

**No. 31015/21/2023-Pricing (E-23302)**  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

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Room No. 310, 'A' Wing, Shastri Bhawan,  
New Delhi-110 001.

**Order**

M/s Glenmark Pharmaceuticals Limited (hereinafter called the “Applicant”) filed a Review Application dated 18.01.2023 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 Cefuroxime Oral Liquid 125 mg / 5ml.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 07.06.2023 and present their respective logics.

**3. Major contentions raised by the Applicant:**

3.1. 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 ceiling price of their formulation by considering the actual PTR on the following grounds:

3.2. Incorrect Price-to-Retailer (PTR) data of the brands “CEFAKIND 125 MG SYRUP 30 ml”, “CETIL 125 MG DRY SYRUP 60 M” & “XOXE 125 MG DRY SYRUP 30 M” manufactured by Mankind Pharmaceuticals Limited, Lupin Limited & Corona respectively, was considered for the purpose of fixing of ceiling price of ‘Cefuroxime Oral Liquid 125 mg / 5ml’. The same was conveyed to NPPA by the submission of their representation dated 07.12.2022 (within prescribed timeline of 10 working days). Hence, ceiling price calculation of ‘Cefuroxime Oral Liquid 125 mg / 5ml’ should have been fixed after considering the revised PTR for ‘CEFAKIND 125 MG SYRUP 30 ml’ at Rs. 117.86 and not Rs.107.14, for ‘CETIL 125 MG DRY SYRUP 60 M’ at Rs.240.89 and not Rs. 219.11 & for ‘XOXE 125 MG DRY SYRUP 30 M’ at Rs. 120.21 and not Rs.109.29.

**4. Gist of clarifications made by NPPA:**

NPPA submitted their views as following:

4.1. Cefuroxime Oral Liquid 125 mg / 5ml has been added in NLEM, 2022 for the first time i.e. this was a non-scheduled formulation under NLEM 2022. Hence Form-II is not applicable.

4.2. Further, the details of Form-V submitted by the companies mentioned in the Review Application are as follows:

i. M/s Lupin Limited and M/s Corona have not filed Form-V with NPPA. Hence, the price revision has not been considered.

ii. M/s Mankind Pharmaceuticals Limited has submitted Form-V on 22.07.2022. For the newly added formulations, Form-V filed till 31.07.2022 are being considered. However, inadvertently Form-V of M/s Mankind Pharmaceuticals has been not considered.

4.3. Considering the above, if Form-V of M/s Mankind Pharmaceuticals Limited was considered, the ceiling price would have worked out to Rs. 4.74 instead of Rs. 4.71 per ml.

## **5. Examination:**


5.1. During the hearing, NPPA acknowledged that inadvertently, Form-V of M/s Mankind Pharmaceuticals was not considered and that, prima facie, if the same had been considered, it would have resulted in a higher ceiling price of Cefuroxime Oral Liquid 125 mg / 5ml at Rs. 4.74 instead of Rs. 4.71 per ml.

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

## **6. Decision:**

In the backdrop of these facts, the case is being referred back to NPPA for recalculation of Ceiling Price of Cefuroxime Oral Liquid 125 mg / 5ml, as per extant provisions of DPCO, 2013.

Issued on this, the 8<sup>th</sup> day of February, 2024.



**(Awadhesh Kumar Choudhary)**

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

## **To:**

M/s Glenmark Pharmaceuticals Limited,  
7-D, Atmaram House, 1 Tolstoy Marg,  
New Delhi- 110001.

## **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