

No. 31015/32/2023-Pricing (E-23321)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

Room No. 340-B, A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s VHB Life Sciences Limited (hereinafter called the "Applicant") filed a Review Application dated 01.02.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 194(E) dated 11.01.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of "Artamin 250 mg capsule 10's containing Penicillamine 250mg".

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 07.06.2023 and present 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 "Artamin 250mg capsule 10's containing Penicillamine 250mg" was included in Schedule-I of DPCO with effect from 11th November, 2022. Hence, the formulation "Artamin 250mg capsule 10's containing Penicillamine 250mg" was included in the draft calculation of ceiling price released by NPPA on 25.11.2022 under the provisions of Para 4, 6, 10, 11, 14, 16, 17 and 18 of DPCO 2013.

3.2 The Applicant had implemented the WPI based revision in MRP and PTR under para 16 of DPCO 2013 in the month of April, 2022. The Applicant had also submitted Form-II and Form-V as per the requirements and timelines under DPCO, 2013, indicating the WPI based revised MRP of "Artamin 250mg capsule 10's containing Penicillamine 250mg". Non-reflection of PTR in the market based data should not be construed as non-implementation of revised MRP, especially when invoices of sale at revised MRP are provided as documentary evidence.

3.3 Hence, ceiling price calculation of Penicillamine 250 mg capsules should have included the revised PTR for "Artamin 250 mg Capsule 10's" at Rs.134.78 and not Rs. 113.05.

4. Gist of clarifications made by NPPA:

NPPA on the other side urged that:

4.1 The draft worksheet for all the formulations are being uploaded on NPPA's website for 10 working days to invite comments from affected pharmaceutical firms in compliance to O.M. No. F. No.31015/44/2016-PI.I dated 11.07.2016 issued by Department of Pharmaceuticals.

4.2. The draft worksheet for D- Penicillamine 250mg capsule was uploaded on NPPA's website on 13.12.2022. But, neither M/s VHB Life Sciences Limited (Market Share – 2.26%) nor other companies i.e. Mankind Pharmaceuticals Limited and Samarth Life Sciences Private Limited (Market Share – 97.74%) filed any representation within the prescribed period of 10 days.

4.3 NPPA has taken PTR for “Artamin 250mg Capsule 10’s” for ceiling price calculation of the ‘D-Penicillamine 250mg’ as available in market based data i.e. Pharmatrac database.

5. Examination:

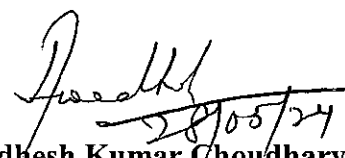
5.1 It is noted that NPPA has not considered the price revision of “Artamin 250mg capsule 10’s containing Penicillamine 250mg”, as the Applicant i.e. M/s VHB Life Sciences Limited did not file any representation within the prescribed period of 10 working days.

5.2 The Applicant has fulfilled all other conditions / provisions i.e. filling of requisite Forms as per the extant provisions of DPCO 2013, and providing the relevant information including the prices. 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:

In the backdrop of these facts, the contention regarding fixation of price of “Artamin 250mg capsule 10’s containing Penicillamine 250mg” without considering the revised PTR in absence of representation is accepted. Accordingly, the case is referred back to NPPA for recalculation of the prices of the subject formulation as per the extant provisions of DPCO, 2013.

Issued on this, the 28th 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:

VHB Life Sciences Limited,
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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