

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

M/s Abbott Healthcare Private Limited (hereinafter called the “Applicant”) filed Review Applications under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against the ceiling price fixation Orders issued by the National Pharmaceutical Pricing Authority (NPPA) for some of the scheduled formulations. The details of such formulations and the relevant Order against which the Review Application has been filed is as provided in the Table-1 below:

Table-1

S. No.	S.O. No. & Date	Formulation	Applicant (Date of Application)	Date of Hearing
1.	S.O. No. 5939(E) dated 19.12.2022	Atorvastatin 80 mg Tablet	M/s Abbott Healthcare Private Limited (13.01.2023)	05.04.2023
2.	S.O. No. 87 (E) dated 06.01.2023	Carbamazepine 200 mg Tablet	M/s Abbott Healthcare Private Limited (03.02.2023)	02.06.2023
3.	S.O. No. 5938(E) dated 19.12.2022	Atorvastatin 40 mg Tablet	M/s Abbott Healthcare Private Limited (18.01.2023)	05.04.2023
4.	S.O. No. 5938(E) dated 19.12.2022	Levetiracetam 500 mg tablet	M/s Abbott Healthcare Private Limited (16.01.2023)	14.09.2023
5.	S.O. No. 5938(E) dated 19.12.2022	Levetiracetam 750 mg tablet	M/s Abbott Healthcare Private Limited (16.01.2023)	14.09.2023
6.	S.O. No. 5938(E) dated 19.12.2022	Linezolid 600 mg tablet	M/s Abbott Healthcare Private Limited (16.01.2023)	14.09.2023
7.	S.O. No. 5938(E) dated 19.12.2022	Paracetamol 650 mg tablet	M/s Abbott Healthcare Private Limited (16.01.2023)	14.09.2023
8.	S.O. No. 5938(E) dated 19.12.2022	Clobazam 10 mg tablet	M/s Abbott Healthcare Private Limited (16.01.2023)	14.09.2023
9.	S.O. No. 5938(E) dated 19.12.2022	Carbamazepine 400mg tablet	M/s Abbott Healthcare Private Limited (16.01.2023)	14.09.2023

10.	S.O. No. 87(E) dated 06.01.2023	Amoxicillin 500 mg and Clavulanic acid 125 mg tablet	M/s Abbott Healthcare Private Limited (24.01.2023)	02.06.2023
11.	S.O. No. 87(E) dated 06.01.2023	Pantoprazole 40 mg- injection	M/s Abbott Healthcare Private Limited (30.01.2023)	02.06.2023
12.	S.O. No. 87(E) dated 06.01.2023	Propranolol 40 mg- tablet	M/s Abbott Healthcare Private Limited (30.01.2023)	02.06.2023
13.	S.O. No. 194 (E) dated 11.01.2023	Propranolol 20 mg tablet	M/s Abbott Healthcare Private Limited (01.02.2023)	02.06.2023

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 drugs listed at Table-1 above 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 25th 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 shots, 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.	Atorvastatin 80 mg Tablet	ATOCOR (DRL), ATORLIP (Cipla), ATORSA VE (Aris), ATORVA (Zydus), XTOR (IPCA)
2.	Carbamazepine 200 mg Tablet	TEGRITAL (Novartis)
3.	Atorvastatin 40 mg Tablet	LIPIKIND (Mankind)
4.	Levetiracetam 500 mg tablet	LEVACETAM (Micro)
5.	Levetiracetam 750 mg tablet	LEVACETAM (Micro), LEVROXA (Eris)
6.	Linezolid 600 mg tablet	LIZOFORCE (Mankind)
7.	Paracetamol 650 mg tablet	P 650 MG (Apex)
8.	Clobazam 10 mg tablet	SOLZAM (Eris)

9.	Carbamazepine 400mg tablet	TEGRITAL (Novartis)
10.	Amoxicillin 500 mg and Clavulanic acid 125 mg tablet	HHAMCLAV (H&H), MOXIFORCE CV (Mankind)
11.	Pantoprazole 40 mg- injection	M/s PANTIN IV (Hetero), PANTOCID IV (Sun)
12.	Propranolol 40 mg- tablet	CIPLAR LA (Cipla), MIBETA (Tas Med)
13.	Propranolol 20 mg tablet	BETACAP (Sun)

3.3 NPPA in its 105th 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-1 above are incorrect as the PTR data of the brands mentioned in Table-2 (Para 3.2 above) 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 15th 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 15th 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.	Atorvastatin 80 mg Tablet	ATOCOR (DRL), ATORLIP (Cipla), ATORSA VE (Aris), ATORVA (Zydus), XTOR (IPCA)	Not filed/Not filed, Not filed/Not filed, Not filed/Not filed, Not filed/Not filed, Not filed/Not filed
2.	Carbamazepine 200 mg Tablet	TEGRITAL (Novartis)	13.06.2022/13.06.2022
3.	Atorvastatin 40 mg Tablet	LIPIKIND (Mankind)	07.07.2022/22.06.2022
4.	Levetiracetam 500 mg tablet	LEVACETAM (Micro)	Not filed/25.07.2022
5.	Levetiracetam 750 mg tablet	LEVACETAM (Micro), LEVROXA (Eris)	Not filed/25.07.2022, Not filed/Not filed
6.	Linezolid 600 mg tablet	LIZOFORCE (Mankind)	07.06.2022/25.07.2022
7.	Paracetamol 650 mg tablet	P 650 MG (Apex)	22.06.2022/22.06.2022
8.	Clobazam 10 mg tablet	SOLZAM (Eris)	Not filed/Not filed
9.	Carbamazepine 400mg tablet	TEGRITAL (Novartis)	13.06.2022/13.06.2022
10.	Amoxicillin 500 mg and Clavulanic acid 125 mg tablet	HHAMCLAV (H&H), MOXIFORCE CV (Mankind)	Not filed/11.06.2022, 07.06.2022/27.05.2022
11.	Pantoprazole 40 mg- injection	M/s PANTIN IV (Hetero), PANTOCID IV (Sun)	Not filed/Not filed, 15.04.2022 with old price
12.	Propranolol 40 mg- tablet	CIPLAR LA (Cipla), MIBETA (Tas Med)	Not filed/20.05.2022, Not filed/Not filed
13.	Propranolol 20 mg tablet	BETACAP (Sun)	Not applicable new added formulation/Not filed

4.3 In view of above, NPPA contended that it has taken correct PTR for the brands as mentioned above from the market based data.

4.4 The clarification provided by NPPA in its 105th Authority Meeting dated 15th December, 2022 referred to by the Applicant (Para 3.3 above) is applicable only in case of Suo Moto corrections in the notified prices. In other cases, where based on the representations, the data has been verified and confirmed from/by Pharmarack, prices will be re-computed based on revised data. Accordingly, corrigendum / addendum /new price notifications will be issued.

5. Examination:

5.1. In fixing the ceiling price of Scheduled formulations, NPPA has followed the due provisions of DPCO. Thus, NPPA has taken due cognizance of the provisions under Para 16(2) and 16(3) of DPCO which 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. NPPA has taken the relevant prices as per the aforesaid provisions of DPCO.

5.2. The decision taken vide para 6.8 of Minutes of 105th Authority Meeting held on 15.12.2022 was only in the context of Suo Moto corrections in the notified prices by NPPA and not in other cases. The practice adopted by NPPA in this regard suffers no infirmity.

5.3. Therefore, in view of the facts at Paras of 5.1 and 5.2 above, arguments and logics given by NPPA are acceptable.

6. Decision:

The action of NPPA fixing the ceiling prices of scheduled formulations is upheld and the Review Applications under consideration is accordingly rejected.

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



(Awadhesh Kumar Choudhary)

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

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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

