

No. 31015/16/2023-Pricing (E-23278)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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Room No. 207, D Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s Cipla Limited (hereinafter called the “Applicant”) filed a Review Application dated 17.01.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 5939 (E) dated 19.12.2022 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of “Lamivir HBV 100mg tablet 10’s” containing “Lamivudine 100mg” and “Montair 4mg 15 tab” containing “Montelukast 4mg”.

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 ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 The ceiling price as fixed by NPPA did not consider the revised PTR of the formulation “Lamivir HBV 100 mg 10’s” containing “Lamivudine 100 mg” and “Montair 4mg 15 Tab” containing “Montelukast 4 mg”.

3.2 Despite presenting the required documents like representation letter dated 07.12.2022, Form-V, invoice and pack shot within prescribed time lines of 10 workings days against the draft working sheet of the ceiling price dated 25th November 2022, NPPA did not consider the correction in PTR in final Ceiling price calculation shared on 23rd December 2022.

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. Therefore, NPPA notification S.O. 5939 (E) dated 19th December 2022, and specifically the ceiling price of formulation “Lamivir HBV 100mg 10’s” containing “Lamivudine 100mg” at Sr. No. 3 and “Montair 4mg 15 Tab” containing “Montelukast 4mg” at Sr. No. 8 should not have been notified without providing manufacturers another opportunity to review the revision in draft calculation of ceiling prices. The ceiling price calculation of following formulations should have included the revised PTR:

Composition	Brand Name	Revised PTR ₹	PTR as per calculation ₹
Lamivudine 100mg	Lamivir HBV 100mg 10’s	113.13	102.85
Montelukast 4mg	Montair 4mg 15 Tab	143.79	130.71

4. Gist of clarifications made by NPPA:

NPPA submitted the following:

4.1 Lamivudine 100mg tablet and Montelukast 4mg tablet have been added in NLEM, 2022 for the first time. Both these were non-scheduled drugs prior to NLEM, 2022. Hence Form-II is not applicable. Since, these two formulations have been added for the first in Schedule-I, Form-V filed till 31.07.2022 (as July 2022 database are being used for ceiling price fixation in line with decision taken in 104th Authority meeting) have been considered.

4.2 The details of Form-V submitted by M/s Cipla are as follows:

Lamivudine 100 mg:

Form-V (19.03.2020) - PTR 102.85 w.e.f. 01/2020

Form-V (03.03.2021) – PTR 113.13 w.e.f. 02/2021

Further, no PTR revision has been reported from 01.04.2021 to 31.07.2022. But as per the last form V filed by M/s Cipla on 03.03.2021, the PTR reported of Rs.113.13 was not reflected in July, 2022 Pharmatrac database. Hence, inadvertently the same was not considered.

4.3 With respect to Montelukast 4mg, Form-V was submitted on 20.05.2022 with PTR of Rs. 143.79 i.e. prior to 31.07.2022. However, inadvertently the same was not considered.

5. Examination:

5.1 M/s Cipla Limited submitted the Form-V for “Lamivir HBV 100mg 10’s” containing “Lamivudine 100mg” and “Montair 4mg 15 Tab” containing “Montelukast 4mg” on 03.03.2021 and 20.05.2022, respectively. During the hearing, NPPA acknowledged that inadvertently, Form-V of the Applicant was not considered while taking the PTR of eligible brands for fixing the ceiling price for the formulation Lamivudine 100mg tablet and Montelukast 4mg tablet. Therefore, the ceiling price for these formulation required recalculation based on revised PTR.

5.2 NPPA may once again look out for all such possible errors in calculation of ceiling price.

6. Decision:

In the backdrop of above facts, the case is being referred back to NPPA for recalculation of Ceiling Price of “Lamivudine 100 mg tablet” and “Montelukast 4mg tablet” as per the extant provisions of DPCO, 2013.

Issued on this, the 27th day of May, 2024.


(Awadhesh Kumar Choudhary)

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

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Copy to:

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

