

**No.31015/86/2023-Pricing (E-25428)**  
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**

This is an order disposing of following review applications filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against the ceiling price fixation order issued passed by the National Pharmaceutical Pricing Authority (NPPA) for the scheduled formulations as detailed in Table-1 below:

**Table-1**

S. No.	S.O. No. & Date	Formulation	Applicant (Date of Application)	Date of Hearing
1.	S.O. No. 5938 (E) dated 19.12.2022	Clarithromycin 250 mg tablet	M/s Abbott Healthcare Private Limited (18.01.2023)	02.06.2023
2.	S.O. No. 194 (E) dated 11.01.2023	Streptomycin 1000 mg per vial injection	M/s Abbott Healthcare Private Limited (30.01.2023)	02.06.2023
3.	S.O. No. 5938(E) dated 19.12.2022	Atorvastatin 10 mg Tablet	M/s Abbott Healthcare Private Limited (13.01.2023)	05.04.2023

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance 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 Applicant is engaged in manufacturing and marketing of scheduled formulations listed in Table-1, for which draft worksheet of ceiling price under NLEM 2022 was uploaded on NPPA's website. NPPA vide its OM 12(90)/2022/DP/NPPA/Div-II dated 25<sup>th</sup> November, 2022 titled "Representations against ceiling prices fixed by NPPA under revised schedule-(NLEM, 2022) of DPCO, 2013" had requested representations against any draft calculation of ceiling prices to be submitted with certain information/documents within a period of 10 working days from the date of the draft working sheets being uploaded on the NPPA website.

3.2 W.r.t. to ceiling price calculation of scheduled formulations listed in Table-1, Applicant submitted that, in spite of providing the pack shot, NPPA did not consider the revised PTR of the following brands of the companies:

Table-2

S.No.	Formulation	Brand (company) of which revised PTR is not considered
1.	Clarithromycin 250 mg tablet	MACLAR (Glenmark)
2.	Streptomycin 1000 mg per vial injection	AMBISTRYN S (Abbott)
3.	Atorvastatin 10 mg Tablet	ATCHOL (Aristo), AVAS (Micro), LIPIKIND (Mankind)

3.3 NPPA in its 105<sup>th</sup> Authority Meeting dated 15th December, 2022 had also clarified 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 Pharmarack, prices will be re-computed based on revised data. Accordingly, corrigendum / addendum / new price notifications will be issued.” NPPA should be directed to follow the decisions taken in the NPPA Authority Meetings and issue the corrected working sheet of the scheduled formulations on NPPA website for 10 working days for comments, if any.

3.4 A delay in the implementation of revised MRP or PTR based on WPI impact should not be construed as non-implementation of WPI based revision. Also, non-reflection/Delayed reflection of PTR in the market-based data provided by Pharmarack should not be construed as non-implementation of revised MRP, especially when pack shots of the relevant month are provided as documentary evidence in support of price revision.

3.5 Accordingly, the Applicant contended that the calculation of ceiling price of the formulation mentioned in table above are incorrect as the PTR data of the brands mentioned in Table-2 of Para 3.2 has not been correctly considered for the said purpose.

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

NPPA on the other side argued that the instant review is not tenable on the following grounds:

4.1 As per the provisions of DPCO [Para 16(2)], the manufacturers may increase the MRP of scheduled formulations once in a year, in the month of April on the basis of WPI. Further, as per para 16(3), 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. This implies that Form-II for price revision based on WPI may be submitted latest by 15<sup>th</sup> May. Accordingly, NPPA has considered price revision in all cases where any representation is received and Form-II/V has been filed by the company on or before 15<sup>th</sup> May, 2022.

4.2 Further, the details of the Form-II/Form-V filed for the brands mentioned in Table-2 of Para 3.2 are as follows:

Table-3

S.No.	Formulation	Brand (company) of which revised PTR is not considered	Date of Form-II / Form-V for brands mentioned in column (3) respectively
(1)	(2)	(3)	(4)
1.	Clarithromycin 250 mg tablet	MACLAR (Glenmark)	14.04.2022/16.06.2022
2.	Streptomycin 1000 mg per vial injection	AMBISTRYN S (Abbott)	13.04.2022/22.04.2022
3.	Atorvastatin 10 mg Tablet	ATCHOL (Aristo), AVAS (Micro), LIPIKIND (Mankind)	13.04.2022/13.04.2022, Not filed/25.07.2022, 07.06.2022/27.05.2022

4.3 The draft worksheet based on the Pharmarac database was uploaded on NPPA's website for 10 working days to invite comments, if any. However, no representation was made by the Applicant in respect of the revised PTR of the brands given in Table 3 above. Therefore, the revised PTR was not considered.

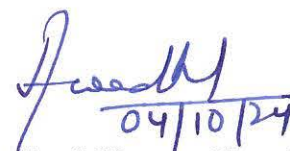
## 5. Examination:

5.1 It is noted that NPPA has not considered the price revision of the brands mentioned in Table-3, as the Applicant did not file representation within the prescribed period of 10 workings days. However, requisite forms under DPCO, 2013 have been filed for the subject brands with 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.

## 6. Decision:

6.1 In backdrop of these facts, the case is referred back to NPPA for recalculation of the prices of the formulation mentioned in Table-1 as per extant provisions of DPCO, 2013.

Issued on this, the 04<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 Abbott Healthcare Private Limited  
Godrej BKC, Plot C-68, G Block,  
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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