

**No.31015/68/2023-Pricing (E-23882)**  
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 Koye Pharmaceuticals Pvt. Ltd. (hereinafter called the “Applicant”) filed a Review Application dated 28.04.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 1577(E) dated 31.03.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Celin 500mg tablet containing Ascorbic Acid 500mg.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 01.08.2023 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 NPPA considered the PTR of the company’s product Celin 500mg tablet and Limcee tablet of M/s Abbott Healthcare based on the data submitted by AWACS. The PTR reflected in Pharmatrac for Celin as well as Limcee tablets are erroneous. Further, the PTR considered by NPPA for the calculation does not include the impact of WPI applicable vide S.O. 1499(E) dated 01.04.2022.

3.2 The incorrect price fixed vide S.O. No. 1577(E) dated 31.03.2023 is unjust and has made the marketing of the product by the company infeasible. Therefore, upward price revision for Ascorbic Acid 500mg tablet may be considered under Para 19 of DPCO, 2013.

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

NPPA on the other side mentioned that:

4.1 The draft working sheet of Ascorbic acid 500mg tablet was uploaded on NPPA website on 09.02.2023 for 10 working days to invite comments, if any. Neither M/s Koye Pharmaceuticals Pvt. Ltd. nor M/s Abbott Healthcare filed representation for revision in PTR within 10 working days.

4.2 As per Para 16(2) of DPCO, the manufacturers may increase the MRP of scheduled formulations once in a year, in the month of April on the basis of WPI. Information about the revision, if carried out, shall be forwarded to the Government in Form-II within a period of 15

days of such revision as per para 16(3) of DPCO. This implies that Form-II for price revision based on WPI may be submitted latest by 15<sup>th</sup> May.

4.3 The claims made in the representation received from company has been cross verified with the Form-II/Form-V submitted by the companies till 15.05.2022 in IPDMS as per provisions of DPCO. In the instant case M/s Koye Pharmaceuticals Pvt. Ltd. did not file Form-II/Form-V for the brand 'Celin 500 mg tablet'.

4.4 M/s Abbott Healthcare Pvt. Ltd. filed Form-II on 13.04.2022 and Form-V on 22.04.2022 in respect of brand 'Limcee Chewable Tablets 15'. However, the same has not been considered as no representation was received from either M/s Koye or M/s Abbott.

## **5. Examination:**

5.1 Para 16(2) and 16(3) of DPCO provides that manufacturers may avail the increase in MRP of scheduled formulations once in a year, in the month of April, on the basis of the WPI; and, that such information about the revision, if carried out, shall be forwarded to the Government on IPDMS in Form-II and Form-V within a period of fifteen days. DPCO also expressly maintains that non-submission of information under Para 16(3) shall be construed as non-revision of MRP. Due to non-submission of Form-II/Form-V by the Applicant within prescribed time limit under extant provisions of DPCO 2013, the revised price of their product cannot be considered for PTR calculation.

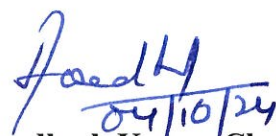
5.2 However, Abbott Healthcare have submitted their Form-II/Form-V within the prescribed time limit informing NPPA of the price rise taken under extant provisions of DPCO, 2013. The revised price was however not considered for PTR calculation as both companies had not represented before NPPA. The failure to represent within ten days against the ceiling price fixed by NPPA, may not deprive the Applicant of the legitimate prices of drugs manufactured by them.

5.3 Therefore, in the present case, NPPA may relook into the issue and revise the ceiling price on the basis of extant provisions of DPCO 2013.

## **6. Decision:**

In the backdrop of these facts, the case is referred back to NPPA for re-calculation of the ceiling price of the subject formulation as per the extant provisions of DPCO 2013.

Issued on this, the 4<sup>th</sup> day of October, 2024.



(Awadhesh Kumar Choudhary)

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

## **To:**

M/s Koye Pharmaceuticals Pvt. Ltd.  
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Mumbai- 400070

**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

