

File No 36(09)/2023/Div-III/NPPA
Government of India/ भारत सरकार
Ministry of Chemicals & Fertilizers/ रसायन एवं उर्वरक मंत्रालय
Department of Pharmaceuticals/ औषध विभाग
National Pharmaceutical Pricing Authority/ राष्ट्रीय औषधि मूल्य निर्धारण प्राधिकरण

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Date/ दिनांक: .01.2024

01/02/2024

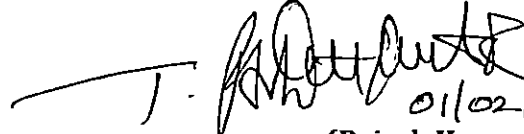
OFFICE MEMORANDUM

Subject: Launch of New Drugs before notification of Retail Prices by NPPA in violation of Paragraph 15 of DPCO, 2013.

As per Paragraph 15(2) of the DPCO, 2013 where an existing manufacturer of a scheduled drug intends to launch a new drug by combining the scheduled drug with another drug or by changing the strength or dosages or both of the scheduled drug, such existing manufacturer shall apply for prior price approval of such new drug in Form-I to the Government. All the Form-I applications are examined by NPPA and if found in order, the retail prices are fixed by the authority in accordance with the extant provisions. Thereafter, the retail prices so fixed by the Authority are notified in the official gazette. In addition, to promote the ease of doing business, NPPA ensures that all the Form-I applications are processed and disposed of in a time bound manner.

2. It has, however, been observed by this office that in some cases, the applicants (manufacturers/marketers) are launching new drugs immediately upon filing of Form-I application with NPPA without waiting for fixation and notification of the retail price. It may be noted that such launch of new drugs before notification of retail price is a blatant and deliberate violation of the extant provisions of law.

3. A serious view has been taken in the matter and all the pharmaceutical manufacturers are, hereby, advised to refrain from such practice and to ensure strict compliance with the extant provisions of law. Otherwise, NPPA would be constrained to initiate penal action against the defaulting manufacturers under the provisions of DPCO, 2013 and Section 7 of the Essential Commodities Act, 1955.


01/02/2024
(Rajesh Kumar T.)
Deputy Director

To,
All manufacturers
All industry associations
All stakeholders