

No.31015/43/2023-Pricing (E-23443)
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 Limited (hereinafter called the “Applicant”) filed a Review Application dated 28.02.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 484(E) dated 02.02.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Azee 250mg tablet 6’s containing Azithromycin 250mg.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 06.11.2023 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 formulation “Azee 250mg tablet 6’s” was included in Schedule-I listed out in the final list of scheduled formulations with effect from 11th November, 2022 and the formulation “Azee 250mg tablet 6’s” was not included in the draft calculation of ceiling price as released on 02.12.2022 under the provisions of Para 4, 6, 10, 11, 14, 16, 17 and 18 of DPCO 2013. Azee 250mg had a market share of nearly 2.3% of the scheduled formulation for the period Aug, 21 to July, 22. Though the representation was duly submitted vide the email dated 13.12.2022 in the prescribed format, with the requested documents, and within the prescribed timelines of 10 workings days, the company’s brand was not considered in the calculation of ceiling price dated 3rd February 2023.

3.2 NPPA notification S.O. 484(E) dated 02.02.2023, and specifically the ceiling price of formulation “Azithromycin 250 mg” at Sr. No. 7 should have included the brand and pack size “Azee 250mg tablet 6’s”. Therefore, the calculation of the ceiling price of the formulation Azithromycin 250mg is incorrect and must be rectified after adding the brand and pack size “Azee 250 mg tablet 6’s”.

4. Gist of clarifications made by NPPA:

NPPA on the other side argued that:

4.1 M/s Cipla Ltd has filed the Form-II for Azee (pack of 6 & 10) on 2.05.2022 with revised PTR of Rs. 9.38 per tablet. Pharmatrac database of July, 2022 has been considered for calculation of ceiling prices. Sale of the brand “Azee 250mg tablet 6’s” is not reflected in

the Pharmatrac database for the period of August, 2021 to July, 2022. Hence, the same was not considered for the ceiling price calculation of the formulation Azithromycin 250mg.

4.2 However, based on the review petition, Pharmatrac was requested to recheck and confirm the pack size and MAT of the following brands of M/s Cipla Limited of Azithromycin 250mg tablet:

AZEE	Cipla Limited	Tablet	10
AZEE	Cipla Limited	Tablet	6
AZICIP	Cipla Limited	Tablet	6
AZIMAX	Cipla Limited	Tablet	10
AZIMAX	Cipla Limited	Tablet	6
AZIPRO	Cipla Limited	Tablet	6
ZOMYCIN	Cipla Limited	Tablet	6

4.3 For Azee (pack of 6), Pharmatrac confirmed that *“this sku was discontinued in Oct 2019 hence the value is zero in the current dataset. But when we analyzed from the data sources, we found that the sku is relaunched in the month of March 2021.”* Pharmatrac vide the email dated 20.07.2023 provided the final data. As per the final data, Azee (pack of 6) qualifies for being considered in averaging of PTR. Hence, re-calculation of ceiling price may be required as Azee (pack of 6) was not considered earlier due to ZERO sales in Pharmatrac database.

4.4 M/s Cipla Limited had filed the Form-II for Azee (Pack of 6 and 10) on 02.05.2022 with revised PTR of Rs. 9.38 per tablet.

5. Examination:

5.1 NPPA's has confirmed the filing of Form-II by the applicant within the time limits prescribed under extant provisions of DPCO 2013.

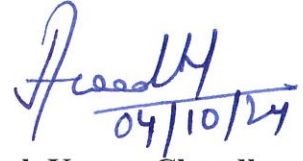
5.2 Further, anomalies in Phramatrac database and their requisite corrections as submitted by NPPA have also been noted. In view of these facts, the ceiling price of the formulation requires revision.

5.3 NPPA may once again look 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 for the formulation Azithromycin 250mg tablet as per extant provisions of DPCO, 2013.

Issued on this, the 04th day of October, 2024.

A handwritten signature in blue ink, appearing to read 'Awadhesh', with the date '04/10/24' written below it.

(Awadhesh Kumar Choudhary)
Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

To:

M/s Cipla Limited,
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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

