

No.31015/37/2023-Pricing (E-23328)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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Room No. 340-B, A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s Cipla Ltd (hereinafter called the “Applicant”) has filed a review application dated 08/02/2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 195(E) dated 11.01.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Acivir 800 mg Tablet DT 5’s containing Acyclovir 800 mg per Tablet.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 25.09.2023 and presented their respective logics.

3. Major contentions raised by the Applicant:

It was contended, on behalf of the Applicant, that NPPA has erred in determining the ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 The formulation “Acivir 800 mg Tablet DT 5’s” was included in the revised Schedule-I of the DPCO, 2013 notified on 11th November, 2022. Hence, the formulation “Acivir 800 mg Tablet DT 5’s” was also included in the draft calculation of ceiling price under the provisions of Para 4, 6, 10, 11, 14, 16, 17 and 18 of DPCO 2013.

3.2 In spite of representation filed against the draft ceiling price with all relevant documents proving that the Applicant has duly implemented the 10% revision in MRP as per Para 20(1), NPPA considered the old PTR for ceiling price fixation. The ceiling price calculation of “Acyclovir 800 mg per tablet” should have included the revised PTR for “Acivir 800 mg Tablet DT 5’s” at Rs.175.88 and not Rs.159.89.

3.3 Non-reflection of PTR in the market based data should not be construed as non-implementation of revised MRP, especially when invoices of sales and pack shots at revised MRP are provided as documentary evidence.

3.4 The Applicant maintained that the manufacturers, as per Para 20(1) of DPCO 2013, reserve the right to increase the MRP of non-scheduled formulations by 10% once in a year. Thus, an increase in PTR post July, 2022 should also be considered in the calculation of ceiling prices of the scheduled formulation.

3.5 The NPPA in its 105th Authority Meeting dated 15.12.2022 had also clarified vide Para 6.8 that in case of any revision in the draft calculation of ceiling prices, the corrected working sheet shall be uploaded on NPPA website for 10 working days for comments, if any. In case of non-receipt of any comments or after addressing any issues received on the revised working sheets, the same shall be placed before the Authority for decision. In those cases, where the data has been verified and confirmed by Pharmarack, prices will be re-computed based on revised data. Accordingly, corrigendum / addendum / new price notifications will be issued. However, NPPA in violation of the aforesaid Para 6.8 and the decision of the Authority Committee, did not upload the revised working sheet, despite presenting the revised Ceiling price to the Authority for approval. Ceiling price calculation was later shared on 23rd December 2022 and 16th January 2023, however correction was not made.

4. Gist of clarifications made by NPPA:

NPPA on the other side argued that the instant review is not tenable on the following grounds:

4.1 As per para 9(5) of the DPCO 2013, the market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six months of notification of revision in the first schedule. Accordingly, the Authority in its 104th meeting held on 23.11.2022 noted that the data to be considered for fixation of ceiling prices would be the prices in the month of April, 2022 which is the month that is six months prior to date of issue of Notification SO No. 5249(E) dated 11.11.2022. However, taking cognizance of the time lag with which price changes carried out due to revision in WPI is reflected/captured by the data; the Authority, under Para 9(7) of the DPCO 2013, decided that data for the month of July, 2022 may be considered for calculation of ceiling prices.

4.2 This strength of the subject formulation has been added in the Schedule-I under NLEM, 2022 for the first time. This formulation was non-scheduled before NLEM, 2022. Hence, submission of Form-II is not applicable in this case. The Applicant has submitted Form-V with NPPA in respect of revised PTR of "Acivir 800 mg Tablet DT 5's" at Rs.175.88 on 03.08.2022. The PTR of the said formulation prevailing in July, 2022 was Rs. 159.89 (Form-V filed on 03.03.2021), which was already reflected in the Pharmarack database. Therefore, the revised PTR of Rs. 175.88, as claimed by the Applicant, was not considered.

4.3 Further, the clarification provided by NPPA in its 105th Authority Meeting dated 15.12.2022 referred to by the Applicant (Para 3.5 above) is applicable only in case of Suo Moto corrections in the notified prices. In other cases, where based on the representations, the data has been verified and confirmed from/by Pharmatrack, prices will be re-computed based on revised data. Accordingly, corrigendum / addendum / new price notifications are issued.

5. Examination:

5.1 The Authority in its 104th meeting held on 23.11.2022 had decided, under Para 9(7) of the DPCO 2013, that data for the month of July, 2022 may be considered for

calculation of ceiling prices instead of April, 2022 so as to accommodate for the time lag with which the price changes carried out due to revision in WPI is reflected/captured in the database. Accordingly, prices as captured by the Pharmarack database for the month of July, 2022 were used for fixing the ceiling price of the subject formulation.

5.2 The subject formulation was earlier non-scheduled and hence, submission of Form-II is not applicable in this case. The Authority has decided to fix the ceiling price based on July, 2022 data. NPPA has taken the relevant price as available in the Pharmarack data for the month of July, 2022 which is the same as the available PTR under Form-V of the Applicant for the month.

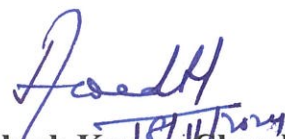
5.3 The decision taken vide para 6.8 of Minutes of 105th Authority Meeting held on 15.12.2022 was only in the context of Suo Moto corrections in the notified prices by NPPA and not in other cases. The practice adopted by NPPA in this regard suffers no infirmity.

5.4 Therefore, in view of the facts as at paras of 5.1 and 5.3 above, arguments and logics given by NPPA are accepted.

6. Decision:

The action of NPPA fixing the ceiling prices of subject formulation is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 18th day of November, 2024.



(Awadhesh Kumar Choudhary)

Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

To,

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Copy to:

1. Chairperson, NPPA, New Delhi.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi.
3. Technical Director, NIC for uploading the order on DoP's Website.
4. Guard File.