

No.31015/79/2023-Pricing (E-25420)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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Room No. 207, D Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s Abbott Healthcare Private Limited (hereinafter called the "Applicant") filed a Review Application dated 13.01.2023 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 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Atorvastatin 20 mg Tablet.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 05.04.2023 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 of their formulation on the following grounds:

3.1 Abbott Healthcare Pvt. Ltd. (AHPL) is engaged in manufacturing and marketing of "STATOR 20 MG TABLET 15's" containing Atorvastatin 20 mg. NPPA issued a notification S.O. 5938 (E) dated 19th December 2022, fixing ceiling prices of 107 scheduled formulations, including the ceiling price of scheduled formulation Atorvastatin 20 mg tablet with the brand name "STATOR 20 MG TABLET 15s".

3.2 The Applicant mentioned that "Atorvastatin 20 mg tablet/ STATOR 20 MG TABLET 15s" was included in revised Schedule-I of DPCO introduced with effect from 11th November, 2022. Accordingly, the formulation "Atorvastatin 20 mg tablet/ STATOR 20 MG TABLET 15s" was also included in the draft calculation of ceiling price as released in Phase-1 on 25th November, 2022 under the provisions of Para 4, 6, 10, 11, 14, 16, 17 and 18 of DPCO 2013. 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 draft calculation of ceiling prices, if any. The representation had to be submitted with relevant information/documents within 10 working days from the date of uploading of the draft working sheets on the NPPA's website.

3.3 The Applicant mentioned that other manufacturers of Atorvastatin 20 mg tablet had implemented the WPI under Para 16 of DPCO 2013 between April 2022 to July 2022 respectively. However, Applicant vide representation ASC/2022/12/09 dated 06.12.2022 contended that incorrect Price-to-Retailer (PTR) data of the following brands was considered for fixing the ceiling price of Atorvastatin 20 mg tablets resulting in the fixation of its lower ceiling price: -

Sr.No.	Competitor Product Name	Company Name
1	ATCHOL 20 MG TABLET 15	ARISTO PHARMACEUTICALS PVT. LTD.
2	AVAS 20 MG TABLET 30	MICRO LABS LTD
3	LIPIKIND 20 MG TABLET 15	MANKIND PHARMACEUTICALS LTD.

3.4 The Applicant maintained that Pharmatrack report for September, 2022 eventually reflected the revision in MRP for the brands mentioned above, which is prior to the implementation of S.O. 5249 (E) dated 11th November, 2022 and subsequent revision of Schedule-I of DPCO 2013.

3.5 NPPA in its 105th Authority Committee 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 its 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 Pharmatrack, 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 Authority Meetings and issue the corrected working sheet of Atorvastatin 20 mg tablet on their website for 10 working days for comments, if any.

3.6 The ceiling price calculation of Atorvastatin 20 mg tablet should have been fixed after considering the revised PTR for the products mentioned in Para 3.3 which is as follows:

Sr. No.	Competitor Product Name	Company Name	PTR Considered	PTR Should be considered
1.	ATCHOL 20 MG TABLET 15	ARISTO PHARMACEUTICALS PVT.LTD	32.82	38.17
2.	AVAS 20 MG TABLET 30	MICRO LABS LTD	319.68	371.70
3	LIPIKIND 20 MG TABLET 15	MANKIND PHARMACEUTICALS LTD.	37.54	43.65

3.7 NPPA notification S.O. 5938 (E) dated 19th December 2022, and specifically the ceiling price of the formulation "Atorvastatin 20 mg tablet" at Sr. No. 63 of the notification should not have been notified without providing manufacturers another opportunity to review the revision in draft calculation of ceiling prices.

3.8 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 Pharmatrack 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.

3.9 Accordingly, the Applicant contended that the calculation of ceiling price of the formulation 'Atorvastatin 20 mg tablet' is incorrect as the PTR data of the brands mentioned in Para 3.3 and Para 3.6 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 of DPCO 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 of DPCO has been filed by the company till 15th May 2022. In this regard, NPPA has indicated that no representation was made by M/S Abbott in respect of PTR of M/s Aristo Pharmaceuticals Pvt. Ltd. in its representation no.ASC/2022/12/15 dated 06.12.2022 filed in prescribed time of 10 working days.

4.2 Further, M/s Aristo Pharmaceuticals Pvt. Ltd. also has not filed any representation with NPPA.

4.3 M/s Micro Labs Ltd. submitted Form-II and Form-V on 25.07.2022.

4.4 Furthermore, M/s Mankind Pharmaceuticals Ltd. submitted Form-II on 24.07.2022 & Form -V on 22.07.2022.

4.5 In view of above, NPPA contended that it has taken correct PTR for ATCHOL 20 mg Tablet 15', AVAS 20 mg tablet 30'and LIPIKIND 20mg Tablet 15' for ceiling price calculation of the formulation 'Atorvastatin 20mg'.

4.6 The clarification provided by NPPA in its 105th Authority Committee Meeting dated 15th December, 2022 referred to by the Applicant (Para 3.5) is applicable only in case of Suo Moto corrections in the notified prices. In other cases, where, based on the representation, the data has been verified and confirmed from/by Pharmatrack, 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 Atorvastatin 20 mg Tablet, 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 following these 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, under the facts cited under the above paras of 5.1 and 5.2, arguments and logics given by NPPA are acceptable.

6. Decision:

The action of NPPA fixing the ceiling prices of Atorvastatin 20 mg tablet vide S.O. No. 5938(E) dated 19.12.2022 is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 8th day of February, 2024.



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[For and on behalf of the President of India]

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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