NPPA

DPCO amendment changes new drug launches and overcharging rules

S.O. 3516(E), the 13th amendment of the DPCO, 2013, changes separate pack prices, overcharging liability, new drug launches, price lists and record keeping.

THE DEPARTMENT OF Pharmaceuticals, Ministry of Chemicals and Fertilizers, issued notification S.O. 3516(E), dated June 30, 2026, making the Drugs (Prices Control) Amendment Order, 2026. It was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), No. 3381, dated June 30, 2026, and comes into force on the date of its publication in the Official Gazette. The Central Government made it under section 3 of the Essential Commodities Act, 1955. It amends the Drugs (Prices Control) Order, 2013 (DPCO, 2013). Its note lists twelve earlier amendments, from S.O. 686(E) of March 9, 2015 to S.O. 2324(E) of May 25, 2023, and the National Pharmaceutical Pricing Authority (NPPA) calls it the 13th amendment. It is signed by Awadhesh Kumar Choudhary, Senior Economic Advisor, under F. No. 31026/16/2026-Pricing.

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Paragraph 11(3) is substituted. In the case of any drug for which a ceiling price or retail price has been fixed, the Government may fix and notify a separate ceiling price or retail price for such drug with specified therapeutic rationale, on an application made by the manufacturer or otherwise. The basis is the type of packaging or pack size or dosage compliance or content in the pack (liquid, gaseous or any other form) in the unit dosage, conforming to the Indian Pharmacopeia or other standards under the Drugs and Cosmetics Act, 1940. In NPPA's consolidated text of the DPCO, 2013, amended up to May 25, 2023, the earlier sub-paragraph covered only injections or inhalation or any other medicine for which dosage form or strength or both are not specified in Schedule-I. A new proviso to paragraph 14(2) covers scheduled formulations produced or available in the market before the ceiling price is notified. Where the manufacturer demonstrates compliance with paragraph 24 and such other guidelines as the Government may issue, its liability for overcharging is restricted to the stock traded through the distributor or retailer found to have overcharged.

In paragraph 15, two provisos to sub-paragraph (2) say that any other existing manufacturer launching the same new drug within twelve months of its retail price fixation "shall not be required to apply", and must intimate the launch in Form-IA within one month. Sub-paragraph (2) is the one under which an existing manufacturer applies for prior price approval in Form-I. Substituted sub-paragraph (5) makes an existing manufacturer of a scheduled formulation that "fails to adhere to sub-paragraph (2)" liable to deposit the overcharged amount over the price fixed, with interest from the launch, in addition to the penalty; before, the trigger was a failure to apply in Form-I. Substituted sub-paragraph (6) bars an existing manufacturer of a scheduled formulation from launching the new drug above the latest retail price fixed for it during the preceding twelve months. As before, one found selling it above the retail price fixed must deposit the overcharged amount with interest, in addition to the penalty. Schedule-II gains Form-IA, a ten-item proforma for intimation of launch of new drugs.

Paragraph 24(1) gets a further proviso. A manufacturer that produces documentary evidence, upon demand, of sufficient effort to spread a price revision to all stakeholders has its

overcharged amount 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), for that batch. The efforts the proviso lists, after the words "including through", are the revised "Market Retail Price" list to dealers and retailers and an advertisement in at least two national newspapers, each immediately and not later than two weeks of the notification; a revised or supplementary price list in Forms V or VI; a Drugs (Prices Control) Order Matters section on the company's homepage, with the revised price notification and Market Retail Price; and batch-wise production and stock details. Substituted paragraph 24(3) sends price lists in Form V or Form-VI to the State Drugs Controllers and the Government; the earlier text also listed the dealers. A new paragraph 29 requires records for not less than seven financial years immediately preceding the current financial year, and until any proceeding is finally disposed of; the earlier paragraph set no period.

The Order does not reproduce the text it replaces. It does not say whether the paragraph 15 changes reach retail prices fixed before it, does not define the "such other guidelines" in the paragraph 14(2) proviso, and sets no form for the evidence under paragraph 24(1). The Gazette issue is dated June 30, 2026, and its Gazette ID carries July 1, 2026. NPPA's Office Memorandum F.No. 12(10)/2021/DP/NPPA/Div.II-Partfile(1), dated July 16, 2026, clarifies how the paragraph 15 changes apply, including that they cover retail prices notified on or after July 1, 2026, which it gives as the date of publication.

Issued by	Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers
Document	Notification S.O. 3516(E), the Drugs (Prices Control) Amendment Order, 2026
Dated	June 30, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), No. 3381, June 30, 2026
Takes effect	On the date of its publication in the Official Gazette; the Gazette issue is dated June 30, 2026, and NPPA's Office Memorandum of July 16, 2026 gives July 1, 2026
Amends	Drugs (Prices Control) Order, 2013 (S.O. 1221(E), May 15, 2013): paragraphs 11, 14, 15, 24 and 29, and Schedule-II
Amendment number	The 13th, as NPPA's Drugs (Prices Control) Order 2013 page and its Office Memorandum of July 16, 2026 call it; the Order's note lists twelve earlier amendments
Applies to	Manufacturers under the Drugs (Prices Control) Order, 2013
Separate prices	For any drug with a ceiling price or retail price, by type of packaging, pack size, dosage compliance or content in the pack, on the

	manufacturer's application or otherwise (paragraph 11(3))
Overcharging	Limited to the stock of the distributor, retailer or stockist found overcharging: under paragraph 14(2), where the manufacturer demonstrates compliance with paragraph 24 and Government guidelines; under paragraph 24(1), where it produces documentary evidence of sufficient effort to spread the price revision, for that batch
New drugs	Other existing manufacturers launching the same new drug within twelve months of its retail price fixation need not apply; Form-IA within one month of launch; no launch above the latest retail price fixed in the preceding twelve months (paragraph 15)
Price lists	Form V or Form-VI to the State Drugs Controllers and the Government (paragraph 24(3))
Records	Not less than seven financial years immediately preceding the current financial year, and until final disposal of any proceeding (paragraph 29)
Made under	Section 3, Essential Commodities Act, 1955
File number	F. No. 31026/16/2026-Pricing
Signed by	Awadhesh Kumar Choudhary, Senior Economic Advisor
Related	NPPA Office Memorandum F.No. 12(10)/2021/DP/NPPA/Div.II-Partfile(1), July 16, 2026: clarifications on filing Form-IA for new drugs under this Order

What S.O. 3516(E) changes in the DPCO, 2013

Clause	DPCO, 2013	Change
2(a)	Paragraph 11(3)	Substituted. A separate ceiling price or retail price may be fixed for any drug with a ceiling price or retail price, by type of packaging, pack size, dosage compliance or content in the pack, on the manufacturer's application or otherwise. It covered only injections or inhalation or any other medicine for which dosage form or strength or both are not specified in Schedule-I.
2(b)	Paragraph 14(2)	Proviso inserted. For scheduled formulations produced or available before the ceiling price notification, a manufacturer that demonstrates compliance with paragraph 24 and Government guidelines is liable only for the stock traded through the distributor or retailer found overcharging.
2(c)(i)	Paragraph 15(2)	Two provisos inserted. Any other existing manufacturer launching the same new drug within twelve months of its retail price fixation need not apply, and intimates the launch in Form-IA within one month.

2(c)(ii)	Paragraph 15(5)	Substituted. Liability for the overcharged amount, interest and penalty follows a failure to adhere to sub-paragraph (2). It followed a failure to apply for prior price approval in Form-I.
2(c)(iii)	Paragraph 15(6)	Substituted. No existing manufacturer of a scheduled formulation may launch the new drug above the latest retail price fixed for it during the preceding twelve months. Selling above the retail price fixed still brings the overcharged amount with interest, plus the penalty. It barred selling above the retail price fixed, with no reference to launch or to the preceding twelve months.
2(d)(i)	Paragraph 24(1)	Further proviso inserted. With documentary evidence, upon demand, of sufficient effort to spread a price revision to all stakeholders, including five listed steps, the overcharged amount is calculated solely on the stock of each retailer, distributor or stockist found selling the formulation above the ceiling price, for that batch.
2(d)(ii)	Paragraph 24(3)	Substituted. Price lists and supplementary price lists in Form V or Form-VI go to the State Drugs Controllers and the Government. The earlier text also listed the dealers.
2(e)	Paragraph 29	Replaced. Records kept in good order for not less than seven financial years immediately preceding the current financial year, and until final disposal of any proceeding under the Order. No period was set.
2(f)	Schedule-II	Form-IA, "PROFORMA FOR INTIMATION OF LAUNCH OF NEW DRUGS", inserted after Form-I.

The notification (PDF, 744 KB)

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