July 16, 2026

NPPA

Other makers may launch a new drug up to its notified price

NPPA's memorandum of July 16, 2026 says other existing makers may launch the same new drug at up to its notified retail price within 12 months, filing Form IA.

THE NATIONAL Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, issued an Office Memorandum dated July 16, 2026 under F.No. 12(10)/2021/DP/NPPA/Div.II-Partfile(1). Its subject is clarifications on filing Form IA for "new drugs" under the Drugs (Prices Control) Amendment Order, 2026. That order is the 13th amendment of the Drugs (Prices Control) Order, 2013 (DPCO, 2013), notified by the Department of Pharmaceuticals as S.O. 3516(E) dated June 30, 2026. The memorandum is addressed to all manufacturers and marketing companies, all industry associations and all stakeholders. It issues with the approval of the Competent Authority and is signed by Priyanka Sachdeva, Joint Director (Pricing).

KEY FACTS

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Office Memorandum, F.No. 12(10)/2021/DP/NPPA/Div.II-Partfile

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The memorandum says the changes the amendment order made to paragraph 15 apply to retail prices notified on or after the date the order was published, July 1, 2026. Retail prices notified before it were for the applicant manufacturer and marketer, and the amended paragraph 15 does not apply to them. Accordingly, an existing manufacturer of a drug with dosages and strengths specified in the National List of Essential Medicines (NLEM) must apply for prior price approval in Form I when it launches a new drug.

Any other existing manufacturer may launch the same new drug, with that reference new drug's exact composition, at no more than its notified retail price. It may do so within twelve months of NPPA fixing that price. It must then report the details in Form IA through IPDMS 2.0 within one month of the launch, with the seven supporting documents in Annexure I. They are the DCG (I) approval of the new drug formulation and a currently valid manufacturing permission from the State Licensing Authority. Two are declarations: that the formulation is not prohibited by DCGI/MoH&FW, and that production of the NLEM, 2022 scheduled formulation combined with the new drug, or whose strength is to change, will not be discontinued or reduced. Another is CA or CMA certified quarterly production and sales of the scheduled component for the last six quarters. The last two are the drug's category (a, b, c, d and so on) under the Kokate Committee report for fixed-dose combinations (FDCs), and its status as per the Drug Technical Advisory Board.

A manufacturer filing Form IA must comply with the DPCO, 2013 and must not make false or incorrect claims in it. Such claims may lead to appropriate penal proceedings against the manufacturer under the DPCO, 2013. All pharmaceutical companies are directed to comply strictly with the revised filing requirements. NPPA says the IPDMS 2.0 portal has been updated to take Form IA online, and problems in filing it may be reported to nppa-ipdms@gov.in and pricing-nppa@gov.in.

The memorandum does not define an existing manufacturer, and it does not say what applies to a launch after the twelve months. It says nothing about overcharging or the recovery of

overcharged amounts; the only consequence it names is penal proceedings for false or incorrect claims in Form IA. It sets no fee and fixes no price for any drug.

Issued by	National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers
Document	Office Memorandum, F.No. 12(10)/2021/DP/NPPA/Div.II-Partfile(1)
Dated	July 16, 2026
Explains	Drugs (Prices Control) Amendment Order, 2026, the 13th amendment of the DPCO, 2013, notified as S.O. 3516(E) dated June 30, 2026
Applies to	All manufacturers and marketing companies, industry associations and stakeholders
Takes effect	The memorandum states no date of its own; the paragraph 15 changes apply to retail prices notified on or after July 1, 2026
Prior price approval in Form I	An existing manufacturer of a drug with NLEM dosages and strengths that launches a new drug
Launch by any other existing manufacturer	Same new drug, exact composition, at no more than the notified retail price, within twelve months of NPPA fixing that price
Form IA due	Within one month of the launch, through IPDMS 2.0, with the seven documents in Annexure I
False or incorrect claims in Form IA	May lead to appropriate penal proceedings under the DPCO, 2013
Filing problems	nppa-ipdms@gov.in and pricing-nppa@gov.in
Related	NPPA's 148th Authority meeting, July 7, 2026: a new drug's "worked out price" is henceforth notified as its "retail price", where the practice had been to notify the lower of the worked out price and the applicant's "claimed price"; the applicant may still launch at its claimed price if that is lower
Signed by	Priyanka Sachdeva, Joint Director (Pricing)

Annexure I: documents filed with Form IA

No.	Document
1	Approval for new drug formulation granted by the DCG (I)
2	Currently valid manufacturing permission by State Licensing Authority
3	Declaration that new drug formulation is not prohibited by DCGI/MoH&FW

4	Declaration regarding non-discontinuation/non-reduction in production of scheduled formulation under NLEM, 2022, which has been combined with the new drug or if the strength is proposed to be changed
5	CA/CMA certified quarterly production, sales for last six quarters in respect of the schedule component of the new drugs
6	Drug category of the new drug (a, b, c, d, etc.) as per Kokate Committee report for FDC's
7	Status of the new drug as per Drug Technical Advisory Board

The office memorandum (PDF, 695 KB)

Source: NPPA's own copy.

Checked against the official copy on October 28, 2026.

IndusDesk

hello@indusdesk.com · +91 11 4141 3939

9th Floor, Hemkunt House, Rajendra Place, New Delhi, Delhi 110008, India

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