

No.31015/45/2023-Pricing (E-23524)
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 Ordain Health Care Global Pvt Ltd (hereinafter called the “Applicant”) filed a Review Application dated 09.03.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 879(E) dated 24.02.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Thiamin 100mg Injection 2ml containing Thiamine 100mg per ml.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 22.06.2023 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 Applicant had implemented the WPI base increase in MRP under para 16 of DPCO 2013 in the month of April, 2022. Further, Form-V was submitted on 06.07.2022 as per DPCO, 2013 requirements. 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 and does not limit the implementation of the said WPI revision in case of an increase in the ceiling price of the formulation. Hence, the ceiling price of formulation “Thiamin 100 mg Injection 2 ml” containing “Thiamine 100 mg per ml” at Sr. No. 4 should have included the revised PTR for ‘Thiamin 100mg Injection 2ml’ at Rs. 46.01 and not Rs. 41.75.

3.2 Further, based on the market information, the petitioner has confirmed that the formulation ‘Vitneurin AQ 100mg Injection 2ml’ as marketed by Corona Remedies Pvt. Ltd. is not a ‘Thiamine 100mg per ml Injection’, but an FDC of “Vitamin B1-100mg, Vitamin B6-50mg, Vitamin B12-1000mg, D Panthenol 50mg”. Therefore, the brand ‘Vitneurin AQ 100mg Injection 2ml’ should be removed from the calculation.

4. Gist of clarifications made by NPPA:

NPPA on the other side argued that:

4.1 As per the provisions of 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. M/s Ordain Health Care Global Private Limited has not filed Form-II for the subject formulation and Form-V too was filed on 06.07.2022 after the prescribed time as per DPCO, 2013. Hence, as per DPCO, 2013, delay in the implementation of WPI beyond April and the non-receipt of information about the revision within 15 days of such revision shall be construed as non-revision of MRP.

4.2 Further, the draft worksheet based on Pharmatrac database was uploaded on NPPA's website on 28.01.2023 for 10 working days to invite comments, if any. However, no representation was filed by M/s Ordain Health Care Global Private Limited or any other company within the prescribed time of 10 working days.

4.3 With respect to the brand "Vitneurin AQ 100mg Injection 2ml" as marketed by Corona Remedies Private Limited, the examination is as follows:

(a) The brand contains Vitamin B1 IP 100mg + Vitamin B6 IP 50mg + Vitamin B12 IP 1000mg + D Panthenol IP 50mg + Phenol IP 0.5%.

(b) The company's contention regarding exclusion of Vitneurin AQ 100mg Injection 2ml from the calculation of PTR is acceptable as the brand does not have composition as mentioned in Schedule. However, the ceiling price was fixed for the drug since no company represented within 10 working days of upload of draft calculation sheet 20(48)/2023/DP/NPPA/DivIII/5851/2023.

5. Examination:

5.1 It is noted that the applicant had not fulfilled the requisite formalities of submission of Forms-II and Form-V within prescribed time limit as per the extant provisions of DPCO 2013. Further, DPCO expressly maintains that non-submission of information under Para 16(3) shall be construed as non-revision of MRP.

5.2 Also, NPPA has considered the "Vitneurin AQ 100mg Injection 2ml" as marketed by Corona Remedies Private Limited, for calculation of ceiling price based on Pharmatrac database. No company filed representation for exclusion of the same to NPPA within the prescribed period of 10 working days.

5.3 However, the brand "Vitneurin AQ 100mg Injection 2ml" marketed by M/S Corona Remedies Private Limited is different from the Scheduled formulation. Therefore, price of the same should not be considered for ceiling price calculation of subject formulation. 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.

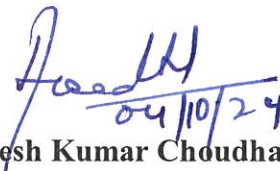
5.4 Therefore, in the present case, NPPA may relook into the issue and revise the ceiling price on the basis of extant provisions of DPCO 2013.

6. Decision:

6.1 The PTR of Thiamin 100mg Injection 2ml considered by NPPA in fixation of ceiling price of the schedule formulation is as per the provisions of DPCO, 2013 and suffers no infirmity.

6.2 However, the contention of the Applicant regarding removing brand 'Vitneurin AQ 100mg Injection 2ml' from the calculation of PTR is accepted. Accordingly, the case is referred back to NPPA for re-examination and re-calculation of the prices of the subject formulation as per the extant provisions of DPCO 2013.

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]

To:

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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

