers,
House No. 8-2-623/A,
Road No. 10, Banjara Hills,
Hyderabad, Telangana - 500034
T: +91 40 7969 6162
E: hyderabad@luthra.com

CHENNAI
Prestige Palladium Bayan,
8th Floor, Greams Road, Nungambakkam Division,
Egmore, Chennai, Tamil Nadu - 600 006
T: +91 95604 88155
E: chennai@luthra.com