NPPA NOTIFIES 30% TRADE-MARGIN CAP ON 137 ANTI-CANCER DRUGS

The Drugs (Prices Control) Order, 2013 ("**DPCO 2013**") constitutes the principal legal framework governing the regulation of drug prices in India. It empowers 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 and monitor the prices of non-scheduled formulations. Paragraph 19 of DPCO 2013 additionally enables the NPPA, in extraordinary circumstances and in public interest, to fix the ceiling price or retail price of any drug for such period, as it may deem fit. Exercising its powers under Paragraph 19 of DPCO 2013, on October 17, 2026, the NPPA issued an order bearing reference no. S.O. 5690(E) ("**Order**"), to cap trade margins of 137 non-scheduled anticancer drugs. The Order was issued in light of serious concerns raised by state authorities, patients, civil society, and through public platforms regarding excessive pricing of anti-cancer drugs, particularly highlighting the wide disparity between the procurement price and the Maximum Retail Price ("**MRP**") charged from consumers. Thus, the Order aims to cap the trade margin of certain high-value anti-cancer drugs, to mitigate the financial burden on patients.

The key features of the Order are as follows:

- The Order applies to non-scheduled formulations containing any of the 137 drugs listed in Table B, whether as a single drug or in combination, and irrespective of dosage strength, dosage form or route of administration.

- Trade margin is the difference between the price at which a manufacturer sells to a stockist or distributor (Price to Stockist "**PTS**" or Price to Distributor "**PTD**") and the MRP charged to the patient, excluding GST. The Order caps this trade margin at 30% (thirty percent) and Table A of the Order lays down the formula for arriving at the revised MRP in compliance with the 30% (thirty percent) trade margin cap.

- For the purposes of determining the PTS/PTD, all categories of sales are counted, but Government sales are excluded. Where a manufacturer supplies the formulation directly to a hospital or medical institution, that hospital or medical institution is treated as the stockist/distributor, and the manufacturer's invoice data is used for the calculation of MRP as per Table A of the Order.

- The manufacturers of the respective formulations, selling branded or generic or both versions of the formulations at MRP higher than the MRP computed as per Table A, shall revise the prices of such formulations in order to not exceed the MRP computed as per Table A. The revised prices take effect from November 9, 2026.

- Within 7 (seven) days of publication of the Order in the Official Gazette, manufacturers must submit the revised price information in Annexure I to the NPPA and the concerned State Drug Controller, even where there is no change in MRP. Failure to submit the information will be treated as non-reduction of MRP and will lead to recovery action by the NPPA. Additionally, within those 7 (seven) days, the manufacturers must also issue the applicable price list in Form

V through the Integrated Pharmaceutical Database Management System ("**IPDMS**") under Paragraph 25 of DPCO 2013 and furnish copies to the State Drug Controller, dealers and other entities as required under the DPCO 2013.

- Manufacturers must now compulsorily report the PTS/PTD and MRP of their formulations on the IPDMS portal. On demand by the NPPA, they must also produce documentary evidence of sufficient effort to disseminate the price revision to all stakeholders through:
    - circulation of the revised MRP list to dealers and retailers within 7 (seven) days from the date of publication of the Order in the Official Gazette, for display to consumers;
    - advertisement in leading newspapers within 7 (seven) days from the date of publication of the Order in the Official Gazette, informing dealers, retailers, and consumers about the price reduction;
    - creating a dedicated Drugs (Prices Control) Order Matters section on the homepage of the company and upload details of this price notification and MRP; and
    - submitting batch-wise production details and stock position of the formulations held by the company and distributors at the time of the publication of the Order in the Official Gazette.

- Since a substantial supply of anticancer drugs is done directly to hospitals and medical institutions, the hospitals and medical institutions are required to monitor the MRP of the respective formulations as per the Order and display the revised prices prominently on their websites.

- Manufacturers of the respective formulations must also maintain current production levels, seek prior permission from the NPPA before reducing average monthly production, and give at least 6 (six) months' notice prior to the intended date of discontinuation under Form IV of Schedule II of DPCO 2013 before discontinuing production or import of the respective formulations.

- Manufacturers which do not comply with the Order will be liable to deposit the overcharged amount along with interest under DPCO 2013, read with the Essential Commodities Act, 1955. The overcharged amount is the difference between the MRP charged (excluding GST) and the MRP computed under Table A (excluding GST).

Read More:
https://nppa.gov.in/storage/uploads/tender/277271-17-10-2026.pdf

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This update is only for general informational purposes and shall not be construed to constitute legal advice (which can only be given after being formally engaged and familiarizing ourselves with all the relevant facts). Should you have any queries, or require any assistance or clarifications with regard to anything contained in this newsletter, please feel free to contact our partner, Mr. Pradnesh Warke

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