

**No. 31015/15/2023-Pricing (E-23277)**  
**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 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. 5938 (E) dated 19.12.2022 and S.O. No. 89 (E) dated 06.01.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Orders, NPPA, inter alia, fixed the ceiling price of Atorlip 10 Tablets 15's containing Atorvastatin 10mg.

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 "Atorlip 10 Tablets 15's" of the Applicant, containing "Atorvastatin 10mg", was not considered in the draft calculation worksheet of ceiling price of "Atorvastatin 10mg" as released in phase 1 on 25.11.2022 under the provisions of Para 4, 6, 10, 11, 14, 16, 17 and 18 of DPCO 2013. The formulation "Atorlip 10 Tablets 15's" had nearly 3% market share of "Atorvastatin 10mg" for the period August, 2021 to July, 2022. The company duly submitted the representation dated 07.12.2022 in the prescribed format, with the requested documents, and within the prescribed time lines of 10 working days.

3.2 It was also clarified in the 105<sup>th</sup> Authority Committee Meeting dated 15.12.2022 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 Pharmatrac, prices will be re-computed based on revised data. Accordingly, corrigendum / addendum / new price notifications will be issued."

3.3 The formulation "Atorlip 10 Tablets 15's containing Atorvastatin 10 mg" of the applicant was not considered in final ceiling price calculation uploaded on 23<sup>rd</sup> December, 2022 and also in revised ceiling price calculation uploaded on 06<sup>th</sup> January 2023.

3.4 Therefore, the ceiling price calculation of formulation are incorrect and should have included the brand "Atorlip 10 Tablets 15's".

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

4.1 The Authority in its 106<sup>th</sup> meeting held on 30.12.2022 noted that 1% market share has been considered on the basis of Pharmatrac database. Any other database, if quoted by any company in its representation is not considered for assessment of 1% market share.

4.2 Pharmatrac database for July, 2022 has been considered for the calculation of ceiling price under NLEM 2022. While calculating the ceiling price of the formulation 'Atorvastatin 10 mg tablet', brand 'Atorlip 10 Tablets 15's' of M/s Cipla was not included as it did not appear under the drug type "tablet". Hence, the price was fixed on the premise that data of brand of M/s Cipla i.e. 'Atorlip 10 Tablets 15's' is not captured in Pharmatrac.

4.3 However, on receipt of review petition, it was confirmed with Pharmatrac vide email that the formulation of M/s Cipla i.e. 'Atorlip' is appearing in database as drug type 'Capsule' whereas it is a 'tablet'. The same is corrected in database of April 2023 by Pharmatrac.

#### **5. Examination:**

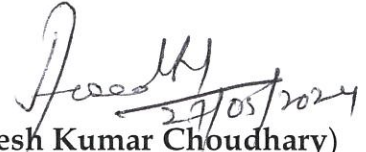
5.1 The decision taken vide Para 6.8 of Minutes of 105<sup>th</sup> Authority meeting held on 15.12.2022 pertain to the Agenda Item No. 6 of the 105<sup>th</sup> Authority Meeting, which specifically pertained to cases of Suo Moto correction in notified prices by NPPA. Other cases are not covered by this Agenda, and hence the decision. Therefore, the submission made by NPPA is accepted.

5.2 Further, the formulation of M/s Cipla Limited i.e. 'Atorlip' was appearing in database as drug type 'Capsule' whereas it is a 'tablet'. The same is corrected in database of April 2023 by Pharmatrac. Therefore, the ceiling price for the formulation Atorvastatin 10 mg tablet require recalculation considering all the brands available in the market database.

#### **6. Decision:**

In the backdrop of above facts, the case is being referred back to NPPA for recalculation of ceiling price for the formulation 'Atorvastatin 10mg tablet' as per extant provisions of DPCO, 2013.

Issued on this, the 27<sup>th</sup> day of May, 2024.



(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  
Cipla House, Peninsula Business Park,  
Ganpatrao Kadam Marg, Lower Parel,  
Mumbai-400013

**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

