F.No. 12(10)/2021/DP/NPPA/Div.II-Partfile(1)
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

5th / 3rd Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi – 110001.
Dated: 16.07.2026

OFFICE MEMORANDUM

Subject: Clarifications regarding filing of Form-IA in respect of "new drugs" under the Drugs (Prices Control) Amendment Order, 2026 - reg.

The undersigned is directed to refer to the Drugs (Prices Control) Amendment Order, 2026 (13th Amendment to the Drugs (Prices Control) Order, 2013), notified by the Department of Pharmaceuticals vide Notification No. S.O. 3516(E) dated 30.06.2026.

2. In this regard, following clarifications are issued:

i. The amendments carried out in Para 15 through Drugs (Prices Control) Amendment Order, 2026 shall be applicable for the retail prices notified on or after the date of publication of Amendment Order i.e. 1st July, 2026. The retail prices notified prior to this Amendment Order were for the applicant manufacturer & marketer, and the amended provisions of Paragraph 15 are not applicable to such prices.

ii. Accordingly, an existing manufacturer of a drug with dosages and strengths as specified in National List of Essential Medicines launching a new drug shall apply for prior price approval of such new drug in Form-I.

iii. Any other existing manufacturer can launch the same new drug (i.e. with the exact composition as specified in case of reference new drug mentioned at (ii) above) at price not exceeding the notified retail price of the subject formulation within twelve months of the retail price fixation of such new drug by the NPPA. Such manufacturer shall intimate the details in Form-IA within one month of the launch through IPDMS 2.0, along with all supporting documents as per Annexure-I.

iv. The manufacturer submitting Form-IA shall ensure compliance with the provisions of DPCO, 2013 and shall refrain from making any false or incorrect claims in the Form-IA which may lead to initiation of appropriate penal proceedings against such errant manufacturer as per the

provisions of DPCO, 2013.

3. All pharmaceutical companies are hereby directed to strictly comply with the revised filing requirements. The IPDMS 2.0 portal has been updated to facilitate online submission of Form-IA. Further, in case any difficulty is encountered while filing the Form-IA on IPDMS 2.0, the applicants may report the same on following emails: **nppa-ipdms@gov.in** and **pricing-nppa@gov.in**.

This issues with approval of the Competent Authority.

16/7/26.

(Priyanka Sachdeva)
Joint Director (Pricing)

To:

1. All the manufacturers and marketing companies
2. All Industry Associations
3. All Stakeholders

Annexure-I

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